CHAPTER 5

INTERNATIONAL COMPARISONS

5.1 The regulation of stem cell research and cloning has been undertaken in a number of countries. Without being comprehensive, the following provides an overview of some of the regulatory regimes in these countries.

United Kingdom

5.1 Issues of assisted reproduction were first considered by the Committee of Inquiry into Human Fertilisation and Embryology, chaired by Dame Mary Warnock. The Committee reported in 1984.[1]

5.1 The Warnock report formed the basis of the Human Fertilisation and Embryology Act 1990 (HFE Act). The Act established the Human Fertilisation and Embryology Authority (HFEA), which regulates the activities authorised under the Act. Destructive embryo research is permitted but must be carried out under a licence. Three types of licence may be issued under the Licensing Committee of HFEA: a licence to provide treatment services; to store embryos and gametes; or to carry out research on embryos. In order for a research licence to be issued, the HFEA must be satisfied that the use of human embryos is 'necessary and desirable' for one of the following purposes:

- to promote advances in the treatment of infertility;
- to increase knowledge about the causes of congenital disease;
- to increase knowledge about the causes of miscarriage;
- to develop more effective techniques for contraception;
- to develop methods for detecting the presence of gene or chromosome abnormalities in embryos prior to implantation;
- other such purposes as may be specified in regulations.

5.1 Certain activities cannot be authorised. These include research on human embryos over 14 days old; placing an embryo in any animal; and replacing a nucleus of a cell of an embryo with the nucleus taken from a cell of any person, embryo or subsequent development of an embryo. In 1977 the HFEA announced a policy not to issue licenses for any procedures involving embryo splitting or nuclear transfer.[2]

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

2 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001, pp.191-94 [hereafter *Human Cloning*].

5.1 In November 2000, following the recommendations of a report by the Chief Medical Officer's Expert Advisory Group entitled *Stem Cell Research: Medical Progress with Responsibility*,[3] draft Regulations were presented to Parliament to extend the permitted research purposed under the HFE Act. The regulations were passed and came into effect on 31 January 2001 as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. The regulations allow the HFEA to licence research involving embryos for the purposes of increasing knowledge about the development of embryos; increasing knowledge about the development of disease; and enabling any such knowledge to be applied in developing treatment for serious disease. The Regulations legalise embryo research to extract stem cells and the deliberate creation of embryos by somatic cell nuclear transfer for research purposes (often referred to as 'therapeutic cloning').[4]

5.1 The ProLife Alliance sought a judicial review of the regulations, claiming that human embryos created by cell nuclear replacement (CNR) were outside the operation of the Act. In November 2001 the High Court ruled in support of the claim. The Government responded by introducing the Human Reproductive Cloning Bill under which it is an offence to use cloning techniques such as cell nuclear replacement for human reproductive cloning. In January 2002, the Government's appeal against the High Court judgement was allowed, in effect bringing embryos created through CNR within the scope of the 1990 Act.

5.1 In February 2002, the House of Lords Select Committee on Stem Cell Research concluded that research on embryonic stem cells to help develop new therapies should be allowed under strictly controlled conditions. The committee did not see any ethical difference between an IVF embryo and an embryo produced by CNR (or other methods) in their use for research purposes up to the 14 day limit. The committee approved further research into the practice of 'therapeutic cloning' under strict regulation by HFEA, while reiterating its total opposition to 'reproductive cloning'.[5]

United States

5.1 In the United States, regulation of human cloning and embryo research has been established at both the State and federal level. Following the cloning of Dolly, the Clinton administration directed that no federal funding for human cloning research be allocated. The President also requested the National Bioethics Advisory Commission (NBAC) examine and report on the ethical and legal implications of human cloning through somatic cell nuclear transfer techniques. The President

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3 Chief Medical Officer's Expert Advisory Group on Therapeutic Cloning, *Stem Cell Research: Medical Progress with Responsibility*, (the Donaldson Report), Department of Health, 2000, http://www.doh.gov.uk/cegc/stemcellreport.htm

4 House of Commons Science and Technology Committee, *Developments in Human Genetics and Embryology*, 4th Report of Session 2001-02, HC791, p.9; also, *Human cloning* pp.196-98.

