SUPPLEMENTARY COMMENTS

Senator Brian Harradine

Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002: Entrenching the Commercialisation and Commodification of Human Life

This legislation will set the unheard-of precedent for the statutory creation of a biological underclass—namely, those unworthy of life but worthy of sacrifice on the commercial slab of experimentation.[1]

Introduction

1.1 The *Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002* (the Bill) would, for the first time, permit destructive experiments on human embryos. The Bill would set a precedent for vivisection of living human beings at the earliest stage of their development. Should the legislation pass, the embryonic human being will have been reduced to the status of a laboratory rat. As a matter of principle, if enacted, the precedent will have been set by which a certain class of human life is held, according to Commonwealth legislation, to be expendable for profit. Other classes of human life could then be added to this list of endangered life.

1.2 Despite the demonstrable humanity of the embryo and the raft of international treaties and declarations which prohibit destructive non-therapeutic research on human subjects, the Bill would open the door to a wide range of destructive and other research on human embryos and stem cells derived from them.

1.3 The Senate Community Affairs Legislation Committee was entrusted with the task of examining the *Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002* and to report to the Senate by 24 October 2002. The Bill was subsequently split into the *Research Involving Embryos Bill 2002* and the *Prohibition of Human Cloning Bill 2002*.

1.4 The process of examining the Bill was rushed to the point that:

- Only three weeks were allocated for public submissions to the Committee;
- Hearings of the Committee were held, unusually, on Senate sitting days;

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1 Submission 981.

- No hearings took place outside Canberra; and,
- Less than one day was allowed after finalisation of the Chair's Report for dissenting reports to be prepared.

1.5 Despite the process being rushed, public interest in the Committee's consideration of the Bill has been high. Of the 1851 submissions received, 1803 opposed destructive research on human embryos.

Broad scope of the legislation

1.6 The Bill under consideration is commonly understood to relate only to research on embryos to produce embryonic stem cells. What is not generally understood is that the Bill would facilitate a wide variety of destructive research on human embryos of which stem cell research would be but a minor part. In effect, the derivation of stem cells on the basis of exaggerated claims of impending cures has been the Trojan Horse used to establish the principle of destructive embryo research.

1.7 The range of embryo research permitted by the Bill includes using human embryos to examine the effectiveness of new culture media used in assisted reproductive technology (ART) practice, to assist in understanding embryonic development and fertilisation, training clinicians in microsurgical ART techniques, transport, observation and storage of embryos, micromanipulation, lasering, cutting and dissecting, studies in genetic makeup and expression, quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results, drug testing including toxicology studies on human embryos as well as the destructive extraction of embryonic stem cells.[2]

1.8 Apart from stem cell research, nothing in this long list of areas of human embryo research was mentioned in the COAG Communique dated 5 April 2002.

1.9 This research would entrench the commercialisation and commodification of human life.

1.10 As one witness told the Committee:

> Where vast sums of money are at stake, it would be impossible to regulate such research so effectively as to prevent more and more destructive research, requiring more and more embryos, be they bar-coded, fresh, frozen or what have you.[3]

1.11 The Committee was also told in a submission:

> Human life is never disposable, at any stage of its development. It should never be seen as a commodity, as a type of property able to be exploited for

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2 *Committee Hansard*, 26.9.02, p.255-256 (Dr Morris)

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

> profit. Nor is the value of any human life, or its claim to protection, reducible to or dependent on age or its utility to others.[4]

Human status of the embryo

1.12 Weighty evidence was put to the Committee as to the human status of the embryo.

1.13 Dr Nicholas Tonti-Filippini provided the Committee with an ontological definition of the human embryo:

> From the moment that the first cell is formed, a human embryo is an individual organism oriented to development to human adulthood, normally requiring only nutrition and a favourable environment for that development to occur, and whose inherited nature is formed by the human genome which carries the inherent radical capacity for rationality that is distinctive of human beings.

1.14 Dr Tonti-Filippini detailed six propositions and a conclusion to develop the argument:

> 1. All members of the human family, (including those who may not be rational especially the developmentally disabled and the mentally ill, children, and the elderly), have inherent dignity and equal and inalienable rights. (ICCPR)
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> 2. The capacity for rationality morally distinguishes human beings from animals.
>
> 3. Being of the kind of being which has the capacity for rationality is a basis for an individual to be recognised as having inherent dignity and hence the bearer of equal and inalienable rights.
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> 4. The human genome contains information that determines that a living individual who possesses and is formed according to the human genome is of the kind of being which has the capacity for rationality.
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> 5. Those living individuals who possess and are formed according to the human genome have inherent dignity and are the bearers of rights.
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> 6. Embryonic human beings are living individuals who possess and are formed according to the human genome;
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> Therefore, embryonic human beings have inherent dignity and equal and inalienable rights.[5]

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4 Submission 981

5 Evidence given on notice to the Committee by Dr Nicholas Tonti-Filippini, 26 September 2002.

1.15 In his submission, Dr Tonti-Filippini also pointed to the implications for other people of a denial of the humanity of the human embryo:

