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Closing date for return of submissions is: 4 October 2006

Inquiry into the Legislative responses to Recommendations of the Lockhart Review

. Terms of Reference

The Senate has referred to the Committee the following matter for inquiry and report by 27 October 2006:

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.

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- An Attachments discussing the peer reviewed scientific research studies on the
- relative successes of adult stem cell research in human applications asc-refs.pdf
- An attachment discussing the peer reviewed studies on the pluripotency of adult stem cells- ASCpluripotency.pdf
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Introduction

The Australian Family Association (the AFA) supports the continuation of a uniform approach and a continuance, at the very least, of the restrictions in place under the current legislative regime. The Association would prefer that there be a complete ban on the use of all human embryos for the purposes of destructive research. The AFA, in general supports the broad range of ethical research into stem cells or cellular development or embryonic development and distinguishes this from the particular aspect of this science in which certain practitioners and commercial interests engage in destructive research on human embryos and the creation of embryos for the purpose of destructive research. This latter research is unethical when measured against long settled principles of law and ethics.

The AFA is concerned to advocate for the promotion of the health and well being of all members of the human family from their earliest stages of development until death. It applauds the many gains being made in a variety of ethical research fields yielding promising therapies and greater understanding of a range of conditions and illnesses that burden many members of the community.

However the AFA is concerned to promote respect for all human beings and their rights to family connection especially when most vulnerable because of illness, disability, frailty or because they are at the earliest stages of development. The AFA is also concerned to promote the human rights of women and to reject any legislative changes that would have the effect of commodifying women's bodies or their ova or of encouraging the exploitation of vulnerable women.

Attachments to this Submission:

Please find incorporated with this submission, 7 Attachments:

- Rev Bishop Anthony Fishers Submission Regarding the Definition of the Human Embryo - **FisherSubmissionDefiningHumanEmbryo.pdf**
- Attachments discussing research outcomes for adult and embryonic stem cells research in treatment appliciations for a number of diseases**:**
    - **ASCRvESCRSpinalCordNEWVersion.pdf**
    - **HeartASvsES.pdf**
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- An Attachments discussing the peer reviewed scientific research studies on the relative successes of adult stem cell research in human applications **asc-refs.pdf**
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The Definition of Human Embryo

The AFA opposes the proposed redefinition of the terms "human embryo" and "embryo" proposed by the 2 bills before the Inquiry and by the Lockhart Report.

Scientific consensus, outside of the very recent and narrow advocacy of embryonic stem cell and cloning proponents, is clear as to the beginnings of human life.

H*uman life ordinarily begins at fertilisation,* the process by which the sperm from a human male and the ovum from a human female unite to give rise to a new organism, a human zygote. This is often described as the moment of *conception*. At this point the process of self-organised development commences. The AFA recognises that other methods have been developed to replace fertilization by a sperm as the instigator of this intrinsic orientation for self-organised and integrated development towards forming a fetus, given a suitable environment.

From the point of this change of fertilization or somatic cell nuclear transfer or other method, from a collection of gametes and other cellular material to the human organism, intrinsically oriented to integrated and self-organised development, nothing other than nutrition, protection and time is needed for a human zygote to become an embryo, and then a fetus, infant, child, and eventually adult human being.

Throughout these phases of development it is the same unique individual living human being who is present. Throughout these phases, the AFA insists that this human being has fundamental rights for the respect of its inherent dignity and respect for its right to be seen as part of the human family of its mother and father and of the broader human family**.** The AFA maintains that these rights and dignity inhere regardless of the cause of its beginning whether by fertilization of a sperm and egg or by other processes. The AFA also insists that these rights and dignity inhere regardless of the intentions of those who participated in bringing it into being and that so called "therapeutic" purposes in no way renders the embryo less human or less deserving of our respect and protection from destructive experimentation, research or commodification.

From the outset, the human zygote is distinctly different from an ovum or sperm or other cells. Ovum and sperm are living human cells, but while they remain distinct cells they are unable to grow and develop into a new human being. It is only after fertilisation or other process such as SCNT that a *new* organism with the natural ability to direct its own development and growth comes into being.

The AFA rejects the use of terminology, such as "unfertilized egg" or "fertilized egg" that seeks to dehumanize early zygotes or embryonic human beings created by methods other than fertilization. The terminology, "unfertilized egg" to designate cloned human embryos has been used recently by advocates of embryonic research and cloning in the media. The Lockhart Committee has used the term "fertilized egg or oocyte" in an attempt to dehumanize the human embryo prior to its first cell division. This attempt to use changes in terminology, definitions and language and the intentions behind it will be discussed further below especially in relation to the recent decisions of the International Society for Stem Cell Research.

The AFA is concerned to urge the continued use of coherent and well-established philosophical, ethical and scientific terminology that is in accord to the inherent dignity of human life even at its most early stage. This submission wishes to direct this Review to the submission by the Rev Bishop Anthony Fisher, an eminent and internationally recognized bio-ethicist who raised the question of the definition of the human embryo and deficiencies in the current legislation with the Lockhart Review. This submission will be attached.

See the attachment: **FisherSubmissionDefiningHumanEmbryo.pdf**

In the light of the above discussion, the AFA indicates that it opposes the Lockhart Report's proposals to further weaken the definition of the human embryo. A number of bioethicists have criticized proposals of the Committee to redefine the term 'human embryo". These recommendations seem to have been made precisely to facilitate the creation of further opportunities for experimentation on the very early embryonic stages after fertilization. The AFA seeks to emphasise that eminent bioethical advice on this matter to the Committee was ignored.

Legislative proposals currently under consideration and the exploitation of women

What has become very evident in recent years is that scientists engaged in human cloning will require very large numbers of very fresh human ova. The current legislative proposals before the Committee contemplate this but give grossly inadequate responses to the dangerous exploitation of women that is likely to ensue. A range of feminists have raised serious concerns about this issue internationally and have pointed to a substantial number of documented cases of abuse and unethical practices. The malfeasance of the Hwang case in obtaining eggs from researchers and laboratory assistants has been the most notorious case on record in which exploitation and coercion have been employed to obtain women's eggs. Also of serious concern is an escalating number of deaths form Ovarian Hyperstimulation Syndrome (OHS). In addition there has been discussion of under reporting of cases of OHS in some UK clinics and elsewhere. The problem of human egg donation and sale is emerging as a major issue in the debate about the ethics of manufacturing human embryos by cloning or other means for the purpose of experimentation and research. It is now clear there are not enough eggs frozen in IVF clinics, that some researchers are finding that they need eggs to be very fresh (within 2hrs old at one UK lab) and that eggs will have to be donated or sold for research.

Samantha Singson writes:

> *" The UN General Assembly passed a political declaration last year calling on Member States to avoid all forms of human cloning. The declaration was nonbinding and not unanimous but a number of nations are actively debating the issue of allowing the sale and use of the human ova for both reproductive and research purposes. Australia, the United Kingdom, Spain and several Eastern European countries are just some of the countries which are currently consulting on the matter.*

" Increasingly, reports are surfacing that women are coming under pressure to have their eggs frozen for future IVF treatment or to donate them for research. Until recently in the United Kingdom, scientists were not allowed to offer financial incentives to women to donate their eggs. For the first time last July, however, the British Human Fertilization and Embryology Authority (HFEA) granted permission to an English fertility center to pay women undergoing IVF treatment to donate their eggs for research cloning.

" The extraction of human eggs is an invasive, high-risk procedure with potentially grave consequences to the life and health of women. Women have been reported to die as a result of egg donation. Studies are currently being conducted on the link between cancer and the drugs given to women to help hyper-stimulate ovulation for egg harvesting. The long-term effects of egg donation on women are still unknown and many groups from both left and right are coming out against egg donation.

" Katrina George, a member of the group "Hands Off Our Ovaries," explained that cloning embryos to obtain stem cells requires a large supply of ova and that the methods used to harvest them posed grave risks to women's health. George argued, "Cloning always amounts to the commodification of women's bodies. Politicians and scientists must not use women as guinea pigs in a technology that has no proven benefits."

" There are mounting concerns that monetary incentives might induce poor women to undergo the procedure without fully being informed of the potential health risks. In August, the European Commission launched an investigation into a Spanish fertility clinic as members of the European Parliament suspected the clinic was targeting poor women immigrants. While Spanish law does not permit payment for egg donation, the clinic had been offering $600 - $1200 to pay for the "discomforts" suffered by women during the process of egg donation.

