



RESEARCH PAPER 01/104  
27<sup>TH</sup> NOVEMBER 2001

# *The Human Reproductive Cloning Bill [HL]*

**Bill 57 of 2001-02**

The Government is introducing a Bill to prohibit human reproductive cloning. The Bill seeks to create an offence where a person places in a woman a human embryo which has been created otherwise than by fertilisation of an egg with a sperm. It sets a maximum penalty of ten years imprisonment.

This follows a High Court judgement which ruled that embryos created by cell nuclear replacement do not fall within the definition of an embryo in the *Human Fertilisation and Embryology Act 1990*, and are therefore not regulated under the Act.

This Paper discusses the background to the Bill. It provides some comment by interested parties, and discusses its passage through the House of Lords.

Alex Sleator

SCIENCE AND ENVIRONMENT SECTION

HOUSE OF COMMONS LIBRARY

**Recent Library Research Papers include:**

<b>01/93</b>	The <i>Employment Bill</i> [Bill 44 of 2001-02]	15.11.01
<b>01/94</b>	The <i>Anti-terrorism, Crime and Security Bill</i> , Parts VI & VII: Pathogens, Toxins & Weapons of Mass Destruction [Bill 49 of 2001-02]	15.11.01
<b>01/95</b>	The <i>National Health Service Reform and Healthcare Professions Bill</i> [Bill 47 of 2001-02]	15.11.01
<b>01/96</b>	The <i>Anti-terrorism, Crime and Security Bill</i> , Parts IV & V: Immigration, asylum, race and religion [Bill 49 of 2001-02]	16.11.01
<b>01/97</b>	The <i>Anti-terrorism, Crime and Security Bill</i> , Part X: Police powers [Bill 49 of 2001-02]	16.11.01
<b>01/98</b>	The <i>Anti-terrorism, Crime and Security Bill</i> , Parts III & XI: Disclosure and Retention of Information [Bill 49 of 2001-02]	19.11.01
<b>01/99</b>	The <i>Anti-terrorism, Crime and Security Bill</i> , Parts I, II, VIII, IX & XII Property, Security and Criminal Justice [Bill 49 of 2001-02]	19.11.01
<b>01/100</b>	The <i>Age Equality Commission Bill</i> [Bill 10 of 2001-02]	16.11.01
<b>01/101</b>	The <i>Anti-terrorism, Crime and Security Bill</i> : Introduction and Summary [Bill 49 of 2001-02]	19.11.01
<b>01/102</b>	Parliamentary Standards	19.11.01
<b>01/103</b>	The <i>Land Registration Bill [HL]</i> [Bill 48 of 2001-02]	21.11.01

*Research Papers are available as PDF files:*

- *to members of the general public on the Parliamentary web site, URL: <http://www.parliament.uk>*
- *within Parliament to users of the Parliamentary Intranet, URL: <http://hcl1.hclibrary.parliament.uk>*

Library Research Papers are compiled for the benefit of Members of Parliament and their personal staff. Authors are available to discuss the contents of these papers with Members and their staff but cannot advise members of the general public. Any comments on Research Papers should be sent to the Research Publications Officer, Room 407, 1 Derby Gate, London, SW1A 2DG or e-mailed to PAPERS@parliament.uk

## Summary of main points

- The Government is introducing a Bill to prohibit human reproductive cloning. The Bill seeks to create an offence where a person places in a woman a human embryo which has been created otherwise than by fertilisation. It sets a maximum penalty of ten years imprisonment.
- The Bill follows a High Court judgement which upheld the ProLife Alliance claim that human embryos created by cell nuclear replacement (CNR) fall outside the statutory licensing framework of the *Human Fertilisation and Embryology Act 1990*. This ruling in effect means that human reproductive cloning using this technique is not illegal.
- The Department of Health states that Regulations introduced in January 2001 which amended the 1990 Act to allow stem cell research on embryos with a view to finding treatments for serious diseases are not affected by the decision. Stem cell research using embryos created by egg and sperm will continue to be allowed and regulated by the Human Fertilisation and Embryology Authority.
- However, following the judgement, none of the protections for embryos encompassed in the Act are applicable to embryos created by CNR which would be produced in the process of "therapeutic cloning" for research into diseases. The Government has appealed against the judgement, and has said that if the judgement is upheld it will re-introduce proposals to regulate therapeutic cloning.
- Some critics of the Bill do not agree with the moral and practical distinction between reproductive and therapeutic cloning. They consider that all human cloning should be prohibited, and regret that the Bill prohibits only the transfer of a human clone to the body of a woman. Criticisms have also been voiced that insufficient time has been allowed for debate.
- The Bill completed its Lords stages on 26 November 2001. Consideration of an Allocation of Time Motion on the Bill will take place on 29 November in the House of Commons, followed by all the Commons stages.
- The House of Lords Select Committee on Stem Cell Research is considering the issues connected with human cloning and stem cell research arising from the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*. It is expected to report by the end of 2001.
- Explanatory Notes to the Bill, prepared by the Department of Health, are published separately as Bill 57-EN