> A fundamental concern I have is that by classifying very immature human beings as not yet human because of their capacities for specifically human activities have not yet come to fruition, capacities such as rationality and thought, we make the status of all human beings dependant upon their capacities rather than simply on membership of the human family.[6]

1.16 Dr Robert Orr from the University of Vermont and Dr Christopher Hook from the Mayo Graduate School of Medicine point to the beginning of life not being determined by where the embryo is positioned:

> The essential nature of humanhood is inherent to the individual, it is not something that is imputed based on location. These arguments based on geography are feeble attempts to avoid the basic fact understood and accepted by scientists for many generations that human life begins with the union of two human gametes.[7]

1.17 They also refute the argument that as the embryo will die anyway it should therefore be used for research:

> [this] only accepts and supports the erroneous and tragic approach of the infertility industry which perceives children as products and embryos as commodities … A society that chooses to capitalise on this tragedy acts as opportunists, not as stewards.[8]

1.18 The Queensland Bioethics Centre clarifies in its submission the difference between killing and allowing to die:

> … in the case of the frozen embryo the decision is made to cease the extraordinary life-support and allow nature to take its course. This [option is] to discontinue the life-support and allow the embryo to return to as natural a state as possible – a warm, moist environment. Development will be restored for a short time, but then nature takes its course. The embryo, because of its immaturity and inability to sustain itself, dies. The person who thaws the embryo in this case is not involved in an act of intentionally killing the embryo anymore than a doctor who does not initiate futile or overly burdensome life sustaining treatment on a dying neonate or who discontinues overly burdensome treatment on a dying patient.
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> On the other hand when someone takes the embryo and extracts its stem cells, we do not have a case of "nature taking its course". The embryo is carefully and slowly thawed to maintain its viability short-term in order that its stem cells can be harvested. It does not die because it cannot sustain itself in this environment. The embryo dies because someone has ripped it apart.

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6 Submission 86

7 Submission 156

8 Submission 156

> The person who so deliberately destroys the embryo might be doing so for all kind of noble motives, but he/she can't escape the fact that he/she is intentionally killing the embryo.
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> In the former case it is not necessary that the person is willing the death of the embryo. In the latter case it is necessarily so.[9]

Human Rights Implications

1.19 Dr Katrina Hallen points out that there is a body of human rights law specifically relating to human experimentation which states that voluntary consent by the subject of the research is absolutely essential:

> The human rights perspective is that the rights of the subject must prevail over the interests of science. Scientific experiments must be designed for the benefit of the subject, not for the destruction of the subject, even if the destruction of the subject may benefit another group of human beings. The use of one group of the human family to serve as experimental subjects, or spare parts resources, for another group is exploitative and abusive. The use of human embryos to serve as experimental subjects for the interests of science, creates a group of human individuals that can be used and destroyed for another group of human individuals. This violates the ethical principles of doing no harm, benefiting the subject experimented on, autonomy, justice and the sanctity of human life.[10]

1.20 Stripping the embryo of its humanity for utilitarian purposes would have frightening implications for other vulnerable minority groups.

1.21 Dr Robert Orr and Dr Christopher Hook examine rationales from the historical record used to justify research abuses on human subjects:

> … codes, guidelines, and regulations have been developed specifically for the purpose of bridling this research enthusiasm with ethical principles. One such principle is that human subjects' research is never to result deliberately in the death of a subject, regardless of how much supposed good may result from the investigation.[11]

1.22 Denying the humanity of the human embryo and using it as an experimental tool, would contravene the principles underpinning a number of international human rights instruments including:

- The Nuremberg Code (1947)
- UN Declaration on the Rights of the Child (1959)

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9 Submission 870

10 Submission 1301

11 Submission 156

- The International Covenant on Civil and Political Rights (1966)
- Protocol I Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflict (1977)
- Convention on Human Rights and Biomedicine (1997)
- Universal Declaration on the Human Genome and Human Rights (1997)
- Declaration of Helsinki (2000)

1.23 Further details of these instruments are given in the Appendix to this report.

1.24 If this Bill is passed, the Australian Parliament will have abrogated the foundational principle of law and public policy regarding the uniform protection of all human life and entrenched in legislation approval for the deliberate destruction of human life for radically utilitarian, commercial purposes.

1.25 The Senate Select Committee on the Human Embryo Experimentation Bill 1985:

> sought guidance in the protective role of the law recognised in the jurisprudence of our legal system as the minimum and for some the only, justification for interference with the freedom of others – in this case the freedom to carry out research on human embryos. It is in this framework that the Committee answers the questions accepted by all as the correct query: what is the respect due to the human embryo?

1.26 The Select Committee recommended "that the principle protecting the embryo from destructive non-therapeutic experimentation be adopted by the Senate in its consideration of this matter."[12]

1.27 The current Bill radically departs from this principle of protection.

1.28 To enshrine in law the destruction of the smallest and most vulnerable members of the human family to obtain marketable human commodities would be inhuman.

