10

International regulatory framework

INTRODUCTION

10.1 This chapter focuses on efforts to regulate cloning and related research at the international level. It also addresses the relevance of these efforts to Australia's consideration of appropriate regulation.

10.2 At the multilateral level, the discussion begins with the *Universal Declaration on the Human Genome and Human Rights* developed by the United Nations Educational, Scientific and Cultural Organisation (UNESCO). Article 11 of this Declaration forms the basis of the first recommendation in the AHEC report: that the Commonwealth Government should reaffirm its support for the UNESCO Declaration, in particular Article 11.

10.3 The Committee will then consider the *Convention for the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine* together with its *Additional Protocol on Human Cloning,* both developed by the Council of Europe. The Additional Protocol was the first binding international instrument to ban cloning for reproductive purposes. These instruments represent the first attempt by communities of nations at the international level to grapple with the issues raised by embryo experimentation and human cloning.

10.4 The Committee is also aware that many other international legal regimes may be relevant to various aspects of cloning related research. A particular example is the international framework governing intellectual property issues such as the Paris *Convention for the Protection of Industrial Property 1883* and the World Trade Organisation (WTO) *Agreement on*

Trade-Related Aspects of Intellectual Property Rights (TRIPS).[1] The Committee has not examined this framework in detail.

10.5 Many countries are considering the appropriate regulation of human cloning and its related research. In the United States of America and the United Kingdom considerable work has been undertaken on the most appropriate regulation of this research. Given the similarity of their legal and political systems to Australia's, their responses to the issues raised are comparable and useful. They are addressed in the remainder of the chapter.

10.6 The chapter concludes with the Committee's observations on the relevance of these international developments to Australia's approach to regulating human cloning and research involving the use of embryos.

UNITED NATIONS: UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANISATION (UNESCO) DECLARATION

10.7 The *Universal Declaration on the Human Genome and Human Rights* (the Declaration), developed by UNESCO, was adopted unanimously by UNESCO's 186 member states (including Australia) on 11 November 1997.[2] The United Nations General Assembly endorsed the Declaration on 10 March 1999.[3]

10.8 Material developed by UNESCO seeks to explain the Declaration and its aims:

> What exactly does this text set out to do and why is UNESCO promoting the promulgation of guidelines that seek to prohibit the application of a revolutionary scientific development? … The answer to this question is that UNESCO is committed to ensuring that, like all other forms of knowledge, science effectively serves the cause of human progress and that the Declaration is concerned with making science accord with ethics in the new Promethean age we are now entering.[4]

1 IP Australia, *Submissions*, pp.S722-723 and S726

2 Attorney-General's Department, *Submissions*, p.S531

3 United Nation General Assembly, Resolution 53/152. The French and German governments are reported to have asked the UN Secretary-General to begin work on an international convention to ban the cloning of humans for reproductive purposes. The governments are reported to have asked for negotiations to begin at the next General Assembly in September 2001, *The Times*, 9 August 2001, http://www.thetimes.co.uk/article/0,3-2001272895,00.html

4 'Reproductive Human Cloning: Ethical Issues', Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.4, *Exhibit* 50

10.9 The impact of the Declaration was noted by the Attorney-General's Department:

> As a Declaration this instrument is not binding under international law however it may be regarded as reflecting current international thinking on these issues.[5]

10.10 Hence, unlike an international treaty, the Declaration does not include any mandatory provisions requiring States to take action to implement it domestically but it does 'set out a framework of principles to guide Member States in the development of national legislation'.[6]

10.11 UNESCO states that although the Declaration:

> … does not have binding force…[it] represents a moral commitment of all Member states of UNESCO to adhere to a coherent set of ethical principles in the field of genetics.[7]

10.12 Part C of the Declaration, containing Articles 10, 11 and 12, is most relevant to the inquiry. This Part of the Declaration 'expresses the fundamental principles that might guide research on the human genome'.[8] Article 10 states the overarching principle of primacy of respect for human rights over research in biology and that respect for human dignity and fundamental freedoms of individuals and groups of people overrides freedom of scientific inquiry:

> No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.[9]

10.13 Article 11 prohibits practices contrary to human dignity and is the only operative provision which refers to reproductive human cloning or any form of cloning. Article 11 states:

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5 Attorney-General's Department, *Submissions*, p.S532

6 Attorney-General's Department, *Submissions*, p.S532. UNESCO preparatory documents note that part of the reason for developing a Declaration rather than a Convention was the rapid pace of the scientific developments in this area, Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, Presentation of the 'Revised Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights', 20 December 1996, BIO -97/CONF.201/4, 6 May 1997, p.4, *Exhibit* 48

7 'Reproductive Human Cloning: Ethical Issues', Document prepared by the Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.5, *Exhibit* 50

8 Attorney-General's Department, *Submissions*, p.S533. Articles 14, 15 and 16 are also relevant. Attorney-General's Department, *Submissions*, p.S534

9 Article 10 of the Declaration. See also Attorney-General's Department, *Submissions*, p.S533

> Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.[10]

10.14 Article 12 promotes equality of access to the benefits of scientific progress and recognises that scientific research is part of freedom of thought, but indicates that scientific research should have as its ultimate aim the relief of suffering and the improvement of human health.[11]

How Should Article 11 Of The Declaration Be Interpreted?

10.15 Given the importance that AHEC assigned to the Commonwealth government reaffirming its support for the Declaration, in particular Article 11,[12] it is important to try to understand the prohibition on reproductive cloning in Article 11. 'Practices contrary to human dignity' is clearly a broad term. Indeed, the Article invites States and competent international organisations to cooperate in 'identifying such practices'.[13] There is no explicit mention in the Declaration of embryo experimentation or the creation of embryos for research purposes or the creation of a transgenic organism for research purposes.[14] UNESCO did not deal with the issue of human cloning in detail and this is not surprising given the nature of the instrument and its primary focus on genetic research more generally rather than human cloning specifically.

10.16 The Attorney-General's Department, in its first submission to the inquiry, interpreted the express reference to reproductive cloning to mean '… the replication of a whole human being with an identical gene set with a viable post-natal existence'.[15] The Department noted that 'any research or research applications aimed at achieving reproductive human cloning would therefore also violate Article 10' and 'it remains unclear to what

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10 Article 11 of the Declaration

11 Attorney-General's Department, *Submissions*, p.S534

12 AHEC report, Chapter 6, p.43, Recommendation 1

13 Article 24 of the Declaration indicates that germ-line intervention is another practice that could be contrary to human dignity

14 Attorney-General's Department, *Submissions*, p.S535 and *Transcript*, p.135

15 Attorney-General's Department, *Transcript*, p.135. For the purpose of its submission the Department defined reproductive cloning as 'the application of cloning techniques to produce a duplicate or descendant human being that is genetically identical to an existing human being living or dead with a viable post-natal existence'. It defined 'human tissue cloning' as 'the application of cloning techniques to human cells in order to grow new tissue. This may but does not necessarily involve the use of human embryonic stem cells', *Submissions*, p.S530

extent techniques for cloning human tissue might be implicated by the principles' in the Declaration.[16]

10.17 The Attorney-General's Department, in a further detailed submission, elaborated on the development of the Declaration. The submission outlined the early development of proposals to incorporate a prohibition on 'cloning for the purposes of reproduction'.[17]

10.18 Member States of UNESCO debated whether a range of specific practices should be included in the final text during the development of the Declaration. The Attorney-General's Department submission outlines this discussion in detail[18] and notes that the Drafting Committee elaborating the Declaration 'decided to accept a proposal to insert in the text a reference to the prohibition of practices which were contrary to human dignity, such as cloning of human beings for reproductive purposes'.[19] Preliminary discussions during the preparation of the Declaration referred to the:

> …necessary distinction between human reproductive cloning aimed at the birth of an individual and non-reproductive human cloning techniques for research, diagnostic or therapeutic purposes.[20]

10.19 After canvassing the range of other practices that were discussed in the course of the development of the Declaration, including the use of embryos for research purposes, the Attorney-General's Department states:

> In conclusion, the records indicate that a wide range of practices and issues were raised during deliberations on the development of the instrument. However, there is little evidence of any in depth analysis or consideration … [of these issues]. There is no evidence of any particular analysis of the issue of the creation of embryos for research purposes by any means occurring either in the lead up to the Revised Preliminary Draft or the finalization of the Declaration …[21]

