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# **Stem Cell Research and Regulations under the *Human Fertilisation and Embryology Act 1990* (Revised edition)**

The Government is introducing Regulations to extend the grounds for research using early embryos permitted under the *Human Fertilisation and Embryology Act 1990* to include a sixth category - increasing understanding about human diseases and disorders and their cell-based treatments.

Research involving human embryonic stem cells, which have the potential to develop into many kinds of human tissue, might lead to future treatments for degenerative diseases and damaged tissues.

The 1990 Act allows, in very limited circumstances, the creation of embryos by in vitro fertilisation and by the new cell nuclear replacement technique (cloning). The Regulations would extend the circumstances for which cell nuclear replacement could be used, to allow "therapeutic cloning". Cloning to produce an individual will remain prohibited.

Use of embryos in research and the cell nuclear replacement technique are controversial and Regulations being laid under the Act to give effect to these proposals are subject to debate and a free vote in both Houses.

Alex Sleator

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## Summary of main points

- The Government has accepted the recommendations of the Donaldson Report, and is bringing forward Regulations to amend the *Human Fertilisation and Embryology Act 1990* to extend the purposes for which research on early embryos is permitted. The purposes are those of increasing knowledge about the development of embryos, or about serious disease, and enabling such knowledge to be applied.
- Stem cells are unspecialised cells of the body at an early stage of development. These cells have the ability to divide and differentiate into a large number of cell types that make up the tissues and organs of the body. The ability of embryonic stem cells to develop into every cell type of the human body holds potential for development of new therapies.
- The creation of an embryo for research purposes is permitted under the Act in very limited circumstances. The Act does not differentiate between creation by fertilisation of an egg with a sperm, and the new cloning technique of cell nuclear replacement.
- The proposed Regulations would allow the use of embryonic stem cells and the creation of embryos by cell nuclear replacement to be used for research into new treatments for degenerative conditions and replacement tissues. Embryos created using this technique (so-called therapeutic cloning) could provide stem cells free from the problems of rejection.
- Alternative sources of stem cells exist which have with advantages and disadvantages. Research involving embryonic stem cells may progress more rapidly as they have the greatest potential to differentiate.
- The only treatments currently permitted under the Act using embryos created outside the body are to help women carry children. Creation of embryos to derive cells for other types of treatment that might become possible as a result of research (such as treatment for degenerative conditions) would require primary legislation.
- Prohibition of cloning of individuals (so-called reproductive cloning) is currently dependent on refusal of the Human Fertilisation and Embryology Authority (HFEA) to license treatment using embryos created by cell nuclear replacement. The Government has said that it will introduce primary legislation to enshrine this principle in law.
- The creation and cloning of embryos and their use in research are controversial. The proposed Regulations are subject to a vote in both Houses. This is to be a free vote, in recognition of the divergent ethical views that these matters generate.



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## I Introduction

The successful cloning<sup>1</sup> of Dolly the sheep in 1997 by the new cell nuclear replacement technique led to debate about scientific and ethical implications.<sup>2</sup> The Science and Technology Committee of the House of Commons published a report on *The Cloning of Animals from Adult Cells* on 20th March 1997.<sup>3</sup> The Government response to that report made clear that the cloning of individuals is "ethically unacceptable" and would not be permitted in the UK.<sup>4</sup>

A public consultation on the issues was set up jointly by the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Commission. The ensuing report *Cloning Issues in Reproduction, Science and Medicine* indicated the possibility that research using the technique of cell nuclear replacement could lead to new treatments for serious disorders by providing a source of new tissue. It recommended that research on human embryos up to 14 days should be allowed for two new purposes: to research development of new treatments for damaged tissues or organs and to allow the development of treatments of mitochondrial genetic diseases.<sup>5</sup>

Nearly 220 responses to the consultation were received, about 40 per cent from individuals and the rest from scientists, clinicians, academics, religious groups, ethicists, lawyers, industry and lay groups. This found a widespread concern about human reproductive cloning, including safety and ethical issues. However, many saw benefit in new techniques which might be developed to treat serious medical conditions.

The report, *Cloning Issues in Reproduction, Science and Medicine*, concluded that the *Human Fertilisation and Embryology Act 1990* has proved effective in dealing with new developments relating to human cloning. It recommended that "These safeguards be recognised as wholly adequate to forbid human reproductive cloning in the UK". However, it suggested that the Government might wish to consider introducing legislation that would ban human reproductive cloning regardless of the technique used, so that the ban would not depend on the decision of the HFE Authority, but would be enshrined in statute.

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<sup>1</sup> Cloning is defined as the production of a cell or organism with the same nuclear genome as another cell or organism

<sup>2</sup> Alex Sleator, *Cloning*, Library research paper 97/43, 27 March 1997 - <http://hcl1.hclibrary.parliament.uk/rp97/rp97-043.pdf>

<sup>3</sup> Science and Technology Committee, Fifth Report, *The Cloning of Animals from Adult Cells*, 20 March 1997, HC 373 1996-97

<sup>4</sup> Science and Technology Committee, *The Cloning of Animals from Adult Cells, Government response to the Fifth Report*, 18 December 1997, Cm 3815 1996-97, paras 9 and 16

<sup>5</sup> Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority, *Cloning Issues in Reproduction, Science and Medicine*, December 1998

The Report also recommended that, as some of the therapeutic advances now being developed were never envisaged when the Act was drafted, consideration should be given to specifying in Regulations two further purposes for which the HFEA might issue licences for research:

- The development of methods of therapy for mitochondrial disease
- The development of therapeutic treatments for diseased or damaged tissues or organs.

The Report highlighted the need for greater public understanding of human genetics, and discussed the issue of genetic identity.

The Government's response issued on 25 June 1999 reaffirmed its opposition to cloning in order to produce identical individuals, and asked the Chief Medical Officer, Professor Liam Donaldson, to set up and chair an independent expert advisory group to clarify the potential benefits of the use of cloning research for therapeutic purposes.<sup>6</sup> The terms of reference were:

- to establish the extent to which there is a current research focus on therapeutic cloning including stem cell studies, when developments are likely to arise and where they could lead;
- to assess the anticipated benefits of such research; the potential risks; and any alternative approaches that might be pursued to achieve the same benefits;
- in the light of the assessed benefits, risks and alternatives to consider whether there are any ethical and social implications beyond those addressed by the HFEA/HGAC Report, *Cloning Issues in Reproduction, Science and Medicine*;
- to advise whether regulations need to be made under the *Human Fertilisation and Embryology Act 1990* to extend the purposes for which the Human Fertilisation and Embryology Authority may issue licences for research involving human embryos;
- to advise on whether any additional regulation of the use of embryonic cell lines (such as stem cells) is required.<sup>7</sup>

The ensuing report, *Stem Cell Research: Medical Progress with Responsibility*, the Donaldson Report, endorsed the need for an extension of research purposes permitted under the Act and made a number of other recommendations.

The Government has accepted the recommendations of the Donaldson Report, and is bringing forward regulations to amend the *Human Fertilisation and Embryology Act 1990* to extend the purposes for which research in early embryos is permitted. The purposes are

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<sup>6</sup> Government response to the report by the Human Genetics Advisory Commission and the Human Fertilisation Authority on *Cloning Issues in Reproduction, Science and Medicine*, Cm 4387

<sup>7</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, Annex A

those of increasing knowledge about the development of embryos, or about serious disease, and enabling such knowledge to be applied.

An adjournment debate on the issues took place on 17 November 2000, and a further debate is scheduled for 15 December. A vote on the statutory instrument may take place before Christmas.

This paper discusses the background to these issues, including current legislation. It sets out the findings of the Donaldson Report, and the proposed Regulations under the 1990 Act. It aims also to give a range of views generated by the proposals.

## II Background

Stem cells are unspecialised cells of the body at an early stage of development. These cells have the ability to divide and differentiate into a large number of cell types that make up the tissues and organs of the body. They can also regenerate themselves so that a relatively small number of cells can be grown in the laboratory into large numbers (or cell lines) that can be used for research or for clinical applications. The potential to derive stem cells from umbilical cord blood, bone marrow and foetal (fetal) tissue and for these to regenerate themselves has been known for some time. Successful transplantation of some stem cells (eg from bone marrow) has been possible for some years. The ability to extract stem cells from embryos and to grow them in culture is a more recent advance. Embryonic stem cells are termed pluripotent - that is they have the potential to develop into every cell type of the human body. This raises the prospect of development of new therapies. The potential of producing insulin-secreting pancreatic cells and dopamine-producing brain cells raises the prospect of new treatment for diabetes and Parkinson's disease, for example.

Cell nuclear replacement (CNR) is the new cloning technique developed by the team at the Roslin Institute that led to the birth of Dolly the sheep.<sup>8</sup> The nucleus of the cell contains the DNA which provides its genetic identity. In this technique the nucleus of a donor cell is fused with the cell of an egg which has had its nucleus removed. The resulting cell starts to divide and forms an embryo which is genetically identical to the donor cell. If the development of this embryo is stopped after 5 or 6 days (the blastocyst stage), stem cells can be extracted and multiplied in the laboratory. It is envisaged that tissues developed from these stem cells would have the advantage of being free from rejection because they would be genetically compatible with the person being treated, from whom the donor nucleus was taken.<sup>9</sup> (A slight difference only remains – the new embryo retains a small amount of DNA contained in the mitochondria of the cytoplasm of the recipient cell. The implications of this difference for compatibility are, as yet, unknown).

The use of embryos in research is controversial. There is a wide spectrum of opinion on this issue. Those who believe that the use of human embryos is unethical on the grounds that a fertilised egg from the moment of conception is entitled to full human status, argue that the early embryo has a right to life and a right not to be used as a means to an end. At the other end are those who believe that an early embryo is a collection of cells with no greater rights than any other collection of human cells. There are also those who consider that although the status and dignity of early embryo should be respected, it is reasonable to weigh this against the benefits of allowing research on such early embryos to proceed. They would argue that Parliament, in passing the *Human Fertilisation and Embryology Act 1990*, accepted that embryo research is morally acceptable for specific purposes, provided it is limited to the 14

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<sup>8</sup> I Wilmut, A E Schnieke, J McWhir, A J Kind and K H S Campbell "Viable offspring derived from fetal and adult mammalian cells", *Nature*, Vol 385, 27 February 1997, pp 812-813

<sup>9</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 2.29

days following fertilisation, before the primitive streak which later becomes the nervous system has developed.

In its 1999 discussion paper *Stem cell therapy: the ethical issues* the Nuffield Council on Bioethics recommended that legislation be amended to allow spare human embryos produced as a result of in vitro fertilisation to be used for stem cell research. The Council concluded that the removal and cultivation of cells from a donated embryo does not indicate lack of respect for the embryo. The Council makes a distinction between stem cell research for therapeutic purposes and reproductive purposes<sup>10</sup>

Some commentators point out that there is a strong ethical argument in favour of allowing research which may result in the development of treatments for many degenerative medical conditions which cause much suffering.

There is also a divergence of opinion about the need to use embryos as a source for stem cells. There are those who consider the use of embryos to be unnecessary as a source of stem cells in the light of developing alternatives. Others consider that stem cells derived from embryos, which have the greatest potential for specialisation into the variety of cells that make up the human body, hold out the greatest potential for rapid advances in knowledge of cell biology and the development of new therapies.

There are also concerns that permitting the use of cell nuclear replacement to produce embryos and allowing them to develop up to 14 days may set a precedent leading to the cloning of a human. Although the Government has confirmed its opposition to such “reproductive” cloning, there are those who consider that the distinction between therapeutic and reproductive cloning will not be maintained, and that therapeutic cloning is the start of a “slippery slope”.

Others do not make a distinction between therapeutic and reproductive cloning. They consider the new cell nuclear replacement technique, as a form of (although incomplete) cloning of humans to be in any case wrong, particularly as the cloned individual is destined for destruction before 14 days.

These arguments have been summarised:

"For some critics, acquiring such knowledge and deriving human pluripotential stem cells is tantamount to society leaving the Garden of Eden. For others, such studies, carried out under appropriate guidelines, holds great promise not only for unexpected insights into biology but ultimately for the alleviation of human suffering".<sup>11</sup>

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<sup>10</sup> Nuffield Council on Bioethics, *Stem cell therapy: the ethical issues*, 1999, Executive summary, see Appendix 1 of this paper

<sup>11</sup> Fiona M Watt and Brigid LM Hogan, "Out of Eden: Stem Cells and their Niches", *Science*, Vol 287, 25 February 2000, pp 1427-1430

### ***III Human Fertilisation and Embryology Act 1990***

United Kingdom law with regard to embryo research and human cloning is governed by the *Human Fertilisation and Embryology Act 1990*.

#### **A. Background to the Act**

A Committee of Enquiry into Human Fertilisation and Embryology was established in July 1982 to examine the social, ethical and legal implications of recent, and potential developments in the field of human assisted reproduction. The first child resulting from the techniques of "in-vitro fertilisation" (IVF) had been born in July 1978, and opened up the horizons of those working in the fields of infertility and embryology.<sup>12</sup> There were also anxieties that the techniques were developing too fast for their implications to be assimilated and assessed by society in general, especially the techniques' potential role in manipulating the early stages of human development.

