PRIME MINISTER
CANBERRA

The Hon R J (Bob) Carr MP
Premier of New South Wales
GPO Box 5341
SYDNEY NSW 2001

- 4 APR 2002

My dear Premier

I am writing to seek your support at the Council of Australian Governments (COAG) meeting of a proposed approach to Human Cloning, Assisted Reproductive Technology (ART) and Related Matters (Agenda Item 1).

At the Council of Australian Governments meeting on Friday I will be seeking your agreement to all the recommendations of the Health Ministers' report on *Human Cloning, Assisted Reproductive Technology and Related Matters* (refer to Attachment A) except for recommendation 2 of Chapter 6 relating to the use of excess ART embryos. To ensure we meet the objective of nationally consistent bans on human cloning and other unacceptable practices being in place by June 2002, I propose that the bans take effect in Commonwealth legislation and be supplemented by nationally consistent legislation in each state and territory. It is also intended that this legislation establish a national regulatory regime in relation to the use of excess ART embryos.

In relation to the issue of the use of excess ART embryos which would otherwise have been destroyed, this is clearly a very difficult area of public policy, involving complex and sensitive ethical and scientific issues. In preparing my approach for COAG I have been assisted by consultation with scientific researchers as well as religious and community leaders. After weighing up disparate views, the Commonwealth position is that COAG agree to allow, against specifically defined criteria, research involving the destruction of excess ART embryos which would otherwise have been destroyed. The reason for this lies in the belief of many in the community that such research is the best or only way to enable Australia to remain at the forefront of research which may lead to enormous benefits in the treatment of disease.

I propose that such research should only be allowed on excess ART embryos that are currently in existence and would ultimately be destroyed. In addition, it will be required that specific permission for the use of these excess ART embryos be given by their donors. However, since science is moving quickly

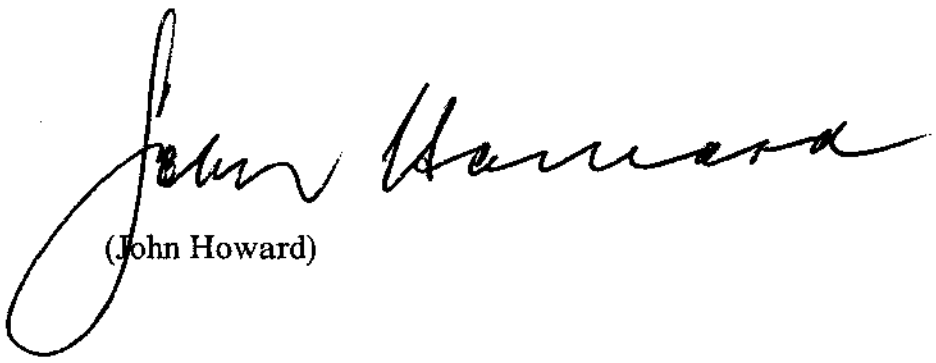
in these areas, the arrangements for research using excess ART embryos will be reviewed in 3 years time.

I also propose that this research be conducted under a regulatory regime (refer to Attachment B) in accordance with National Health and Medical Research Council and Australian Health Ethics Committee guidelines. This arrangement would be overseen by the National Health and Medical Research Council underpinned by the legislative arrangements referred to in paragraph 2 above.

In considering the Commonwealth legislation, all Government members will be allowed a free vote on this issue. As such, individual members would have the ability to propose amendments or even bring forward a private Member's Bill in this area.

I look forward to meeting with you on Friday to discuss these complex issues further. I propose that the attachments to this letter provide the basis for our discussions and that the desired outcome would see agreement to: the recommendations in the Health Ministers report at Attachment A, noting that the Commonwealth intends to enact legislation supplemented by nationally consistent legislation in each state and territory; and, the proposed approach to a regulatory regime for research uses of excess ART embryos which would otherwise have been destroyed, at Attachment B.

Yours sincerely



(John Howard)

ATTACHMENT A

RECOMMENDATIONS - REPORT ON HUMAN CLONING, ASSISTED REPRODUCTIVE TECHNOLOGY (ART) AND RELATED MATTERS

A nationally consistent ban on the cloning of a human being[1] (Chapter 3)

It is recommended that COAG:

1. Agree the following wording as the basis for a nationally consistent ban on the cloning of a human being:

   1.1 A person must not:

   a) create, or attempt to create, a human clone by means of a technological or other artificial process; or

   b) cause a human embryo clone to be placed in the body of a human or animal for any period of gestation.

   1.2 For the purposes of establishing that a human clone or human embryo clone is a genetic copy:

   a) it is sufficient to establish that the set of genes in the nucleus of the human cell has been copied; and

   b) it is not necessary to establish that the copy is an identical genetic copy.

   1.3 It is not a defence that the human clone or human embryo clone did not or could not survive.

   "human clone" means a human that is a genetic copy of another living or dead human.

   "human embryo clone" means a human embryo that is a genetic copy of a living or dead human.

   "embryo" is a developing organism from the completion of fertilisation, or initiation of development by any other means, until 8 weeks when the organism becomes known as a fetus.