16 Attorney-General's Department, *Submissions*, p.S535

17 Attorney-General's Department, *Submissions*, pp.S876-877

18 Attorney-General's Department, *Submissions*, pp.S877-880

19 Attorney-General's Department, *Submissions*, p.879. Final Report of the Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, UNESCO, 25 July 1997, Paris, BIO-97/CONF.201/9, p.9, paragraph 40, *Exhibit* 46

20 'Reproductive Human Cloning: Ethical Issues', Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.1, *Exhibit* 50

21 Attorney-General's Department, *Submissions*, pp.S880-881

10.20 Dr Nicholas Tonti-Filippini argued that the AHEC report had misinterpreted the meaning of the ban in the Declaration on human reproductive cloning:

> … UNESCO did not make a distinction between cloning a human embryo for therapeutic or research purposes only and cloning a human embryo to have it develop to adulthood.[22] …
> [The] inclusion of the word "reproductive" was to distinguish the reproduction of a human being via cloning from the reproduction of a somatic cell or cell line which is now a well established practice in medicine. At no stage did the International Bioethics Committee or UNESCO endorse the view that reproductive cloning did not include cloning human embryos for research purposes.[23]

10.21 The Queensland Bioethics Centre also argued that the distinction between 'reproductive' and 'therapeutic' cloning was not used by UNESCO in its Declaration:[24]

> It does not appear in the Declaration itself and … [the Centre was informed that] it does not appear in the official documents used in the development of the Declaration. At no stage did UNESCO endorse the view that reproductive cloning did not include cloning human embryos for research purposes.[25]

10.22 The submission from the Attorney-General's Department also considered the argument raised by Dr Tonti-Filippini in some detail. The Department concluded that it:

> … does not find any evidence that "reproductive cloning of human beings" was intended to cover, in addition to the reproductive cloning of whole human beings, the creation of embryos for research purposes or other uses of cloning techniques involving human embryos. References to cloning as a practice contrary to human dignity as they appear throughout the [International Bioethics Committee] and UNESCO record suggest that it was the full reproduction of a whole human being alone that was intended to be covered by the phrase 'reproductive cloning of human beings'. Nor is there any clear evidence that Member States were required to form a collective view as to whether the creation of embryos for research purposes or a range of other practices would be contrary to human dignity and

22 Dr Nicholas Tonti-Filippini, *Submissions*, p.S588
23 Dr Nicholas Tonti-Filippini, *Submissions*, p.S591
24 Queensland Bioethics Centre, *Submissions*, p.S706
25 Queensland Bioethics Centre, *Submissions*, p.S706

> therefore inconsistent with the general principle enshrined by Article 11.[26]

10.23 A resolution on the implementation of the Declaration[27] provided for a system of follow-up to promote its implementation and invited the Director-General of UNESCO to prepare a global report on the issues dealt with in the Declaration. The first report, published on 23 August 1999, states in relation to Article 11 that:

> This prohibition concerns the reproductive cloning of human beings and should not be interpreted as prohibiting other applications of cloning.[28]

This report, however, does not resolve the issue, as 'other applications of cloning' could refer to the cloning of cells or tissue.

10.24 In the light of all of the above, the Attorney-General's Department considers that:

> It would be reasonable to expect that if 'reproductive cloning of human beings' included a global ban on the creation of human embryos for research purposes, that it would have been reflected in the record of the Committee of Experts, and found its way into documents produced since the adoption of the Declaration. Similarly, if there was an in-depth discussion and consensus reached that a particular practice violated the principle of 'respect for human dignity' and was therefore brought within the scope of the first sentence of Article 11, the Department would expect this to be reflected in the official record also.[29]

10.25 The Department concludes that:

> Consequently, it appears that the Committee of Governmental Experts did not intend to pronounce a universal prohibition on the deliberate creation of embryos for research purposes or for sources of tissue for therapeutic purposes. This is consistent with the approach adopted by Member States that the Declaration was intended to articulate key principles and provide an ethical framework to guide Member States in the development of national

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26 Attorney-General's Department, *Submissions,* p.S882

27 UNESCO Resolution 29 C / Resolution 17 entitled 'Implementation of the Universal Declaration on the Human Genome and Human Rights'

28 Division of the Ethics of Science and Technology of UNESCO, *Global Report on the Situation World-Wide in the Fields relevant to the Universal Declaration on the Human Genome and Human Rights,* BIO – 503 / 99 / CIB – 6 / 2, 23 August 1999, p.13, *Exhibit* 47

29 Attorney-General's Department, *Submissions,* p.S882

> policy and law to regulate scientific research, primarily in the field of genetics.[30]

10.26 The Attorney-General's Department notes that such an interpretation does not mean that practices such as the deliberate creation of embryos for research purposes or for sources of tissue for therapeutic purposes are therefore to be regarded as permissible under the Declaration. Rather the issues arising from these practices are a matter of domestic policy to be settled by Australia.[31]

10.27 In the light of the above, it is clear that Article 11 of the Declaration covers the use of cloning technology to produce whole human beings. However, there are differing views internationally as to the further operation of the Article. The breadth of the wording and the non-binding nature of the Declaration provide scope for countries to determine the operation of the provisions of the Declaration domestically.

EUROPE: BIOMEDICINE CONVENTION

10.28 In November 1996 members of the Council of Europe approved the *Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine* (the Biomedicine Convention).[32] The Convention 'provides a broad framework of principles to guide the development of the national legislation [of member states] regulating biology and medicine'.[33]

10.29 The Attorney-General's Department noted:

> A number of particularly contentious issues, including human cloning, and embryo protection, were deferred for particular attention and are the subject of additional protocols.[34]

10.30 The Biomedicine Convention differs from the UNESCO Declaration in relation to embryo experimentation, Article 18 of the Convention states:

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30 Attorney-General's Department, Submissions, pp.S882-883

31 Attorney-General's Department, *Submissions*, p.S883

32 The Council of Europe was set up in 1949 and consists of 41 European states. Australia is not a party to the Convention. Whilst neither the Convention nor its Additional Protocol on Human Cloning (to be discussed below), impose binding legal obligations on Australia, the Convention and the Protocol may be signed by States that are not members of the Council of Europe but which have participated in their elaboration, for example, Australia. AHEC report, Chapter 5, paragraph 5.7 and http://conventions.coe.int/Treaty/EN/cadreprincipal.htm. Other countries in this category are Canada, the Holy See, Japan and the United States

33 Attorney-General's Department, *Submissions*, p.S535

34 Attorney-General's Department, *Submissions*, p.S535

> 1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
>
> 2. The creation of human embryos for research purposes is prohibited.[35]

Britain, as the only Member State to allow the creation of embryos for research, is entitled to opt out of this provision when the Convention is ratified by the UK Parliament. Germany, Poland and Belgium abstained from support for the Convention because the Convention does not impose a total ban on embryo research.[36]

Convention Protocol Banning Human Cloning

10.31 The first binding international instrument to ban cloning for reproductive purposes was the Additional Protocol to the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, on the *Prohibition of Cloning of Human Beings*.[37] It was adopted by the Parliamentary Assembly on 22 September 1997 and by the Council of Europe on 12 January 1998.[38]

10.32 Only states that have signed the Biomedicine Convention may also sign the Protocol which supplements the Convention.[39] The Protocol builds on Articles 1, 13 and 18 of the Biomedicine Convention.[40]

10.33 Article 1 contains a prohibition on reproductive cloning and Article 2 prohibits any exceptions to this ban. Article 1 states:

> 1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
>
> 2. For the purpose of this article, the term human being "genetically identical" to another human being means a

35 Attorney-General's Department, *Submissions*, p.S536

36 House of Commons Library, *Cloning Research Paper* 97/43, 27 March 1997, p.31

37 For the text of the Protocol see - http://conventions.coe.int/treaty/en/Treaties/Html/168.htm. See also the *Charter of Fundamental Rights of the European Union* (Official Journal of the European Communities, 2000/C 364/01) adopted in Nice, France on 7 December 2000. It expressly prohibits reproductive cloning of human beings, eugenic practices (in particular those aimed at the selection of persons) and making the human body and its parts as such a source of financial gain (Article 3). The Charter does not contain a provision on embryo research

38 Attorney-General's Department, *Submissions*, p.S536

39 See Articles 3 and 4 of the Protocol. Member States of the Council of Europe, the European Community and other states that have participated in the Protocol's elaboration may sign it. As noted above, Australia is one such country

40 Explanatory Report on the Protocol, http://conventions.coe.int/treaty/en/Reports/Html/168.htm. Paragraph 1

> human being sharing with another the same nuclear gene set.[41]

The interpretation of the Protocol

10.34 The Explanatory Report on the Protocol[42] states that it is necessary to distinguish between three situations—the cloning of cells, the use of embryonic stem cells in cloning techniques and the cloning of human beings. Only the last is covered by the Protocol.

