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Sent: Tuesday, 6 September 2005 9:59 PM
To: 'lockhartreview@secretariat.com.au'
Subject: Supplementary Submission (member ID no. 198)

SUPPLEMENTARY SUBMISSION: THE LOCKHART REVIEW OF THE RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002 (CTH) AND THE PROHIBITION OF HUMAN CLONING ACT 2002 (CTH)

From: Adam Johnston

Date: 6 September 2005

Dear Justice Lockhart,

I am prompted to write to your Review for a second time, thanks to significant developments in science announced over the past few days. The genome of the chimpanzee has been recently decoded.[1] This has resulted in a number of observations, many of which could ultimately have significant impacts on human health. For example, a *Sydney Morning Herald* report stated:

> "…Already some of the bits of DNA that have been found to be duplicated in humans, but not in chimpanzees, have been linked to human diseases such as spinal muscular atrophy and Prader-Willi syndrome…On the other hand humans appear to have lost the function of a gene that may protect chimps and other animals from Alzheimer's disease…"[2]

In this context, I note the Commonwealth Government's *Intergenerational Report 2002-03* and various historical developments which led governments in a number of nations to make the public provision of health care services a policy priority.

The forces that propelled all these political communities to assume a public responsibility for health are still present, though arguably in different forms. In my view, the debate over stem-cell research, somatic cell nuclear transfer[3] and xenotransplantation are related elements of the same policy dilemma which confronted policymakers in the late 19th and early 20th centuries. Our forebears resolved these questions to the benefit of mankind, but I fear that the contemporary debate could be overwhelmed by the combined forces of *alleged* religion, *alleged* morality and *alleged* ethics.

Public interest and health policy

History is useful in how it reveals patterns in human behaviour and consistency in many of the problems we face, either as individuals or society at large. However, we

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[1] For example, see Deborah Smith (Science Editor), *Meet Clint, your closest relative,* Sydney Morning Herald, September 1, 2005, available at http://smh.com.au/news/science/meet-clint-your-closest-relative/2005/08/31/1125302628279.html

[2] Smith, Deborah, *Humanity redefined,* Sydney Morning Herald, September 1, 2005, available at http://smh.com.au/news/science/humanity-redefined/2005/08/31/1125302628430.html

[3] As stated in my previous submission to this Review, the use of the phrase "human cloning" is legally and scientifically inaccurate, as well as being unnecessarily emotive.

will likely be surprised at how many of cultural, moral, policy and other societal "norms" we accept as an ordinary part of our lives may lack the timelessness or consistency we assume they posses.

The development of public health regimes in various countries exemplifies all of these elements and can guide us through the current public policy questions. For example, Roy Porter explains that:

"…(In) 1911…the (British) Liberal politician Lloyd George launched his National Insurance scheme modelled along Bismarkian lines…It was a measured devised to be popular with the electorate (it gave 'ninepence for fourpence', boasted Lloyd George) while ameliorating the wretched health of ordinary workers. This had been critically exposed when a high proportion of Boer War volunteers had been found unfit to serve for medical reasons…"[4]

This quotation bears out two important points. Firstly, the British Government saw the need to intervene in the health of its population because this matter not only influenced an Administration's longevity, but had a real impact on the nation's productive and combat capability. At the time of their introduction, such programs of universal social support had a more limited impact on national budgets. For instance, Latham observes that:

"…(At) the time of the establishment of the first universal age pension, by Bismark in Germany (in the 19th century), only 1 per cent of each age cohort was expected to live long enough to access it. Benefits for the aged were made affordable by the small proportion of aged citizens…"[5]

Demographic change

In modern times, this has changed significantly, causing the Government to make the *Intergenerational Report* (the Report) a requirement of its *Charter of Budget Honesty Act 1998*.[6] While conventional wisdom argues that the growth in the elderly population will necessarily increase the cost of health care, the Report states that this is only partly true. Another significant factor will be the developments of new medicines and treatments, combined with the public's expectation that "these treatments will be provided to them soon after the technology first becomes available."[7]

It is important to ask what the outcomes of the new treatments are. As mentioned earlier, Porter noted that Lloyd George's insurance scheme was aimed at "ameliorating the wretched health of ordinary workers".[8] Some may argue that