5 House of Lords Stem Cell Research Committee, *Report,* February 2002, Session 2001-02, HL 83(i), http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm

introduced into Congress the Cloning Prohibition Bill 1997. This did not pass Congress and subsequently, a number of other Bills have been introduced.[6]

5.1 Federal funding for human embryo research was banned under provisions attached to the spending bills that fund the National Institutes of Health (NIH). A report from the NBAC in January 2000 concluded that federal funding should not be provided for making embryos solely for the generation of human embryonic stem cells. Rather, funding should be provided for research using embryonic stem cell using cadaveric fetal tissue and surplus embryos from fertility treatment. It was also recommended that no funding be provided for research involving the derivation or use of human embryonic stem cells from embryos made using somatic cell nuclear transfer.[7] In August 2000, the NIH published guidelines for use of human pluripotent stem cells. The guidelines include that NIH funds may only be used for research on cells derived from frozen embryos excess to fertility treatment; there is no inducements for the donation of the embryo; and there is informed consent for the donors.[8]

5.1 In August 2001, President Bush announced that US Government funding may only be spent on research using existing embryonic stem cell lines, as listed on the National Institutes of Health Human Embryonic Stem Cell Registry, but not on derivation of new lines. The rationale of this decision was that using already destroyed embryos it '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'.[9] The President also announced the formation of 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 biomedical innovation.

5.1 In March 2002, the NIH issued a clarification of its policy that allows federally-funded researchers to work on new embryonic stem cell lines or create new lines, as long as they can prove that this research is not paid for with Government money. Biotechnology Australia stated 'this effectively allows all US researchers, both those in the public and private sector, to derive and work with new embryonic stem cell lines'.[10]

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6 For a more extensive discussion of the US situation, see *Human cloning,* pp.180-91.

7 NBAC, *Ethical Issues in Human Stem Cell Research*, Rockville, Maryland, January 2000; see also *Human cloning,* pp.184-85.

8 National Institutes of Health, *Guidelines for Research Using Human Pluripotent Stem Cells,* http://www.nih.gov/news/stemcell/stemcellguidelines.htm see also *Human cloning*, pp.186-87.

9 President George W Bush, *Remarks by the President on Stem Cell Research*, 9.8.01, http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html

10 *Submission* 1263, p.14 (Biotechnology Australia).

5.1 While the federal government has acted to control the use of federally funded embryo research, there is no federal control of privately funded research. Privately funded research is generally subject to State rather than federal regulation. There is significant variation between States. Currently, nine States prohibit such research, however, in the other States there is effectively no control over private research on embryos.

5.1 In August 2002, California became the first US State to allow researchers to use public funds for research involving the derivation of and use of human embryonic stem cells and human embryonic germ cells from any source, including somatic cell nuclear transfer for the purpose of developing new medical treatments. The Californian legislation bans reproductive cloning.[11]

5.1 In July 2001, the US House of Representatives passed Republican-backed legislation to ban both reproductive and therapeutic cloning. But Senate Democrats are drafting legislation that would allow cloning for medical research, but not for producing live clone births. On 1 May 2002 a Bill 'To prohibit human cloning while preserving important areas of medical research, including stem cell research' was introduced, was read twice and referred to the Senate Committee on the Judiciary.[12]

Canada

5.1 In 1993, the Canadian Royal Commission on New Reproductive Technologies reported after a four year examination of activities related to human reproduction in Canada. The Royal Commission made 293 recommendations. The two overarching recommendations were for federal legislation to prohibit certain practices and the establishment of a national regulatory body to govern permissible assisted human reproduction activities.

5.1 Following the release of the Report, the Canadian Government conducted extensive consultations with interested stakeholders and the public on the main recommendations of the Royal Commission. Health Canada also established the Discussion Group on Embryo Research to provide policy advice on embryo research. The Discussion Group reported in November 1995.

5.1 In July 1995, the Canadian Government announced a voluntary moratorium on nine applications of human reproductive and genetic technologies as the first phase in the development of an overall framework to regulate these technologies. The applications included human embryo cloning, sex selection, and the buying and selling of eggs, sperm and embryos. An advisory committee was established to help monitor compliance by researchers and health professionals.

5.1 In June 1996, Bill C-47, the Human Reproductive and Genetic Technologies Bill was introduced. The Bill proposed a series of prohibitions based on the voluntary

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11 http://info.sen.ca.gov/pub/bill/sen/sb_0251-0300/sb_253_bill_20020830_enrolled.html

12 *Submission* 23, p.23 (NHMRC).

moratorium. The Bill did not complete the legislative process before the calling of the 1997 federal election.