" During negotiations for the UN Declaration on Human Cloning, it was clear that there was a North-South divide. While the majority of industrialized, Western countries fought against any restrictions on cloning for research purposes, many developing nations expressed their concerns regarding the potential exploitation of women. Nigeria warned that "developing countries, particularly in Africa, are most likely to be at risk as easy source[s] of millions of eggs required for the so-called therapeutic cloning" because "poverty and ignorance" will expose women to "exploitation by the emerging 'academic entrepreneurs'."

" Australia is currently debating whether to renew its ban on all forms of human cloning. Australian deputy health minister John Anderson asked, "As cloning embryos for their stem cells depends on a sufficient supply of ova, who's going to supply the eggs?" He continued, "I venture to say it won't be ordinary, comfortably-off, middle-class Australian women who'll be doing it."

"[in the UK] HFEA's public consultations on egg donation will continue through November and a ruling is expected early next year. [**Nations Begin to Debate Ethics of Sale and Donation of Human Ova,** Copyright 2006 - C-FAM (Catholic Family & Human Rights Institute). Permission granted for unlimited use].

Use of Animal Eggs is strongly opposed

As an alternative the current legislative proposals would also seek to allow the creation of hybrid embryos using denucleated animal eggs in a SCNT process. This proposal is ethically abhorrent to ordinary Australians. In addition the usefulness of embryos created by this means has been strongly questioned by a range of scientists. Australia's Chief Scientist Dr Jim Peacock has, despite being an advocate for the implementation of the Lockhart Report, indicated serious concerns about the use of animal eggs "*Nevertheless, I think most scientists would say there could be complications introduced by using that egg rather than a human egg," he said. "We're learning more about the interactions and variances between different living organisms*." *(Chief scientist backs animal egg ban*,The Australian Sept 1 4 2006) It is well known that other cellular material including mitochondria in the denucleated egg may have influences on the organism that are not yet understood. Accordingly, these legislative proposals should be rejected on both scientific and ethical grounds.

Problematic Assumptions Underpinning the Analysis and Reasoning of the Lockhart Report.

The Lockhart Committee was largely composed of persons who had been previously engaged in advocacy for expanded freedoms to conduct embryonic research and manufacture by means including cloning.

The AFA wishes to place on record its concern that the Lockhart Review at its outset sought ostensibly to exclude revisiting the underpinning community debate and rationale for the legislation and that it had no mandate to re-examine the ethical decisions of the parliament in 2002 in regard to the status and appropriate treatment of human embryos. Yet it engaged in a strange attempt to reassess community standards, to sidestep widespread ethical concerns to arrive at its recommendations. The committee's treatment of the notion of "community standards bore no relation to the normal understandings of this concept in Australian law and social science. Brennan concluded after analyzing a range of legal decisions on the question of the meaning of the term "community standards" that "…*in the context of stem cell research, community standards would then be those standards which "ordinary decent-minded people" would accept, rather than the standards of scientists*". (Brennan, *Public Ethics in Bioethics – A Response to the Lockhart Review*, The 2006 Thomas More Lecture, 22 June 2006)

The Lockhart Committee has claimed that it recognized the diversity of community views on the issues and practices addressed in the Commonwealth Acts, and the difficulties associated with formulating a position, which would be met with universal approval. However, it sought in its reasoning to discount submissions that addressed the issue from a view point informed by religious or ethical traditions not based on utilitarian modes of analysis.

The Association wishes to place on record grave concerns about a number of key assumptions that appeared to be adopted at the outset of the Lockhart Review and that supported flawed analysis and reasoning in regard to the issues raised by a large number of well researched and considered submissions to the Review.

Some of these assumptions were evident in the Lockhart Review Issues Paper in which the Committee appeared to invite dissatisfaction with any restraints currently imposed on research by the relevant legislation. For example the Issues Paper for the Lockhart review indicated that:

- there may be lack of clarity or ambiguity in the definitions of 'human embryo and 'human embryo clone'
- these definitions might not appropriately reflect community standards or cover all of the activities that should be regulated under the legislation? [p.***12]***
- the legislative restrictions may have meant that researchers in Australia have not been allowed to use stem cells from human embryo clones for "research on cellular therapies"[p.***15***]
- the prohibited embryos and practices described in the legislation may no longer be relevant or appropriately reflect community standards [p.***15***]
- that, because other countries allow embryos to be created specifically for destructive research, Australia should do likewise.**[p.*25*]**

The issues Paper also appeared to

- encourage those involved in (a) ART programs and (b)stem cell research activities to advocate changes to the current import and export prohibitions affecting their operations [p.***22***]
- canvas the advantages of a stem cell bank and question whether Australian researchers have "appropriate access" to overseas banks with no clarification given as to the source of the stem cells which has always been a critical point at issue in the debate and a critical cause of concern on the community[p.***23***]
- present the argument against the production and use of human embryo clones in prejudicial terms without any acknowledgement of the controversy in community, scientific and ethical debates. The Issues paper describes early stage embryos as "capable of *becoming* a human being". The AFA is not alone in arguing that it is well established in science and ethics that the human embryo *is* a human being in the early stages of development. [p.***15***]
- encouraged those scientists who argue for 'reform' especially in *Terms* **(ii) (d) – (g)** in which the review is said to invite consideration of lifting the import ban on material from cloned human embryos and the possible economic effects of continuing the current ban on such activities.

It was well known at the time of commencement of the Lockhart Review that there would be advocacy to the Committee on these issues as there had been to Parliament previously. Such advocacy has been conducted in the media as well over that time as is also happening currently. The Lockhart Committee did not need to champion this advocacy at the outset. There has been inadequate attention to the substantial commercial interests involved in advocating for the lifting of these restrictions and inadequate recognition of the nature and intensity of this lobbying and the commercial motives driving it, at least in part.

Most telling in relation to the Lockhart Review's lack of neutrality, was the failure to include any term of reference which simply advocated or at least canvassed the desirability of retaining the current restrictions and prohibitions.

Hence the statement by the Chairman of the Review, Justice John Lockhart, that the Committee's task was "... to strike a balance between *emotional reaction* and *rational progress*" further compromised the neutrality of the Review. In reading the Review's Issues Paper and its Report, it becomes very apparent that the use of the words "emotional reaction" was indicative of a dismissive attitude at the outset to those in favour of the current legislative restrictions.

Such terminology as "rational progress" in this context and in the light of the Lockhart Report indicates that the assumption of a 'scientific imperative'- that our society should approve of anything that it is possible- has been very influential in the Committee's response to the submissions it addressed. In essence such assumptions rule out any role for ethical considerations of the rightness or wrongness of particular actions. However our community and constitutional institutions and frameworks continue to operate on fundamental assumptions about the importance and necessity of judgment, and legal and moral restrictions. This is also the case in international laws and conventions.

Our society relies on a coherent legal system that restricts certain actions in order to protect the common good. Most in the community would maintain that our law, quite rightly, generally seeks to protect the weak and not-yet-born from exploitation for profit motives or any other desired outcome of the powerful.

No substantive evidence has been brought before the Lockhart Review or recently to indicate any significant change in community attitudes against cloning and any other creation of human embryos for the sole purposes of research. Indeed two recent studies using careful questioning have shown that community views have not really changed since 2002. The 2004 Swinburne Study (by Christine Critchley and Lyn Turney, *Understanding Australians' Perceptions Of Controversial Scientific Research,* Australian Journal of Emerging Technologies and Society, Vol. 2, No. 2, 2004, pp: 82-107) indicated that approximately 63% of Australians were comfortable with the use of adult stem cells in research but were uncomfortable with research using embryonic stem cells. More recently the Southern Cross Bioethics Institute commissioned poll conducted by Sexton Marketing in January 2006 indicated majority opposition to human cloning to obtain embryonic stem cells and a significant minority expressed opposition to all destructive research on human embryos. Other polling quoted by cloning advocates has been characterized by manipulative push polling and poorly worded questioning

designed to obscure the reality of the research under discussion.

Lockhart Committee reasoning rhetoric sought to identify alleged points of common ground, which included:

- *maintenance of a national approach;*
- *universal disapproval of human reproductive cloning;*
- *the special regard for an embryo created by fertilisation of a human egg by human sperm, and that these embryos should never be created for research, only ART practice;*
- *recognition of the importance of research for fertility treatment; for understanding normal and abnormal development and for addressing disease; and*
- *strong repugnance for implanting an embryo anywhere except in the reproductive tract of a woman.*
- *broad acceptance for using excess ART embryos for research if appropriate consent is obtained, if there is scientific justification and potential for a public good outcome from the work (for example for improvements in fertility treatment, for understanding normal and abnormal development, and for addressing disease), and if the embryos are not allowed to develop beyond 14 days or ever be implanted.*

The AFA indicates that these aspects of the Lockhart Committee's analysis are flawed and that there was less than unanimous acceptance of the use of excess ART embryos and then only because they would die anyway. There was also generally expressed repugnance for the deliberate creation of embryos by any means for research purposes- less than 10% of the community was estimated to support creation of embryos solely for research at that time whether by fertilization or cloning. Concerns were also raised that allowing research on "excess" ART embryos could lead to perverse incentives to create extra embryos in the ART process.

