

CHAPTER 6

INTERNATIONAL PERSPECTIVES

- 1 The tensions between the potential benefits conferred to mankind and the ethics of human stem cell research, reproductive and therapeutic cloning have also sparked intense debate internationally. In addition to embarking on an extensive local consultation process, the BAC examined in detail the perspectives and positions adopted by countries and organisations worldwide.
- 2 The BAC obtained information from various sources, including legislation, guidelines, reports and recommendations of ethics committees, and news reports and articles. The study revealed that different countries adopted diverse views and positions, serving to highlight the diversity in our global and pluralistic society. Indeed, ethical positions adopted by one country may be deemed unacceptable in another, and vice versa. To illustrate the spectrum of views, the positions of a major organisation and some large jurisdictions are described in detail below.

UNESCO's report

- 3 UNESCO's Report by the International Bioethics Committee (IBC)¹ accords recognition to the diverse opinions on the ethical acceptability of human stem cell research and recognises that the solutions adopted by different countries may differ. Ethical debate of human stem cell research should be carried out at appropriate national regulatory levels, reaching, if possible, a consensus on 'the limits of the permissible'. This should be coupled with an on-going process of education and information, and also dialogue within the society with concerned parties.
- 4 UNESCO recommends that whatever the form of research involving embryos, if allowed, should be carried out within a regulatory framework with

¹ United Nations Educational, Scientific and Cultural Organisation (UNESCO), "The Use of Embryonic Stem Cells in Therapeutic Research", Report of the International Bioethics Committee (IBC) on the Ethical Aspects of Human Embryonic Stem Cell Research, 6 April 2001.

appropriate guidelines and controls, giving due weight to ethical considerations. As the dignity and rights of both parental donors of embryos should be given particular attention, the donation of embryos should only come after the implications of research are fully disclosed and subject to free, informed consent having been obtained. New and alternative technologies for obtaining human stem cell lines (such as from adult stem cells or nuclear transfer techniques) in the area of therapeutic transplantation research should be considered, with a careful weighing of the advantages and risks. In this respect, nuclear transfer should only be used for therapeutic research.

- 5 UNESCO's Report also states that in all aspects of research involving human embryos, importance must be given to the respect of human dignity and also in respect of the principles set out in the Universal Declaration of Human Rights (1948)² and the Universal Declaration on the Human Genome and Human Rights (1997)³.

United Kingdom

- 6 In the United Kingdom, the Human Fertilisation and Embryology Act 1990 ('the Act') allows the creation and use of human embryos up to 14 days old for research purposes. Amendments made to the Act (Schedule 2 paragraph 3(2))⁴ have widened the scope of research to include therapeutic cloning. All such research is subject to a licence being issued by the Human Fertilisation and Embryology Authority (HFEA), with other strict conditions under the Act. In addition, the conduct of such research is governed by guidelines issued by the Department of Health and a wide range of professional bodies.
- 7 The Act does not distinguish between embryos created by IVF and those created by SCNT. However licenses will be issued only if the HFEA is satisfied that such research involving the creation of an embryo is necessary for the purposes of the project and that the project is within the list of specified

² Article 3 proclaims a right to life in general.

³ Article 1 proclaims that "Practices which are contrary to human dignity such as reproductive cloning of human beings shall not be permitted".

⁴ Human Fertilisation and Embryology (Research Purposes) Regulations 2001.

purposes. To date, the HFEA has not received any application to conduct research involving the creation of an embryo using cell nuclear replacement. Reproductive cloning is not expressly banned by the Act, as the HFEA believes that the current regulation and guidelines offer sufficient protection.

- 8 The Act does not apply to the keeping of, or research on, human stem cell lines after extraction from embryos. Stem cells derived from adult tissue are governed by the Human Tissue Act 1961. Stem cells derived from foetal tissue (EG cells) are governed by the Code of Practice on the Use of Foetuses and Foetal Material in Research and Treatment (the “Polkinghorne Code of Practice”)⁵. All research proposals must be approved by a research ethics committee.

- 9 The Nuffield Council on Bioethics, in addressing ethical issues in human stem cell therapies, has concluded that the removal and cultivation of embryonic stem cells from donated embryos do not indicate a lack of respect for them. The Council was also of the view that there was no moral distinction between embryo research into reproductive and diagnostic methods, and research into potential therapies. The Council therefore recommends that research involving human embryos be permitted for the purpose of developing tissue therapies from the derived ES cells. As regards the creation of additional embryos, the Council expressed the view that while there was sufficient and appropriate donated embryos from IVF treatments available, there would be no compelling reason to allow such creation to increase the number of embryos for ES cell research or therapy. It was also emphasised that informed consent as regards stem cell research and subsequent use of the developed cell line must be obtained from the donors of foetal material and embryos from which ES cells are derived, as a safeguard to protect these donors who could in theory, be identified by DNA analysis. The Polkinghorne Code of Practice, which this report endorses, requires such consent to be in the written form.

⁵ Drawn up by the Polkinghorne Committee in 1989.