## CONTENTS

<b>I</b>	<b>Introduction</b>	<b>7</b>
<b>II</b>	<b>Background</b>	<b>9</b>
	1. <i>Human Fertilisation and Embryology Act 1990</i>	9
	2. Cell nuclear replacement (CNR)	10
	3. Previous considerations of CNR and the Act	10
	4. High Court Ruling	13
	5. <i>The Human Fertilisation and Embryology (Research Purposes) Regulations 2001</i>	14
<b>III</b>	<b>International debate</b>	<b>15</b>
<b>IV</b>	<b>The Bill</b>	<b>17</b>
	1. Comment	18
	2. The Bill in the House of Lords	20
	<b>Appendix 1 - Prohibitions in connection with embryos and gametes under the <i>Human Fertilisation and Embryology Act 1990</i></b>	<b>24</b>



## I Introduction

The Government is introducing a Bill to prohibit human reproductive cloning, the creation of a child by cloning.<sup>1</sup> The Bill seeks to create an offence where a person places in a woman a human embryo which has been created otherwise than by fertilisation. It sets a maximum penalty of ten years imprisonment.

Regulations amending the *Human Fertilisation and Embryology Act 1990* (the Act) to extend the ground for research on human embryos came into force on 31 January 2001<sup>2</sup>. These allow for stem cell research on embryos with a view to finding treatments for serious diseases.<sup>3</sup>

Following the passage of this legislation, the ProLife Alliance<sup>4</sup> applied for judicial review, seeking a declaration that an organism created by cell nuclear replacement (CNR) did not fall within the definition of "embryo" in s.1(1) *Human Fertilisation & Embryology Act 1990* because CNR did not involve fertilisation. The High Court has upheld this view. The Human Fertilisation and Embryology Authority (HFEA) therefore has no powers to regulate research and treatment using embryos created in this way, and to prevent human reproductive cloning. It can regulate only embryos created by union of egg and sperm. The Government has been given leave to appeal against this decision. It is hoped this will take place early in 2002.

In the light of assertions by an Italian fertility expert, Professor Severino Antinori, that he plans to produce a cloned human in the UK in the near future, the Government has introduced emergency legislation to close this legal "loophole". Advances in the technology have been underlined by the announcement by an American biotechnology company, Advanced Cell Technology (ACT), that it has cloned a human embryo to be used as a source of stem cells.<sup>5</sup>

The Department of Health states that Regulations introduced in January 2001 are not affected by the decision.<sup>6</sup> Stem cell research using embryos created by egg and sperm

---

<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> *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001*

<sup>3</sup> Stem cells are unspecialised cells of the body 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, and hold potential for development of new therapies.

A political party which seeks to "Secure legislation which confers the full protection of the law on all human life from the one cell embryo stage until natural death".

<http://www.prolife.org.uk/about/manifesto.htm>

<sup>5</sup> "Controversy over human embryo clone", BBC News online, 26 November 2001 [http://news.bbc.co.uk/1/hi/english/sci/tech/newsid\\_1676000/1676234.stm](http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1676000/1676234.stm)

<sup>6</sup> Department of Health press release 2001/0554, *New legislation to outlaw human cloning*, 16 November 2001

will continue to be allowed and regulated by the HFEA. It states that no licence applications have been made to the HFEA for stem cell research using embryos created by CNR<sup>7</sup> and that "In practice, therefore, as the creation of cloned embryos are some way off the existing provisions govern all treatment and research involving human embryos in the UK".<sup>8</sup>

However, following the judgement, none of the protections for embryos encompassed in the Act are applicable to embryos created by CNR which would be produced in the process of "therapeutic cloning" for research into diseases; prohibitions under Section 3 (3) of the Act are:<sup>9</sup>

- 3(3) A licence cannot authorise-
- a) keeping or using an embryo after the appearance of the primitive streak,<sup>10</sup>
  - 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.

