Supplementary Report in Favour of the Legislation

1. Introduction

1.1 The provisions of the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* concern, directly and indirectly, issues of considerable public interest.[1]

1.2 The decision of the Council of Australian Government (COAG) of 5 April 2002 and subsequent legislation, are important stages in a long running debate in Australia and overseas concerning biotechnology, cloning and the regenerative potential of stem cell research.

1.3 In the course of this inquiry the committee received submissions and heard evidence from people and organisations with divergent and sometimes irreconcilable views. We recognise and respect the wide range of sincerely held views.

1.4 We do not believe any one particular group, be they politicians, scientists or church leaders, has any special privileged access to wisdom in such matters thus welcome robust and informed debate as an essential feature of a pluralist democracy.

Having considered the evidence and views carefully, we recommend that the Bills be passed.

2. Consideration of the Legislation

The Chair's Report

2.1 It is customary in a Senate Legislation Committee for the Chair's report to provide recommendations on the legislation before it. However, as the Coalition and Opposition granted Senators a conscience vote, the Committee decided that the purpose of the Chair's report was to balance the major issues and arguments relating to the provisions of the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002,* without providing recommendations or conclusions (1.5).

2.2 We support this decision but simply state that no inference can or should be drawn from this concerning the capacity of the Parliament to arrive at a coherent majority position.

History of Debate

2.3 As the Chair's report points out, the issues concerning cloning and research involving embryos has been extensively debated over the past two decades,

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[1] All references to sections and clauses in the Chair's report are to the original Bill. However, as this was split in the House of Representatives subsequent to the referral to the Senate Committee, all references in this supplementary report will be to the two Bills that the Senate will actually debate.

particularly since 1998 (1.11 – 1.32). Moreover, the issues have been exhaustively debated in other jurisdictions notably in the United Kingdom, the USA (federally and in various states, including California) and Canada.

Research Involving Embryos and Prohibition of Human Cloning Bill 2002

2.4 On 29 August, 2002, the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, was split in the House of Representatives. The *Prohibition of Human Cloning Bill 2002* was passed by the House on 29 August and the *Research Involving Human Embryos Bill 2002* was passed on 25 September 2002.

2.5 Though not noted in the Chair's report, the review provisions in the original bill were changed when it was split.

2.6 In the original Bill, the National Health and Medical Research Council (NHMRC) is required to cause an independent review of the Act (s61). This is retained in the *Research Involving Human Embryos Bill 2002* (s61) however in the *Prohibition of Human Cloning Bill 2002*, it is the Minister who causes an independent review (s25).

2.7 s.61(2) of the *Research Involving Human Embryos Bill 2002* requires the review be undertaken by the same people and concurrently with the Minister's review of the *Prohibition of Human Cloning Act*.

2.8 The net effect is to ensure the Minister rather than the NHMRC selects the people who will conduct the review. However, there is a requirement in both the original and subsequent split bills that the persons selected must be approved by each State. Therefore, we do not consider this change to be of material significance or inconsistent with the intent of the COAG communiqué, thus see no compelling reason to amend the Bills to bring these provision strictly into line with the original Bill.

2.9 In our view, the *Prohibition of Human Cloning Bill 2002* is very widely supported throughout the community and for very good reasons. We believe human reproductive cloning is unethical and unacceptable and recommend the Bill be passed in its current form.

2.10 By contrast, the *Research Involving Human Embryos Bill 2002* is more contentious and most of our supplementary comments go to issues directly or indirectly related to this Bill.

COAG and the Legislation

2.11 The legislation enacts the COAG communiqué of 5 April 2002, and

- provides for a national framework for the regulation of research on excess assisted reproductive technology (ART) embryos that would otherwise be destroyed;

- prohibits the creation, importation, export or implantation of a human embryo clone and provides for legally enforceable sanctions against these and other prohibited practices;

- establishes a national licencing committee of the NHMRC that will assess applications for licences to conduct;

    - research,

    - training in ART techniques

    - quality assurance in ART

    - examine effectiveness of new culture media in ART.[2]

- provides a centralised, publicly available database of information about all licences, the number of research projects involving excess ART embryos, the nature of those projects and the numbers of excess embryos being used.

2.12 The legislation seeks to treat all uses of excess ART embryos even-handedly. All non-exempt activities will require scrutiny and approval at the local human research ethics committee (HREC) level and at the national level of the NHMRC licencing committee.[3]

2.13 We also make the point that the legislation is relatively conservative. For instance, the *Prohibition of Human Cloning Bill 2002* bans;

- Somatic Cell Nuclear Transfer (s.13) - which is permissible in the UK, Israel and non-National Institutes of Health funded research in the USA.

- Cytoplasmic transfer (s.15), a new ART treatment, which may be of benefit for older women and is permissible, for example, in the USA, Italy, Israel and Taiwan.

- Germ line gene therapy (s.18) - which may have considerable benefits overcoming heritable diseases such as Spina Bifida.

2.14 In addition, the *Research Involving Human Embryos Bill 2002* applies a new level of regulation on some practices in IVF clinics that have been carried out, with no apparent systematic abuse, for up to 25 years in some cases.

Consequences if Research Involving Human Embryos Bill Fails

2.15 We believe it is important to understand what will occur if the *Research Involving Human Embryos Bill 2002* is not passed.

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2 EM, Research Involving Embryos and Prohibition of Human Cloning Bill 2002, p. 18

3 Dr Clive Morris, NHMRC, *Committee Hansard*, 29.8.02, p. 7

a) It will have no impact on the rate of production and disposal of ART embryos;

b) Embryonic stem cell research will continue on existing lines (which we are advised are not acceptable for future clinical research – and are limited for research purposes - as they were created using mouse feeder cells);[4]

c) As most jurisdictions do not ban or regulate destruction of embryos to derive embryonic stem cells then retention of status quo will mean such activities are permissible in all jurisdictions apart from VIC, SA and WA;

d) The States and Territories can determine their own approach and given the public comments of several State premiers, this may result in more liberal regimes than this Commonwealth legislation permits;

e) Substantial differences between VIC, SA and WA relative to the other States and Territories may lead to inconsistent approaches, criteria and "possible loopholes and safe havens";[5]

f) There will be no central agency to provide oversight, informed monitoring or review;

g) There will be no central data collection agency; and

h) Research may be hampered as researchers will only be able to access existing stem cell lines, or lines from overseas from, most likely, commercial sources who may require some rights over IP developed from the research.[6]

2.16 In addition, defeat of the legislation may send a strong negative message about Australian science policy, both domestically and internationally. Uncertainty and inconsistency may lead to a loss of scientists – in an area where Australia is recognised as a world leader – to more liberal or consistent regulatory regimes including the UK, Singapore and the USA.[7]

2.17 Such an outcome is inconsistent with recent policy initiatives or election statements including the *Wills report*, the Coalition's *Backing Australia's Ability*, the Labor Party's *Knowledge Nation* and the Democrats' Higher Education, Innovation and Science policy statements. Having said that, it can be argued that the impact on the science community – in terms of 'brain drain' and loss of control over commercialisation of research done in Australia - is not sufficient, in and of itself, to support the Bill.

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4 Bresagen, Submission No. 1030.

5 Queensland Government, Submission No. 1500.

6 Professor de Kretser, Submission No. 1041, Professor Trounson, *Committee Hansard*, 24.9.02, p. 153

7 Bresagen, Submission No. 1030, p. Privately funded ES research is largely deregulated in the USA.

3. Scientific and Ethical Issues

3.1 Chapters 2 and 3 of the Chair's report provide a summary of the scientific and ethical issues and views put to the committee in this inquiry. Moreover, as the Chair's report points out, the scientific and ethical issues have been well canvassed in various reports and inquiries (2.2).

3.2 Unsurprisingly, much of the inquiry focused on the scientific and ethical dimensions of embryonic stem cell research, and the relative merits of embryonic and adult stem cells.

3.3 Strictly speaking, many of the concerns raised in the Committee's inquiry are outside the direct concerns of the provisions of the Bills but nevertheless form a helpful backdrop to understanding the issues at hand.

Ethical question

3.4 The central ethical question posed by the legislation is whether people believe destructive research on excess ART embryos that have been donated with consent, and which would otherwise be allowed to succumb, is acceptable or not. Or to pose that question in more general, philosophical terms: Is an embryo the moral equivalent of an adult or a child?

3.5 We believe that for any one person, the answer to that question ultimately relies on their personal commitments. As Dr Best, representing Dr Jensen, the Anglican Archbishop of Sydney, pointed out;

> The moral status of an embryo is not a fact but a value. We will each decide that which is valuable to us on the basis of our world-views. But we live in a multicultural democracy and world-views abound.[8]

3.6 While we respect the wide range of sincerely held views, there is clearly no prospect of consensus or the acceptability of an absolute position in a pluralistic society.

3.7 Chapter 3 of the Chair's report provides a framework for considering the question and we do not intend to recapitulate that work here.

3.8 We do, however, wish to offer some comments about the ethical debate both in terms of the inquiry and more broadly.

a) To a significant extent, the Committee can only deal with the submissions and oral evidence it receives. It cannot be assumed therefore, that the views expressed in an inquiry exhaust the issues or are broadly representative of community opinion.