Opposition to destructive research on embryos -even surplus IVF embryos ignored in the Lockhart Report.

The recent Sexton poll indicated a significant portion of the community were concerned about destructive research on human embryos, with the polling suggesting only 14% of those surveyed supported cloning for the purpose of destructive research.

The AFA wishes to indicate again its opposition to the maintenance of the status quo in regard to the legislative regime and believes that a significant number in the broader community are at least concerned about such activities or are also opposed.

Science almost universally regards human embryos, even those embryos prior to their first cell division, as complete, though immature, human beings. Ethics requires that all human beings be treated with respect for their human dignity and that their basic human rights be observed. The current legislative scheme in allowing destructive research on "excess" ART human embryos for experimental, commercial or therapeutic uses is contrary to medical ethics as summarized in the World Medical Association's Declaration of Helsinki (2000) which insists that: "in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interest of science and society."

The *Research Involving Human Embryos Act 2002* created, for the first time in Australian political and legal history, a class of human life, designated by statute as expendable. The AFA opposes the maintenance of this legislative regime's sub-class of embryos and their subjection to a utilitarian calculus that regards their status and destruction as acceptable for generating outcomes, (commercial or health) beneficial for others.

The general community is right in recognizing that the law should not endorse the deliberate killing of innocent human beings for the benefit of others and the AFA urges that this community standard be re-introduced into the legislative regime in question under this review.

Rather than acknowledge community disquiet over human cloning and destructive embryo research by at laest maintaining the status quo, proposed legislative provisions under consideration seek to give effect to, the Lockhart recommendations for the further widening of this class of expendable humans through the relaxation of regulations limiting access to and use of ART embryos, and through lifting the ban on the creation of embryos by means other than fertilization of an oocyte by a sperm and the AFA opposes this.

Other changes recommended by the Lockhart Committee include "*changes to the powers of inspectors; administrative improvements to the current licensing process; the establishment of a stem cell bank and donated embryo registry; and the " improvement" of consent guidelines and procedures". G*iven that, Association wishes to indicate its concern in regard to this range of proposed changes that may very well weaken parliamentary oversight, ethical supervision, consent procedures and administrative and regulatory frameworks in regard to a field of research and biotech business that does not have substantial acceptance in the community. Hence the Association opposes most of these aspects of the Lockhart Recommendations and would argue for greater transparency and parliamentary oversight and tighter restrictions.

The Current Operation of the Licensing System.

The AFA wishes to express concerns about the lack of rigour in the current licensing schemes and to oppose any proposals to weaken it further.

The Sydney Archdiocese Submission to the Lockhart Review indicated that

> *According to the Database of Licenses authorizing the use of excess ART embryos (29 Jun 2005) 1,731 human embryos have been consigned to destructive research under the Act. Of these, only 550 human embryos will be used to create new human embryonic stem cell lines, the remaining embryos being used to improve IVF culture of human embryos, train technicians in the techniques of embryo biopsy and develop pre- implantation screening techniques.*
>
> *At the time of passage of this legislation, the range of matters for which a license could be granted, was not satisfactorily disclosed to the public. This situation has not improved. The vast majority of the community remains unaware of the purposes to which the excess ART embryos have actually been consigned.*

It is likely that if the public were aware that the majority of excess ART embryos have been consigned to destructive research for reasons that are not directly related to the development of much promised and hoped for medical treatments, they would oppose the current legislation where arguments of 'necessity' have trumped sound democratic principles such as respect for human life and human dignity.

Conflicts Of Interest and Ethical Obligations

A most glaring omission in the Report, is the failure to acknowledge, let alone to caution against and to recommend measures to avoid, conflicts of interest. Many Australian biotech scientists lack a solid understanding of the risks of simultaneously combining roles as researcher and entrepreneur. Australian Research establishments are moving towards the benchmarking of their ethical guidelines in regard to conflicts of interest with best international practice, typically found in major US universities. However, as in some other research areas here, instances can be found of Australian biotech researchers having substantial equity in listed companies, the major assets of which are the 'intellectual property' of the researcher. This is a critical issue for the regulation and licensing regimes under the Acts, given the active encouragement of commercialisation in the Australian biotech research sector. The AFA therefore opposes any further weakening of these regulatory frameworks as proposed by the Lockhart Report.

Appropriate Assessment of the merits of Research Proposals and Licensed Use Proposals

The Lockhart Committee has also made a number of assertions about their incapacity to make judgements about the relative potential of embryonic stem cell research vis a vis adult and other stem cell research and also about the merits of particular proposals that might be contemplated under the licensing regime. However, assessments about the relative potential of research proposals are a routine and core consideration for funding allocation in all scientific research areas. No speculation is necessary as data on the track record of the funding applicant, the field to which the proposal relates and precursor experiments – usually with animal models – from the applicant's lab would be a routine starting point for any discussion on research potential. Such data would also be a standard prerequisite for any grant application. The Committee failed to make a case on these grounds for its recommendations.

Recommendations and proposals to weaken Consent provisions

The AFA opposes the various recommendations to weaken the consent requirements of parent donors of embryos and oocytes. Lockhart Committee Recommendations for a laxer consent processes should be rejected and current consent procedures should not be further weakened. The legislative regime should seek to maintain an appropriate standard of consent procedures such that generally high standards pertaining to medical research in human subjects, especially minors, should not be further departed from.

Provision of Stem Cell Registries and Banks

Any proposed establishment of a donated embryo registry will weaken the nexus between the donors' consent and the uses to which the donated embryo will be put. Such a bank risks diluting the accountability of researchers to donors and to a rigorous

and meaningful consent process that is specific as to the use to be made of donated embryos. The introduction of a bank would represent a further departure from standard consent procedures deemed appropriate for research on human beings and especially infant children.

A national stem cell bank of adult stem cell lines for research and therapeutic developments *may* make an important contribution to biomedical research and healthcare, both in Australia and internationally. However, embryonic or fetal stem cell lines ought not be included in this bank if they have been obtained by unethical means

Parliamentary accountability must be maintained

The AFA rejects any Lockhart proposals for the removal of any aspect of parliamentary accountability presently in place from the regulatory regime. Recommendations to give the Licensing Authority power to make binding decisions about embryonic research should be rejected. It has already been noted that there are concerning aspects to the effective operation of the licensing regime and that many in the community would be concerned at the types of research being granted licenses at the present time. Proposals to lock in a further review of the legislation and further removal of restrictions on destructive embryonic research and the manufacture of human embryos by cloning or other means represents a further attempt to remove the community and parliament from decision-making around a highly contentious area of research and commercial activity. This issue will be discussed further below.

The Lockhart Report is fundamentally flawed

There continues to be strong community opposition to human cloning and other creation of embryos solely for the purposes of destructive experimentation. However, the Lockhart Committee inquired into the regime currently in place under the *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* and made a series of quite radical proposals to greatly expand the freedom of the biotech industry to experiment on and clone human embryos.

Ostensibly, the Lockhart Committee engaged in extensive consultation with groups and individuals and received over 1000 written submissions from members of the Australian community. However, a very large majority -probably close to 80% -of those submissions indicated opposition to any further relaxation of the legislative restrictions, a fact which the Lockhart Committee sought to dismiss as representing only one section of the community. The Committee in responding to this level of opposition again resorted to reasoning supported by the scientific imperative and unfounded claims as to the likely benefits of cloning and expanded use of embryos in research.

The Lockhart Committee's Recommendations to allow creation of human embryos by cloning and other means for the purposes of destructive experimentation do not reflect ethical or community standards. The Committee did not contain any independent bioethicists or any community representation. It has not sought to make up for its deficits by any attempt to properly consider the range of independent bioethical advice submitted to it during the course of its inquiry. And, in its final report, the Committee also showed a complete lack of interest in or regard for the overwhelming majority of submissions

urging a rejection of human cloning. Its recommendations are also out of step with international opinion.

Human Cloning is recognized nationally and internationally as controversial and unethical. In March 2005 a clear majority of member states including Australia US, Ireland, Germany, Italy and Uganda supported the UN Resolution calling for the prohibition of all forms of human cloning: The resolution stated that any form of human cloning is incompatible with human dignity and the protection of human life.

