Marie Kawaja
Secretary
House of Representatives Standing Committee
on Legal and Constitutional Affairs
Parliament House
CANBERRA, ACT 2600

14 February, 2000

Dear Ms Kawaja,

**Re: Inquiry into the scientific, ethical and regulatory aspects of human cloning**

Thank you for inviting me to make a submission to the Standing Committee prior to my attending the public forum to be held on March 29, 2000. As you know, I was asked to provide comments to the Australian Health Ethics Committee of NHMRC about the current status of cloning technology as part of the consultation process in development of the AHEC discussion paper published in December 1998.

My submission to AHEC, dated 11 August 1998, is attached as an 'exhibit' for the Standing Committee's information. It summarizes my views on what I consider to be the main ethical issues. I would draw the Standing Committee's attention to the following points:

- There are compelling reasons to permit research involving cellular cloning techniques to develop methods of producing histocompatible cells, tissues and/or organs for the treatment and prevention of disease and alleviation of human suffering.

- I believe cellular cloning technology would be best regulated by enhanced NHMRC guidelines rather than by proscriptive legislation.

- Attention to semantics is crucial if we are to promote informed public debate. My arguments made to AHEC are amply borne out by many of the submissions made to the Standing Committee. Though currently popular, the terms *'reproductive cloning'* and *'therapeutic cloning'* are problematic, and I would prefer to see them abandoned.

- I cannot see any justification for cloning intact human individuals for purposes of reproduction.

## Current NHMRC guidelines

The existing *Ethical Guidelines on Assisted Reproductive Technology* produced by AHEC and issued by NHMRC in 1996, section 11 ("Prohibited / unacceptable practices") includes:

> *"11.2 Experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals."*

I was a member of AHEC when this section was drafted. At that time, the possibility of cloning intact human individuals by somatic-cell nuclear-transfer was not anticipated. However, the intent of the sub-section was to proscribe the use of cloning techniques for reproductive purposes. In the light of recent developments, a more explicit rewording of this section would be appropriate.

## Disadvantages of proscriptive legislation

The understanding of cellular differentiation, tissue and organ development, and genetic regulatory mechanisms is a very rapidly evolving area of biological research. It is entirely within the bounds of possibility, if not probability, that within the next decade technical advances will render obsolete many of the moral objections raised in the submissions to the Standing Committee. Furthermore:

- legislation lacks the flexibility required to respond rapidly to new developments;
- legislation may be 'hijacked' — i.e. unduly influenced by narrow sectional interests with disproportionate political influence;
- although legislation should reflect 'community opinion', this can be seriously distorted by sensational, misleading or poorly informed media reports;
- once in place, legislation can be very difficult to change.

## The existing regulatory system

The disadvantages of guidelines generally are well recognized:

- they have no direct legal authority;
- compliance is voluntary;
- they cannot be enforced by the courts;
- there is no legal sanction.

However, these are balanced by their advantages:

- flexibility in specific circumstances;
- responsiveness to rapidly changing technology;
- accurate reflection of community and professional values and expectations;
- they can be enforced indirectly.

**How can the existing regulatory system be strengthened?**

(1) AHEC Ethical Guidelines on Assisted Reproductive Technology (ART)

- In the *Background* section of the 1996 ART guidelines (page v) it is stated that:

> *"The practice of ART involves social issues of eligibility, surrogacy, consent for posthumous use, genetic diagnosis and selection and gene therapy, and storage of gametes and embryos. These are issues that are beyond the remit of AHEC in relation to medical research."*

Although these are labeled as "social issues", they are in fact *ethical* issues, and ethics committees responsible for oversight of ART activities have had to grapple with them on a regular basis in the absence of formal guidelines.

There is no specific requirement for AHEC to confine its considerations narrowly to *research* ethics. Indeed, in the preceding paragraph of the *Background* to the ART guidelines this is clearly stated:

> *"It has been argued that research into ART should be subject to more stringent ethical constraints, and stricter control mechanisms, than those which apply to routine clinical practice in this field. Some of the submissions called for such a clear distinction between research and clinical practice. However, in many areas of clinical practice this distinction is difficult to make. In the area of ART there is a broad overlap between research and clinical practice. These guidelines address innovations in clinical practice as well as research."*

Moreover, in the last triennium AHEC did in fact produce two sets of guidelines it previously considered to be "… beyond the remit of AHEC …".[1,2]

Thus, there is no reason why AHEC could not revise the ART guidelines so as to extend and strengthen them, as outlined below.

- Section 2 of the 1996 ART guidelines ("Accreditation and approval processes") outlines the role of Institutional Ethics Committees (IECs) in approving new treatment methods and innovations in ART practice. This section should be extended and strengthened as follows:

  - The relationship between the IEC and the Reproductive Medicine Unit (RMU) conducting ART procedures should be clearly defined. This is necessary so as to ensure that ethical scrutiny is conducted at arm's length by an IEC that is independent of the RMU. Such independence is particularly important for ethical oversight of RMUs operating in the private sector.

[1] Guidelines for Ethical Review of Research proposals for Human Somatic Cell Gene Therapy and Related Therapies. NHMRC, 1 January, 2000.
[2] Guidelines for Genetic Registers and Associated Genetic Material. NHMRC, 1 January, 2000.

- The IEC should be required to review *all* clinical and research practices conducted in a RMU. An IEC can only review what is put before it. Under the present guidelines, RMUs have the discretion to define 'innovative practices' as they see fit, and thereby to evade ethical scrutiny when it suits them.

- Suitable sanctions for non-compliance should be included. The most appropriate would be withdrawal of accreditation.

(2) Review of the RMU accreditation process

At present, the Reproductive Technology Accreditation Committee (RTAC) carries out accreditation of RMUs. This is a committee of the Fertility Society of Australia (FSA), the professional association to which practitioners in this field belong.

I believe self-regulation is inappropriate in the field of ART. Whilst it is entirely proper — necessary even — for the FSA to be *represented* on any RMU accrediting body, such a body should be completely independent of the professional association to which those being accredited belong. Otherwise there will always be opportunities for 'special pleading', favored treatment or 'you-scratch-my-back-and-I'll-scratch-yours" arrangements within the professional network. A combination of the profit motive and the intense competition between RMUs operating in the private sector adds to the moral hazard.

Prescriptive legislation in this area may be useful.

I would be pleased to elaborate on the above points or any other issues the Standing Committee may wish to explore at the public forum.

Yours sincerely,

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