10.35 The Explanatory Report outlines the thinking behind the Protocol:

> Deliberately cloning humans is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning.[43]

10.36 The precise behaviour that is prohibited by the Protocol is 'any attempt artificially to produce genetically identical human beings'. The Report states that the Protocol 'explicitly restricts genetic identity to sharing the same nuclear gene set….'[44]

10.37 The Report also states:

> The term "nuclear" means only genes of the nucleus—not the mitochondrial genes—are looked at with respect to identity, which is why the prohibition of cloning human beings also covers all nuclear transfer methods seeking to create identical human beings. The term "the same nuclear gene set" takes into account the fact that during development some genes may undergo somatic mutation.[45]

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41 The Protocol is limited to a ban on reproductive cloning by means of, for example, embryo splitting or somatic cell nuclear transfer. It does not address issues such as cloning of cells and the use of embryonic stem cells in cloning techniques. These issues will be dealt with in a further protocol on embryo protection which has not yet been developed, Attorney-General's Department, *Submissions*, p.S536

42 The text of the Explanatory Report does not constitute an instrument providing an authoritative interpretation of the text of the Protocol, although it might facilitate understanding of the provisions http://conventions.coe.int/treaty/en/Reports/Html/168.htm

43 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 3

44 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 5

45 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 7

10.38 On the meaning of the term 'human being', the Report states that 'it was decided to leave it to domestic law to define the scope of the expression … for the purposes of the application of the present Protocol'.[46]

10.39 The Protocol stipulated that it would come into effect after five States had ratified the text.[47] It was ratified by Slovakia, Slovenia, Greece, Spain, Georgia and Romania and took effect on 1 March 2001. Twenty-two of the Council of Europe States have now signed the Protocol.[48]

The European Group on Ethics

10.40 The European Group on Ethics in Science and New Technologies (EGE) is a multi-disciplinary body answering directly to the President of the European Commission.[49] Its role is to advise the European Commission and also the European Parliament and the Council of Ministers—which may all refer questions to it—on how the ethical values of European society can be taken into consideration in the scientific and technological development promoted by European Community policies.

10.41 Its opinion on 'Ethical Aspects of Human Stem Cell Research and Use'[50] was adopted unanimously by the Group and made public on 14 November 2000. The opinion seeks to clarify for European institutions the ethical questions relating to the exercise of their powers in this area. Such powers could include financing research or adopting safety standards. It also adopts as a basis for its views Europe's 'legal and ethical pluralism—a reminder that it is for each member state to legislate on the derivation of stem cells from human embryos'.[51]

10.42 The opinion states that, while the Group recognises the major interest of research on human stem cells, it considers that at present 'the creation of embryos by somatic cell nuclear transfer ["therapeutic cloning"] for research on stem cell therapy would be premature' since there are

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46 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 6. The Netherlands lodged a declaration at the time of signature stating that: 'In relation to Article 1 of the Protocol, the Government of the Kingdom of the Netherlands declares that it interprets the term 'human being' as referring exclusively to a human individual, ie a human being who has been born'. European Treaty Office, http://conventions.coe.int

47 Article 5 of the Protocol provides for entry into force after five ratifications including four member states

48 http:// conventions.coe.int/Treaty/EN/cadreprincipal.htm. The Protocol has taken effect as an international instrument. The effect of the Protocol within the member states of the Council of Europe is subject to the constitutional arrangements of each of the member states

49 This body is a product of the European Union not the Council of Europe

50 The European Group on Ethics makes public in Paris its opinion on '*Ethical Aspects of Human Stem Cell Research and Use*', Paris, 14 November 2000, IP/00/1293

51 '*Ethical Aspects of Human Stem Cell Research and Use*', Paris, 14 November 2000, IP/00/1293

alternative sources of human stem cells such as spare embryos, foetal tissues and adult stem cells.

10.43 The Group therefore recommended a specific European Community budget for research on alternatives such as adult stem cells, the broad dissemination of the results of such research at European level without it being hidden for reasons of commercial interest, an ethical assessment of research on stem cells financed by the European Community budget prior to the launch of the project and steps to ensure that the demand for spare embryos and oocyte (egg) donation does not increase the burden on women undergoing fertility treatment.

10.44 In relation to the use of stem cells in clinical testing, the Group stressed the need for safety and the protection of the health of the patients. It mentioned the risk that the transplanted stem cells could cause abnormalities or induce the creation of cancerous tumours and stressed that the potential benefits for the patients should be taken into account but not exaggerated.[52]

UNITED STATES OF AMERICA

10.45 Regulation of human cloning and embryo research has been undertaken at both national and state level in the United States. In that respect, the regulatory environment in the United States has some similarity to Australia.[53]

10.46 The most significant feature of the regulation of human cloning and embryo research at the federal level in the United States is the rigid separation between the public and private sectors. Federal funding for human embryo research is, in fact, banned under provisions attached to the spending bills that fund the National Institutes of Health (NIH), the leading provider of research funds in the United States.[54] On the other hand little, if any, federal regulation applies to research involving the use

52 In a resolution of 7 September 2000, the European Parliament stated its opposition to the creation of supernumerary embryos and to therapeutic cloning. European Parliament, B5-710, 751, 753 and 764/2000. A report by the International Bioethics Committee of UNESCO contains a useful summary of national legislation in several countries. International Bioethics Committee UNESCO, 'The Use of Embryonic Stem Cells in Therapeutic Research' – a report of the IBC on the ethical aspects of human embryonic stem cell research, BIO-7/00/GT-1/2(Rev.3), Paris, 6 April 2001

53 There is a variety of complex legislation in the 50 States of the United States. The national initiatives are most relevant to Australia. For this reason, as well as to keep the discussion as brief as possible, the discussion will canvass only federal regulation

54 Meredith Wadman, 'Backing for anti-cloning bill reopens embryo debate', *Nature*, Volume 388, 7 August 1997, p.506

of embryos if it is funded by the private sector, although the Food and Drug Administration (FDA) has recently asserted jurisdiction over reproductive cloning as long as safety issues are raised.[55]

10.47 The following discussion outlines:

- the US federal regulatory response to the cloning of Dolly the sheep and more recent media reports of efforts to clone a human being; and
- the regulatory initiatives regarding embryonic stem cell research.

Human Cloning For Reproductive Purposes

10.48 In March 1997 in the immediate aftermath of the announcement of the cloning of Dolly, President Clinton directed that no federal funds should be allocated to any research procedure for the cloning of human beings. In addition the President requested that the National Bioethics Advisory Commission (NBAC)[56] examine and report within 90 days on the ethical and legal implications of human cloning through somatic cell nuclear transfer techniques.[57]

10.49 The NBAC's report thus focused on human reproductive cloning.[58] The NBAC noted that there were no federal regulations prohibiting the use of private funds for the purpose of cloning human beings.[59] It was unable:

> … to agree at this time on all the ethical issues that surround the issue of cloning human beings in this manner. It seems clear to all of us, however, given the current stage of science in this area, that any attempt to clone human beings via somatic cell nuclear transfer techniques is uncertain in its prospects, is unacceptably dangerous to the fetus and, therefore, morally unacceptable.[60]

10.50 The NBAC recommendations included:

- a continuation of the moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer;

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55 See paragraphs 10.56 – 10.58 below

56 The NBAC was established by President Clinton in 1995 to advise and make recommendations to the National Science and Technology Council and to others on bioethics issues and their policy implications

57 AHEC report, Chapter 5, paragraph 5.13. National Bioethics Advisory Commission (NBAC), *Cloning Human Beings: Executive Summary*, June 1997