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[4] Porter, Ray, *The Greatest Benefit to Mankind,* London, Harper Collins, 1997, p.638-639 (extracts cited in James Gillespie, *POL 341 - The Politics of Health: Readings,* Department of Politics and International Relations, Macquarie University, 2003)
[5] Latham, Mark, *Civilising Global Capital: New thinking foe Australian Labor,* Allen & Unwin, 1998, p.200
[6] *See* Costello, The Hon. Peter, *Intergenerational Report 2002-03: 2002-03 Budget Paper No.5,* Commonwealth of Australia, 14 May 2002, p.3, available at http://www.treasury.gov.au/contentitem.asp?NavId=012&ContentID=378
[7] Ibid, p.38
[8] Refer to footnote 4

things are not nearly so wretched now. If you look at indicators of mortality, morbidity, life expectancy and the like, comparing them with figures from the early 1900s, this is undoubtedly true. However, as we have learned to sustain the life of people, not only with one diagnosed, temporary condition, but multiple, long-term ailments, we have not always managed to care for them. Equally, while medical science has learned to sustain many who have very complex needs, it is another question entirely as to whether such people have been given a quality of life any of us not so infirmed would want, or merely granted extended misery?

In this respect, I am thinking particularly of those disabled people (notably the young) who end up residing in aged care facilities. This is a problem acknowledged frankly by a Government website, which says:

> "…There are a number of younger people with disabilities living in residential aged care as a result of a lack of more suitable accommodation. This situation is problematic both for the residents and for the providers. Young disabled residents may not get the services they need, they may suffer social isolation and they may be disadvantaged financially. Aged care providers are geared to the provision of care to the elderly, as is the funding system, and both may not take sufficient account of the needs of the profoundly disabled, who reside in residential aged care. Further, the demand on providers' resources required to care for young disabled residents may disadvantage frail aged residents…"[9]

This is a very complex problem concerning resources, funding, finding and appropriately training personal care attendants, to mention just a few elements. I am not proposing any immediate solutions. What I wish to draw to the Review's attention, which is immediately relevant to the question of stem cell technologies, is the subtle change in the emphasis of medicine.

If you look to the dictionary definition, to ameliorate is "to make (something) better".[10] Meanwhile, alleviation means "to lessen (pain or suffering)".[11] The dictionary also advises that these two words are often used interchangeably and incorrectly.[12]

From amelioration to alleviation

While it is important to provide the sick, elderly and disabled with appropriate services to lessen pain and suffering, is it not also vital to foster research that makes them better? I think this second element is being lost in the public policy debate about health. Amelioration was clearly an objective with Lloyd George, as a healthy electorate would maintain the Government in office, grow the economy and staff the services. Equally, from the perspective of disability (something I know from personal

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[9] Department of Health and Ageing, *Investing in Australia's Aged Care: Chapter 13. Interaction between the Australian Government, states and territories: 13.2 Disabled young people in aged care,* available at *http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-investinginagedcare-report-13-13-2.htm* (Page currency, Latest update: 22 September, 2004)
[10] Treffry, Diana (Publishing Manager), *Collins New English Dictionary,* Harper Collins Publishers, 1998, p.20
[11] Ibid, p.17
[12] *See* ibid, p.20

experience) the past 20 years have seen increasing efforts to integrate those with physical and other handicaps into mainstream society. For example, in a 2002 Senate inquiry "*Education of students with disabilities"*, the Senate Employment, Workplace Relations and Education References Committee observed that:

"…Inclusive practices in regard to education of students with disabilities have become the prevailing orthodoxy. The committee received scarcely any evidence to suggest that segregation of students with disabilities with disabilities should be the normal learning experience, except in circumstances of serious disability in which the student posed a danger (to) other students…"[13]

Perhaps this is noble on one level, but on another it accepts disability as a social constant and aims only to address its negative outcomes; that is, exclusion from education services. At the other end of the age spectrum there appears to be a similar degree of fatalism in the medical and policy making fraternity. For example, in an issues paper dealing with the care of people with chronic conditions (produced as part of a Procurement Feasibility Plan for a proposed new hospital) the then Northern Sydney Area Health Service identified heart disease, renal failure, diabetes and respiratory illnesses as the categories of infirmity where sufferers would need long-term support and care from a variety of clinical and rehabilitation specialists.[14]

