Stem Cell Research

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Embryos and Stem Cells: What next after the passing of the Patterson Bill?

Introduction

Recently, we, as a community, have been asked to come to terms with some interesting new possibilities. Genetic manipulation[ii] technologies have given rise to the possibility of all kinds of new embryonic forms — embryos designed with inheritable mutations, embryos with a chimerical combination of cells, hybrid embryos, embryo clones and more.[iii] The possibility of these multiple embryonic forms, when combined with the burgeoning and successful field of assisted reproduction, suggests the spectre of multiple human forms such as chimerical humans, hybrid [1]humans, enhanced humans and cloned humans. What does it mean to be a human person, in a world where these transformations at the embryonic level are possible? Does it change anything? Does it change everything?

Recent Legislative Changes

Recent changes to the *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth), via the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth.), have caused a great deal of controversy in the community at large concerning just these questions.[iv] The changes have primarily been aimed at enabling scientific research using embryonic stem cells.

Source of stem cells - history

However, in order to do research using such stem cells, there needs to be a source of those stem cells. Prior to the recent amendments to this legislation by the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006, human embryonic stem cells could be obtained from donated surplus IVF embryos only, and then only under special licence. Part of the requirements for use of donated surplus embryos was a 14-day cooling off period, having the effect of making so-called 'fresh embryos' completely unavailable.

New legislation — new sources of stem cells

The first thing to note about the amended legislation is that it not only enables a new source of embryonic stem cells to be explored, namely those derived by "somatic cell nuclear transfer" or what is more commonly known as therapeutic cloning (more on that in a moment), but it also opens up the source of fresh embryos to include those designated as unsuitable for implantation.

New source of embryos for research

The new legislation has increased the pool of potential sperm and egg embryos available for research purposes by the addition of section 7(1) of the RIHE. This section now allows the donation of fresh embryos, created for IVF for reproduction, for use in research where they been determined as unsuitable for implantation either because they are diagnosed, through preimplantation genetic diagnosis, as having a genetic defect or because they are assessed in the normal course of IVF as not viable on the basis of several criteria.

Selection of embryos

The determination as to suitability of all embryos, even those not undergoing PGD, is done by the observations of a scientist looking at the embryos through a microscope. Some embryos are created which do not develop, or which fragment or die at a very early stage. Because they are too fragile to be frozen, such embryos are generally discarded and are termed 'unsuitable for implantation'. Under the RIHE, the NHMRC will now issue guidelines setting out objective criteria to be used in making these determinations when donating these unsuitable embryos for research.

Ethics of selection of embryos

While this may seem uncontroversial for those not concerned by the use of early stage embryos for research *per se*, some disability studies scholars and bioethicists have raised concerns about these changes — because they legally determine the embryo diagnosed as having a potential defect as unsuitable, whereas previously these decisions or determinations were seen as contextual and determined by the potential parents, and because some raise concerns that such a provision may lead scientists to lean towards finding unsuitability where there is uncertainty about the application of the objective criteria. While this may seem a trifle paranoid, Nisker and Mykitiuk argue, for instance, that these changes raise "the possibility that standards for what is considered a 'suitable' or 'unaffected' embryo may become narrower in the interests of ensuring a supply of fresh embryos for research."[v]

Somatic cell nuclear transfer (SCNT) and other embryos: what is not allowed

What is not allowed is as interesting for what it does not say as for what it does. What is not allowed is to create an embryo of any kind, other than a traditional egg and sperm embryo, for reproductive purposes. In other words, while it is now possible to create different kinds of embryos for research purposes, nothing has changed in terms of who or what can be reproduced. Section 9 of the PHC makes that clear.

Legislation — cannot create an embryo for reproduction other than traditional egg and sperm

In order to make sense of the prohibitions it is easiest to view the legislation in reverse. Section 20(4) of the Prohibition of Human Cloning Act states clearly that the following embryos are prohibited:

(4) In this section: *prohibited embryo* means:

(a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or

(b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman; or

(c) a human embryo that contains genetic material provided by more than 2 persons; or

(d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or

(e) a human embryo created using precursor cells taken from a human embryo or a human foetus; or

(f) a human embryo that contains a human cell (within the meaning of section 15) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or

(g) a human embryo that was removed from the body of a woman by a person intending to

collect a viable human embryo; or

(h) a chimeric embryo or a hybrid embryo.