The unacceptable precedent

1.29 The Bill will set a dangerous precedent in Australian law where human embryos will be defined as disposable and commodities available for use in research. Dr Warwick Neville for the Australian Catholic Bishops' Conference pointed out this legislation would mean that there would be different levels of respect accorded to the human embryo under different branches of the law:

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12 Senate Select Committee on the Human Embryo Experimentation Bill 1985, *Human Embryo Experimentation in Australia*, Parliamentary Paper 437/1986, p.xiv.

> This legislation will set the unheard-of precedent for the statutory creation of a biological underclass—namely, those unworthy of life but worthy of sacrifice on the commercial slab of experimentation. That is the precedent that would be set by this legislation. And what of the inchoate rights of embryos already recognised by the Supreme Court of Tasmania in the landmark case in 1996 of Re K? The frozen generation will be denied the ultimate right of having those rights ever crystallised.[13]

1.30 Dr Gregory Pike from the Southern Cross Bioethics Institute argues that such a precedent as contained in the Bill may have a significant negative impact on Australians' ethical approach to life and death issues:

> My … point is that we have tried to clarify what we see as a distinction which in one respect we hoped would never have to be made, and that is the distinction between intentional killing and allowing to die. It is a difficult one, but one recognised in ethics in several different arenas. What concerns me most about this particular application of the `they're going to die anyway, so let's use them' approach is that that line of reasoning has been used in other arenas in the past and some of those have been quite disturbing. As often happens in ethics and philosophy, what is a consistent argument in one arena gets transferred into another arena.[14]

Informed consent inadequate

1.31 Concern was raised in submissions that parents of embryos would not be given adequate information or control over the end uses of their embryos. The Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE), for example, observed:

> Informed consent is a central issue which we believe has yet to be properly addressed. Will donors be informed of the full implications of the research and the commercialisation of the research undertaken using the embryos they donate? Holland (1996) points out that '…downstream commercialisation is a potent and problematic issue. How to safeguard it ethically and how to keep women from potential exploitation is the rub. The potential profitability of cell lines derived from donated embryos is huge given the promise of regenerative medicine.'[15]

1.32 Dr Tonti-Filippini made a similar observation about this downstream commercialisation:

> Once couples have consented to their embryos being used, they have no further say over what may be done. They do not even have to be informed about what is done with their embryos or their embryonic stem cells. Their legal relationship with their embryos ceases when they give consent.

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

14 *Committee Hansard*, 17.09.02, p.54 (Dr Pike)

15 Submission 1036.

> The Cloning Bill incorporates the interests of the researchers and their corporate supporters so that the embryonic stem cells become the unencumbered assets of the company. There is no restriction on their use, export or subsequent trade in them. An IVF couple will have no way of knowing what research is being done on their embryonic stem cell cultures, or whether the cell cultures remain identified with the couples and who the end-users might be.
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> One would expect that couples would be interested in whether
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> Genomically related information is obtained which is medically relevant to them and to their families
>
> The cultures and their DNA are used as a commercial asset and the couple may have lost an opportunity to profit from that commercial exploitation
>
> the end-uses of their cultures and products derived from them are ethically acceptable to them, and whether they should have exercised greater responsibility in donating their embryos.[16]

Overproduction of human embryos

1.33 The Chair's Report fails to place the current issue of human embryo research into any context. How has it come to pass that thousands of human embryos – with no chance of ever being implanted - have been deliberately created? We are on the verge of establishing a national scheme for capitalising and profiting from a situation which should never have been allowed to develop: more than 70,000 human embryos stored in a frozen state, with no questions asked as to why such a massive stockpile of embryos was allowed to accrue in the first place.

1.34 FINRRAGE argued in its written submission that:

> … this bill will act to cover up for the mistakes of the IVF industry in creating many thousands of so-called spare embryos in the first place.[17]

1.35 The number of human embryos in storage since 1994 has risen from about 22,000 to 72,000[18], a proportion of which are available for use in research.

1.36 Medical and Managing Director of Sydney IVF, Professor Robert Jansen, admitted before the last Senate committee to examine this issue that it was not difficult to manipulate a "surplus" of human embryos. Professor Jansen told the Senate Select Committee on the Human Embryo Experimentation Bill 1985:

> It is a fallacy to distinguish between surplus embryos and specifically created embryos in terms of embryo research. The reason why I say this is that any intelligent administrator of an IVF program can, by minor changes in his ordinary

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16 Submission 86.

