Submission by the
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To the Senate Community Affairs References Committee

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The GeneEthics Network makes this submission on the following reference:

> "The Senate has referred to the Community Affairs Committee the following matter for inquiry and report by 27 October 2006:
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> - Legislative responses to recommendations of the reports of the Legislation Review Committee on the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 (the Lockhart review).
> - That in undertaking this inquiry the committee may consider any relevant bill or draft bill based on the Lockhart review introduced or tabled in the Senate or presented to the President by a Senator when the Senate is not sitting."

Who we are and what we do

Founded in 1988, GeneEthics is a network of Australian citizens that promotes critical community education, discussion and debate on the economic, market, environmental, social and ethical impacts of using genetic manipulation (GM) technologies and their products. We also promote community participation in policy-making on all GM-related topics. The Network seeks to have the precautionary principle ie: better safe than sorry, rigorously applied to all genetic manipulation technologies and their various uses, including their use with humans and animals.

In this submission we will comment on the Lockhart Review Report recommendations, the exposure drafts of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 and the Regulation of Human Embryo Research Amendment Bill 2006. The Bills seek to give effect to the Lockhart Review recommendations by changing the Prohibition of Human Cloning Act 2002 to allow the use of SCNT. SCNT would use human or animal eggs to attempt to rewind the programming of adult DNA in the nucleus of a somatic cell back to its totipotent state, as though it were newly fertilised and at the threshold of embryonic development.

Applying the precautionary principle to cloning

The development and use of most new technologies, including stem cell research and cloning, is driven primarily by commercial goals. But proponents seek to justify their proposals with promises of possible positive therapeutic benefits. The profound impacts on our society and its citizens – both this and future generations - are rarely acknowledged, discussed, or acted on.

The precautionary principle directs us, among other things, to make realistic assessments of the forces driving the science/corporate/military/industrial political lobby. This complex nexus of vested interests and power is driving society's publicly funded research and development priorities, not exclusively for the altruistic reasons offered to the public in the news media, nor to policy-makers. Scientists are rarely disinterested or objective

advisers. For instance, Ian Wilmut who created Dolly the sheep recently advocated human cloning, including germline gene manipulation.[1]

Recommendation 23 of the Lockhart Review proposed that:

> "Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days."

We ask you to favourably consider our serious concerns over such statements.

1. SCNT is the same technique used to create Dolly the sheep and other cloned animals, all of which died or were euthanased prematurely. This technology has failed but scientists and industry appear determined to use it anyway.

SCNT is a failed technology and it should not be used in animals or humans because:

> "...animal cloning so far results in high rates of abortions and neonatal losses. Attempts to produce children... Many cloned animals display birth defects, including respiratory failure, immune deficiency, and inadequate renal function—all leading to premature deaths." [2]

> "In all mammalian species where cloning has been successful, at best a few percent of nuclear transfer embryos develop to term, and of those, many die shortly after birth .... Even apparently healthy survivors may suffer from immune dysfunction or kidney or brain malformation, perhaps contributing to their death at later stages. Most frequently cloned animals that have survived to term are overgrown, a condition referred to as "large offspring syndrome."[3]

> "...[I]t is quite clear that across multiple species there are far more failures in the development of cloned foetuses than there are live normal births...The most notable defects are increased birth size, placental defects, and lung, kidney, and cardiovascular problems. Other problems have included liver, joint, and brain defects, immune dysfunction, and postnatal weight gain. Thus, a wide variety of tissues and organs can fail to develop properly in cloned animals...Animal cloning can also result in danger to the mother of any cloned offspring."[4]

The reported problems in animal cloning reflect fundamental problems and misconceptions about SCNT. The technology is imprecise, the processes are 'hit and miss', and scientists do not fully comprehend the complexities of what is being attempted. If scientists fully understood the biological systems and processes used in

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[1] "Backing for baby cloning to beat disease" Daily Telegraph (London) June 5, 2006

[2] Schatten, G., Prather, R., and Wilmut, I. 2003. Cloning Claim Is Science Fiction, Not Science *Science*, 299:344

[3] [3] Rideout, W.M., Eggan, K., and Jaenisch, R. 2001. Nuclear Cloning and Epigenetic Reprogramming of the Genome *Science*, 293:1093-1098.

[4] U.S. Committee on Science, Engineering, and Public Policy, et al. 2002. *Scientific and Medical Aspects of Human Reproductive Cloning.* National Academy Press

animal cloning and the technology was reliable, it would be unnecessary to treat thousands of eggs to create just a single live clone.

As scientists and clinicians do not even know which genes are functioning normally and which are adversely affected by the cloning process, we cannot envisage any benefit from creating human embryo clones using flawed, random and little understood technology. Embryonic stem cells derived from human embryo clones are not suitable for studying human diseases, for drug testing, nor for developing therapies.

2. Somatic cell nuclear transfer technology could be used to create a human embryo clone for development past 14 days with or without implantation into a woman's or an animal's body.

The Lockhart Review and the Bill's proponents say they reject the implantation of a human embryo clone into a woman's body. However, the precautionary principle requires us to consider not just the immediate applications of new technologies but also the implications of all its future uses.

In the uses of gene technology, embryo research and cloning, the boundaries of technical possibilities and proposed uses are constantly and rapidly changing. For instance, many scientists and politicians have rapidly and incautiously abandoned the supposedly fixed limits to cloning agreed to by the Australian public.