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8 *Committee Hansard*, 24.9.02, p. 155

b) It is fair to say that the vast majority of the evidence opposed to destructive research on embryos on ethical grounds came from individuals or organisations with explicit religious or church commitments.[9]

c) The committee neither sought nor received evidence from other professional philosophers who may have provided other perspectives on the ethical questions.

d) We do not believe it is helpful or fair to reductively characterise the debate as a battle between, say, 'radical Utilitarians' or 'dogmatic Christians' (or, indeed, science and religion). The evidence, particularly from those opposed to destructive research on embryos, ranged from the highly nuanced through to very direct, simple dogmas.

3.9 There are elements of the ethical debate, which are not novel.

3.10 The ethics of donating organs or tissue is well considered. The question of whether an embryo or foetus has the equivalent moral status as an adult has been widely addressed in debates on abortion. Moreover, the issue of whether there is an important distinction between actively facilitating death or allowing someone to die by withdrawing medical life-support systems is widely canvassed in voluntary euthanasia debates.

3.11 However, as Dr Best pointed out, analogies to other ethical debates are limited;

> When you create an embryo in an ART process, you are planning for that to become a life and it is very carefully made and implanted; whereas most pregnancies, in an abortion context, have occurred by accident – they were not planned pregnancies. Also in the case of an abortion you have the competing needs of a mother. In New South Wales, abortion is allowed because of the mother's rights to avoid any particular hardship that any pregnancy would cause – whereas in the case of a frozen embryo, the mother is not pregnant and there is no risk to her health.[10]

3.12 The substantive difference between destructive research on embryos and, say, the abortion debate is highlighted by Dr Van Gend, a General Practitioner representing Do No Harm, who stated:

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[9] Eg Australian Catholic Bishops Conference, submission 981, Anglican Diocese of Sydney, Social Issues Executive, Submission No. 672, Queensland Bioethics Centre is an agency of the Catholic Archdiocese of Brisbane. Mr Campbell, *Committee Hansard*, 26.09.02, p. 217 (We make it clear this is a transparent relationship and no attempt was made by QBC to represent itself as independent). Catholic Health Australia, Submission No. 897, Catholic Women's League Australia Submission No. 882, Catholic Archdiocese of Melbourne, submission No. 876, Right to Life Australia, Submission No. 1003. In addition, Southern Cross Bioethics Institute's parent is Southern Cross Care which was established by the Knights of the Southern Cross: *Committee Hansard* 17.09.02, p61. Dr Nicholas Tonti-Filippini is a consultant ethicist to the Catholic Church.

[10] *Committee Hansard*, 24.09.02, p. 168

> at the heart of the matter before us is whether we do harm to the human embryo by commodifying it as a raw material for science, whether we cross the line where for the first time a subgroup of the human family becomes defined as material that can be used destructively for the benefit of others.[11]

3.13 However, to what extent people will choose to weight the various ethical dimensions to this debate is a personal choice. Potential donors of embryos, for instance, face a rather different set of ethical issues than a non-donor, and these do include considerations of autonomy and choice.

3.14 As a community, we do not currently accept an absolutist determination on the moral status of an embryo or hold 'uniform protection of all human life'. This does not mean, however, that the embryo is of no account.

3.15 We are concerned, therefore, that in considering the ethical debate, the options should not be collapsed to a choice between a (morally sophisticated) rejection of destructive research on embryos and a (laissez-fair) utilitarianism that supports it.

3.16 We do not accept Archbishop Wilson's claim that "the radically utilitarian public policy which supports this legislation creates a significantly dangerous, if not chilling, precedent."[12] There is nothing inevitable about what choices people might make in the future.

3.17 We do not believe people have to be committed to a crude utilitarianism or moral relativism to hold a position that supports regulated and prudent research on genuinely excess ART embryos that have been donated with full and informed consent.

Stem Cell Science

3.18 The committee received considerable evidence and commentary on stem cell science and this is extensively considered in the Chair's report (primarily chapter 2).

3.19 In our view, the key points that emerged from that evidence are as follows.

- Stem cell science is in its infancy. Human embryonic stem cells were first isolated and characterised in 1998 and adult stem cell research followed shortly after (although some therapeutic uses of adult stem cells associated with bone marrow have been successfully used for approximately 40 years).

- Stem cell science is a fast moving field with new insights and research results appearing in the scientific literature with great rapidity.

- Possible therapies that may arise from stem cell science include:

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[11] *Committee Hansard*, 24.09.02, p. 175

[12] *Committee Hansard*, 24.09.02, p. 214

  - Replacing or transplanting damaged or diseased cells with tissue developed from stem cells; and

  - Development of drugs or other therapies to control and direct cell differentiation.

- While some results in adult stem cell research and therapies and mouse embryonic stem cell research appear well confirmed, many results, including, for instance, Professor Verfaillie's recently published work identifying and culturing a rare adult stem cell, have not been confirmed or replicated in other laboratories.[13]

- The characteristics of stem cells and basic biological questions such as understanding the factors that contribute to cell differentiation, specialisation and regeneration are not at all well understood. This constitutes a fundamental and significant ongoing research challenge for stem cell science.

3.20 Consequently, we believe it is premature and unreasonable to expect definitive answers on many of the questions that arise from stem cell science. We see unpredictability and uncertainty as intrinsic characteristics of science particularly at the forefront of a new and complex field. Whether scientists will fully or partially address the myriad challenges and questions in the short, medium or long term is simply not known.

Embryonic Stem Cells

- Embryonic stem cells are derived from embryos, which necessarily results in the contentious destruction of the embryo.

- Embryonic stem cells by definition, can give rise to all tissue types (pluripotent). Specialised cell types from human ES cells, including heart muscle, insulin producing cells and nerve cells have been successfully derived.[14]

- ES cells can be placed in a culture medium and replicate and remain undifferentiated indefinitely.

- There have been no therapies, treatments or cures developed from human embryonic stem cells to date.

- There are considerable problems to overcome if embryonic stem cells will have therapeutic application for tissue transplantation because of immunological rejection and insufficient knowledge to control differentiation (in animal

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[13] Yiang Y et al, *Pluripotency Of Mesenchchymal Stem Cells Derived From Adult Marrow*, *Nature* 418, pp. 41-49, 4 July 2002. Given the weight attached to this paper in arguments privileging adult stem cell research over embryonic stem cell research we emphasize that this comment does not infer that Verfaillie's results are flawed. It would be surprising if the result had been replicated so soon after publication.

[14] Associate Professor Pera, Submission No. 873, p. 2

experiments, embryonic stem cells have demonstrated a tendency to produce benign tumors called teratomas).[15]

3.21 These problems were acknowledged by all proponents of stem cell research and the committee was advised of a variety of research projects seeking to overcome them.[16]

- Bresagen described its current work exploring methodologies to 'reprogramme' adult stem cells from a patient by fusing them with an embryonic stem cell to avoid immunological differences. This work has had qualified success with mouse models but to date, is neither successfully established nor practical.[17]

- Professor Trounson advised the committee (and provided relevant academic articles) of work being conducted by Associate Professor Boyd to 'tolerise' tissue.[18]

3.22 It is not possible to predict whether such work will be successful in overcoming immunological rejection of ES cells in some or all transplantation therapies. That is an empirical question that cannot be decided at this stage. As a consequence, proponents of ES research advised that transplantation therapies may be 5, 10 or 15 years away if at all.[19]

3.23 Professor Bartlett informed the committee that:

> In fairness to companies like Bresagen, they are aware that therapy is 10 – 20 years away. Stem Cell International's CEO has said publicly that therapy, in their eyes, is 10-20 years away.[20]

3.24 He also outlined the 'clearly defined' difficulties that need to be overcome to achieve ES therapies. He concluded:

> In no way am I suggesting that we should not have a shot at seeing if embryonic stem cells really can fulfil a potential that these other cells cannot

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15 Refer Professor Good, Submission 614, also his contributions in *Committee Hansard*, 19.9.02, pp. 89-91.

16 However, Dr Simmons also stated "but to be fair, in kidney transplants patients are given immunosuppressive drugs and they may be on those for many years, as a means of combating rejection in that setting, and that is viewed as a perfectly acceptable therapy". *Committee Hansard*, 19.9.02, p. 97

17 Bresagen, Submission No. 1030, p. 4. Dr Tonti-Filippini also referred to such techniques suggesting that such an approach may yield an embryo if placed on a bed of tetraploid embryos. Although he qualified this by noting that it is not known whether this capacity (totipotency) is intrinsic to stem cells or to the capacity of the bed of embryos. *Committee Hansard*, 24.9.02, pp. 169-170. It is widely held that stem cells are not totipotent, in any event, the use of this technique to create an embryo would be banned in the legislation.

18 *Committee Hansard*, additional material.

19 See, for example, Professor Tuch, *Committee Hansard*, 17.9.02, p. 47

20 *Committee Hansard*, 19.9.02, p. 99

> … as a scientist I know that discoveries do not often come in a linear manner; they come from left or right field. So I would never cut off a potential cure base or a potential discovery because of the thought that you know the answer.[21]

3.25 We conclude that ES cell research may lead to successful therapeutic applications in the future. It is not certain what form therapies might take (drugs or transplants), nor is it certain which diseases may be amendable to ES therapies. In view of the potential of embryonic stem cell research, we believe it is premature to unnecessarily constrain or prohibit research.