Section 20(3) makes the placing of any of those prohibited embryos in the body of a woman an offence. Section 19 prohibits a human embryo being put in an animal (ss1) and in anything other than a reproductive tract of a woman (ss2) and prohibits the placing of an animal embryo in the body of a human.

Consideration of prohibitions

If we take a step back from the sensationalist rhetoric around human cloning and hybrids and chimeras, it is worth considering whom it is imagined will be gestating these embryos which would otherwise be made if not prohibited. This requires a leap of the imagination that depends either on the disappearance of women as essential to the process of person-making or the assumption that, where there are embryos, there are women who will gestate them no matter how they are made. Through these two modes, technologically produced embryos are imbued by some with the full potential of personhood, even though they have no uterine home and, in most cases, no possibility of a uterine home. In my opinion, the legislation has some serious questions to answer in terms of how it imagines (or fails to imagine) women's roles in developing these so-called 'prohibited embryos'.

Legal history — prohibition of cloning

As should now be clear, up until November 2006, in Australia, the legal response to the transformative possibilities of genetic manipulation technologies in relation to cloned and hybrid embryos amongst others, was simply to prohibit and criminalize their creation. [vi]

The new position, genetic cloning

On June 12 2007, when the amendments passed in December of 2006 are due to come into effect, the landscape will change markedly. The amendments give the green light to therapeutic cloning or somatic cell nuclear transfer.

The legislation was a response to recommendations made by the Lockhart Committee which had been set up to review the original legislation of 2002, as required under those Acts (the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*). The Lockhart Committee[vii] recommended significant changes, but most notably a relaxation of the prohibition of human cloning to allow for SCNT to be used to create embryonic stem cells for research purposes only. Debates over the proposed amendments lasted two days in the Senate with the Bill finally passing with a very slim majority, 34 to 32, and two days in the House with the Bill passing 62-42.

The essence of the new position

The essence of the changes are effected by sections 22 of the PHC, which prohibits the creation of SCNT embryos except under license, and section 20 of the RIHE, which sets out the conditions under which the license will be granted. Importantly, there are no exceptions to the rule that embryos cannot be developed for more than 14 days and that non-sperm-and-egg embryos cannot be implanted.

Are embryos human beings?

Much of the debate around the enactment of the amending legislation referred to the embryos to be created under the new provisions as if they were both potential human beings and already human beings. This was partly due to the fact that the Lockhart Report had made a distinction between embryos that were fated for research and therefore had no human potential and embryos intended for reproduction therefore having an altogether different trajectory towards personhood. However, in a confusing, somewhat circular process, those embryos fated for research were further distinguished by the means by which they were created.

For instance the Lockhart Committee stated, "if the embryo created by SCNT is not intended to be implanted, it does not represent a potential new individual in the way that the product of fertilisation does."[viii] However, the Committee went on to say (Lockhart Review page 170):

> [it] agreed that human embryo clones are human embryos and that, given the right environment for development, could develop into a human being. Furthermore, if such an embryo were implanted into the body of a woman to achieve a pregnancy, this entity would certainly have the same status as any other human embryo, and were this pregnancy to result in a live birth, that child would enjoy the same rights and protection as any other child. However, a human embryo clone created to extract stem cells is not intended to be implanted, but is created as a cellular extension of the original subject. The Committee therefore agreed with the many respondents who thought that the moral significance of cloned embryos that are not implanted is linked more closely to their potential for research developments, including the development of treatments for serious medical conditions, than to their potential as a human life.

Gestation still required to become human

A central, significant and much neglected fact is that the potential for any embryo to become someone is contingent upon female embodiment and a willingness to gestate and create the person in question. Clearly, the Lockhart Committee recognised this when it distinguished the SCNT embryo fated for research as fundamentally different from the sperm-and-egg embryo created for reproduction. While this seems clear enough, the distinction that the Lockhart Committee makes between artificially created sperm-and-egg embryos and artificially created SCNT embryos as seemingly already set upon different trajectories is problematic. That trajectory has, in fact, been carefully constructed through legislative prohibition against the creation of sperm-and-egg embryos for research purposes. Under the new legislation, the only embryos that can specifically be created for research purposes are those that were not created by the fertilisation of a human egg by a human sperm, but were created by other means.

