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Inquiry into the Legislative responses to Recommendations of the Lockhart Review

The Social Issues Executive of the Anglican Diocese of Sydney (the SIE) is grateful for the opportunity to submit our response to the recommendations of the report of the Legislation Review Committee on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* (the Lockhart review) to the Senate Committee (the Committee). We have grave concerns regarding the shortcomings of the Lockhart review itself as well as some of the recommendations found therein.

Like all sensible people, we want to see the development of new therapies that will improve the health of our community. However, a basic concern of the SIE is that the notion of 'what can be done must be done' pervades the Lockhart review, with the accompanying ethos that if any scientific advantage can be had, however theoretical, then any ethical concerns are immediately outweighed.

Yet ethical boundaries in medical research have not caused medical research to stop progressing, but instead have moved it forward by promoting creative solutions that have avoided the need to challenge professional guidelines which existed since the

time of Hippocrates, in the 5th century BC[1]. It is precisely through such creative impetus that Australia will come to the forefront of biomedical research and practice, not by the adoption of ethically dubious technologies in order to 'catch up' or compete with overseas research. Over 2000 years of Western tradition holds that human life should be treated with respect, and the onus of proof is on those who seek to change the ethical framwork that expresses that respect, rather than upon those who do not.

We will structure this submission according to the numbering of the recommendations and refer to the documentation relating to the inquiry through the text.

Recommendation 1

The SIE welcomes the recommendation that clinical practice and scientific research involving assisted reproductive technologies (ART) and the use of human embryos for research purposes should continue to be subject to specific national legislation.

The wording of the recommendation is slightly incorrect as to date, creation of human embryos for research purposes has never been legal, and the SIE would like to see this prohibition remain in force. This point is fundamental to medical research ethics that have been in force since World War II. After the revelation of the atrocities in Nazi medical experiments during the war, international consensus was that if a human being is a subject of experimentation, the purpose of that experimentation should always be for the benefit of the person involved. Human beings should never be used as a means to an end. The documents that reflected, and continue to reflect, these sentiments are still held as necessary restrictions upon medical research today. They include the *Nuremburg Code* (1946)[2] and the *Declaration of Helsinki* (1964)[3]. Australia's own *National Statement on Ethical Conduct in Research Involving Humans* (1999) bans harmful research (1.17). To create human life in order to destroy it for research purposes obviously falls outside such statutes.

Recommendation 2

The SIE supports a continued ban on reproductive cloning. Reproductive cloning denies innate human dignity, held by all human beings regardless of their abilities or stage of life.

Recommendations 3-11

The SIE supports the continuation of all prohibited practices as documented in the *Prohibition of Human Cloning Act 2002*, including those listed in recommendations 3-11. We noted that some of these recommendations (6, 8 and 9) are effectively overridden by subsequent recommendations, which we will address in due course.

Recommendations 12-13

The SIE supports the recommendations that restrict the creation of fertilised embryos to use for reproductive purposes only. We note that the strength of recommendation 13 is significantly reduced by the new definition of 'embryo' in recommendation 15 (see below) and also recommendations 26 and 27.

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[1] Hippocratic Oath, http://www.pbs.org/wgbh/nova/doctors/oath_classical.html (accessed 2 October, 2006).

[2] Nuremberg Code, http://ohsr.od.nih.gov/guidelines/nuremberg.html (accessed 2 October, 2006).

[3] The World Medical Association. (1964). *Declaration of Helsinki*, www.wma.net/e/policy/b3.htm (accessed 2 October 2006).

Recommendation 14
The SIE does not support destructive human embryo research on grounds of it being contrary to human dignity.

Recommendations 15–17, 28. Definition of a human embryo
Recommendations 15-17 need to be addressed alongside recommendation 28. By changing the definition of a 'human embryo', the Lockhart Committee has surreptitiously allowed destructive research on the early fertilised embryo, making a mockery of recommendations 12 and 13. Also, while the SIE agrees that recommendation 28 (b) is sufficient to capture all non-fertilised embryos and commends the focus on potential, we do not agree with 28(a). We do not see evidence of why the completion of fertilisation, rather than its beginning, is used to define the starting point of fertilised embryonic life. The text of the Lockhart Report suggests that the primary purpose of this change is to allow recommencement of research during the early stage of fertilisation, rather than being based upon any biological criteria (see p.xv). However, precisely these restrictions on research were identified in the debate prior to the passing of the 2002 legislation, so it is unclear how they can now be seen as having 'apparently unintended consequence(s) of impeding valuable research and clinical practice in ART clinics'(p. xv).

