11

AHEC's recommendations and other options for regulation of human cloning

INTRODUCTION

11.1 This chapter outlines the responses of those who gave evidence on the recommendations contained in the AHEC report. The Committee will outline its suggested framework for the appropriate regulation of human cloning and related research in Chapter 12.

COMMENTS ON THE AHEC RECOMMENDATIONS

11.2 The AHEC recommendations and resolutions are set out in full at Appendix D. In summary, AHEC recommended that the Commonwealth Government reaffirm its support for the UNESCO *Universal Declaration on the Human Genome and Human Rights* (in particular Article 11) (Recommendation 1) and that the Minister for Health and Aged Care should urge those states and territories without legislation regulating research on human embryos (Recommendation 2) or without statutory authorities with power to regulate research on human embryos (Recommendation 3) to legislate to achieve these ends. The legislation and statutory authorities should accord with the principles set out in Guidelines 6 and 11 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (set out at Appendix F). AHEC also recommended that informed community debate on potential risks and benefits of the development of cloning techniques be encouraged (Recommendation 4).

11.3 In its submission to this inquiry, AHEC stated that its reasons for making Recommendations 2 and 3 (see Appendix D**)** were:

- there are social and ethical issues attendant on these research programs and these are appropriately the subject of legislation rather than review by IECs whose responsibility is for the welfare of participants in research;
- it is undesirable that approval of research using cloning techniques especially the cloning of human embryonic stem cells, be dependant on geography—a national regulatory framework would ensure that no one State or Territory is perceived as a 'safe harbour' for the conduct of research which is not permitted elsewhere;
- mandatory monitoring procedures should be instituted and researchers subjected to compulsory record keeping;
- the auditing of research on embryos should be done by statutory authorities such as already exist in three states;
- an authority should issue licences to competent professionals and thereby prohibit others from undertaking such research;
- the legislation could bring about consistency between existing state legislation and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the Reproductive Technology Accreditation Committee Code of Practice and establish limits on research involving embryos;[1]
- research will be facilitated by clarifying the kind of research on embryos which is permitted and which requires approval, thus assisting researchers.[2]

11.4 Very little evidence to this inquiry responded to the AHEC recommendations in detail. Perhaps this is because some felt that the debate and scientific developments had moved beyond the recommendations. The more common approach adopted by most was to outline the kind of regulation they thought most appropriate.

11.5 AHEC's recommendations drew little unqualified support. The Australian Medical Association generally supported the recommendations[3] and the Royal College of Pathologists of Australasia also indicated its support.[4]

1 The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the Reproductive Technology Accreditation Committee Code of Practice are discussed in Chapter 9

2 AHEC, *Submissions*, pp.S351-352

3 AMA, *Submissions*, p.S26

4 Royal College of Pathologists, *Submissions*, p.S161. The Consumers Health Forum also indicated its support for Recommendations 1 and 2, *Submissions*, p.S792

11.6 As might be expected, the views expressed in relation to ethical issues (discussed in Chapters 6 and 7) flowed through people's comments on AHEC's recommendations.

11.7 Hence, while the Human Genetics Society of Australasia[5] and Queensland Right to Life[6] supported Recommendation 1, some, such as the Catholic Archdiocese of Melbourne were more restrained. The Archdiocese argued that 'reproductive cloning', mentioned in Article 11 of the UNESCO *Universal Declaration on the Human Genome and Human Rights* also included the creation of embryos. Before the Archdiocese could fully support Recommendation 1, it argued, it was necessary to clarify the Australian Government's interpretation of Article 11.[7] It argued that if its view of the correct interpretation of Article 11 was adopted then AHEC's Resolutions 1 and 2 were inconsistent with Recommendation 1.[8] In a similar vein, the Queensland Bioethics Centre supported Recommendation 1 so long as it was understood to refer also to cloned embryos.[9] The Caroline Chisholm Centre for Health Ethics was prepared to agree with the recommendation, but argued that it should be more specific and include a legislative provision that detailed what was meant by 'reproductive cloning'. The Centre understood reproductive cloning to mean cloning human embryos, human foetuses, children and adults.[10]

11.8 The effect of previously expressed ethical views on the assessment of AHEC's recommendations was most apparent in the case of Recommendations 2 and 3 and Resolutions 1 and 2.