Introducing the Bill in the House of Lords, Lord Hunt of Kings Heath said that the Government is appealing against the judgement, and if it loses the case "when parliamentary time allows we shall seek to bring back to Parliament proposals for the regulation of therapeutic cloning".<sup>11</sup>

During the debate on the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001* the Government supported the proposal that a Select Committee of the House of Lords on Embryonic Stem Cell Research should consider the issue further, and the Government would review the regulations in the light of the Committee's conclusions. The Select Committee has taken evidence and intends to report by the end of the year.

Further background to the issue of stem cell research and cloning is provided in Research Paper 00/93 "Stem cell research and Regulations under the *Human Fertilisation and Embryology Act 1990*", issued 13 December 2000.<sup>12</sup> The Paper includes a range of views of interested parties on the controversy over therapeutic cloning, cloning of cells for

---

<sup>7</sup> Department of Health press release 2001/0547, *Health Minister reiterates opposition to human cloning*, 15 November 2001

<sup>8</sup> HDEP 2001/336, General Briefing concerning the High Court Judgement on human cloning; includes quotes from embryo research debates, Department of Health, 21 November 2001

<sup>9</sup> Prohibitions in connection with embryos and gametes (eggs and sperm) under the Act are set out in Appendix 1 of this Paper.

<sup>10</sup> The beginning of neural development

<sup>11</sup> HL Deb 21 November c 1129

<sup>12</sup> <http://www.parliament.uk/commons/lib/research/rp2000/rp00-093.pdf>

therapeutic purposes. The issue of cloning was also recently discussed in an Adjournment debate initiated by Dr Ian Gibson on 7 November 2001.<sup>13</sup>

## II Background

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

United Kingdom law with regard to embryo research is governed by the *Human Fertilisation and Embryology Act 1990*. 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. The Authority's function is to regulate research on human embryos, storage of gametes (eggs and sperm), and embryos produced outside the human body. No distinction is made in the Act between embryos produced as a result of fertilisation, and embryos produced by CNR; the technique had not been developed when the Act was passed.

Prohibition of reproductive cloning has been treated under the Act as dependent on refusal of the HFEA to license treatment using embryos created by CNR. The Act provides that:

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.

The Government has previously said that it will introduce primary legislation to enshrine the prohibition of human reproductive cloning in law.

The meaning of "embryo" is defined under s.1(1) of the Act:

- 1.(1)In this Act, except where otherwise stated -
- (a) an embryo means a live human embryo where fertilisation is complete, and
  - (b) references to an embryo include an egg in the process of fertilisation,
- and, for this purpose, fertilisation is not complete until the appearance of a two day cell zygote.

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

---

<sup>13</sup> HC Deb 7 November 2001 c 115-120WH

licensed by the Human Fertilisation and Embryology Authority (HFEA) for tightly defined purposes. The creation of an embryo for research purposes is permitted under the Act for very limited purposes.

## **2. Cell nuclear replacement (CNR)**

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>14</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 almost genetically identical to the donor cell. If the development of this embryo<sup>15</sup> 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>16</sup> (There is a slight difference only – the new embryo retains a small amount of DNA contained in the mitochondria<sup>17</sup> of the cytoplasm of the recipient cell. The implications of this difference for compatibility are, as yet, unknown).

The creation of an embryo using CNR for research purposes is commonly called therapeutic cloning. To create a cloned human, commonly called reproductive cloning, implantation of a cloned embryo into the uterus is required, and subsequent development allowed to continue.

This distinction is disputed by those who consider that cloning per se is wrong, and that the organism created by cloning is an individual from the outset; they would argue that prohibiting human reproductive cloning is an artificial distinction; it merely prevents implantation of a cloned human individual.

## **3. Previous considerations of CNR and the Act**

Prior to the recent High Court ruling a number of reports held that the new CNR technique falls within the remit of the 1990 Act, and the Government accepted this view.

---

<sup>14</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>15</sup> but see court judgement re definition of an embryo Section II4 of this paper

<sup>16</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, June 2000, para 2.29

<sup>17</sup> mitochondria are cell structures concerned with providing energy in the cell

The successful cloning of Dolly the sheep in 1997 by cell nuclear replacement led to debate about scientific and ethical implications. 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>18</sup> The Government response to that report made clear that the cloning of human individuals is "ethically unacceptable" and would not be permitted in the UK.<sup>19</sup>

A subsequent report, *Cloning Issues in Reproduction, Science and Medicine*, produced jointly by the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority, 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". The Report considered that the CNR 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>20</sup>

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 HFEA, but would be enshrined in statute.

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.