Even though the combination of genetic material from the sperm and oocyte does not occur until syngamy, both are present in the zygote before this. We know that when the sperm enters the oocyte, it begins a process in which a human being with potential develops dynamically in a continuum through pregnancy, childhood and adulthood. We reiterate our previous claim that to choose any starting point of embryo development following the beginning of fertilisation is arbitrary. Fertilisation, rather than syngamy, has long been established by embryologists as the point at which human life begins.[4]

If the Senate Committee is determined to support the change in legislation to allow research on the early zygote, these human beings need to be included in the definition of embryo so that this research is under the scrutiny of the Licensing Committee of the National Health and Medical Research Council (the NHMRC). It is important for public concern regarding reproductive technologies that such research is transparent and accountable.

Interspecies fertilisation
Recommendation 17 allows for interspecies fertilisation and research on early zygotes as a result of the change in the definition of the embryo. We note that this recommendation qualifies the prohibition in recommendation 6. If such research is allowed under new legislation, it is important that this practice, which is surely repugnant to the community, be allowed only under licence.

Recommendation 18
The SIE opposes the use of human embryos for destruction during training and quality assurance activities. Such procedures can be done using animal embryos. If training is allowed under the new legislation, it is vital that animal embryos should be

[4] Carlson, B. (1996). *Patten's Foundations of Embryology, 6th edition*. (p.3) New York, N.Y.:McGraw-Hill.

used by the trainee as a pre-requisite. We do not approve the use of human embryos for quality assurance under any circumstances. The use of mouse embryos for this purpose is well established.

Recommendation 19

Cytoplasmic transfer is a procedure that creates an embryo which has the potential to develop into a human with at least three genetic parents. This procedure is known to be unsafe[5] as well as having the potential of confusing the genetic identity of any child born from the process. This may explain the wording of this recommendation (ie to give consideration, rather than recommend). As the role of the Lockhart Review was to suggest changes on the basis of scientific developments, and international consensus is that cytoplasmic transfer is still a problematic procedure[6], surely the responsible decision is to limit this procedure to animal research until doubts are resolved.

Recommendations 20–21

Use of fresh ART embryos

Recommendations 20 and 21 provide for the identification and licensing of fresh ART embryos which are unsuitable for implantation. We are surprised that this category of embryo has been recommended for inclusion as according to research it does not exist. While there have been suggestions that there is some correlation between the external appearance of an embryo and its likelihood of implantation and successful development, research has previously shown that appearances can be misleading. Some unhealthy-looking embryos implant and develop successfully while some healthy-looking embryos fail to implant or have developmental problems.[7] We are not aware of any method of embryo assessment that has been proven effective or valid in terms of predicting the viability of ART problems. If there are viable cells present, some clinicians would consider going ahead with uterine transfer, despite unfavourable morphology, considering this the only way to determine true viability. Therefore, fulfilment of recommendation 20 is not possible.

A second problem for recommendation 21 is that of consent. Fresh ART embryos that have been created with the intention of implantation, and then are determined unsuitable for implantation, technically would be 'excess ART embryos'. However, according to the RIHE Act, all destructive research on excess ART embryos must comply with the *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research 2004* (the Ethical Guidelines), and the *National Statement on Ethical Conduct in Research Involving Humans 1999* (the National Statement). The RIHE Act also requires that proper consent be obtained from those responsible for the excess ART embryo (21.3). This is a complex process.

According to the National Statement (1.7), the ethical and legal requirements of consent have two aspects: the provision of information about the research, and the exercise of a voluntary choice to participate. Furthermore, consent must not be

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[5] Gosden, R. (1999). *The role of cytoplasmic transfer*. Accessed at http://www.obgyn.net/women/women.asp?page=/firstcontroversies/prague/1999gosden.