Adult Stem Cells

- Adult stem cells pose no additional ethical issues beyond those associated with convention clinical practice.

- Adult stem cells are difficult to isolate and are not easy to grow or remain undifferentiated in culture. Dr Simmons, an adult stem cell scientist, advised;

  > adult stem cells are limited in numbers and we cannot grow all the adult stem cell populations we would like. These are two important limitations of adult stem cells which, in fairness, the committee needs to take on board if it is to engage in a rational debate on the relative merits of embryonic and adult stem cells.[22]

- Treatments using adult stem cells have been successful or promising with quite a range of diseases including cancer, damaged heart tissue and anaemias.[23] However, it was also argued that adult stem cells have not demonstrated the capacity to meet all needs for cell therapy.[24]

3.26 There was broad based and well-founded support for adult stem cell research. No evidence or oral evidence advocated cessation of adult stem cell research.

3.27 We conclude this is an important area of stem cell science well deserving of public support including funding.

3.28 It should be noted that the legislation has no impact on adult stem cell research.[25] Therefore, it could be argued that, strictly speaking, much of the evidence concerning the utility and potential of adult stem cells was irrelevant to the inquiry. We do not hold that view as the evidence and discussion on adult stem cell research

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[21] Professor Bartlett, *Committee Hansard*, 19.9.02, p. 95

[22] Dr Simmons, *Committee Hansard*, 19.9.02, p. 92

[23] For an extensive bibliography of treatments using patients own stem cells refer Dr Tonti-Filippini, Submission No. 86, pp.10-17. See also Do No Harm, Submission No. 1042

[24] Dr Chris Juttner, Bresagen, *Committee Hansard*, 17.9.02, p. 32

[25] That is not strictly true as there are implications for resource allocation and competition for funds whether the legislation was passed, amended or defeated.

provided a useful perspective to consider embryonic stem cell research specifically and stem cell science more broadly.

Synergies Of Adult And Embryonic Stem Cell Research

3.29 As the Chair's report notes a number of submissions argued or implied that recent developments in adult stem cell research and therapies made embryonic stem cell research redundant (2.98).

3.30 This was firmly rejected by a number of scientists specialising in embryonic and adult stem cell work.[26]

3.31 Dr Simmons argued that many of the experiments purporting to demonstrate 'plasticity' of adult stem cells had not been replicated and "some reported phenomena have been shown to be artefacts due to contamination of transplanted cells."[27]

3.32 Considerable interest was shown throughout the inquiry in the recently published work of Professor Verfaillie and her team. They isolated rare cells from bone marrow, muscle and brain called Multi-potential Adult Progenitor Cells (MAPCs). These cells are slow growing, and to date, their isolation has only been achieved by Professor Verfaillie's team.[28]

3.33 Dr Elefanty advised the committee that MAPCs:

> are able to differentiate into a range to tissue types in vitro and upon transplantation in vivo, although this is not yet an efficient process. MAPCs are different from embryonic stem cells in their appearance, the genes they express and their growth requirements.

3.34 He further added:

> To highlight the difference between adult and embryonic stem cells, I refer to an analysis of the genes expressed by embryonic stem cells and adult stem cells and neural stem cells performed by Melton's group in the USA. These results were published on-line in *Science* on 12 September of this year:
>
> > Our results show that SC's (stem cells) are distinct in that each SC can clearly be identified by highly enriched genes that are not present (or not enriched) in other SCs
>
> It is apparent that adult stem sources of stem cells have great potential to provide cellular therapies and, indeed, no scientist or physician working on embryonic stem cells are advocating that research into these sources for transplantation be abandoned. However, it is just as clear that there are restrictions on the availability and

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[26] Professor Simmons, Dr Elefanty.

[27] Submission No. 1292, p. 2 and also refer table 1.

[28] Drs Elefanty and Stanley, Submission No. 477, p. 2

> applicability of cells from any individual organ and that embryonic stem cells and adult stem cells are not identical.
> Therefore, it is prudent to isolate and investigate the capabilities of both embryonic and adult stem cells, since it may transpire that cells from different sources have specific applications for which they are best suited – horses for courses.[29]

3.35 Dr Simmons stated:

> Adult stem cell researchers and the embryonic stem cell researchers will benefit from understanding the two systems. In the end we both benefit. I think integration between the two is really important. There is a synergy there and it is a driving force for discovery, which neither field of stem cell research alone would likely produce.[30]

3.36 Professor Williamson, Director, Murdoch Children's Research Institute and Professor of Medical Genetics, University of Melbourne (and an adult stem cell researcher), stated:

> What I believe to be absolutely certain is that there are real benefits in allowing adult and embryonic stem cell research to proceed side by side in the same laboratories, so the experiments cross-refer and so that lessons can be learnt by comparing the two systems.[31]

3.37 Professor Trounson advised the Committee that a key feature of the National Stem Cell Centre will be the integration of researchers in adult stem cells, embryonic stem cells, transplantation biology and tissue engineering.[32]

3.38 Professor Verfaillie has adopted a similar approach. In a recent interview on the ABC she stated

> And so I think my message has always been, even though we're excited about the adult cells, that its too early to say that they will replace embryonic stem cells to the point that our institution, the Stem Cell Institute, we actually recruited and investigated who has extensive experience in human embryonic stem cell work, so we're now in a position to do … parallel research and comparing and contrasting the two cell types.[33]

3.39 We conclude that it is a false dichotomy to consider the issue in terms of embryonic stem cells versus adult stem cells. We believe a very strong case has been made to encourage research on both with a view to understanding their relative merits

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29 *Committee Hansard*, 24.9.02, p. 138

30 *Committee Hansard*, 19.9.02, p. 106

31 Submission No. 1002

32 *Committee Hansard*, 24.9.02, p. 142

33 Transcript of interview, Professor Catherine Verfaillie, The World Today, 22 August 2002, http://www.abc.net.au/worldtoday/s656192.htm

and disadvantages. Moreover, there is a very good case to be made for encouraging productive cross-fertilisation of ideas and methodologies. While not relevant to the Bill as such, we note that this synergy between adult and embryonic stem cell research is a central feature of the National Stem Cell Centre.

Embryonic Stem Cell Research – Broader Than Therapies

3.40 The strongest criticisms of proponents of human embryonic stem cell research (as science) was directed at the claims of the potential for the development of therapies to treat or cure diseases including Alzheimer's Parkinsons, Motor Neurone Disease and Type 1 diabetes.

3.41 For instance, Emeritus Professor Martin asserted

> All the proponents of human embryonic stem cell research rely ultimately on the one argument – that cures for chronic disease are sure to follow.[34]

3.42 In our view, a significant consequence of the focus on potential therapeutic applications was that there was a lack of appreciation that ES research is, in fact, multi-faceted.

3.43 A balanced view needs to be mindful that human embryonic stem cell research is a broad term that encapsulates a range of research projects.

3.44 In the course of the inquiry a number of these were identified including;

- Discovering the factors that influence and regulate cell differentiation and tissue formation[35];
- Developing methodologies to control differentiation
- Understanding how diseases occur and how particular genes lose their regulators and are associated with cancer or are involved in formation of cells of genetic diseases;[36]
- Screening drugs for toxicology and effectiveness on stem cell lines that have differentiated into liver, kidney, heart and other cell types[37] (not to be confused with possible toxicology studies on embryos); and
- Possible therapies including tissue transplant and pharmaceuticals.[38]

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[34] Submission No. 162, p. 4

[35] Professor Trounson, *Committee Hansard*, 24.9.02, p. 135

[36] Professor Tuch, *Committee Hansard*, 17.09.02, pp. 40-1, professor Trounson, *Committee Hansard*, 24.9.02, p.135

[37] Dr Juttner, *Committee Hansard*, 17.9.02, p. 40, see also comments of Professor Trounson, *Committee Hansard*, 24.9.02, p. 141, submission Elefanty and Stanley

[38] Professor Trounson, *Committee Hansard*, 24.9.02.

3.45 While science does not neatly divide into basic and applied research, there is clearly a spectrum of discovery and application elements to these broad strands of human ES research.

Are more stem cell lines required?

3.46 If, as we have concluded, there is a strong case for ongoing human embryonic stem cell research, there is a question as to whether existing stem cell lines are adequate.

3.47 Throughout the inquiry there was extensive discussion on how many embryos would be required. Oddly, there was little discussion on the more fundamental question of *why* more embryos might be required.

3.48 It was suggested to the Committee that as there was little prospect of clinical trials using human ES cells in the short to medium term there was no need for additional stem cell lines (thus access to more embryos) because there were adequate existing stem cell lines available for research.