---

<sup>18</sup> Science and Technology Committee, Fifth Report, *The Cloning of Animals from Adult Cells*, 20 March 1997, HC 373 1996-97

<sup>19</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>20</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

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, and to advise on regulation.<sup>21</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.<sup>22</sup>

The Government accepted the recommendations of the Donaldson Report, and introduced Regulations to amend the *Human Fertilisation and Embryology Act 1990* to extend the purposes for which research in early embryos is permitted, as discussed below. The Government accepted the recommendations of the Report with regard to human reproductive cloning:

**Recommendation 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.**

9. The Government has made its position on reproductive cloning absolutely clear on a number of occasions. On 26 June 1997, the then Minister for Public Health stated in response to a Question in Parliament:

"We regard the deliberate cloning of human beings as ethically unacceptable. Under United Kingdom law, cloning of individual humans cannot take place whatever the origin of the material and whatever the technique is used".

This remains the Government's position. The Report from the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Commission considered that the safeguards currently in place in the United Kingdom are wholly adequate to forbid human reproductive cloning. The transfer of an embryo created by cell nuclear replacement into the uterus of a woman will continue to be a criminal offence. However, to put the matter beyond any doubt and to ensure that research using the cell nuclear replacement technique to create embryos does not inadvertently lead to reproductive cloning, the Government will bring forward primary legislation to give added clarity to the ban on human reproductive cloning, when the Parliamentary timetable permits.<sup>23</sup>

---

<sup>21</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>22</sup> *Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility"*, August 2000 <http://www.doh.gov.uk/cegc/>

<sup>23</sup> Cm 4833, *Government response to the recommendations made in the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility"*, August 2000, <http://www.doh.gov.uk/cegc/govresp.htm>

#### 4. High Court Ruling

The Law Report sets out the Court's judgement:

*R v Secretary of State for Health, ex parte Bruno Quintavalle (on behalf of Pro-Life Alliance [2001]*

**Organisms created by cell nuclear replacement did not fall within the definition of "embryo" in s.1(1) Human Fertilisation & Embryology Act 1990.**

The claimant applied for judicial review, seeking a declaration that an organism created by cell nuclear replacement ('CNR') did not fall within the definition of "embryo" in s.1(1) Human Fertilisation & Embryology Act 1990 because CNR did not involve fertilisation but cloning. The claimant's challenge was addressed to the Government's published response to the Donaldson Report, accepting the report's recommendations concerning developments in stem cell research and CNR to benefit human health. Both documents assumed that the definition in s.1(1) of the Act covered organisms produced by CNR. The defendant argued that s.1(1)(a) of the Act should read: "embryo means a live human embryo where (if it is produced by fertilisation) fertilisation is complete". Issues also arose concerning delay and jurisdiction.

HELD: (1) The grounds to make the claim first arose when the response was published in August 2000. The claimant had acted with reasonable promptness. In any event, it was open to the court to deal with late applications if the applicant had behaved sensibly and reasonably or the matters raised were of general importance. (2) The response was a definitive Government response to a proposal that new purposes of research be permitted not only on embryos undoubtedly within that definition but also on organisms produced by CNR, on the assumption that those fell within the definition in the Act and the response proposed regulations based on that assumption. The Human Fertilisation & Embryology Authority had stated that it would not issue licences under the regulations until these proceedings were resolved. The question of law raised was not merely hypothetical. It was undesirable for responsible researchers and the Authority to be left in doubt, or for the matter to be tested in ex post facto criminal proceedings. As the claimant had raised a legitimate concern about the meaning of s.1 of the Act, the court had and should exercise jurisdiction (*Gillick v West Norfolk & Wisbech Area Health Authority & Anor* [1985] 3 WLR 830 and *Airedale NHS Trust v Bland* [1993] AC 789 applied). (3) The defendant's argument for a purposive interpretation of s.1 of the Act was powerful. If the CNR technology had existed at the time the Act was enacted, it was inconceivable that Parliament would have ignored it. (4) Even if the defendant's purposive construction of s.1(1) of the Act was adopted, s.1(1) of the Act could not be stretched to cover organisms produced by CNR, involving no fertilisation. The claimant's argument was supported by the way in which the provisions of s.3(3)(d) and Sch.3 of the Act were worded. (5) Although the reason for inserting the words "where fertilisation was complete" in s.1(1)(a) of the Act and the following words in s.1(1)(b) was to define the moment at which the Act's

protection applied to the organism, the words were nevertheless there. It would be impermissible to insert the additional words argued for by the defendant. This conclusion was reached with some reluctance since it left organisms produced by CNR outside the statutory and licensing framework.