58 NBAC, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, June 1997

59 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

60 NBAC, *Cloning Human Beings: Executive Summary*, June 1997, Letter to the President, 9 June 1997

- an immediate request to all firms, clinicians, investigators [researchers], and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium;
- federal legislation be enacted to prohibit anyone from attempting, in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It was critical, however, that such legislation include a sunset clause to ensure a Congressional review of the issue after a specified time period (three to five years).[61]

10.51 The NBAC also concluded:

- any regulatory or legislative actions undertaken to effect the prohibition on creating a child by somatic cell nuclear transfer be written carefully so as not to interfere with other important areas of scientific research;
- if a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer techniques to create a child should be preceded by research trials governed by the twin protections of independent review and informed consent, consistent with existing norms of human rights protection;
- the United States Government cooperate with other nations and international organisations to enforce any common aspects of their respective policies on the cloning of human beings.[62]

10.52 The NBAC did not close off the possibility of regulating rather than banning the use of such procedures in the future.[63] The position adopted by the NBAC is not totally consistent with the UNESCO Declaration which expressly prohibits reproductive human cloning on the basis that it is contrary to human dignity.[64]

10.53 On 9 June 1997, President Clinton introduced into Congress the Cloning Prohibition Bill 1997. It proposed that a review of the prohibition of human cloning be undertaken by the NBAC five years after the passage of the legislation. The Bill would have prohibited the cloning of humans or research for the purpose of cloning a human embryo and also would have prohibited any federal funds being used for any such research.[65]

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61 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

62 NBAC, *Cloning Human Beings: Executive Summary*, June 1997. See also testimony by Dr Thomas Murray a member of the NBAC to the Subcommittee on Oversight and Investigations of the House of Representatives Energy and Commerce Committee of Congress at the hearings on issues raised by human cloning research, http://www.house.gov/commerce/hearings/03282001/-141/Murray 206.htm, 28 March 2001

63 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

64 The same point was made by AHEC, AHEC report, Chapter 5, paragraph 5.15. See earlier discussion in this report at paragraphs 10.15-10.27

65 AHEC report, Chapter 5, paragraph 5.16

10.54 Attempts to legislate a prohibition on cloning a human being through Congress foundered in 1998. Patients' groups successfully argued that a cloning ban would also bar the use of somatic cell nuclear transfer techniques for therapeutic purposes. Groups opposed to the use of embryos in research would not accept a bill that might have allowed the creation of human embryos only for researchers to then destroy them.[66]

10.55 A number of Bills relating to either human cloning and/or stem cell research were introduced into Congress during the latter half of 2000 and the first half of 2001.[67] These take generally one of two approaches—either to completely ban the cloning of human embryos no matter what the purpose or to prohibit reproductive cloning only.[68] President Bush announced his support for legislation which would ban all forms of human cloning and recently made an announcement relating to the conduct of embryonic stem cell research (see paragraph 10.72 below).[69] On 31 July the House of Representatives voted to ban human cloning. The legislation (proposed by Representative Weldon) would make it a crime to clone a child or to create embryos for medical research. The bill is yet to be considered by the Senate.[70]

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66 Aaron Zitner, LA Times, http://www.latimes.com/cgi-bin/print.cgi, 25 March 2001. The States of California, Michigan, Louisiana and Rhode Island ban any type of cloning both publicly and privately funded- Miriam Falco and Matt Smith, CNN, http://www.cnn.com/2001/HEALTH/03/28/human.cloning/ 28 March 2001. Dr Thomas Murray, a member of the NBAC, in evidence to a Congressional hearing (discussed below) stated that NBAC staff had surveyed state laws in 1999. At that time five states (not named) had enacted legislation to directly prohibit human cloning and ten states had laws regulating research on embryos and fetuses that could also restrict cloning activities, http://www.house.gov/commerce/hearings/03282001-141/Murray 206.htm, 28 March 2001

67 At the time of the completion of this report nine Bills dealing with human cloning and/or stem cell research had been introduced into either the House of Representatives or the Senate of the US Congress

68 The 'Human Cloning Prohibition Act of 2001' (HR 1644) introduced by Representative Dave Weldon would completely ban the cloning of human embryos no matter what the purpose. It would allow some forms of scientific research such as research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans. The 'Cloning Prohibition Act of 2001' (HR 2172), introduced by Representative James Greenwood, would prohibit 'reproductive cloning' only, that is, the use or attempted use of human somatic cell nuclear transfer technology with the intent to initiate a pregnancy. The Bill would not apply to the use of somatic cell nuclear transfer technology to clone molecules, DNA, cells or tissues. Another Bill, the Stem Cell Research Act of 2001 (HR 2059), introduced by Representative James McDermott, would provide for the conduct of embryonic stem cell research using only embryos that have been donated from *in vitro* fertilisation clinics within set parameters. The Bill would require that the research conducted on the stem cells must not result in the creation of human embryos or in reproductive cloning. http://www.senate/gov/search/index.html

69 Francis Temman, 'Bush Administration backs ban on human cloning', 22 June 2001

70 Lisa Richwine, 'US House approves a broad ban on human cloning', http://biz.yahoo.com/rf/010731/n31177001_5.html

Food and Drug Administration (FDA) regulatory control

10.56 Recent announcements of attempts to clone a human being (discussed in Chapter 3) have led to Congressional Committee hearings such as those conducted by the Subcommittee on Oversight and Investigations of the House of Representatives Energy and Commerce Committee in March 2001.

10.57 At these hearings the Food and Drug Administration (FDA) which has the authority to regulate medical products (including biological products, drugs and devices) responded to what it called the 'incorrect' view that there are no legal controls in place in the United States governing the use of cloning technology to clone a human being.[71] It:

> … views the use of cloning technology to clone a human being as a cause for public health concern…Because of unresolved safety questions on the use of cloning technology to clone a human being, FDA would not permit the use of cloning technology to clone a human being at this time.[72]

10.58 The FDA issued a rule for cellular and tissue based products in January 2001 that establishes the regulatory framework for human cells, tissue, cellular and tissue-based products and requires establishments to register with the Agency and list their products.[73] Some have expressed doubt as to whether the FDA has authority to regulate the matter even though the agency has claimed jurisdiction.[74]

Research Involving Embryonic Stem Cells

10.59 The NBAC issued a report—*Ethical Issues in Human Stem Cell Research*[75]—examining issues connected with research involving embryonic stem cells

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71 Dr Kathryn Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, http://www.house.gov/commerce/hearings/03282001-141/zoon205.htm, 28 March 2001

72 Dr Kathryn Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, http://www.house.gov/commerce/hearings/03282001-141/zoon205.htm, 28 March 2001

73 The established FDA process in overseeing clinical research is based on Title 21, Code of Federal Regulations, 312.42, Congressional evidence of Dr Zoon, 28 March 2001

74 http://energycommerce.house.gov, 28 March 2001 and Aaron Zitner, LA Times, http://www.latimes.com/cgi-bin/print.cgi, 25 March 2001. Michael Soules, for example, President of the American Society of Reproductive Medicine, gave evidence to Congressional hearings that he was satisfied that the FDA had requisite authority in this area and did not see the need for any further legislation, http://www.house.gov/commerce/hearings/03282001-141/soules208.htm, 28 March 2001. Rick Weiss, 'Legal barriers to human cloning may not hold up', Washington Post, 23 May 2001, http://washingtonpost.com/wp-dyn/health/specials/genetherapy/A61636-2001May22.html12/07/2001

75 NBAC, *Ethical Issues in Human Stem Cell Research*, Rockville, Maryland, January 2000

in January 2000. It concluded that federal funds should not be provided for making embryos solely for the generation of human embryonic stem cells. Federal funding for the use and derivation of embryonic stem cells should be limited to two sources of such materials: cadaveric foetal tissue and embryos remaining after fertility treatments. It recommended that an exception be made to the present statutory ban on federal funding of embryo research to permit federal agencies to fund research involving the derivation of human embryonic stem cells from these sources under appropriate regulations that include public oversight and review. It also recommended that federal agencies should not fund research involving the derivation or use of human embryonic stem cells from embryos made solely for research purposes using *in vitro* fertilisation (IVF).

