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21 January, 2000

Ms C Surtees
Secretary
House of Representatives Standing Committee
on Legal and Constitutional Affairs
Parliament House
Canberra ACT 2600

Dear Ms Surtees,

Inquiry into scientific, ethical and regulatory aspects of human cloning

I have pleasure in enclosing a submission from the Academy to the above inquiry. The submission expands on the Academy's position statement and reaffirms our four key recommendations which are provided below.

1. The Academy considers that reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited. However, human cells, whether derived from cloning techniques, from ES cell lines, or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology.

2. The Academy strongly supports the recommendation of AHEC that the "Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques".

3. If Australia is to capitalise on its undoubted strength in medical research, it is important that research on human therapeutic cloning is not inhibited by withholding federal research funds or prevented by unduly restrictive legislation in some States.

4. It is essential to maintain peer review and public scrutiny of all research involving human embryos and human ES cell lines undertaken in Australia. The Academy supports the view that a national regulatory two-tier approval process be adopted. Approval to undertake any research involving human embryos and human ES cell lines would need to be obtained from a duly-constituted institutional ethics committee (IEC) prior to assessment by a national panel of experts, established by NHMRC, of the scientific merits, safety issues and ethical acceptability of the work.

A summary of the forum held on 16 September is near completion and I will arrange copies to be sent to you as soon as it is available. The Academy looks forward to working with the Committee on this very important undertaking.

Yours sincerely,

John White

John W White

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Submission to the Standing Committee on Legal and Constitutional Affairs

Inquiry into scientific, ethical and regulatory aspects of human cloning

Australian Academy of Science

27 October 1999

The Australian Academy of Science has made public its position on scientific, ethical and regulatory aspects of human cloning, outlined in the enclosed booklet (with glossary) entitled *On Human Cloning: A Position Statement*, published on 4 February, 1999. The Position Statement has the unanimous endorsement of the Council of the Australian Academy of Science. The Academy has made four recommendations regarding application of cloning technology in humans (Appendix I).

The Academy, in establishing its position on human cloning, reviewed the report of the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* dated 16 December 1998.

Therefore the Academy is pleased to respond to the House of Representatives Standing Committee on Legal and Constitutional Affairs Inquiry into the scientific, ethical and regulatory aspects of human cloning, that intends to review the AHEC report to the Minister for Health and Aged Care.

The reports of the Academy and of AHEC have several commonalities.

1. The Academy and AHEC agree that it is very important to promote informed community discussion on the risks and benefits that might flow from applications of cloning technologies. For this reason, the Academy welcomes the timely Inquiry by the House of Representatives Standing Committee on Legal and Constitutional Affairs as an opportunity to improve public understanding of this area of medical research.

   Further public debate would be encouraged if the Australian Health Ethics Committee was to undertake a formal, two-stage, public consultative process into the scientific, ethical, and regulatory aspects of embryonic stem cell research.

2. Another point of agreement relates to concerns about reproductive cloning. The Academy makes a distinction between *reproductive cloning* to produce a human fetus and *therapeutic cloning* to produce human stem cells, tissues and organs. The need for this distinction is illustrated by the scientific developments in the past year, many of which were reported at a Forum on *Therapeutic Cloning for Tissue Repair*, hosted by the Academy on September 16, 1999. The Academy considers reproductive cloning to produce human fetuses unethical and unsafe, and recommends that reproductive cloning should be prohibited. AHEC recommends that the Commonwealth Government should reaffirm its support for the UNESCO *Declaration on the Human Genome and Human Rights*, Article 11, which states in part that *practices which are contrary to human*

dignity, such as reproductive cloning of human beings, shall not be permitted.

3. A third point of agreement between the Academy and AHEC is that cloning technology is an exciting advance in medical research which has the potential to revolutionise treatment of degenerative diseases. As the Academy observed in its publication *On Human Cloning: A Position Statement*:

Cloning techniques may one day revolutionise medical treatment of damaged tissues and organs, should it become possible to use human adult cells as the starting material for growth of new tissues. At present, one human organ, skin, can be grown in the laboratory to provide self-compatible skin grafts for burns victims. The possibility of growing other self-compatible cells, such as nerve cells for patients with spinal injuries or muscle cells for heart attack victims, could one day be a reality, albeit within an unknown time-frame. That such a possibility could become a reality is suggested by the combined application of knowledge arising from three recent and significant advances in biomedical research.

These advances are

(a) the cloning of mammals from adult cells;

(b) the establishment of cultures of 'all-purpose' cells, human embryonic stem (ES) cells with the potential to grow into many different cell types; and

(c) the demonstration that human fetal nerve stem cells can develop into multiple and appropriate nerve cell types following transplantation (into experimental animals).