The paper also acknowledges that there are varying degrees of infirmity and, in the early stages of a disease's progress "a person's medical condition may be predominantly self managed through exercise and diet."[15] This is unquestionably prudent advice, which could well delay the onset of more serious and debilitating symptoms of numerous complaints, for some time. But should we, the sick, elderly or disabled accept this as the only answer? "Management" of a condition does not mean we will get better, or that the symptoms will go away altogether. Implicitly, I think medicine, for all its advances, is short-changing us, both as individuals and a community. Again, to draw on history and language, Lloyd George aimed to ameliorate wretched health; today we appear to focus on alleviating the eventual decent into wretched health.

I do not see any great public outcry about this issue, but surely there should be one. It is at this point that I draw you back to the question of the chimpanzee genome. The potential that the chimp's DNA holds answers to various forms of muscular atrophy, while also holding answers to the horrific afflictions of old age like Alzheimer's is something this Review and the Government must pursue in the national interest. As a former student of the now closed special school (for children with disability)[16] I watched a number of classmates with various muscular atrophy conditions descend slowly into arguably wretched health and eventual death. Attending several funerals

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[13] Carter, John (Committee Secretary), *Education of students with disabilities*, Employment, Workplace Relations and Education References Committee, Australian Senate, Commonwealth of Australia, December 2002, p.29

[14] *See generally*, Northern Sydney Area Health Service (Document Owner: NSH Area Executive), *Issue Paper No. 9: Ongoing (chronic) Conditions: Northern Beaches*, Date Last Modified: 11 June 2002, available at http://www.nsh.nsw.gov.au/majplanning/northbeach/providingservice/issuespapers/003671315.pdf