The Committee of Enquiry into Fertilisation and Embryology was chaired by Dame Mary (now Baroness) Warnock and its Report was subsequently known as the Warnock Report.<sup>13</sup> The terms of reference of the committee were:

To consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.<sup>14</sup>

A lengthy consultation period followed with the publication in 1986 of the consultation paper *Legislation of Human Infertility Services and Embryo Research*<sup>15</sup> followed by the White Paper *Human Fertilisation and Embryology: a Framework for Legislation*,<sup>16</sup> culminating in the *Human Fertilisation and Embryology Act 1990 (HFE Act)*.

In addition to reforming the lawful grounds for access to abortion, the Act sets the boundaries within which research on early embryos is permitted. It also legislates for the establishment of the Human Fertilisation and Embryology Authority (HFE Authority). The Authority's function is to regulate research on human embryos, storage of gametes (eggs and sperm), and embryos produced outside the human body. Much of the Authority's work relates to the inspection and licensing of centres carrying out IVF, donor insemination treatment, or embryo research and it aims to ensure that "human embryos are used responsibly and that infertile patients are not exploited at a vulnerable time".

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<sup>12</sup> *In vitro* literally means in glass (in the test tube) as opposed to *in vivo*, in the body

<sup>13</sup> *Report of the Committee of Enquiry into Fertilisation and Embryology* Cm 9314

<sup>14</sup> Mary Warnock, *A Question of Life*, 1985, p 4

<sup>15</sup> *Legislation of Human Infertility Services and Embryo Research*, December 1986 Cm 46

<sup>16</sup> *Human Fertilisation and Embryology: a Framework for Legislation* Cm 259

There was recognition that with the advance in knowledge of human embryology changes in regulation might be necessary. The HFE Authority was therefore required to keep under review information about embryos and any subsequent development of embryology as well as of treatment services and other services prohibited or which require a licence under the Act.

## **B. Regulation of embryo research**

Under the 1990 Act, research on embryos of more than fourteen days or after development of the primitive streak (the beginning of the first signs of neural development) is prohibited.

Research on younger embryos is permitted only if it is licensed by the Human Fertilisation and Embryology Authority (HFEA) for tightly defined purposes. Schedule 2 of the *HFE Act* states that the HFEA cannot license any research unless it appears to the Authority to be necessary or desirable for one of five 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 techniques of contraception
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation<sup>17</sup>

Additional purposes may be added by Regulations, but must relate to increasing or applying knowledge about the creation and development of embryos, or about disease. Regulations require “affirmative resolution”, that is they require a vote in both Houses of Parliament.

The Act requires that the Authority should be satisfied that the use of embryos is necessary for the purpose of the specific research proposal before issuing a licence. Consent is required from the individuals whose gametes (eggs and sperm) have been used to create the embryo.

The Act allows research on embryos which have been created in the course of in vitro fertilisation treatment but are surplus to clinical need and on embryos created specifically for research. The number of embryos created between 1992 and March 1998 and the categories of use are as follows:<sup>18</sup>

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<sup>17</sup> Schedule 2 paragraph 3(2)

<sup>18</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 3.5

**Embryos created by IVF: 1991-1998<sup>19</sup>**

763,509 embryos created  
351,617 used in infertility treatment  
183,786 stored for future treatment  
48,444 given for use in research  
118 created in the course of research  
273,603 not used for any purpose and destroyed.

Prohibitions in connection with embryos and gametes are set out in Appendix 2 of this paper. Regulations governing the use of embryos for research purposes are set out in Appendix 3 of this paper.

**C. Stem cells and the *HFE Act***

These cells are not treated differently under the Act than other embryonic cells - their extraction is permitted for one of the five purposes indicated above. The Act permits an extension of research purposes to be made under Regulations and this could be used to include research into increasing understanding about human diseases and disorders and their cell-based treatments.

One research licence has been issued by the HFEA for research involving the extraction of human embryonic stem cells. Details were given in response to a Parliamentary Question:

Mr. Amess: To ask the Secretary of State for Health if he will make a statement on the granting of a licence by the HFEA in 1996 to the Centre for Genome Research, University of Edinburgh for the culture of multipotential human embryos.

Yvette Cooper: [holding answer 16 November 2000]: In February 1996 the Human Fertilisation and Embryology Authority issued a two-year research licence for a project entitled "Culture of Multipotential Human Embryo Cells" at the Centre for Genome Research, University of Edinburgh. The objective of the proposed research was to establish cell lines from human embryos with a view to analysing the factors that affect the development of embryos fertilised and grown "in vitro" and to assess their development potential. An application was made for renewal in February 1998 and a licence was granted in May 1998 for a further two years.

The objectives of this research are (i) to promote advances in the treatment of infertility; (ii) to increase knowledge about the causes of congenital disease; and (iii) to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

The centre is required to provide reports on the progress of the research and is subject to inspection by the authority.<sup>20</sup>

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<sup>19</sup> Source: HFEA. 1 August 1991 to 31 March 1998 Embryos may be counted in more than one category

<sup>20</sup> HC Deb 20 November 2000 c 50W



There is no specific legislation in force to regulate research on stem cells once extracted from embryos or research aimed at deriving stem cells from other, non-embryonic sources such as an aborted foetus or adult cells. A Code of Practice laid down by the Polkinghorne Committee in 1989 governs the use of foetal tissue,<sup>21</sup> while guidance from professional and research bodies governs research more generally.

There is no legal bar to importation of stem cells from abroad. Importation of gametes (eggs and sperm) or embryos would require special directions from the HFEA.<sup>22</sup>

#### **D. Cell nuclear replacement and the *HFE Act***

When the new cell nuclear replacement technique was developed it was unclear whether it was possible to regulate this under the Act. The Human Genetics Advisory Commission and the HFEA make it clear that the technique does fall within the remit of the Act:

The Act (section 3(3)(d)) expressly forbids one type of cloning technique, that is the nuclear substitution of any cell whilst it forms part of an embryo. The Act also (section 3(1)) requires a licence from the Authority for any creation, storage or use of a human embryo outside the body. The cell nuclear replacement technique involves nuclear substitution into an egg and not into an embryo. Thus it is not specifically covered by section 3(3)(d). Some have argued that, as fertilisation is not involved, section 3(1) also does not apply. The Department of Health and the HFEA have taken Counsel's advice on this issue. As a result, both Ministers and the Authority reject this position and are content that the Act does allow the HFEA to regulate nuclear replacement into an unfertilised egg through its licensing system.<sup>23</sup>

The position is therefore that the Act does not differentiate between embryos created using eggs and sperm and those created by combining the nucleus of a cell with an egg which has had its nucleus removed (cell nuclear replacement). Research involving the creation of an embryo by cell nuclear replacement is not prohibited under the Act, provided that the research is for one of the five specified purposes. As indicated above, the HFEA would have to be satisfied that the creation of an embryo in this way was necessary for the purposes of a specific research project. Thus stem cells derived from an embryo created by CNR can be used under the Act for research under the same specified conditions.

The HFEA has not to date received any application to conduct research involving the creation of an embryo using cell nuclear replacement.<sup>24</sup>

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<sup>21</sup> "The Use of Foetuses and Foetal Material in Research and Treatment: the Polkinghorne guidelines" .see section IV B5 of this paper

<sup>22</sup> HFE Authority official personal communication, 16 November 2000

<sup>23</sup> The Human Genetics Advisory Commission and the Human Fertilisation and Embryology, *Authority Cloning Issues in Reproduction, Science and Medicine*, December 1998, para 3.4

<sup>24</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 3.11

The Authority has made it clear that as a matter of policy it will not issue a licence for treatment (ie for implantation creating a pregnancy or “reproductive cloning”) involving the use of embryos created by cell nuclear replacement. To undertake such a procedure without a licence is a criminal offence.

### **1. Egg cell nuclear transfer and mitochondrial disease**

A different type of cell nuclear replacement could be used to prevent a woman passing on an inherited mitochondrial disease to her child.

Mitochondria are structures concerned with providing energy for the cell. They are found in the cytoplasm of a cell that surrounds the nucleus. Most of an individual’s DNA is contained within the nucleus, but a small amount of DNA is present in the mitochondria, and this is inherited only from the mother. The DNA contained in the mitochondria affects a number of important functions in providing energy for the cell. If a mother’s mitochondrial DNA carries a disorder then it will always be passed on to the child. Defects in mitochondrial DNA are known to cause a large number of inherited metabolic diseases.

The Donaldson report explains its thinking on oocyte (egg cell) nuclear transfer:

In theory it may be possible to prevent a child inheriting damaged mitochondria from the mother by inserting the nucleus of the mother’s egg into a donor egg with healthy mitochondria which has had its nucleus removed (a form of cell nuclear replacement). The egg formed in this way would then need to be fertilised by the father’s sperm using in vitro fertilisation techniques. Any child born would inherit its nuclear DNA from the mother and the father plus healthy mitochondrial DNA from the donor egg. Very little research has been undertaken to investigate whether the theoretical promise of this form of cell nuclear replacement for the prevention of mitochondrial disorders is real.

Given the genetic make up of any child born as a result of this technique, it would not constitute reproductive cloning. The resulting child would not be genetically identical to anyone else. Nonetheless, concerns have been expressed that oocyte nucleus transfer represents a modification to the human genome which can be passed on to the next generation. Such modifications are subject to a moratorium in many countries, although basic research to modify eggs or sperm would be permitted under both international conventions and UK law. There does not appear to be any ethical objection to initiating this kind of basic research.<sup>25</sup>

Research into this technique could currently be licensed under the Act to increase knowledge about the causes of congenital diseases or to promote advances in the treatment of infertility. If Regulations were made under the Act to permit research into possible treatments for disease, and this was successful in developing treatment for mitochondrial disease, such treatment could be licensed by the HFEA.

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<sup>25</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000

## E. Use of embryos for treatment

At present the only treatment services using embryos created outside the body which can be licensed under the 1990 Act are medical, surgical or obstetric services to help women to “carry children”. Thus, if research proves successful, an embryo created by oocyte nuclear transfer for the treatment of mitochondrial disease could, as stated above, be licensed for treatment ie to create a pregnancy. The creation of embryos to derive cells for other types of *treatment* that might become possible as a result of research (such as treatment for degenerative conditions) would require a new Act of Parliament.

As indicated above, prohibition of cloning of humans using the CNR technique is currently dependent on refusal of the HFE Authority to licence treatment using such embryos. The Government has stated that it will introduce primary legislation when Parliamentary time allows to enshrine this principle in law.

## F. Summary

The Donaldson Report summarises current legal restrictions:

- 13. The UK has a well-established system for regulating the creation and use of embryos, both in research and treatment, embodied in the *Human Fertilisation and Embryology Act 1990* (the 1990 Act). This Act is administered by the Human Fertilisation and Embryology Authority (the HFEA). The 1990 Act allows for the creation and use of embryos for research, provided that the research is for one of the five purposes currently specified in the Act and is granted a licence by the HFEA. Before a research project can receive a licence, the HFEA must be satisfied, on a case by case basis, that the use of embryos is necessary for the purposes of the research. Research can only be pursued under the aegis of the Act and with a licence from the HFEA. Embryos used in research cannot be kept for longer than 14 days (excluding periods of storage). Some 48,000 embryos which were no longer needed for in vitro fertilisation treatment were used in research between August 1991 and March 1998 and 118 embryos were created in the course of research in the same period.
- 14. Research involving the creation of an embryo by cell nuclear replacement is not prohibited under the 1990 Act provided it is for one of the existing specified research purposes. In such circumstances, the HFEA would consider each application for a research licence on its merits and would need to be satisfied that the creation of an embryo by cell nuclear replacement was necessary for the purposes of the research. So far no applications for a licence for such research have been made.
- 15. At present the creation or use of embryos for research to improve understanding or treatment of non-congenital diseases is not permitted under the 1990 Act although there is scope within the Act for additional research purposes to be added through Regulations (rather than new primary legislation).
- 16. There is no specific legislation currently in force in the UK to regulate research on stem cells once extracted from embryos or research aimed at deriving stem cells from other, non-embryonic, sources such as an aborted fetus or adult cells. A Code of Practice laid down by the Polkinghorne Committee in 1989 governs the use of fetal tissue, while guidance from professional and research bodies and from the Department of Health governs research more generally.<sup>26</sup>

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<sup>26</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, Summary, June 2000

## IV Stem cell research

### A. Therapeutic potential

A stem cell is an unspecialised cell at an early stage of development which has the potential to divide and to differentiate, or become specialised, into a large number of cells that make up the tissues and organs of the body. They can also undergo self-renewal, a process whereby an unspecialised cell divides to produce two unspecialised cells. In this way ‘cell lines’ or large collections of such stem cells can be produced.