3.49 Professor Silburn, whilst highly critical of the claims concerning possible therapeutic applications of embryonic stem cells, did not object to ongoing research but questions why more embryos are required.[39]

> I think the research should go ahead – absolutely – and it will go ahead whether or not the bill fails … Parkinson's Australia is very happy for research to continue, and I will be pleased to report to everybody that if the bill fails that research will continue.[40]

3.50 Professor Good stated:

> There are already ES lines that will not be affected by the act, which could be used for research. They are already there, they will not be blocked by the act. So why do they want more embryos? The only reason I can think of is that drug companies may wish to use them for screening.[41]

3.51 There seems to be some difference of opinion on this among scientists. Bresagen, for instance, submitted that there is no current need to derive new human embryonic stem cell lines for research, in part, because, new ESC lines will not be eligible for world wide National Institutes of Health research funding.[42]

3.52 In response to a question from Senator Barnett, Mr Ilyine advised the committee:

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39 *Committee Hansard*, 17.9.02, p. 52

40 *Committee Hansard*, 17.9.02, p. 53

41 *Committee Hansard*, 19.9.02, p. 98

42 Submission No. 1030, p. 3

> You suggested that there are a number of people who provided evidence that said that there were no further cell lines needed more or less forever. I think experience in time has shown that that is not really the correct position, which is that there are in fact additional cell lines needed for all sorts of reasons. We already have made some progress from mouse feeder cell systems to human feeder systems, but I would argue that perhaps that is not far enough either, and that actually the cells in time, to be fully GMP compliant, would have to be able to grown in a fully defined medium where all the components of the medium were known and understood to be safe in their own right.[43]

3.53 In evidence and discussion a range of reasons why new embryonic stem cells were required for research were offered.

- Existing stem cell lines have been created with mouse feeder cells "which produce as yet unidentified substances necessary for stem cell research.[44]

- New stem cell lines will need to be created because feeder layers give signals to the cells to allow them to change from inner cell mass lines to cell lines but it is likely that those cell lines will behave differently so that research conducted with mouse-derived feed cells will need to be repeated with human-derived feeder cells.

- Restricting access to existing SC lines is a problem for obtaining proof of principle because "you do not want to be doing experiments on cell lines that have been passaged for hundreds and hundreds of passages. If one were restricted to a very few lines, whether they be mouse or human, the likelihood of being able to obtain that proof of principle may be difficult. You would want to be dealing with cells that were in the best possible state."[45]

- As ES research is in its infancy, it is likely that future methodological improvements in initiating and growing stem cell lines will lead to second generation lines with improved properties.[46]

- Where there are commercial barriers to existing stem cell lines, researchers will want to create their own lines[47]

3.54 In addition, a number of reasons why additional stem cell lines were required for therapeutic reasons were identified, including:

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43 *Committee Hansard*, 17.9.02, p. 40

44 Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135

45 Professor Bartlett, *Committee Hansard*, 19.9.02, p. 100

46 Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135, Dr Stanley, ibid, p. 139

47 Mr Ilyine, *Committee Hansard*, 17.9.02, p. 40, Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135, Professor Trounson, ibid, p. 140

- Human ES lines using mouse feeder cells are considered by the FDA to be contaminated by animal pathogens (xenotransplant) and thus not permitted for clinical trials;[48]

- If and when there is a prospect of safe human trials, stem cell lines compliant with the FDA's current Good Manufacturing Practice (cGMP) guidelines will be required; and [49]

- Clinical therapies using embryonic stem cell lines will have to address immunological rejection and this may require larger panels of stem cell lines.[50]

3.55 Moreover, relying on mouse ES lines is problematic when trying to investigate some diseases. Professor Bartlett informed the committee that:

> animal models are in fact deficient in terms of reflecting the actual disease process. This is because we do not actually know what causes Alzheimer's disease or what causes motor neurone disease. So you have animal models that result in a similar complaint, but they may not reflect the underlying cause of that disease.[51]

3.56 We conclude that a strong case has been made to support the need for new stem cell lines and that existing stem cell lines are not adequate for research and, in the longer term, therapeutic purposes.

How Many Embryos required?

3.57 Recognising that there is an established need for new stem cell lines, the next question - and one that prompted considerable debate during the course of the inquiry - is how many embryos will be required.

3.58 It is likely that the biggest call in the short term will come from IVF Clinics. Professor Jansen advised that hundreds of embryos will be required to develop meaningful results in development of culture medium.[52]

3.59 In respect of embryonic stem cell research, there was a very wide range of numbers offered including 20 – 50 (Trounson), 600 – 1000 (Bresagen), through to millions (Good).

3.60 There was considerable comment on the disparity of these figures. Professor Silburn stated, for instance, that:

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48 Professor Trounson, *Committee Hansard*, 24.9.02, p.140

49 Dr Juttner, *Committee Hansard*, 17.9.02, p. 38, Professor Tuch, *Committee Hansard*, 17.9.02, p. 39

50 Associate Professor Pera, *Committee Hansard*, 24.9.02, p.135

51 *Committee Hansard*, 19.9.02, pp. 100-101

52 *Committee Hansard*, 26.9.02, p. 211

> clearly if the point of the bill is how many we need and nobody can agree on how many we need, we are lacking some science here.[53]

3.61 Professor Trounson explained that part of the difficulty in estimating the number of stem cell lines needed in the future was that:

> it would depend on the outcome of the research. If the research were shown to be successful in the induction of (immunological) tolerance to embryonic stem cells and their derivatives, we may need a panel of embryonic stem cells, in which case maybe 50 is sufficient. I am not really certain, but it would be a number of them. They would have to give you advice in the future when the research was done.[54]

3.62 Dr Juttner believed that 600 – 1000 such therapeutic lines will provide adequate immunological matching.[55]

3.63 Professor Good disputed these figures and outlined some of the complexities of donor matching: I believe that to get a (stem cell line) 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.[56]

3.64 Professor Silburn is correct, there is some science missing. What is missing, as discussed above, is certitude as to how or whether immunological rejection of embryonic stem cells can be overcome. That is the fundamental basis of the disparity in the figures.

3.65 Although it may seem odd, the arguments are entirely consistent. Professor Good is arguing that millions of stem cell lines are likely to be required to maximise a good match to minimise or eliminate immunological rejection *if no other techniques are discovered to avoid this*.

3.66 Bresagen and Trounson are arguing that they might be able to overcome that by a variety of approaches *and if that is successful* then they believe considerably less lines will be required.

3.67 While we understand the preference and desire for certitude we see uncertainty as an intrinsic feature of new and complex areas of research. We do not regard the disparity as a defect, but simply underscores the fact that this is emergent research. It does, however, reinforce the argument for good, nationally consistent regulation.

3.68 We find it quite unremarkable that there were divergent and at times strongly held differences between scientists concerning the therapeutic potential of embryonic

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53 *Committee Hansard*, 17.9.02, p. 52

54 *Committee Hansard*, 24.9.02, p. 141

55 Bresagen, Submission 1030, No. 1

56 Professor Good, *Committee Hansard*, 19.9.02, p. 90

stem cells. Disputes over the facts and the meaning of the facts is common, typical even, in science, particularly in fields as complex and new as stem cell research.[57]

3.69 It should be noted that COAG requested the NHMRC report within 12 months on the adequacy of supply of excess ART embryos which otherwise would have been destroyed because of the lack of detailed knowledge on the numbers of embryos available for research.[58]

Are there really 70,000 'excess' embryos?

3.70 It was widely claimed in inquiry submissions and by witnesses that there are about 70,000 excess ART embryos. This is not correct.

3.71 The Committee was advised that there are 71,176 ART embryos in *storage* because the couples for whom they are created either still want them; have not decided that they are no longer required; or if excess, have not determined what they want to do with them.[59]

3.72 It is not known how many of these are excess in any given year or how many would be available for research.

3.73 The NHMRC provided data from the South Australian Council on reproductive Technology which shows that, as of 31 December 2001;

- 5718 embryos in storage
- 1239 were stored for couples who at the time still intended to use the embryos
- in 2001, 423 embryos were destroyed (374 at the couples request)
- 110 embryos donated for use by other couples
- 137 embryos donated for research.[60]

3.74 Professor Peter Illingworth, also provided advice to the Committee that

- 450 letters were sent out to couples with embryos in storage for more than 2 years
- 100 couples responded;

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[57] There is a vast literature in History, philosophy and sociology of science that outlines the nature of scientific disputes. The work of Kuhn, Latour, Cangelheim and Feyerabend, for example, are well established 'classics' in these fields.

[58] Council of Australian Governments – Communiqué http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm. See also Dr Clive Morris, NHMRC, *Committee Hansard*, 29 8.02, p. 7 and p. 29

[59] NHMRC Submission No. 23, additional information, 13.9.02, p. 11

[60] ibid, p. 12

- 50 couples had moved; and
- 250 couples did not respond.

3.75 Only 15 couples (3% of couples written to) decided that their embryos were excess to their requirements. Of these;

- 7 couples requested that their embryos be allowed to succumb; and
- 8 couples indicated an interest in donating their embryos. All attended counselling but only three couples went on to donate their embryos.[61]

3.76 The SA data combined with Professor Illingworth's experience suggest:

- There are manifestly not 71,000 excess ART embryos;
- The number of embryos available for research and stored prior to 5 April 2002 is likely to be very small;
- It can not be assumed that many couples will seek to donate embryos excess to their requirements.

Creation of excess embryos

3.77 The prospect of creating excess embryos for research was also raised in the context of restrictions on accessing embryos created after 5 April 2002 after three years or earlier if determined by COAG.

3.78 In their submission to the inquiry, the Southern Cross Bioethics Institute asserted;

> If embryos created at any time and excess to the requirements are available to researchers, it would not be difficult to create an excess of embryos by simple changes to practice of IVF clinics. This would in effect constitute the *de facto* production of human embryos deliberately for the purpose of research.[62]

3.79 In a question on notice by Senator Stott Despoja, witnesses were asked

> Do you agree with the assertion that creation of excess embryos could be done with 'simple changes to practices'? It seems to me that there are two elements to this – the regulatory and the medical.