11.9 The Council on Marriage and the Family rejected Recommendations 2 and 3 'on principle' because they would permit destructive embryo research in some instances and enable institutional ethics committees (IECs) to permit such research.[11] The Caroline Chisholm Centre for Health Ethics

5 Human Genetics Society of Australasia, *Submissions*, p.S506

6 Queensland Right to Life, *Submissions*, p.S263

7 Catholic Archdiocese of Melbourne, Submissions, p.S521. Paragraphs 10.15-10.27 discuss the interpretation of Article 11 of the UNESCO Declaration

8 Catholic Archdiocese of Melbourne, *Submissions*, p.S521. The Archdiocese argues that the two resolutions would seem to enable cloning for 'therapeutic purposes'. See also Queensland Bioethics Centre, *Submissions*, p.S707

9 Queensland Bioethics Centre, *Submissions*, p.S706

10 Caroline Chisholm Centre for Health Ethics, *Submissions*, p.S490

11 Council on Marriage and the Family, *Submissions*, p.S494. This consequence arises because recommendations 2 and 3 of the AHEC report urge States and Territories without current legislation or statutory authorities regulating embryo research to establish them based on the principles set out in sections 6 and 11 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (set out at Appendix F). Guideline 6.4 enables non-therapeutic research using embryos to be approved in certain exceptional circumstances. The Catholic Women's League Bioethics Working Party, *Submissions*, p.S104. Queensland Right to Life, *Submissions*, p.S263

supported Recommendation 2 but thought it should have gone further to review Guidelines 6.2 and 6.4 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* because these sections of the Guidelines permit destructive research on embryos in some circumstances which the Centre believes is ethically unacceptable. The Centre supported both resolutions.[12]

11.10 The Catholic Archdiocese of Melbourne regarded the two resolutions in the AHEC report as 'a wholly inadequate response to the Australian Government's moral and legal obligations'.[13] While the General Synod of the Anglican Church of Australia welcomed the notion of an expert advisory committee to assist IECs in relation to scientific issues in human cloning, it stated that 'much more is needed'.[14]

11.11 AHEC's Recommendation 4 (see Appendix D) drew little comment. The Australian Research Council supported the recommendation[15] as did the Australian Academy of Science and the Caroline Chisholm Centre for Health Ethics.[16]

OPTIONS FOR REGULATION

11.12 There was virtually unanimous support for any regulatory framework adopted being nationally uniform.[17] The Australian Catholic Bishops Conference preferred uniform regulation to unenforceable guidelines or self-regulation and accreditation.[18] The Consumer's Health Forum argued that human cloning is a national issue and Commonwealth leadership is required.[19]

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and the Coalition for the Defence of Human Life, *Submissions*, p.S270-271 also expressed the same view

12 Caroline Chisholm Centre for Health Ethics, *Submissions*, pp.S490-491

13 Catholic Archdiocese of Melbourne, *Submissions*, p.S522

14 General Synod of the Anglican Church of Australia, *Submissions*, p.S344

15 Australian Research Council, *Submissions*, p.S226

16 AAS, *Submissions*, p.S245 and Caroline Chisholm Centre for Health Ethics, *Submissions*, p.S490

17 Those articulating this view included- AMA, *Submissions*, p.S27; Mr / Ms Hartwig, *Submissions*, p.S22; Mr / Ms Murrell, *Submissions*, p.S42; Country Women's Association of NSW, *Transcript*, p.95; Catholic Women's League of Australia Bioethics Working Party, *Submissions*, p.S102; Mr Latchford, *Submissions*, p.S111; Dr David Gawler, *Submissions*, p.S628; Queensland Bioethics Centre, *Submissions*, p.S708

18 Australian Catholic Bishops Conference, *Submissions*, p.S733

19 Consumers Heath Forum, *Submissions*, p.S792

11.13 Members of the public who urged uniform national regulation included Dr David Elder [20] and Mr Richard Dewis who considered the AHEC recommendations to be 'redundant' and urged national legislation 'so that the entire nation is operating at the same level and by the same definitions'.[21]