5.1 When Bill C-47 was introduced, Health Canada published *Setting Boundaries, Enhancing Health*, outlining the Government's intention to establish a regulatory framework for assisted human reproduction. Consultations were held with stakeholders and provincial and territorial representatives. Draft legislative proposals were submitted by the Minister for Health to the House of Commons Standing Committee on Health in May 2001. The Committee reviewed the draft and provided recommendations.

5.1 Bill C-56, An Act Respecting Assisted Human Reproduction, was introduced in May 2002. The proposed legislation seeks to protect the health and safety of Canadians using assisted human reproduction (AHR) to build their families by regulating ethically acceptable practices such as *in vitro* fertilisation; to prohibit certain unacceptable activities; to regulate AHR activities and related research; and establish a regulatory body, the Assisted Human Reproduction Agency of Canada.[13]

5.1 The proposed legislation seeks to ban the following activities:

- creating a human clone for any purpose (ie reproductive or therapeutic purposes);
- creating an *in vitro* embryo for any purpose other than creating a human being or improving assisted reproduction procedures;
- creating an embryo from an embryo or fetus for purposes of reproduction;
- maintaining an embryo outside the body of a woman past the 14th day of development;
- identifying the sex of an embryo created for reproductive purposes, except for medical reasons such as sex-linked disorders;
- changing the DNA of human sperm, eggs or embryos so that the change can be passed to subsequent generations (germ-line alteration);
- transplanting non-human reproductive material/embryo into humans;
- creating a human being from reproductive material or an embryo that was previously transplanted into an animal;
- creating human/non-human combinations for reproductive purposes;
- paying a woman a financial incentive to be a surrogate mother;
- paying a donor for their sperm or eggs or providing goods or services in exchange; and
- selling or buying human embryos, or providing goods or services in exchange.

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13 http://www.parl.gc.ca/37/1/parlbus/chambus/house/bills/government/C-56/C-56_1/C-56_cover-E.html; *Submission* 23, p.24 (NHMRC).

5.1 Regulations will also be developed to govern AHR activities such as the collection, alteration, manipulation or treatment of any human reproductive material for the purpose of creating an embryo; the storage, handling and use of reproductive materials and embryos; the type of research allowed; and the donation of embryos no longer needed for reproduction.[14]

5.1 The Assisted Human Reproduction Agency of Canada will issue licences to AHR clinics and researchers conducting AHR-related activities regulated under the legislation to ensure that the activities are conducted in a safe and appropriate manner. It will inspect facilities to ensure compliance and will maintain a donor/offspring registry. The Agency will also provide reliable information on AHR to Canadians.

5.1 The Canadian Parliament has not completed its consideration of the Bill.

Sweden

5.1 In Sweden, there is no legislation specifically directed at stem cell research, however, other legislation applies. Adult stem cells and stem cells from aborted fetuses are regulated through the law on transplantation. Research on fetal tissue may only be performed with approval of the National Board of Health and Welfare and where special circumstances exist. The *In Vitro* Fertilisation Act 1988 and the Act Concerning Measures for Research or Treatment Involving Fertilised Human Ova 1991 govern embryo research. The 1988 Act regulates the practice of assisted reproduction and also permits some research on human embryos. The research must be performed within 14 days of fertilisation and only with the consent of the donors. Any research that seeks to genetically modify the embryo is prohibited. The Act stipulates that once research is completed the embryo must be destroyed and prohibits the implantation of a research embryo in a woman. The 1991 Act regulates reproductive research and research on embryonic development, covers storage of embryos and allows for embryos to be cryopreserved for five years.[15]

5.1 The Swedish Research Council issued guidelines in December 2001 covering stem cell research.[16] The use of embryos in research is permissible if there are no acceptable alternatives to attain equivalent results and if the project is judged to be necessary for the advancement of stem cell research. Embryos must be considered to be of no use for IVF treatment and the donors must give informed consent. The Council did not endorse the creation of embryos solely for research. The Council considered stem cells from embryos created by somatic cell nuclear transfer may be 'ethically justifiable' but cannot be allowed due to present laws in Sweden. The Council recommended a review to enable regulated therapeutic cloning to be

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14 Health Canada, *Proposed Act Respecting Assisted Human Reproduction-An Overview*, May 2002, http://www.hc-sc.gc.ca/english/media/releases/2002/2002_34.htm

15 European Parliament, Directorate General for Research, *The Ethical Implications of Research Involving Human Embryos, Final Study*, July 2000, p.49.