3.80 In response Professor Illingworth advised the committee that:

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61 Professor Illingworth, Westmead Fertility Clinic, Communication to the Secretary, 10.02

62 Rev. Dr John Fleming and Dr Gregory Pike, Southern Cross Bioethics Institute, Submission No. 892, p. 9

This assertion is unfounded. I would like to make the following points in response.

Medical

1. As outlined in my presentation, due to the variable and highly unpredictable factors involved in the achieving the result of healthy embryos for implantation, current clinical practice is to stimulate the ovaries with the aim of collecting 10 or so healthy eggs in the hope that sufficient will fertilise normally then develop satisfactorily in order to give a chance of a successful pregnancy.

2. The number of eggs is primarily dictated by the number of eggs already growing in the ovary at the time of starting treatment with fertility drugs. The number of eggs already growing in the ovary at the time of treatment cannot be altered by any means currently known to medical science.

3. Thus most patients undergoing IVF already receive a maximal dose of fertility drug and giving a higher dosage will not increase the number of available eggs.

4. There are however a small number of younger patients where a sub-maximal dose is used. This is because the maximum dosage would stimulate a very high number of eggs to grow in these women. This outcome would put those patients at risk of a serious medical condition (called ovarian hyperstimulation syndrome) which leads to accumulation of fluid in the abdomen and sometimes chest with very serious health consequences for the patient.

5. The deliberate and dangerous use of these maximal doses in a minority of younger patients is thus the only way that creation of excess embryos could be initiated

Regulatory

Such a practice would be contrary to explicit RTAC guidelines. As of this year, the data reporting process for IVF clinics to the National Perinatal Statistics Unit has been extended to include a requirement for every clinic to report quite specific information about the number of eggs collected and the number of embryos being collected per treatment cycle for every clinic in Australia. Through this process, these data for each clinic will be compared with natural means. If any clinic did opt for the unethical and unacceptable practice

> suggested above, this will be readily apparent to RTAC from this data set and RTAC would be able to act accordingly.[63]

3.81 In a subsequent communication to the Committee, Southern Cross Bioethics cited evidence given by Dr Jansen to the Senate Select Committee on the *Human Embryo Experimentation Bill 1985* where he stated:

> It is a fallacy to distinguish between surplus embryos and specifically created embryos in terms of embryo research … any intelligent administrator of an IVF program can, by minor changes, in his ordinary clinical way of going about things, change the number of embryos that are fertilised .. it would be but a trifle administratively to make those embryos surplus rather than special.[64]

3.82 Following on, Southern Cross Bioethics stated:

> "Presumably, all that would need to change would be more eggs would be collected and fertilised. Coupled with a trend towards less embryos being transferred, it is likely that even more surplus embryos would be created surplus to requirements and therefore able to be used in research.[65]

3.83 This, they stated, was the basis for their statement that it would not be difficult to create an excess of embryos, in their submission (cited above).[66]

3.84 The 1985 quote of Professor Robert Jansen was referred to a number of times during this inquiry, notably by Senator Harradine.

3.85 It is important to note that in his submission to this inquiry, Professor Jansen explicitly refuted his position of 1985.[67] He pointing out he had changed his position of 17 years prior because of advances in scientific knowledge of the ovulation process.[68] In evidence entirely consistent with Professor Illingworth's and Dr Pope's, he stated that "the number of eggs and embryos available to the woman also is fixed by physiological processes out of the physician's control".[69]

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63 Professor Peter Illingworth, response to Question on Notice. Evidence consistent with Professor Illingworth's comments was also provided by Sandra Dill of Access and Professor Doug Saunders, Chair of RTAC. See also ACCESS fact sheet #32 – Ovarian Hyperstimulation Syndrome by Professor Geoffrey Driscoll.

64 Hansard Report 1986, Vol. 1, p. 391-2, cited in Southern Cross Bioethics Institute, Submission 892, additional information, 2.10.02

65 Southern Cross Bioethics, *Letter to Secretary, Senate Community Affairs Committee*, October 2, 2002

66 ibid

67 Professor Robert Jansen, Submission 897, see also *Committee Hansard*, 26.9.02, pp 207-208

68 ibid

69 ibid

3.86 While we take Southern Cross Bioethics' point that a trend to less embryos being transferred may increase the number of excess embryos it does not follow that there are medical grounds to reduce the number of ova taken for IVF treatments.

3.87 Professor Jansen advised the committee that "it is not medically possible to vary the numbers of eggs that respond to stimulation upwards at all and it is not possible downwards without compromising the chance of success for the woman."[70] The clear message being there are good medical reasons for the current numbers of ova utilised for IVF treatment.

3.88 We conclude that there are no grounds to substantiate Southern Cross Bioethics' assertion that "it would not be difficult to create an excess of embryos by simple changes to practice of IVF clinics… (for) … the *de facto* production of human embryos deliberately for the purpose of research". Moreover, the Bill makes it an offence to deliberately create embryos for research.

3.89 Senator Harradine and a number of witnesses made much of Professor Jansen's 1985 comments to highlight concerns about deliberate production of excess embryos.[71] We would like to place on record our belief that Professor Jansen's refutation of his earlier position is highly credible and entirely consistent with the medical and scientific evidence provided by Professor Illingworth and Dr Pope. Consequently, we contend that any further citation of his 1985 statements that deliberately seeks to advance a position contrary to his current view must be considered mischievous.

4. Impact on IVF Practices

4.1 The committee heard evidence that the legislation would have a significant impact on current IVF practices.[72]

4.2 A major concern is the requirement that training, quality assurance and testing of culture mediums would need to be a licenced activity. These activities are already routine in IVF clinics and "are crucial for maintaining the highest quality care and improving success rates and so impact on couples currently on treatment.[73]

4.3 It was argued that the requirement that these activities be licenced meant the Bill went further than the COAG agreement (also see below).[74] The Committee was

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[70] Professor Robert Jansen, *additional information e-mailed to the Secretary*, 1 October 2002. Professor Jansen also points out that in 1985 embryos were not frozen, so embryos became surplus immediately. Dr Pope gave similar evidence.

[71] *Committee Hansard*, 29 8.02, p. 29

[72] Dr Adrienne Pope, Submission No. 1001, Monash IVF, Submission No. 1007, Access Australia Infertility Network, Submission No. 47, Professor Peter Illingworth, Westmead Fertility Clinic, *Committee Hansard*, 26.9.02, pp

[73] Access Australia Infertility Network, Submission No. 47, p. 4. Under Victorian, South Australian legislation there are some restrictions on such practices.

[74] Access Australia Infertility Network, Submission No. 47, p. 2

advised that these activities should be made exempt from requiring a licence and amendments (the 'Gambaro amendments') passed to treat training, quality assurance and testing of culture mediums as exempt items in s.25(2) of the Research Involving Embryos Bill 2002.[75]

4.4 However, the NHMRC advised the committee 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.[76]

4.5 The committee was also advised that the extension of the licencing requirements to practices that have long been conducted in all jurisdictions was to ensure consistent legal and ethical treatment of different uses of embryos.[77]

4.6 IVF clinics will be entitled to apply for a licence to conduct such activities on excess ART embryos created before 5 April 2002. However, it was argued that the ban on fresh or frozen embryos created after that date would "severely compromise" embryology training programs, laboratory quality assurance processes and embryo culture system improvements.[78]

4.7 An additional matter was raised by Professor Robert Jansen, Sydney IVF, who advised the committee that s.15 of the Prohibition of Human Cloning Bill would ban Cytoplasmic transfer, a new ART technique that may be of significance in treating older women.[79]

4.8 In our view, the new licencing requirements will have an impact on IVF Clinics. At least one consequence will be increased costs for treatments as there will be compliance costs although it is not yet known how much they will be.

4.9 While sympathetic to the IVF Clinics concerns, we conclude that the benefits of including training and other practices in the framework of the licencing arrangements is justified.

4.10 We note the Bill provides for a review (s.61) and it will be useful to gauge what actual impacts the Bill has had on IVF practice.

5. Concerns Over Nature of Evidence

5.1 In many submissions and in oral evidence given to the committee, concerns were raised about the nature and quality of evidence given to the media, Members of

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75 The Member for Petrie, Ms Teresa Gambaro proposed these amendments prior to the debate in the House of Representatives on the legislation. The amendments were withdrawn prior to debate.

76 NHMRC, Submission No. 23, p. 21

77 Dr Clive Morris, *Committee Hansard*, 29 8.02, p. 25

78 Monash IVF, Submission No. 1007, p. 1

79 Sydney IVF, Submission No. 897.

Parliament and this Committee during the course of the inquiry. These concerns include allegations of misinformation, misrepresentation of science, deliberate omission of relevant information, creation of false or unrealistic expectations and exploitation of people with disabilities.[80]

5.2 Mr Sullivan, Chief Executive, Catholic Health Australia asserted, for example:

> Put simply, there is a ruse being perpetrated by members of the scientific and business community. I would go so far as to suggest that a deliberate campaign of misinformation is being conducted. They have built up false expectations that miracle cures are just around the corner, if only experimentation on embryos can be permitted … As a consequence, we have COAG making an illogical and rushed decision."[81]

5.3 While many of the criticisms were directed at Professor Trounson with claims he misled politicians by omitting information (see below), we believe some balance is required.