Application allowed<sup>24</sup>

The effect of the Ruling is that none of the prohibitions with regard to embryos provided in the 1990 Act or the amending Regulations described below is applicable with regard to embryos produced by cell nuclear replacement.

##### **5. *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001***

Schedule 2 of the Act originally stated 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>25</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. It makes no distinction between embryos created by fusion of egg with sperm and those created by CNR; this technique had not been developed.

---

<sup>24</sup> Lawtel Law Report, *R v Secretary of State for Health, ex parte Bruno Quintavalle (on behalf of Pro-Life Alliance)* [2001], QBD Administrative Court (Crane J) 15 November 2001

<sup>25</sup> Schedule 2 paragraph 3(2)

The *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*<sup>26</sup> were passed in the Commons on 19 December 2000.<sup>27</sup> The House of Lords debated and passed the Regulations on 22 January 2001, and they came into force on 31 January 2001. There was a free vote in both Houses.

The Regulations extended the grounds for research using early embryos permitted under the *Human Fertilisation and Embryology Act 1990*. They enable the HFEA to issue a research licence for the purposes of increasing knowledge about the development of embryos or about serious disease, or enabling any such knowledge to be applied in developing treatments for serious diseases. Since the regulations were passed, the HFEA has received two applications for research under the extended regulations. Those applications involve not cloning embryos but using embryos that are already available.<sup>28</sup>

The creation of an embryo for research purposes was already 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 Regulations therefore 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. They relate only to the granting of licences for research, and do not make provision for licences for treatment.

The ruling of the High Court does not affect the legislation with regard to embryos created by fertilisation, but removes regulation from embryos created by CNR. Research could therefore be carried out on such embryos at a later stage of development. The *Human Fertilisation and Embryology Act* restricts this to within 14 days of fertilisation or the beginning of neural development.

### III International debate

In Europe and beyond there is debate about cloning and stem cell research.

The European Parliament has backed proposals that the European Union should be allowed to fund research into the use of human stem cells, but money should not go towards human cloning for reproductive purposes or the creation of embryos for research. This first vote on the issue will be followed by adoption of an initial position on the proposals in December 2001.

Before then, the European Parliament will vote on a separate report on the ethical

---

<sup>26</sup> SI 2001/188

<sup>27</sup> HC Deb 19 December 2000 c 211-266

<sup>28</sup> HC Deb 7 November 2001 c 118WH

implications of genomic research, drawn up by the "Temporary Committee on Human Genetics" under the chairmanship of Francesco Fiori, of the conservative Forza Italia party. The report calls for a highly restrictive regime on genomic research.<sup>29</sup>

The Department of Health states:

The original report was drafted by the Italian rapporteur in a way that raised few major issues for the UK. However, many of the 560+ amendments have introduced "pro-life" and/or anti gene science elements which are in conflict with existing law and practice. The final report was supported by a vote of 18 to 13 on the committee.

The EP plenary at which the Committee's report is likely to be considered is scheduled for 29 November. If approved, the Report will be passed to the Commission as reflecting the views and wishes of the European Parliament. Although the Commission is not obliged to implement the recommendations, the Report will greatly influence future Community actions.<sup>30</sup>

In the US, President George W. Bush has already set out limits on federally funded research into stem cell lines. The current position in the US is complex:

For many years there has been a ban on any embryo research in the public sector. Federal funds have not been made available for such research. In contrast there is a near "free for all" in the private sector with no Federal law and a minority of States with laws.

In 2001 President Bush announced a limited relaxation on Federal funding in respect of embryonic stem cell research using cell lines obtained before August 2001.

A Bill to ban all cloning (reproductive and therapeutic) in Congress gained early support but has now been dropped from the timetable of the Senate in the light of events post September 11. It is not expected to be revived in the short term. As a result, therapeutic cloning is not controlled in the private sector except in a few States that have local laws.<sup>31</sup>

The Parliamentary Under-Secretary of State for Health, Ms Hazel Blears, commented during an adjournment debate on cloning in Westminster Hall:

It is true that there are different national approaches to embryo and stem cell research. They reflect the differing legal, historic and religious approaches throughout the world. The international bioethics committee of UNESCO

---

<sup>29</sup> "Vote allows EU to fund stem cell research", *Financial Times*, 15 November 2001

<sup>30</sup> HDEP 2001/336, General Briefing concerning the High Court Judgement on human cloning; includes quotes from embryo research debates, Department of Health, 21 November 2001