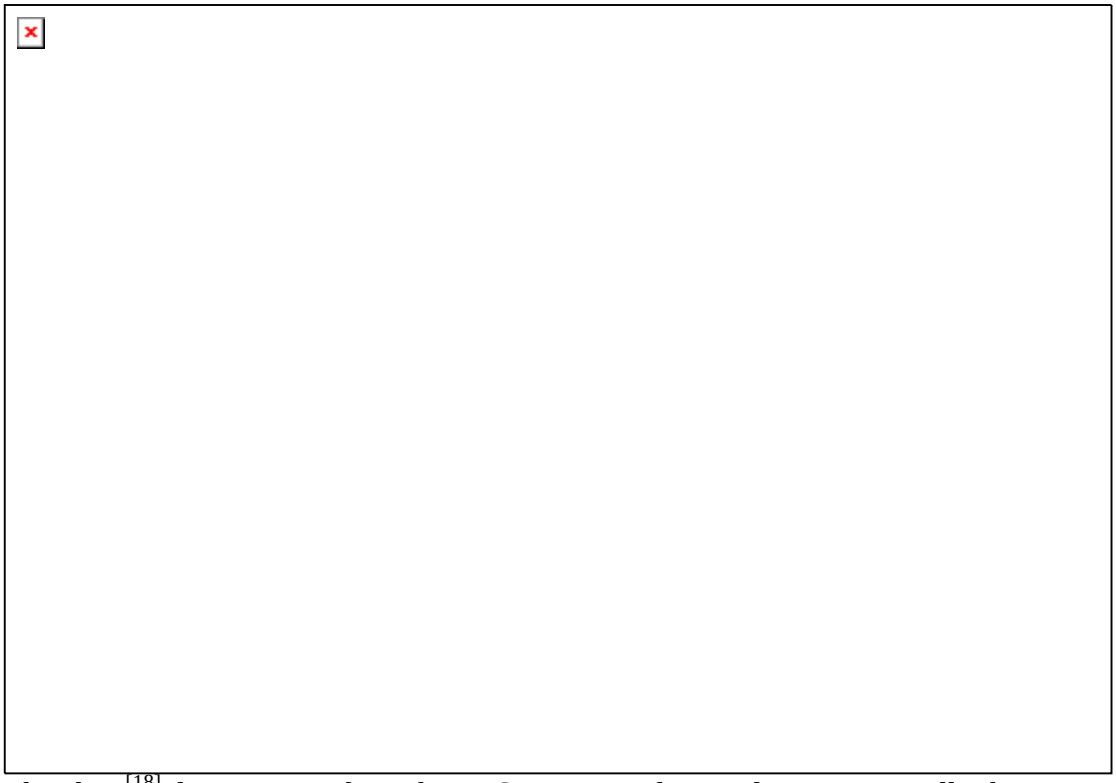
[15] Ibid, p.1

[16] *See* Carter, op. cit., pp. 32-33

before you leave school could not fail to leave an impression on you. These experiences go a long way to explaining my annoyance at the opponents of the emerging genetic technologies. The individuals lost had indomitable personalities and some of the most irreverent senses of humour I have ever met. All these factors stood in stark contrast to the medical reality of their physical state. And despite this, there was no outward anger about their fate; several must have known their life-expectancy was unjustly shortened.

Economic reality

I would further suggest that governments of all political persuasions will be forced down this route, as the pills, potions and lotions model of alleviation (better known in Australia as the Pharmaceutical Benefits Scheme or PBS) more that doubled its impact on revenues, as a percentage of GDP in the 1990s.[17] Projections contained in the Report show this exceptional growth in the PBS will continue, as demonstrated below.



The chart[18] demonstrates how the PBS is expected not only to outstrip all other components of health spending by 2041-42, but do so by a significant margin. This should improve both the economic conditions for stem cell research, somatic cell nuclear transfer and xenotransplantation, as well as the political palatability of all three technologies.

As such, nothing in my argument should be read as a denial of the significant research costs involved with the new technology. Rather, what medicine has been doing up until now, by way of alleviation, has real clinical and economic limits. We will be running up against these boundaries in the coming decade alone, unless we begin to

[17] *See* Costello, op. cit., p.8
[18] Ibid, p.9

change our policy strategies surrounding health and the appropriate treatment of illness, particularly chronic incapacity.

The failure of a key advisory body

This is where a far-sighted approach from bodies such as the National Health and Medical Research Council (NHMRC). However, the members of this body did, if I can put it discreetly, show they were individuals singularly lacking in "ticker" as the Prime Minister has termed it. Their failure to support recommendations or even endorse the Final Report of their Working Party on *Animal-To-Human Transplantation* shows a failure of leadership and conviction.[19] Indeed, the tenor of the NHMRC's Statement can be summed up in a similar fashion to Treasurer Peter Costello's characterisation of Opposition Leader Kim Beazley's approach to the July 1st tax cuts. The Treasurer has said:

"…It is regrettable, however, that the Labor Party has yet to announce its position on those (tax) schedules. The Labor Party still maintains determinedly that it is determined not to determine a position in respect of those income tax schedules…"[20]

A similar rebuke can justifiably be leveled at the NHMRC with regard to xenotransplantation.

Given the exciting possibilities of chimp DNA, I think the NHMRC's approach verges on negligence. They deferred further consideration of xenotransplantation for five years and, one of few definitive statements was "that non-human primates should not be considered as source animals for clinical trials of animal-to-human transplantation".[21]

While critical of the NHMRC, I acknowledge that there were a number of concerns about the safety of the technology, particularly around the issue of the transmission of diseases between species and the all-too-recent examples of how bovine spongiform encephalopathy (mad cow disease) moved from cows to humans.[22] Additionally, the NHMRC also noted that the term xenotransplantation was not widely understood by the public and that this led to challenges in defining and explaining the parameters of the term.[23] The NHMRC attempted to deal with this problem by identifying three distinct forms of research and therapies involving animals.[24] Despite this, public understanding was not significantly enhanced, although people who did apprehend the distinctions "were more supportive of cell and external therapies than of organ transplants".[25]

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[19] See National Health and Medical Research Council, National Health and Medical Research Council Statement on Animal-to-Human Transplantation (Xenotransplantation) Research, (including the Final report and advice to the National Health and Medical Research Council, September 2004), 10 March 2005, available at http://www.nhmrc.gov.au/ethics/human/issues/xeno/index.htm

