

## **HGA Analysis of legal details of HFE Bill sent to House of Commons, April 2008**

April 2008: note that the Clause and paragraph numbers mentioned in this document refer to the version of the Bill sent to the House of Commons on February 5 2008.

### **1. Creation of genetically modified human embryos**

#### **1.1 Schedule 2**

The Government's decision to allow scientists to create genetically modified (GM) human embryos was stated clearly in the White Paper which preceded the Act (Paragraph 2.52). However, the words 'genetically modified', do not appear in the Bill, because what the Government has done is to remove the prohibition on genetic modification in the 1990 Act.

Schedule 2 of the 1990 Act Specifies what scientists can do with embryos. Paragraph 3(2)(4) states that: A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations.

The reference to regulations means that the Secretary of State for health can decide to make new legally binding rules which modify the legislation. These regulations (often referred to as secondary legislation. the Act being the primary legislation) must be placed before Parliament for approval, but there is very little time allowed for debate and no possibility for ammendment – the Parliamentary process is generally little more than a rubber stamp on the Secretary of State's decision. In fact, such regulations as mentioned in this paragraph were never made.

In the new Bill, this sub-paragraph of Schedule 2 has been removed, so there are now no rules regarding genetic modification of embryos. Therefore, when a scientist applies to the Human Fertilisation and Embryology Authority to create GM embryos, his/her application will be treated like any other research license application. The HFEA has never finally rejected a research license application in the 18 years of its existence.

#### **1.2 Clause 4A(5)(c)**

In addition to the deletion of sub-paragraph 3(2)(4) of Schedule 2, the Bill also positively permits the creation of a sub set of GM embryos, those containing animal genes, in Clause 4A(5) of the Bill. This Clause defines what are referred to in the Bill as 'human admixed embryos', (see below) previously referred to as 'interspecies embryos' or 'human-animal hybrid embryos'. There are five types of such embryos:

- Cytoplasmic hybrid embro, created by placing a human cell nucleus into an animal egg;
- true hybrids, which are genetically half human, half animal;

- GM embryos;
- chimeras, which contain a mixture of human and animal cells;
- 'such other thing as may be specified in regulations'.

Schedule 2, paragraph 3 allows the creation of such embryos defined in Clause 4A(5) and Schedule 3 paragraph 13 deals with people's consent for their eggs to be used to create 'human admixed embryos. Thus the Government, in addition to removing the prohibition on creating GM human embryos has positively allowed the creation of one type of such embryos, which contain animal, but not eg. plant genes.

## **2. Ban on creation of GM babies**

### **2.1 Clause 3(2) and 3ZA**

The 1990 Act (Schedule 2(1)(4)) prohibits genetic modification of embryos followed by implantation of such embryos in a woman. The HFE Bill, keeps this ban in place and improves certain definitions in a way that makes the ban cover different GM techniques more comprehensively. However, this should not be taken to mean that the Government is opposed to human genetic modification (HGM) in principle, and permanently. The Government has refused to state clearly that HGM is wrong, and has indicated that it wishes to allow embryo GM in order to develop safe techniques of genetic modification for later use to create GM babies. In fact, at one stage, the government was proposing that the law might be changed to allow creation of GM babies, by means of regulations, rather than a full Parliamentary debate(Consultation document on review of the HFE Act, paragraph 5.38).

The Bill defines which embryos may be implanted into a woman as 'permitted embryos' (Clause 3(2) and 3ZA), and paragraphs 2b,3b and 4b of Clause 3ZA state that an embryo, egg or sperm cannot be 'permitted' unless their nuclear or mitochondrial DNA has not been altered.

### **2.2 Major loophole in the ban: Clause 3ZA(5).**

During the passage of the Bill through the House of Lords, the Government has introduced a major new loophole in the ban. Clause 3ZA(5) allows the Government to introduce regulations permitting the creation of GM babies if the aim is to treat mitochondria genetic disease.

Cells contain mitochondria, which are small subcellular bodies which produce energy for the cell. These mitochondria contain DNA coding for a small number of genes, and in some families, where there is a mutation in this DNA, a genetic disease results, just as mutation in nuclear DNA can cause disease. For several years it has been suggested that these diseases might be cured by various different techniques. The most common scenarios, (which have already been used to treat types of infertility thought to be caused by mitochondrial problems), involve removing the nucleus of an egg (containing only one set of chromosomes) from the woman to be treated, and injecting this nucleus into an egg from another woman (the second egg having had its

own nucleus removed). The result would be an egg with healthy mitochondria which could then be fertilised by the standard IVF techniques, to create a baby. This baby would have genes from 3 different people, and since the process has altered the genome (the sum of a person's DNA) of the egg, this could be viewed as a form of genetic modification.

Moreover, it is not impossible that the mitochondrial disease might be treated by more conventional genetic modification of either mitochondrial or nuclear DNA of the egg. The secretary of State for Health could permit this by means of regulations. Once this was permitted, it would be very difficult to argue that the creation of GM babies to treat other genetic conditions should be prohibited. Thus this clause creates a major loophole in the ban on creation of GM babies.

### **Summary**

The HFE Bill permits the creation of GM human embryos by means of deletion of the existing ban. It also positively permits the creation of a subset of GM embryos containing animal genes.

The Bill bans, for the present, the creation of GM babies. However there is a major loophole in this ban, since the Secretary of State can allow HGM for the treatment of mitochondrial disease.