<sup>31</sup> *ibid*

reported on the matter earlier this year. It concluded that every society has a right and a duty to debate and decide on ethical matters with which it is confronted, and that embryonic stem cell research is a subject on which national debate is desirable. We have taken forward that approach in the United Kingdom. The round table meeting of science Ministers at UNESCO last month reaffirmed the unanimous commitment to the prohibition of human reproductive cloning. However, given the lack of international agreement on the status of the embryo, the UNESCO bioethics committee did not recommend international regulation of embryonic stem cell research now, but it considered that if such research was considered to be permissible following the national debate, it should take place only in the context of a state-sponsored regulatory system. In our case, that is the HFEA and, therefore, we are fully compliant with the international recommendations.

Later this month, the United Nations will consider proposals for developing a United Nations convention to prohibit human reproductive cloning. Developments are gradually spreading throughout the world and there is abhorrence for human reproductive cloning.<sup>32</sup>

## IV The Bill

The Human Reproductive Cloning Bill was introduced into the House of Lords on 21 November 2001.<sup>33</sup> It appears in the Commons without amendment.<sup>34</sup> It has 2 clauses:

### 1 The offence

- (1) A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.
- (2) A person who is guilty of an offence is liable on conviction on indictment to imprisonment for a term not exceeding 10 years or a fine or both.
- (3) No proceeding for the offence may be instituted -
  - (a) in England and Wales, except with the consent of the Director of Public Prosecutions;
  - (b) in Northern Ireland, except with the consent of the Director of Public Prosecutions for Northern Ireland.

### 2 Short title and extent

- (1) This Act may be cited as the Human Reproductive Cloning Act 2001.

---

<sup>32</sup> HC Deb 7 November 2001 c 119WH

<sup>33</sup> Human Reproductive Cloning Bill [HL], Bill 27 2001-2002

<sup>34</sup> Human Reproductive Cloning Bill [HL], Bill 57 2001-2002

(2) This Act extends to Northern Ireland

(3) Her Majesty may by Order in Council direct that any of the provisions of this Act are to extend, with such exceptions, adaptations and modifications (if any) as may be specified in the Order, to any of the Channel Islands.

## 1. Comment

Some commentators consider that embryology legislation is flawed and that comprehensive revision of the 1990 Act is needed.

The ProLife Alliance states:

The ProLife Alliance welcomes the news that the Government at last intends to bring forward legislation to close the cloning loopholes exposed by the Alliance in the High Court last Thursday.

Any emergency legislation which attempts to ban only the implanting of cloned embryos and not the cloning procedure itself will be wholly inadequate. It will not succeed in banning live birth cloning and will be open to fresh legal challenge.

Government lawyers were forced in Court to concede that under the current legislation cloned embryos would not be subject to the 14-day storage and experimentation limit. They were also forced to admit that no consent provisions would apply to the creation, storage or use of cloned embryos. Bringing experimental cloning under the governance of the Human Fertilisation and Embryology Act 1990 will involve wholesale revision of the Act, it cannot be achieved by rushed legislation. Pending this revision a total ban on cloning must be enacted, anything less cannot meet the problems exposed by Mr Justice Crane's judgement.<sup>35</sup>

Professor Jack Scarisbrick, chairman of the leading pro-life group Life has called on the Government, "as a matter of urgency, to introduce a bill to outlaw all cell nuclear replacement, for whatever purpose, and to encourage research using stem cells taken from adults, which offers much better prospects for conquering diseases like Alzheimer's, Parkinson's, etc." He said "It was never necessary to go down the cloning road."<sup>36</sup>

In response to the ruling by Mr Justice Crane, Sir Brian Heap, Vice-President of the Royal Society, said:

---

<sup>35</sup> ProLife Alliance press release, *New cloning legislation must be foolproof*, 22 November 2001

<sup>36</sup> BBC News online, "Campaigners hail cloning verdict", 15 November 2001  
[http://news.bbc.co.uk/1/hi/english/sci/tech/newsid\\_1658000/1658220.stm](http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1658000/1658220.stm)

"As we have stated previously, the Royal Society believes that the government should ensure that the law explicitly prohibits human reproductive cloning in the UK.

"Both Houses of Parliament have signalled their approval for the principle of allowing licensed research into embryonic stem cells using cell nuclear replacement. This should be respected by any proposed new legislation.

"We do not believe that any scientists based in the UK who have the know-how would use, or support other scientists to use, cloning technology to produce human embryos in the UK for any purposes, until the legal situation here has been clarified."<sup>37</sup>

The British Medical Association says it is extremely concerned by the court's judgement:

"Ironically, this 'victory' for the Pro-Life Alliance means that there currently exists no legal prohibition to human cloning.