In 1997, when Ian Wilmut announced Dolly the sheep had been cloned, the almost universal response from all sections of society was that this technology must *never* be used on human beings. But within a short time advocates began to propose a variety of possible justifications for cloning in human research and for human reproduction. Wilmut has shifted from his 2002 position that, "nobody should be attempting to clone a child"[5] to now advocating cloning and germline gene manipulation, to produce children.[6]

Some Australian politicians have also made the rapid transition from precaution to uncritical promotion. In 2002 Senator Kay Patterson, now the proponent of a Bill to allow the creation of human embryo clones, said:

> "I believe strongly that it is wrong to create human embryos solely for research. It is not morally permissible to develop an embryo with the intent of truncating it at an early stage for the benefit of another human being. However, utilising embryos that are excess to a couple's needs after a successful implantation is a very different matter. I believe it is disingenuous to suggest that approving this research will open the door to further killing of living human beings when the Prohibition of Human Cloning Bill 2002 bans the creation of a human embryo for a purpose other than achieving a pregnancy."[7]

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[5] Jonathan Leake "Gene defects emerge in all animal clones". The Sunday Times (London) April 28, 2002

[6] "Backing for baby cloning to beat disease" Daily Telegraph (London) June 5, 2006

[7] Senate Official Hansard No. 13, 2002 Tuesday, 12 November 2002 p. 6136

We have sound reasons to anticipate that if either of these Bills were passed - to allow the production and development to 14 days of a human embryo clone – very soon there would be pressure for further changes to the law to allow:

- the development of a human embryo clone beyond 14 days; and
- implantation of a human embryo clone (and/or a human/animal chimera) into a woman or an animal.

The so-called 'ethical' case for cloning to the foetal stage, to procure tissue and whole organs for transplantation, has already been made by vocal Australian gene technology proponent Julian Savulescu, who said:

> "If one believes that the morally significant event in development is something related to consciousness, then extracting tissue or organs from a cloned foetus up until that point at which the morally relevant event occurs is acceptable."[8]

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 seems to provide the mechanisms by which the prohibitions on cloning technology and its uses may be further lifted. Sections 8 and 35 of the Bill provide for concurrent reviews of the Prohibition of Human Cloning for Reproduction Act and the Research Involving Human Embryos Act to be carried out only 3 years after the amended Acts are enacted. As part of these Reviews consideration must be given to:

> "an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions"[9]

The reviewers may then apply the same reasoning as the Lockhart Review Panel. If any significant 'community' of interest within Australia, such as research scientists and their commercial backers, were to demand permission to develop clones past 14 days or to implant them, the review may have to recommend such a legislative change. Once the 'expert' review had recommended this amendment, the present round of political activism for legislative change would be repeated, to further satisfy the aspirations of the science lobby and their backers.

3. Summary on applying the precautionary principle to human cloning

The precautionary principle requires any review of the costs and possible benefits of a new technology, to consider both present proposed uses and also all reasonably predictable or foreseeable future uses – including any future uses that would become feasible if further development of the technology were permitted now.

The GeneEthics Network has profound concerns over all genetic manipulation technologies, particularly where a genetic trait is heritable. Heritable genetic manipulation would affect the human gene pool of future generations in unpredictable

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[8] Julian Savulescu "Should we clone human beings? Cloning as a source of tissue for transplantation." Journal of Medical Ethics 25.2 (April 1999): p87

[9] Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 Sections 8 and 35

ways that may adversely impact their health, welfare and rights. The GATTACCA scenario, for instance, while a present fiction and beyond the scope of existing technology, is nascent in contemporary society.

We support the position of the UK Green Party on the Cloning and Genetic Manipulation of Embryos, which says that:

> "Experiments on human embryos could have unforeseen outcomes harmful both to individuals and to society. The Green Party believes that an immediate international ban should be placed on all cloning and genetic manipulation of embryos, whether for research, therapeutic or reproductive purposes.
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> However, the use of 'adult' (or 'mature') stem-cells has promise for both research and therapeutic purposes and does not involve the same risks and ethical issues as embryonic stem-calls. The Green Party would therefore allow such use of adult stem-cells, subject to the precautionary principle."[10]

Applying the precautionary principle to hybrids

Our views on cloning apply, even more vehemently, to creation of human/animal hybrids.

Recommendation 23 of the Lockhart Review proposed that:

> "In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days."

We strongly reject this proposal and its mirror in the Bills. We also reject any proposal to satisfy a shortage of ova for cloning by harvesting ova from female cadavers.

An enucleated animal oocyte also contains mitochondrial DNA that interacts with nuclear DNA in ways that are little understood. A hybrid embryo clone produced by SCNT from a human somatic cell into an enucleated animal oocyte would have mixed animal (mitochondrial) and human (mitochondrial and nuclear) DNA in each cell.

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 (Section 6) anomalously defines a hybrid embryo as not a human embryo, despite the fact that all of its nuclear DNA would be of human origin. This definitional trickery would make it easier for the proposed three-year review to consider lifting the prohibitions on growing a hybrid embryo beyond 14 days and on placing a hybrid embryo into an animal.

Such definitional changes could mean that if it were technically possible to nurture a hybrid embryo so that it survived to the foetal or live born stages it would, by definition,

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[10] UK Green Party Policy Document H342 at: http://policy.greenparty.org.uk/mfss/health.html

not be a human foetus or child. Our concern is that such an organism, defined as a hybrid foetus or hybrid child, might be considered suitable for research or for tissue and organ harvesting. A line of hybrids with heritable traits might also be possible.

The precautionary principle directs us all to exercise the utmost precaution in any allowing any research or commercial activity that includes cross-species DNA transfer and heritability.

Conclusion

In accordance with our mission of applying the precautionary principle, *better safe than sorry*, to all genetic manipulation and related technologies, we urge the Senate Community Affairs Committee to recommend to the Senate that it:

1) reject the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006;
2) not consider the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006;
3) not legislate to implement any of the recommendations of the Lockhart Review; and
4) maintain all the present comprehensive bans on any form of human cloning and the other means of creating embryos for research.