Mr Elton Humphery
Secretary, Community Affairs Committee
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Legislative responses to recommendations of the Lockhart Review

Dear Mr Humphery,

Thank you for your letter inviting me to make a submission in response to the Community Affairs Committee's inquiry into the above matter. Please find below my submission, which is informed by my own research on embryo research ethics and regulation and the extensive documentation made available through the Committee's website on this matter.

I understand that the Committee intends to hold public hearings in Canberra, Sydney and Melbourne later this month. Unfortunately I will not be able to attend any of those hearings as I will be in Canada, on a research trip investigating the process of regulation of ART and embryo research in Canada. I would be happy to respond to any email requests for clarification or elaboration of any of the matters raised in my submission.

Yours sincerely,

Prof Susan Dodds

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4 October 2006
submitted by email

Given the Committee's terms of reference, this submission focuses on the two legislative proposals made available for this purpose, the Exposure Draft *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006* offered by Senators Stott Despoja and Senator Webber and the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* introduced by Senator Patterson. Each Bill seeks to give effect to some of the key recommendations of the Lockhart Review in amending the *Research Involving Human Embryos Act* (Cth 2002) and *the Prohibition of Human Cloning Act* (Cth 2002) (hereafter RIHE and PHC 2002). While there are substantial areas of similarity between the two Bills, Senator Patterson's Bill retains a number of the restrictions on ART research (specifically research that involves gamete fertilisation for research; research involving the development of embryos that contain genetic material from more than two humans; research into SCNT cloning (therapeutic clones; cloning for research); research involving "fresh" human embryos obtained from consenting donors; and research involving ART embryos that are determined by objective criteria to be inappropriate for transfer to women's bodies for development). My comments will be of three orders: first some general comments about the Lockhart Review and its recommendations and the response to those recommendations articulated in the mpconsulting report; then articulation of some principles that are relevant to legislation, especially laws containing criminal sanctions, in areas of significant ethical disagreement; and third some specific comments about remaining unclarity or infelicitous drafting in the two Bills.

Comment re the Lockhart review, its process and recommendations

Following the provisions of the RIHE and PHC Acts (2002), a review of both Acts was required by the third anniversary The Lockhart review was announced in June 2005, and was required to report by the end of December. Given the discussion papers that the Review Committee prepared, the body of national and international research that the Review Committee sought to digest, the number of submissions, and the public and *in camera* hearings held by the Committee, it must be said that the Review Committee was given precious little time to develop a response to its terms of reference. Indeed, one of the terms of reference required the Review Committee to consider any changes to "community standards" since the debate surrounding the 2002 Acts. There was no baseline and no time to conduct an appropriately framed study of Australians understanding of and acceptance of therapeutic or reproductive cloning, embryo and stem cell research. The Committee, sensibly, chose not to pretend to have met that item. Instead, it drew on its own expertise and that of the legal, ethical and scientific experts and other stakeholders that it canvassed to evaluate the arguments concerning the restrictions imposed by the RIHE and PHC Acts (2002). The recommendations of the Review reflect that temporally compressed process and the critical reflection of the Review Committee on the expert advice it received, while clearly acknowledging that there does not exist a single set of community standards obtaining in these areas. The Committee, and its late Chair, is to be commended for its efforts in developing defensible policy recommendations informed by well-articulated argument.

"Analysis of advice on developments in assisted reproductive technology and related medical and scientific research" mpconsulting report

By contrast with the approach taken by the Lockhart Review, the mpconsulting report seeks not to evaluate the state of the science, the ethical and legal arguments for restrictions on research and the impact of the 2002 RIHE and PHC Acts on the potential for the development of significant health and scientific breakthroughs. Rather it offers a very conservative approach to legislative amendment. This is conservative in the technical sense of cautioning against any changes to the status quo. The overarching principle governing this report appears to be: if a position or

argument was considered – no matter the force of the argument presented in defence of the position at the time, nor the quality of the public or parliamentary understanding of the position, nor the force of the argument presented subsequently– during the course of the 2002 debates on embryo research and cloning, then the matter appears to be deemed to have been duly considered by the legislators in framing the 2002 Acts. If a position or argument was not presented during the course of the 2002 debates, then there is no basis for a comparison of any change in the relevance of that position or argument, and again, no reason to consider that position to justify and legislative change. On such logic it would be extraordinary to find the mp consulting report to acknowledge that there could be any justification for the legislative changes recommended by the Lockhart report (or any other legislative changes following any other legislative review). I would argue that the mp consulting report should not inform legislators' consideration of the value of any recommendations made by the Lockhart review, these recommendations should be evaluated on the merits of the arguments (ie whether the recommendations are backed by sound scientific, ethical or legal reasoning and evidence).