Although research into the laboratory conditions needed to encourage differentiation into specific types of cell is in its infancy, it is apparent that such research may result in the ability to form tissues such as skin, heart muscle, or insulin-producing pancreatic cells, which could then be used in treatment. In addition to improving understanding of the biological processes of cell division and differentiation, the potential exists to produce a sustainable source of cells to repair organs damaged by trauma or disease. The Chief Medical Officer’s report sets out some possible uses of tissue derived from stem cells to treat disease:<sup>27</sup>

Cell type	Target disease
Neural (nerve) cells	Stroke, Parkinson’s disease, Alzheimer’s disease, Spinal cord injury, Multiple sclerosis
Heart muscle cells	Heart attacks, Congestive heart failure
Insulin producing cells	Diabetes
Cartilage cells	Osteoarthritis
Blood cells	Cancer, Immunodeficiencies, Inherited blood diseases, Leukaemia
Liver cells	Hepatitis, Cirrhosis
Skin cells	Burns, Wound healing
Bone cells	Osteoporosis
Retinal (eye) cells	Macular degeneration
Skeletal muscle cells	Muscular dystrophy

Cell nuclear replacement is one of the potential methods whereby an individual could be their own source of material for tissue or organ donation, circumventing the problem of rejection. This would involve transferring the nucleus (containing the genetic material) from one of the patient’s own adult body cells into a donor egg that has had its own nucleus removed. The egg would then be stimulated so that it begins to divide but it would only be allowed to develop to the stage needed to separate and culture embryonic stem cells. Scientists are hopeful that as knowledge advances these embryonic cells could eventually be stimulated to develop into whatever tissue was needed by the patient.

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<sup>27</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 2.8

## B. Alternatives to embryonic stem cells

There are a number of alternative sources of human stem cells, but research is in its infancy.<sup>28</sup>

- From early embryos (blastocysts) created by in vitro fertilisation – either those which are not needed for infertility treatment (sometimes called ‘spare embryos’) or created specifically for research;
- From early embryos created by inserting the nucleus from an adult cell into an egg with its nucleus removed – cell nuclear replacement (sometimes called ‘cloning’);
- From the germ cells (reproductive cells) or organs of an aborted foetus;
- From the blood cells of the umbilical cord at the time of birth;
- From some adult tissues (such as bone marrow);
- From mature adult tissue cells reprogrammed to behave like stem cells (theoretical source)

Stem cells can be categorised according to how committed they are to develop into cells of a particular type.

### 1. Embryonic stem cells

In theory stem cells derived from early embryos hold the greatest potential for differentiation into different types of tissue cells. They have been referred to as pluripotent. These cells, taken from the inner cell mass of an embryo at the blastocyst stage of development about 5 to 6 days after fertilisation before specialisation has begun, appear to have the ability to differentiate into nearly any cell type. It is thought that stem cells extracted from the blastocyst stage of a human embryo created by the technique of cell nuclear replacement would have the same potential to differentiate into a wide variety of cell types as stem cells derived from embryos created by fertilisation of an egg with a sperm. The Donaldson report elaborates:

The blastocyst begins to form as a 15-10 cell cluster just beginning to develop into identifiable parts that will go on to form the placenta, fetus and other associated tissues. Blastocysts used for the isolation of stem cells would probably have been between 150 and 200 cells. After the blastocyst stage the opportunity to extract stem cells is gradually lost as the stem cells start to become specialised and no longer have the potential to become all types of tissue.

In 1998 a research report from the USA described the successful culture of human stem cells from early embryos...

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<sup>28</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 4

...This work was confirmed in April 2000 when researchers in Australia and Singapore reported that they had isolated human embryonic stem cells from four blastocysts. Cell lines from two of them were successfully maintained in culture for extended periods and the researchers also demonstrated that stem cells can be frozen for storage and grown again once thawed. In further experiments, groups of these stem cells were induced to differentiate into the forerunners of several kinds of body cells. Neural stem cells were then identified and isolated and persuaded to form what appeared to be mature neurons (nerves).<sup>29</sup>

If the embryo from which the stem cells are derived is created by cell nuclear replacement, and the nucleus placed in the empty egg is from the person needing treatment, it is probable that the resulting cells or tissues would be compatible. However, there is some uncertainty because a small amount of mitochondrial DNA is inherited from the recipient egg cell, and the implications of this for compatibility are not known.

Using the CNR technique to provide embryos would be dependent on a limited source of human eggs. Human donors are currently the only source of eggs, and there is a shortage of availability for fertility treatment. The CNR technique has been accomplished in several animal species, but has a low success rate. It has been estimated that 12 or 13 human eggs would be needed to develop one blastocyst by CNR to the stage where embryonic stem cells could be extracted. While it could be useful in research, it is unlikely to provide sufficient embryos to be used as a basis for treatment.

## **2. Stem cells derived from foetal tissue or umbilical cord blood**

Cord blood is rich in stem cells but these appear to have limited ability to differentiate ie they may only produce blood cells or bone marrow cells. This source of stem cells has the advantage of ready availability. Cord blood is being stored in the USA by a number of laboratories, with a view to use by the donor individual in later life. If required for the treatment of leukaemia, for example, there would be no problem of rejection.

Some foetal tissues are also rich in stem cells. Liver stem cells, for example, can be extracted and successfully grown and concentrated in the laboratory.

Stem cells from these sources are already partially committed in development, and it is as yet uncertain what potential exists for differentiation of foetal and umbilical cord blood stem cells into different tissue cells other than those from which they were derived. In the future it may be possible to change the programming of these stem cells so that they mature into other types of tissue.

Stem cells derived from primitive sex cells of the foetus up to about 6 weeks of development (that are destined to develop into eggs and sperm) have a greater potential to differentiate.

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<sup>29</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, paras 2.20-2.21

They have a similar capacity to develop into other kinds of tissues as embryonic stem cells - they could be termed pluripotent.

Some have ethical objections to the use of foetal tissues as these are obtained from aborted fetuses. The consent of the mother is required, and the use of foetal tissue is regulated by the (non-statutory) Polkinghorne Code of Practice 1989 which requires approval of a Research Ethics Committee for both research and therapeutic use.

### 3. Stem cells derived from adult tissue

Stem cells have been isolated and cultured from adult tissues such as bone marrow and peripheral blood for some years. These have been used for transplantation, for example to treat leukaemia and in some inherited single gene disorders. It is now thought that stem cells are present more widely in adult tissues than was previously thought.

Stem cells lines derived from adult tissue have until recently been thought to have very limited potential for specialisation into other types of cell. They have been thought to be developmentally committed to the type of tissue from which they come. However, recent research has shown that adult stem cells can differentiate into developmentally unrelated cell types, such as nerve cells into blood cells.<sup>30</sup> The hope is that this previously unrecognised plasticity can be exploited to regenerate cells for transplantation which do not cause rejection.

The *British Medical Journal* reports:

New research indicates that adult neural [brain] stem cells previously thought to be committed to becoming either neurones, astrocytes, or oligodendrocytes [types of nerve cells] can de-differentiate and reinvent themselves as haemopoietic [blood cell] precursors (Science 1999;283:471, 534-7).

This finding raises the possibility that adult human stem cells may some day be coached to grow into organs, regenerate damaged tissue, or reconstitute the immune system. The problem of immune rejection may also be circumvented if an individual's own cells can be used.

It also means that the need for fetal cells as a source of stem cells for medical research may soon be eclipsed by the more readily available and less controversial adult stem cells.<sup>31</sup>

Further research has endorsed this plasticity. The research, published on 19 September 2000 in the *Nature Neuroscience* journal, was undertaken by a group of scientists from the

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<sup>30</sup> Fiona M Watt and Brigid LM Hogan, "Out of Eden: Stem Cells and their Niches", *Science*, Vol 287, 25 February 2000, pp 1427-1430

<sup>31</sup> "Adult stem cells may be redefinable", *British Medical Journal*, Vol 318, 30 January 1999, p 282

National Neurological Institute and the Institute for Stem Cell Research, based in Milan. The *Daily Telegraph* provides comment:

An Italian group led by Drs Angelo Vescovi and Giulio Cossu reported in the journal *Nature Neuroscience* yesterday that nerve stem cells from an adult were more flexible than thought and could give rise to skeletal muscle.

When placed in contact with other neural stem cells, they gave rise to neurons and glia - the support cells for nerve cells. But neural stem cells in contact with muscle tissue gave rise to muscle. Yesterday Dr Vescovi said scientists did not know enough to say whether embryonic or adult stem cells were most promising for transplantation and that both avenues should be explored further.

Dr Vescovi, co-director of the Institute for Stem Cell Research in Milan, said that adult stem cells were indeed unexpectedly pliable "but we are far from showing that adult stem cells equal embryonic stem cells with respect to their growth potential and plasticity".

It was not possible to say whether any adult stem cell could turn into any tissue, depending on where it was in the body. "I am wary of generalisations. I hope, though, that that is the case.

"The implications for therapy of human diseases would be astounding (and I am being conservative here)."

An editorial in the journal, written by Dr Charles Jennings, said that there were key differences in adult and embryonic stem cells, such as their ability to proliferate and form different cell types.

"Common sense dictates that it is not possible to decide which approach is more promising until both have been explored."<sup>32</sup>

Bone marrow stem cells are thought to be even more versatile. *Science* reports preliminary research that indicates the possibility that bone marrow stem cells from children and adults can become brain and muscle cells and liver cell precursors. This is very early work, and such stem cells are hard to find.

It has been suggested that adult stem cells may be easier to manage than embryo derived stem cells. Adult stem cells only become different types of cells when they are given new signals to do so. Placed in their usual environment, they seem to produce only the cell types of that particular tissue which is needed to repair such tissue.<sup>33</sup>

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<sup>32</sup> "The cloning of embryos may not be needed", *Daily Telegraph*, 20 September 2000

<sup>33</sup> Gretchen Vogel, "Can old cells learn new tricks" (news article), *Science*, Vol 287, 25 February 2000, pp 1418-1419



Adult stem cells have the drawback in that they appear to lose their ability to divide and differentiate after a time in culture. By contrast, mouse embryonic stem cells have a long track record in the laboratory and appear to have an infinite capacity to divide.

*Science* comments:

For these and other reasons, many researchers say, adult-derived stem cells are not going to be an exact substitute for embryonic or fetal cells. "There are adult cell types that may have the potential to repopulate a number of different types of tissues," says Goodell. [a researcher concentrating on adult stem cells] "But that does not mean they are ES cells. Embryonic stem cells have great potential. The last thing we should do is restrict research" right now, she says, stem cell specialists want to study both adult and embryonic stem cells to find out just what their capabilities might be.<sup>34</sup>

The derivation of stem cells from adult tissue and cells not only has the advantage of producing genetically compatible tissue if self derived from the person needing treatment, but would also overcome the ethical problems of using embryo cells or cells from aborted foetuses.

Much research is going on in this field, but there are reservations among many scientists whether adult stem cells will prove to have as good a potential for differentiation as embryonic cells, at least in the early days of research. Research involving embryo stem cells, with their greater inherent ability to develop into a wide range of tissues, could provide the basic biological understanding of the mechanisms involved.

#### **4. Reprogrammed adult cells**

Adult tissue cells have been thought, once programmed, to produce a particular type of cell, eg blood, bone or muscle, and to have no capability to form other types of tissue cell.

In the long term the theoretical prospect exists of reprogramming an adult body cell to make it revert to its unspecialised stem cell state and subsequently to influence it to develop into a different type of tissue cell.

Tissues produced in this way would be genetically compatible with the person from whom the cells were taken. Stem cells derived in this way from adult cells would avoid the use of embryos and the cell nuclear replacement technique, circumventing the ethical dilemmas and also the shortage of eggs. There are no specific legal restrictions on such research.

However, these possibilities are at present theoretical.

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<sup>34</sup> Gretchen Vogel, "Can old cells learn new tricks" (news article), *Science*, Vol 287, 25 February 2000 pp 1418-1419

## 5. Regulation of derivation of stem cells from non-embryonic sources

The use of foetal tissue is governed by the Code of Practice on the Use of Foetuses and Foetal Material in Research and Treatment drawn up by the Polkinghorne Committee in 1989.

The Use of Foetuses and Foetal Material in Research and Treatment: the Polkinghorne guidelines.

Principles governing the use of foetal tissue

- There should be clear separation between decisions and actions relating to the termination of pregnancy and decisions and actions relating to the use of the foetal material made available.
- The decision to carry out a termination must be reached without consideration of the benefits of subsequent use of the foetal tissue. Deliberately conceiving or terminating a pregnancy to produce suitable material is unethical.
- The management of the pregnancy should not be influenced by the potential use of the foetus in research or therapy. This includes the method and timing of an abortion or the management of a mother whose foetus dies in the womb or who has a spontaneous abortion.
- No inducements, financial or otherwise, should be put to the mother, or those who may influence her decision, to have her pregnancy terminated or to allow foetal tissue to be used.
- The mother should not be informed of the specific use which may be made of the foetal tissue or whether it is to be used at all.
- The written consent of the mother should be obtained before any research involving the foetus or foetal tissue takes place.
- Consent to the termination of pregnancy must be given before consent is sought to the use of foetal tissue.