The Lockhart Review, in its Issues Paper, commented that 35 countries did not support the UN Resolution, counting the 34 formal votes against the resolution and an indication from Greece that it would have so voted if it had been present for the vote. The Lockhart Review neglected to acknowledge the full voting record: 84 in favour, 34 against, 37 abstaining, with 36 absent. Of those countries absent from the vote, 3 specifically indicated later that they would have supported the resolution if they had been present- hence indicating 87 total in favour of the resolution. International law holds that States who abstain from voting on a resolution are taken not to have vigorous objection to a resolution. Hence it can be seen that only a small number of member states had any substantial opposition to the resolution banning human cloning and the overwhelming majority supported the ban, whether for reproductive purposes or for research, and the reiteration of clear ethical standards in scientific research.

Of course support for the UN Resolution did not indicate an opposition to scientific research on stem cells obtained from ethical sources. The United States, which voted for the Declaration, issued a position paper clarifying its support for the development of non-destructive cell and tissue- based therapies including research for producing DNA molecules, organs, plants, tissues, cells (other than human embryos), or animals (other than humans). Notably there is nothing in the current federal or state legislation that would prohibit such non-destructive research.

Presently at the international level and especially in the US, there is broad discussion amongst bioethicists and scientists about a range of theoretical potential alternative techniques for deriving embryonic-like or pluripotent stem cells that may avoid the ethical pitfalls of requiring the use or creation of human embryos by cloning or other means. Recent research in Japan has shown proof of concept for the derivation of pluripotent stem cells from somatic cells (see Takahashi, K and Yamanaka, S, *Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors.* Cell, Vol 126, 1-14, Aug 25 2006). This paper reports that it is possible to "reprogram" an adult mice cells by providing it with a set of specific genes - 4 in number - and finish with cells that can behave pluipotently-virtually as ES cells- in the tests that were applied. It remains to be translated to human cells.

Scientific commentators on this Japanese research have indicated a keen awareness of the very real ethical problems besetting human cloning and destructive experimentation on human embryos. Writing in August this year, Rodolfa and Eggan explicitly identified its possible potential to solve the current ethical problems surrounding the pursuit of workable pluropotent stem cells without the use of embryos. *A Transcriptional Logic for Nuclear Reprogrammin,g Cell*,Vol 126 652-655.

Robert Lanza of Massachusetts-based biotechnology company, Advanced Cell Technologies (ACT) also sought to market his latest stem cell technology wares recently by postulating on the potential to obtain stem cells from embryos without destroying them. Leaving aside the actual ethicality of his proposal and the accuracy of his reporting in *Nature* , the incident did reveal a growing accommodation amongst stem cell scientists of the significant ethical problems involved in embryonic stem cell research.

Professor Alan Mackay-Sim, a leading neurobiologist from Griffith University in Brisbane who discovered pluripotency of stem cells from the nasal passage, recently wrote: "In the case of adult stem cells and embryonic stem cells, knowledge of the one will illuminate knowledge of the other but the ethical issues raised by the embryonic stem cell debate should be informed by knowledge of alternative technologies."

In recent years, scientists have come to the realization that no degree of rhetoric for cures can circumvent community concern over experimentation on embryos.

Theoretical alternative sources of pluripotent stem cells

Dr Alistair Barros discusses an overview of recent trends in the debate concerning theoretical Proposals concerning the derivation of plurpotent stem cells as alternatives to embryonic stem cells:

> The present inquiry into the private members bills to give effect to the Lockhart Recommendations, like other legislative debates overseas is fundamentally concerned with questions about whether any or some satisfactory concessions are ethically permissible to allow human embryonic stem cell research. One thing is clear: suggestions of a change in public attitudes on this fundamental question are at best representative of wishful thinking on the part of pro-cloning advocates and at worst, are based on dishonest and manipulative push polling strategies engaged by parties with vested interests in the lifting of bans on such activities.
>
> The onus of science lies in obtaining pluripotent stem cell lines without creating and destroying embryos. Behind the ACT spin, was not a scientific, but an *ethical,* breakthrough, since it claimed to be the first to harvest stem cells *without* destroying embryos. As it turns out, ACT's is one of many efforts around the world in search of ethically acceptable sources for embryonic stem cells.

Emerging techniques pose further challenges for scientific and ethical discernment, and the question arises about the adequacy of past (especially the Lockhart Review) and present deliberations to engage these. In 2005, the (US) President's Council of Bioethics, chaired by Leon Kass released a white paper[1], *"Alternative Sources of Human Pluripotent Stem Cells",* after considerable deliberations. It provides an analysis of four alternative proposals in which embryonic stem cells or their equivalents might be obtained without the need to create embryos through cloning or use embryos discarded from fertility clinics.

[1] "Alternative Sources of Human Pluripotent Stem Cells", President's Council of Bioethics white paper, May 2005 - http://bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf

Two proposals relate to stem cells obtained from embryos, living and dead, through non-destructive biopsy. While extraction of cells (blastomeres) from early-stage embryos is currently used in IVF for preimplantation genetic diagnosis, the council raised concerns about the survivability of embryos and, beyond that, the health effects on the children who began life as embryos subjected to blastomere biopsy. No studies are available to address the latter concern. A further risk is the propensity of blastomeres to end up as individuals – a way twins come into being when a fertilized egg divides, *in vivo*. The council was concerned about the uncertainty as to when, why or how blastomeres, *in vitro*, lose their capacity for the integrated, organismic development of an embryo – i.e. lose their *totipotency*.

The proposal for use of cells from dead embryos explored use of frozen embryos created in fertility treatments that cease cell division as they thaw, and are considered dead. Although this sometimes happens because of damaged cells in the embryo, which might therefore defeat the purpose of biopsy, the council explored whether it might still be possible to salvage viable blastomeres from these embryos. A major stumbling block discussed in the council's whitepaper is knowing with certainty whether an embryo is dead, and whether the proposal might be abused through intentional production and deaths of embryos for their cells.

Between them, the biopsy techniques garnered little support in the 18-member council comprising eminent bioethicists, scientists, legal experts and others. However, two further techniques attracted cautionary interest, because they appear *not* to involve embryos but rather the creation of *biological entities* from which to derive pluripotent stem cells, without the entities themselves being embryos. Under Altered Nuclear Transfer (ANT), proposed by Professor William Hurlbut (Standford University), the DNA of an adult cell taken from a patient is altered so that when it is transferred to an oocyte (an unfertilised human egg cell) whose nucleus has been removed, the resultant artefact can generate the functional equivalent of embryonic stem cells.

ANT has similarities with the somatic cell nuclear transfer (SCNT), the widely touted technique for cloning, however there are crucial differences. Under successful SCNT, a single-cell embryo results from the fusion of the adult nucleus with an enucleated ooctye because the restricted genetic state of the nucleus is stripped off by the oocyte's cytoplasm (non-nucleic cellular fluid) and is restored to a totipotent state - the genetic "signature" of a single-cell embryo. As such, it has a pattern of gene expression that is *unique* for the purposes of orchestrating development of an organism, from the generation of the first cells in orderly progression where genes required for the earliest stages of development are progressively shut-off while others yielding specialized cells are turned on, eventually giving way to multicellular structures.

Under ANT, the nucleus of the adult cell is modified *prior* to fusion with the enucleated oocyte, to block totipotent gene expressivity. Conceptually, the ANT cell would lack the integrated, organismic development capacity of embryos.

Rather development would theoretically be restricted to pluripotent stem cells only, through simple cleavage divisions.

Even so, the ANT technique has attracted serious ethical concerns. While key genes are deleted in the donor nucleus to prevent the formation of an embryo, it is not known for sure whether a short-lived embryo could not inadvertently arise during the intermediate steps. As the council put it: "Some critics may wonder how the product of that nuclear transfer is in fact essentially different from – and less an embryo than – a fertilized egg into which the same disabling genetic alteration is introduced only *after* normal fertilization." A range of bioethicists has expressed concern over whether the true nature of the entity created could be anything other than an embryo and possibly that the process might actually create profoundly disabled embryos.

A further concern relates to the controversy over whether any ethical system is possible for obtaining a supply of human oocytes (as discussed above).

Nevertheless, a mature and apolitical precedent was established through the Kass chaired Presidents Council of Bioethics for future debate genuinely seeking to address the substantial ethical problems surrounding this research. Shortly after the release of its white paper, a refinement of ANT was announced, making use of the last and least ethically controversial alternative discussed in the white paper: direct reprogramming of an adult nucleus to a pluripotent state. Instead of a "defensive" mechanism of avoiding embryonic formation, so to speak, ANT was extended so that the donor nucleus is reprogrammed to enter into a pluripotent state *directly*.