Different approach for 'sperm-and egg' embryos

One of the primary arguments made in favour of new amendments allowing SCNT embryos for research purposes was that that the prohibition against creating sperm- and-egg embryos for research purposes would remain intact.

Opposition to the bill from a number of quarters picked up on this inconsistency, but rather than reading it as the Lockhart committee suggested (that the value of an embryo is determined by whether or not it is intended for implantation), many who argued against the bill saw the distinction between the two kinds of embryos as key and inequitable. They argued for both to be valued equally as potential human beings. The alternate argument that neither has value until a woman agrees to gestate it into a human being was not part of this discussion, although Senator Bartlett came closest to that view when he said:

> [T]he counterintuitive result of my position would be that it would be better if sperm-egg embryos were able to be created specifically for research as well so there was no potential for a different value to be attached to different classes of embryos. I continually have in my mind the view that all people are created equal, even though I realise that embryos are created in different ways."[ix]

By contrast Tony Abbott the Health Minister in the House of Reps debate responded to the distinction as follows:

> The proponents of this bill claim that there is a difference between embryos created for research and embryos created for reproduction. There is a difference all right: one is created for life and the other is created for death — one is an end in itself and the other is part of what is intended to become a burgeoning human spare parts industry.

The phantasmal embryo

Abbott's suggestion that one is created for life the other for death is particularly interesting because it illustrates the idea of what I call the 'phantasmal embryo'.[x] This embryo occupies the legal imaginary with the force of a vivid premonition of the child-to-be. It is an embryo disconnected from the female body, as if already born. In this way, it becomes possible for Abbot to describe

these embryos as created for death though in fact they have not yet lived, because he is relying upon their premonitional status as giving them life, pre-emptively.

In fact, the premonitional life of the embryo is contingent upon a woman agreeing to gestate it and to carry it to term; but in Abbott's rhetorical turn, that which makes the human — female gestation — has disappeared.

Existing outside the gestating body of the woman, the technologically produced embryo that is the subject of these debates disturbs these parliamentarians because it is uncanny in the Freudian sense of the *unhiemlich*, or unhomely.[xi] This extra-uterine embryo is no longer at home in the female body. Disconnected from the bodies from which it originated or from any body that might welcome it in, this embryo both pre-empts its possible gestation via female embodiment and questions the need of it. In the Freudian conceptualisation of the uncanny, the uncanny develops from the transformation of something that once seemed homely into something decidedly not so.[xii] Freud's idea of the uncanny is useful in attempting to map the unnerving impact that these embryos have upon the legal imagination — at once utterly familiar, the routine stuff of life, and yet frighteningly other. The technologically produced embryo[xiii] existing outside the female body is at its most uncanny when it doubles for the child. Apparently the same and yet it is not even a person. Its uncanniness lies in the familiarity it offers while it simultaneously evokes the horror of the alien presence. This is particularly so when the possibility of creating hybrid embryos is debated.

Hybrid embryos

Hybrid embryos amplify the uncanny nature of the technologically produced embryo. This becomes evident in the discussion by Senator Bartlett of proposed amendments to allow limited creation of hybrid embryos for research purposes. Apart from cloned embryos, the new legislation also allows for the creation of hybrids for research purposes via the fertilisation of an animal egg by human sperm. A proposed subsection allowing the 'creation of hybrid embryos by introducing the nucleus of a human cell into an animal egg' was, however, deleted by an amendment from Senator Bartlett before the bill was passed through the Senate.

Why hybrid embryos are prohibited

One of the key reasons that these kinds of hybrid embryonic forms have been prohibited to date is because they give rise to questions about how we define the human.

There is no definition of 'human' in the current legislation, although the definition of a human embryo requires, in a rather circular fashion, that it have a 'human' nuclear genome or an altered 'human' nuclear genome. Concerns about the creation of hybrid embryos that still prevailed when the bill was passed through the Senate suggest that even those who now support the creation of embryonic stem cells still view the embryo as having a human-like status sufficient to make mixing it with animal eggs repugnant.