[1] It is important to read this prohibition in conjunction with the proposed prohibition on the creation of embryos for purposes other than assisted reproduction by processes other than the fertilisation of a human ovum by a human sperm, as discussed in Chapters 4 and 6.

Regarding nationally consistent regulation of certain unacceptable practices (Chapter 4)

It is recommended that COAG:

1. Agree that the following practices are unacceptable and should be prohibited in Australia[2]:

    1.1 A person must not create or develop an embryo outside the body of a woman:

        a) for purposes other than assisted reproduction; or

        b) by a process other than the fertilisation of a human ovum by human sperm.

    1.2 A person must not create or develop an embryo for assisted reproduction that contains genetic material from more than 2 people.

    1.3 A person must not create or develop an embryo for assisted reproduction that uses any precursor cells of eggs or sperm from an embryo or fetus.

    1.4 A person must not maintain an embryo outside the body of a woman after the 14th day of its development excluding any time in which its development has been suspended.

    1.5 A person must not alter the genome of a cell of a human being or in vitro embryo such that the alteration is inheritable.

    1.6 A person must not conduct embryo flushing.

    1.7 A person must not:

        a) create or develop a hybrid embryo; or

        b) place a hybrid embryo in the body of a human or animal for any period of gestation.

        "Hybrid embryo" means a single living organism which has a mixed genetic origin as a consequence of combining cells derived from humans and other species.

    1.8 A person must not:

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[2] Please note that all of the prohibitions reflected in (Chapter 4) 1.2-1.9 must be read subject to 1.1. - 1.1 bans the creation or development of a cloned embryo to any stage. The ban on human cloning prohibits the implantation of a cloned embryo in a woman (refer Chapter 3)

a) place a human embryo in an animal or in any human body cavity other than the female human reproductive tract; or

b) place an animal embryo in a human for any period of gestation.

1.9 A person must not give or offer valuable consideration to any person for donation of gametes or embryos of that person or of any other person.

"Valuable consideration" includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.

2. Agree that the prohibited practices be comprehensively reviewed within 3 years of nationally consistent legislation taking effect, taking into account changes in technology, the potential therapeutic uses for such technology and any changes in community standards.

A nationally consistent approach to research involving human embryos (Chapter 5)

It is recommended that COAG:

1. Agree that research involving human embryos should be regulated through nationally consistent legislation.

2. Agree that the following principles should underpin nationally consistent legislation:

2.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally consistent standards;

2.2 the nationally consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted (that is, the "rules" to be observed by researchers undertaking work with embryos) and should be based on NHMRC guidelines as devised by AHEC;

2.3 these national standards should be applied consistently throughout Australia, recognising that jurisdictions may use different mechanisms to establish that proposals comply with the national standards;

2.4 the system should provide for public reporting of research involving embryos so as to improve transparency and accountability to the public; and

2.5 the system should enable appropriate monitoring of compliance with the national standards and provide legislated penalties for non-compliance.

3. Agree that there is a range of legislative options that could meet these principles including systems of accreditation, licensing or mandating of compliance with the revised AHEC guidelines.

A nationally consistent approach to the development and/or use of embryos for the derivation of stem cells (Chapter 6)

It is recommended that COAG:

1. Agree that research with existing stem cell lines be permitted to continue in Australia subject to observance of conditions set by NHMRC/AHEC.

2. Agree that research and possible therapeutic applications which involve the destruction of excess IVF embryos (or which may otherwise not leave the embryo in an implantable condition) be permitted in exceptional circumstances, as described in revised NHMRC/AHEC guidelines, and subject to close regulatory oversight (as detailed in Chapter 5).

3. Agree that the ban on the development of embryos for purposes other than for assisted reproduction be maintained and reviewed within 3 years taking into account the implications for therapeutic use of embryonic stem cells (as detailed in Chapter 4).

Relating to a nationally consistent approach to ART (Chapter 7)

It is recommended that COAG:

1. Agree that RTAC accreditation should provide the basis for a nationally consistent approach to the oversight of ART clinical practice in Australia, noting that compliance with the NHMRC/*AHEC Ethical Guidelines on ART* are a key requirement of RTAC accreditation.

2. Agree that individual jurisdictions may choose to mandate RTAC accreditation in legislation or supplement requirements for RTAC accreditation with an additional layer of oversight (for example, through a system of licensing or accreditation of ART service providers).

3. Agree that non-legislative measures should be implemented to improve clarity regarding the role of HRECs in relation to innovative practice and to increase public reporting of research and innovative practice (as detailed in Chapter 5).

ATTACHMENT B

Regulatory regime criteria for research uses of excess ART embryos

Governments agree to put in place a strict regulatory regime under Commonwealth legislation supplemented by nationally consistent state and territory legislation and administered by the National Health and Medical Research Council as the national regulatory and licensing body. The National Health and Medical Research Council would issue a licence for a person to use an excess embryo from an assisted reproductive technology program for research or therapy that damages or destroys the embryo. A licence would only be issued where that project has the approval of an ethics committee established, composed and conducted in accordance with National Health and Medical Research Council guidelines, and that the approval is given on a case by case basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;

- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;

- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the ethics committee and the national licensing body;

- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to the specific form of research for each embryo used and that the embryo had been created prior 5 April 2002;

These regulations should be reviewed within 3 years.