

Review of the

National Health and Medical Research Council
Australian Health Ethics Committee's Report Entitled

*Scientific, Ethical and Regulatory Considerations
Relevant to Cloning of Human Beings*
dated 16 December 1999

Submitted to the

House of Representatives Standing
Committee on Legal and Constitutional
Affairs

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

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on 30 September 1999

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1. EXECUTIVE SUMMARY

The “*Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*” report (the report) was clearly written from a technical perspective. And the outcomes stated in the report – the recommendations and resolutions – reflect this technical perspective.

I found that report provided a wealth of information about cloning techniques and related subject-matter, but failed to provide any guidance about how our society might deal with the complex issues that must inevitably follow genetic research.

I take issue with the Committee when it assumes that decisions about human cloning can be made only by scientists “... *with the technical competence to do so.*”

This assumption permeates the report, and may well be the reason that:

- There is almost no information about the social impact of genetic research; and
- The report is narrowly focused, even though its Terms of Reference invited a wide-ranging report.

To illustrate my points, I have reviewed Chapters 3, 4, 5 and 6, and Appendix 1. I have followed this with a conclusion and summary.

Many of the recommendations in the report lay outside the “Recommendations” chapter, and I have included a table to show their locations in the report.

My conclusion includes a high level diagram for a “Consultation Model” – a model that could be used to allow our society to come to a majority view about human cloning and related genetic research.

I am certainly not arguing the case for human cloning. I am arguing a case for providing a framework for the research that our society will accept.



2. TERMS OF REFERENCE

**House of Representatives Standing
Committee on Legal and Constitutional
Affairs**

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

Terms of reference

The Committee shall review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* dated 16 December 1998.

3. INTRODUCTION

The “*Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*” report (the report) was clearly written from a technical perspective. Although it is dense and jargonistic, I was able to work my way through it and understand what was being said. And when looking at the technical aspects of cloning, this is of course, a perfectly valid approach.

However, the outcomes stated in the report – the recommendations and resolutions – are another matter. I do not accept the concept of the scientific community assuming the role of spokesmen for our society on a particular issue – based largely on their scientific knowledge.

For example, in Chapter 2.1 of the report, we see:

“... proposals to produce new human individuals with a postnatal existence have been almost universally disavowed as unjustifiable and unethical by scientists with the technical competence to do so.”

No, I’m certainly not arguing a case for the cloning of human beings, but I reject the argument that questions of justification and ethics in this debate are the domain of suitably qualified scientists alone. In fact, the report clearly demonstrates the shortcomings associated with this approach. The technical sections of the report are packed with information – they represent the collective expert knowledge of the authors. By comparison, some of the other sections of the report (especially the chapter containing the recommendations) are extraordinarily weak and superficial.

In part, that is because:

- The recommendations are stated in three locations within the report, and some of the most definite of them lay outside the “Recommendations” chapter; and
- While the report “considers” various aspects of human cloning, it comes to few conclusions about it, and therefore has little to say about how our society might deal with it.

A table on Page 12 shows the locations of the recommendations.

To illustrate my points, I have reviewed Chapters 3, 4, 5 and 6, and Appendix 1. I have followed this with a conclusion and summary.



4. CHAPTER REVIEWS

4.1 Review of Chapter 3

“CHAPTER 3 - ETHICAL ISSUES

Introduction

3.1 It is sometimes assumed that ethics is either a matter of individual preference or that it is always relative to the conventions of a particular society. Ethical issues can be extremely difficult and challenging and in an important sense they are irreducibly personal. None the less the assumption which informs this chapter is that ethics is something about which we can reason. Its specific subject matter concerns how we ought to live as individuals in a society. It is true, however, that there is often plenty of room for disagreement in the analysis and resolution of ethical issues. The aim of this chapter is to identify, in relatively summary form, a series of ethical issues associated with human cloning.”

This chapter is rich in detail about the ethical issues associated with human cloning – and it covers a lot of ground. But the summary does not set out the choices that we face, or the decisions that we must make. Even the final sentence – which is as close as the report gets to making a statement about the issue – is written in the passive voice.

“3.33 *Overall, it has been suggested that the more convincing, weighty and cogent arguments support constraints on the use of cloning techniques which involve human embryos.”*

I found it interesting to go back to the NHMRC *Ethical guidelines on assisted reproductive technology* (ART), (the Guidelines) Section 6 *Research on embryos* which commences with:

“Research involving early human embryos raises profound moral and ethical concerns. There are differences of opinion amongst Australians regarding the moral status of the human embryo, particularly in its early stages of development.”