While Senator Bartlett, who proposed the amendment, argued that the basis for rejecting this clause was an inadequate consideration of the rights of animals, he did say:

> The other point I want to emphasise is that, whilst I do not at all agree with the distorted view that somehow this legislation would allow half-horse or half-animal creatures or rabbit men bouncing around the neighbourhood or whatever, this legislation does at least remove the potential for that distortion and even for that misunderstanding.

Protection of women?

The real problem is Senator Bartlett's inadequate attention to women's health and well being. He acknowledged that, by removing the section allowing animal eggs to be used as hosts for SCNT rather than human eggs, he was creating a situation where more pressure would be applied to women to donate their eggs; but he was satisfied that enough safeguards were in place to make sure that it was voluntary. The larger point, that it is not appropriate to put women at greater risk (and it is always risky and invasive to retrieve eggs) when animal eggs are an alternative, does not get made. Instead, the animal rights argument trumps the rights of human women when, in the author's opinion, there is no real argument for using women's eggs if animal eggs can be used for that

purpose.

This is despite the fact that the Lockhart Committee made explicit its concern for women when it reviewed the federal legislation.

Changed definition of a human embryo

This was done in two ways:

1. by changing the definition of a human embryo as coming into being only after the first mitotic cell division, and not, as previously, as soon as fertilisation takes place; and
2. by allowing research on the entity that exists once fertilisation has occurred, but before the first mitotic cell division.

Research before the first mitotic cell division

Under section 20(1)(e)

A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

(e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART;

This is the one instance where research can take place on sperm-and-egg entities; but, importantly, under the new definition, there is no embryo involved until the first mitotic cell division has occurred.

According to Lockhart, this shift would allow research to be undertaken on

> culture and maturation of immature eggs ('in vitro maturation of oocytes' or IVM), frozen oocyte storage, various aspects of in vitro fertilization (IVF), and gamete (egg and sperm) development. The ability to produce mature oocytes in culture provides a way of reducing the use of follicle stimulating hormone and would therefore benefit women undergoing ART. It may also allow the production of mature oocytes from frozen ovarian tissue, such as tissue stored before cancer therapy.[xiv]

In the end, because Bartlett's amendment did not remove the proposed section 20(1)(f) from the Bill, it is permissible, for the purpose of testing sperm quality, to fertilise an animal egg by a human sperm up to, but not including, the first mitotic cell division.

Can only use human eggs

Senator Bartlett only removed proposed section 20(1)(g), which would have allowed the transfer of human somatic cell nuclei into animal oocytes or eggs for the creation of human embryo clones for research and training etc. Instead, actual human eggs will have to be harvested from women who are willing to donate them.

A woman cannot gestate her embryo clone

In the parliamentary debates around the amendments passed in December, one member of Parliament, speaking in opposition to the Bill, surprisingly voiced his concerns in terms that, it could be argued, did take into account the perspective of the woman who might become pregnant with one of these prohibited entities. He suggested that it might be wrong to deny a woman the right to gestate a human embryo clone made from her donated ovum should she wish to do that. Tony Burke said:

> We have the argument here that there is an absolute ban on reproductive cloning and that, once these embryos are created, it is illegal for them to be implanted in the womb and brought to term. If a woman has donated her ova and we have what people regard as either a human life or a potential human life, I do not know what argument will be used to tell the woman who is the mother — or potential mother, depending on where you sit in the debate — that, 'Even if you want to have that embryo implanted, we're not going to let you.' Logically, I am not sure at what point she ceases to be the mother. I am not

> sure at what point she loses those rights. It is unlikely that that request is going to be made, but I am not sure, and I am yet to hear, what the logical argument is that says she has no right to make that request. Under this bill she does have no right, and I am not quite sure how that next line gets drawn when this step is taken (page 16 Hansard)

Parentage

This perspective (one so uncommonly voiced) raises a whole series of further questions that are yet to be considered, precisely because this perspective of the woman is submerged. For instance, Burke assumes that the egg determines future parentage, whereas many might have thought that the nuclear DNA would determine it. It also raises the question of how relinquishment of future claims over such genetic material needs to be managed in the donation regime. For instance, were the embryo to be illegally implanted in the uterus of a willing woman, to whom would the resultant child, should it be brought to term, be related and to whom would it belong? And what about the illegally implanted embryo – are we to coerce the woman carrying it to abort it?