[6] Malter, H. & Cohen, J. (2002). Ooplasmic transfer: animal models assist human studies. *Reproductive Biomedicine Online.* 5(1): 26-35.

[7] Scott, R. et al. (1991). Embryo quality and pregnancy rates in patients attempting pregnancy through in vitro fertilization. *Fertility and Sterility* 55:426.

subject to any coercion (1.10) and a participant must be free at any time to withdraw consent to further involvement in the research (1.11). In the case of destructive embryo research, this last requirement is met by instituting a cooling-off period to allow patients time to reconsider their decision before irreversible damage is done. While the current 14-day recommendation in the Ethical Guidelines (17.17) is not fixed, some time of reflection is required according to both the National Statement and the Ethical Guidelines.

Consent for research would need to be given quickly in the case of fresh excess embryos, in order to avoid their deterioration. Certainly it would be less than the recommended 14 days. According to the Ethical Guidelines, the provision of information must be at the level of comprehension of the patient and presented in oral and written format, with the written information able to be taken away and considered before consent is given (17.16.1). It is difficult to see how this information-giving process could be adequately completed according to the recommended steps of the Ethical Guidelines in such a short time, let alone allowing for a cooling-off period.

Also, if consent for research were to be given immediately, it would be difficult to ensure that there was no coercion involved, given the time-pressure for decision-making. One would also want to be convinced that the persons responsible, at such an early stage of treatment when they will be extremely vulnerable and expecting treatment to be successful, were completely sure they have no further use for the embryos, especially considering the research mentioned above regarding the non-correlation of appearance and viability of embryos. Would the less-perfect embryos still be considered 'excess' if the implantation of apparently more suitable embryos proved unsuccessful? If prospective parents' choice was between a less perfect embryo and none at all, it is highly likely that some would deeply regret the relegation of these embryos to research. The decision is therefore too complex to make quickly and in advance of knowing the results of treatment.

We do not see how proper consent can be obtained for the use of non-cryopreserved excess ART embryos given the problems listed above. The Lockhart Report does not contain discussion of why fresh embryos are specifically needed for research. We would suggest that such embryos be cryopreserved and declared excess (when appropriate) by the current regulations.

Recommendation 22
Fresh ART embryos diagnosed by preimplantation genetic diagnosis (PGD) also present problems regarding consent, as previously mentioned. While in the case of PGD consent might be obtainable in advance to allow for cooling off, the same advantage does not apply to embryos judged as inappropriate for implantation on other grounds.

The types of genetic conditions that should or should not be the subject for study will be determined by the Ethical Guidelines, which specify those where PGD can be used. Ethical Guideline 12.2 restricts the use of PGD to the following conditions: those which seriously harm the person to be born, or sex selection in the instance of sex-linked genetic disorders. While the SIE believes that discarding of all embryos without the desired characteristics constitutes discrimination and risks increasing prejudice against the disabled in our community, we recognise that this is now a

routine procedure in ART clinics. Our concern is regarding the lack of enforcement of current regulations (see comments on recommendation 40).

Obviously the term 'serious harm' is open to interpretation. However, it certainly means that the mere existence of a genetic test does not necessarily qualify it for use in PGD (particularly with polygenic disorders, where disease expression is unpredictable). Disorders causing 'serious harm' would be conditions which are life-threatening from an early age and untreatable. The use of PGD for sex selection on social grounds is clearly not allowed in the Ethical Guidelines (12.2). The Reproductive Technology Accreditation Committee (RTAC) has made adherence to the Ethical Guidelines mandatory in its 2005 Code, which we are glad to see. However, the Lockhart recommendations do not ensure such adherence, and seem to accept self-regulation as the preferred option. The SIE finds self-regulation problematic when there is no way the public can be sure that it occurs, both for use of PGD and in the matter of creating only those embryos likely to be needed for the treatment of a particular patient (Ethical Guidelines 5.2).