16 http://www.vr.se/fileserver/index.asp?fil=LCK7HDEK3U6H

undertaken. The Council also recommended the banning of reproductive cloning. The Swedish Government is currently preparing legislation on research ethics.[17]

Germany

5.1 The Embryo Prohibition Act 1992 prohibits all forms of 'consumptive research' on human embryos; that is, research not explicitly designed to preserve the embryo and facilitate implantation in a woman contravenes the Act. Those contravening the Act face up to five years imprisonment. The Act also creates a number of criminal offences for engaging in practices involving IVF technology. For example it is an offence to attempt to fertilise an egg cell for any purpose other than bringing about pregnancy in a woman from whom the oocyte originated or attempt to fertilise more oocytes than may be reimplanted within one treatment cycle. Research on the human embryo is only permitted where the objective of the research is to benefit the embryo. Cloning is prohibited.[18]

5.1 The use of fetal germ cells following abortions does not fall within the terms of the Embryo Protection Act. Fetal cells and tissues may be used for experimental and therapeutic purposes regulated through the Guidelines for the Utilisation of Fetal Cells and Fetal Tissues produced by the German Federal Medical Council.

5.1 In May 2001 the DFG (Germany's research funding agency) issued a statement supporting research on imported embryonic stem cells produced from surplus embryos. The DFG noted that imported ES cells were not subject to the Embryo Protection Act and that there was no justification to bar research on ES cells legally produced in a foreign country as a matter of principle. The DFG refused to endorse the production of embryos exclusively for research. It also stated that therapeutic cloning was neither scientifically or ethically justifiable.[19] Two ethics commissions then considered the issue, with each coming to differing conclusions. In January 2002 the German Parliament voted to allow human embryo stem cells to be imported for medical research. A motion to allow eventual production of embryonic stem cells in Germany was rejected.[20]

European Union

5.1 In early 2001, following the UK Government's decision to support therapeutic cloning, the EU established the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine. The Committee was to report to the European Parliament on the ethical, social, legal and economic developments in modern medicine. The report was extensively amended before its final adoption and

17 Information provided by the Embassy of Sweden, 1.10.02.

18 European Parliament, Directorate General for Research, *The Ethical Implications of Research Involving Human Embryos, Final Study*, July 2000, p.47.

19 DFG, *New DFG Recommendations concerning research with human stem cells*, May 2001, http://www.dfg.de/english/press/releases/Archive/presse_2001_16_eng.html

20 BBC News, *Germany authorises stem cell imports*, 03.1.02, http://www.bbc.co.uk

called for a complete ban on all forms of cloning, a prohibition on funding for stem cell research on surplus embryos and proposed that the report's guidelines take priority over national procedures.[21] In November 2001, the European Parliament rejected the report.

5.1 In July 2002, the EU agreed to a compromise to postpone all EU funding, except in certain specified cases, for research on human embryos and embryonic stem cells until the end of 2003. No EU funds may be used for research activities aimed at human reproductive cloning, modification of the genetic heritage of human beings, or the creation of embryos solely for research or stem cell procurement. At the core of the compromise was a commitment to establish by 31 December 2003, detailed implementation provisions for bioethical scrutiny of research activities within life science involving the use of human embryos and human embryonic stem cells.[22]

5.1 The EU's decision does not effect national governments which are free to spend their domestic research budgets as they see fit.

Other countries

5.1 The NHMRC also provided information on other countries and indicated that many countries currently do not have legislation relating to ART and research involving ART embryos. In these countries, such work may be undertaken.

5.1 In addition to Germany, no human embryo research is currently permitted in France, Switzerland, Norway, Ireland, Austria, Poland and Brazil. The Swiss national ethics committee is currently considering allowing use of existing embryonic stem cell lines. The French government has proposed allowing derivation and use of embryonic stem cells.

5.1 Both the derivation and use of stem cells from excess IVF embryos is permitted in Japan, Spain, Italy, Finland, Sweden, Israel and Singapore.[23]

Senator Sue Knowles
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21 The Scientist, *Never European twain shall meet*, 26.11.01, http://www.biomedcentral.com

22 Danish EU Presidency, *Press release,* 31.7.02, http://www.eu2002.dk/news/news_read.asp?iInformationID=21356

23 *Submission* 23, p.24 (NHMRC).