5.4 Recently, Dr David Prentice of Do No Harm (America) travelled to Australia to lobby against permitting embryonic stem cell research. He presented himself as an independent scientist with expertise in adult stem cell research.

5.5 However, neither in the promotional material provided by Do No Harm or Dr Prentice was his work as an "ad hoc science advisor" to Senator Brownback and Congressman Weldon (the Republican sponsors of an anti-cloning Bill) advised. While this makes no claim on the veracity of Dr Prentice's scientific arguments, affiliations of this nature are of more than passing interest in the context of a parliamentary debate, particularly as transparency of interests and misleading information have been key topics of discussion.

5.6 Senator McLucas asked Dr van Gend whether Do No Harm funded Dr Prentice's travel and accommodation. He advised the committee that the visit was initially underwritten for about five thousand dollars by the National Civic Council and this money was largely repaid through Professor Prentice's public meetings in Australia.[82]

Exploitation and False Hopes

5.7 In his submission, Dr McCullagh was highly critical of proponents of ES cell research accusing them of:

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[80] See, for example, Professor Colin Masters, Submission 87, Dr Tonti-Filippini, Submission No. 86, Do No Harm, Submission No. 1042, Australian Catholic Bishops Conference, Submission No. 981. Dr van Gend, *Committee Hansard*, 24.9.02, p. 177, Dr McCullagh, Submission No. 480 and *Committee Hansard* 24.9.02, p. 156,

[81] *Committee Hansard*, 26.9.02, p. 219

[82] Dr van Gend, e-mail to secretariat, 1 October, 2002.

> exploitation of highly vulnerable people living with disabilities … to legitimize ES cell production … individuals with major chronic disabling conditions are a resource to be manipulated in television studios.[83]

5.8 This was rejected by Ms Knott, Director, Australasian Spinal Research Trust, who responded to Dr McCullagh's comment, saying:

> I think it is very sad that you would try to take an opinion like that without actually living through the condition, but I for one was responsible for founding the Australasian Spinal Research Trust, so no one could say I am being manipulated into doing that.[84]

5.9 Mr Robert Turner, Honorary Chief Executive Officer, Australasian Spinal Research Trust stated:

> One of the things … (people with such diseases) … fight against is being talked down to like that as though they have not got the ability to discriminate between what is exploitation and what is not.[85]

5.10 Ms Knott added:

> The reality is that we do follow very closely and we have done for a number of years, what research has gone on around the world, and I think we do have a good sense of what is credible and what is not.[86]

5.11 A number of submittees suggested politicians had been notably susceptible to emotive arguments and over-blown claims of cures. Dr van Gend asserted that:

> It is vital to realise that the debate has largely been driven among the politicians and the public by the emotional images of suffering patients with afflictions … we have let loose an army of mothers on all of you politicians, battering down your doors and saying, 'How dare you get in the way of embryo research when it is going to cure my child of cystic fibrosis?', or of its spinal injury.[87]

5.12 The Chair rejected this assertion, saying:

> I have to say, Doctor, that that is simply not true as I sit here today. There are people who hold hope. They do not hold hope that it is tomorrow or next week or next year. I think it is quite wrong for anyone to come before this committee

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83 Submission No. 480, p. 8 (not numbered in original)

84 *Committee Hansard*, 17.9.02, p. 85

85 *Committee Hansard*, 17.9.02, p. 85

86 *Committee Hansard*, 17.9.02, p. 74

87 *Committee Hansard*, 24.9.02, p. 182

> and tell me that that is what has been put to me... because quite frankly that is not so.[88]

5.13 We can confirm that our experience reflects that of the Chair.

The Trounson Debate

5.14 Strong criticism was directed at Professor Trounson for the way he represented experiments on a rat, by Dr Kerr of Johns Hopkins University, at Parliament House in August 2002.

5.15 As the Chair's report notes the key criticisms went to him misleading politicians and the media by stating the experiment used human embryonic stem cells when it was subsequently established that they were human germ stem cells and his use of unpublished material (2.20-2.23).

5.16 In evidence to the Committee, Professor Trounson explained his terminology:

> I did not mislead members of parliament because the terms 'embryonic stem cells' and 'embryonic germ cells' are often used interchangeably.

5.17 He provided a number of examples, including:

> Firstly, embryonic stem cells are defined as 'cultured cells obtained by isolation of inner cell mass cells from blastocysts – these are the IVF embryos – 'or by isolation or primordial germ cells from the foetus' in the Andrews committee report on human cloning.[89]

5.18 As the Andrews Report (The House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning*, August 2001) has been a key reference for parliamentary and public debate on this issue, the failure of the Chair's report to draw attention to the definition it adopts for embryonic stem cells is a significant oversight.[90]

5.19 Professor Trounson also stated:

> Secondly, the primary review of the subject *Stem Cells: Scientific Progress and Future Research Directions* by the United States Institutes if Health, available on their website, describes the Kerr Research as follows:
>
> > Researchers at Johns Hopkins University recently reported preliminary evidence that cells derived from embryonic stem cells can restore movement in an animal model of amyotrophic lateral sclerosis, ALS.[91]

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88 *Committee Hansard*, 24.9.02, pp. 182-3

89 *Committee Hansard*, 24.9.02, p. 136

90 The definition cited by Professor Trounson is in the Glossary of Terms, p. 270

91 *Committee Hansard*, 24.9.02, p. 136

5.20 Professor *Trounson* went on to address the issue of using unpublished material by stating:

> It is not permissible to distribute manuscripts submitted to *Nature* journals until after publication. This is an undertaking that authors agree to when submitting their papers to these journals. I concluded, therefore, that the manuscript must have been published. … My error was in assuming, as would thousands of scientists familiar with the publication rules of *Nature* journals, that the article had been published.[92]

5.21 On this explanation, Dr van Gend, of Do No Harm, stated:

> It is a fair comment, I think, to say that he thought it had been sent by Dr Kerr meaning that it must have been published – the fact that it was sent in this way gave him an impression.[93]

5.22 Professor Trounson's explanation is on the public record.

5.23 This incident provoked strong attacks impugning the motives of Professor Trounson.

5.24 Professor Silburn stated, for instance:

> it was said that this was a naïve attempt and all that. Professor Trounson is very well regarded, and I do not see how it could be naivety that did that.[94]

5.25 Dr van Gend, claimed:

> there is a much more widespread and pervasive distortion of the science (than the rat), which has primarily been carried out by Dr Trounson because he is the main spokesman."[95]

5.26 However, Dr Tonti-Filippini stated that

> it seems to me that this debate has been greatly harmed on both sides by a lack of reference to materials.[96]

5.27 Claims about misrepresentations of aspects of stem cell science in the media functioned as an unexamined, generalised 'given' in the inquiry, as very few copies or citations of media stories were provided.

5.28 In our view, the evidence provided to the committee by scientists supporting embryonic stem cell, notably Dr Juttner, Associate Professor Martin Pera, Dr

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92 *Committee Hansard*, 24.9.02, 136

93 *Committee Hansard*, 24.9.02, 182

94 *Committee Hansard*, 17.9.02, p. 52

95 *Committee Hansard*, 24.9.02, p. 176

96 *Committee Hansard*, 24.9.02, p. 155

Simmons, Professor Williamson, Dr Stanley and Dr Elefanty were measured, supported and realistic. On the basis of the evidence they provided to the Committee, we do not feel that they, or Professor Trounson, can be accused of building "up false expectations that miracle cures are just around the corner, if only experimentation on embryos can be permitted."[97]

5.29 Nor did representatives from groups with disease or disability over-estimate ES research.

5.30 James Shepherd, a 13 year old who has lived with Juvenile Diabetes since he was 5 years old, told the committee:

> There are approximately 100,000 juvenile diabetics in Australia, and there are more being diagnosed each year. I think all of us deserve a chance for a cure… the cure could lie in adult stem cells or embryonic stem cells or it could lie in one of the many other types of research, but I think that every possibility for a cure should be fully explored before it is banned completely.[98]

5.31 Ms Knott, Director, Australasian Spinal Research Trust, said:

> It is imperative that we protect important areas of medical research that we offer hope to hundreds of thousands of Australians. I do not expect a cure tomorrow or even next year, and I do not intend to overstate the promise of research, but how can you overstate hope?[99]

Public involvement in bioethical issues

5.32 Evidence given to the inquiry shows that there is a need for better mechanisms to educate and involve the public in the bioethical debates. We need to ensure that the public has access to information, that they are educated about the issues in language they understand, and that they feel able to make their voices heard on the issues.

5.33 For some years now, under both Clinton and Bush, the United States has had a Presidential Commission on Bioethics. It is a model we could well adopt here.[100]

5.34 The US Commission provides a forum for a national discussion and exploration of bioethical issues. It is charged with exploring the ethical and policy questions related to developments in biomedical science and technology and assessing public concerns about these developments.

5.35 The Commission is guided by the need to articulate and present a variety of views rather than reaching a single consensus opinion.

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97 Mr Sullivan, Catholic Health Australia, *Committee Hansard*, 26.9.02, p. 219

98 *Committee Hansard*, 17.9.02, p. 71

99 *Committee Hansard*, 17.9.02, p. 73

100 As suggested by the Leader of the Labor Party, Simon Crean, in his second reading speech on this legislation in the House of Representatives.