And a little later:

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“These differences of opinion were understood and reflected in the discussions which led to the development of these guidelines. At the present time these differences cannot be resolved.”

This Section of the Guidelines (and Section 11) form part of the recommendation about the legislative framework in the report.

In the Guidelines, we see that the “[moral and ethical] *differences cannot be resolved*”, and in the report we see a lot of material about ethical issues – but only a hesitant attempt to arrive at a conclusion. It seems unlikely that the moral and ethical questions about human cloning are going to get any easier, and that is why we need a framework that will allow our society to come to a majority view about these issues. I don’t think we will be able to use the word “consensus” – opinions are going to be strongly held. But I don’t think it is helpful for the report to say that the issues cannot be resolved and that is what the Committee is continuing to recommend. Especially when the introduction to this chapter says “***None the less the assumption which informs this chapter is that ethics is something about which we can reason***”. If we can reason about it, we can come to a majority view about it.



4.2 Review of Chapter 4

“CHAPTER 4 - AUSTRALIAN LEGISLATION AND GUIDELINES RELEVANT TO CLONING IN EXISTENCE AT NOVEMBER 1998

Introduction

4.1 This chapter discusses current State legislation and NHMRC ethical guidelines⁵⁹ governing research which deal directly or indirectly with human cloning. The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia also issues a Code of Practice for accreditation of all IVF clinics.”

The report sets out the current stance taken by each of the States and Territories. It includes a substantial amount of analytic material, but fails to draw any conclusions. The recommendations that flow from this chapter are weak when considering the information presented in the chapter.

Summary of the information about legislation presented in the chapter

State	Legislation in place	Concerns expressed about the legislation	Approvals available for specific projects
Vic	Yes		Yes
WA	Yes		Yes
SA	Yes	Yes	Yes
NSW	Proposed		

The other States and both Territories are covered by the NHMRC *Ethical guidelines on assisted reproductive technology (ART)*. Presumably *all* States are covered by these guidelines. The report itself does not indicate which has precedence – a piece of State legislation or the ART guidelines – but Section 1.1 of the Guidelines states that:

“In those States where there is specific legislation regulating assisted reproductive technology (ART), compliance with provision of the statutes must be observed. Where both the State law and the guidelines apply, the State law prevails.”

The report notes two important points:

1. The relevant legislation is not consistent among the States.

“4.3 The definition of cloning in the three States which have relevant legislation is not consistent.⁶⁰ The importance of clearly defining this term will be of great importance

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in ensuring adequate regulation of this expanding area of science.”

Although the report states that: “... *the AHEC considers that it is unsatisfactory to have variations between the States and Territories on important issues such as embryo experimentation and the application of cloning techniques to human parts such as DNA and cells.*” (At 1.20 Page 5); it makes no comment on how this might be addressed.

One example of a co-operative approach between the Commonwealth and all the States is company law. A uniform set of company law was introduced in 1961, and a National Corporations Law was introduced in 1991. In this case, the States agreed that the issue was important enough to warrant a National approach. Embryo research and cloning techniques would surely fall into a similarly important category.

2. The Guidelines are simple that – guidelines.

“4.14 Although infringement of their provisions is not a legal offence, sanctions for Infringement usually involve loss of access to research funds from the fund managed and administered by the Council or publication of the names of infringers in Parliament.”

“4.15 ... A practical requirement of note is that "the recognition that any experimentation and research involved in these technologies should be limited in ways which reflect the human nature of the embryo ...”

The impact of these points is not reflected in the recommendations that flow from this chapter.



4.3 Review of Chapter 5

“CHAPTER 5 - INTERNATIONAL LEGISLATION AND GUIDELINES RELEVANT TO CLONING IN EXISTENCE AT NOVEMBER 1998

This chapter considers overseas regulations which have been introduced as a response to widespread and unequivocal international concern about the possible applications of cloning processes to produce an identical human being.”

The report then sets out the position taken by a number of states and organisations (the United Nations, and the United Kingdom, for example). However, there is precious little comment about each model, and there is no comment at all about the relative values of the different models. Neither does the report consider which model might be suitable for Australia.

