# Consumers' Health Forum
# Position Paper on Human Cloning

**Prepared for the**
**House of Representatives Standing Committee on Legal and Constitutional Affairs**

*Inquiry into Scientific, Ethical and Regulatory*
*Aspects of Human Cloning*

## Introduction

The Consumers' Health Forum (CHF) is a national consumer organisation that represents consumers on health care issues. It provides a balance to the views of governments, service providers, insurers and other health professionals. Over the last twelve years CHF has been active in contributing to consumer oriented policy in many areas, including health financing, chronic pain management, mental health, rational prescribing of medicines and consumer rights.

CHF is pleased to provide this draft position paper to the *Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning*. It responds to the recommendations contained in the Australian Health Ethics Committee's (AHEC) report to the Minister for Health and Aged Care of 16 December 1998 and presents the issues in the same order as they are presented by those recommendations. (The recommendations are provided at Attachment A.) CHF has a strong position regarding consumer involvement in decision making, in both broad research priorities and the approval of specific projects.

This paper is a consultation draft currently being discussed by CHF member organisations. In developing it, CHF has drawn on its past consultations and recommendations to various inquiries. CHF continues to consult with its members in preparation for its appearance at the public hearing.

The paper uses the term 'reproductive cloning' in discussing cloning for the purposes of creating a human being and 'therapeutic cloning' to mean the use of cloning technology in producing human stem cells, tissues and organs, following the definitions used by the Australian Academy of Science (AAS). [1]

## Reproductive cloning

CHF believes that reproductive cloning is ethically unacceptable and should not be permitted. CHF is strongly of the view that technology should be used for the advancement of human kind and it is difficult to see how reproductive cloning could contribute to human advancement. Disability and indigenous communities, in particular, are concerned that developments in gene technology promote a narrow view of 'normality', rather than valuing diversity. For example, Christopher Newell[2] wrote:

> *I want to emphasise the fundamental importance of promoting therapy which promotes the human rights of all of us, founded upon human dignity. This requires the affirmation of difference ...*

> *... the new genetics may actually serve to further the oppression already experienced by those who identify, and are identified, in society as having disability and difference.* (p. 59)

CHF also took into account the comments of the AAS and the Murdoch Institute for Research into Birth Defects, which both considered that reproductive cloning would be likely to be medically unsafe.[3] In regard to the potential for reproductive cloning to avoid genetic disorders, CHF notes the Murdoch Institute's conclusion 'that there are no circumstances where there is a medical reason for reproductive cloning'.[4]

Some commentators in the United States have used an argument based on the 'right to procreate' to support the development and use of reproductive cloning to assist infertile people to have biologically related children.[5] CHF recognises that some infertile health consumers in Australia may support the introduction of reproductive cloning procedures for this purpose. However, on balance, CHF considers that the risks involved with reproductive cloning (medical, psychological and social) outweigh any potential benefits — especially given that there are likely to be significant improvements in other procedures to assist infertile people to have biologically related children before reproductive cloning could be proven to be safe and effective.

*Draft CHF position: CHF supports AHEC's Recommendations 1 and 2.*

**The need for national consistency**

CHF agrees with many other submissions (including AAS, the Murdoch Institute and the Australian Medical Association[6]) that regulation of research using human embryos is a national issue. Commonwealth leadership is required to ensure national consistency. This can be achieved either through uniform legislation adopted by the Commonwealth and all States and Territories, or through Commonwealth legislation giving the Commonwealth the pre-eminent role. At the least, uniform State and Territory legislation should be implemented to bind both public and private researchers.

CHF supports the recommendation of the AAS for a two-tiered approach, under which projects approved by Institutional Ethics Committees (IECs) and Research Ethics Committees (RECs) would then be assessed by a national panel of experts to determine the scientific merits, safety and ethical acceptability of the work. Given the current inability of most IECs and RECs to effectively take account of consumer interests (see below), any such 'national panel' should include consumer representatives nominated by the organised consumer movement. The panel should also be required to undertake further consultation with any group which may be directly affected by the specific project under consideration.