Again, an oocyte's natural epigenetic programming is leveraged, in which specialized cells are restricted in the range of total genetic data to produce the necessary proteins for their required function. Through ANT-OAR (oocyte assisted reprogramming), the reverse - "dedifferentiation" - is proposed where the adult cell enters a pluripotent state directly, but where the possibility of epigenetic reprogramming all the way back to totipotency has been shut-off.

Bioethical debate continues in relation to these developments in the context of a greater acknowledgement of the serious ethical hurdles that exist. This debate is being carried out by a range of participants who, coming from varying ethical viewpoints are nonetheless acknowledging the reasonableness of appreciating at least the special status and dignity if not inviolability of the human embryo. There is also vigorous debate amongst ethicists who agree on the inviobility of the human embryo but who disagree about the nature of the entity potentially created by such techniques. It will be some time before a consensus emerges in regard to the range of ANT-OAR possibilities. At present, critics include David Schindler who has argued that whenever an enucleated oocyte is fused with a diploid nucleus, we "mimic conception". Since according to Schindler it is the embryo itself that directs its own epigenetic reprogramming back to a state of totipotency, ANT-OAR can modify only the end of the process (to a state of totipotency or pluripotency, etc.). Thus, the entity that originally comes into being in a species-specific way remains a human embryo.

Rebuttals to the ANT-OAR criticisms, mostly reflecting the Schindler thesis, have appeared in *First Things*. Earlier this year, theologian Christian Brugger wrote: "An entity is a human embryo only if the organic material is *able to be human*—if, in the language of Aristotle, it is *apt* to receive a substantial human form. Not every collection of organic material, even material that includes an oocyte and a diploid nucleus, can be a human being. We know this because we know that teratomas (naturally occurring tumors)—together with hydatidiform moles (disorganized entities that occur in humans and other animals as a result of certain types of defects in fertilization) and even oocytes themselves—are not human embryos, yet they all have as their starting material an oocyte and a diploid nucleus." Thus, the biological condition for single-celled entity brought into existence must possess the active biological faculty for self-directed development – seen through an epigenetic state of totipotency. By contrast, the ANT-OAR technique may arguably result in a cell that, from its *first* moment, exhibits organic properties biologically *incompatible* with totipotency.

Indeed experimental proof, sought by ANT-OAR proponents to support this conviction, first appeared last year, when Harvard scientists converted an ordinary human skin cell back to the pluripotent state. No embryo was produced in the process, however the results were not without flaws. The recent Japanese research noted above improved the procedure, turning a mouse skin cell into the precise equivalent of an embryonic stem cell.

Still, Schindler and others in the US and Australia maintain that a single-celled entity can at once be a human embryo and yet manifestly not be (or ever have been) characterized by an epigenetic state of totipotency.

Developments and disagreements over ANT-OAR, nevertheless, bode well for further techniques to yield pluripotent stem cells. The fourth proposal described in the Council of Bioethics white paper required reprogramming of an adult cell proceeds without use of an oocyte. A recent result in the literature suggests that this could be accomplished rather simply (through the overexpression of just four genes). With many researchers pursuing direct reprogramming technique, the biggest and least ethically contentious news for embryonic stem cell research may not be that far away.

Informed by these ethically unproblematic steps forward in embryonic stem cell research, President Bush and a bipartisan majority in Congress have voiced strong support. "Researchers are investigating new techniques that might allow doctors and scientists to produce stem cells just as versatile as those derived from human embryos without harming life," said the president in July 2006, "and we must continue to explore these hopeful alternatives, so we can advance the cause of scientific research while staying true to the ideals of a decent and humane society." The US Senate has now passed a bill unanimously that would provide funds for research that does not require the use of human embryos.

In the Australian context, the Lockhart Review was commissioned to inform legislative decision-making of "changes in the state of play" in human cloning and embryo and stem cell research. A number of its recommendations are favourably

disposed to SCNT cloning, against the moral sensitivities of Australians. Lockhart's only reference for successes using human embryonic cloning and harvesting of embryonic stem cells were from Korean scientist Hwang's breakthroughs. In late December 2005, only three days after Lockhart's report was published, the world discovered that these were fraudulent. Curiously, not a single a reference to promising developments in search of pluripotent stem cells without embryos appears in Lockhart's literature review.

As this present Senate Inquiry proceeds a harbinger is emerging from science itself. Just as the growing reputation of research from adult stem cells remained in the shadows of the media and politically riven deliberations four years ago, ushering in the only clinical treatments from stem cell research since, a new mood is sweeping over the field. Scientists are finding ways to obtain embryonic stem cells without harming nascent human life – marking the end of human therapeutic cloning.

(Dr Alistair Barros is a research leader at SAP Research, and state president of the Australian Family Association in Queensland, Also see White Paper: Alternative Sources of Pluripotent Stem Cells**,** The President's Council on Bioethics , Washington, D.C., May 2006 *http://www.bioethics.gov/reports/white_paper/index.html.)*

Proposals to lock in a further review should be opposed

The AFA wishes to raise strong objection to Clause 25A of Schedule 1 of the Patterson Bill and the Lockhart recommendation that a review be locked in and conducted on the assumption that further weakening of legislative restrictions on human cloning and other embryo research will be necessary. The AFA also objects in the strongest terms to the bias constructed into the terms of reference as set out in the Patterson Bill as follows:

> *(4) The persons undertaking the review must consider and report on the scope and operation of this Act as amended by the amending Act, taking into account the following:*
>
> *(a) developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;*
>
> *(b) developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;*
>
> *(c) community standards;*
>
> *(d) a brief analysis of international developments and legislation relating to the use of human embryos and related research;*
>
> *(e) an analysis of research resulting from the licenses granted;*
>
> *(f) any National Stem Cell Centre and any national register of donated excess ART embryos;*
>
> *(g) an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;*

(h) an evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;

(i) an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;

(j) the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings;

(k) the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.

(5) The report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned in subsection (4).

(6) The persons undertaking the review must consult:

(a) the Commonwealth and the States; and

(b) a broad range of persons with expertise in or experience of relevant disciplines;

and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

The AFA is very concerned at the directional nature of the above provisions that will effectively lock in a predetermined outcome that is conducive to the advocates of unfettered research and experimentation on embryos including human cloning research and other technologies to manipulate and create human embryos and other embryos with human genetic components,

There are no terms of reference criteria admitting of the possibility that such research will be found to be so unethical as to rule out any further relaxation of restrictions let alone the possibility that community, scientific or bioethical opinion would be such that there should be a tightening of restrictions or whether a complete ban should be legislated.

This concern is broadly acknowledged currently as evidenced by the decisions taken at the 2005 San Francisco Meeting of the International Society of Stem Cell Research to reconstruct the language used to distract the community form the real nature of their research. This concern was reflected in the *Nature* Editorial that responded to this decision and in debates internationally and in the United States about the advantages of devising new techniques for obtaining embryonic stem cell equivalents without using human embryos or even using human ova

There are no terms of reference to allow consideration of progress in other areas of non-embryonically derived stem cell technologies or other fields of medical or scientific research. Such research would be considered by many to be highly relevant to considerations of the need to continue allowing or expanding a specific field of research particularly beset by substantial ethical concerns as was discussed above especially in regard to current US debates. The failure to properly examine this research constitutes

a major failing of the Lockhart Report. Indeed the report has relied almost entirely on the completely discredited and fraudulent work of the Korean Scientist Hwang.

The terms of reference proposed by clause 25A make no provision for engagement with bioethical debate nationally or internationally.

The biotech Industry's claims made about the benefits of cloning and embryo experimentation have been misleading and exaggerated whilst its risks have been dishonestly minimized. The AFA provided further discussion of this in the attachments to this submission prepared by the "Do No Harm" Coalition of scientists and ethicists in the US.

The Lockhart Report and its current advocates fail to acknowledge adult stem cell progress.

The pro Lockhart Report Lobby has consistently demonstrated an unwillingness to acknowledge the substantial progress and successful human therapy applications already demonstrated for adult stem cell technologies.

The Biotech lobby has proven to be unreliable in its claims. Advocates of human embryo experimentation and cloning have proved insatiable in their demands for ever expanding freedoms to create, manipulate and destroy human embryos in the service of personal and commercial ambitions. They have promised the public that the destructive exploitation of human embryos created by Artificial Reproductive Techniques and Cloning will advance the quest for cures and treatments of a variety of illnesses and conditions.

To date there have been no cures or treatments obtained from embryonic stem cells or any other exploitative experimentation of embryos. Some of the scientist advocates are now openly admitting that embryonic stem cells derived form human embryos are unlikely to furnish any therapeutic applications for the foreseeable future. (See Trounsen's comments reported in *Forget about therapies, says stem cell researcher* Sunday Age, June 5 2006)

It is worth noting that most of the recent media reporting of advances in stem cell technologies have failed to indicate that the advances were achieved using non-embryonic stem cells.

