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SENATE COMMITTEE
Parliament of Australia

Legislative responses to the Lockhart review

My Background: I spent five years in the Ontario Cancer Institute, Ontario Canada, working on Cancer Models. On returning to Australia I started work on plant stem cells. We can grow a whole plant from a single plant cell and are involved in describing the cellular, molecular biology and gene-networks involved in the commitment and differentiation of these cells as they pass through different stages of development. Because the questions that we ask are in principle the same as those of the researchers using mouse or human stem cells I am also a member of the NSW Stem Cell Network and often attend their Workshops and Seminars even though I am at the ANU in Canberra. I also teach the subject to my PhD students and therefore try to keep up with the current trends and recent experimental data of this growing field of research. Thus, I have tried to maintain an understanding of the situation faced by the mammalian stem cell workers here in Australia, USA and the UK.

The Stem Cell Research Bill: I went through the original bill but my most recent update on the legislation comes from Elizabeth Finkel's book on Stem Cells (pages 92-93). The legislation "bans all forms of human cloning, therapeutic cloning or reproductive cloning. It allowed the use of surplus test-tube embryos for the production of human embryonic stem cells, but only under strict conditions and only with the consent of the donors and only frozen embryos created before April 2002 could be used". … The bill "would be reviewed in three years time with a possibility of **cancelling** the legislation", and that time is now upon us.

There are several matters that I would like to raise:
• I have re-read and studied the 54 recommendations of the Lockhart Review committee and have concluded that the whole 54 should be accepted - let me explain.

• National legislation:
Recommendation 1- totally reasonable
• Reproductive cloning:
Recommendation 2- in total agreement
• Prohibitions on developing and implanting embryos
Recommendation 3 to 11 – generally in total agreement with each but **#6** is coupled with **#17,** which I think is almost irrelevant as it will not be widely used, **#10** I have some problems with because, if I understand the recommendation properly, this could rule against the wise use of gene therapy to correct a metabolic disease.
• Creation of human embryos by fertilisation
Recommendation 12 and 13 – are reasonable and even the linkage to #15**,** should be accepted
• Use of excess ART embryos in research
Recommendation #14 -definitely in agreement should be accepted
• ART clinical practice and ART research

Recommendation 15 to 19 - each recommendation has the appropriate balance position and therefore should be accepted

• Use of fresh ART embryos

Recommendation #20 to 22 – the essence of these three recommendations is the regulation and use of "unsuitable for implantation embryos". As long as an expert body does the assessment these three recommendations should be accepted, see also #34 the NHMRC (the Licensing Committee) that recommends such a body which could/will provide such a "protective body"

• Use of human embryos created by somatic cell nuclear transfer

Recommendation - #23 and #24 for some folk these are the most contentious recommendations but the recommendations do contain the limits of such a permission so it should be accepted and with the wise use of the Licensing Committee the valuable information gained by the Community through research, training and clinical applications and the regulations will control excesses, **#24** I think is almost irrelevant because the scientific information of this suggestion is not very useful – I can think of too many scientific criticisms that I would make for its use, besides the strict limits are requested.

• Use of human embryos created by activation methods not involving fertilization of a human egg by a human sperm or somatic cell nuclear transfer

Recommendation - #25 to #27 – like as for **#s23** and **#24** these recommendations are only permitted in a regulated manner and with the wise use of the Licensing Committee the valuable information gained by the Community through research, training and clinical applications and the regulations will control excesses,

• Definition of a human embryo

Recommendation #28 – I see that the comment by Senator Stott Despoja (Schedule 1) wants an additional substitution under (b) however, I am not convinced that it is necessary, so I would argue maintain the Lockhart recommendation

• Consent arrangements for the donation of embryos

Recommendation #29 and #30 – these recommendations seems very reasonable to me and acceptable recommendation

• Egg donation

Recommendation #31, 32 and #33 – totally reasonable and should be accepted

• Licensing arrangements

Recommendations #34 to 37 – should be accepted and the NHMRC (the Licensing Committee) should be continued, strengthened and its role extended

• Monitoring powers

Recommendations #38 and #39 – both of these recommendation are reasonable so should be accepted, the community should be confident to put reliance on the Licensing Committee to do its job properly. This depends on politicians behaving without hype and fear mongering!

• Oversight of ART clinical practice and research

Recommendation #40 - Accept

• Import and export of human reproductive materials for personal use

Recommendation #41 – having had a lot to do with the quarantine regulation of biological materials the suggested recommendation is very sensible and should be accepted

• Trade and international exchange of human reproductive materials and stem cells

Recommendations #42 and #43- both are acceptable if using the approval by the appropriate authority and the quarantine regulation of biological materials is perfectly able to oversee these regulations

• Biotechnology and commercialisation

Recommendations #44 to #46 – if Australia is to be part of the international efforts on the analysis and use of stem cell biology it will have to encourage and carefully regulate a potential industry of great outcomes for human, animal and plant biology. Trade in human gametes or embryos is unacceptable but there are issues of Intellectual Property (IP) that will arise in the near future so careful thought on this set of recommendations should be made.