Yes, the material in this chapter agrees with its chapter title. But what’s the point if it doesn’t go anywhere?

We need an analysis of those models. That analysis must be within the context of *our* society’s expectations. And I don’t think that analysis is going to be provided by genetics scientists – it’s going to need input from people who can tell us about the likely social consequences of these models.



4.4 Review of Chapter 6

“CHAPTER 6 – RECOMMENDATIONS AND RESOLUTIONS

The following recommendations and resolutions are made in respect of an appropriate regulatory framework and in relation to allied matters.”

4.4.1 Recommendations

The recommendations lack force and imagination – they are not likely to generate the attention and action that the subject warrants, and that we as a society need. In most cases, the recommendations do not convey any sense of the magnitude of the issues. The report itself contains very few pieces of concrete guidance, and yet the recommendations do not provide any advice on a suitable working environment that might be used to further explore these issues.

For example;

Recommendations 2 and 3 deal with the legislative framework.

The report raises a number of concerns about the current arrangements. Not the least of which is the differing approach being taken by individual Australian States. In this case, the Committee *had* the information, but chose not use it in the recommendations. This recommendation opts for an extension of the existing arrangements – without qualification of any kind.

Recommendation 4 deals with informed community discussion.

The recommendation suggests that the Minister “*should encourage and promote informed community discussion*”. **But the report is** bereft of ideas about how this might be done, how our society can participate in this discussion, and what it should expect from that discussion.

4.4.2 Other Recommendations

The recommendations in this report are stated in three locations – and some of the most definite of them lay outside the “Recommendations” chapter. The following table shows where the recommendations are located.

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Table showing the location of the recommendations in the report

Chapter	Sub-heading	Paragraph	Topic
1	Response to Terms of References 5 & 6	1.20 Page 5	Introducing uniform legislation in all States and Territories.
1	Response to Terms of References 5 & 6	1.21 Page 5	Issuing a statement in support of research involving the copying of DNA and cell. Making it clear that this research does not involve the cloning of a human being.
1	Response to Terms of References 5 & 6	1.22 Page 5	Establishing a non-human primate facility.
1	Response to Terms of References 5 & 6	1.23 Page 5	Running the non-human primate facility by the AHEC. And the type of research using cloning techniques that will be supported.
1	Response to Terms of References 5 & 6	1.24 Page 5	Funding a non-human primate facility.
1	Response to Terms of References 5 & 6	1.25 Page 6	Promoting an informed discussion about research in this area.
6	Recommendations	1 Page 43	Re-affirming the Commonwealth's support for the UNESCO <i>Declaration on the Humane Genome and Human Rights</i> .
6	Recommendations	2 Page 43	Introducing legislation in all States and Territories.
6	Recommendations	3 Page 43	Establishing a regulatory authority with power to regulate research on human embryos in the States and Territories that do not already have such an authority.
6	Recommendations	4 Page 43	Promoting community discussion about cloning techniques.
6	Resolutions	1 Page 44	Collecting information from States and Territories that have not introduced legislation about cloning techniques.
6	Resolutions	2 Page 44	Establishing an expert advisory committee.
	Appendix 1	A1 Page 45	Establishing a non-human primate facility.
	Appendix 1	A2 Page 45	Funding a non-human primate facility.

4.4.3 Resolutions

The report contains two resolutions, both under the heading: “**Resolutions of the Australian Health Ethics Committee pending State and Territory Legislation**”.

“Resolution 1

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the AHEC will collect information from institutional ethics committees (IECs) in these States and Territories on IEC research approvals of projects involving the application of current cloning techniques to human embryos.”

The report does not indicate:

- Why the information needs to be collected.
- Who will use it.
- Whether it is being collected now from the States that have legislation.
- Whether it will be collected from States after legislation is introduced.

In other words, the report does not provide a rationale for the resolution.

I note however, that the Guidelines at 5.1 provide a more detailed list of reporting requirements – including “... *short and long-term health status and psycho-social effects of ART for participants, donors, and offspring ...*”. This appears to take the NHMRC into the social impact areas of gene technology.

“Resolution 2

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the NHMRC should consider the establishment of an expert advisory committee to assist IECs which seek advice on the scientific aspects of research projects involving the application of current cloning techniques to human embryos.”

Again, we see the scope of the discussion reduced to the scientific aspects of the research. Undoubtable the scientific aspects are important, but much greater emphasis needs to be placed on the impact that these issues will have on our society.