17 Submission 1036

18 Submission 981

> clinical way of going about things, change the number of embryos that are fertilised. So in practice there would be no purpose at all in enshrining in legislation a difference between surplus and specially created embryos. It would be but a trifle administratively to make those embryos surplus rather than special.[19]

1.37 Professor Jansen has since attempted to recant this statement by referring unconvincingly to difficulties in collecting human ova rather than the issue of creating surplus human embryos.[20]

Embryonic stem cells for developing therapies

1.38 The research used to 'sell' this legislation in debate has largely been limited to embryonic stem cell research and claims by some researchers that this may lead to cures for conditions such as diabetes and Parkinson's disease.[21] However other scientists were more cautious and some were dismissive.

1.39 Deputy Vice Chancellor (Research) at the Australian National University, Professor John Hearn, warned:

> it is premature to anticipate therapeutic results that will treat patients with Alzheimers, Parkinsons, Diabetes and other disorders. The field is less than five years old. Use of patients in wheelchairs, film stars, and emotional statements from scientists, industry or the media are inappropriate and risk damaging the credibility of research.[22]

1.40 Professor Peter Rowe, Director, Children's Medical Research Institute, Westmead, Sydney said:

> I have an interest in a number of these things that are thrown around in the press, particularly things like Alzheimer's, diabetes and Parkinson's. These are very complex disorders. To say that you will cure them by putting in a few cells is a joke. We do not even know the genetic basis.[23]

1.41 Similar views were expressed by Professors Colin Masters, John Martin, Peter Silburn, Michael Pender and Michael Good.[24]

1.42 Emeritus Professor of Medicine at the University of Melbourne, John Martin, pointed out that there was no 'proof of concept' for embryonic stem cell research:

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19 Senate Select Committee on the Human Embryo Experimentation Bill 1985, Committee Hansard, 26.02.86, pages 391-392 (Dr Jansen)

20 Submission 897

21 Submission 871, 1041; Committee Hansard, 24.09.02, p.144 (Prof Pera)

22 Submission 1300

23 *Committee Hansard*, 19.9.02, p.95 (Professor Rowe)

24 Submissions 84, 87, 162, 614; Committee Hansard, 17.09.02, p.53; Committee Hansard, 19.09.02, p.95; Committee Hansard, 19.09.02, p.89-91.

> All the proponents of human embryonic stem cell research rely ultimately on the one argument – that cures for serious chronic diseases are sure to follow. If that were true it would be difficult to be opposed to it, but there is no evidence to support these claims from appropriate animal experimentation …
>
> Why, then, should we not require a substantial body of evidence to justify destructive research on human embryos? Why do we not have from animal models of disease, ample proof of the principle that, say in diabetes or Parkinson's Disease, prolonged therapeutic benefit can be obtained from the use of ES cells, and that this can be achieved free of the problems of tumour development, and overcoming the immunological barriers? Why do we not have laid out clearly the milestones to be achieved in fulfilling these conditions, and the time-lines required?[25]

Destroying human embryos for research

1.43 The broader range of destructive human embryo research received less attention than embryonic stem cell research. As outlined earlier, the range of embryo research permitted by the Bill includes using human embryos:

- to examine the effectiveness of new culture media used in assisted reproductive technology (ART) practice;
- to assist in understanding embryonic development and fertilisation;
- training clinicians in microsurgical ART techniques;
- transport, observation and storage of embryos;
- micromanipulation, lasering, cutting and dissecting;
- studies in genetic makeup and expression;
- quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results;
- drug testing including toxicology studies on human embryos as well as the destructive extraction of embryonic stem cells.[26]

1.44 The Southern Cross Bioethics Institute noted that the list of research that will be carried out on human embryos is likely to include "toxicology studies on live human embryos, and testing new drugs on humans rather than animals".[27]

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25 Submission 162

26 Committee Hansard, 26.9.02, p.255-256 (Dr Morris)

27 Submission 892, attachment *Human Embryos: A Limitless Scientific Resource?*, page 8-9.

1.45 Dr Tonti-Filippini commented on some of the areas of research which might involve human embryos and human embryonic stem cells:

> We are seeing a whole opening up of this area to unregulated, unrestricted and unsurveyed research on both the stem cells and the embryos. You ask questions like these: who stops the stem cells finishing up in cosmetics and who stops them being sent for biowarfare to one of the less democratic regimes in the world? Remember, they can be sold off. Alan Trounson was talking earlier about buying and selling the stem cells. If he has got products here in Australia within the companies that he is associated with, what stops those companies selling them to anybody?[28]

1.46 The Committee also heard evidence from Sydney IVF Medical Director Professor Robert Jansen that "hundreds" of embryos would be needed "in the development of culture medium for meaningful results".[29]

Alternative stem cell sources

1.47 A number of submissions gave references to over one hundred articles published in peer reviewed scientific and medical journals which detail successful therapies now available to patients using adult stem cells. These include treatments to treat patients with stroke, cancer, bone defects, and muscle, gut and retina problems. There have also been promising results published where there have been successful adult stem cell experiments using animal models to treat conditions such as spinal injury, Diabetes and Parkinsons.[30]

1.48 Dr Tonti-Filippini noted that to-date no successful therapies for humans have been published using embryonic stem cells:

> Treatments using a patient's own stem cells have been achieved for many diseases. Claims about treatments of disease using embryonic stem cells are just hype. There just is no such track record for embryonic stem cells. In these circumstances, it is ludicrous to be claiming the development of treatments using embryonic stem cells as a reason for passing a Bill allowing human embryonic experimentation. There is no such necessity. The truth of the matter is that human embryos and embryonic stem cells have many research and industrial uses …[31]

1.49 Adult stem cells have been compared unfavourably with embryonic stem cells on the basis that they do not have pluripotentiality – the ability to produce many types of tissue. However Professor Michael Good, Director of the Queensland Institute of Medical Research has described this limitation as an advantage:

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28 *Committee Hansard*, 24.09.02, p.165.