The RIHE Act sunset clause (46) was originally included to allow time for authorities to ensure that there would be no increase in production of embryos beyond that needed for the patient (Ethical Guidelines 5.2). We would think that if non-cryopreserved embryos are going to be approved for licensed research, it is vital that such precautions are in place and transparent. While the Lockhart report suggests that the RTAC database collects relevant data (ie embryos created per patient, per live birth etc) (p.xvi), and in fact did so even before the 2002 legislation was passed (p.77), we have not been able to find evidence of such data collection. Until this situation is clarified, we suggest that the sunset clause be reinstituted. While we recognise that the Lockhart committee felt there was no evidence to suggest that there has been an over-production of embryos for ART treatment (p. xvi), the SIE feels that over 70,000 cryopreserved embryos in ART clinics around Australia constitutes sufficient evidence of the problem.

Recommendations 23-24 Somatic cell nuclear transfer

The SIE strongly opposes the recommendations to allow creation of human and hybrid clones, either by somatic cell nuclear transfer (SCNT) or other means. The arguments given in the Lockhart Report to justify these recommendations will be addressed one at a time. We appreciate the tabling of journal articles by Senator Patterson which support our case. These will also be mentioned.

'The potential to provide embryonic stem cell therapies (patient-matched) for serious untreatable conditions justifies use of cloning.'

Patient-matched cellular therapy using embryonic stem cells (ES cells) is now considered unlikely ever to eventuate, due to advances in research, the continued difficulty in controlling tumour formation by ES cells in animals, and the prohibitive cost of developing such treatments[8].

Furthermore, Senator Patterson's tabled article by Barberi et al[9] described treatment of chemically induced Parkinson's disease in mice with both fertilised and cloned ES

[8] See http://www.cloning.org.au/Documents/cloningisunnecessary.pdf

[9] Barberi, T. et al. (2003). Neural subtype specification for fertilisation and nuclear transfer embryonic stem cells and application in parkinsonian mice. *Nature Biotechnology.* 21(10): October.

cells, and no advantage was gained with the cloned cells. The study was not of sufficient duration to provide for development of tumours, so the safety aspect was not addressed in this experiment (and as previously mentioned, this aspect remains a concern with ES cell therapies in general).

'Cloning is required for specific genotype cell lines for disease modelling and other research.'
SCNT is not necessary to create specific genotype cell lines. Senator Patterson's tabled article by Klimanskaya et al[10] describes the establishment of ES cell cultures from single cells removed at the 8-cell embryo stage in a procedure similar to PGD. It would therefore be a method which could be used for the study of single gene diseases. Although this is a high-risk procedure, it is undertaken according to specific clinical indications. As this procedure did not interfere with the embryo's developmental potential, use of this procedure would be possible in Australia.

'Cloning is necessary so that ES cell treatments can be pursued to develop effective disease treatments.'
We realise that adult stem cell therapy is not a topic for the current debate, but it must be mentioned that the success in this field (now providing 72 clinical therapies[11]) makes stem cell (regenerative) therapy available to the public without the need for destructive embryo research or cloning of human embryos.

Indeed, Senator Patterson's tabled article by Takahashi and Yamanaka[12] illustrated a new approach which removes any need for therapeutic cloning. The paper reports that it is possible to reprogram an adult cell, so that a pluripotent cell can be generated from the adult cell without cloning. Similarly, the tabled paper by Strelchenko et al[13] describes an attempt to bypass the need for therapeutic cloning by reprogramming adult cells by another method. Although this study used human cells, the work by Takahashi and Yamanaka is at a more advanced stage. Restrictions on human embryo and ES cell research in many countries have demonstrated the creativity of scientists who accept and work within a community's ethical framework, and much exciting work is being done internationally in the search for sources of human pluripotent stem cells which do not require destructive human embryo research.[14]

While it is true that ES cells can be used for study of diseases, papers such as Senator Patterson's tabled article by Blelloch[15] are a vivid reminder that this work has no relevance to the need for therapeutic cloning in Australia. Such research (in this case, looking at cancer) can only be carried out if embryos are allowed to develop beyond 14 days, including after transfer to the uterus. In view of the 14 day limit upon human