In addition all proposals for the use of foetuses or foetal tissue must be referred to a research ethics committee whether the work is classed as research or novel therapy – in recognition of the sensitivity surrounding the use of such tissue.<sup>35</sup>

There are no specific legal restrictions on derivation of stem cells from adult sources, although the general legal provisions on removal and use of human tissue apply:

If stem cells were taken from adult tissue retrieved after death, the *Human Tissue Act 1961* would apply. This governs the use of tissue and body parts from deceased persons both for research and therapeutic uses. Tissue may be obtained from living adults either specifically for research purposes or retained from the adult's treatment (for example, after surgery). Where tissue is obtained specifically for research, an explanation of the proposed use must be given or consent to the removal procedure would not be valid.

Similarly the use of cord blood requires an explanation and the mother's consent. The conduct of research on human tissue is governed by guidance from the Medical Royal

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<sup>35</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 3.17

Colleges and the Medical Research Council. Research projects conducted in the NHS which involve the removal and subsequent use of human tissue require approval from a research ethics committee<sup>36</sup>

### C. Stem cell research spending

The amount spent on research into stem cell therapy, as set against research spending on Parkinson's disease, was set out in response to a Parliamentary Question from Nigel Jones MP:

Mr. Denham: The main Government agency for research into the causes of and treatments for disease is the Medical Research Council (MRC) which receives its funding via the Department of Trade and Industry. The Department of Health funds research to support policy and the delivery of effective practice in the National Health Service. The Department also provides NHS support funding for research commissioned by the research councils and charities that takes place in the NHS.

The estimated expenditure figures available for directly commissioned research into Parkinson's disease and stem cell therapy are as shown. They include Medical Research Council and Department of Health support:

	Parkinson's disease £million	Stem cell therapy and related basic research £million
1995-96	1.7	2.5
1996-97	1.7	2.2
1997-98	1.8	2.1
1998-99	1.8	2.4
1999-2000	1.9	2.4

The stem cell research undertaken by the MRC involves mainly projects relating to stem cell transfer involving adult stem cells, for example in the treatment of leukaemia using bone marrow transplantation, which the MRC have been undertaking successfully for many years.

In addition, the MRC has funded basic research into the development of animal embryos and the properties of stem cells--involving mostly mouse embryos--which, along with studies of human reproduction, informs current assessments of the potential for new stem cell therapies. None of this work involves specially created human embryos or the use of human cells for cell nuclear transfer.

In addition, the Biotechnology and Biological Science Research Council has a diverse programme of research in the basic science of stem cells, potentially underpinning therapeutic applications, which has involved about £15 million of expenditure over the last 10 years.<sup>37</sup>

<sup>36</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 3.17, para 3.18

<sup>37</sup> HC Deb 30 November 2000 c 630W

## **V Recommendations of the Donaldson Report and proposed Regulations under the *HFE Act***

### **A. Recommendations of the Donaldson Report**

Scientific evidence provided to the Chief Medical Officer's Expert Group indicated that stem cells have enormous potential as a source of new tissue for therapeutic use.

The Expert Group concluded that, within current knowledge and technology, embryonic stem cells have the potential to develop into a far greater range of tissues than adult derived stem cells. The Group went on to say that while the long term promise of stem cells derived from adult tissue may equal or surpass that of embryonic stem cells it was probable that scientific advances from embryonic stem cells research would be necessary to understand how to make greater use of stem cells derived from adult tissue.<sup>38</sup>

The Group concluded that research was warranted across a range of sources of stem cells, including embryos created by *in vitro* fertilisation or cell nuclear replacement. The Department of Health comments

While recognising the views of those opposed to embryo research on ethical grounds, the Group concluded that the proposed new research did not raise fundamentally new ethical issues, different from those raised by currently permitted forms of embryo research. There is already a well-established framework for the control of embryo research under the *Human Fertilisation and Embryology Act 1990*, which would provide the necessary safeguards for this new research.

The Group makes a number of recommendations to enable and monitor developments in stem cell research. These include a call for research councils to fund research into stem cells, including alternative sources of stem cells, and to establish collections of embryonic stem cells to minimise the need for the use of embryos in this research and for the importation of stem cell lines.<sup>39</sup>

#### **The nine recommendations are:<sup>40</sup>**

1. Research using embryos (whether created by *in vitro* fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell-based treatments should be permitted, subject to the controls in the *Human Fertilisation and Embryology Act 1990*.
2. In licensing any research using embryos created by cell nuclear replacement, the Human Fertilisation and Embryology Authority should satisfy itself that there are no other means of meeting the objectives of the research.

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<sup>38</sup> HC Deb 23 October 200 c 90W

<sup>39</sup> <http://www.doh.gov.uk/cegc/index.htm>

<sup>40</sup> <http://www.doh.gov.uk/cegc/stemcellreport.htm#recs>

3. 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.
4. Research to increase understanding of, and develop treatments for, mitochondrial diseases using the cell nuclear replacement technique in human eggs, which are subsequently fertilised by human sperm, should be permitted subject to the controls in the *Human Fertilisation and Embryology Act 1990*.
5. The progress of research involving stem cells which have been derived from embryonic sources should be monitored by an appropriate body to establish whether the research is delivering the anticipated benefits and to identify any concerns which may arise.
6. The mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted.
7. 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.
8. The need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.
9. The Research Councils should be encouraged to establish a programme for stem cell research and to consider the feasibility of establishing collections of stem cells for research use.

The report considered and made recommendations on aspects of cellular *research and development*. The only treatments using embryos created outside the human body which the Human Fertilisation and Embryology Authority can license are those intended to help a woman become pregnant. A new Act of Parliament would be needed to allow the creation of embryos to derive cells for other types of *treatment*.

## **B. Government response and proposed Regulations**

The Government accepted the recommendations of the Donaldson report in full and announced its intention to bring forward legislation where necessary to implement them "as soon as the Parliamentary timetable allows". Regulations necessary to extend the purposes for which embryos may be used in research are "affirmative", and are subject to a debate and a vote in both Houses. The Government intends to make this a free vote.<sup>41</sup> The Government said it will also bring forward legislation when time allows to reinforce the ban on "reproductive cloning" - the cloning of individuals.<sup>42</sup>

The Government's response recognises that research involving embryos is a sensitive subject on which there are divergent views. For some people any research involving embryos is unacceptable, while for others the potential benefits of the research may be weighed against the respect due to an embryo at the very earliest stages of its development. It states:

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<sup>41</sup> *Government response to the recommendations made in the Chief Medical Officer's Expert Group report "Stem Cell Research: Medical Progress with Responsibility"*, Cm 4833, Foreword

<sup>42</sup> DOH press release 2000/0484, *Chief Medical Officer's expert group proposes extending research on cells*, 16 August 2000

Following consideration of these issues by the Warnock Committee in the early 1980s and extensive debate in both Houses, the *Human Fertilisation and Embryology Act 1990* (the 1990 Act) allows for research involving embryos for specified purposes under very strict conditions. It also provides for an extension of those purposes under the same conditions. Given these conditions, and on the basis of the scientific and medical benefits which could arise from research to extract stem cells from embryos at a very early stage in their development, the Government accepts that such an extension should be made to allow for research to increase understanding about human disease and disorders and their cell-based treatments.<sup>43</sup>

## **1. Human Fertilisation and Embryology (Research Purposes) Regulations 2000**

Regulations to specify additional purposes for which the Human Fertilisation and Embryology Authority may grant licences for research involving embryos under the *Human Fertilisation and Embryology Act 1990* were laid on 27 November 2000. The purposes were those of increasing knowledge about the creation and development of embryos, or about disease, and enabling such knowledge to be applied.

Revised draft Regulations were issued on 12 December 2000, omitting "creation" of embryos, and restricting the purposes to "serious" disease. This is in response to concerns that embryo research might be permitted toward minor ailments or trivial complaints. "Creation" was considered both unnecessary in the text (creation is already permitted under the Act) and to imply an emphasis not intended in the Donaldson Report.<sup>44</sup>

The purposes, as stated in the Explanatory note which accompanies the draft Regulations, are now those of "increasing knowledge about the development of embryos, or about serious disease, and enabling such knowledge to be applied". The Regulations, if passed, will come into force on 31 January 2001.

The new draft Regulations amend Schedule 2 of the Act as follows:

Now therefore, the Secretary of State in exercise of powers conferred by section 45 of and paragraph 3(2) and (3) of Schedule 2 to *the Human Fertilisation and Embryology Act 1990* (a), hereby makes the following Regulations:-

### **Citation, commencement and interpretation**

1.-(1) These Regulations may be cited as the Human Fertilisation and Embryology (Research Purposes) Regulations 2000 and shall come into force on 31 January 2001.

In these Regulations "the Act" means the Human Fertilisation and Embryology Act 1990.

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<sup>43</sup> *Government response to the recommendations made in the Chief Medical Officer's Expert Group report "Stem Cell Research: Medical Progress with Responsibility"*, Cm 4833, Foreword

<sup>44</sup> Department of Health, personal communication, 13 December 2000

**Further purposes for which research licences may be authorised**

2.-(1) 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

The Regulations give effect to recommendation 1 of the Donaldson report, and through this give effect to recommendation 4, which relates to research into mitochondrial diseases using cell nuclear replacement techniques in human eggs. They relate only to the granting of licences for research, and do not make provision for licences for treatment.

The Regulations will therefore extend the use of early embryos in research to include research into treatment of serious disease, including the use of embryos created by cell nuclear replacement for this purpose.

## VI Embryo research and Europe

The proposals have had a mixed reception in European countries. The President of the European Commission, Romano Prodi, has called for a serious debate on all the ethical and medical issues. However, the European Parliament has passed a Resolution (which is advisory only) urging the British government to withdraw plans to allow human embryos to be cloned for medical research, saying the creation of human embryos for research "irreversibly crosses a boundary in research norms".<sup>45</sup> The text of the Resolution is as follows:

Parliament: believes that human rights and respect for human dignity and human life must be the constant aim of political legislative activity; considers that 'therapeutic cloning' poses a profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to public policy; calls on the United Kingdom Parliament members to reject the proposal to permit research using embryos created by cell nuclear transfer; repeats its call to each Member State to enact binding legislation prohibiting all research into any kind of human cloning within its territory and to provide criminal penalties for any breach; calls on the appropriate national and Community authorities to ensure that the ban on patenting or cloning human beings is reaffirmed; and repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development.<sup>46</sup>

The answer to a Parliamentary Question set out the Government's response to the resolution of the European Parliament:

**Rev. Martin Smyth:** To ask the Secretary of State for Health if he will make a statement on the resolution of the European Parliament (Official Journal C034, 2/2/1998. p0164) on embryonic research and therapeutic cloning.

**Yvette Cooper:** We agree with the aim of this Resolution to the extent that human reproductive cloning should be prohibited. This is entirely in accordance with the stated view of the United Kingdom Government. However, we announced in August our intention to bring forward Regulations to extend the purposes for which embryos may be used in research to include research into human diseases and their treatments. This would include embryos created by cell nuclear replacement (therapeutic cloning).

Resolutions of the European Parliament have no legal status. We are aware that the European Union has no competence to legislate specifically on embryo research and that strong and deeply divided views are held on this issue in Europe.<sup>47</sup>

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<sup>45</sup> "UK must ban embryo cloning", *Financial Times*, 8 September 2000

<sup>46</sup> "European Parliament Plenary Session Minutes Publication", *Financial Times*, 7 September 2000

<sup>47</sup> HC Deb 24 November 2000 c 357W



This Resolution was issued in advance of a report by a European Union ethics panel, the European Group of Ethics in Science and New Technologies (EGE), which advises the European Commission and European Parliament. This said that the benefits of stem-cell transplant were “very promising” but required prudence. It commented both that therapeutic cloning was “premature” and said there was a wide range of alternative sources of human cells: from spare embryos, foetal tissues and adult stem cells.<sup>48</sup>

Brief details of the laws relating to cloning in other countries were set out by the Human Genetic Advisory Commission and the Human Fertilisation and Embryology Authority in December 1998:

Brief details of the laws in some other countries:

Australia - Legislation banning cloning exists in three states: the *Infertility Treatment Act 1995* in Victoria; the *Reproductive Technology Act 1988* in South Australia; and the *Human Reproductive Technology Act 1991* in Western Australia. The Western Australia legislation is currently under five- year compulsory review.

Belgium - Legislation covering medical ethics including cloning is currently being considered by Parliament.

Denmark - Act No. 503 on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects (1992) Research on cloning (production of genetically identical individuals) is forbidden as is nuclear substitution. Act No. 460 on Medically Assisted Procreation in Connection with Medical Treatment, and Research (1997) This confirms the Danish Parliament’s position, of 25 January 1995, that treatment cannot be initiated in areas where a research ban already exists under the 1992 Act.