These findings provide new opportunities for research in cellular and developmental biology and, taken together, suggest that future possibilities may exist for self-compatible tissue and organ repair.

The possibility of partial reversal of differentiation of a person's adult cells to form regenerative stem cell types was mooted at the Forum on *Therapeutic Cloning for Tissue Repair*. The Academy recognises that this is an approach preferred, from certain religious viewpoints, to the complete reprogramming of adult cells using cloning techniques. This route will not be available until a great deal more is known about cell growth factors and their receptors, and, even then, may not be available for all types of tissue repair. Furthermore, research in one of the identified approaches (say, in ES cells) is currently the most obvious way ahead to inform research in other areas, such as in stimulation of dispersed, partially-committed stem cells.

4. Finally, the Academy and AHEC both recognise the need for regulation of research using cloning techniques in humans, so that the public can be assured that only responsible research, properly assessed on its scientific merit, on safety issues and on its ethical acceptability, will be undertaken in Australia.

Despite this general commonality between the Academy's position and the AHEC report, there are some differences with respect to human embryo experimentation and how such research is best regulated. The Academy is of the view that human cells, whether derived from cloning techniques or from embryonic stem (ES) cell lines should not be precluded from use in approved research activities in cellular and developmental biology.

In Australia at present, production of human ES cells would be approved only in exceptional circumstances under National Health and Medical Research Council (NHMRC) *Ethical guidelines,* originally prepared to ensure ethical practices in *in vitro* fertilisation (IVF) clinics. Therapeutic cloning is not permitted. For Australia to participate fully and capture benefits from recent progress in research, it may well be necessary to clarify the 1996 NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and repeal restrictive legislation in some States. This could be done in the context of establishing a national regulatory arrangement, taking into account advances in biomedical research and best practice elsewhere. The regulations should be binding on both publicly and privately-funded research activities. An appropriate two-tiered regulatory **model** is already in place in Australia, where the Gene Therapy Research Advisory Panel advises and supports Institutional Ethics Committees.

It is essential to maintain peer review and public scrutiny of all research involving human embryos and human ES cell lines undertaken in Australia. The Academy supports the view that a national regulatory two-tier approval process be adopted. Approval to undertake any research involving human embryos and human ES cell lines would need to be obtained from a duly-constituted institutional ethics committee (IEC) prior to assessment by a national panel of experts, established by NHMRC, on the scientific merits, safety issues and ethical acceptability of the work.

The Academy has recommended in our Position Statement that legislation **set limits** on research practices, such as prohibiting the cloning of human fetuses, but that details of research practice should be subject to regulation under the law. Regulation of therapeutic cloning research should take account of the rapid development of new technologies and the changing applications of those technologies. A national panel of experts, sensitive to community values and to a changing research environment, should be established. National regulation provides more consistent application of national standards and would ensure

greater accountability than individual IECs operating within varying State laws. The need for national oversight of therapeutic cloning, rather than local oversight, is crucial if the public is to be assured that any work in human stem cell research is of the highest scientific standard, is safe, and is ethically acceptable.

Several countries have recommended establishment of national regulatory bodies to license and regulate assisted reproductive treatments, including Canada (The Canadian Royal Commission into New Reproductive Technologies, 1989), the United Kingdom (under the Human Fertilisation and Embryology Authority) and the United States (draft report of the National Bioethics Advisory Commission, 1999). In Australia, the regulatory system has worked well in those States without legislation regarding assisted reproduction and embryo research, for both privately and publicly-funded clinics, as well as laboratories, guided by the standards set by the National Health and Medical Research Council. With more than 200 Institutional Ethics Committees active in Australia, there is ample evidence that regulation rather than legislation can provide the transparency and accountability that the public demands.

There is another matter on which the Academy has comment. The AHEC Report suggests the establishment of a primate research facility for a program related to cloning and its associated technologies. The Academy does not support this proposal because primate work is less relevant now than at the time of writing of the AHEC report.

Appendix I

5. The Academy considers that reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited. However, human cells, whether derived from cloning techniques, from ES cell lines, or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology.

6. The Academy strongly supports the recommendation of AHEC that the "Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques".

7. If Australia is to capitalise on its undoubted strength in medical research, it is important that research on human therapeutic cloning is not inhibited by withholding federal research funds or prevented by unduly restrictive legislation in some States.

8. It is essential to maintain peer review and public scrutiny of all research involving human embryos and human ES cell lines undertaken in Australia. The Academy supports the view that a national regulatory two-tier approval process be adopted. Approval to undertake any research involving human embryos and human ES cell lines would need to be obtained from a duly-constituted institutional ethics committee (IEC) prior to assessment by a national panel of experts, established by NHMRC, of the scientific merits, safety issues and ethical acceptability of the work.