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Regulation of embryonic stem cell research *and* therapeutic cloning: The Australian debate

The regulation of research involving embryos was the subject of considerable debate, both inside and outside parliament, for much of 2002. This debate raised numerous ethical, scientific, social and economic issues that in turn informed the proposed legislation governing embryo research regulation. This article examines the legislation that has been passed by parliament as part of the government's attempt to find an acceptable consensus on these issues.

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INTRODUCTION

Embryonic stem cell (ESC) research is a rapidly developing area of biological and biomedical science that may provide treatments for currently incurable conditions such as Parkinson's disease, Alzheimer's disease, spinal chord injury and insulin-dependent diabetes. Because the realisation of these putative gains involves the destruction of early embryos, its regulation has become the focus of public and political debate in Australia.

ISSUES OF DEBATE THAT HAVE INFORMED THE PROPOSED LEGISLATION

The Efficacy and Sufficiency of Adult Stem Cells

Some opponents of ESC research argue that it is unnecessary because Adult Stem Cells (ASCs) can be as clinically effective as ESCs. Unlike ESCs, which are derived from the inner cell mass of a blastocyst and result in the destruction of an embryo, ASCs are removed from the patient who is undergoing treatment, causing minimal harm. ASCs have been used experimentally to treat patients with Parkinson's disease, multiple sclerosis and other disabilities with moderate success.[1] Using a patient's own ASCs raises fewer ethical dilemmas, these proponents argue, and also has fewer medical limitations. Transplant cells or organs derived from the ASCs of a patient would not stimulate an adverse immune response because they would be immunologically compatible with the patient.[2] This would only be the case with transplants created using ESCs from an embryo produced by somatic cell nuclear transfer (SCNT), or therapeutic cloning.

Proponents of ESC research reject the argument that ASCs are a viable alternative to ESCs. They counter that ASCs can be painful to extract and difficult to isolate[3] and their plasticity is controversial. Some studies have demonstrated that ASCs are capable of differentiating into a wide variety of cell types, although a narrower range than ESCs.[4] Two recent studies have suggested that these observations may be the result of stem cells fusing with the cell types within which they have been inserted, producing cells with twice the normal complement of DNA and abnormal capabilities.[5] The ability of ASCs to match all the potential therapeutic advantages of ESCs is unresolved.

Moral Status of the Embryo

The ethical issue most explicitly discussed in debate about an Australian regulatory system has been the moral status of the embryo. There are roughly three schools of thought found in the Australian (and international) debates about the moral status of the early embryo.

The first, and arguably most contentious view, is that human life and moral status both begin at *conception*. On this view, the moral status of the embryo is equal to that of a human adult and hence destructive embryo research is morally equivalent to killing adults. All ESC research and cloning techniques would be ruled out on this belief.

A second less definitive group holds a *developmental* view, according to which the embryo's potential for personhood expands as it grows and develops.[6] The Jewish and Islamic faiths, and views that attach moral significance to foetal *viability* and *quickening*, fall into this category.[7] Generally, a developmental view recognises that at some point an embryo acquires an undefined, 'special' moral status. Most advocates of this view would probably regard ESC research using surplus IVF embryos as morally permissible, but they may not accept the prospect of research performed on embryos created for that purpose.

A third group of views hold that *personhood*, which in the richest sense involves having consciousness, sentience, memory, life-history, or some combination of these, is a necessary condition for deserving moral consideration.[8] Since an early embryo does not possess any of these qualities, on this view the early embryo does not enjoy any special moral status. Thus research using early embryos is morally permissible, especially when it holds the promise of producing major therapeutic gains for adult human beings.

Alleviation of Human Suffering

ESC research will potentially provide opportunities to treat diseases by replacing or regenerating many types of diseased tissue. Among the most commonly mentioned potential applications are: the regeneration of pancreatic islet cells in diabetic sufferers; the replacement of diseased brain tissue in Alzheimer's and Parkinson's patients; and meeting demands for donor organs such as hearts, kidneys and livers.

The alleviation of suffering has been the strongest justification used by proponents of ESC research and therapeutic cloning. There is also evidence that the general public support ESC research because they believe that it may lead to the development of cell replacement therapies that will alleviate suffering on a large scale.[9] Replacement cell therapies will conceivably improve the symptom management of some illnesses at the very least and may reverse tissue degeneration and promote tissue regeneration at the very best. There is no doubt that the 'alleviation of suffering' has been the most persuasive argument for permitting the use of embryos in ESC research.