If this report demonstrates nothing else, it demonstrates that scientists alone cannot make decisions for the whole of our society on such important issues. Their focus is much too narrow.

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4.5 Review of Appendix 1

“APPENDIX 1

PRIMATE RESOURCES FOR RESEARCH IN EMBRYOLOGY AND DEVELOPMENT IN AUSTRALIA”

In some ways, this appendix is another list of recommendations.

For example;

“A1 Consideration should be given to establishing a primate research facility in Australia to carry out a small program related to cloning and its associated technologies (stem cell biology, cell lineage, twinning) and the associated disciplines (reproductive biology, gamete biology, endocrinology, immunology, primate management and veterinary care).⁸⁵”

“A2 The existing primate resources in Australia would have to be expanded ...”

A1 list five benefits associated with the establishment of a primate research facility in Australia, and A2 has some indicative costing information about this expanded resource. However, this recommendation assumes that our society has agreed to this course of action. The report demonstrates no such thing, and provides no model achieving such a mandate.

Some of the other paragraphs are also predicated on the assumption that we *are* going to increase our activity in this area, but again, they provide no information about what we should be researching.

For example;

Under “Developing an Australian Program” we see:

“A6 The NHMRC has responsibility for primate resources in Australia. The NHMRC should therefore be responsible for increasing and developing the Australian capability. This would require a number of key decisions to be made about the species of animals to be acquired, housing, management and welfare of these animals, and any increase in animal numbers.”

And under “Alternative Strategy” we see:

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“A7 If Australia were not to develop its own primate resources capacity to enable

Australian researchers to carry out this type of work, the NHMRC could be invited to

develop and support travel and research grants for Australian researchers who could

travel to use facilities and laboratories overseas.”

A6 states that some key decisions need to be made. The key decisions listed relate to mechanics of expanding the primate resources. But it is difficult to see how these decisions can be made without a model for the research. The closest the report gets to a model is the list of five benefits detailed in paragraph A1 – and most of those are couched in terms of “could be” or “would be”.

A7 simply states that if we cannot carry out our research in Australia, then we should do it overseas. Again, there is no indication as to the model for the research.



5. CONCLUSION

The ultimate decision as to what research is done, and under what conditions it is carried out, must surely be in the hands of our society. Research that can materially affect the substance of life itself is not the province of a single section of our society – no matter how knowledgeable or well intentioned that section might be. I know the term “informed debate” has now achieved cliché status, but that is what it gets down to in the end. What will it take to get an informed answer from our society? One that we can accept, our politicians can endorse, and our scientists can carry out.

Quoting from *Encyclopædia Britannica*:

“Related to the latter, [controversies over abortion and euthanasia] are the ethical implications of various developments in regard to reproduction as, for example, in vitro fertilization, sperm banks, gene manipulation, and cloning. This field of applied ethics, known as bioethics, frequently involves the cooperative efforts of philosophers, physicians, scientists, lawyers, and theologians.”

Copyright 1994-1999 Encyclopædia Britannica

Perhaps the last line of this quotation contains the words that should drive our expectations. We *do* expect that any view of these matters presented to us by an expert panel:

- Acknowledges the social context, and
- Provides a framework for dealing with the issues.

I believe that these things can only come from an expert panel that:

- Includes a wide range of disciplines, and
- Operates within a suitable consultation model.

5.1 Consultation Model

I have included an example of a consultation process. Although it is a high-level diagram, it does provide an indication of the scope of the process and could be used as the basis for a working model.

And in case anyone doubts the need for such a process, consider these two points:

- **The general public is expressing grave concern about gene technology. The following quotation comes from an article in the *Business Review Weekly*, 10 September 1999, entitled “*Consumers Bite Back at Genetically Modified Food*”.**

“The consumer backlash over genetically engineered foods, and the subsequent push by regulators for mandatory labelling of foods produced using gene technology, is causing the biggest upheaval in the food industry in decades.”

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“The source of much of the angst for both industry and consumers is the fact that the United States is the biggest supplier of [Genetically Modified] GM commodities. In 1992, the US Food and Drug Administration ruled that genetically engineered food ingredients were considered to be ‘substantially equivalent’ to ordinary foods if they looked and tasted similar. As a result, there is no requirement to label them or separate them from unmodified produce.”