29 Committee Hansard, 26.9.02, p.211 (Professor Jansen)

30 Submissions 86, 480, 1042, 1571.

31 Submission 86.

> …the ideal cell that you want in a transplantation situation is one that does not have great pluripotency, that cannot differentiate into multiple unwanted tissues, that has a limited tissue differentiating profile and that you have enough of. Those cells are provided by adult stem cells. Furthermore, if they are taken from the patient, you will not have this problem of graft rejection, which to me is the major problem of embryonic stem cell derived tissue."[32]

Communities opposed to destructive embryo research

Aboriginal and Torres Strait Islanders

1.50 The National Aboriginal Community Controlled Health Organisation made a submission to the Committee which drew attention to Aboriginal and Torres Strait Islander people's concern with the Bill. The submission referred to "strong cultural beliefs opposed to the destruction of human life from its earliest stage. Embryonic stem cell research would violate such beliefs and accordingly we could not support such research."[33]

People with disabilities

1.51 A significant number of submissions from people with disabilities opposing the destruction of embryos were received, though none were invited to give evidence before the Committee.

1.52 Diabetics for Ethical Treatment argued that:

> It is unethical, and an insult to the integrity of persons with diabetes, to pursue research into therapies which involve harming or destroying human beings, including human embryos … We firmly believe that an attack on the dignity and well-being of any group of human beings is an attack on human dignity itself. It is a profound insult to people with disabilities and illnesses, including diabetics, to presume that we are willing to accept therapies developed at the cost of other human lives.[34]

1.53 Some families made submissions to the Committee, with Olivia and Vicki Dunne drawing attention to their experience living with Cystic Fibrosis:

> As a sufferer and as a carer, we would submit to the members of the Committee that it is not legitimate to look for those cures at the cost of another human being. We have seen that in embryonic stem cell research the donor is always destroyed. If the price of new lungs and new pancreases for the members of our family is someone else's life then it is too high a price to pay.[35]

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32 Committee Hansard, 19.9.02, p.91 (Professor Good)

33 Submission 1837

34 Submission 1293

35 Submission 1081

1.54 The Sadkowsky family drew attention to the experience of their daughter, who has Rett Syndrome:

> We share both happy and sad times with her, along with our other children, and we are very proud of the progress she has made despite the difficulties imposed on her by Rett syndrome. In the 23 years of her life she has made an immeasurable, positive contribution to our family, our friends and community in general. Over the years, we have met many wonderful people through association with Veronica … Adult stem cells are available in the body, without resorting to the destruction of human embryos … It is our opinion that the resources would be better channelled into this form of research.[36]

1.55 The Archdiocese of Melbourne's also recorded that in the United States:

> … James Kelly, a 45-year-old paraplegic due to spinal cord injury, wrote to US President Bush asking him to support embryonic stem-cell research. Since then he has undertaken a great deal of research into the area himself. He discovered that while adult stem-cells can and have been used safely in humans for various therapies, and are clearly our "brightest hope", the embryo industry has instead promoted embryonic stem-cells. During his US Senate testimony, Mr Kelly stated: "I think it is highly immoral for researchers and others to encourage the sick, crippled and dying to cut their own throats by supporting cloning [and embryonic stem-cell research], a research avenue whose extremely speculative potential lies somewhere in the distant, hazy future, to the detriment of proven avenues that offer more than futile help.[37]

Women

1.56 There were a number of submissions received from women's groups concerned about embryo research and cloning to produce embryos for research or therapies.

1.57 Feminists for Life (ACT) commented that:

> Embryo research raises serious ethical questions about the exploitation of women - especially in regard to the demand for eggs to produce what are now deemed to be surplus embryos or, if some science lobbyists get their way, for the cloning of embryos for research.[38]

1.58 FINRRAGE point out that:

> To justify the research goal, women and people with disabilities are sometimes held up as future beneficiaries of this research. But the debate is being driven by the immediate beneficiaries, the research and biotechnology

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36 Submission 1084

37 Submission 876

38 Submission 1064

> communities, which are determined that this research go ahead. The science lobbyists are intolerant of voices from other communities and in some cases have misled Parliamentarians in their determination to get their way.