If women were at the front and centre of legislative visibility, it would change the way in which the legislation were drafted in the first place.

Stem cell centre

The new legislation does not set up a stem cell bank. It does, however, in section 47B of the RIHE Act, require the Minister to report to Parliament within six months on the establishment of a national stem cell centre. There was a fair bit of debate in parliament about the importance of this, with Kerry Nettle proposing several unsuccessful amendments to the legislation to have it required by law.

Potential stem cell bank

A publicly funded national stem cell bank would be one way of ensuring that stem cell lines derived in Australia were available to the general research community, including the international research community. If such a bank were established, it would be possible for mechanisms to be put in place for the community to be involved in determinations concerning which stem cell lines were established. Rachel Ankeny, Susan Dodds and Wendy Rogers have argued that this is particularly important

> because banking might allow closer matching (and hence likely more effective therapies) for certain ethnic or minority groups (eg Aboriginal and Torres Strait Islander Australians) who might otherwise be disadvantaged if research and future therapies are reliant on the usual sources of donated embryos (given they are currently provided only by those who have undergone ART) or internationally-established lines (such as those in the UK).[xv]

In addition, a publicly run and funded stem cell bank could ensure fair access to everyone by agreements between governments that limited the capacity to attach expensive transfer agreements to stem cell lines.

The Lockhart Committee found, "although commercialisation of therapeutic products would be an outcome if research is successful, stem cell banks help to keep research resources in the public domain."[xvi] Stem cell banks exist or are being planned in a number of countries, including the United Kingdom, the United States, Sweden, China, South Korea and the United Arab Emirates.

The UK Stem Cell Bank

The United Kingdom Stem Cell Bank, for example, is funded by the United Kingdom's Medical Research Council and by the Biotechnology and Biological Sciences Research Council. It began operating officially in January 2003 and will 'curate ethically sourced, quality controlled adult, foetal and embryonic stem cell lines and will be open to academics and industrialists from the United Kingdom and overseas'.[xvii]

The bank does charge users, but the charges are based on the nature of the user — ranging from marginal cost recovery for academic researchers to full cost recovery for commercial users.[xviii]

[i] Karpin, I Choosing Disability: Preimplantation Genetic Diagnosis and Negative Enhancement (2007) Journal of Law and Medicine 15, 89-103;
Karpin, I, 'The Uncanny Embryos: Legal Limits to the Human and Reproduction Without Women' (2006) *Sydney Law Review* 28(4), 599-623.
Bennett, B, Carney, T & Karpin, I, (eds), *Contemporary Perspectives on Health Law and Policy*, Federation Press: Sydney (2007 - in press) which includes a chapter, "Constructing the body inside and out: genetic and somatic body modification"

[ii] This article is focused on those technologies that involve the creation of embryos through genetic manipulation technologies, including the combining of human and non-human genetic material. These are the subject of federal legislation through the *Prohibition of Human Cloning Act* (Cth) 2002 (PHC) and the *Research Involving Human Embryos Act* (Cth) 2002 (RIHE). Technologies such as preimplantation genetic diagnosis (**PGD**) are currently used to identify and select embryos with certain traits, rather than to alter or manipulate the genetic makeup of those embryos. Sarah Franklin's and Celia Roberts's book *Born and Made: An Ethnography of Preimplantation Genetic Diagnosis* (Princeton University Press, USA, 2006) offers a comprehensive analysis both of the rise of PGD in the UK and its description as a technology for making so-called 'designer babies'. In addition, recent research has suggested that a method of single cell embryo biopsy, similar to that which is used in PGD, might offer a source of stem cells that will not involve destruction of the embryo. (Chung Y, Limanskaya I, Becker S, Marh J, Lu S-J, Johnson J, Meisner L and Lanza R, 'Embryonic and extra-embryonic stem cell lines derived from single mouse blastomeres', *Nature,* 2006, Vol 439 pp 216-219) The current Federal legislation does not regulate single cell biopsy of an embryo. However, it might regulate the creation of a stem cell line from that biopsy, since even the single cell removed could, theoretically, be grown into a human embryo clone and, co-extensively, a human. (see ss13, 14, 17 PHC).