These developments have been in addition to the use of stem cells from bone marrow and umbilical cord blood. According to the *Journal of Clinical Oncology* last year, treatments using adult stem cell technologies account for the treatment of 45,000 patients a year.

In 2002 a range of pro-life advocates, ethicists and scientists disputed the inflated claims made by biotech interests concerning the usefulness of the stem cells extracted from surplus embryos from IVF programs. As predicted, they have not proved useful for the development of cures and treatments because of incompatibility to recipients and inherent instability and mutation risks. In the use of these "surplus" embryos, actual research consent processes have become extremely complex, protracted and difficult.

The Lockhart Committee has demonstrated serious ineptitude in regard to bioethical analysis generally and they have sought to maintain the spurious distinction between the ethical status of so called “therapeutic” and “reproductive” cloning. To produce an embryo is always ‘reproductive’; to destroy an embryo is never ‘therapeutic’. The European Parliament has declared the distinction to be a sleight of hand and the Australian Health Ethics Committee described it as lacking transparency and concealing the truth. So-called ‘therapeutic cloning’ involves the manufacture of a new subclass of laboratory humans with the intention, right from the beginning, to exploit and destroy them as if they were laboratory animals. This would be the worst of all possible uses of cloning technology.

There is no essential difference between the procedure of cloning for reproduction or cloning for research. The result in each case is a cloned human being. Cloning for research means that a new embryonic human being is produced so that it can be destroyed for research – a repugnant practice.

The scope for ethical stem cell research is rapidly expanding -Australia can strive to maintain high international standing in ethical research.

Governments can support the development of established, ethical and safe technologies involving adult and other non-embryonic stem cells. Australia can be a world leader in ethical and effective adult stem cell research. The Federal Government’s recent allocation of funding to adult stem cell research is a welcome step in the right direction.

The established medical technology of using a patient’s own tissues as a source of stem cells for developing therapies has demonstrably greater direct therapeutic potential in terms of tissue compatibility. Currently over 70 therapeutic uses of this ethical technology have been demonstrated in real patients.

Scientific developments over the past 5 years confirm that adult stem cells show similar, if not greater potential for the development of cell-based therapies than embryonic stem cells. These non-embryonic stem cells have been found in almost every major body tissue type, including in human cord blood, placenta and amniotic fluid, bone marrow, and human fat tissue.

Scientific evidence is mounting of a substantial range of adult stem cells which are capable of transdifferentiation to become other types of cells. The research team at Griffith University, Queensland, led by Professor Alan Mackay-Sim has shown that adult stem cells from the human olfactory mucosa are able to give rise to new nerve, glial, liver, heart, kidney and muscle cells.

The AFA will attach further information on the advances made in adult stem cells therapies and the failure of embryonic stem cell research to produce the same level of successful results. Please note that this information has been updated to mid July 2006. These attachments have been prepared by a coalition of concerned scientists and ethicists in the US "Do No Harm".

These Attachments discuss the relative successes of embryonic verses adult stem cell research in application to a range of conditions citing peer reviewed studies:

- Spinal Cord treatment -ASCRvESCRSpinalCordNEWVersion.pdf
- Heart tissue and vessel damage -HeartASvsES.pdf
- Diabetes -DiabetesASvsES.pdf
- Parkinsons-ASvsES.pdf

In addition the following 2 documents discuss, with peer reviewed citations, the relative overall success of adult stem cell research and the studies that have shown the pluripotency of adult stem cells:

- asc-refs.pdf
- ASCpluripotency.pdf

The Lockhart Committee, in recommending the lifting of most of our present prohibitions of cloning and experimental embryo creation, would usher in a new regime of ruthless exploitation of human life and ever diminishing restrictions on the scientists and commercial interests involved. The enactment of the proposed legislative provisions currently under consideration would do great harm to the Australian Scientific community's reputation for ethical responsibility within the broader international community. Australia's reputation for the promotion of human rights would be further harmed if the commodification and exploitation of vulnerable and poor women was encouraged by the enactment of this legislation.

The Next Step will be embryo farming

The Committee has recommended and the Bills propose that all conceivable cloning technologies be employed so long as no embryos are allowed to develop beyond 14 days or be implanted in the womb of a woman. How long before these biotechnologists push for release from those limitations too?

Embryonic Stem Cell Research Advocates may assure us at the present time that they do not wish to harvest tissue from embryos beyond a 14 day limit.

However as the number of studies of animal embryonic stem cells mount there has been a failure to yield anything other than disappointing results and researchers may push for the lifting of this limit as well as the prohibition on implanting cloned human embryos. Indeed some scientists and ethicists are warning that embryonic stem cell researchers have been conducting this type of research in animal subjects. A range of studies in animals have sought to obtain better results by implanting cloned embryos in the womb and then harvesting the embryo at a later date to extract more developed stem cells or embryonic organ tissue.

When translating these animal studies into a human gestational time frame, the studies suggest that if cells from human cloning are to have any therapeutic use in treating human patients, then fetus farming – implanting and growing human embryos up to or even beyond the fetal stage -- may be necessary to yield the promised results of embryonic stem cell research advocates.

Julian Savulescu argues that , .."it is not merely morally permissible but morally required that we employ cloning to produce embryos or fetuses for the sake of providing cells, tissues or even organs for therapy, followed by abortion of the embryo or fetus". (*Should we clone human beings? Cloning as a source of tissue for transplantation,* Journal of Medical Ethics 1999; 25:87-95)

Greater detail is attached in a discussion of the specter of Fetal Farming in the context of US debates on the issue.

See the attachment : FetusFarm.pdf

Key recommendations of Lockhart for permitting gravely unethical practices:

Recommendations and proposed legislative provision for permitting cloning, human-animal, chimera and multi-donor embryo experimentation:

The AFA explicitly opposes any aspects of the proposed legislative changes under consideration that seek to either fully or in part adopt any of the following Lockhart Committee Recommendations set out below:
The AFA insists that many of the Lockhart Recommendations and the bills proposed clauses such as 22-23B of schedule 1 and clause 15 of schedule 2 the Patterson Bill propose gravely unethical practices such as those in relation to the proposed permitted creation and use of human embryos by SCNT or other cloning techniques, use of animal eggs, certain fertilisation experiments involving interspecies or chimeric experiments. Such recommendations or proposals are opposed by the AFA as practices of exploitative and destructive intent in the creation and manipulation of human embryos.

Whilst the AFA welcomes Recommendation 6 in so far as it prohibits development of a human–animal hybrid or chimeric embryo, it opposes the introduction of any exception to this prohibition as set out in Recommendation 17 or under the proposed new legislative schemes under consideration.

> *17. Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.*

The legislation, in seeking to give effect to the main Lockhart Inquiry recommendations proposes allowing under licence the creation of human-animal hybrids, and embryos created from multiple donors. The Committee has recommended that all conceivable cloning technologies be employed so long as such embryos are not allowed to develop beyond 14 days or be implanted in the womb of a woman. While the Patterson Bill appears to stop short of putting into effect the full recommendations in regard to chimeric experimentation, it should be expected that this may be pursued in the next round of de--regulation envisaged under clause 25A of Schedule 1 of her Bill.

The Lockhart Committee states at p.164 of the Report:

> *The Committee noted that the creation of human–animal hybrid or chimeric embryos was only mentioned in a few of the submissions and hearings. However, there was an implicit understanding that the creation of such entities could be of concern to the community. Therefore, the Committee's view is that creation of such embryos for reproductive purposes (that is, development beyond 14 days and implantation of such embryos) should continue to be prohibited.*
> *However, because of the potential benefits, and to avoid the need for obtaining additional human gametes for research purposes, the Committee considers that fertilisation of animal gametes by human gametes should be permitted up to, but not including, the first cell division, to allow testing of human gamete maturity or viability as indicated in Recommendation 17.*
>
> *The Committee also suggests that, under limited circumstances, human–animal hybrid or chimeric embryos could be used, under licence, for preliminary investigations of nuclear transfer technologies. The Committee reached this view because this procedure could reduce the need for human egg donation (see Recommendation 24).*
>
> *Similarly, with respect to embryos with more than two genetic parents (including those created using cytoplasmic transfer), embryos using precursor cells from a human embryo or a human fetus, and embryos carrying heritable changes to the genome, the Committee's view is that the creation of such embryos for reproductive purposes should remain prohibited (that is, development and implantation of such embryos should be prohibited) due to the lack of social support for these practices and concerns about safety*. [note that the Committee recommends creation of these types of embryos for research and experimentation]

This is, essentially, a reneging of promises, in 2001-2 by advocates of embryonic stem cell research that they would not seek these objectives. Again the Committee seeks to rely on false distinctions between so-called "therapeutic cloning" or reproduction and "reproductive cloning" or creation of embryos by other means. The Lockhart advocates wish to give scientists freedom to create so as to manipulate, exploit, and destroy human embryos.