France - Human cloning is implicitly prohibited by the French bio-ethics legislation passed in 1994 (laws 94-653 and 94-654 of 29 July 1994). The French National Bioethics Committee recommended that the ban should be made more explicit when the bioethics legislation is revised in 1999.

Germany - *Federal Embryo Protection Act 1990* The creation of an embryo genetically identical to another embryo, fetus or any living or dead person is an offence.

Japan - A Committee of the Council for Science and Technology is discussing ways of regulating human cloning, and is due to report by the end of March 1999.

Norway - Law No 56 on the medical use of biotechnology 1994. Implicitly prohibits embryo cloning.

Slovakia - 1994 Health Care Law. Implicitly prohibits embryo cloning.

Spain - Law No 35/1988 on Assisted Reproduction Procedures Explicitly prohibits embryo and oocyte cloning with criminal sanctions.

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<sup>48</sup> “French premier backs embryo research, remains opposed to cloning”, Agence France Presse, 28 November 2000

Sweden - Law No 115 14 March 1991. Implicitly prohibits embryo and oocyte cloning with criminal sanctions.

Switzerland - Federal Constitution Legally binding, implicitly prohibits embryo cloning.

These details were correct to the best of our knowledge at the time of publication.<sup>49</sup>

France, which adopted legislation in 1994 banning embryo research, has drafted (November 2000) legislation to allow stem cell research “to improve techniques in medically assisted reproduction...(and) research into new therapies.” It would centre on ‘spare’ embryos produced as a result of in vitro fertilisation, but would allow cell nuclear transfer, or “therapeutic cloning” in order to acquire stem cells if this proves necessary in the future. The draft legislation will be submitted to the French cabinet in March. Reproductive cloning will remain prohibited.<sup>50</sup>

Embryo research is carried out in the United States in the private sector, where there is no regulation. It is not currently possible to carry out embryo research using federal funds.<sup>51</sup> The United States has issued cautious guidelines that would allow embryo stem cells to be used in specific areas of research.<sup>52</sup>

The Netherlands has issued a draft bill (October 2000) which seeks to define the conditions and limitations governing the use of gametes and embryos. It forbids the creation of embryos specifically for research. The *British Medical Journal* reports:

The ban contradicts advice from the government’s scientific advisers, the health council, that creating embryos should be permitted in limited areas of scientific research. But scientists will be allowed to use "surplus" embryos from the 12,000 in vitro fertilisation treatments carried out each year in order to carry out medical research, including culturing embryonic stem cells.

...It prohibits human cloning, gender selection, and, for the next five years, altering genetic material....Importing created embryos is also forbidden.

Parliament will have a chance to reconsider the ban on cloning three years from enacting the legislation.<sup>53</sup>

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<sup>49</sup> Human Genetic Advisory Commission and the Human Fertilisation and Embryology Authority, *Cloning Issues in Reproduction, Science and Medicine*, Annex E, December 1998

<sup>50</sup> “French premier backs embryo research, remains opposed to cloning”, Agence France Presse, 28 November 2000

<sup>51</sup> HC Deb 17 December 2000 c 1230

<sup>52</sup> “French premier backs embryo research, remains opposed to cloning”, Agence France Presse, 28 November 2000

<sup>53</sup> "Netherlands bans cloning of human embryos for research," *British Medical Journal*, Vol 321, 7 October 2000, p 845

## VII Debate and views

### A. Ten Minute Rule bill

Dr Evan Harris introduced a Ten Minute Rule bill on 31 October 2000.<sup>54</sup> He moved:

That leave be given to introduce a Bill to amend the *Human Fertilisation and Embryology Act 1990* to allow the use of early embryonic tissue for the purposes of research into the development of regenerative therapies.

Dr Harris argued on behalf of those who could benefit from the results of stem cell research, and of the possibility of allowing patients with cancer, organ failure, degenerative diseases or spinal cord injury to have a ‘transplant’ of some of their own cells that have been reprogrammed to replace the missing, failing or cancerous cells, and without the problem of rejection.

Dr Harris affirmed his opposition to reproductive cloning. While respecting but not agreeing with those who believe that life begins at conception and that the fertilised egg and early embryo have the same rights to life and integrity as a viable foetus, baby or adult, he argued his Bill is not about undermining the special status accorded to the embryo:

Embryos of up to 14 days are much smaller than the head of a pin ...Research on the cells involves microscopic techniques and there is no question of experimenting on anything that remotely resembles a foetus or of there being sentient life involved.

...Some have argued that embryos should not be used as spare parts for surgery or treatment, but it is not the intention to use embryos as the source of cells to cure degenerative diseases, organ failure or cancer. If such research is successful, it will be possible to derive all the stem cells needed from the patient’s own cells, without the need to use embryos...<sup>55</sup>

He pointed out that three separate authorities, all of which have had medical and theological input, the Human Fertilisation and Embryology Authority, the Human Genetics Advisory Commission and the Chief Medical Officer’s inquiry, have agreed that there is no moral or ethical barrier to extending such research to cover stem cell research, but that the existing ban on reproductive cloning should continue. The Nuffield Council on Bioethics and the British Medical Association have also considered the matter and agree.

Edward Leigh, Member for Gainsborough, opposed the Bill. He argued that research on embryos is unethical, that the proposals could pave the way to human cloning, and that it is unnecessary; the use of adult stem cells represents an alternative.

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<sup>54</sup> HC Deb 31 October 2000 cc 626-630

<sup>55</sup> *ibid* cc 627-628

Believing that life begins at conception, he said:

Surely it cannot be argued that it is ethical to perform experiments on such unborn children and to harvest them purely for their stem cells. To allow the creation of life purely for commercial ends and research would take away the inherent value of individuals and their right to life...

He argued that the distinction between 'therapeutic' and 'reproductive' cloning is only a matter of degree.

The cell nuclear replacement process involves the insertion of a cell from someone into an emptied egg cell, which then divides and multiplies, just as an embryo would. The development of therapeutic research requires the extraction and use of stem cells that are formed by the egg as it multiplies. It would be only one stage further to allow the egg to develop, implant it into a foster mother and allow it to be born...<sup>56</sup>

He pointed out that adult stem cells provide an ethically less controversial alternative in research, and that in this case consent can be obtained:

Recent research has shown that adult stem cells can be just as effective at developing new tissue. Scientists in Florida have shown that bone marrow stem cells taken from adults can be turned into immature nerve cells and so could be used to help combat diseases such as Parkinson's. As more research has been conducted, adult stem cells have proved to be far more effective than scientists believed. The beauty of the alternative is that it deals with consenting adults; people give permission...

The Bill was rejected. The House voted Ayes 83, Noes 175<sup>57</sup>

Dr Evan Harris subsequently tabled an Early Day Motion:

That this House notes the findings of the report of the Chief Medical Officer, Donaldson Report, into the ethics and practice of embryonic stem cell research, so-called therapeutic cloning; supports its recommendation that the provisions of the *Human Fertilisation and Embryology Act 1990* be extended to allow the use of embryonic cells up to 14 days old for research into treatments for degenerative diseases, cancer, spinal injury and mitochondrial diseases in addition to the existing proposals already allowed; further supports its recommendation of a new law banning human reproductive cloning which is already not permitted by the 1990 Act; welcomes the Department of Health's support for these recommendations; notes that Parliament will soon be given a change to decide on the statutory instrument on a free vote; further welcomes the support of the Parkinson's Disease Society, the Medical Research Council, the Association of Medical Research Charities, the British Heart

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<sup>56</sup> HC Deb 31 October 2000 c 630

<sup>57</sup> *ibid* cc 626-630

Foundation, the Genetic Interest Group, the Nuffield Council on Bioethics and the British Medical Association for these proposals; and calls on honourable Members to support the forthcoming regulation to extend the provision of the *Human Fertilisation and Embryology Act 1990*.<sup>58</sup>

## **B. Adjournment debate**

The Parliamentary Under-Secretary of State for Health, Yvette Cooper, introduced an adjournment debate on embryology on 17 November 2000.<sup>59</sup>

She responded to Members' concerns that the proposed measures to extend embryo research are being brought in by regulations, which are not amendable, rather than by primary legislation, saying:

The issues were fully aired in the House during the passage of the *Human Fertilisation and Embryology Act 1990*, which provides for such regulations to be made. The possibility of allowing such regulations to be made was fully debated at that time, so making regulations is fully in keeping with the conclusions that were reached in 1990.<sup>60</sup>

The Minister said that difficult scientific and moral questions are at stake, and that as the proposals involve matters of conscience, the issue will be decided on a free vote. She acknowledged that:

Those who oppose the 1990 Act will doubtless oppose the regulations too. Those who oppose any form of research with embryos will oppose the regulations. Those who oppose the creation and, inevitably, the destruction of embryos through IVF treatment will also oppose the regulations.<sup>61</sup>

She pointed out, however, that the moral arguments cut both ways and that there are strong ethical arguments in favour of the regulations, given their potential to relieve the suffering of many:

It is important to recognise how many people's lives could be transformed by such a breakthrough. A total of 50,000 people in this country suffer spinal cord injuries...A total of 120,000 people suffer from Parkinson's disease and could potentially be spared the debilitating and distressing effects of the disease...A total of 1.4 million people with insulin-dependent diabetes could be spared the regular routine of injections and all the complications of that illness...Should the stem cell research

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<sup>58</sup> EDM 1094, 1999-2000, "*Stem Cell Research*", 26 October 2000

<sup>59</sup> HC Deb 17 November 2000 cc 1175-1230

<sup>60</sup> *ibid* c 1175

<sup>61</sup> *ibid* c 1177

lead ultimately to treatment for Alzheimer's nursing homes throughout the country could be emptied.<sup>62</sup>

The Minister emphasised that research would take place within the strict constraints of the 1990 Act; that the HFEA must still license every research proposal and it will remain illegal to use embryos after 14 days. The HFEA will also have to ensure that the use of embryos is necessary for the research and, that the research cannot be carried out in any other way. She said that the aim is to produce stable collections of stem cells that can be used as a replaceable resource without having to use, or to create, embryos for each study.

She argued that although other sources of stem cells are available those derived from embryos have the greatest potential in research and in developing understanding about cellular development. If scientists can understand how they work, it may be possible to re-programme adult cells:

Many scientists and researchers believe that the purpose of carrying out embryonic stem cell research is to discover techniques and treatments that could be applied using adult stem cells, and that could be the holy grail that could allow huge breakthroughs in the treatment of degenerative diseases.<sup>63</sup>

The Minister confirmed that the regulations allow only for research using embryonic stem cells. Treatment using these cells is not permitted under the Act, and would require further legislation.

The Minister emphasised that although creating embryos by the cell nuclear replacement technique is already permitted under the Act, the proposed regulations would not give the go-ahead for reproductive cloning. The HFE Authority will not license the implantation of a cloned embryo. The regulations would extend the purposes for which research on such embryos could be carried out, treating them in the same way as embryos created by IVF. The Act does not distinguish between the two:

The regulations covering the use of embryos in research...whether through IVF or cell nuclear replacement are extremely clear and strict...

The existing controls operated by the HFEA will apply. In addition, in the case of cell nuclear replacement, the HFEA would need to take particular steps to satisfy itself that there are no other means of meeting the objectives of a research proposal. Couples donating embryos would need to give specific consent to their embryos being used in stem cell research, not just general consent to their use in research.<sup>64</sup>

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<sup>62</sup> HC Deb 17 November 2000 c 1179

<sup>63</sup> *ibid* c 1180

<sup>64</sup> *ibid* c 1181

The Minister commented on attitudes in Europe, confirming that although the European Parliament has passed a Resolution (by a narrow majority) against research using embryos created by cell nuclear replacement, there is no European Union competence in this matter. She commented that research is carried out in Belgium and the Netherlands, where there is no regulation, and also in the United States in the private sector, where there is no regulation. (It is not possible to carry out stem cell embryo research using federal funds). She said that research will go ahead in other countries, predominantly in the private sector, without the prospect of publicly funded research:

...it is important to have a publicly funded research role... there is a strong case for public-private partnerships to ensure the right sort of ethical framework is in place for the application as well as the initiation of research.<sup>65</sup>

Members responded to the debate exploring the moral, scientific and theological arguments. Some of these are reflected here.

Philip Hammond, Member for Runnymede and Weybridge, acknowledged that there were potential benefits in the proposed regulations but expressed scepticism on two counts. He recognised that the creation and destruction of life for other purposes is a legitimate and deeply held concern. The second concern is that the cell nuclear replacement technique is open to abuse - that it will result in cloning of humans. He expressed the view that, although there are scientific problems in using adult-derived stem cells in this research, these are not insurmountable.

He acknowledged that research using embryonic stem cells will continue in the United States:

The issue is not for or against stem cell research. Rejecting embryonic research, which is already underway in the United States, does not close the door to these scientific developments, although it could possibly slow down the process...