1.59 Further, they note that:

> It is ironic that under the proposed legislation, women would not be able to sell their ova or embryos, while researchers are later able to commercialise the results of their experiments and may potentially make substantial sums of money.[39]

Conscientious objection not protected

1.60 Another concern expressed was for the right to conscientious objection of stem cell scientists or students who are opposed to using embryos as research tools, and protection from discrimination because of their position. Conscientious objection is also of concern to potential recipients of drug treatments derived from destructive research on embryos.

1.61 There is a concerted attempt by those supporting embryonic stem cell research to promote the integration of adult stem cell research with embryonic stem cell research either directly or indirectly.[40]

1.62 The use of human embryos and human embryonic stem cells in the testing of drugs and toxicology studies for drug development has major implications for those objecting on ethical grounds.

1.63 Dr David van Gend, representing Do No Harm, argued that if widespread embryo research is allowed to go ahead, Australians will have difficulty exercising their right to conscientiously object or opt out of involvement:

> Conscientiously, people can object from certain practices—abortion, euthanasia, going to war and so on. But if the fabric of medical knowledge is stained, as it were, by knowledge derived from destruction of human embryos, then people will be beneficiaries of that knowledge when they take from their doctor these new drugs. It is a novel predicament. To me, it is an uncivil predicament, because never before have we faced a situation where certain members of society who would conscientiously object from using things like drugs derived from embryos will have no way out. They will not be able to opt out of standard medical care when, as would happen with embryo research, the whole body of pharmaceuticals is tainted with that research.[41]

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39 Submission 1036

40 Committee Hansard, 19.09.02, p.105.

41 Committee Hansard, 24.09.02, page 175 (Dr van Gend)

Cloning still an issue of concern

1.64 The Chair's report does not address the ethical issues surrounding one half of the referred Bill, now called the *Prohibition of Human Cloning Bill 2002*. Human cloning is an area of significant concern and, while there appears to be a very clear Parliamentary majority to support the prohibition of human reproductive cloning, it is important to state clearly what human cloning is and the reasons why it is unacceptable.

1.65 Universal opposition to human cloning cannot be assumed. The Academy of Science, a senior member of the IVF research community and the science adviser to a Cabinet minister are all on the record as not opposed to cloning in various forms.

1.66 Dr Thomas Barlow, science adviser to Education, Science and Training Minister, Dr Brendan Nelson, wrote in a column in the UK *Financial Times* (1 September 2001) that he considers human reproductive cloning to be no more serious an issue than "having sex". "Not to beat about the bush, is there any honest reason why we should treat it more seriously, say, than having sex?" he wrote.

1.67 Professor Martin Pera from the Monash Institute of Reproduction and Development, stated that:

> … although the scientific case for the clinical application of therapeutic cloning in man is not compelling at present, basic research on reprogramming in humans may eventually be very important to successful development of adult stem cell based therapies. I therefore endorse in principle the original recommendation of the report of Mr. Kevin Andrews' committee of inquiry for a moratorium, rather than a ban, on this area of research.[42]

1.68 In testimony before the Committee, the Academy of Science reaffirmed its support for cloning embryos so that they could be destroyed for their stem cells, which could then theoretically be used in therapies. This would be achieved by somatic cell nuclear transfer.

1.69 Distinctions are frequently drawn between cloning for reproduction and cloning where the embryo is destroyed to produce therapies, there is little difference in the basic process.

1.70 The House of Representatives report *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, employed this distinction when it summarised the most common arguments against cloning for reproductive purposes as:

- A lack of any medical need for cloning for reproductive purposes;

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42 Submission 873

- Cloning for reproductive purposes would constitute an infringement of human dignity;
- Cloning for reproductive purposes would have a negative effect on the family and personal relationships;
- Cloning for reproductive purposes would undermine individuality and identity;
- It would be unsafe;
- Cloning for reproductive purposes would potentially pose a threat to human diversity and run the risk of reintroducing notions of eugenics; and
- It would raise the potential for coercion of women.[43]

1.71 However, when asked whether somatic cell nuclear transfer was cloning, whether or not the embryo was placed in a woman's uterus or in a petri dish for experiments, Professor John White from the Academy of Science agreed it was the same process:

> … I am glad to agree with you. It certainly is cloning, and the academy has never resiled from that point of view. It is the method, which was used to produce the sheep "Dolly", that can actually allow the DNA from any particular donor to be expressed in embryonic stem cells. The only virtue of it from the point of view of future science is that that particular potential is the only way we know to go about the point. So, of course, it is destructive cloning – I am afraid I have to agree with you.[44]

1.72 One particular danger of accepting human cloning – the danger of women being exploited - was raised by a number of groups including FINRRAGE (Australia):

> Women's bodies are central to the hopes and aspirations of scientists determined to work in the embryonic stem cell area. Without access to women's bodies to harvest their ova, scientists would not be able to produce the surplus of embryos we are being asked to release to scientific research. Women's eggs don't drop out of the ether. They come from a woman's ovary which is in a woman's body. The ovary has to be hyper-stimulated with dangerous drugs and the egg cells mechanically extracted.[45]

1.73 FINRRAGE notes that:

> If therapeutic cloning were to go ahead - and there is no doubt the pressure for it will only intensify - the scientists would then need to work out ways to harvest thousands more ova from women. Scientists undertaking this

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43 Human Cloning, pages 77-78.