10.60 Further NBAC recommendations included that federal agencies not fund research involving the derivation or use of human embryonic stem cells from embryos made using somatic cell nuclear transfer into oocytes (eggs). The NBAC also recommended that, in giving informed consent for the donation of excess embryos after fertility treatments, the option of donation to stem cell research should only be presented after the donor has decided to discard (not donate to another couple or store) the embryo.[76]

National Institutes of Health (NIH)—stem cell guidelines

10.61 On 23 August 2000 the National Institutes of Health (NIH) published their final guidelines for embryonic stem cell research—'National Institutes of Health Guidelines for Research using Human Pluripotent Stem Cells'—(the Guidelines). The Guidelines became effective on 25 August 2000. Compliance with the Guidelines will be imposed as a condition of the award of a grant of research funding.[77]

10.62 A moratorium on research using human pluripotent stem cells derived from human embryos and foetal tissue put in place by the Director of NIH in January 1999 was lifted on 25 August 2000.[78]

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76 These recommendations are similar to the subsequent National Institutes of Health (NIH) Guidelines for Research using Human Pluripotent Stem Cells discussed below

77 National Institutes of Health, *Guidelines for Research Using Human Pluripotent Stem Cells*, http://www.nih.gov/news/stemcell/stemcellguidelines.htm. In June 2001 the National Institutes of Health issued a report on the state of the science on stem cells: *Stem Cells: Scientific Progress and Future Directions.* This had been requested by the Secretary of Health and Human Services in February 2001. See http://www.nih.gov/news/stemcell/scireport.htm

78 The Guidelines define 'human pluripotent stem cells' as 'cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos'. These

10.63 The Guidelines:

> … prescribe the documentation and assurances that must accompany requests for NIH funding for research using human pluripotent stem cells from human embryos or fetal tissue. The *Guidelines* state specific criteria for informed consent and establish a Human Pluripotent Stem Cell Review Group to review documentation of compliance with the NIH *Guidelines*. In addition, the *Guidelines* delineate areas of research involving human pluripotent stem cells that are ineligible for NIH funding.[79]

Requirements established in the Guidelines

10.64 The US NIH Guidelines require:

- for studies using cells derived from human embryos, NIH funds may be used only if the cells were derived from frozen embryos created for the purposes of fertility treatment and in excess of clinical need;
- no use of inducements, monetary or otherwise, for the donation of the embryo, and a clear separation between the fertility treatment and the decision to donate embryos for this research;
- investigators [researchers] who propose to use human pluripotent stem cells from foetal tissue will follow both the Guidelines and all laws and regulations governing human foetal tissue and human foetal tissue transplantation research;
- the informed consent specify whether or not information that could identify the donor(s) will be retained;[80]
- the donation of human embryos or foetal tissue be made without any restriction regarding the individual(s) who may receive the cells derived from the human pluripotent stem cells for transplantation;
- review and approval of the derivation protocol by an Institutional Review Board;[81]

Guidelines were described by Professor Alan Trounson as the 'international gold standard', *Transcript*, p.12

79 NIH News Release - 'NIH Publishes Final Guidelines for Stem Cell Research', http://www.nih.gov/news/pr/aug2000/pd-23.htm, 23 August 2000

80 To ensure that human embryos donated for research are in excess of the clinical need of the individuals seeking fertility treatment and to allow potential donors time between the creation of embryos for fertility treatment and the decision to donate for research purposes, only frozen human embryos should be used to derive human pluripotent stem cells. In addition, individuals undergoing fertility treatment should be approached about consent for donation of human embryos to derive pluripotent stem cells only at the time of deciding the disposition of embryos in excess of the clinical need

- informed consent to have been obtained from individuals who sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes.[82]

10.65 The NIH state:

> Federal law currently restricts the use of Department of Health and Human Services (DHHS) funds for human embryo research. DHHS funds cannot be used for the derivation of stem cells from human embryos. The Congressional restriction, however, does not prohibit funding for research utilizing human pluripotent stem cells because such cells are not embryos.[83]

Thus, while NIH funded researchers may conduct research on embryonic stem cells once they are derived from the embryo, they may not actually derive the stem cells because that would result in the destruction of the embryo.

10.66 The Guidelines make no distinction based on the country in which a human pluropotent stem cell line is developed. All stem cell lines to be used in such stem cell research funded by NIH must meet the same requirements. This would apply to Australian researchers seeking NIH funding.[84]

10.67 In relation to compliance, the NIH state:

> Compliance with the *Guidelines* will be largely determined prior to the award of funds. Follow-up to ensure continued compliance with the *Guidelines* will be conducted in the same manner as for all other conditions of all other NIH grant awards. It is the responsibility of the investigator [researcher] to file progress reports, and it is the responsibility of the funded institution to ensure compliance with the NIH *Guidelines*. NIH staff will also monitor the progress of these investigators as part of their regular duties.[85]

10.68 Work involving human pluripotent stem cells that is ineligible for NIH funding includes research in which human stem cells are used to create or

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81 Such bodies are generally equivalent to an institutional ethics committee (IEC) in Australia.

82 The requirements for the informed consent process are listed in Chapter 12 – see paragraph 12.77

83 NIH Fact Sheet on Human Pluripotent Stem Cell Guidelines, http://www.nih.gov/news/stemcellfactsheet.htm, 23 August 2000. The NIH cited advice by the DHHS General Counsel to the same effect, *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, http://www.nih.gov/news/stemcell/stemcellguidelines.htm

84 Professor Alan Trounson, *Transcript*, p.25

85 NIH Guidelines, http://www.nih.gov/news/stemcellguidelines.htm

contribute to a human embryo, the use of stem cells that were derived from human embryos created for research purposes rather than fertility treatment, derivation or use of stem cells derived using somatic cell nuclear transfer, research in which stem cells are combined with an animal embryo and research in which stem cells are derived using somatic cell nuclear transfer for the purposes of reproductive cloning of a human.[86]

10.69 These new Guidelines to allow federal funding of human embryonic stem cell research drew both praise and opposition. Opposition arose because the research requires the destruction of the embryos to obtain the stem cells. Federal law forbids research on the embryo itself. The likely practical effect of the Guidelines is that privately funded researchers will derive the stem cells from embryos and then provide them to NIH funded researchers for use in federally funded research projects.[87]

Review of federal funding using the NIH Guidelines

10.70 There were reports in early 2001 that President Bush would block NIH research funding under the new Guidelines. President Bush was reported as saying in January 2001 that federal money should not be used for research on foetal tissue or on so-called stem cells derived from embryos. He was said to support adult stem cell research and research using stem cells from foetuses that died a natural death (but not from aborted foetuses).[88]

10.71 By February 2001 it was reported that there was a struggle over ES cell research at the political level in the United States pitting opponents of embryo research against patients' advocates and scientists. Rather than banning NIH funding of embryonic stem cell research the Bush administration sent the issue to be reviewed by the US Department of Health and Human Services.[89]

10.72 A decision on whether federally funded research can continue on human stem cells taken from embryos was expected by mid-2001.[90] On 9 August

86 Professor Alan Trounson noted that the Guidelines would not permit the creation of embryos for the purposes of therapy, *Transcript*, p.26

87 The announcement by President Bush of his approval of federal funding for research on existing lines of embryonic stem cells (see paragraph 10.72) throws some doubt on the current status of these Guidelines as they would have permitted federal funding for the use of embryos surplus to assisted reproductive technology programs to obtain embryonic stem cells.