...The question is not whether the research will be done but whether it will be done in the United Kingdom: whether we, within the limited scope of our jurisdiction, wish to sanction such activity in order to promote our pharmaceutical research base...<sup>66</sup>

He also suggested that the public has reservations about advances in science, generated by the BSE crisis and the genetically modified crops debate, which have caused the public to re-evaluate the role of science in our society. He suggested that the age of deference to science is over, and said it would be dangerous if science were constantly pushing ahead of where the body of society is comfortable and happy to be. It is incumbent on those who seek to make changes to carry public opinion with them.

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<sup>65</sup> HC Deb 17 November 2000 c 1230

<sup>66</sup> *ibid* c 1188

Mr Hammond stated:

..At a personal level I would like to place on the record the fact that I approached the debate with an open mind, and with no predisposition to believe that the issue should be determined in one way or the other. I have considered carefully the arguments on both sides, and I do not believe that a case has been made with a standard of proof that is adequate to overcome my real moral concerns and fears about where this road will lead us...<sup>67</sup>

Peter Bottomley, Member for Worthing West, was among those arguing that more time is needed before the House votes on the regulations. He argued that there is little public understanding of the matters under consideration:

To many of us, the most important question is whether the public understand what we are proposing. If I thought that they did, I would find it easier to support the regulations.<sup>68</sup>

Dr Ian Gibson, Member for Northwich, North, sought to clarify the potential of adult stem cells, explaining that

There is not an either/or situation, as there is serious research into adult cells and embryonic cells..I think, at this stage, the embryonic stem cell usage is much more productive...

...Why not use adult stem cells? That argument keeps coming up. Apart from the fact that it is difficult to obtain them, as there are not as many in the human body as other cells, it is difficult to show good results with them. I have never seen any explanation for that in the literature, but shall put one forward. When a stem cell develops into an adult organism it is affected by ageing...part of that ageing process will be mutations and chromosomal changes. If one tries to use an adult stem cell one is running against nature, as changes have taken place in it. That probably explains why such cells do not work as well...Work is going on in that field which I have discussed with eminent scientists. Indeed, they are looking at the changes that occur in adult cells, as that will contribute to the holy grail of using them that will come about. We are a long way from doing that and, at this stage, the most exciting results will certainly come from embryonic cells.<sup>69</sup>

Dr Peter Brand, Member for the Isle of Wight, raised concerns that Recommendation 2 of the Donaldson Report, which requires that in licensing any research using embryos the HFEA should be satisfied that the research could not be carried out by other means, could be used by those who argue that all the answers lie in adult, or other alternative stem cell research.

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<sup>67</sup> HC Deb 17 November 2000 c 1189

<sup>68</sup> *ibid* c 1188

<sup>69</sup> *ibid* cc1191-1192



He argued that although this is possible, it seems silly to deny the opportunity to get an answer from a different direction, or more quickly, using the less differentiated foetal cells:

If foetal stem cell research helps us reach that goal five or 10 years earlier, it would be irresponsible, amoral and unethical, as well as unscientific, not to take those opportunities.<sup>70</sup>

Gareth R Thomas, Member for Harrow, West, expressed the view that the Donaldson recommendations will not undermine the sanctity of life, and that the proposals do not alter the special status of the embryo. Describing the day to day experiences of sufferers from Parkinson's disease, he said:

Given the huge potential benefit to health that stem cell research could bring, the value that we attach to the embryo should not prevent carefully regulated and controlled research that may improve the quality of life of some of our constituents. If we close off opportunities for that research, are we not implying that we do not value existing life highly enough?...<sup>71</sup>

Mrs Ann Winterton, Member for Congleton, strongly opposed the proposals and endorsed the view expressed by others that a vote on the statutory instrument before Christmas would be precipitate and would not reflect the Leader of the House's statement that these matters should be thoroughly aired.

She also condemned the use of a statutory instrument, which cannot be amended, to bring in the proposals which involve:

a major change to the Act in a matter that was not fully debated during the Bill's passage through Parliament in 1990. Surely that is an abuse of Parliament. I took part in the debates, and no one seriously considered the possibility of cloning.<sup>72</sup>

Mrs Winterton asserted that a propaganda campaign in which the Royal Society, the Medical Research Council, the British Medical Association, the BioIndustry Association and the Nuffield Council on Bioethics, announced their support for human cloning was necessitated because "it is well known that the public is very much opposed to human cloning".

She said that public opinion on "so-called therapeutic cloning" is generally supportive until people realise what is involved. She noted that the term "cloning" is avoided in the Donaldson report. The term cell nuclear replacement, a morally neutral term, disguises the reality that this technique results in a genetically identical embryo.<sup>73</sup>

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<sup>70</sup> HC Deb 17 November 2000 c 1196

<sup>71</sup> *ibid* c 1198

<sup>72</sup> *ibid* c 1208

<sup>73</sup> *ibid* c 1201

She expressed the view that “cloning - the manufacture of a human embryo for the sole purpose of bit-part treatment and other destructive experiments” completely denies the special status of the human embryos as designated by the Warnock committee.

Mrs Winterton asserted that the Donaldson Report is outdated in its analysis that adult stem cells have limited potential to develop into other kinds of tissues:

Research is continually emerging from Scandinavia, Britain, America and elsewhere on the uses of adult stem cells, showing the Donaldson report to have been completely eclipsed...the latest document [from the Department of Health] appears to accept, contrary to original assertions, that a majority of research scientists, now consider adult stem cells to be “pleuripotent” - that is, of almost unlimited potential.<sup>74</sup>

...For at least a year, adult stem cells have been used either exclusively or in combination with other treatments to achieve significant health benefits for sufferers of the following conditions: brain tumours, ovarian cancer, non-Hodgkin's lymphoma, multiple sclerosis, systemic lupus, rheumatoid arthritis, anaemia, stroke, blindness and immunodeficiency...<sup>75</sup>

She also expressed concerns about commercial pressures to endorse the proposals, and questioned why the Donaldson report did not refer to the commercial stakes in cloning. The potential rewards in biotechnology are “overwhelming”:

...the human embryo initiates, sustains, controls and directs its own developments by virtue of its ability to synthesise a whole range of biochemical products that could be used in other aspects of biotechnology. These can be extracted, refined, purified and sold to the highest bidder in the world-wide biotechnology industry.<sup>76</sup>

Mrs Winterton argued that Britain is out of step with the rest of Europe in the matter of cloning:

Cloning is completely outlawed in Germany, Denmark, Norway, Spain, Switzerland and Slovakia. In the last three years- between March 1997 and 7 September 2000 - the European Parliament has voted for a ban on human cloning, and it was not just a north-south divide; Germany is the greatest opponent in Europe of cloning. The latest Resolution called on the United Kingdom Government to review their position on human embryo cloning, and called on Members of Parliament to "Exercise their votes of conscience to reject the proposal to permit research using human embryos".

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<sup>74</sup> HC Deb 17 November 2000 c 1204

<sup>75</sup> *ibid* c 1205

<sup>76</sup> *ibid* c 1206

In addition, the United Kingdom will not benefit from research moneys provided by the European Union...as many hon. Members will know, the Council of Europe has also condemned human cloning...<sup>77</sup>

Mrs Joan Ruddock, Member for Lewisham, Deptford, suggested that a sound body of scientific opinion is of the view that embryo-derived stem cells hold the most promise for fundamental research, and that “a spate of papers, which suggest that adult stem cells can be used to produce cells of different sorts of tissue”, does not mean there is no need for such fundamental research. She expressed the view that the House should take a positive decision and that “We have a duty to society and to the sufferers of degenerative diseases”.<sup>78</sup>

Mr Robert Key, Member for Salisbury, explored moral and theological arguments and concluded that if we can offer hope for the alleviation of the miseries of diseases such as Alzheimer’s, then we have a duty to do so. If that involves cell transplant or genetic manipulation, let us pursue such goals: “Let us recognise that, in changing some genes in some human beings, we are not changing human nature.”<sup>79</sup>

Dr Evan Harris, Member for Oxford, West and Abingdon, commented that Church bodies are not necessarily on one side of the argument:

Briefings from the Church of England, which supports generally the provisions of the 1990 Act, are clear about the benefits. There is no clear – Anglican, at least – theological objections to the proposals. My local bishop, the Bishop of Oxford, Richard Harries – has clearly said to me, and is willing for me to report, that he supports the proposals, although he recognises the ethical concerns. I suspect we will find that, although the Church of England’s Board of Responsibility represents different views, the Church is generally supportive both of careful regulation and of progress being allowed when there are no new ethical issues.<sup>80</sup>

Dr Harris drew the House’s attention to the views of the Royal Society, which supports the proposals. These are set out in section C below.

Following the debate two Early Day Motions have been tabled on the issues and calling for further time for discussion. EDM 37 was tabled on 6 December 2000 by Jim Dobbin. This has received 23 signatures to 12 December 2000:

Request for full debate on human cloning

That this House notes that when introducing the Human Fertilisation and Embryology Bill at Second Reading, the then Secretary of State for Health, the right honourable Member for Rushcliffe, assured the House that ‘all honourable Members

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<sup>77</sup> HC Deb 17 November 2000 c 1207

<sup>78</sup> *ibid* c 1121

<sup>79</sup> *ibid* c 1216

<sup>80</sup> *ibid* c 1218

would like to prohibit certain activities, which include cloning and other science fiction possibilities. There can be little doubt that infringing such prohibitions should attract severe penalties provided by the Bill' (2nd April 1990, Official Report, column 920); notes in that debate the statement by the late Right honourable Sir Bernard Braine, honourable Member for Castle Point that 'apart from cloning, genetic engineering and producing animal hybrids, the scientist will be able to do what he likes under the Bill' (column 934); notes that nowhere throughout the debates was any differentiation made between cloning by cell nuclear transfer and other techniques, or between therapeutic and reproductive cloning; notes nonetheless the claims made by the Under Secretary of State that those matters were fully debated in 1990; invites the Government to cite those sections of the debates on the Bill covering such matters; further calls on the Government to cite that section of the *Human Fertilisation and Embryology Act* which makes cloning legal by any technique including cell nuclear transfer and for whatever purpose; and calls for the withdrawal of the draft Human Fertilisation and Embryology (Research Purposes) Regulation 2000, until such evidence has been provided and Right honourable and honourable Members have had adequate opportunity to consider these issues of profound ethical importance.<sup>81</sup>

EDM 49 was tabled on 6 December 2000 by David Atkinson. This has received 41 signatures to 12 December 2000:

That this House notes the strong polarisation of views both among the people of the country and among Right honourable and honourable Members on the important issue of human cloning; acknowledges that cloning raises important ethical and scientific questions which require the most careful consideration; welcomes as the commencement of a process of consideration the debate on these issues on Friday 17th November; regrets that a majority of Right honourable and honourable Members did not have sufficient notice to be able to attend this important debate; believes that prudence and wisdom require much more detailed consideration before decisions are taken; and invites Her Majesty's Government to pause for further reflection, to withdraw the Statutory Instrument they have laid to implement the proposals of the Donaldson Report, and to wait before acting until such time as this House and the people of this country have had a full opportunity to judge the long-term implications of human cloning.<sup>82</sup>

### **C. Views of interested groups**

Strongly held convictions arise on both sides of the argument on the issue of embryo research and cloning.

The Department of Health, in a briefing memorandum prepared for Members and Peers, states that:

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<sup>81</sup> EDM 37, 1999-2000, "Request for full debate on human cloning"

<sup>82</sup> EDM 49, 1999-2000, "Human Cloning",

A wide range of professional, academic, scientific and other bodies support the need for this research including the Royal Society, the Medical Research Council, the Biotechnology and Biological Sciences Research Council, the Human Fertilisation and Embryology Authority, the British Medical Association, the Nuffield Council on Bioethics, the British Fertility Society, the BioIndustry Association, the Association of Medical Research Charities, the Parkinson's Disease Society, Special Parkinson's Research Interest Group, the British Heart Foundation, the Genetics Interest Group and a wide range of academic bodies.<sup>83</sup>

## 1. Royal Society, Nuffield Council on Bioethics and Medical Research Council

The Medical Research Council, the Royal Society and the Nuffield Council on Bioethics endorse the Government's proposals for stem cell research, and convened a meeting to brief Members on recent scientific developments. The Royal Society issued a press release:

Research on early human embryos will be required to develop powerful new cell-based treatments for serious injuries and degenerative diseases, despite exciting recent reports about the potential of adult stem cells, according to a Royal Society report published today (7 November 2000).

Both embryonic and adult stem cells have advantages and shortcomings, but it will not be possible to determine which will ultimately prove to be of greater value therapeutically without allowing a critical evaluation of the potential of stem cells from both sources, a review by the Royal Society working group on therapeutic cloning has found. The results of the review were published at a briefing for MPs and Lords organised jointly by the Royal Society, the Medical Research Council and the Nuffield Council on Bioethics

The working group considered scientific papers that had been published during the 12 months since it submitted evidence to the Chief Medical Officer's consultation on stem cell research. The group concluded that progress on new therapies could be hindered unless the 1990 *Human Fertilisation and Embryology Act* is extended so that embryos before 14 days of development can be used for studies on stem cells, in addition to the research purposes currently permitted.