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[10] Klimanskaya, I. et al. (2006). Human embryonic stem cell lines derived from single blastomeres. *Nature online*. August 23.
[11] See http://www.stemcellresearch.org/facts/treatments.htm
[12] Takahashi, K. & Yamanaka, S. (2006). Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. *Cell*, 126:1-14, August 25.
[13] Strelchenko, N. et al. (2006). Reprogramming of human somatic cells by embryonic stem cell cytoplast. *Reproductive Biomedicine Online*. 12(1), 107-11, January.
[14] The President's Council on Bioethics. (2005). *Alternative Sources of Human Pluripotent Stem Cells.* Washington, D.C.: US Government.
[15] Blelloch, R. et al. (2004). Nuclear cloning of embryonal carcinoma cells. *PNAS* 101(39) 13985-13990. September 28.

research of this kind, it is absolutely essential that all such research be confined to animal models for the foreseeable future.

For completeness, we will comment here on another paper tabled by Senator Patterson, that of Chang.[16] This is not a therapeutic cloning paper, but instead discusses an application of gene therapy. Though the authors used ES cells made by SCNT for their work to correct an abnormality leading to sickle cell anaemia, it is possible that the starting point could be (adult) haemopoietic stem cells instead of ES cells. This paper does not provide evidence for the need of cloned human embryos for research.

In summary, the Lockhart Report was unable to report any clinical advances to justify a change in the law. Even if human embryonic stem cells were produced from human clones tomorrow, it would not be possible to use them on human subjects and we are concerned that this problem is not sufficiently addressed in the report.

'Production and destruction of excess ART embryos is permitted so cloning should be too.'
The rationale of the Lockhart Report was that, if production and destruction of excess ART embryos is allowed and SCNT is not, then it would be inconsistent and appear to attach more importance to the treatment of infertility than other conditions which might be helped through cloning. This is a fatuous argument. It is not sensible to equate embryos created specifically with the aim of implantation with cloned human embryos created specifically for destruction.

'Reproductive cloning will be controlled by regulation and is not a danger if therapeutic cloning is allowed.'
Since therapeutic and reproductive cloning use the same technology, the Lockhart Committee recounts the argument that to allow cloning for extraction of stem cells would in turn develop technologies needed for reproductive cloningreproduction. The Committee dismissed these concerns *only* on grounds that reproductive cloning would be prevented by regulation. However, while it is charming to see such confidence in human nature, it is naïve to think that those who have promised to pursue reproductive cloning despite international bans (such as Dr Severino Antinori and the Raelian Sect) will be stopped in their projects by Australian legislation.

We note a parallel problem in a different field. Current public debate about whether Australia should engage in uranium enrichment pivots on the fact that enrichment technology for nuclear power is also used to produce weapons-grade uranium. Advancement and proliferation of this technology increases the likelihood of proliferation in atomic weapons; the technology employed makes no distinction about how its product will be used. The same issues are at stake in cloning technologies: to advance them is simply to make reproductive cloning easier and more likely.

Furthermore, it will be impossible to police such a prohibition. Embryos are transferred to womens' uteruses every day in ART clinics. Microscopically, a fertilised and cloned embryo look alike. It will be impossible to police a ban that

[16] Chang, J. et al. (2006). Correction of the sickle cell mutation in embryonic stem cells. *PNAS*, 103(4), 1036-1040, January 24.

prevents transfer of cloned embryos to female reproductive tracts once the embryos exist. As the Lockhart Report points out, 'Reproductive cloning of humans is considered unacceptable through the world because of ethical concerns…' (p. 55).

'Cloning is not unethical because the moral status of a cloned embryo is linked to its' purpose, not its capacity.'

Moral objections to the creation of human embryos with the expressed intention of destroying them for research (using SCNT and other methods) were dismissed in the Lockhart Report. The argument was put to the Lockhart Committee that, as human embryo clones are human embryos with the capacity to develop to birth, it is wrong to treat them this way. Human beings, however small and immature, should not be used as a means to an end but respected regardless of the benefits their death would give others. The Lockhart Committee denied the moral significance of a cloned human embryo on the grounds that it was indeed created for destruction; but the nature of a human embryo does not alter because of others' plans for it. It remains a human being and dismissing it as 'a cellular extension of the original subject' (p.xvii) is a mere semantic claim that changes neither the biology of this kind of embryo nor the moral concerns inherent in its use.