This is an example of our genetic scientists and food companies using a model from another society for a gene-related activity. It now appears that our society does not accept that model – and our genetic scientists and food companies do not seem to know what kind of model would be acceptable. The parallels between this form of genetic engineering and human cloning are obvious enough – we must have a model that our society will accept.

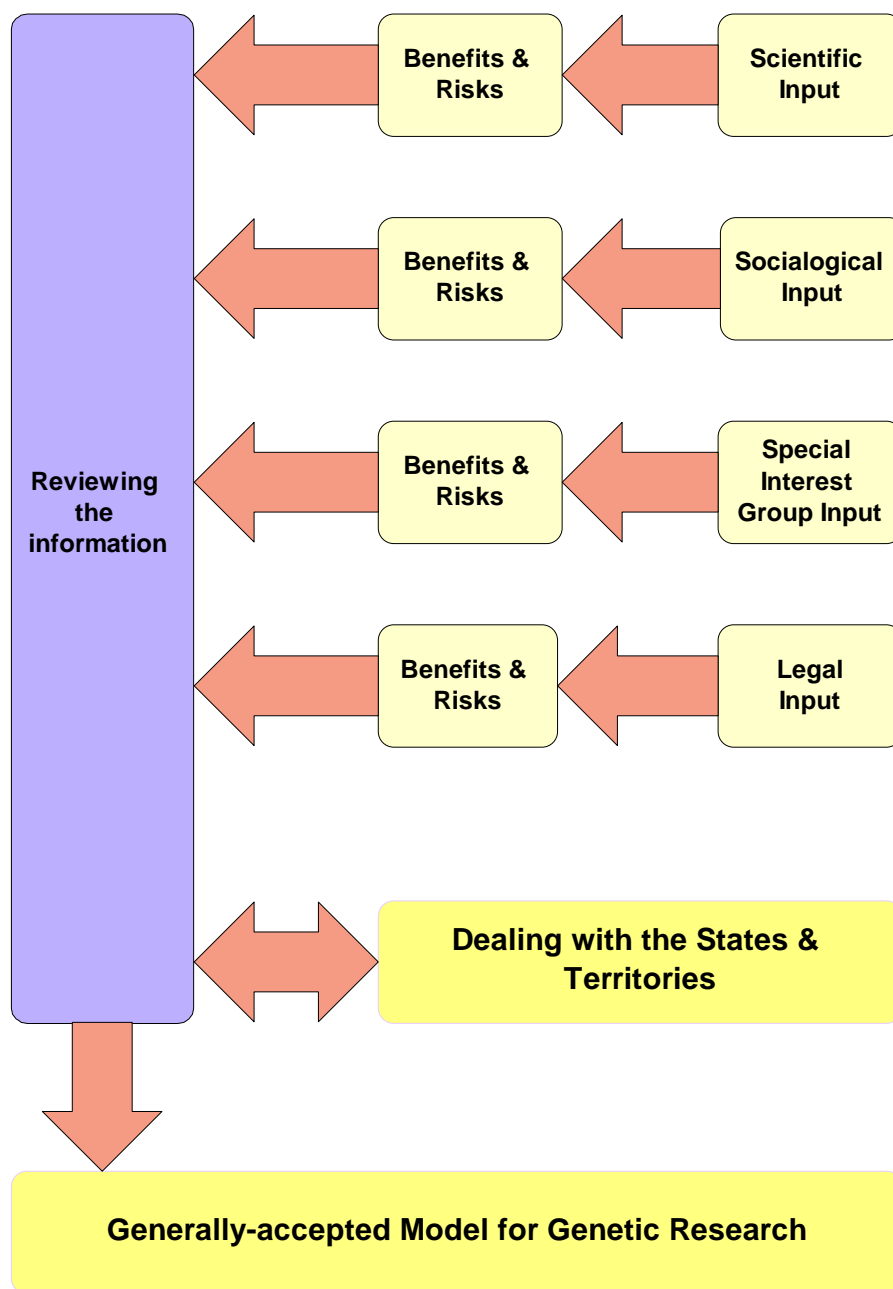
- Recent television documentaries on gene-related technologies will undoubtedly raise both public awareness and expectation about these issues.

In September 1999 alone, we had one documentary on each of the following topics:

- Genetically Modified food.
- IVF (including human cloning).
- The manufacture of spare body parts.

We must have a model that deals with that increased expectation. It will not be good enough to say that the ethical issues are unresolved.

