Legislative responses to recommendations of the Lockhart Review – submission to the Senate Inquiry

Associate Professor Wendy Rogers
Coordinator, Medical Ethics and Health Law
Co-coordinator, International Network on Feminist Approaches to Bioethics
Leader, Health Ethics theme of the Ethics Centre of South Australia
Department of Medical Education
School of Medicine
Flinders University
GPO Box 2100
Adelaide SA 5001

These comments are submitted to the Australian Senate Community Affairs Committee in response to the 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).

Given the relatively brief time between the tabling of draft legislation and the due date for submission to the Community Affairs Committee, I limit my comments to three key areas:

1. Amending the definition of human embryo
2. Permitting SCNT
3. Allowing fresh embryos that have been determined unsuitable for implantation due to the existence of disease to be used in research

1. Amending the definition of human embryo

I support the definition of the human embryo used in the draft bills by Senators Stott-Despoja and Patterson. Both drafts use the definition developed by the NHMRC which attempts to clarify when an embryo comes into existence. As fertilisation is a process which occurs over time, rather than a discrete event, any definition relating to embryos created by fertilisation of an egg by a sperm will be somewhat arbitrary in the sense that it selects one moment in the process as the marker to define when a human embryo begins to exist. The NHMRC definition uses a biologically observable feature (first mitotic division) to anchor their definition for an embryo created for reproductive purposes, thereby clarifying what is and is not a human embryo in ways that can be verified, as opposed to using syngamy which is not as easily observable. The definition captures morally relevant criteria – for a embryo resulting from fertilisation of an egg by a sperm, the first mitotic division demonstrates the initial success of fertilisation such that a human being might ensue from the process if carried through to full term pregnancy.

For entities created in other ways, the potential to develop to the point of appearance of the primitive streak indicates that a human being might ensue from the process, whilst excluding other entities that have no potential to develop into a human being. Recognition of potential is one of reasons often cited for giving moral regard to embryos, so that recognising this in the definition is consistent with widespread moral views.

Given the diversity in Australia of moral and religious views on the status of the embryo, this definition provides a straightforward way of arbitrating on which entities are embryos, deriving either from fertilisation or from other means, and therefore deserving of protection under legislation.

2. Permitting SCNT

Permitting SCNT recognises that there are significant moral differences between SCNT (therapeutic cloning) and reproductive cloning. The continued ban on reproductive cloning is in accord with widely expressed views on the moral repugnance of this kind of cloning. There is however, a much broader spread of views in the Australian community on the morality of therapeutic cloning. The aims of SCNT are beneficent in that the ultimate goal is to develop therapies that will decrease the burden of ill health suffered in the Australian population. Such beneficence is absent in reproductive cloning.

Further, there are distinct ways of distinguishing SCNT embryos from ART embryos that help to demonstrate why we can treat these in different ways. Embryos (a) created via SCNT and (b) created 'normally' via ART can be distinguished on at least three grounds:

1. Method of creation: (a) mature nucleus plus egg cytoplasm versus (b) sperm plus egg
2. Potential for entity so created to grow into a healthy human baby: relatively large for embryos created by union of sperm and egg, versus very small for an entity created by putting an adult nucleus into egg cytoplasm
3. Intention: in ART, embryos are typically created for reproductive purposes and have the genetic potential to grow into new and unique human beings, whereas SCNT entities are created for research aimed at developing therapeutic applications, are not implanted, and often do not have a new and unique human genetic complement.

Given the beneficent aims and the lack of similarity with ART and other reproductive embryos, it is morally justifiable to permit SCNT.

However, the moral permissibility of SCNT does not address the source of oocytes to be used for transfers. I encourage this committee to consider the circumstances under which donation for research might occur and issues that will need to be addressed in order for women to participate as oocyte donors in a manner that is fair and respectful but non-paternalistic. Relevant issues include the number of oocytes required for successful SCNT, the possible health risks to women from donation (e.g., due to hyperstimulation of the ovaries), the kinds of coercive pressures (financial and otherwise) that might operate to induce women to donate oocytes, consent processes to ensure voluntary and informed participation, and adequate oversight procedures to ensure compliance with community and regulatory standards particularly for consent. Because of the potential risks to women, women donating oocytes or other tissues for research should be offered all relevant information about the likely use of their donation, including details about likelihood of production of patentable products and profits, and whether profits will accrue to the public or private sector. Women seeking fertility treatments may be unusually vulnerable in terms of feeling dependant upon staff and technology and therefore fell obliged to consider donating eggs if requested.

3. Allowing fresh embryos that have been determined unsuitable for implantation due to the existence of disease to be used in research

At present, fresh embryos that have been identified through pre-implantation genetic diagnosis (PIGD) as unsuitable for attempting pregnancy, cannot be used for research as the consent processes require a 'cooling off' period of two weeks. As embryos unsuitable for implantation are not usually frozen, these embryos are discarded despite their potential for research. I believe that couples can give informed consent to research with these embryos without the 2 week cooling off period on the grounds that they have spent considerable time and effort in reaching the point of PIGD, and are aware of the possibility of some of the embryos being unsuitable for implantation. In these circumstances, it is not wrong to allow discussion of the fate of the embryos that will not be used for attempting pregnancy prior to the results of tests which will identify any such embryos. Allowing donation of unsuitable embryos for research allows the donating couple to retrieve some good from the process, and also allows them to express agency in ways that we usually recognise in Australia. Other couples with ART embryos that are not required for reproductive purposes have the opportunity to donate their embryos for research if they so wish; making this change in the legislation will accord couples with PIGD-identified unsuitable embryos the same options.

Please note that these comments apply to embryos diagnosed as unsuitable after PIGD. The process of judging the quality of embryos when choosing which to implant is a very inexact science, and any embryos judged as "less vigorous" on clinical grounds alone should not be considered for use in research when fresh if there is any chance that they might be considered for implantation at a later stage.

Finally, some of the key issues in the Lockhart Report have not been addressed in the proposed legislation. In particular the establishment of a stem cell bank and conditions for benefit sharing are not considered. Some of the reasons for these omissions have been explained, but in my view there is a serious ethical issue of equity that arises when tissues donated by Australians for the benefit of the Australian community (including both researchers and patients) are then used to develop commercial products for private enterprise. The products and profits from the research involving SCNT and the development of stem cell lines including a stem cell bank (should they proceed in Australia) should remain in public control, and equally available within the public healthcare system. The current climate of competition between the states for commercial biotechnology investment raises concerns that there will not be public ownership of many resources donated by Australian women for stem cell research. It is appropriate that any legislation recognises the interest of those groups who provide the basic resources for the development of potential therapeutic treatments in having access to those treatments.