*Draft CHF position: That there should be uniform national legislation governing human embryo research. Consistency should be ensured through a process of review at the national level, including effective consumer representation and consultation.*

**Consumer involvement in research policy and practice**

CHF is concerned that research priorities too often appear to be driven by the professional interests of researchers and the potential for technological breakthroughs

rather than improvements in the health and wellbeing of the community. CHF has consistently argued for increased consumer involvement in decision making about health and medical research priorities and practices.[7] In particular, CHF's submission to the *Health and Medical Research Strategic Review* (Wills Review) in April 1998, recommended that:

> *The Review should recognise the various levels of consumer involvement in relation to health research and recognise the need for cultural change within organisations such as NHMRC to facilitate the acceptance of an active role for consumers by the research community.*

The submission listed the areas in which consumers should be involved, including (but not restricted to):

- allocating resources to research
- identifying important research questions
- decisions about funding or approving individual research projects
- ensuring ethical standards are maintained.

The first three points are particularly important in an environment of scarce resources, and where a significant proportion of research funding is provided by governments. The last two points reflect the importance of involving consumers in processes to ensure the ethical conduct of research — both before projects are undertaken and in assessing outcomes.

### *Allocating scarce health and medical research funding*

Therapeutic cloning has significant potential to improve the health of people who are suffering, or will potentially suffer, from a broad range of medical problems. From the point of view of these consumers, continued research in this area is highly desirable. However, in an environment of limited resources, it is not only the absolute merit of particular projects which needs to be considered, but also their relative potential for promoting improved health outcomes for all Australians.

In 1999, CHF undertook consultations with its members to establish their views on strategic health and medical research priorities. While different groups obviously had different priorities, there was concern overall about poor utilisation of medical research findings and that too little weight is given to 'low-tech' research which can significantly improve quality of life. CHF concluded that more work should be done to ensure positive research findings actually result in positive health outcomes through the development and implementation of best practice guidelines. The term 'health and medical research' needs to be interpreted broadly to include, and give a greater priority to, work on practical implementation and sociological factors. In its submission to the Wills Review, CHF recommended the adoption of the term 'health research and development' to reflect this broader interpretation.

Research into the use of therapeutic cloning procedures is very much 'state of the art' medical research. While this research has the potential to extend and improve many lives, it is important that it is not undertaken at the expense of lower technology (and significantly cheaper) research, simply *because* it is cutting edge — it is certainly no

panacea for all the ills of the world. Furthermore, there is a need to recognise that, despite Australia's outstanding record in the research field, it is still a relatively small country and cannot be expected to be play a leading role in every major technological development.

In addition, the general community appears to have very little knowledge of the potential benefits and risks associated with cloning technology. It is crucial that this be redressed so that consumers may participate fully in what will no doubt be an ongoing debate over the value of such technology.

*Draft CHF position: Based on its past consultations, CHF sees no compelling reason to withhold Commonwealth funding for research into or using therapeutic cloning. For the purposes of allocating funding, however, this research should not be treated separately from other health and medical research, but should be funded only where it reflects Australia's overall research priorities, developed with consumer input.*

*In order that consumer input into funding priorities can be well informed, CHF supports Recommendation 4 of AHEC's report, that the Minister for Health and Aged Care encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.*

***Consumer involvement in maintaining ethical standards***

In August 1998, CHF provided a submission to AHEC commenting on the *Draft Statement on Ethical Conduct in Research Involving Humans*. In its submission, CHF stated that the existing practice of recruiting unaffiliated lay people to serve as consumer representatives on IECs and RECs fails to offer consumers an effective voice on such committees. Whilst lay people may have a strong grasp of consumer interests, this is by no means certain, as they do not necessarily have the benefit of links to and support from the organised consumer movement which would allow them to have access to the opinions of a broad range of consumers.

Unfortunately, these concerns have not been reflected in the final version of the *National Statement on Ethical Conduct in Research Involving Humans*[8], released in 1999. The document specifically states that members of Human Research Ethics Committees (HRECs) 'are appointed for their expertise and not in a representative capacity' (p. 16). Further:

> The institution or organisation may recruit members for an HREC in such a manner and shall appoint them for such a period and on such terms and conditions as it determines (p. 16).