88 Ron Fournier, 'Bush Won't Fund Stem Cell Research' http://dailynews.yahoo.com/h/op/20010126/tsbush-abortion.html, 26 January 2001 and Lisa Richwine, Reuters, 29 March 2001

89 Robin Toner, New York Times, http://www.nytimes.com, 18 February 2001

90 BBC news, http://news.bbc.co.uk, 7 March 2001

2001 President Bush announced his approval of federal funding for research on existing lines of embryonic stem cells. He stated:

> As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research.
>
> I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made.
>
> Leading scientists tell me research on these 60 lines has great promise that could lead to breakthrough therapies and cures. This allows us to explore the promise and potential of stem-cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.
>
> I also believe that great scientific progress can be made through aggressive federal funding of research on umbilical cord, placenta, adult and animal stem cells, which do not involve the same moral dilemma. This year your government will spend $250 million on this important research.
>
> I will also name a president's council to monitor stem-cell research, to recommend appropriate guidelines and regulations and to consider all of the medical and ethical ramifications of bio-medical innovation.
>
> This council will consist of leading scientists, doctors, ethicists, lawyers, theologians and others, and will be chaired by Dr Leon Kass, a leading bio-medical ethicist from the University of Chicago.[91]

President Bush's proposal will go to Congress. Private funding of such research would not be affected by any change of policy by the new administration over NIH funding of stem cell research. The most probable impact of a change in policy would be to slow the pace of research because fewer researchers would be able to participate.[92] Following President

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91 ABCNews.com, http://abcnews.go/com/sections/plitics/DailyN…/stemcells_Bush_transcript010809.htm 9 August 2001

92 Lauran Neegaard, Associated Press, 25 January 2001 and Aaron Zitner, LA Times, http://www.latimes.com, 15 March 2001

Bush's address, the NIH issued a statement which included the following points:

> Using the more than 60 existing cell lines from around the world, many more researchers will now be able to explore the potential of human embryonic stem cells, in addition to the extensive work already sponsored by NIH using human adult stem cells. We believe this combined research has high potential both for opening new doors in basic scientific understanding and for discovery of new treatments for some of our most devastating diseases.[93]

10.73 Following President Bush's announcement on 9 August regarding federal funding for research on existing stem cell lines, the NIH, which will oversee federal funding of this research, is reported to have held meetings with parties which have rights to the stem lines. The NIH is endeavouring to develop a policy to end uncertainty over access to the research and is reported to have promised to provide researchers at NIH and elsewhere as much access as possible to stem cells.[94] On 27 August 2001 the NIH issued an 'Update on Existing Human Embryonic Stem Cells' in which it listed the ten entities that have advised it they have derived human embryonic stem cells that meet the President's criteria. The Update reported that NIH is creating a Human Embryonic Stem Cell Registry that will list the human embryonic stem cells that meet the eligibility criteria, and NIH welcomes grant 'applications proposing research using such stem cells, including requests to use existing funds or for supplements to existing grants to conduct such research.' Initially the Registry will contain only basic information about the cells.[95]

10.74 It has been reported that many of the stem cell lines approved for research funding under President Bush's new policy have been mixed with mouse cells. To ensure that animal diseases are not transmitted to people the FDA has required special safety testing of cell therapies that use animal products. It appears therefore that FDA guidelines would make it difficult to use these cells in human tests because the cells would be treated as though they were transplants of animal tissue, and this might rule out their use on some groups of patients.[96] A subsequent report stated that

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93 NIH Acting Director, Ruth Kirschstein, MD, National Institutes of Health, 9 August 2001, http://www.nih.gov/news/pr/aug2001/od-09.htm

94 'NIH aims to craft stem-cell policy', *The Boston Globe*, 23 August 2001; http://www.boston.com/dailyglobe2/235/…NIH_aims_to_craft_stem_cell_policy+.shtm

95 US Department of Health and Human Services, National Institutes of Health Update on Existing Human Embryonic Stem Cells, 27 August 2001, http://www.nih.gov/news/stemcell/082701list.htm

96 At the same time it was reported that when researchers are ready to begin tests scientists will be able to grow stem cells without mouse cells or will be able to work within the FDA's guidelines, Gillis, Justin and Connolly, Ceci, 'Stem Cell Research Faces FDA Hurdle',

provided the stem cell lines met FDA safety requirements, they could still be used. However, until details of the cell lines are known, the use that can be made of them will not be certain.[97]

UNITED KINGDOM

10.75 The United Kingdom has approached the regulation of human cloning and its related research from within an existing framework of legislative regulation of assisted reproductive technologies and embryo experimentation. That existing regulation has allowed research involving the use of embryos since 1990 under strict regulation and for purposes specified in legislation as detailed below. More recently, the licensing regime in the United Kingdom was expanded by the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. These Regulations enable the issue of a licence for research to extract stem cells from an embryo and to deliberately create an embryo for research by somatic cell nuclear transfer.[98]

The Human Fertilisation and Embryology Authority

10.76 In 1984 the *Report of the Committee of Inquiry into Human Fertilisation and Embryology*—the Warnock Report, named after the inquiry Chair Dame Mary Warnock—was issued.[99] It recommended the establishment of a statutory body to oversee the practice of certain fertility treatments and human embryo research in the UK.[100]

10.77 The *Human Fertilisation and Embryology Act 1990* (UK) (the HFE Act) was passed in 1990. It established the Human Fertilisation and Embryology Authority (HFEA). The HFEA has comprehensive authority and jurisdiction over all clinics and laboratories dealing with gametes or

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Washington Post, 23 August 2001; http://www.washingtonpost.com/wp-dyn/articles/A53580-2001Aug23.html

97 'Current Stem Cells May Get FDA's OK', 24 August 2001, http://dailynews.yahoo.com

98 See paragraph 10.93 below

99 Report of the Committee of Inquiry into Human Fertilisation and Embryology, HMSO, July 1984 (cm.9314)

100 The conduct of medical research is also governed by guidance produced by the Department of Health and a wide range of professional bodies and, if carried out in the National Health Service, requires approval from a research ethics committee. Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human health, *Stem Cell Research:- Medical Progress with Responsibility*, (Chief Medical Officer's Report) Department of Health (UK), June 2000, p.32

embryos[101] whether those clinics and laboratories are in the private sector or the public sector.

10.78 The HFEA's principal tasks are to license and monitor those clinics that carry out *in vitro* fertilisation (IVF), donor insemination and human embryo research.[102] The HFEA also regulates the storage of gametes and embryos and keeps a register of all licensed treatments carried out in the UK.

10.79 Every centre in the UK that offers clinical treatment involving assisted reproductive technologies, storage of gametes or embryos or which carries out research involving the use of human embryos must be licensed by the HFEA. All licensed centres may be subject to an annual inspection.[103]

10.80 The approval of a properly constituted independent ethics committee is a prerequisite to the HFEA considering an application for a research licence to enable research using human embryos. In addition, all applications for a research licence are submitted for peer review.[104]

10.81 The HFE Act makes it a criminal offence to bring about the creation of an embryo outside the human body or to keep or use an embryo without a licence from the HFEA.[105] The HFE Act also sets out the parameters within which the HFEA may issue treatment, storage or research licences. Sections 3(3) and (4) of the HFE Act provide that:

> (3) A licence cannot authorise –
>
> (a) keeping or using an embryo after the appearance of the primitive streak,

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101 An embryo is defined in the HFE Act as 'a live human embryo where fertilisation is complete and references to an embryo include an egg in the process of fertilisation and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote (Section 1). There is a clear ambiguity in this definition given that somatic cell nuclear transplant does not involve 'fertilisation' as such but transfer of the nucleus. This ambiguity remains. House of Commons Library, *Cloning Research Paper 97/43*, 27 March 1997, p.23

102 Section 16 outlines the procedure for the grant of a licence. Section 12 sets out general conditions relating to all licences granted under the Act. Section 15 sets out general conditions for research licences, including that no embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project (section 15 (4)). The HFE Act does not apply to the keeping of, or research on, stem cells once extracted from an embryo and grown in a laboratory, Chief Medical Officer's Report, p.33

103 Section 9(8). Any particular premises need not be inspected in any particular year if the licence committee considers an inspection in that year unnecessary, section 9(9)

104 Section 25 of the HFE Act provides that the HFEA shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence granted under the HFE Act. Reference is made to these requirements in the Human Fertilisation and Embryology Authority, Code of Practice at paragraphs 11.6,11.7 and 11.8. Paragraph 11.7 sets out the requirements for the composition of ethics committees for these purposes and notes that the membership of the ethics committee should be approved by the HFEA

105 Section 3 (1)

(b) placing an embryo in any animal,

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or

(d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.[106]

(4) For the purposes of subsection 3(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

10.82 Schedule 2 of the HFE Act states that the HFEA cannot authorise a research project involving the use of human embryos unless it appears to the HFEA to be necessary or desirable for one of the following purposes:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriage;
- developing more effective methods of contraception;
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;
- other such purposes as may be specified in regulations.[107]

10.83 The HFE Act further requires that such research licences may only be granted if the HFEA is satisfied that any proposed use of embryos is necessary for the purposes of the research.[108] Acceptable embryo research is hence governed by the purpose of the research not the source or mode of creation of the embryos to be used in the research.