44 Committee Hansard, 19.09.02, p.125

45 Submission 1036. See also submission 1046.

> research therefore need the cooperation of women to produce the embryos they need for experiments.[46]

1.74 FINRRAGE also pointed out that one US source estimates that if cloning was allowed to produce compatible tissue for therapies:

> … if embryonic stem cells were to provide up to 1.7 million therapies per year, this would require a minimum of 5 – 8 million ova each year. This estimate generously assumes that it would only take between three and five embryos to produce one embryonic stem cell culture.[47]

1.75 The Australian Catholic Bishops' Conference also raised the issue of the quality of frozen embryos and whether the call of some biotech companies for access to 'fresh' embryos, which may be a future pressure for cloned embryos:

> There is growing evidence that children born from IVF suffer from a range of adverse medical conditions. Presumably IVF practitioners have selected for implantation those embryos which are deemed the "best of the crop." If that is so, it would mean that those embryos now deemed "spare" or "excess" might well be of a second order in quality. One might ask, from the prevailing utilitarian perspective, whether researchers would really want, or should be allowed, to use embryos of perhaps inferior quality? If not, would there not then be a push for the need for and use of "fresh" embryos? This has already been suggested in the debate by some of the biotech companies. How would a pro-research licensing committee resist such an application? [48]

The Bill

1.76 A large range of problems with the Bill were raised in submissions and in the Senate Committee hearings. This evidence pointed to major flaws and gaps in the Bill in the areas of regulation, monitoring, reporting requirements, accountability, absence of guidelines and lack of independence in oversight bodies.

1.77 In his written submission, Dr Tonti-Filippini also pointed out that there was no regulation of industrial and other uses of human embryonic stem cell cultures:

> Human embryonic stem cell cultures fall outside existing ethical guidelines because they are not considered human tissue. They are considered not to have been removed from a human body but generated in the laboratory from human embryos. For ethics committees the stem cells do not constitute a human subject and hence are not within their jurisdiction. The Bill contains no restriction on the use of human ES cells.[49]

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46 Submission 1046

47 Submission 1046

48 Submission 981

49 Submission 86

1.78 Clause 10 deals with the offence of intentionally importing or exporting a human embryo clone. Dr Morris from the NHMRC advised the Committee that there is nothing to prevent a person from taking stem cells from a human embryo and then selling them for profit overseas:

> The use of cells derived from any tissue would be permitted to be sent overseas … [The legislation] does not prohibit any uses of embryonic stem cells.[50]

1.79 Among other interesting omissions in the Chair's Report is the fact that literature from biotechnology academics has noted the relevance of other statutory regimes concerning the regulation of matters relevant to ART. Other relevant regimes include not only the Trade Practices Act, but matters relating to intellectual property.

1.80 In further evidence before the Committee, Dr Neville argued that given that the legislation provides for the concealment of confidential commercial information, other ways of keeping the embryo research industry accountable to the public might include the Trade Practices Act and anti-discrimination legislation.[51]

1.81 Concern was expressed that the Bill was being considered when the new NHMRC guidelines referred to in the Bill had not yet been sighted:

> … those guidelines were published in 1996 and they are the subject of review at the moment. So, again, it only adds to the speculative nature and, therefore, also the difficulty of this committee and the parliament to enact legislation when, as it were, all of the balls are still in the air. [52]

1.82 In relation to clause 28, which establishes the NHMRC Licensing Committee, there was evidence given to the Committee that it was inappropriate for the Licensing Committee to be located within the administration of the NHMRC. The ACF GeneEthics Network commented that:

> The NHMRC is impenetrable and effectively answerable to no-one outside. GTRAP and AHEC are examples of NHMRC with whom we have attempted to engage over many years, with very little success. We propose that this licensing function be vested in the Office of Gene Technology Regulator who has statutory responsibilities and authority commensurate with the importance of this licensing work, and has processes and mechanisms to engage with the interested and general publics.[53]

1.83 Dr Tonti-Filippini drew attention to inappropriateness of having the National Health and Medical Research Council as the parent body for the licensing authority:

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50 Committee Hansard, 26.09.02, p.256-257 (Dr Morris)

51 Committee Hansard, 26.09.02, p.216 (Dr Neville)

52 Committee Hansard, 26.09.02, p.220 (Dr Neville)

53 Submission 1843

> We do have a culture here with the Human Research Ethics Committee and the NHMRC, and now the licensing authority … There is not openness in reporting or stringent reporting requirements, so you have got no reporting of, for instance, the Human Research Ethics Committee's decisions or anything like that. The public does not have access to those. So we have got a fairly secretive culture, a non-consultative culture. In fact, the institutions will defend that in terms of their own commercial interests and so on and also their interests in not having public scrutiny."[54]

Conclusion

- The Bill sets an unacceptable and profoundly disturbing precedent in permitting for the first time destructive experiments on human embryos. A certain class of human life will be considered expendable for profit. The Bill will entrench the commercialisation and commodification of human life.