With regard to lay people, the *Statement* says these should 'preferably [be] from the community in which the institution or organisation is located' (p. 15). This provides no means of ensuring that lay people on IECs and RECs can effectively represent the interests of any group which will actually be affected by the research proposals being considered, let alone the broader community. CHF's concern over this issue is supported by studies which have found that 'consumer representatives' on RECs usually wield far less influence than other members of the committee and are susceptible to direct or indirect co-option.[9]

In its submission on the *Draft Statement*, CHF recommended that:

- *RECs be required to recruit health consumers with experience in consumer advocacy who, through membership of a consumer organisation, are accountable to a consumer constituency;*
- *protocols for research that involve people from particular communities or who have specific conditions or disabilities must ensure that people from within those communities participate in assessing the ethical aspects of the research; and*
- *measures must be put in place to support consumer representatives and assist them to fulfil their role appropriately.*

CHF considers that implementation of these recommendations is crucial in ensuring that consumer confidence in health research is maintained in light of the increasing ethical dilemmas introduced with cloning technology.

*Draft CHF position: That CHF's recommendations made to AHEC with regard to consumer representation on IECs and RECs in the context of the* Draft Statement on Ethical Conduct in Research Involving Humans *be implemented, and that these conditions apply to all IECs and RECs.*

**Conclusion**

While CHF sees the potential benefit in research involving therapeutic cloning, it is important that any such research is undertaken only where it reflects Australia's overall health research priorities. Consumers must have input into determining these priorities through effective representation at all levels.

The real possibility that technology will soon be available to clone human beings has brought the issue of ethical research to prominence in the minds of consumers. Above all, consumers are concerned to ensure that they, through their legitimate representatives, are actively involved in determining the guidelines and boundaries of research.

Further information is available from:
Rachel Stephen-Smith
Policy Development Adviser

Matthew Blackmore
Executive Director

Consumers' Health Forum of Australia Inc.
PO Box 52
LYONS ACT 2606

Tel: (02) 6281 0811
Fax: (02) 6281 0958
E-mail: info@chf.org.au
Website: www.chf.org.au

14 March 2000

**Attachment A**

AHEC Recommendations

**Recommendation 1**
The Commonwealth Government, through the Minister for Health and Aged Care, should affirm its support for the UNESCO Declaration on the Human Genome and Human Rights, in particular Article 11, which states that:

*Practices which are contrary to human dignity, such as reproductive cloning, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in determining, nationally or internationally, appropriate measures to be taken to ensure that the principles set out in this Declaration are respected.*

**Recommendation 2**
Noting that Victoria, South Australia and Western Australia have legislation regulating embryo research and prohibiting the cloning of human beings, the Minister for Health and Aged Care should urge the other States and Territories to introduce legislation to limit research on human embryos to the principles set out in Sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*.

**Recommendation 3**
Noting that there are statutory authorities established in Victoria, South Australia and Western Australia which consider and may approve human embryo research under strict conditions, the Minister for Health and Aged Care should urge the remaining states and Territories to establish similar statutory authorities with power to regulate research on human embryos according to the principles set out in Sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*

**Recommendation 4**
The Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks from the development of cloning techniques.

---

[1] Sub 79, p. 3.

[2] Newell, C. 1999, 'Critical Reflections on Disability, Difference and the New Genetics', *Goodbye Normal Gene: Confronting the genetic revolution* (O'Sullivan, G., Sharman, E. and Short, S. – Eds), Chapter 6, pp. 58-74.

[3] Sub 79, p. 3 and Sub 97, p. 2.

[4] Sub 97, p. 1.

[5] Robertson, J.A. 1998, 'Human Cloning and the Challenge of Regulation', *The New England Journal of Medicine*, Vol. 339, No. 2, 9 July.

[6] Sub 16.

[7] For example: Submission to AHEC's review of the *Draft Statement on Ethical Conduct in Research Involving Humans*, August 1998; Response to the *Preliminary Report of the Health and Medical Research Strategic Review* (Wills Review), March 1999.

[8] Australian Health Ethics Committee of the National Health and Medical Research Council 1999, *National Statement on Ethical Conduct in Research Involving Humans*.

[9] McNeill, P.M., Berglund, C.A. and Webster, I.W. 1994, 'How much influence do various members have with research ethics committees?', *Cambridge Quarterly Journal of Healthcare Ethics*, Special Section: Research Ethics, No. 3, pp. 522-532.