5.1.1 High-level diagram of a consultation model



1. Inputs

I think it is crucial to have input from the sociological disciplines as well as the scientific and legal disciplines. And the social context should not be subjugated to the scientific disciplines.

2. Benefits and Risks

Those groups providing input to the process should have considered the benefits and risks within the context of their own discipline.

3. Dealing with the States

Can we come to an agreement with the States to treat genetic science on a National basis? Is there a forum in place that we could use to explore these issues?

4. Reviewing the information

The items that should be considered may include:

- The forum in which the discussions can take place.
- The type of research that will be done.
- The impact on our society.
- The impact on the research institutions.
- The impact on our legal system.
- How the information will be promulgated.
- How the research will be monitored.
- The review cycle. This will be important, given the rapid rate of change in this field.

5. The Generally-accepted model

We need an outcome that:

- We can accept.
- Our politicians can endorse; and
- Our scientists can carry out.

Whatever the outcomes, whatever the decisions, there are going to be sections of our society who will resolutely oppose them. But we should be able to reach a majority view. Such is the diversity and strength of our democratic society.

5.2 Summary

While the report contains a lot of information, it fails to take the process forward. It fails to provide a social context, and it fails to provide any meaningful framework for dealing with these issues.

The *Background* Section in the Guidelines does mention the social context – talking about ART rather than human cloning. At Point 5 we see that “*The practice of ART involves social issues of eligibility, surrogacy, consent for posthumous use [etc]...*”, and then “*These issues are beyond the remit of AHEC in relation to medical research.*”

The report does not state this – it just leaves the social issues alone.

The Terms of Reference for the report however, gave the Committee every opportunity to produce a wide-ranging report.

For example;

Terms of Reference 2

“2. identify potential risks and benefits as well as ethical considerations in approving the cloning of human beings;”

Clearly flagging the social context.

Terms of Reference 5

“5. recommend the appropriate regulatory framework
- through uniform legislation; or
- other further pronouncement;”

Offering the opportunity to say more than just comment on the existing arrangements.

Terms of Reference 6

“6. in accordance with the recommendations arising from TOR 5, recommend the most appropriate model of legislation or pronouncement.

In providing the above advice, the Working Group is to identify / consider:

- the current legislative position nationally and internationally on the cloning of human beings;**
- guidelines and other codes or pronouncements on the cloning of human beings; and**

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- *the ethical issues underpinning the potential support for cloning of human beings.*

Again, the Terms of Reference invited the Committee to look beyond the narrow scientific view – but the Committee chose to restrict its advice to those areas.

We can also gain some insight to the Minister's thinking about these issues from a speech that he made about genetics at the "*Functional genomics: new horizons in genetics and disease*" conference in 1997.

In that speech he said:

- *"... the great essence of science - that takes it beyond art or literature - is its capacity to improve humanity."*
- *"... there is a crucial task for all involved in this field to educate the public about the benefits of genetics."*
- *"... I have asked the Australian Health Ethics Committee (AHEC) of the NHMRC to provide me with advice on the need for further pronouncement or possible legislation regarding human cloning."*
- *"The Chairman of AHEC, Professor Don Chalmers, has welcomed the opportunity to provide advice on the appropriate action and further implications arising from research involving human cloning."*

Although he said: "*As part of a broader endeavour to look at the full range of ethical issues involving the use of genetic information, I am please to inform you that the AHEC has commenced work to examine the acquisition, access and use of genetic information.*", it seems clear to me that he was inviting the Committee to provide a wide-ranging report – not one that simply described the subject material.

I am not against the wonderful benefits to our society that genetic research might provide. But I believe that the sociological impact that genetic research will have on our society is critically important. The recommendations in the report provide no guidance in this area and no model for establishing that guidance.

Nevertheless, we should not diminish the importance of the technical expertise and advice from our genetic scientists. We should *build* on that advice.

It is clear enough that:

- The genetic revolution has already begun.
- We cannot stop it, but we can (and should) harness it.
- The science of genetics will dramatically affect our society.
- We must listen to our social scientists.
- We have great power and we should use it with care and discrimination.

"Man is a singular creature. He has a set of gifts which make him unique among the animals: so that, unlike them, he is not a figure in the landscape – he is a shaper of the landscape."

Jacob Bronowski, *The Ascent of Man* (1973)

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