11.14 Youth Concerned with Cloning considered that:

> …cloning technology is not, in principle, policeable. However, we believe that legislation is a better option than self-regulation through institutional ethics committees.[22]

11.15 Regulation that applies consistently to both private and public sectors was also supported. Dr David Elder commented that the sort of 'double standard' that operates in the United States in the regulation of public and private research was 'highly unacceptable'.[23]

11.16 The Australian Academy of Science noted that in the United States the private sector is virtually unregulated. In the Academy's view this has resulted in an element of secrecy whereby the information being gained as the result of research is not in the public domain. In its view regulation must be binding on both private and public sectors and the right regulatory tool is not the withholding of funds from research (as is currently the case in relation to the NHMRC).[24]

What Should Be Regulated?

11.17 The evidence suggested strong support for several specific aspects of human cloning and related research to be strictly regulated. The first and clearest of these specific aspects was the overwhelming support for cloning for reproductive purposes to be prohibited.[25]

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20 Dr David Elder, *Submissions*, p.S202

21 Richard Dewis, *Submissions*, p.S12

22 Youth Concerned with Cloning, *Submissions*, p.S547

23 Dr David Elder, *Submissions*, p.S194. See Chapter 10 for a discussion of regulation of human cloning and its related research in the United States. Others to stress the importance of covering both the public and private sectors included—Country Women's Association of NSW, *Submissions*, p.S160 and *Transcript* p.95; Consumers Health Forum, *Submissions*, p.S792; Human Genetics Society of Australasia, *Submissions*, p.S509; AAS, *Submissions*, p.S250 and the Anglican Diocese of Melbourne, *Submissions*, pp.S308-310

24 AAS, *Transcript*, p.78

25 This was supported by, for example - Human Genetics Society of Australasia, *Submissions*, p.S509; Catholic Archdiocese of Melbourne, *Submissions*, p.S522; AAS, *Submissions*, p.S251; Law Society of NSW, *Submissions* p.S280. See also submission numbers 69, 70, 72, 76, 81, 82, 89, 92, 99, 110, 111, 112, 144, 146, 160, 164, 166, 171, 175, 196, 204, 216, 224, 239, 244, 253, 257,

11.18 There were arguments both in favour of and against banning research and experimentation involving the use of embryos.[26] There were also views expressed both in favour of and against the import and export of embryos and embryonic material.[27]

11.19 Other matters regarded as requiring inclusion in any regulatory framework were the protection of genetic privacy[28] and measures to ensure that consent to the donation of eggs or embryos for research was not the result of pressure or coercion.[29]

How Should These Matters Be Regulated?

A national licensing system

11.20 The most common suggestion for an appropriate regulatory framework to govern human cloning and associated research was the institution of a national licensing system. The Social Responsibilities Committee of the Anglican Diocese of Melbourne regarded the present control mechanisms using local ethics committees with different approaches operating under NHMRC guidelines as insufficiently accountable to society. It argued that:

> For questions such as cloning national legislation and a national control and licensing structure must be introduced[30]…The Government must develop mechanisms whereby the ongoing research, development, introduction and patenting of the technology to reproduce human materials and cell lines of human origin will be made publicly accountable and responsive to the needs of the community by regulation and licensing.[31]

11.21 The Social Responsibilities Committee also argued that the existing controls and regulation are the product of conditions developed for assisted reproductive technology. The current model of NHMRC

260, 272, 302, and 316. Dr Russell Blackford, *Submissions*, pp.S1-2 and Dr David Swanton, *Submissions*, p.S121 did not support a ban on reproductive cloning

26 See submission numbers – 47, 54, 69, 70, 72, 76, 81, 82, 92, 94, 97, 99, 110, 111, 112, 142, 144, 146, 149, 160, 164, 166, 171, 175, 196, 204, 216, 224, 239, 244, 253, 254, 257, 260, 272,.295, 302, 316

27 Youth Concerned with Cloning, *Submissions*, p.S547; Federation of Right to Life Associations, *Submissions*, p.S323 and the Festival of Light SA, *Submissions*, p.S336, Professor Robert Norman, *Transcript*. pp.82 and 115-116. See also Submission numbers – 69, 70, 72, 239, 244, 257, 295

