Dr Peter Jensen - Archbishop

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The Most Reverend Dr Peter Jensen
St Andrew's House,
Sydney Square,
Sydney, NSW, 2000

The Secretary
Senate Community Affairs Legislation Committee
Suite S1 59
Parliament House
Canberra ACT 2600

Dear Secretary,

The Anglican Diocese of Sydney's Social Issues Executive welcomes this opportunity to make comment to the Committee about this important piece of legislation. The Diocese has made an active contribution throughout the debate including representations to the Prime Minister and Federal Parliament. We also participated in the consultations with the National Health and Medical Research Council (NHMRC) when the legislation was being drafted and would be happy to provide the Committee with our follow up submission if so requested.

The following submission outlines our position which we look forward to discussing with you in full at the consultations later this month.

I trust the following comments will be considered thoughtfully,

Yours faithfully,

Dr Peter Jensen,
Anglican Archbishop of Sydney

SENATE SUBMISSION: RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002.

Anglican Diocese of Sydney Social Issues Executive

Preamble

The most difficult ethical dilemmas are those which should never have been allowed to develop in the first place. While we realize that regulation of Assisted Reproductive Technology (ART) is outside the scope of this enquiry, we would like to say at the outset that the Executive is concerned that it was possible for 70,000 frozen embryos, surplus to the needs of patients, to be created. We believe that the regulation of ART in Australia is integral to the issues surrounding this bill and that its review is crucial. The NHMRC Guidelines created for this task have obviously failed to achieve their goal.

The Executive is opposed to destructive research on human embryos and believes it should not be legalized. We support the listed prohibitions. We realize that the bill has been divided to separate these two issues and will focus on the arguments against destructive research on human embryos in this submission.

We are strongly opposed to human cloning, whether it be for biomedical research or reproductive purposes. However, we realize that this is prohibited in the current bill.

Moral status of the embryo

The Executive bases its opposition to destructive research on human embryos on its understanding that human life begins at fertilization. This is consistent with Biblical references and supported by recent research in embryology.

Researchers in the United Kingdom recently published a report demonstrating that the human body is shaped from the moment of fertilization. Some studies suggest that differentiation happens as early as the two celled stage. This obviously calls into question the findings of the Warnock Report.[1] This report argued that individualization did not occur during the first two weeks of life and is often quoted as the justification for experimentation on human embryos up to 14 days. The 14 day limit is also proposed on the basis that twinning can no longer occur by this time. The suggestion is that you cannot have an individual if it can potentially become two individuals. However, it is now known that monozygotic twinning is not a random process but a repair mechanism activated by an assault on the embryo (mechanical or biochemical). The implication for individuation is not that an individual is absent, but that 'crucial relational dynamics of position and intercellular communication are already at work establishing the unified pattern of the developing individual.[2]

[1] The *Report of the Committee of Inquiry into Human Fertilisation and Embryology* chaired by Baroness Warnock and presented to UK Parliament in July 1984.
[2] The President's Council on Bioethics. *Human cloning and human dignity: an ethical inquiry.* (2002). P.175.

We contend that the human embryo is an individual from the time of fertilization and as such deserves protection by the state. This is not to say the moral status of an embryo is absolute, ie greater than that of an adult. However we wish to include the human embryo, even those 'excess' embryos which are frozen, in the human family.

There are precedents for the protection of minors where those who are responsible for them wish to see them harmed. In such a case the state takes over the role of guardian. For those who are uncomfortable to view the embryo as anything other than a potential community member, we also have laws which look after the interests of future generations, for example environmental laws.

Protection of embryos

We believe that it is important to protect embryos which are surplus to the needs of ART services for several reasons.

1. Firstly, they were created as a result of a desire of an ART patient to have a child. At the time of their creation the intention was to implant them and attempt a live birth. If some parents are now saying they do not want to nurture these embryos it raises the disturbing possibility that the parents view their offspring as a commodity, to be discarded at will, and are therefore not acting in the best interests of the embryo. Therefore we suggest that such parents not be allowed to decide the fate of such an embryo and that their guardianship should be transferred.

2. Secondly, while we understand the utilitarian argument that it would be a waste to let the embryos succumb when they could be used for research, we do not agree. In the first instance, we do not agree that these are the only two possible futures for the embryos[3] but even if the only alternative were to let the embryos die, still we argue that this is preferable to destructive research.