"Members of both Houses should accept that this research on early embryos is scientifically necessary if we are to ensure that patients benefit from the full range of potential treatments as quickly as possible," said Professor Richard Gardner FRS, the chairman of the working group. "Embryo research is very strictly regulated in the UK and we believe an extension of the present law to allow studies on stem cell therapies is highly desirable."

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<sup>83</sup> Department of Health Memorandum, "*Background Information on Stem Cells and the Proposed Human Fertilisation and Embryology (Research Purposes) Regulations*", 10 November 2000, para 30

The group concluded it was very unlikely that scientists will be able to answer within the next 10 years all of the outstanding questions about stem cells, and it might be several decades before we achieve a full understanding of how the specialised state of cells is achieved and maintained.

Scientists still need to discover how stem cells from non-embryonic sources can be extracted, kept alive in the laboratory, multiplied for extended periods of time, and directed to form specific types of specialised cells. The group warned that scientists might never be able to overcome all of the hurdles blocking the path to the therapeutic use of adult rather than embryonic stem cells.

The working group's review also concluded that allowing scientists to obtain embryonic stem cells from cloned early embryos was important since it offers a way of overcoming the problem of graft rejection.

"Scientists will need a licence from the Human Fertilisation and Embryology Authority to produce and carry out research on embryos obtained through cloning technology," said Professor Gardner. "Implanting a cloned embryo into a womb will not be allowed, so we will not see reproductive cloning as a result of the proposed extension of the 1990 Act."<sup>84</sup>

## 2. British Medical Association

The BMA supports the view of the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority that Schedule 2 of the 1990 Act should be amended to include, among the list of purposes for which embryo research may be carried out:

- the development of tissue for transplantation; and
- the development of methods of therapy for mitochondrial diseases.

The BMA would also wish to see the continuation of important basic research provided this is strictly controlled and regularly monitored.<sup>85</sup>

## 3. LIFE

The registered charity LIFE sums up its opposition:

LIFE's case can be summarised thus:

a) We do not need human cloning in order to provide stem cells for what all agree is important medical research. There are alternative sources. Stem cells taken from adults may be better subjects than those produced by embryonic cloning.

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<sup>84</sup> Royal Society press release, *Embryo research is scientifically necessary to develop stem cell therapies says Royal Society*, 7 September 2000

<http://www.royalsoc.ac.uk/templates/press/releasedetails.cfm?file=2000110700.txt>

<sup>85</sup> <http://web.bma.org.uk/public/ethics.nsf/webpagesvw/cloningbriefing>

- b) The European Parliament has repeatedly condemned human cloning for any purpose. On the last occasion (8 September 2000) it specifically asked the British Government to think again about its response to Donaldson and called on our MPs to reject any proposals to allow human cloning in this country.
- c) Many people regard this further manipulation and subsequent destruction of deliberately manufactured human beings as morally objectionable.<sup>86</sup>

A letter to the Government by Professor JJ Scarisbrick, Trustee and National Chairman of LIFE, sets out the arguments:

1. It has long been known that umbilical cords and placenta are a rich source of stem cells which can be used for both research purposes (i.e. for developing the technique of "programming" those basic pluripotent cells to become the required materials - tissues, organs, etc) and, as the recent story from the USA about a brother's umbilical cord supplying stem cells to repair an elder sister's bone marrow reminds us, even for actual treatment. Stem cell research must initially give much attention to developing the complex technology of "programming". Stem cells taken from these morally acceptable sources could be used to achieve this.

2. Research is being reported from around the world showing that adults retain their stem cells, that these are unexpectedly versatile and have wide therapeutic potentialities. To cite a few examples:

- The National Neurological Institute in Milan reported in 1999 that mice brain cells could produce blood cells. (Science 283 : 534-537) Recent research in Texas shows that muscle cells could develop into brain cells of new-born mice.
- In June last a team in Stockholm reported that mice may have all the stem cells needed for treating neurological and heart diseases, and damaged organs. See Science, 2 June 2000.

3. Other research is increasingly discovering that a human adult's stem cells possess the same versatility and are therefore capable of much broader differentiation than had been supposed. Thus in April 1999 a research team reported that stem cells in human bone marrow could grow into bone, muscle, cartilage, tendon and fat tissue (Science 284 : 143-147). In December 1999 similar findings were reported from Florida (Experimental Neurology, 164). London's Imperial College School of Medicine has recently shown that liver cells can be derived from human blood cells (Nature, 20 July 2000). Researchers in New Jersey claim they can produce an almost unlimited supply of nerve cells to repair patients' own bone marrow stem cells (Journal of Neuroscience Research, 15 August 2000). Massachusetts General Hospital reports a new technique for isolating human stem cells in the adult and thereby increasing their supply. See New Scientist, 19 August 2000.

4. UK scientists are already planning to inject stem cells into stroke patients' brains and, if this is successful, to use the technique for treating Parkinson's disease and

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<sup>86</sup> "LIFE's urgent appeal to the Prime Minister on human cloning: draw back from the rubicon", 10 October 2000 - <http://www.lifeuk.org/pressrel/pressreleases.html>

Alzheimer's. They predict that there will be drugs on the market within six years. (British Association Festival of Science report, 7 September 2000) Almost every week we hear about new discoveries in stem cell research and especially the potentialities of adult stem cells for treating degenerative diseases like Alzheimer's, heart disease, leukaemia, etc. None of this requires stem cells from human cloning (CNR).

5. Some scientists allegedly insist that embryonic stem cells will always be better subjects to work with than adult stem cells. To this one could reply:

- given the speed with which research is progressing such a judgement may be premature.
- material produced from an adult's stem cells will match perfectly the recipient's DNA, whereas stem cells derived from a clone will retain some of the ovum donor's DNA and be liable to rejection by the recipient's body.
- the 'ideal' subject for research may not always be used for that purpose. For instance, live people may not be used in research into reducing motoring fatalities or testing vehicles' safety.
- 6. As indicated above, important new research has been published since the Chief Medical Officers' Expert Group Report was presented to the Government in June last. That Group had taken account of earlier work and it was not its fault that, even before its Report had been published on 16 August, major evidence had appeared which threw significant new light on the issues it had been considering. The fact is that the Report was already outdated...<sup>87</sup>

LIFE comments on the legal basis of the proposed regulations:

For years we have been told that the use of CNR (which produced Dolly the sheep) for manufacturing cloned human embryos would require a change in the law.

...But now the official line is that CNR is already permitted. So the regulations just laid before Parliament yesterday to amend the *Human Fertilisation and Embryology Act 1990* and allow human embryos to be used for therapeutic research will not, we are now categorically told, 'make "therapeutic cloning" legal, because it is legal already!' (So the Department of Health circular 'Background Information on Stem Cell Research and the proposed Regulations to amend the 1990 *HFE Act*' - undated, but received by LIFE from the Department on 29.11.00).

So what has all the fuss been about? Nothing, apparently. CNR (i.e. cloning) has always been legal, thanks (we must believe) to the 1990 Act.

This is dishonest. The 1990 Act does not legalise CNR. It makes no mention of it, because in 1990 CNR was unknown. The Act did do something which is very

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<sup>87</sup> "LIFE's urgent appeal to the Prime Minister on human cloning: draw back from the rubicon", 10 October 2000 - <http://www.lifeuk.org/pressrel/pressreleases.html>



relevant, however. Its subsection 3 (2) bans the replacement of a nucleus of a cell of an embryo. This was presumably intended to block what was then thought to be the only possible method of cloning. CNR involves replacing the nucleus of a cell (ovum) with the nucleus of another (adult) cell.

An honest interpretation of the Act would conclude that it would have banned that, too, if simple cell nuclear replacement had been known then.<sup>88</sup>

#### **4. Society for the Protection of Unborn Children (SPUC)**

The Society for the Protection of Unborn Children opposes human cloning. It endorses the Resolution of the European Parliament, quoting Recital G:

...an attempt is being made to use linguistic sleight of hand to erode the moral significance of human cloning.

Proponents of cloning like to make out that there are two types of human cloning, namely 'reproductive' and 'therapeutic'. In fact, these are not types of cloning, but descriptions of the ways in which clones might be used. The apparently benign term conceals the fact that the cloned person is discarded once tissue has been taken from him or her.<sup>89</sup>

The Society comments on the membership of the HFEA:

The HFEA includes strong representation from the test-tube baby industry, and its membership is open only to those who agree to sanction destructive experiments on embryos.<sup>90</sup>

The Society also draws attention to recent advances in stem cell technology using sources other than human embryos, quoting examples. It comments on a biotechnology company in the United States (Orisis Therapeutics, Inc) which focuses on using human adult bone marrow to isolate mesenchymal stem cells which have the potential to give rise to connective tissues including bone, cartilage, ligament, tendon and fat, as well as muscle. The company believes these cells could potentially provide effective treatment for this type of tissue affected by injury, ageing or degenerative diseases.

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<sup>88</sup> LIFE press release, "*Cloning is given the final 'spin'*", 29 November 2000  
<http://www.lifeuk.org/pressrel/pr00001.htm>

<sup>89</sup> Society for the Protection of Unborn Children quoting European Parliament, Resolution on Human Cloning, 7 September 2000 - <http://www.spuc.org.uk/cloning/briefing.htm>

<sup>90</sup> Society for the Protection of Unborn Children <http://www.spuc.org.uk/>

The Society says:

Some argue that the British biotechnology industry would lose out to European competition if research into human cloning were prohibited. However, Germany has the strongest rules in Europe for the protection of embryos in research, yet it has overtaken the United Kingdom in terms of the number of biotechnology firms locating there.<sup>91</sup>

## 5. Catholic Church

On 24 August 2000, the Pontifical Academy for Life issued a declaration 'on the production and the scientific and therapeutic use of human embryonic stem cells.' It discusses both the scientific aspects and the ethical problems. It states that it is not licit to employ techniques which involve the destruction of human embryos.

Details of the arguments around stem cell research are set out in a further document. It concludes:

In conclusion, it is not hard to see the seriousness and gravity of the ethical problem posed by the desire to extend to the field of human research and the production and/or use of human embryos, even from a humanitarian perspective. The possibility, now confirmed, of using adult stem cells to attain the same goals as would be sought with embryonic stem cells – even if many further steps in both areas are necessary before clear and conclusive results are obtained – indicates that adult stem cells represent a more reasonable and human method for making correct and sound progress in this new field of research and in the therapeutic applications it promises...<sup>92</sup>

The Catholic Bishops of England and Wales issued a statement endorsing this view:

We are greatly concerned by the implications of allowing the cloning of human embryos for research purposes, soon to be decided by Parliament.

The Government has undertaken to allow a free vote on the new regulations to be put forward following the report of the Chief Medical Officer, Professor Donaldson. We urge all who are concerned about the profound ethical implications to write to their Member of Parliament.

We believe that research on cloned human embryos is both immoral and unnecessary. It is immoral because it involves the deliberate creation and destruction of new human lives for the sole purpose of extracting stem cells for research. It strips an individual human life, in its earliest form, of all dignity, reducing it to no more than a commodity, a supply of disposable organic matter. It is also unnecessary because

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<sup>91</sup> Society for the Protection of Unborn Children <http://www.spuc.org.uk/>

<sup>92</sup> "Production and use of stem cells", Vatican City, 2000  
<http://www.tasc.ac.uk/cc/briefing/0010/0010004.htm>

other avenues of stem cell research exist which may offer the same potential benefits without the ethical difficulties.

Scientific medical advances have brought our society extraordinary benefits, and we recognise the laudable motives behind research to cure disease. But what is technically possible is not for that reason alone morally acceptable.

The claim that embryonic stem cell research is essential for new medical advances has been brought into question by recent breakthroughs in adult stem cell research. The Royal Society admitted this month that it is not known whether research on embryonic or adult stem cells will ultimately prove to be of greater value therapeutically.

In these circumstances, the right course surely is to press ahead with research that will command acceptance and support throughout our society, so that everyone will be able to accept treatments derived from such research.