28 Dr David Elder, *Submissions*, p.S205

29 Ridley College, *Submissions*, p.S35

30 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S299

31 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S302

guidelines and local ethics committees is inadequate, in the view of the Social Responsibilities Committee, to deal with such a 'fast moving, wide-ranging and complex issue with its implications for the whole of society'.[32] It argued that as well as:

> … establishing Statutory authorities, in all States the Commonwealth should implement a national Authority to licence, approve and regulate all work in the area of cloning and embryo research.[33]

11.22 The General Synod of the Anglican Church of Australia considered that this is 'a matter which requires explicit regulation as opposed to just guidelines'.[34] It sought a prohibition on the cloning of human beings and embryos and stated that the clear intent of NHMRC Guidelines and current legislation had been 'circumscribed by the well-known practice of border-hopping'.[35]

> … it is apparent that this is an area that cannot be left merely to self-regulation or NHMRC guidelines…it is quite clear that privately financed interests are quite capable of undertaking research in Australia, including States/Territories where there is not legislative prohibition.[36]

11.23 The Humanist Society of Victoria advocated a licensing model based on that used in the United Kingdom. Such a system would regulate:

> … all creation, research and treatment of human embryos *in vitro*… Were such a model to be used here, on a Federal scale, it would remove the problem of legislative differences between States.[37]

11.24 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists also supported licensed and accountable facilities undertaking:

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32 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S308

33 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S308

34 General Synod of the Anglican Church of Australia, *Submissions*, p.S342

35 General Synod of the Anglican Church of Australia, *Submissions*, p.S342

36 General Synod of the Anglican Church of Australia, *Submissions*, p.S343

37 Humanist Society of Victoria, *Submissions*, p.S150. The Human Genetics Society of Australasia also supported the creation of a national statutory body to review all proposals and policies relating to the use of new reproductive technologies for human cell or tissue cloning in any context, *Submissions*, p.S509

> Non-reproduction cloning, and stem cell research where the primary focus is on transplant and tissue graft potential, from bone marrow to full organs….[38]

11.25 The Royal College of Nursing cited an urgent need for 'strengthened regulation and community debate', as well as a separate body, accountable to the people, to review, monitor and regulate the scientific, ethical and social impact of human genetics.[39]

11.26 The Murdoch Institute for Research into Birth Defects also made a similar suggestion and recommended a National Regulatory Committee for Reproductive and Genetic Technology (NRC) be established to which all groups, public or private, should be legally bound to submit any proposals for research with human material in this field. The NRC should determine that no reproductive cloning procedures that could lead to a viable human being or foetus of more than 28 days be permitted. The NRC should be directed to permit a limited number of procedures on embryos that are surplus to assisted reproductive technology programs provided that consent procedures were followed. The recommendations of such a NRC should be in force throughout all States and Territories.[40]

11.27 The Caroline Chisholm Centre for Health Ethics agreed with the view that if the Commonwealth, States or Territories were to make new laws, the legislation should only contain basic ethical principles and provisions that would not become outdated quickly. Regulatory authorities should interpret the legislation and control new developments.[41]

Two-tier regulatory process

11.28 The other principal suggestion for an appropriate regulatory framework was that proposed by the Australian Academy of Science (AAS). The AAS suggested a two tier regulatory process which would involve approval to undertake research involving human embryos and human ES cell lines being sought from IECs first. Then those research proposals could be assessed for their scientific merits, safety and ethical acceptability by a national panel of experts established by the NHMRC.[42]

11.29 The AAS argued that both the Academy and AHEC recognise the:

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38 Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Submissions*, p.S190

39 Royal College of Nursing, *Submissions*, p.S283

40 Murdoch Institute for Research into Birth Defects, *Submissions*, p.S348

41 Caroline Chisholm Centre for Health Ethics, *Submissions*, pp.S491-492

42 Australian Academy of Science, *Submissions*, p.S250

> …need for regulation …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.[43]

11.30 The AAS suggested that the only real difference between the position taken by the AAS and that of AHEC, is that in the view of the AAS, human cells, whether derived from cloning techniques or embryonic stem cell lines, should not be precluded from use in approved research activities.[44] On the other hand the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* would only allow the production of embryonic stem cell lines in exceptional circumstances.[45] In the AAS' view these restrictive provisions should be amended.