General principle

Clarity of the scope of laws involving criminal penalty

In a pluralist democracy, legislators who seek to develop regulatory instruments in areas where there are strongly held ethical disagreements, they are pressed to develop justifications for regulating where and when they do (and not elsewhere). When law is made that creates criminal sanctions for activities that are considered to be ethically defensible by a substantial proportion of the (otherwise law-respecting) community; and where those criminal sanctions restrict activities that are likely to lead to outcomes that very many view as of great public value (alleviation of forms of infertility; enhancement of health; understanding of disease, etc), then legislators must act so as to clearly delineate the scope and intent of the law and its sanctions. Where there is genuine ethical disagreement about what is at stake, ethically, then it is valuable to distinguish what the law requires or prohibits from any particular ethical stance. The ethical differences that exist in the community regarding the moral status of embryos cannot be resolved by legal artifice, and laws that depend on a particular ethical perspective for their interpretation are likely to be found to be unjustified. For that reason one of the most important features of both Bills is that they offer a non-circular definition of the human embryo that uses objective, observable, scientific features of the development of fertilised oocytes into embryos to establish the scope of the legal provisions: there are now proposed three distinct categories: 1. gametes and other biological entities with human genetic material that have not undergone the first mitotic division nor have developed the primitive streak; 2. embryos up to 14 days of development; and 3. embryos that have either developed beyond 14 days. The licensing and criminal penalties of the RIHE and PHC Acts, once amended, ought to be able track those three categories clearly. Researchers ought to be confident (at least so long as the science supports first mitotic division and development of the primitive streak as clear identifiers) that they can predict when and whether the laws apply to their research. This removes a significant impediment to research, while respecting that the clear legal definition offered in the Bills may not fit any particular ethical view about the significance of embryos. Rather the definition identifies a relatively conservative point of human development that will not offend the vast majority of views (and people who hold them) concerning a stage or feature or physiological process establishing the moral significance of humans.

Respect for men and women who provide gametes or embryos

Both Bills are almost exclusively concerned with the status, creation, use and disposition of embryos and downplay the women and couples who provide the gametes, consent to research involving embryos or benefit from advances in ART

research. Frequently the two Bills appear to take a paternalistic approach to these men and women; and seek to relieve them of responsible decision-making. Senator Patterson's Bill (*RIHE Part 2 8 Section 8 definition of proper consent*) continues the restriction on such women or couples donating "fresh" embryos for research, because the NHMRC guidelines on consent to such donation requires as 2 week "cooling-off" period--during which time any potentially donated embryo will be frozen—thus undermining the possibility of research on early embryonic development that might shed light on a range of infertility problems. It is lamentable that the original Acts and these two Bills do not attend to the ethical, legal and medical circumstances of the men and women who provide the gametes that make this research possible to the same degree that they attend to the fate of very early embryos that will (mostly) be disposed of at the end of the research process.

Specific concerns

"Animal" throughout Scientists and many ethicists reject the distinction between humans and animals. Charles Darwin's work (and that of a vast array of evolutionary scientists) demonstrates that *all humans are animals*. The fact of our continuation of the language of humans and lesser beasts reflects a bygone (and unscientific) era of human chauvinism. More appropriate terminology throughout both Bills is to distinguish humans from "non-human animals".

Senator Patterson's Bill 6 (6) "living embryo" (line 4): there is a need for a definition of a "living human embryo" as embryonic life does not readily fit existing indicators of human life (respiration, heart beat, brain stem function, etc).

Senator Patterson's Bill 15 Offence Heritable alterations (1) (a) and (b) if it is possible for a genetic alteration to occur before as well as after the first mitotic division or development of the primitive streak, then there is an ambiguity in this section (and in the similar Offence in Section 12 of Senators Stott Despoja and Webber's Draft Bill). The ambiguity is between the gamete cell undergoing fertilisation (which might be thought to be the cell of the person who is the genetic parent of any resulting child) and the embryonic cell, which is what I assume this provision is directed towards—the cell of any resulting child (or twins etc) who has undergone a heritable genetic alteration.

Senator Patterson's Bill 16 Offence collecting a viable human embryo from the body of a woman and *Senators Stott Despoja and Webber's Bill 13 Offence collecting a viable human embryo from the body of a woman.* The idea of a "viable human fetus" is comprehensible as it refers to a human fetus at around 1000 grams that has developed to a point such that (with medical support) it is capable of surviving outside a woman's uterus. It is not at all clear what a "viable human embryo" is given that no embryo up to 8 weeks development is capable (at least in the current state of science) of survival *ex utero*. Perhaps "viability" here is intended to contrast with those ART embryos deemed by objective criteria to be inappropriate for transfer into a woman's body. Either a definition or a better term is strongly recommended here.

Senator Patterson's Bill 25A Further review of the operation of the Act (4) (c) "community standards". It is important that RIHE and PHC Acts and any amendments to them should be regularly reviewed in light of scientific developments, legal developments and evolving ethical attitudes (as is seen in the changes in attitudes towards IVF over the past 25 years), nonetheless any group responsible for such a review will need a tool or baseline or set of criteria to be able to assess "community standards", especially as it is accepted that the underlying ethical differences in attitude towards human embryos at various stages of development will very likely continue to exist.

Conclusions

Overall, the overall thrust of Senators Stott Despoja and Webber's Bill is more defensible than Senator Patterson's Bill, as it offers a more comprehensive attempt to incorporate the scientifically, ethically and legally defensible policy recommendations presented in the Lockhart Review for Amendments to the RIHE and PHC Acts 2002. Senator Patterson's Bill would have the effect of continuing many of the restrictions on research on ART and human embryonic stem cell research that currently affect all Australian researchers in this area. This conservative approach appears retrograde when one compares the legislative regimes covering such research in the UK (where creation of embryos for research and SCNT (cloning) are permitted under license, Canada and the US (it very important to remember that the US prohibitions on the development of new hESC lines only applies to publicly funded research and in the US substantially more privately funded research occurs compared with publicly funded research.

Therapeutic cloning and embryo research are ethically contentions matters and merit legal regulation. It is important to develop defensible rather than reactive regulation, given the important values that may be realised or forsaken depending on the regulatory regime and the fact of sincere ethical disagreement.