Recommendations for permitting cloning, human-animal, chimera and multi-donor embryo experimentation:

Recommendation 17 providing for "Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice." Is given full effect by the Patterson Bill and would permit gross violations of the dignity of the human embryo at its earliest stages of development.

The creation of human embryos and human embryo clones by means listed in Recommendations 23- 27 (clauses 22 to 23B of Schedule 1 of the Patterson Bill seek to permit when licensed, otherwise illegal means of creating and developing human embryos or hybrid embryos in accordance with the Lockhart recommendations)

- *to be permitted under licence and subject to the criteria to be outlined in the amended* act [Apart form the criteria listed here it is not clear whether the Committee envisaged a set of appropriate criteria but the legislation does not appear to provide any such outline beyond the broad restrictions set out in the Lockhart Recommendations]
- *for the purposes of* research, training and clinical application, including the production of human embryonic stem cells
- but not to be implanted into the body of a woman or allowed to develop for more than 14 days. :
  - Recommendation 24:To reduce the need for human oocytes, the transfer of human somatic cell nuclei into animal oocytes
  - Recommendation 23: Human somatic cell nuclear transfer
  - Recommendation 25: by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis)
  - Recommendation 26: using the genetic material from more than two people, or including heritable genetic alterations,
  - Recommendation 27: using precursor cells from a human embryo or a human fetus

Such proposed permitted means of creating human embryos are opposed by the AFA as abhorrent and gravely offensive to the injerent dignity of the human embryo.

The AFA opposes any proposed legislative changes seeking to give effect in full or in part to recommendations addressing regulatory issues – that would diminish accountability to parliament. These recommendations are-

50 The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.

51 The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.

52 A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.

53 In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.

The AFA rejects the implicit assumption of a scientific imperative underpinning these recommendations and urges that strong ethical oversight is best maintained and supported with rigorous legislative regulation and on-going accountability to parliament and hence to the community.

The AFA specifically wishes to raise strong objections to the proposed clause 25A of the Patterson Bill as discussed above.

Use of fresh ART embryos

21 Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.

22 Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under license, for research, training and improvements in clinical practice.

The AFA opposes these and argues that any effort to set guidelines in regard to the appropriate criteria with which to judge suitability will be subject to pressure for dilution so as to meet commercial demand for more access to embryos. It gives explicit credence and force to already worrying eugenicist tendencies amongst ART researchers

Consent arrangements for the donation of embryos- weakening -opposed

As discussed above these recommendations are opposed and a strong nexus ought to be maintained between the specific uses of donated embryos and the specific consents of the donors so that appropriate and standard ethical principles can be made to apply.

29 The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues:

- *the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal*
- *the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared 'excess'*
- *the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess*

•the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess.

30 The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice
(see Recommendations 20–22).

The Patterson Bill proposed changes that would give power completely to the licensing authority to determine and then modify consent guidelines are not in the best interests of maintaining appropriate standards of medical research ethics. This research is to be conducted on the most vulnerable - embryos; with consent being sought from donors who may also be exploited at a time when they are most under pressure through deeply held desires to have children or because of poverty or powerlessness. The more vulnerable the persons and parties, the more care should be taken to ensure the highest consent standards.

Further elements of the Lockhart proposals opposed

The AFA urges the Senate Inquiry to oppose the changes to the current legislative regime recommended by the Lockhart Committee and proposed by the 2 bills before it. Whilst some recommendations of the Committee are for a preservation of some aspects of this regime and specifically some prohibitions remain on cloning and other uses of embryos many of the recommendations and proposed legislative changes seek to introduce exceptions to these prohibitions to further facilitate the creation of embryos for destructive research.

Further Comments in response to specific aspects of the proposed legislative changes under consideration by the current Senate Inquiry.

The Stott-Despoja Bill provides for the Act, when it is enacted, to be cited as the *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Act 2006*.

The AFA submits that this title is not appropriate because it is reflective of a clear agenda on the part of human cloning advocates to mask the reality of their proposals behind inaccurate and confusing language.

Frank Brennan has discussed the use of language in this way in a lecture in which he cited the US Presidents Council on Bioethics:

The Presidential Council asked, "What shall we call the product of SCNT?"[2] Despite their varying moral assessments of the value of the human embryo, they were unanimous in their approach:[3]

[2] Quoted in President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry*, Washington DC, 2002,., p. 47
[3] Ibid., pp. 47-8

> *The technical description of the cloning method (that is, SCNT) omits all reference not only to cloning but also to the immediate product of the activity. This obscurity enables some to argue that the immediate product of SCNT is not an 'embryo' but rather 'an egg' or 'an unfertilized egg' or 'an activated cell', and that the subsequent stages of development should not be called embryos but 'clumps of cells' or 'activated cells'. To be sure, there are genuine difficulties and perplexities regarding what names to use, for we are dealing with an entity new in our experience. Partly for this reason, some people recommend avoiding the effort to describe the nature of the product, preferring instead to allow the uses we human beings have for it to define its being, and hence its worth. But, for reasons of both truth and ethical conduct, we reject this approach as improper. We are all too familiar with instances in which some human beings have defined downward the status of other beings precisely to exploit them with impunity and with a clear conscience. Thus, despite the acknowledged difficulties in coming to know it accurately, we insist on making the effort to describe the product of SCNT as accurately and as fairly as we can.*

The Council then concluded that the product of SCNT should be defined as a cloned human embryo, regardless of the reason for producing it:[4]

> *The initial product of somatic cell nuclear transfer is a living (one-celled) cloned human embryo. The immediate intention of transferring the nucleus is precisely to produce just such an entity: one that is alive (rather than nonliving), one that is human (rather than nonhuman or animal), and one that is an embryo, an entity capable of developing into an articulated organismic whole (rather than just a somatic cell capable only of replication into more of the same cell type).*

(Brennan, Public Ethics in Bioethics – A Response to the Lockhart Review, The 2006 Thomas More Lecture, 22 June 2006)

Last year a *Nature* Editorial severely criticised the decisions of a meeting of the International Society for Stem Cell Research in San Francisco to engage in "a bizarre semantic debate"

> *"the society decided to formally adopt the term 'somatic cell nuclear transfer' to describe the procedure in which an adult cell nucleus is transplanted into an egg to produce embryonic stem cells*[extracted from the embryo made by the SCNT process]. *This procedure had been called 'therapeutic cloning' to distinguish it from 'reproductive cloning', which would use the same technique in an attempt to make a baby.*

> *"But the work is far from yielding any therapies, and scientists realized that the word 'cloning' was generating public concern. So they decided to adopt a more technical term less likely to stir up strong emotions. At least that re-branding had the positive effect of toning down the hype surrounding therapeutic cloning.*

[4] Ibid., p. 49

> ***"The name change debated at last month's meeting would be a step too far, however. In the future, researchers may isolate pluripotent stem cells from biological entities that do not have the same developmental potential as embryos. This may justify the creation of a new set of words. Until then, stem-cell biologists should stick to debating the merits and ethics of their work using clear and simple language. They have a strong case to make that will not be helped by playing semantic games in an effort to evade scrutiny.*** "[Playing the name game, Nature Editorial, Nature 436, 2 (7 July 2005) | doi: 10.1038/436002b] (Our emphasis)

It should also be noted that substantial aspects of both bills and the Lockhart recommendations relate to lifting prohibitions on a range of experimental technologies to create and manipulate embryos by fertilisation and cloning techniques not limited to SCNT. Another aspect of the dishonesty of the Lockhart advocates is their proposals to redefine the human embryo so as to lift prohibitions on a range of experiments on early stage embryos that ordinary Australians would find abhorrent. These include chimeric experiments, hybrid experiments using animal somatic cells and human eggs., or vice versa, interspecies fertilisation experiments etc.

The proposed title of the Patterson Bill is equally objectionable because it also seeks to mask, with inaccurate language, the true nature of the effect of the legislation proposed:
Clause 1 states that "This Act may be cited as the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*.'

A more accurate title would be

> "*Regulation of the Manufacture of Human Embryos by Cloning and other Permitted Techniques for the Purposes of Experimentation, Research, Commercial Exploitation and Other Related Activities."*

All legislative proposals that seek to give effect to any aspects of the decision of the International Society for Stem Cell Research (referenced above) to reconstruct language in order to mask the real nature of research being undertaken or advocated ought to strongly rejected.