11.31 Under the AAS proposal legislation would limit research practice by, for example, legislatively prohibiting the cloning of human foetuses. The national panel of experts would then regulate research practice under the legislation.

11.32 The AAS argued that 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.[46]

11.33 AHEC did not support the AAS two tier model and argued that it has the following problems:

- it would have no jurisdiction over private facilities;
- it could be ignored by the existing regulatory bodies in Victoria, Western Australia and South Australia;

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43 Australian Academy of Science, *Submissions*, p.S250

44 Australian Academy of Science, *Submissions*, p.S250

45 Australian Academy of Science, *Submissions*, p.S250. The Coalition for the Defence of Human Life argued that, in their view, the AAS would achieve the desired uniformity in regulation by relaxing restrictions in the three states with existing legislation and relaxing restrictions in the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* which have no force but which may affect research funding. The Coalition urged legislation to ban destructive embryo research and allow only research that was therapeutic for the individual embryo, *Submissions*, p.S271

46 Australian Academy of Science, *Submissions*, p.S251

- it would have no enforcement powers; and
- reporting to such a body could not be made mandatory.[47]

11.34 The Human Genetics Society of Australasia offered a similar proposal to that of the AAS. It suggested a national regulatory committee for reproductive and genetic technology with appropriate legislation mandating that any group undertaking such research in Australia would first submit its proposal for research using human material in this field to such a committee. That committee could then determine the extent of research that could be undertaken on human embryos.[48]

Other proposals

11.35 The Catholic Archdiocese of Melbourne suggested two options whereby the Commonwealth could achieve regulation. These were first, a uniform legislative ban by the Commonwealth, States and Territories or, second, failing this, Commonwealth legislation to fill the lacuna in those States and Territories where no legislative ban has so far been enacted or where the current legislation is inadequate or ineffective.[49]

11.36 The Australian Research Council suggested that it was highly desirable in order to ensure consistent legislation that the Commonwealth develop model legislation for the States or for the States to refer their power over this area to the Commonwealth under section 51 (xxxvii) of the Constitution.[50]

11.37 The Law Society of NSW supported uniformity in the laws regulating human cloning amongst the States and Territories but argued that a sunset clause should be included to ensure the issue was reviewed and a decision made as to whether a prohibition on cloning for reproductive purposes was still needed.[51]

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47 Letter from AHEC to AAS, 23 April 1999, *Exhibit* 10

48 Human Genetics Society of Australasia, *Submissions*, p.S507

49 Catholic Archdiocese of Melbourne, *Submissions*, p.S523. The Archdiocese suggested that the Commonwealth should rely on its constitutional powers over family law, corporations, finance, external affairs and customs, excise and patenting

50 Australian Research Council, *Submissions*, p.S225. The referral of the relevant constitutional powers by the States to the Commonwealth is regarded as unlikely and has not been pursued by the Committee

51 Law Society of NSW, *Submissions*, p.S280

Australian Health Ministers' Agreement

11.38 A further initiative for the regulation of human cloning was announced in a media release on 31 July 2000. The Commonwealth Minister for Health, the Hon. Dr Michael Wooldridge MP, announced that Australian Health Ministers had agreed to 'the development of a national framework to prevent the exploitation of human cloning'. The announcement stated the Ministers acknowledged that:

> The development of complementary legislation across the states and territories was essential to ensure a consistent national approach to the cloning of humans … each jurisdiction will need to work cooperatively to ensure consistency in banning the cloning of human beings.

11.39 Submissions from State and Territory Health Ministers advising on their progress in implementing this decision and their proposed time frame for doing so provided little information on either of these matters.[52]

11.40 The Committee has also noted the decision of the Council of Australian Governments (COAG) on 8 June 2001 to develop nationally consistent provisions in legislation to prohibit human cloning. COAG agreed that jurisdictions would work towards nationally consistent approaches to the regulation of assisted reproductive technology and related emerging human technologies. Health Ministers are expected to report back to COAG by the end of the year on technical issues arising from this decision with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002.