- The scope of the legislation is so broad as to facilitate a wide range of destructive research on human embryos of which stem cell research will be a minor part. None of these areas of human embryo research were the subject of the original COAG agreement.

- The embryonic human being has inherent dignity and equal and inalienable rights due to membership of the human family.

- The Bill contravenes the body of human rights law on human experimentation in using one section of the human family to serve as experimental subjects or spare parts resources for another group.

- Stripping the embryo of protection for utilitarian purposes has frightening implications for other vulnerable minority groups.

- The consent process for donating embryos to research is inadequate. The Bill contains no restriction on embryonic stem cell use, export and subsequent trade. Once couples have consented to their embryos being used they have no further say in how their embryos will be used.

- More than 70 000 human embryos are currently in storage. The Chair's report fails to address the crucial question as to why such a massive stockpile of embryos were allowed to accrue in the first place.

- Prominent scientists have cast significant doubt on the overblown claims of pro embryonic stem cell research advocates.

- No successful therapies using embryonic stem cells have been published. A number of submissions gave references to more than 100 articles published in

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54 Committee Hansard, 24 September 2002, p.165.

peer reviewed scientific and medical journals detailing successful therapies using adult stem cells.

- A number of specific communities, among them indigenous people, people with disabilities, and women expressed specific concern about destructive embryo experimentation. Some people with disabilities stated that it was unethical and an insult to their integrity to pursue research which involved harming other human beings.

- The right to conscientious objection is threatened by this Bill.

- The Chair's report does not properly address the ethical issues surrounding one half of the Bill. A number of scientists have publicly expressed their support for cloning embryos so they could be destroyed for their stem cells. There is no distinction between cloning for reproduction and so-called therapeutic cloning.

- Regulation and licensing has been shown to be inadequate. There is no regulation of industrial and other uses of human embryonic stem cell cultures.

- If this Bill is not rejected the Australian Parliament will have abrogated the foundational principle of law and public policy regarding the uniform protection of all human life and will entrench in legislation the deliberate destruction of human life for radically utilitarian, commercial purposes.

Senator Brian Harradine (Ind, Tas.)

Appendix

International human rights and medical research

The International Covenant on Civil and Political Rights (1966)

Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life (Article 6(1)).

"sentence of death … shall not be carried out on pregnant women" (Article 6 (5)).

UN Declaration on the Rights of the Child (1959)

Governments are obliged "to provide appropriate legislative protection for the child, before as well as after birth." (preamble)

"every child [ie before as well as after birth] has the inherent right to life" (Article 6)

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation (Article 7).

The Nuremberg Code

Principle 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Principle 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

Protocol I Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflict, 8 June 1977

Article 11 - Protection of persons

1. The physical or mental health and integrity of persons who are in the power of the adverse Party or who are interned, detained or otherwise deprived of liberty as a result of a situation referred to in Article 1 shall not be endangered by any unjustified act or omission. Accordingly, it is prohibited to subject the persons described in this Article to any medical procedure which is not indicated by the state of health of the person concerned and which is not consistent with generally accepted medical standards which would be applied under similar medical circumstances to persons who are nationals of the Party conducting the procedure and who are in no way deprived of liberty.

2. It is, in particular, prohibited to carry out on such persons, even with their consent:

(a) physical mutilations;

(b) medical or scientific experiments;

(c) removal of tissue or organs for transplantation, except where these acts are justified in conformity with the conditions provided for in paragraph 1.

3. Exceptions to the prohibition in paragraph 2 (c) may be made only in the case of donations of blood for transfusion or of skin for grafting, provided that they are given voluntarily and without any coercion or inducement, and then only for therapeutic purposes, under conditions consistent with generally accepted medical standards and controls designed for the benefit of both the donor and the recipient.

Convention on Human Rights and Biomedicine (1997)

The European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the Convention on Human Rights and Biomedicine of 4 April 1997. Council of Europe.

Article 2 – Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

…

(ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

(iii) the research project has been approved by the competent body after independent examination of its scientific merit, …

(v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 – Protection of persons not able to consent to research

Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

1…

iii research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

v the person concerned does not object.

2 Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 – Research on embryos *in vitro*

1 Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

2 The creation of human embryos for research purposes is prohibited.

Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

October 2000

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

Universal Declaration on the Human Genome and Human Rights

This declaration was adopted unanimously and by acclamation at the twenty-ninth session of UNESCO's General Conference on 11 November 1997. The following year, the United Nations General Assembly endorsed the Declaration.

Article 5

e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 10

No research or research its applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.