The SIE is disappointed that this whole debate over cloning has been hindered by the continued use of the term 'SCNT', confusing the public regarding its meaning and suggesting that it is different from cloning. The report's contention that a human embryo clone created to extract stem cells is not a human being but 'a cellular extension of the original subject' is unscientific and unhelpful.

If the Australian public is to decide whether it wants cloning, we need an accurate and transparent debate, so all can know what it is being discussed.

'The Literature Review reveals scientific advances in human cloning since 2002, which justifies legalising cloning in Australia.'

The **only** peer-reviewed papers reporting successful human cloning to blastocyst stage in the Lockhart Report were those by Hwang et al[17]. **This work has since been discredited.** The report from a group of researchers in Newcastle-on-Tyne, United Kingdom was also mentioned (Stojkovic et al) in the Report, and also in Senator Patterson's literature table.[18] It describes unsuccessful attempts to conduct therapeutic cloning. The group were able to conduct nuclear transfer of a human ES cell nucleus to an enucleated ovum, but developed only one blastocyst out of 36 attempts. This work was not published in an adequately peer-reviewed journal, and apparently they have still not developed human cell lines by SCNT. This is perhaps not surprising as the primary author commented that they relied heavily on Hwang's advice.[19]

In fact, **no reports** of successful human embryo cloning exist in peer-reviewed literature and therefore those advances documented in the Lockhart Report are now known to be invalid. In view of the original brief to the Committee, since there has

[17] Hwang W et al. (2004). Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. *Science.* 303(5664):1669-1674.
Hwang, W. et al. (2005). Patient-specific embryonic stem cells derived from human SCNT blastocysts. *Science.* 308(5729):1777-1783.

[18] Stoljkovic, M. et al. (2005). Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes. *Reproductive Biomedicine Online.* 2(226-31), August 11.

[19] http://www.guardian.co.uk/genes/article/0..1683735.00.html

been no scientific progress to justify a change in the law, we suggest that all forms of human cloning should continue to be prohibited.

'Public opinion has changed since 2002 and the majority of community members now support cloning.'
The community attitudes survey (Public Awareness Research 2005, p.83ff.) was limited to the Morgan Poll which did not explain therapeutic cloning with sufficient clarity to know what respondents thought of it. In the report there is no evidence that respondents were given a clear explanation that the embryonic stem cells being discussed may or may not come from cloned embryos, or that 'cloning' did not necessarily result in reproduction. In fact, it is difficult to know what this poll actually shows in the absence of these questions.

It is difficult to know why the Lockhart Committee did not refer to the research from Swinburne University[20] which found that almost 30% of the sample had doubts about the use of cloned embryos, with 63.4% of respondents scoring mid-range. The mean score for cloning was well below 5 and the mode was zero. This suggests that the Australian public does not support the cloning of human embryos for research.

Although this report dates from 2004, more recent market research concurs with its result. Research into public attitudes to human cloning was conducted by Sexton Marketing Group for the Southern Cross Bioethics Institute in January this year. It found that only 29% of respondents support the cloning of human embryos as source of stem cells while 51% opposed the cloning of human embryos for stem cells. This increased to 55% when the respondents realised that the embryos were destroyed when stem cells were harvested. (43% of respondents did not realise this). These two surveys bring the conclusion of the Lockhart Report into question with regard to public consensus regarding cloning.

Hybrid embryo cloning
The SIE welcomes the concern of the Lockhart Committee that, should human cloning become legal, enormous numbers of oocytes would be required for research, and that vulnerable women may be at risk of coercion to donate them. The risks involved are mentioned in the report (p.65). We do not, however, believe that the creation of hybrid human embryos is in line with community values. This is particularly the case when, according to the Report, the purpose of doing so is for training and quality control measures. Does this purpose meet the criteria for a change in the law?

Recommendation 25
Recommendation 25 allows for the creation of human embryos and human embryo clones by means other than fertilisation. We do not support this recommendation. Our objections are based on previous comments regarding the need to respect nascent human life.

Recommendation 26

[20] Critchley, C. & Turney, L. (2004). Understanding Australians' perception of controversial research. *Australian Journal of Emerging Technologies and Society.* 2, p.95.