Reproductive Cloning and the Slippery Slope

Some opponents of ESC research argue that it will be the first step down a 'slippery slope' towards more morally objectionable types of research and practice.[10] A common form of this argument is that allowing SCNT and therapeutic cloning will facilitate the later use of this technology for reproductive purposes.

It is difficult to sustain the slippery slope objection both logically and empirically.[11] One reason for this is that it is not certain that if we allow one technique to go ahead and disallow another (for example, by banning or placing stringent restrictions on it), that the restricted technique will be practised. The adoption of strict regulations to prohibit practices found to be morally unjustifiable, such as reproductive cloning, may satisfy those who find the use of SCNT technology objectionable. This is the stance taken in the United Kingdom where legislation permits the use of SCNT but prohibits the implantation of a cloned embryo in a woman.[12]

Intellectual Property and Commercialisation

The potential for ownership and commercialisation of ESCs has been a point of significant debate, particularly in the Senate.[13] Some types of ESC research are likely to have ▶

commercial applications in the future and may therefore become the subject of patent applications. It has been argued that ownership of some ESC-related technologies must be permitted so researchers can attract investors and gain funding.[14] However, some fear that this could lead to these technologies becoming unaffordable for the majority of the population.

AUSTRALIAN LEGISLATION

The *Research Involving Embryos and Prohibition of Human Cloning Bill* 2002 (Cth) was the outcome of negotiation between the Prime Minister and state premiers to produce nationally consistent regulation of ESC and cloning research.[15] The Bill was introduced into the House of Representatives on 27 June 2002 but, due to its controversial nature, it was divided into the *Prohibition of Human Cloning Bill* 2002 (Cth) and the *Research Involving Embryos Bill* 2002 (Cth). The former Bill was passed by the House of Representatives on 29 August and the Senate on 14 November. The latter was passed by the House on 15 October, and by the Senate on 5 December.

'Constitutionally, the Commonwealth does not have any specific powers relating to human cloning or the use of embryos.'

In combination, the Acts prohibit all scientific techniques that involve copying or altering a person's genes with the intention of creating a new individual, thereby addressing community concerns about the possibility of reproductive cloning. The Acts also stipulate the type of procedures involving embryos that will and will not be permitted. Although the Acts do not accord the embryo a status equal to that of a neonate or adult, they require that the early embryo be respected and protect its 'special' status by limiting the type of research that may be done on embryos. Any embryo research that is approved must have a beneficial and potentially therapeutic outcome. Additionally, the creation of embryos specifically for research purposes is prohibited, as is the commercial trading of human eggs, sperm or embryos. Violation of the Acts' prohibitions will result in imprisonment or monetary fines. For example, reproductive cloning incurs an imprisonment term of fifteen years, while the creation of an embryo for a purpose other than achieving pregnancy in a woman is subject to a ten-year gaol term.

The *Research Involving Embryos Bill* 2002 (Cth) creates the NHMRC Embryo Research Licensing Committee and a national licensing system to regulate embryo research. Under this system, researchers must obtain proper consent from each 'responsible' person[16] in relation to the excess embryos[17] that are to be used, ensure that these excess embryos were created before 5 April 2002, and have the project assessed by a Human Research Ethics Committee. The NHMRC Licensing Committee will then review the license application, taking into account the number of excess embryos that the project would use, and the probability that the research will have a significant outcome that could not be achieved without the use of the embryos.

Constitutionally, the Commonwealth does not have any specific powers relating to human cloning or the use of embryos. It therefore relies on powers such as the corporations power, and the trade and commerce power to support the legislation.[18] However, the legislation does not rely entirely on the powers of the Commonwealth. Instead it aims to create a cooperative scheme in which the states and territories pass complementary legislation on embryo research and cloning which confer powers, functions and duties on the Commonwealth licensing authority. As a result, researchers in all states and territories will be governed by the same regulatory code, regardless of where the research is conducted and whether it is publicly or privately funded.

In order to prevent IVF embryos being created solely for research purposes, the Council of Australian Governments (COAG) limited the excess embryos that could be used by researchers to those created before 5 April 2002. This restriction should be removed after a maximum of three years. The *Research Involving Embryos Act* 2002 (Cth) reflects this by including a sunset clause which specifies that after 5 April 2005 (or at an earlier date agreed upon by COAG) excess embryos created after 5 April 2002 may also be used for research purposes.[19] Both Acts also require that a review of the legislation be undertaken two years after the Acts receive Royal Assent.