"The BMA considers this situation to be totally unacceptable and shares public opinion that embryo research must be controlled.

"It is extremely important to remember that it was the clear intention of Parliament that research using CNR embryos should be permitted with the strict controls set out in the HFE Act of 1990.

"This was because embryonic stem cell research offers huge potential to patients suffering very debilitating diseases."<sup>38</sup>

Cardinal Cormac Murphy-O'Connor, Archbishop of Westminster, states that the Bill offers an opportunity to reconsider human cloning:

...The Government's proposed Bill does nothing to stop the creation of a human clone: it merely prohibits the transfer of the cloned human embryo to the body of a woman. The clone may be treated in any conceivable way, with no time limit on experimentation, as the High Court judgment makes clear. Experimental cloning is left wholly unregulated. The Bill merely prevents an attempt, in this country, to give the clone a chance of being born. It is often suggested that "therapeutic" cloning is simply the production of stem cells for research - thus glossing over the creation of the cloned embryo from whom the cells are taken.

The Government, meanwhile, has wished to argue in favour of cell nuclear replacement for such a purpose, while opposing "human cloning", suggesting that this would be banned. This court judgment makes clear that the technique of cell nuclear replacement - whereby a nucleus from an adult cell is inserted into an egg from which the nucleus has been removed - is itself the cloning of a new human

---

<sup>37</sup> Royal Society press release, *Royal Society statement about legal ruling on cloning*, 15 November 2001 <http://www.royalsoc.ac.uk/news/index.html>

<sup>38</sup> BBC News online, "Campaigners hail cloning verdict" 15 November 2001 [http://news.bbc.co.uk/1/hi/english/sci/tech/newsid\\_1658000/1658220.stm](http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1658000/1658220.stm)

organism. In other words, the Government is in favour of human cloning, provided the newly created cloned embryo is not permitted to survive.<sup>39</sup>

## 2. The Bill in the House of Lords

The Bill passed unamended through the House of Lords, receiving support from Conservative Opposition and Liberal Democrat parties.

During the Second Reading of the Bill,<sup>40</sup> the Parliamentary Under-Secretary of State, Lord Hunt of Kings Heath drew attention to the tightly drawn provisions of the Bill. He clarified the purpose of the Bill in the light of the High Court judgement:

The Bill is short and focused. It makes it an offence for any person to place in a woman a human embryo, other than an embryo created by fertilisation. The offence carries with it the penalty of 10 years in prison or a fine, or both. The penalty applies to the person who places the embryo in a woman. It does not penalise the woman, although, as with many offences, the woman may be liable under the general rules of criminal law if she is an active and knowing participant.

The Bill does not use terms such as "cell nuclear replacement" or "cloning". That is because, first, such terms mean different things to different people in an area of rapidly developing science; and, secondly, because the mischief at which the Bill is aimed is to prevent anything other than fertilised embryos, using sperm and eggs, from being implanted into a woman.

The additional and significant benefit of that approach arises from the fact that all embryos created by fertilisation are automatically subject to the full protection of the 1990 Act. That means that the only embryos which may be implanted into a woman are those which are subject to licensing under the Act by the Human Fertilisation and Embryology Authority. That is particularly significant in the light of the judgment of the High Court in which Mr Justice Crane said:

"it is conceded, in my view correctly, that the organism produced by cell nuclear replacement is naturally described as an 'embryo', at least when the 2 cell stage is reached. This is consistent with the expert evidence before the court".

Therefore, the only question which needs to be asked is: how was the embryo created? If the answer is "by fertilisation", the embryo may be implanted but only in accordance with a licence issued by the licensing authority. If the answer is "by means other than fertilisation", as a result of the Bill, if enacted, the embryo may not be implanted at all.