Recommendation 26 allows for the creation of fertilised human embryos using genetic material from more than two people (such as by cytoplasmic transfer), or including heritable genetic alterations (germ-line therapy). This recommendation contradicts recommendation 12. For our objections to destructive research see comments on recommendation 14. For our objections to cytoplasmic transfer see comments on recommendation 19.

Germ-line therapy
The SIE has concern about the provision to allow research on germ-line therapy when our community has not engaged in discussion of its dangers and benefits. This is a complex and irreversible treatment which has implications that reach future generations. Our community should not make choices that radically affect future human beings, and such therapies may wrongly assume that our community knows what will be needed by future human beings and their communities. We risk tampering with future social ecologies to an extent that is unwarranted. We have no evidence that the Lockhart Committee gave sufficient thought to these social and environmental matters. Therefore we believe that provision to allow research into germ-line therapy is a premature step which should be postponed until after relevant community discussions have taken place.

Recommendation 27
We do not support this recommendation on grounds of violating human dignity. If research were to be allowed using human embryos or human fetus precursor cells, extremely restrictive guidelines would be necessary to avoid coercion of those responsible for the nascent life involved.

Recommendation 28
For our objections to the change in the definition of a human embryo, see comments for recommendations 15-17 above.

Recommendation 29
Informed consent is a vital aspect of ethical research. Any changes to the current consent arrangements for the donation of human embryos must be in accordance with the National Statement and the Ethical Guidelines.

Recommendation 30
The SIE knows of no evidence to support that any embryo can be deemed unsuitable for implantation on grounds of appearance. See our comments on recommendations 20-21.

Recommendations 31–33 The SIE supports the recommendations 30-31. Once again we would be concerned that any efforts to develop guidelines for egg donation be very stringent, to avoid coercion and to avoid any dangers to a woman involved in hyperstimulation of her ovaries.

Recommendations 34-39
The SIE supports the continuing role of the Licensing Committee and welcomes the improved ability they would have to monitor relevant activities under the proposed expanded powers for the Licensing Committee inspectors. While we understand the need to avoid full compensation of costs incurred at present by the NHMRC due to

the limited number of researchers, we do not understand why a fee is not charged, especially when some licences are sought by researchers aiming towards commercial gains (this will only increase – see recommendation 46).

Recommendation 40
The SIE supports the continued role of RTAC in regulating ART in Australia. New legislation should include provision for policing adherence to regulations in such an important area of health care. While the concern regarding RTAC's lack of monitoring regarding the compliance of clinics to the Ethical Guidelines was raised in the Lockhart Review (p.125), it does not seem to have been investigated or addressed in the recommendations.

Recommendation 41
The SIE supports the alteration in custom laws to allow for facilitation of private ART treatment.

Recommendation 42
The SIE is opposed to human cloning and does not support this recommendation.

Recommendations 43–45
The SIE supports these recommendations.

Recommendation 46
Insufficient detail was given in the Lockhart Report to know what this recommendation means.

Recommendations 50-51
The SIE objects strongly to the suggestion that the Licensing Committee be given the authority to make rulings regarding the granting of licences where the legislation does not strictly apply. We have seen from the example of the Human Fertilisation and Embryo Authority in the United Kingdom that when unelected committees start to make decisions in this area, there is no guarantee that community standards will be maintained. Assisted Reproduction and manipulation of human embryos must absolutely remain within the jurisdiction of Parliamentary oversight.

Recommendation 54
The SIE agrees that ongoing public education is important, but such education must be honest and transparent, and conducted by a neutral organization such as the NHMRC.

We have not mentioned the final document table by Senator Patterson.[21] We did not find that this article added to our understanding of the Lockhart Report. While the author was enthusiastic regarding all recommendations, we were not persuaded by the utilitarian grounds of her justification.

Legislation relating to this enquiry

[21] Cooper, D. (2006). The Lockhart Review: Where now for Australia? *JLM* 14, 27.

We observe that the Bills tabled by both Senators Patterson and Stott-Despoja aim to implement the Lockhart Review as a whole. Our concerns regarding both Bills reflect our concerns regarding the recommendations as documented above.

We thank the Senate Committee for their patience in reading our submission.

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