106 The technique used to produce Dolly involved placing the nucleus from the donor cell into an unfertilised egg, not into another embryo. Because of this it could be argued that Section 3 of the HFE Act is ambiguous. The HFEA has stated that it would not allow human cloning attempts – a licence would not be granted. Embryo splitting is forbidden for treatment purposes under the Code of Practice paragraph 9.11. See also House of Commons Library, *Cloning, Research Paper 97/43*, 27 March 1997, pp.22-23

107 Paragraph 3(2) of Schedule 2 to the HFE Act. Paragraph 3(3) of Schedule 2 of the HFE Act provides that 'Purposes may only be so specified [in regulations] with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied'

108 Paragraph 3(6) of Schedule 2 to the HFE Act. The licence may be given subject to such conditions as are specified in the licence and may authorise the performance of the activities authorised by the regulations in such manner as may be specified in the licence (paragraphs 3(7) and 3(8) of Schedule 2 to the HFE Act). A licence under this paragraph may be given for any period up to a maximum of three years (paragraph 3(9) of Schedule 2 to the HFE Act)

10.84 Schedule 3 of the HFE Act sets out detailed requirements for the giving of valid consent by donors to the use of gametes or embryos. Consent must be in writing and must not have been withdrawn.[109]

10.85 The HFE Act expressly prohibits one type of cloning technique, namely the nuclear substitution of a cell whilst it forms part of an embryo,[110] but the technique used to create Dolly involved nuclear substitution into an unfertilised egg not an embryo. While the HFE Act does not expressly prohibit this form of cloning or embryo splitting, since both involve the use or creation of embryos outside the body, a licence is required. In 1997 the HFEA announced a policy not to issue licenses for any procedures involving embryo splitting or nuclear transfer.

Joint Report By HFEA and Human Genetics Advisory Commission

10.86 In December 1998 a joint Committee of the Human Genetics Advisory Commission (HGAC)[111] and the HFEA published a report entitled *Cloning Issues in Reproduction, Science and Medicine*. The report concluded that the HFE Act has proved effective in dealing with new developments relating to human cloning. It recommended that the existing safeguards be recognised as wholly adequate to forbid human reproductive cloning in the UK. However, it suggested that the Government might consider introducing legislation that would explicitly ban human reproductive cloning (regardless of the technique used) so that the full ban would not depend on the decision of a statutory authority (the HFEA) but would be enshrined in statute. The report also recommended that the Secretary of State for Health should consider specifying in regulations two further purposes for which the HFEA could issue research licences (in addition to those listed in paragraph 10.82 above) so that potential benefits to be derived from cloning technology could be explored. These additional purposes were the development of:

- methods of therapy for mitochondrial disease; and
- therapeutic treatments for diseased or damaged tissues or organs.[112]

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109 Note also that paragraph 7.20 of the HFEA Code of Practice requires that the specific consent of people providing gametes must be provided to the export of those gametes or of embryos produced using them

110 Section 3(3)(d)

111 Established in December 1996 to provide independent advice to the Ministers for Health and Industry in the UK on issues arising from developments in human genetics that have social, ethical and/or economic consequences. This body has merged with others to form part of the Human Genetics Commission— see below. HGAC/HFEA, *Cloning Issues in Reproduction, Science and Medicine,* December 1998, paragraph 1.7, http://www.dti.gov.uk/hgac/papers/papers-d.htm

112 http://www.dti.gov.uk/hgac/papers/papers-d.htm, section 9

10.87 In June 1999 the UK Government issued its response to this report. It reaffirmed that the deliberate cloning of individual humans is unacceptable and welcomed the recognition that the existing safeguards were adequate to prevent it. It requested the Chief Medical Officer to establish an expert advisory group to consider the HGAC / HFEA recommendations for additional grounds to be added to the HFE Act for the grant of research licences.

Chief Medical Officer's Report

10.88 The Chief Medical Officer's Expert Advisory Group was asked to assess developments in stem cell research and research involving cell nuclear replacement and the likely timescales of the research; to establish more clearly the evidence of potential benefits for human health of such research; to consider possible alternatives to research involving embryos which might achieve the same ends and potential technical and safety issues that might arise. In particular the Expert Advisory Group was asked to consider whether regulations should be made to extend the purposes for which human embryos could be used in research.[113]

10.89 In June 2000 the Chief Medical Officer's Expert Advisory Group handed down its report. Its recommendations included:

- permitting research using human embryos (created by *in vitro* fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell based treatments, subject to the existing controls in the HFE Act;
- the HFEA, in licensing any research using embryos created by cell nuclear replacement, should satisfy itself that there are not other means of meeting the objectives of the research;[114]
- individuals whose eggs or sperm are used to create the embryos to be used in research should give specific consent indicating whether the resulting embryos could be used in a research project to derive stem cells;[115]

113 Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health, *Stem Cell Research:- Medical Progress with Responsibility*, Department of Health, June 2000, p.12

114 There is already a requirement for the HFEA to satisfy itself in relation to any individual research project that the use of embryos is necessary for meeting the objectives of that research – paragraph 3 (b) of Schedule 2 of the HFE Act. See also Government Response to the Recommendations made in the Chief Medical Officer's Expert Group Report, 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

115 The UK Government in its response to the report requested the HFEA to incorporate such a provision as a condition in relevant research licences. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

- the progress of research involving stem cells derived from embryonic sources should be monitored by an appropriate body to establish whether the research is delivering the anticipated benefits and identify any concerns;[116]
- the mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted;
- the transfer of an embryo created by cell nuclear replacement into the uterus of a woman (so called 'reproductive cloning') should remain a criminal offence; and
- the need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.[117]

10.90 The major recommendation of the report—that research using embryos (created by assisted reproductive technologies or cell nuclear replacement) be permitted in order to increase understanding about human disease and disorders and their cell based treatments—would permit the deliberate creation of embryos by means of somatic cell nuclear transfer.[118]

10.91 In August 2000 the UK Government announced that it accepted the Expert Advisory Group's recommendations in full and would bring forward the necessary legislation to implement them.[119]

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

10.92 The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 implement the primary recommendation of the Chief Medical Officer's Expert Advisory Group. The Regulations were passed

116 The UK Government has requested in its response that the HFEA and the Human Genetics Commission undertake this task. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

117 The UK Government has requested in its response that the HFEA and the Human Genetics Commission advise on this. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

118 The Chief Medical Officer's Expert Advisory Group report states that, if research is successful, a question could arise over the creation or use of embryos to develop tissue specifically for treatment purposes, particularly if it was necessary to create a particular embryo for patients in order to provide compatible tissue. At present the only treatment services using embryos which can be licensed under the HFE Act are medical, surgical or obstetric services to help women to 'carry children'. The possibility of an amendment to the Act would need to be considered by Parliament if the research suggested that the use of embryo-derived cells for broader treatment purposes was necessary and acceptable. Chief Medical Officer's Report, p.34

119 Chief Medical Officer's Report, p.34

on a conscience vote of both Houses of the United Kingdom Parliament[120] and came into force on 31 January 2001.[121] The Regulations provide that in addition to the purposes specified in paragraph 10.79 above:

> The Authority may issue a licence for research under paragraph 3 of Schedule 2 to the Act for any of the purposes specified in the following paragraph.
>
> (2) A licence may be issued for the purposes of –
>
> (a) increasing knowledge about the development of embryos;
>
> (b) increasing knowledge about serious disease; or
>
> (c) enabling any such knowledge to be applied in developing treatments for serious disease.