[iii] For definitions of each of these forms see s8 of The *Prohibition of Human Cloning Act* (Cth) 2002

[iv] Except for the Northern Territory, all State and Territory jurisdictions have passed legislation corresponding with the original 2002 Acts. They will now have to amend that legislation in line with the changes made in December 2006. Victoria has already amended its Act and NSW is currently debating amendments in the Parliament. See *Infertility Treatment Act* 1995 (VIC) amended most recently in 2007 by the *Infertility Treatment Amendment Act* 2007 (Vic), *Human Cloning and Other Prohibited Practices Act* 2003 (NSW), *Research Involving Human Embryos (New South Wales) Act* 2003 (NSW) amended by the *Human Cloning and Other Prohibited Practices Amendment Bill* 2007 (NSW) (June 2007), *Research Involving Human Embryos and Prohibition of Human Cloning Act* 2003 (QLD), *Research Involving Human Embryos Act* 2003 (SA), *Human Cloning and Other Prohibited Practices Act* 2003 (TAS), *Human Embryonic Research Regulation Act* 2003 (TAS), *Human Cloning and Embryo Research Act* 2004 (ACT), *Human Reproductive Technology Act* 1991 (WA).

[v] R. Mykitiuk and J. Nisker, "Embryo 'Health': Biomedical and Social Determinants" (2007, forthcoming)

[vi] See generally Part Two of the *Prohibition of Human Cloning Act* 2002 (Cth). Note that s18 of the Act precludes inheritable genetic modification. However, somatic cell modification of an embryo of the kind that might be called gene therapy is not precluded. Genetic alterations to a single embryo are less controversial than inheritable alterations. There is some concern within the scientific community that such alterations could accidentally result in heritable changes. See Kaplan JM and Roy I, Accidental germ-line modification through somatic cell gene therapies: some ethical considerations, *The American Journal of Bioethics* 1 (2003), 1–6, who argue that the risk of accidental germ-line modification is not significant enough to preclude further somatic therapies. Section 18 prohibits only intentional inheritable alterations and the definition of a human embryo in s8 includes an embryo with an altered human genome.

[vii] The Legislation Review Committee, 2005 *Review of Australia's Prohibition of Human Cloning Act*, 2002 *and Research Involving Human Embryo's Act*, 2002.

[viii] *Legislation Review Report on The Prohibition of Human Cloning Act, 2002 and the Research Involving Human Embryos Act, 2002* ("the Lockhart Review") p 171. See also the Lockhart Committee's reference to the NHMRC Discussion Paper: Human Embryo – A Biological Definition (NHMRC December 2005) where it was suggested, "potential for implantation and future development to a live birth could provide a useful criteria for considering whether such an entity should be included in the definition of a human embryo or not." However, that potential was noted at p173 to be determined by the appearance of the primitive streak.

[ix] HANSARD 7 November p 81 Senate debate Bartlett

[x] Isabel Karpin 'The Uncanny Embryos : Legal Limits to the Human and Reproduction without Women' *Sydney Law Review* Vol., 28 at 599-623

[xi] Sigmund Freud, 'The Uncanny' in The Standard Edition of the Complete Psychological Works of Sigmund Freud (1953).

[xii] Anthony Vidler, The Architectural Uncanny: Essays in the Modern Unhomely (1994) at 6.

[xiii] 'Technologically produced embryo' refers to any embryo that is made outside the womb with the intervention of technology. whether or not they have been manipulated genetically or mixed with cells from non-humans.

[xiv] Lockhart Review id at p167

[xv] Lockhart Committee, 2005 id, at p150

[xvi] Lockhart Committee, 2005, id at p181

[xvii] Lockhart Review, 2005, id at p143

[xviii] Lockhart Review 2005, id at p144