• **National stem cell bank**

Recommendations #47 to #49 – these are straight forward and should be accepted

• Regulation approach to legislation

Recommendations #50 to #53 – the basis of numbers **#50 and #51** really is the use of the Licensing Committee and its authorisation these should be acceptable, the **#52** is very important for authorised researchers and their future work, this recommendation must be accepted if any future progress is to be made especially for **Biotechnology and commercialisation; #53** has an important recommendation of six (6) years before the next review, given the huge variation of timing of science advances an expanded period is well warranted and the suggested 6 years should be accepted.

• Public education

Recommendation #54 – I cannot disagree but it is more than just a public education in stem cell biology, it is also about "what is science and what is the scientific method and its consequences". Currently, there is an anti-intellectual and an anti-science movement and if we are not careful the growth of **superstition** will become more influential with many negative consequences.

• I have read through the document released by the PM called **"Analysis of advice on developments in assisted reproductive technology and related medical and scientific research,** prepared by mpconsulting for the Department of the Prime Minister and Cabinet June 2006. Why any serious consultants would put their name to this document is beyond me and makes the reported comment in the press "cash for comment" have a certain ring of truth to it. Certainly no serious and thoughtful politician should take notice of the document.

There are five essential weaknesses to the document:

(1) It is an anti-abortion argument when it is supposed to be an objective analysis of progress.

(2) It is carrying out an analysis of progress when there was, I am reliably told, a delay of about 18 months after December 2002 before the permitted activities of research were able to get under way. Clearly the consultants of this document know little about science research or they would have made comment on this and recognised that with so little time to expect "great breakthroughs" is thoughtless.

(3) The document did not define "significance" therefore how can one conclude that little of significance has been achieved?

(4) How did the consultants expect rapid advances given the current Australian legislation – scientists are not mechanics!

(5) The document does not provide any evidence that they consulted with any real expert mammalian stem cell biologist; so how could the consultants really evaluate significant progress? Moreover, what are the qualifications of the consultants and what association do they have? I could not establish this from their web site or google analysis.
"Cash for comment" does sound a correct analysis of this document.

• I have tried understand and to examine the objections of people who claim an ethical position (see recorded comments to the Lockhart Committee). While in London last June (2005) I listened to a BBC radio interview with Lord Robert Winston where he questioned the positions of morality of certain pressure groups. He asked the question "what reason is there that a Roman Catholic moral position was more superior than say his as a Jewish person, or that of a humanist non-religious person, or a more mainstream Protestant person"? It seems to me that this is the crucial question for all members of the Committee. As a number of us in the research field see it, the current Federal government position is mainly that of the Roman Catholic Church via Minister Tony Abbott and that is unacceptable to many thinking people. The government position appears to be rather political than ethical, as surely we should all examine our positions and ask what right have we to **"withhold"** the development of possible cures from people based on a limited emotional view of the world that is not shared by the majority of the population. When the Committee makes a decision it should explain the ethical and moral position underpinning it. There is a lot more disgust and anger out here in the real world than most of you realise and the general public have a right to know.

• Because of the current government position on the whole stem cell legislation, we are starting to lose excellent Australian scientists to the private research institutions in the USA. Martin Pera, has gone, and I spoke to Professor Paul Simmons at the June 6 Stem Cell Meeting in Sydney and he has now gone off to a Research institution in Texas. It will not be long before we lose more young researchers to the growing effort in the northern hemisphere. Australia can ill afford to keep on losing such brains and science leadership overseas.

• The advances being made in research into adult stem cells should in no way preclude research using embryonic stem cells. I am studying the concept of stem cell reprogramming and it is clear from the research to date that we need as many comparisons as possible to work out how to go forward from a totipotent stem cell to a defined pluripotent stem cell type and how one might progress "backwards" from a pluripotent cell to a true totipotent cell. Resolution of this question could help to bypass all the future fuss over embryonic stem cells. We cannot possibly know what such research may lead to, so a comparison is very valuable.

• Finally, I want to remind you that all you can do is to slow the pace of research in this country, as new stem cell developments will go on around the world. If you are unwilling to support the 54 recommendations of the Lockhart Commission, you will be compared to the Roman Catholic Church and its treatment and banning of Galileo Galilei in the 1616-1630 period? It took them about 400 years to catch up with the real world.