10.93 The Regulations legalise embryo research to extract stem cells and deliberate creation of embryos by somatic cell nuclear transfer for research purposes; they faced impassioned opposition from religious leaders and other campaigners in Britain.[122]

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120 The Regulations passed the House of Commons 366-174. A vote in the House of Lords to refer the Regulations to a Select Committee was defeated 212-92. In March 2001 the House of Lords appointed a Select Committee to consider and report on issues connected with human cloning and stem cell research arising from the Regulations. These issues include the ethical, legal, scientific, medical and commercial issues surrounding the regulations, House of Lords, Current Inquiries and Invitations to Submit Evidence, Session 2000-2001, http://www.publications.parliament.uk/pa/Id199697/Idselect/Idscenqs.htm

121 The full implementation of the new Regulations has been delayed by a court challenge. The Prolife Alliance has successfully sought judicial review of the coverage of the Human Fertilisation and Embryology Act 1990. At issue is whether the cloning of human embryos by means of somatic cell nuclear transfer for birth as well as research is legal without a licence from the HFEA because of a loophole in the law. A decision is still pending. The Prolife Alliance is arguing that the definition of 'embryo' in the HFE Act does not include cloned embryos because such embryos do not involve fertilisation. The new Regulations are based on the existing definition. Patrick Goodenough, 'UK court case may upend decision to legalize embryonic cloning', 26 January 2001, 'Loophole May allow Cloning', http://www.cnsnews.com/viewForeignBureaus.asp?Page=/Foreign.../For 20010126g.htm. Dominic Kennedy, *The Times*, 15 January 2001, http://www.latimes.com/egi-bin/print.egi. In response to the challenge the HFEA has stated it will not make any decision on research applications under the new Regulations involving embryos created using cell nuclear replacement until the proceedings have concluded. The HFEA will accept licence applications under the new categories provided embryos have not been created by cell nuclear replacement. HFEA, *HFEA Update*, Issue 5, February 2001, p. 2

122 For example, eleven religious leaders of different faiths joined forces to try to halt the regulations in the House of Lords. The leaders included the Archbishops of Canterbury and York, the Roman Catholic Archbishops of Westminster and Glasgow and the President of the Muslim College, the Chief Rabbi and Orthodox, Sikh, Baptist and Evangelical leaders. They claimed that the 'philosophical and ethical implications' of cloning had not been fully considered. They wanted the matter referred to a select committee. This move was defeated. Victoria Combe, 'Faith leaders join forces to oppose human cloning law', *Daily Telegraph*, http://www.telegraph.co.uk, 15 January 2001. See also *Sydney Morning Herald*, 16 January

10.94 The Parliamentary Under-Secretary of State for Health (Ms Yvette Cooper) stated, during debate on the Regulations in the House of Commons, that 'the purpose of the regulations is to permit embryonic stem cell research' citing the potential of the research for the alleviation of serious disease.[123] She noted that the Regulations:

> … do not change the regulatory framework, the strict limits, the 14-day limit or the need for an individual licence from the HFEA. They also do not permit research if there is any other way of doing the research without embryos. They also still require embryos to be donated with informed consent.[124]

10.95 With respect to the purpose of permissible research, Ms Cooper stated:

> … embryo research should not be permitted for just any old thing. That is why the regulations specify serious disease. We are talking not about the common cold but about spinal injuries, burns, osteoporosis, stroke, cancer, heart disease—about serious disease and disability.[125]

10.96 Ms Cooper reiterated the position of the UK Government on reproductive cloning: 'Human reproductive cloning is illegal. It must stay illegal. Under these regulations it will stay illegal'.[126]

2001, p.8. Reaction to the House of Commons vote was strong in Germany where production of human embryos for research is banned, Mark John, Reuters, 21 December 2000. For reaction to the British changes in Europe see House of Commons Library, *Stem Cell Research and Regulations Under the Human Fertilisation and Embryology Act 1990*, Research Paper 00/93, 13 December 2000, pp.32-34

123 House of Commons, *Hansard*, Debates for 19 December 2000, column 212. Ms Cooper noted that the Parkinson's Disease Society, Diabetes UK, the Alzheimer's Disease Society, the Huntingdon's Disease Association, the Royal Society, the British Medical Association, British Heart Foundation, the Cancer Research Campaign and Breakthrough Breast Cancer all supported the regulations, column 213

124 House of Commons, *Hansard*, Debates for 19 December 2000, column 214. The Under-Secretary of State stated that between 1991 and 1998, 48,000 embryos were used in research after being donated by couples going through IVF treatment while 250,000 embryos created through IVF were destroyed. House of Commons, *Hansard*, Debates for 19 December 2000, column 215. See also Chief Medical Officer's Report, paragraph 3.5 which also stated that 118 embryos were created in the course of research

125 House of Commons, *Hansard*, Debates for 19 December 2000, column 215.

126 House of Commons, *Hansard*, Debates for 19 December 2000, column 220. She further stated that the UK Government would embed the ban on human reproductive cloning in primary legislation, Ibid, column 220. She also stated that the HFEA Act does not distinguish between research on embryos created through IVF and those created through somatic cell nuclear transfer. House of Commons, *Hansard*, Debates for 19 December 2000, column 220

Human Genetics Commission

10.97 On 20 December 1999 the UK Government announced the establishment of a new Human Genetics Commission. The Cabinet Office had reviewed the advisory and regulatory framework for biotechnology in May 1999. It concluded that the system for regulating individual products and processes operated satisfactorily. However, the advisory framework should be more transparent (to gain public and professional confidence); more streamlined (to avoid gaps, overlaps and fragmentation); and ensure a capacity to deal with rapid developments and take broad social and ethical issues fully into account.[127]

10.98 The new Commission incorporates responsibilities formerly addressed by other bodies including the Human Genetics Advisory Commission.[128] Its terms of reference include to:

- analyse current and potential developments in human genetics and advise Ministers on their likely impact on human health and health care and their social, ethical, legal and economic implications;
- advise on strategic priorities in the delivery of genetics services by the National Health Service;
- advise on strategic priorities for research; and
- consider specific issues related to human genetics and related technologies as requested by Ministers.[129]

RELEVANCE OF THESE INTERNATIONAL DEVELOPMENTS TO AUSTRALIA

10.99 There are clearly great differences in approach to matters involving human cloning and embryo research in various countries. The varying approaches outlined in this chapter demonstrate the difficulty in developing or discerning a clear international consensus especially on issues as sensitive as the use of embryos in research.

10.100 Elements of an international consensus are emerging on some issues. It appears to be well accepted (although not in all quarters) that a distinction

127 http://www.hgc.gov.uk. The Food Standards Agency will have similar responsibilities for GM foods and the Agriculture and Environment Biotechnology Commission will have responsibility for all other areas of biotechnology

128 The other bodies were the Advisory Committee on Genetic Testing and the Advisory Group on Scientific Advances in Genetics, http://www.hgc.gov.uk

129 http://www.hgc.gov.uk

must be made between the application of cloning techniques to the replication of a person or the creation of a child and the application of cloning techniques to the creation of tissues and cell lines with the aim of developing therapies for use in the treatment of disease and disability.

10.101 The use of cloning techniques for reproductive purposes has brought international condemnation and there appears to be a consensus against reproductive cloning. The provisions of the UNESCO Declaration, the Protocol to the European Biomedicine Convention, the Charter of Fundamental Rights of the European Union, the regulatory mechanism in the United Kingdom and the legislative attempts to prevent cloning for reproductive purposes in the United States provide clear evidence of this.

10.102 The potential for significant developments and gains to be made from stem cell research is accepted in the United States and the United Kingdom. Recent regulatory developments in the United States and the United Kingdom have reflected attempts to balance the harnessing of this potential with the protection of the human embryo, the special status of which is widely acknowledged in those countries. The tension between harnessing the potential of stem cell research and the protection of human embryos is also evident in the more cautious approach of the European Group on Ethics.

10.103 The approach taken by the United Kingdom is similar to that in Victoria, South Australia and Western Australia. The advantages of such a regulatory approach are that it is clear and consistent, applies throughout the country and the requirements and procedures for any research involving the use of embryos are plain to researchers, practitioners and the general public. The general principles are well established and have been debated extensively. The regulatory framework in the United Kingdom has not inhibited the conduct of research in that country since the United Kingdom is a world leader in this research and the regulatory mechanism has proved flexible enough to accommodate developments in the science. The United Kingdom framework also covers both the public and private sectors. The Committee regards the distinction drawn on this basis at the federal level within the United States regulatory framework and the lack of consistent national coverage as the greatest weaknesses of the United States system.

10.104 Some of the international developments outlined in this chapter have been drawn on by the Committee in developing its recommended regulatory framework for Australia. This is outlined in Chapter 12.