[20] *House of Representatives Hansard* (Proof), Chamber, Thursday, 23 June 2005, Commonwealth of Australia, p.48, available at http://www.aph.gov.au/hansard/reps/dailys/dr230605.pdf

[21] National Health and Medical Research Council, op. cit., p.1

[22] *See* ibid., p.17

[23] *See* ibid., p.8

[24] *See* ibid., p.9

[25] Ibid

In this context, it is noteworthy that the NHMRC's definition of xenotransplantation excluded "processed, nonviable products, such as pig heart valves".[26] In my opinion, the aim of therapeutic stem cell technologies (as popularly understood) is to grow specific organs, which are replacements for diseased counterparts in a patient. As such, this Review should recommend that the NHMRC's deferral of further consideration be lifted, and the question actively pursued. Equally, I note that pig organs and cells may provide the closest biological parallels to human tissues.[27] However, to reduce the changes of rejection of a transplanted organ, the NHMRC explains that:

> "…Genetic modifications of pigs have involved both gene silencing (ie when specific genes are 'switched off') and insertion of human genes, to increase the immune compatibility between pig and human tissues and to overcome other physiological problems…"[28]

Noting the capacity of science to 'switch on' and 'switch off' genes, it may well be possible to switch on or turn off certain human and chimpanzee genes, in order to produce the positive medical outcomes identified at the beginning of this submission.

The chimpanzee genome

Given this, it is unreasonable for the NHMRC to quarantine nonhuman primates from all forms of xenotransplantation research. Nonetheless, I understand and agree with the comments attributed to Professor Marc Hauser of Harvard University, namely that:

> "…When a chimp looks back at you, your soul has been penetrated. You feel as though your inquisitiveness has been volleyed back, no words or actions exchanged…"[29]

My point of difference is that I believe you can justifiably employ xenotransplantation techniques, if these are undertaken at the embryonic or stem cell level, where genes can be manipulated so that positive attributes will be 'switched on' and those which make people vulnerable to numerous illness will (as far as possible) be 'switched off'.

This is the combined promise of stem cell research, somatic cell nuclear transfer and xenotransplantation. The potential uses and capabilities of various xenotransplantation techniques are summarized in the Table[30] below:

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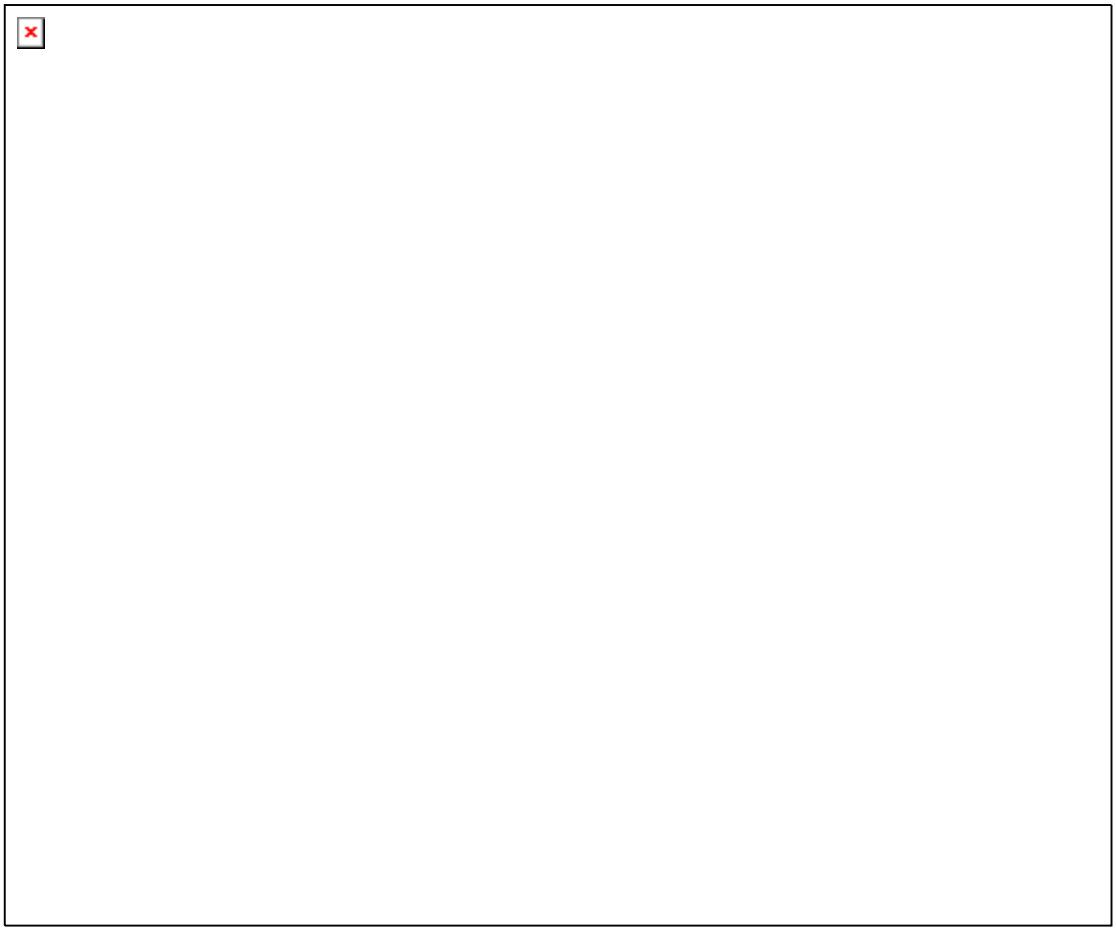
[26] Ibid., p.8
[27] *See* ibid., p.17
[28] Ibid., p.22
[29] Smith, op. cit.
[30] National Health and Medical Research Council, op. cit., p.8