We welcome the Government's undertaking to bring in legislation prohibiting so-called "reproductive" cloning. We urge Members of Parliament to exercise their free vote to rule out the creation and destruction of cloned embryonic human lives as well.<sup>93</sup>

## 6. Church of England

A Briefing Paper on therapeutic uses of cell nuclear replacement has been prepared by Canon Dr John Polkinghorne on behalf of the Church of England Board for Social Responsibility. This briefing paper does not represent the policy or formal position of the Church of England, but is intended to help Christians think through the issues. The paper states that while use of the CNR technique to reproduce an individual is ethically unacceptable, therapeutic cloning is an entirely different potential use of CNR:

...for its purpose would not be the cloning of a human being but the production of human tissue that would be immunologically compatible with the intended recipient, thereby avoiding the problems of rejection, and permitting the treatment of serious kinds of degenerative disease... Therapeutic cloning can readily be fenced off from reproductive cloning through the prohibition of the implantation of an embryo generated through CNR, so that its use would not appear to give rise to 'slippery slope' anxieties...<sup>94</sup>

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<sup>93</sup> Catholic Bishops of England and Wales press release, *Bishops urge 'no' to therapeutic cloning*, 15 November 2000

<sup>94</sup> "*Therapeutic uses of cell nuclear replacement*", Canon Dr John Polkinghorne on behalf of the Church of England Board for Social Responsibility, December 2000

While recognising that embryos are not the only source of stem cells:

...Many experts hold the opinion that, at the very least, research on embryos will be a necessary initial stage in developing stem cell therapies, particularly for the study of how such cells may be induced to produce specific kinds of tissue. It is also widely agreed that more extensive animal experiments would be necessary before research using human embryos was appropriate.<sup>95</sup>

The paper discusses "playing God":

An anxiety often present in debates about the use of new scientific developments is whether they do not represent a step too far, a usurpation of humans of prerogatives that properly belong to the Creator... Certainly, not everything that can be done should be done and medical ethics has always recognised that there are limits to what is acceptable. It is clear that interventions in human genetics raise particularly sensitive issues of this kind, because of the involvement of DNA, the 'thread of life', and because of the human potentiality, at the very least, present in the embryo. Two general points may be made in relation to these anxieties.

One is that it is widely held that a distinction between 'natural' processes and 'unnatural' processes is one that is sometimes hard to make and which does not of itself carry a clear ethical or theological significance. Human beings are themselves part of created nature. Much medical practice is concerned with ameliorating the effects of natural processes that left unchecked would lead to disability or death. A heart transplant is as radically unnatural a procedure as CNR.

The second point is that theologically one may see the human intellectual abilities that permit us to understand and manipulate the world of which we are inhabitants as being God-given powers and a part of the *imago dei*. The point then is to use those powers aright and in accordance with the divine will. Once again, one must say that not everything that can be done, should be done. To scientific knowledge, and the powers that it confers, we need to add the wisdom to accept the good and refuse the bad.

With regard to treatment for mitochondrial disease, the paper comments:

There is, however, the issue that this would represent a modest kind of germ-line therapy, since the combined DNA would propagate eventually in the normal way to the child's descendants. It is very widely held that such germ-line therapy (with its implications for future generations) is not ethically acceptable at present, in comparison with the ethical acceptance of somatic genetic therapy (which only has consequences for the individual treated). If the reason for this view is because of the uncertainty of long-term effects, there could be an argument for relaxation in this case if careful research established that there is no need to fear the consequences. If,

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<sup>95</sup> "Therapeutic uses of cell nuclear replacement", Canon Dr John Polkinghorne on behalf of the Church of England Board for Social Responsibility, December 2000

however, the objection is that it is morally unacceptable to intervene in the chain of human life at all, then this procedure would be ethically ruled out. However, this objection in itself would not seem to apply to research to establish the feasibility of the treatment provided that research was not carried to the point of implantation but held within the 14 day period of the *HFEA Act*.<sup>96</sup>

## 7. Chief Rabbi

Rabbi Chaim Rapoport, the member of the Chief Rabbi's Cabinet with responsibility for medical ethics, has made the following statement on cloning:

"It is a hallmark of the Jewish tradition that it sees in the advances of science the unfolding and revealing of divine mysteries. The letter and spirit of Jewish law welcomes, in principal, any technological advances, which have the potential of enhancing human life. The art of human cloning could provide relief for children who require a genetically compatible bone marrow transplant, it may be beneficial in cell and tissue therapy, and it is also possible that ultimately this "science" may provide much sought after organs for transplants. Judaism does not consider man's intervention in human procreation to be an "intrusion into G-D's domain". In this Judaism parts ways with some religious denominations that condemn cloning prima facie on fundamental, doctrinal grounds. For Jewish theologians the harnessing of modern technology for the noble calling of alleviating human suffering and deprivation, is one of the greatest contributions man can give to society. Far from undermining faith in the Creator of the Universe it is a bold demonstration of the Jewish belief that G-d channels his blessings through the active creativity of the human being.

However, the divine mandate to utilise human ingenuity for the betterment of the human condition is coupled with an equally challenging responsibility, namely, to resist the temptation of embarking on such adventurous routes that could wreak havoc for mankind. The hallowed institution of Shabbat gives tangible expression to an essential Jewish doctrine in which the cessation from creativity is considered to be an integral part of G-d's design for universal perfection. This leads us to consider the practical dangers in legalising human cloning, before we take steps that cannot be reversed which could lead to incalculable disaster.

The "slippery slope syndrome" whereby scientists and doctors lacking integrity will utilise their knowledge for less than noble purposes are an obvious and immediate concern. Even a minimal degree of foresight should be sufficient to caution us about many dangers inherent in the transition from theory to practice. Untrammelled cloning could result in a disproportionate number of clones of one gender, and an imbalance in the distribution of physical attributes and human talents. These demographic considerations come in addition to the very real danger that human cloning, at least in its present "state of art" could cause untold physical, psychological

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<sup>96</sup> "*Therapeutic uses of cell nuclear replacement*", Canon Dr John Polkinghorne on behalf of the Church of England Board for Social Responsibility, December 2000

and sociological suffering for the clone. Finally, for a variety of reasons, the spirit of Jewish law has never been comfortable with fertility techniques which are effective via the combination of different men and women who do not themselves represent organic family nuclei.

For these and other reasons the Jewish tradition would advocate a state of heightened caution and trepidation before allowing advances to be made in the field of human cloning. Society has the obligation to establish precautionary measures, in order to prevent the abuse of science, especially in this "fertile" albeit new, area of human endeavour. Governments have both the right and the responsibility to impose bans on practices, which could endanger the moral and physical fabric of society. Given the "tightrope" balance that must be employed in order to enable maximum benefit whilst ruling out the potential for abuse, strict regulations and accountability should be advocated to ensure that the experimental endeavours and the application of technology should serve only as a medium for channelling G-d's blessing to mankind."<sup>97</sup>

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<sup>97</sup> Office of the Chief Rabbi press release, *Cloning*, 16 August 2000 - <http://www.chiefrabbi.org/pr-index.html>

## Appendix 1 - Nuffield Council on Bioethics

In its 1999 discussion paper *Stem cell therapy: the ethical issues* the Nuffield Council on Bioethics recommended that legislation be amended to allow spare human embryos produced as a result of in vitro fertilisation to be used for stem cell research. The Council concluded that the removal and cultivation of cells from a donated embryo does not indicate lack of respect for the embryo. The Council makes a distinction between stem cell research for therapeutic purposes and reproductive purposes.

The Executive Summary sets out its arguments:

The ability to culture human stem cells long term, and possibly indefinitely, and to control how such cells specialise to form the different tissues of the body offers the possibility of major advances in healthcare. Stem cells have been isolated and cultured, but a great deal of research is required to develop cell lines which can generate replacement cells and tissues to treat many diseases. The use of human pluripotent stem cells is controversial primarily because much of the current research is focused on deriving these cells from human embryos and cadaveric fetal tissue. We have examined the ethical issues raised by the potential of stem cells derived from donated embryos, embryos created specifically for research purposes, cadaveric fetal tissue and somatic cell nuclear transfer (SCNT).

We conclude that the removal and cultivation of cells from a donated embryo does not indicate lack of respect for the embryo. We take the view that there are no grounds for making a moral distinction between research into diagnostic methods or reproduction which is permitted under UK legislation and research into potential therapies which is not permitted. **We therefore recommend that research involving human embryos be permitted for the purpose of developing tissues to treat diseases from derived embryonic stem (ES) cells and that Schedule 2 of the *Human Fertilisation and Embryology Act* be amended accordingly.** As long as there are sufficient and appropriate donated embryos from IVF treatments for use in research, the Council takes the view that there are no compelling reasons to allow additional embryos to be created merely to increase the number of embryos available for ES cell research or therapy. However, we suggest that this issue be kept under review.

We conclude that the code of practice set out in the Polkinghorne Review provides an adequate framework for the use of fetal tissue in the derivation of embryonic germ (EG) cells. We suggest, however, that the question of consent for the use of donated fetal tissue for the purpose of deriving EG stem cells be re-considered in the context of the current guidance and regulation. While we recommend that research be permitted, **we also recommend that as a safeguard to protect all embryo donors who could theoretically be identified by analysis of DNA of an ES cell line, they be specifically asked to consent to this research and any subsequent use of the cell line.**

We consider that research into SCNT and other forms of reprogramming the nuclei of human somatic cells may potentially offer very significant medical benefits. Where such research falls within the remit of the *HFE Act*, adoption of the amendment to

Schedule 2 recommended above would permit such research to be licensed. We understand that a possible objection to this is that it could prepare the ground for reproductive cloning. However, reproductive cloning (which has the intention of producing a new individual who is genetically identical to the nuclear donor) is not permissible under UK law; the purpose of this proposed use of SCNT, by contrast, is to allow research into means of producing stem cells for cell and tissue therapy.<sup>98</sup>

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<sup>98</sup> Nuffield Council on Bioethics, *Stem cell therapy: the ethical issues*, 1999  
[http://www.nuffield.org/bioethics/publication/stemcell/p\\_0022221.html](http://www.nuffield.org/bioethics/publication/stemcell/p_0022221.html)



## **Appendix 2 - Prohibitions in connection with embryos and gametes under the *HFE Act***

### ***Human Fertilisation and Embryology Act 1990***

#### *Prohibitions in connection with embryos.*

3. (1) No person shall
  - a) bring about the creation of an embryo, or
  - b) keep or use an embryo, except in pursuance of a licence.
- (2) No person shall place in a woman-
  - a) a live embryo other than a human embryo, or
  - b) any live gametes other than human gametes.
- (3) A licence cannot authorise-
  - a) keeping or using an embryo after the appearance of the primitive streak,
  - 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.
- (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.

#### *Prohibitions in connection with gametes.*

4. (1) No person shall
  - (a) store any gametes, or
  - (b) in the course of providing treatment services for any woman, use the sperm of any man unless the services are being provided for the woman and the man together or use the eggs of any other woman, or
  - (c) mix gametes with the live gametes of any animal, except in pursuance of a licence.
- (2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.
- (3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except, in pursuance of a licence.
- (4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.
- (5) Activities regulated by this section or section 3 of this Act are referred to in this Act as "activities governed by this Act".

## Appendix 3 - Research licences

The details of regulations governing the use of embryos for research purposes is given in the HFE Authority Code of Practice:<sup>99</sup>

10.1 All research which involves the creation, keeping or using of human embryos outside the body must be licensed by the Authority.<sup>100</sup> A centre **must** apply to the authority for each research project.<sup>101</sup>

10.2 The authority may grant licences for research projects for the following purposes only:

- a. to promote advances in the treatment of fertility;
- b. to increase knowledge about the causes of congenital disease;
- c. to increase knowledge about the causes of miscarriages;
- d. to develop more effective techniques of contraception;
- e. to develop methods for detecting the presence of the gene or chromosome abnormalities in embryos before implantation.

10.3 The Authority cannot grant a licence unless it is satisfied that the use of human embryos is essential for the purposes of the research.

10.4 The following activities are prohibited by law:

- a. keeping or using an embryo after the appearance of the primitive streak, or after 14 days, whichever is the earlier;
- b. placing an embryo in a non-human animal;
- c. replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or a subsequent development of an embryo;
- d. altering the genetic structure of any cell while it forms part of an embryo.

10.5 The Authority will not license research projects involving embryo splitting with the intention of increasing the number of embryos for transfer (see Section 7 Para 7.22 above).

10.6 Embryos which have been appropriated for a research project **must not** be used for any other purposes<sup>102</sup>

10.7 Centres should refer each research project to a properly constituted ethics committee for approval before applying for a research licence.

10.8 Centres within the NHS should refer projects to the Local Research Ethics Committee (LREC) of the relevant District Health Authority. Centres outside the NHS may also refer projects to the LREC by prior arrangement, or may wish to set up their

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<sup>99</sup> Human Fertilisation Authority Code of Practice, 4<sup>th</sup> edition, 1998, part 10-research

<sup>100</sup> *HFE Act 1990* s.3(1)

<sup>101</sup> *HFE Act 1990* Schedule 2 para 4(2)(b)

<sup>102</sup> *HFE Act 1990* s. 15(4)

own committee. If so, this should be an independent body of not fewer than 5 members. The chairman should be independent of the centre. No more than one third of its members should be employed or have a financial interest in the centre. Membership of the ethics committee should be approved by the HFEA. For further information on the establishment of and operation of a research ethics committee, centres should contact the Department of Health.

10.9 Proposals for research projects involving the use of embryos will be submitted for peer review to appropriate academic referees chosen by the HFEA.

10.10 Centres' attention is drawn to paragraphs 5.9 to 5.20 on consent to storage and use of gametes and embryos, paragraphs 7.5 and 7.6 on the use of gametes and embryos which have been subject to procedures which might prejudice their developmental potential, and paragraphs 7.24 to 7.26 on the termination and disposal of embryos which have been used for research.