11.41 The Committee is concerned at the delays that have occurred since July 2000 in implementing the earlier decision of the Australian Health Ministers and the lack of progress on this matter in some States and Territories. The Committee urges the Commonwealth to take the lead in ensuring that the proposed timetable for the implementation of the decision of the Council of Australian Governments is adhered to.

11.42 This raises the issue of the extent of the Commonwealth's constitutional power to enact legislation that would regulate human cloning and its related research.

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52 Minister for Human Services in South Australia, *Submissions*, pp.S857-858; Minister for Health in Western Australia, *Submissions*, p.S859-860; Minister for Health in Victoria, *Submissions*, p.S861; Minister for Health in Queensland, *Submissions*, p.S862; Minister for Health and Human Services in Tasmania, *Submissions*, p.S864; Minister for Health in NSW, *Submissions*, p.S866; Minister for Health and Community Care in the ACT, *Submissions*, p.S863

11.43 In relation to the Commonwealth's constitutional power to legislate, the Attorney-General's Department submitted:

> … it may be possible to legislate in a piecemeal fashion using a number of Commonwealth heads of power such as the trade and commerce power and the corporations power, ultimately it is probably the case that the Commonwealth Parliament does not have the power to enact legislation that would provide a comprehensive basis for prohibiting scientific research aimed at achieving reproductive human cloning or cloning research that involves the use of embryonic tissue.[53]

11.44 The Department also made the point that:

> … Commonwealth powers to legislate is one part of the issue, but, even assuming the Commonwealth parliament does have power to legislate, it would be doing so because there was a perceived gap in state and territory legislation, or in order to override state and territory legislation… even if the Commonwealth parliament were to legislate on these issues, … it would … be necessary to consult quite heavily with the states and territories and ideally to have agreement … So … there are some other political dimensions as well.[54]

11.45 The Committee agrees. It also notes Associate Professor Skene's comment:

> …Federal Parliament could legislate to establish a federal body to oversee developments in cloning and like technology (cf the regulatory scheme in the [*Gene Technology Act 2000*]). This could be achieved under the External Affairs power.[55]

11.46 The Committee considers the Commonwealth has the constitutional power to enact legislation regulating most aspects of research involving the use of cloning technologies. The legislation could be enacted relying on the Commonwealth's constitutional power over areas such as corporations, trade and commerce, quarantine, territories, import and

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53 Attorney-General's Department, *Submission*s, p.S537. In a further submission the Attorney-General's Department stated that reproductive cloning is not yet a matter of sufficient 'international concern' to support Commonwealth legislation based on the external affairs power although it considers that it is 'arguable that an international expectation is evolving that human cloning for reproductive purposes should be prohibited, but evidence of this international expectation is still emerging', Submissions, pp.S874 and S885

54 Attorney-General's Department, *Transcript*, pp.137-138

55 Associate Professor Loane Skene, *Submissions*, p.S689. Associate Professor Skene later clarified her view: only Article 11 of the UNESCO *Universal Declaration on the Human Genome and Human Rights* 'is clearly adequate to found legislation under the external affairs power', *Transcript*, p.45

export, patents, statistics, external affairs, actions by the Commonwealth or Commonwealth authorities as well as its power to attach conditions to its funding of projects and institutions.

DISCUSSION

11.47 The Committee outlined what it saw as the flaws in the current regulatory framework applicable to human cloning and its related research at the conclusion of Chapter 9.

11.48 In the light of the evidence presented throughout this inquiry it is clear that AHEC's recommendations have been overtaken by the developments that have occurred since the AHEC report was concluded. However, the Committee supports the general approach taken by AHEC and seeks to build on its recommendations.

11.49 Reaffirming the UNESCO Declaration (particularly Article 11), as recommended by AHEC, does not go far enough in the light of regular press reports of attempts to clone a human being (however unrealistic and distant in reality). These continuing reports simply serve to heighten public concern.