   If we choose to acknowledge that we have made a mistake in allowing the frozen embryos to accumulate, we can work towards addressing how we can avoid it recurring and see the passing of this particular generation of embryos as a tragedy. If, on the other hand, we decide to establish an industry which is dependent on human embryos for laboratory material, we are establishing human embryos as a resource the demand for which may well continue. Requests for more human embryos, be they frozen excess ART embryos created after 5 April or fresh ones created specifically for research, will come before Parliament. The establishment of embryonic stem cell research in local biotech industries will invariably lead to requests for embryos which will meet current Good Manufacturing Practice (cGMP) safety requirements if therapeutic product development is to occur. These cGMP requirements are different from the standards required in IVF programmes and are more stringent. Frozen excess ART embryos will never be adequate as a source.

3. Furthermore, if this bill is passed, we are establishing a precedent for destructive research on human subjects who cannot consent. The *Senate Select*

[3] Countries such as the UK, USA and France have programs which allow the adoption of embryos to infertile couples. In view of the shortage of egg donors in Australia, this seems a practical and ethical option.

Committee on the Human Embryo Experimentation Bill 1985 report states that 'the embryo of the human species should be regarded as if it were a human subject for the purposes of biomedical ethics.'[4] Destructive experimentation on humans without their consent is contrary to many ethical codes, including the Nuremburg Code (1946), the Declaration of Helsinki (1964) and the Council of Europe (1997). The only way to avoid this implication is to exclude these embryos from the human family, reversing the decision of the Senate Committee above. We view such a reversal as arbitrary, opportunistic, unscientific, unethical, and dangerous. Once these humans are denied protection, what basis is there for prohibiting the use of human fetuses of a much longer gestation for transplant organs (as has been suggested by scientists already) or alternatively those at the end of their lives whose contribution to society is over? While many people suggest that slippery slopes are controlled by adequate regulation, they occur anyway. Consider the video of a rodent 'cured' by an injection of not embryonic, but nine week old foetal cells, or the change in public perception of ART since its inception. It is interesting to consider whether destructive research on human embryos will contravene prohibited practice 13(i) of this legislation.

4. Finally, the Australian public was told that the justification for the destructive research on human embryos was the promise of life-saving cures for the ill through embryonic stem cell therapy. We note that the Bill does not restrict the destructive embryonic research to any particular area (see below) and are concerned that it has progressed under false pretences. Furthermore, we do not find the scientific evidence for embryonic stem cell research sufficiently encouraging to justify its use as an excuse for destroying human embryos anyway. In every area in which embryonic stem cell therapy has been attempted, adult stem cells have been more successful. Patients with spinal cord injuries, cancer, diseases of the blood and immune system, diabetes and cardiac disease, for example, have already been successfully treated with adult stem cells. So far embryonic stem cells have provided no successful treatments for humans and even animal experiments lag behind adult stem cell equivalents.[5] Also, recent research has shown that stem cells may not be needed at all for regenerative medicine, with somatic cells being reprogrammed into different types of adult cells. For example. Skin cells have been turned into immune cells[6] and in Sydney orthopaedic surgeons have turned fat into bone cells.[7] In the recent report on Human Cloning from President Bush's Council on Bioethics, Dr William Hurlbut from Stanford University suggests the possibility that the promise of stem cell therapy may be realized without resorting to the destruction of human embryos.[8] We support the development of medical therapies which will relieve the suffering of many in our community and believe that this can be done without resorting to the destruction of human embryos.

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[4] *Human Embryo Experimentation in Australia: Senate Select Committee on the Human Embryo Experimentation Bill 1985,* Australian Government Publishing Service, Canberra, 1986, p.28.
[5] See www.stemcellresearch.org for details,
[6] See *Nature Biotechnology 5.1.02.*
[7] Personal communication, Dr Warwick Bruce August 2002.
[8] The President's Council on Bioethics. *Human cloning and human dignity: An ethical inquiry.* [On-line]. Available: http://www.bioethics.gov/cloningreport/fullreport.html [22.8.2002], p.178.

Even though it is outside of the current debate, we also oppose embryonic stem cell research on the grounds that either cloning of human beings or embryo farming will be required to make therapeutic treatments available to a sufficient range of HLA types to be practical. Despite recent assurances from some scientists that cloning is no longer contemplated by those in embryonic stem cell research, we are concerned that it is still on the agenda for some.

In summary, we can find no justification for the argument that it is better to use the excess ART embryos created before 5 April for destructive research.

Specific concerns regarding the Bill

The Executive is fundamentally opposed to the intention of this bill, that is, to regulate research which involves the destruction of human life. However, if it is to proceed, we would appreciate consideration of the following.