The United States of America

- 10 The position in the United States is unique. Privately funded research projects are not subject to any restriction, whilst research using public funding is regulated. In 1998, the National Bioethics Advisory Commission was charged with the task of conducting a thorough review of the issues associated with human stem cell research. In its Report produced in 1999⁶, the Commission recommended that federal funding be allowed for research involving the derivation and use of human EG cells from cadaveric foetal tissue, but not for research involving the derivation or use of human ES cells from embryos created solely for research purposes using IVF or SCNT.
- 11 The position in the United States, as at 10 August 2001, supports limited public funding for research on human embryonic stem cells obtained from established human stem cells lines only. Following from this, the National Institute of Health (NIH) established a Human Embryonic Cell Registry to list human embryonic stem cells meeting the eligibility criteria, in order to grant funding for such research⁷. Before federal funding is granted, each request for federal funding must cite one of the human embryonic stem cell lines listed on the NIH Registry, meet existing scientific and technical merit criteria and must be recommended by the National Advisory Council. In contrast, privately funded human stem cell research remains free from control. Reproductive cloning is forbidden with federal funding. Although there are no legal barriers to carrying out reproductive cloning with private funds, there is a voluntary moratorium in place.

Japan

- 12 In October 2001, the Japanese government approved guidelines governing therapeutic cloning, embryonic research and stem cell research. The guidelines require researchers to, *inter alia*, obtain individual consent before

⁶ “Ethical Issues in Human Stem Cell Research”, USNBAC, Rockville, Maryland 1999.

⁷ US National Institute of Health, NIH Guide: “Notice of criteria for federal funding of research on existing human embryonic stem cells and establishment of NIH Human Embryonic stem cell registry”, 7 November 2001.

using stem cells for research purposes. A law in effect as of 6 June 2001 bans reproductive cloning but allows cloning for certain limited purposes.

Australia

13 The House of Representatives Standing Committee on Legal and Constitutional Affairs was tasked to review the report of the Australian Health Ethics Committee (AHEC) entitled “Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings” and developed its own recommendations, including recommending a regulatory mechanism within which the research could progress. This was presented to Parliament in September 2001, and is at this point in time, still under consideration. The final decision will be made by the Commonwealth, State and Territory Parliaments and a consistent approach nationally is anticipated to be in place by June 2002.

14 The Committee has recommended enactment of legislation to regulate this area of research for both publicly and privately funded research, as well as the setting up of a licensing body. The Committee reiterated that reproductive cloning research directed towards producing a whole human being must be banned. The use of adult stem cells and embryonic stem cells derived from surplus embryos is permitted. The Committee was however of the view that given the number of surplus embryos available, the specific creation of new embryos for research purposes is unnecessary and should perhaps not be permitted⁸. The Committee also set out parameters within which such research should be carried out, if permitted.

15 The Committee recommends that should the final decision permit such creation, a three-year moratorium could be imposed on the creation of embryos via SCNT, as there is currently no therapeutic purpose to be served. To date, research has not identified any specific opportunities that require the deliberate formation of embryos. The Committee further recommended that

⁸ The deliberate creation of embryos for research is not permitted under the Western Australia, South Australia and Victoria legislations, and the NHMRC Ethical Guidelines on Assisted Reproductive Technology.

surplus embryos from IVF treatments could be used for research, subject to approval by an international ethics committee, a national licensing body, and adherence to stringent guidelines. It was an unanimous view that research using AS cells should be encouraged and pursued, as this source of stem cells is wholly accepted, even by those who oppose the use of embryos in research.

Sweden

16 There is currently no legislation in Sweden regulating the research on or handling of human stem cells. The Swedish Research Council recognises the lack of or insufficient regulation in respect to human stem cell research and has presented guidelines on the review of such research⁹. Current research and cultivation of human stem cells from adults, umbilical cord blood and aborted fetuses have been invoked under existing laws and regulations. The derivation of adult stem cells for research is regarded as tissue donation, and the use of cord blood constitutes the utilisation of biological material. Research on the derivation of stem cells from aborted fetuses before week 14 may be done only under special circumstances, subject to the consent of the mother and of the National Board of Health and Welfare. The use of surplus embryos from IVF treatment is permissible only if there are no acceptable alternatives and is deemed necessary to advance research on human stem cells. This is subject to informed consent by the donors and the stem cells must be derived from embryos within the 14-day old limit. While the creation of embryos by IVF solely for research purposes is not allowed, the Council is of the view that the creation of embryos via SCNT may be ethically defensible for therapeutic purposes. However such research is incompatible with the Council of Europe's Convention on Human Rights and Biomedicine¹⁰. The European Union Commission's Advisory Group on Ethics and the Nordic Council of Minister's Bioethical Committee have proposed a renunciation of research with SCNT, even for the purposes of treatment, as this technique is open to misuse.

⁹ Swedish Research Council's Guidelines for Research – Ethical review of human stem cell research, 4 December 2001.

¹⁰ The Convention includes a ban on creating embryos for the specific purpose of research.

Other countries

17 Some countries such as Ireland, Costa Rica and Ecuador expressly prohibit research on human embryos, stating that the right to life of an “unborn child” is equal to that of the mother. In other countries, such as Austria, Canada, Finland, Hungary, Italy, Norway, Peru, Switzerland and Tunisia, the creation of human embryos, other than for the purpose of reproduction, is prohibited.

Conclusion

18 The above are illustrations of the diverse views taken by different countries, with regard to human stem cell research, and which were carefully considered by the BAC in coming to its recommendations.

19 A summary of perspectives and positions adopted by other countries worldwide studied by the BAC is attached as **Annex J**.