---

<sup>39</sup> "Human cloning is immoral and Parliament should ban it", *Daily Telegraph*, 23 November 2001

<sup>40</sup> HL Deb 26 November 2001 c 10-60

That answers one of the questions which has been asked in the past few days about what happens if a woman has only one embryo created by fertilisation and wants to create a number of further embryos from it in order to improve her chances of having a child. As the embryo has been created by fertilisation, it is subject fully to the 1990 Act and it cannot be used in any way without a licence from the HFEA. It cannot be subject to embryo splitting to create more embryos because the HFEA has said that it will not license that procedure for treatment purposes. Nor can it be cloned using cell nuclear replacement because the licensing authority has said that it will not issue licences for that purpose. Nor can it be exported because the HFEA will issue a direction allowing export only where the proposed use abroad would be legal in the United Kingdom.<sup>41</sup>

He made clear that the Government does not intend to ban the use of embryos created by cell nuclear replacement in essential research. He acknowledged that the High Court ruling leaves these embryos unregulated, but stated that the Government will await the result of the High Court Appeal. If at the end of the legal process the Government lose their case it will bring forward further legislation when parliamentary time allows to ensure that embryos created in this way are regulated in the same way as embryos created by fertilisation. It will also be informed by the consideration of the House of Lords Select Committee on Stem Cell Research.

While there was general support for prohibition of human reproductive cloning, Members criticised the limited time for debate of the issues, and the timing with regard to the Lords Select Committee, which has not yet reported.

There was debate about the moral and ethical background to the issue of cloning. Members voiced concerns that the Bill does not go far enough. It does not prohibit implantation of cloned embryos into animals, nor does it prevent creation of hybrid clones ie the placing of human DNA in animal eggs. The prospect was also raised that embryos cloned in the UK could be exported for implantation elsewhere.

Lord Alton of Liverpool was among those who considered that the Bill should for moral reasons encompass all human cloning, and not be limited to prohibition of implantation. He criticised it also for its failure to define "human embryo" and "fertilisation". He discussed the international perspective:

...the Bill fails to meet our obligations under Articles 2 and 14 (to be read in conjunction with Article 2) of the European Convention on Human Rights in that it permits a category of human life to be created that is destined for destruction through research and experimentation.<sup>42</sup>

---

<sup>41</sup> HL Deb 26 November 2001 c 13

<sup>42</sup> HL Deb 26 November 2001 c 33

The Lord Bishop of Oxford, Chairman of the Lords Select Committee, while unable to pre-empt its Report, stated that the Committee has heard no witnesses speak in favour of human reproductive cloning.

Baroness Warnock, welcoming the Bill, commented that:

Some of the objections to stem cell research have been based on the supposition that once therapeutic cloning was permitted, reproductive cloning would be sure to follow by the route of the dread slippery slope. If the Bill is passed, we need no longer try to answer such objections because the slippery slope will have been definitively blocked by primary legislation. We shall therefore be in a position to concentrate on the arguments based on the premise that stem cell research, and embryo stem cell research in general, is in itself intrinsically evil, however beneficial its possible consequences. I believe that our being able to concentrate on that fundamental issue will lead to a considerable improvement in clarity.<sup>43</sup>

Amendments tabled for the Committee stage were withdrawn or not moved after debate.<sup>44</sup> Some sought to clarify the wording (such as fertilisation) or the extent of the Bill. Baroness Blatch sought to introduce a definition of "embryo" for the purposes of the Bill:

After Clause 1, insert the following new clause--

"DEFINITION OF EMBRYO

In this Act, except where otherwise stated, references to an embryo include--

- (a) a unicellular embryo;
- (b) a totipotent embryonic stem cell; and
- (c) an egg undergoing a process which will lead to the formation of an embryo."

Lord Hunt argued that this could be used to stop stem cell research:

This amendment seeks to define what an embryo is for the purpose of the Bill. The way in which the Bill is drafted means that if an embryo is created other than by fertilisation, whatever the means, that embryo may not be transplanted into a woman. My concern is that the amendment could restrict the class of embryos that may not be placed in a woman. Of particular relevance is a reference to a totipotent embryonic stem cell, which has no relevance as it simply cannot develop into an embryo. But it could be used to stop therapeutic research, which the Government are anxious not so to do.<sup>45</sup>

Lord Alton of Liverpool tabled an amendment to clause 1 to provide that no proceedings for the offence may be instituted against a woman in whom an embryo created otherwise than by fertilisation has been placed.

---

<sup>43</sup> HL Deb 26 November 2001 c 22

<sup>44</sup> HL Deb 26 November 2001 c 106-130

<sup>45</sup> HL Deb 26 November 2001 c 128

In Response, the Parliamentary Under-Secretary of State said that in the context of the Bill the principal offender would be the person who places the embryo, but that under other provisions in the criminal law the woman in certain circumstances could be prosecuted, but only if it were proved that she intended to assist or encourage the commission of the offence.<sup>46</sup>

---

<sup>46</sup> HL Deb 26 November 2001 c 115

## **Appendix 1 - Prohibitions in connection with embryos and gametes under the *Human Fertilisation and Embryology Act 1990***

### ***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".