Part 1: 3(b)

The wording of this clause does not limit destructive embryonic research to stem cell therapy, which we understood was the reason for the decision at COAG to create this legislation. We are aware that pharmaceutical companies and perhaps other industries are interested in the use of human embryos for research. We object to the use of human embryos for research in areas such as pharmaceuticals. Not only can it be done with other models, but it would be misleading to extrapolate the effect of drugs on embryo models due to the absence of confounding factors. We are aware that currently human embryos are destroyed in the routine training of technicians for IVF laboratories but we are offended that this practice has been allowed to develop when, once again, animal models could be used. The possibility exists that cosmetic companies will be interested in destructive human embryo research. We request that the wording be changed to restrict the areas of research where destructive human embryo research is allowed.

Part 1:7 (1)

It is now recognized that in the process of cloning, genetically identical organisms are not created. As soon as cell division commences in the clone, minor genetic mutations occur which alter the genome. A more accurate definition would refer to asexual rather than sexual reproduction.[9]

Part 2: Prohibited practices

In view of the seriousness of the offences listed, we would like automatic cancellation of a research license and permanent exclusion from future licensing to occur where an offence is committed.

Part 2 Division 2: 22

We would like clarification on the distribution of profits made through the use of excess ART human embryos, or the products of destructive research such as stem cells. We believe that if human embryos are to be used at all, it should certainly not be for the commercial gain of any parties. We would like to see explicit consideration

[9] The President's Council on Bioethics, *op. cit.*,p.7.

of the commercial rights to financial benefits derived from the destruction of excess ART human embryos in this legislation.

Part 3 Division 2: 25(2)(d)
The terms 'suitable' and 'diagnostic investigations' require more specific definition to limit use of embryos in these situations to universally recognized protocols.

Part 3 Division 4: 36(4)(b)
We are concerned that the NHMRC will be responsible for decisions made in the issuing of licenses in view of the fact that it was under their guidelines that 70,000 excess embryos were allowed to accumulate in ART laboratories around the country.[10] As the NHMRC does not have the resources to police current human embryo use, we do not feel that they are currently the ideal organization to have the responsibility for enforcing adherence to the legislation under consideration. In an area as important as this, we feel that legislation should not be allowed which cannot be effectively enforced. We would therefore like to see provisions in the legislation to provide the NHMRC with the authority and resources required for enforcement.

Part 3 Division 4:39 (5)
We would like to more specific instructions regarding the licensee's accountability within the licensing system. For example, records should be available on the premises of research so inspectors have access to these records when visiting clinics. We encourage the notion of sport checks. Licensees should be required to report back to the NHMRC licensing committee on the results of their research which can then be disseminated through the public database when the license has expired.

Part 3 Division 5:44
We are concerned that this legislation appears to provide for the protection of commercial interests in association with destructive embryo research. We would prefer the legislation to follow the pattern of the Canadian legislation which regulates research on human embryos. In this bill, financial incentives are discussed openly. Clauses put limitations on payment for embryos (direct or indirect) or for stem cell lines developed from donated embryos. Researchers are to disclose actual, perceived or potential conflicts of interest to the licensing body. Copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information is to be provided to the licensing body so that any potential or actual conflict of interest can be examined and evaluated, and to ensure the right to publish freely after the expiration of the license.[11]

Part 6 Division 1:60
We oppose an automatic repeal of the listed paragraphs, which removes the 5 April 2002 cut-off for frozen human embryos. If a review of the legislation is planned anyway, the question of further use of embryos needs to be carefully considered so that the possibility of the creation of embryos specifically for research is avoided.[12]

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[10] We are aware that RTAC oversees the self-regulatory mechanism for ART clinics.
[11] Canadian government bill C56. [On-line]. Available<www.parl.gc.ca>.
[12] The creation of human embryos for research is specifically prohibited in the Council of Europe's *Convention on human rights and biomedicine*, 1997.

Part 6 Division 2:61
In view of the widespread agreement on the need for prohibition of practices listed in Part 2, including human cloning, we suggest that Part 2 be excluded from the Review of Act. The listed prohibitions would be banned permanently.

Conclusion
The Social Issues Executive is of the opinion that scientific and medical progress has been a great blessing to our community in terms of the relief of suffering that has been possible as a result. However, with the expansion of the scope of biotechnological innovation, it is time for us as a society to carefully consider where this revolution is taking us. We believe that we are at an important crossroads and we now have the opportunity to decide the ethical foundation on which future research will develop. It is time for us to consider what it means to be a human, and we believe that the human embryo must be protected from destructive research now, because otherwise this legislation will be 'vulnerable to transgression through the persuasive promise of further scientific benefit.'[13]

[13] The President's Council on Bioethics, *op. cit*. p. 173.