11.50 Considerable frustration was plain in much of the evidence to the inquiry at the lack of regulatory activity by some State and Territory governments over matters of embryo research and assisted reproductive technology and the continual postponement of action into the future. The aftermath of the Australian Health Ministers' Agreement appeared to be following the same pattern.

11.51 Professor Norman made the point that people have been struggling with national regulation of *in vitro* fertilisation for many years and it still appears a long way from actually happening. He commented: 'I am not aware that it has progressed in any way at all.'[56]

11.52 The AHEC report and its recommendations need to be placed in the larger context of the rapid pace of the research and the continuing announcements of scientific discoveries that have occurred since the AHEC report was completed.

11.53 It is clear (as was demonstrated in Chapter 3) that this research activity cannot be ignored. It proceeds and public concern and interest will not diminish. The issue of the appropriate regulation of this research will

56 Professor Robert Norman, *Transcript*, p.80

become more and more pressing. The current lack of action at Commonwealth, State and Territory level is increasingly likely to lead to the research taking place altogether outside public scrutiny.

11.54 What is so different about this research that makes the mechanism of unenforceable guidelines and institutional ethics committees that regulate most general research involving humans so inappropriate? Research into human cloning, like assisted reproductive technology, evokes continuing calls for tighter regulation.

11.55 The reason may be found in the discussion of the ethical issues in Chapters 6 and 7. Most research involving humans is generally relatively non-controversial. Research that involves the creation or use of embryos, or involves the possible development of human life is, of its nature, controversial and always has been.

11.56 The evidence presented throughout this inquiry demonstrated a high level of concern about the ethical issues raised by the use of embryos in research in particular. There was no consensus in favour of prohibiting such research, as was the case with cloning for reproductive purposes, although strong support was evident for such a move. Indeed, to prohibit research involving the use of embryos would be contrary to most current practice in Australia which permits research involving the use of embryos within carefully defined parameters.

11.57 The Committee agrees with Professor Chalmers that:

> … the legislation in the various states and the principles embodied in a number of national reports suggested and led to no other conclusion than the fact that this country has a view about the integrity and dignity of the human embryo and that research should not be conducted on the human embryo, except according to prescribed legislation.[57]

11.58 It appears that there is a consensus in favour of the need to regulate embryo experimentation, even if the consensus does not extend to the specific limits that should be imposed. The imperative to regulate in a clear and transparent way arises out of the need to maintain public confidence that decisions about the use of embryos are being made by qualified, accountable people in an open way.

11.59 Those who advocate research involving the use of embryos also acknowledge the sensitivity surrounding the issue and the need for greater scrutiny and care in dealing with this kind of research.

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57 Professor Donald Chalmers, *Transcript*, p.3

11.60 The Committee also agrees with Professor Chalmers that:

> … if the science is to proceed, as a community we owe it to the scientists to try and clarify, through legislation, those circumstances in which procedures may be acceptable after consideration and those cases in which a line may be drawn and where this country might prefer not to follow those particular procedures.[58]

11.61 Hence regulatory mechanisms that may be sufficient in their application to other research are not appropriate for research involving human cloning technologies because the issues raised are so much more fundamental and sensitive.

11.62 It is absolutely essential that public confidence be developed in the system of regulation applicable to research involving human cloning and related technologies. The public must be assured that all research in this area is properly considered and soundly based, that it is being conducted in the interests of benefiting the community and that governments are exercising a firm oversight to ensure that it accords with community standards. Only if these conditions are met will the public develop confidence that this research is appropriate.

CONCLUSIONS

11.63 The Committee favours consistent national regulation of cloning research that applies equally to both public and private sectors. The principles on which the regulation of this research should be based are transparency, accountability, enforceability, responsiveness, flexibility, practicality and consistency.

11.64 With this in mind the Committee has developed a suggested regulatory framework for a national licensing scheme to regulate research involving human cloning and related technologies. The suggested regulatory framework responds appropriately to the concerns raised in the evidence, is achievable, realistic and flexible.

11.65 The Committee's suggested regulatory framework for the regulation of human cloning and its related research in Australia is outlined in the next chapter.

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58 Professor Donald Chalmers, *Transcript*, p.3