Considering the table, my aim in prompting your Review to consider xenotransplantation as part of the stem cell debate is principally directed towards Animal External Therapies (AET) and Animal Cell Therapies (ACT). These techniques are the least likely to run into significant ethical objections about causing unnecessary distress or death among animals from whom cells were sought.

Regulatory arrangements

You may believe that I have collapsed a range of scientific research areas into one. In many ways this is true, and in line with bringing the science together, I would also bring the administration and regulation "under-the-one-roof "as well. The Office of the Gene Technology Regulator (OGTR) should be given authority over the legislation. While understanding that the OGTR's focus is principally on genetic alteration of agricultural products, the Senate Committee which investigated the OGTR legislation recommended that, with regard to genetically modified organisms (GMOs) "there may be significant benefits in introducing a 'one-stop (regulatory) shop' arrangement for business and the community generally."[31]

Such a reform also emphasises that, as I recommended in my prior submission, all genes and gene products should be treated in a like manner. I still see no case for human genetic material to be considered as a "special case", as this only gives license to emotive arguments.

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[31]Crowley, Sen. The Hon. Rosemary (Committee Chair), *A cautionary tale: Fish don't lay tomatoes A report on the Gene technology Bill 2000*, Senate Community Affairs Committee, November 2000, Commonwealth of Australia, 2000

I also believe that the precautionary approach was suitably articulated by both the Senate Committee[32] and the OGTR's advice to the Committee,[33] balancing the need for environmental protection with the national interest of seeing scientific knowledge and application advanced. As a result, I believe that the OGTR has the appropriate skills and 'corporate knowledge' to appropriately oversee the administration of the legislation currently under review.

A few questions of ethics

I am sure that there will be plenty of those who will read this entire submission and call every part of it unethical. In that case, let me deal with a few points about ethics. The first issue is to identify what ethics is; the dictionary definition states that ethics is:

> "…a code of behaviour, especially of a particular group or profession, or individual; the moral fitness of a decision, course of action etc; the study of the moral value of human conduct…"[34]

Ideas regarding one's beliefs and values also have a role to play in our understanding of ethics. Ross and MacFarlane indicate that these phrases have been used interchangeability, as well as having shifting meanings themselves "the more we either re-enforce them or replace them".[35]

In this context, it is difficult to settle on an exact ethical or moral formulation; though I note that a number of submission writers on your web-page,[36] are able to articulate their views (usually of outright opposition to stem cell technology) in one page or less. I think the issues involved in this Review deserve far more measured and considered deliberations by all interested parties, regardless of their views. The 1999 Federal Parliamentary Committee which inquired into the proposed (and highly contentious) Multilateral Agreement on Investment. The Committee made the following observations:

> "…In addition (to receiving many submissions), we received a large number of 'form' letters which were not counted as submissions, but which have been retained with other papers from the inquiry…"[37]

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[32] *See* ibid., p. 43, where the Committee notes that "(while) there is clearly consensus on the need to ensure a cautious approach to the development and adoption of gene technologies, there is also acknowledgment of the need to ensure the continuation of research and development on the basis of current scientific understanding of potential risks: [The] Regulator's deliberations must be based on sound, consistent and reproducible scientific and technical data generated according to world best practice standards."

[33] *See* ibid., pp. 96-97

[34] Treffry, op. cit., p.254

[35] Ross, Stan and Peter MacFarlane, *Lawyers' Responsibility and Accountability: Cases, Problems and Commentary*, Butterworths, 1997, p.5

[36] *See generally* http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=16

[37] Stephens, Peter, *Report 18: Multilateral Agreement on Investment: Final Report*, Joint Standing Committee on Treaties, The Parliament of the Commonwealth of Australia, March 1999, p.4

The Standing Committee recognised that this behaviour was occurring and decided to take deliberate action. I suggest your Review consider similar action.

The challenge for opponents of stem cell research

Ultimately, each individual must decide (with reference to law and whatever professional or personal obligations they hold) how they will approach moral and ethical issues about stem cell technologies. I place on record though, several questions opponents should consider.

Firstly, it is relatively clear that whatever happens with the legislation, clinical applications are still a prospect for the medium or long term. Nonetheless, the prospects of amelioration from disability give heart to many like me. Is there anything wrong with that?

Secondly, if opponents believe that stem cell and related research is contrary to the value of "life". It would be appreciated if I could indulge in a reframing of the question. The new question would ask: 'How many physical functions or abilities would you be prepared to lose, before you considered that your life had been reduced to a degree you would not accept? Admittedly, some commentators argued that simply being should be celebrated and that this is enough.[38] However, if you are completely unable to communicate with the outside world, or express your wishes in any other way, what are you getting out of life? Watt suggests that:

"…(We should not) be confident that brain-damaged patients, particularly those who are not, in fact, dying, are unable to experience hunger or thirst. There is evidence that thirst, at least, can persist in those with massive damage to the brain. The fear of dying of thirst while one is suffering but unable to communicate cannot be dismissed…"[39]

If the test of human life and its value is the question of whether urges of hunger and thirst can be felt by an individual, is there really anything left that distinguishes us from the animal kingdom? I would never want to be maintained by medical technology if my life had been reduced by such a degree. In my view, life is lifted beyond the realm of mere existence when you can interact with others and have some influence, however small, on the world around you.

Ameliorating disability, chronic illnesses and the like, would seem to be some of the greatest scientific and medical opportunities of our time. I would hate to think the Australia was missing these opportunities, but note that advances are being made around the world,[40] as we continue to debate the detail of legislation.

Recommendations

I recommend that the Review:

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[38] *See* Watt, Helen, *In defence of just being*, Posted Friday, June 18, 2004, available at http://www.onlineopinion.com.au

[39] Ibid

[40] For example, *see* Gina Kolata, *South Koreans Streamline Cloning of Human Embryos*, May 19, 2005, The New York Times, available at http\\:www.nytimes.com

1. Note the advance in scientific knowledge generated by the decoding of the chimpanzee genome.
2. Note the reported suggestion that this research may have some very positive impacts on particularly debilitating human diseases.
3. Consider whether it agrees with my contention that the focus of medicine has shifted from amelioration to alleviation.
4. Reconsider the NHMRC's report on xenotransplantation. Further, I recommend that your Review give some consideration whether elements of xenotransplantation technology (particularly AETs and ACTs) may be usefully combined with stem cell and somatic cell nuclear transfer technology.
5. Restructure the legislation so that the OGTR becomes the sole responsible regulatory authority for all elements of genetic technology.
6. Consider all received submissions, and decide how 'form letters' should be handled.

Yours truly,

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