5.36 Such a process, properly constituted, could help facilitate a greater understanding of bioethical issues and a better public debate here in Australia.

6. Specific Issues Related To The Bill

Scope of the Bill

6.1 A concern raised by a number of submittees to the Committee was the Bills went further than the intent of the COAG agreement.

6.2 Dr Best, representing Dr Jensen, the Anglican Archbishop of Sydney stated

> 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 Licencing Committee feels is worth while is approved, under this legislation. … If the legislation is to be passed, I would be much happier if there were tightening of the legislation so that the human embryos currently frozen in ART labs can only be used for the extraction of human embryonic stem cells.[101]

6.3 The *Research Involving Embryos Bill 2002* requires all proposed research activities using excess ART embryos are assessed and licenced by the licencing committee and that licences must satisfy;

- consent provisions (36(3)(a) also 39(1)(a))
- embryos must be created before 25 April 2002 if the research will damage or destroy the embryo (36(3)(b); and
- the proposal has been assessed and approved by the local Human Research Ethics Committee (36(3)(c)).

6.4 The bill permits some activities to be exempt from requiring a licence (25(2)) including the storage, removal (from storage), transport and observation of excess ART embryos.

6.5 According to the Explanatory Memorandum activities that would need to be licenced include;

- For research (for example, to derive stem cells or to improve ART clinical practice)
- To train people in ART practice

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[101] *Committee Hansard*, 24.9.02, p. 158

- For quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and

- To examine the effectiveness of new culture medium.[102]

6.6 Dr Clive Morris, NHMRC, informed the committee that research could also include understanding embryonic development and fertilisation, studies in genetic make-up and expression and drug testing including toxicology providing any such proposal met the licencing requirements and would be subject to whatever the conditions the licence requires.[103]

6.7 The net affect is to ensure all uses of excess ART embryos are prohibited unless they are licenced or exempt.

6.8 In the introduction to the COAG communiqué, it is stated that:

> the Council agreed that research be allowed only on existing excess ART embryos, that would have otherwise been destroyed, under a strict regulatory regime … donors will be able to specify restrictions, if they wish, on the research uses of such embryos.[104]

6.9 In the appendix to the communiqué (that provides more detail on the contents of the framework), the relevant points are:

> A nationally-consistent approach to research involving human embryos
>
> 5. Research involving human embryos should be regulated through nationally consistent legislation.
> 6. The following principles should underpin nationally-consistent legislation:
>
> > 6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;
> >
> > 6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted
>
> …
>
> A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells
> 8. Research with existing stem cell lines will be permitted to continue in Australia subject to the observance of conditions set by the NHMRC/AHEC.

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[102] Explanatory Memorandum, *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, p. 18

[103] *Committee Hansard*, 26.9.02, p. 256

[104] http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm p. 1

> 9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime …[105]

6.10 There is nothing in this that supports the contention that COAG intended that stem cell research exhausts all possible research activities. While other research activities such as testing culture mediums are not specified, we believe the broader coverage is not inconsistent with the general consideration of research in the Bill.

AHEC Guidelines

6.11 There was considerable discussion concerning the guidelines.

6.12 One concern was that AHEC are reviewing the current guidelines, and will continue that review after the bill is passed. Thus, Parliament will not have the opportunity to examine the guidelines at the time the Bill is debated.

6.13 One potential approach is to make the guidelines a disallowable instrument. This would ensure parliamentary scrutiny of the guidelines, but may not be consistent with previous treatment of other ethical guidelines issued by AHEC.

6.14 In any consideration of this issue, it needs to be noted that the current AHEC guidelines go beyond activities covered by this Bill and include information about storage of embryos, counselling and other ART clinical practices.

6.15 A specific concern with the guidelines, relates to the provisions relating to the giving of consent to research involving excess ART embryos.

6.16 The Research Involving Embryos Bill requires that proper consent is required from all "responsible persons" before an excess ART embryo can be used in research.

6.17 The Bill defines "proper consent" and identifies who is a "responsible person" with respect to an embryo.

6.18 "Proper consent" is consent that has been obtained in accordance with the Ethical Guidelines on Assisted Reproductive Technology issued by the NHMRC or other guidelines issued by the NHMRC.

6.19 "Responsible person" means:

> (a) each person who provided the egg or sperm from which the embryo was created; and
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> (b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and

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[105] http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm p. 7

(c) any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and

(d) any person who was the spouse of the woman mentioned in paragraph (b) at the time the embryo was created.

6.20 The current guidelines, which are currently under review, provide among other things that consent must be in writing and should be given following the provision of information and adequate opportunities for personal preparation.

6.21 While the review of the guidelines which relate to consent in assisted reproductive technology procedures is appropriate, there is no evidence that the existing guidelines have been ineffective or have resulted in consent being inappropriately given.

Constitutional issues – Commonwealth, State and Territory arrangements

6.22 The heads of power in the legislation provide wide Commonwealth coverage of corporations, commerce and trade that cover organisations that engage in interstate trade or are corporations. However, Ms Andrea Matthews advised the committee that the Commonwealth's power may not cover individuals. This opens the prospect of an individual challenging the constitutionality of the legislation if the NHMRC initiated a prosecution against an individual.[106]

6.23 This was acknowledged at COAG and the States and Territories agreed to introduce complementary legislation to ensure full coverage, including individuals within six months after royal assent of the Commonwealth Bills (when the regulatory scheme would commence).[107] Ms Matthews advised that the States and Territories could do this by introducing legislation that mirrored the Commonwealth legislation or applied the legislation in their own legislation.[108]

6.24 We conclude that while complementary State and Territory legislation is required to ensure complete constitutional coverage, there are no compelling grounds to believe that any State or Territory would act in bad faith and not honour the intent of the COAG agreement. Accordingly, we do not believe the requirement for complementary State and Territory legislation constitutes a reason to delay or defeat the Bills.

National Legislation

6.25 The Bill allows for the Commonwealth, to the extent of its constitutional powers, to over-ride existing legislation in Victoria, South Australia and Western Australia.

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[106] *Committee Hansard*, 29.8.02, p. 11

[107] COAG

[108] *Committee Hansard*, 29.8.02, p. 11

6.26 As the Chair's report notes (4.129), some submissions argue that allowing the Commonwealth to over-ride State laws is not consistent with COAG nor democratic.[109]

6.27 This argument is seriously flawed. It ignores the fact that the States and Territories are parties to the COAG communiqué and thus the States-rights rhetoric is misconceived.

6.28 We believe one of the real strengths of the COAG is that it unequivocally intends a nationally consistent legislative and regulatory regime.[110] Indeed, as Ms Matthews of Matthews Pegg, consultants to the NM&MRC pointed out "one of the major drivers for a nationally consistent regulatory system was the absence of regulation previously."[111]

6.29 The Member for Sturt, Mr Pyne, introduced an amendment in the House of Representatives proposing that State laws not be affected if consistent or inconsistent with the Bills (the amendment was defeated).

6.30 We believe permitting significant differences between jurisdictions - which would occur if the Bill is defeated or an amendment analogous to Mr Pyne's was successful – is unacceptable.

6.31 We note the recent Canadian legislation is national, not province based, moreover we believe the significant inconsistencies in US regulation, notably between public and privately funded embryonic stem cell research, has nothing to commend it.

'Therapeutic' Cloning

6.32 The Prohibition of Human Cloning Bill bans human reproductive cloning and 'therapeutic' cloning (s9, 13, 14 and 17). However, a point raised on a number of occasions by Senator Harradine and in evidence to the committee was that 'therapeutic' cloning is misleading as it

> collapses both a) therapeutic and non-therapeutic research on embryos and
>
> b) the distinction between destructive and non-destructive experimentation on embryos.[112]

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[109] See, for example, National Civic Council – WA Division, Submission 282, p. 11, Festival of Light, Submission No. 1076, p. 6

[110] The Attorney General, Mr Williams, advised the House of Representatives that South Australia, Victoria and Western Australia are currently amending their legislation to complement the Commonwealth's legislation. (*House Hansard*, 24.9.02, p. 6866)

[111] *Committee Hansard*, 29.8.02, p. 2

[112] Dr Kerry Breen, Chair, Australian Health Ethics Committee, *Tabled Document*, Australian Senate, 7 February, 2001, p 21477

6.33 We believe the case against the term 'therapeutic cloning' is well made and accept the distinctions between therapeutic and non-therapeutic and destructive and non-destructive are important.

6.34 In one sense, this is not an issue as both reproductive and so-called 'therapeutic' cloning are banned in the legislation, however, it is clear, that more accurate nomenclature would be of considerable benefit in public debates on such issues.