CONCLUSION

The ESC debate in Australia has been simplified to a choice between two ethical positions. Proponents argue that human ESC research is ethically justified because the potential benefits to sufferers from diabetes, Parkinson's disease, spinal chord injury and heart disease outweigh the rudimentary moral interests of a six-day-old embryo or blastocyst that would be destroyed in obtaining ESCs. Moreover, they argue that the ESCs are obtained from surplus IVF embryos that would be destroyed in any case.

Opponents of human ESC research argue that the extraction of ESCs from a six-day-old embryo is wrong because it destroys the human life which began at conception. They also argue that human ESC research is unnecessary because its alleged benefits can be obtained from research on stem cells extracted from adults. Additionally, opponents contend that permitting the use of such techniques could lead to reproductive cloning, and that the possibility for commercialisation of ESC research could prevent many people from accessing its

potential benefits.

The legislation has been informed by the scientific, ethical and economic issues that have been raised in public and parliamentary debate and represents a compromise between many conflicting points of view. The legislation will provide a nationally consistent approach to legislation and regulation of human ESC research. It will ban reproductive cloning, place a moratorium on therapeutic cloning using SCNT, and allow ESC research on surplus IVF embryos created before 5 April 2002 and donated by their parents. This set of recommendations is consistent with public opinion that it is morally defensible to use excess IVF embryos that would otherwise be destroyed.

The parliamentary debates that followed the introduction of the *Research Involving Embryos and Prohibition of Human Cloning Bill* 2002 highlighted a number of issues concerning ESC research that were not addressed by the legislation. These issues include intellectual property rights, ownership, and patent law relating to human embryos, commercialisation of embryo research, and the regulation of any commercial products such research may produce. It remains to be seen how these issues are addressed, but there is no doubt that they will become the topic of further public debate. PL

Endnotes:

1 Smith WJ (23 April 2002) Spinning stem cells: A damning reporting pattern, *National Review*, 23 April 2002 from http://www.nationalreview.com/comment/comment-smith042302.asp

2 Donovan PJ and Gearhart J (2001) The End of the Beginning for Pluripotent Stem Cells, *Nature* 414(685):92-97.

3 Committee on the Biological and Biomedical Applications of Stem Cells Research (2002) *Stem Cells and the Future of Regenerative Medicine*, Washington DC: National Academy Press.

4 Donovan and Gearhart, op cit.

5 Dewitt N and Knight J (2002) Biologists Questions Adult Stem-Cell Versatility, *Nature* 416(6879):354.

6 Juengst E and Fossel M (2000) The Ethics of Embryonic Stem Cells - Now and Forever, Cells Without End, *JAMA* 284:3180-184.

7 Savulescu J (2000) The Ethics of Cloning and Creating Embryonic Stem Cells as a Source of Tissue for Transplantation: Time to Change the Law in Australia, *Australian and New Zealand Journal of Medicine* 30(4):492-98 at 494.

8 Harris J (1993) *Wonderwoman and Superman*, Oxford: Oxford University Press, chapter 3.

9 (18 July 2001) Embryonic Intent, *Bulletin*, reported that a Morgan Poll found that 72% of Australians, 66% of New Zealanders and 62% of Britons were in favour of using ESCs for research if they had the potential to treat debilitating diseases.

10 Lanza R et al. (2000) The Ethical Validity of Using Nuclear Transfer in Human Transplantation, *JAMA* 284(24):3175-179.

11 Lanza et al., op cit.

12 Britton I and Murton R (2000/01) 'Embryo Farm?' A survey of developments in the regulation of stem cell research, *Bio-Science Law Review* 4(5):215-219.

13 Centre for Law & Genetics (5 December 2002), *Australian Developments in Embryo Research & Cloning Legislation: A Review of the Debate*, at 11.

14 Resnik DB (2002) The commercialisation of human stem cells: ethical and policy issues, *Health Care Analysis* 10(2): 127-54.

15 A detailed account of this process can be found in Norberry J (2002) *Research Involving Embryos and Prohibition of Human Cloning Bill 2002, Bills Digest No. 17*, Canberra: Department of the Parliamentary Library, at 16.

16 A 'responsible' person is defined by the legislation as the people from whom the egg and sperm were taken, the woman for whom the embryo was originally created, and any spouses these people may have at the time in question.

17 Note that both Bills Acts differentiate between determining that an embryo is excess to a couple's needs and obtaining their consent for its use in research.

18 The heads of Commonwealth constitutional power that might support the proposed legislation are detailed in Norberry, op cit at 11.

19 National Health and Medical Research Council (2002), *A Guide to the: Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, Canberra: National Health and Medical Research Council.