As an example, Patterson Bill clauses 1 and 2 of Schedule 1 are purely employed to, in Orwellian fashion, mask the meaning. To seek to continue to advocate and legislate for the spurious distinction between so-called "therapeutic cloning" and 'reproductive cloning" is dishonest and irresponsible in the extreme. This distinction was rejected by the *Nature* Editorial of last year, referenced above, as well as a broad range of scientists and bio-ethicists. The distinction is philosophically absurd. The intention of the creator in the lab does not change the nature of the organism in the petrie dish.

Clause 6 of schedule 1 of the Patterson Bill, in seeking to define hybrid embryos made from SCNT using the genetic code of a human somatic cell, is again engaging in the semantic ruse recommended by the International Society of Stem Cell Research.

It is proposed that the Lockhart recommendations are right to propose a wider scope of research than is permissible under existing legislation. It is argued that there are some practices currently prohibited under the act that should be allowed provided a license has been obtained. It is also argued that proposed legislation should aim to "redress

some of the unintended consequences of the current legislation that prevented previously allowed research into improved methods for achieving pregnancy via ART and also allow the development of improved techniques in clinical ART practice." (Explanatory Memoranda provided by Stott-Despoja)

The AFA submits that the current legislative regime prohibits a range of previously allowed research quite deliberately and with full understanding of the grave violations of the dignity of the human embryos involved in that research. It should be understood that the broader community had not been aware of the extent of some of the unethical practices being conducted under the banner of ART research. There was not one dissenting vote in regard to the legislative prohibitions imposed on fertilisation and other embryo experiments involving interspecies gametes and genetic material or chimeras. Renaming such experiments as being on fertilised eggs does not change the abhorrent nature of the research. The unethical nature of such proposals is compounded by the proposal to mask the nature of this research with changed semantics.

Proposals for the strengthening of the penalties for breach of the legislative prohibitions are welcomed by the AFA. However the AFA submits that such penalties should be strengthened and applied to the current legislative prohibitions.

The AFA submits that the proposals to allow, under licence, the export or import of human embryos whether created by cloning or other techniques is abhorrent. It notes that the Patterson Bill would prohibit this practice for the time being.

Further comments on the proposed redefinition of the "human embryo":
The explanatory memoranda attached to the Stott-Despoja Bill argue that:

> *"The key difference is the identification of the 'primitive streak' as the marker of a developing embryo, a more advanced stage of development than the 'pro-nuclei' stage given in the original Act. This definition allows medical science more options in research involving embryos, but it maintains the limitation in the original Act that the embryo must have undergone no more than 14 days of development.*
> *"They arrived at this definition by forming the Biological Definition of Embryo Working Party, comprising three NHMRC Embryo Research Licensing Committee members and three other Australian experts. Their draft report of the Biological Definition of Embryo Working Party was peer reviewed by Australian and international experts and was the subject of a public consultation process*."

Again the AFA submits that the public consultation processes undertaken by the Lockhart committee and the NHMRC licensing committee were not genuine and that the vast bulk of submissions to the Lockhart committee were ignored. It is true that these changes to the definition of "human embryo" were subject to consultation. However the consultation process was conducted with a narrow range of pro cloning and pro Lockhart advocates whilst substantial and long held scientific and bioethical opinion and consensus at the national and international level was deliberately ignored.

In regard to proposals to allow research beyond the scope of those declared excess for ART purposes, including a broadening of the class of embryos deemed as licensable for research (including those designated as such by proposed pre-implantation genetic diagnosis criteria:
The AFA submits that this proposed weakening of the current legislative restrictions does not accord with community attitudes. These proposals are offensive to the status and inherent dignity of human embryos. It is abhorrent that embryos are proposed to be sorted along eugenic lines into those destined for respect and those destined to be designated laboratory fodder.

Proposals to change the existing legislation so as to allow the creation of human embryos for research under licence should be strongly rejected.

Conclusion

Our own Federal Parliament voted unanimously for a total ban on human cloning in 2002. A vast majority of submissions to those parliamentarians indicated strong community opposition to human cloning. This opposition was also reflected at the State level.

Lockhart recommendations to totally overturn some of the most important prohibitions that our parliaments thought fit to legislate in 2002 pertaining to the use of embryos and the cloning of embryos are opposed by the AFA.
In reading the Committee's reasoning, the lack of any serious consideration of independent ethical advice becomes evident. Poor bioethical analysis is evident throughout the report and the Committee made a number of quite ludicrous assertions in justification of their recommendations.

Eric Cohen has sought to characterise the US Bush Government's reluctance to promote human cloning or the manufacture of human embryos for research as ultimately an eminently humane stance. In Australia, our current legislative regime, whilst not as restrictive as the AFA would like, approaches towards a more ethical and humane conduct of stem cell research. Cohen writes:

> *The point of the Bush policy, for all its many limitations and drawbacks, is to show that science can proceed without violating human dignity or destroying nascent human life, even if it cannot proceed as quickly and by as many simultaneous routes. The choice it offers is not between science and ethics, but between a devotion to science and health so total that it abandons all ethical limits, and a devotion to science and health balanced and constrained by a respect for human equality and dignity, and committed to a culture of life largely understood. (http://article.nationalreview.com/?q=OGFmM2E5N2E3NTI4NGU0ODIxZDU3MzdmZTk0NzY5Yjk= Cohen)*

The AFA maintains that there is no dignity in developed human beings seeking cures and therapies from the destructive and exploitative research conducted on the weakest and most vulnerable members of the human family. There is also no dignity in conducting scientific research or biotech business in a way that is exploitative of vulnerable women. There is no dignity is seeking to profit from research and biotech business that preys on the human embryos or vulnerable women who will be pressured to submit their bodies to invasive, unpleasant and possibly life threatening processes for the harvesting of human ova.

The AFA submits that the Lockhart Report be shelved as fundamentally flawed, unreliable, biased and outdated. Accordingly any legislative provisions seeking to implement its recommendations or further weaken the current restrictions on human embryo creation and research should be firmly, strongly and completely rejected.

The legislative proposals and recommendations under consideration are generally directed towards a general and substantial weakening of the regulatory regime and the permitting of pretty much wholesale reproduction of human embryos for the sole purpose of research. These recommendations therefore represent a radical departure from the regime agreed to by COAG and the Australian Parliaments in 2002.

Frank Brennan argues:

> *"But the moral argument is the same as it was in 2002. We can still show some respect for all embryos, not just treating them as a means to an end, by giving every embryo created an opportunity to be selected for implantation and growth to term. At the end of an IVF procedure, we then have the choice of letting the excess embryos succumb or permitting experimentation for the good of humanity. We abandon universal respect for embryos, and simply use them as a means to an end, when we create some embryos with no intention of giving them the opportunity to be selected for implantation, creating them with the sole purpose of experimentation and destruction, creating them for someone else's good, not their own.*
>
> *Even those politicians who approved experimentation on excess ART embryos in 2003 saw the validity of this moral distinction between means and ends. Some Australians hope they will continue to see it in 2006. To date, there is not even hard scientific evidence of utilitarian benefits from embryo creation, experimentation and destruction to cloud that moral vision. In 2002, our elected politicians decided that we would not permit the creation of embryos unless they were created with the possibility of implantation in a womb. To create embryos with no intention of permitting implantation is to cross a moral Rubicon. It should not be crossed by politicians simply endorsing the report of an unelected committee whose mandate was to report on scientific developments and changes to community standards. The Lockhart committee was not mandated to make moral changes or leaps. …."*

" On the vast plain of embryo research, there are two Rubicons. The Australian community may well have crossed the first in 2002, given the lack of community reaction to the Parliament's decision to permit experimentation on excess embryos which were created with the intention of their being part of a project aimed at successful implantation of one of the batch, and with the strict requirement that there not be any more embryos created than were required for a successful implantation of a healthy embryo. But there is a second Rubicon. That is where we now stand. Beyond this second Rubicon is a city where the scientist is justified in creating human life only so that he might experiment upon it and destroy it without the need for any respect of the dignity of that potential human life. The US Presidential Commission found that there is a diversity of viewpoints in the US community looking across the second Rubicon to that city of morally unbounded scientific research. Some of the Australian community are not even prepared to cross the first Rubicon. Our parliament having crossed the first Rubicon in 2002 and having deliberately stopped short of crossing the second, there is still no evidence of a change in community standards that would warrant the second crossing." (Brennan, Public Ethics in Bioethics – A Response to the Lockhart Review, The 2006 Thomas More Lecture, 22 June 2006)

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