Prohibition on Human Cloning – additional comment

6.35 It would seem that the provisions of this Bill are not entirely understood. In evidence to the committee, Ms Riordan, Executive Director, Respect Life Office, Archdiocese of Melbourne, Australian Catholic Bishops Conference, stated:

> I would like to quote two women legal academics in the United States … Cynthia Cohen … wrote
>
> > Producing eggs engenders increased risks for women. Hyperstimulation can lead to liver damage, kidney failure, or stroke … Although women might be willing to undergo such risks for the sake of having a child, it seems clear that either payment from eggs or coercion would have to be used to persuade women to produce eggs for stem cell research … Thus, before considering embryonic stem cell research, procedures need to be developed to protect women's health and freedom from overbearing financial or other pressure.
>
> Rebecca Dresser … noted in the same journal:
>
> > Creating human embryonic stem cell lines from somatic cell donors would require a large supply of oocytes. Experience in infertility treatment indicates that obtaining such oocytes will not be easy.
>
> These basic issues have never been addressed either at all or satisfactorily by advocates of stem cell research. To my knowledge, they have not been addressed directly in evidence before this committee. These fundamental issues are not addressed in the legislation under consideration.[113]

6.36 Not so. The *Prohibition of Human Cloning Bill* makes it an offence to

a) create an embryo for research (s.14);

b) engage in trade of human eggs, sperm or embryos, including giving (and accepting) financial inducements, including handling fees (s.23);

c) create embryonic stem cell lines from somatic cell donors (s.9 and 13).

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[113] *Committee Hansard*, 26.9.02, pp. 214-5. See also comments of Mrs Ulhmann, National Bioethics Convenor, Catholic Women's League Australia Inc, *Committee Hansard*, 26.9.02, p. 218

6.37 In addition, these issues were widely canvassed in evidence to the committee.[114]

7. Additional Matters not directly related to the Legislation

Intellectual Property

7.1 As the Chair's report notes, an issue that was raised frequently during the course of the inquiry was concerns over intellectual property rights over embryos, stem cell lines and the products of stem cell lines (4.48 – 4.53).

7.2 The issue of patents and intellectual property is not covered by the Bill and the licencing committee will not include the commercial interests of an applicant in their determinations on licence applications.[115]

7.3 Some concerns went to problems for *bona fide* researchers accessing unencumbered stem cell lines. Stem Cell Sciences, for instance, advocated that Australia adopt a recommendation of the European Union's Ethics Group to prohibit patenting of unmodified human stem cell lines.[116] This would mean the unique biological material that underpinned research would be accessible for all researchers and patents could only be taken out on research that generated novelties.[117]

7.4 There were also many comments by some submittees and some Senators seeking to cast aspersions on the motivations and interests of researchers.

7.5 Dr Neville, Research Fellow, Australian Catholic Bishops Conference, advised the committee that

> The use of patents and other intellectual property rights has at least two negative consequences. Firstly, it promotes a view of medicine and the provision of therapy solely as a commercial business. This has implications for those without adequate financial resources to gain access to developments and innovations. Thus, there are very significant questions of justice and equity, not to mention discrimination. Secondly, contrary to standard medical practice and codes of research, patenting and IP rights actually inhibit the distribution of research benefits.[118]

7.6 However, Dr Juttner, Executive Director of Bresagen, noted that patenting was necessary to ensure an inventor had a period of time "to gain some recompense for the hundreds of millions of dollars they invest in development".[119] He added that

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[114] Bresagen, for instance, specifically rejects Somatic Cell Nuclear Transfer for precisely the sort of reasons raised by Ms Riordan.

[115] *Committee Hansard*, 29 8.02, p.28

[116] Stem Cell Sciences Ltd, Submission No. 1012, p. 2

[117] Mr Ilyine, *Committee Hansard*, 17.9.02, p. 45

[118] *Committee Hansard*, 26.9.02, pp. 215 - 6

[119] *Committee Hansard*, 17.9.02, p. 37

Bresagen's "preferred position is to make cells available for a small training fee of $5,000 and then to have a right of first refusal to negotiate on new IP, but with no guarantee or ownership built into that".[120]

7.7 We are sympathetic to many of the concerns raised concerning patents and intellectual property rights. Senator Stott Despoja, in particular, has a long standing interest in such matters and has introduced private members bills seeking to prevent patenting of naturally occurring genetic material and gene sequences and other related genetic issues.[121]

7.8 We do not favour, however, bringing patent and intellectual property amendments forward during debate on these Bills. Ad hoc changes to complex areas of law can create more problems than they solve, despite good intentions. Rather, we would prefer to see a considered approach that is well grounded in the challenges genetic sciences pose to lawmakers seeking to balance the interest of inventors and the community.

7.9 We are well aware of the Australian Law Reform Commission (ALRC) and AHEC's ongoing and comprehensive review of issues relating to the protection of genetic information. We are also aware that stem cell science is outside the terms of reference of that review. The final report is due to be tabled in March 2003.

7.10 We believe it is appropriate that the ALRC and AHEC are given another reference to consider issues of patenting, intellectual property and stem cell science and that this reference should feed directly into the review of this legislation (s.61).

Stem Cell Bank

7.11 The committee was advised by Mr Ilyine that on 9 September, the UK Medical Research Council announced the establishment of a National Stem Cell Bank to:

> hold all of the stem cell lines in a central point where there would be free and unencumbered access to those stem cell lines to qualified researchers.[122]

7.12 It was suggested that such a facility might minimise the number of embryos that would be required to create new stem cell lines.[123] Mr Ilyine advised the committee that UK initiative was to ensure researchers could access stem cell lines but the committee was not provided with specific evidence whether this was to overcome an actual problem. Nevertheless, we believe this idea has merit and believe that the independent review of the act should examine the UK model of a Stem Cell Bank to ascertain whether an analogous facility would be desirable in Australia.

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120 ibid

121 Genetic Privacy and Non-discrimination Bill 1998, Patents Amendment Bill 1996. Also refer to discussion between Dr Neville and Senator Stott Despoja, *Committee Hansard*, 26.9.02, p. 217

122 *Committee Hansard*, 17.9.02, p. 36

123 *Committee Hansard*, 17.9.02, p. 45

Recommendation: That an additional term of reference be applied for the review of the act as outlined in s61 (REIB)/s.25 (PHCB) to investigate the operations and applicability of the UK Stem Cell Bank.

7.13 The Chair's report discusses this and another bank idea (tissue bank) proposed during the course of the inquiry (4.52-3). It should be pointed out that a tissue bank for immunological matching is quite a different concept and should not be conflated with the stem cell bank discussed above. It is premature to consider a tissue bank for this purpose. Any need will be entirely dependent on what success is achieved (or otherwise) in overcoming the significant immunological challenges for ES therapies.

Resource Allocation

7.14 As the Chair's report points out a number of submissions questioned the allocation of resources to embryonic stem cell research on ethical grounds, suggesting that the money would be better spent on disability support or other healthcare programs such as for drug addiction and Aboriginal health (3.112).

7.15 In terms of priorities in research funding, Professor Good argued:

> When there is a limited amount of money for research in this country – I deal with this issue every day and am trying to increase the amount of funding for research – why would we waste it on putting something into human embryonic stem cell research that, in my estimation, will never make it into a therapy.[124]

7.16 A resource allocation argument was (fallaciously) taken further in some submissions to infer a prohibition argument along the lines of; resources are scarce, embryonic stem cell research is 'a huge waste of limited resources', these resources should be committed to 'ethically uncontentious but scientifically more promising avenue' of adult stem cell research; thus prohibit 'embryo destruction for stem cells'.[125]

7.17 While not relevant to the Bill, the funding of the National Stem Cell Centre drew some adverse comments during the course of the inquiry. There seems to be a misconception that the $46.5 million (over four years) for the National Stem Cell Centre is only for embryonic stem cell research.[126] This is not correct. While the funding mix will presumably not be known until all documentation is finalised, the money provided and the Centre becomes operational, Professor Trounson advised the committee that the Centre will have four broad areas of research;

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[124] *Committee Hansard*, 19.9.02, p. 97 It is important to note that Professor Good is not arguing that resources are scarce therefore ban embryonic stem cell research. See exchange between Professor Good and Professor Bartlett clarifying Professor Good's position. *ibid*

[125] Catholic Archdiocese of Melbourne, Submission No. 876, p. 7

[126] Catholic Archdiocese of Melbourne, Submission No. 876, p. 7, Dr Silburn, *Committee Hansard*, 17.9.02, p. 52 and numerous references from Senators Harradine and Boswell in the course of the public hearings.

- Embryonic stem cell;
- Adult stem cell;
- Transplantation, and
- Tissue engineering.[127]

7.18 The Committee was advised by Bio-technology Australia that the Centre will split funding 50:50 between adult and embryonic stem cell research. This does not match the description of the four main areas, but the central point remains that the public investment is by no means exclusively for ES research.

7.19 Professor Pettigrew, CEO, NHMRC, advised the committee that currently the NHMRC fund approximately $10 million for stem cell research; none of which is for human embryonic stem cell research.[128] However, there are other sources of funding available, both public and private, and, as the Chair's report notes, the committee received no analysis of the distribution of funds between adult and embryonic stem cell research (3.117).

Acknowledgement

7.20 On a final note, we would like to acknowledge the work of the Chair of the Committee in managing the hearings of what was at times contentious material in an even-handed and fair manner. Her report provides a good overview of the issues and she has been very generous in accommodating concerns of Senators opposed to some of the provisions of the Bill.

7.21 We would also like to acknowledge the efforts of the Community Affairs Committee staff.

Senator Natasha Stott Despoja

Deputy Chair

Senator Jan McLucas

Senator Ruth Webber

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[127] *Committee Hansard*, 24.9.02, p. 142

[128] *Committee Hansard*, 29.8.02, p. 10