

## HFE Bill Report Stage October 22<sup>nd</sup> 2008 Briefing on amendment (no. 41) to close loopholes in Clause 3ZA (5)

David Drew, David Taylor, Michael Meacher, Michael Foster, Vincent Cable Page 3, line 26, [clause 3], at end insert –

"() Regulations made by virtue of section 3ZA (5) may not provide for an egg or embryo whose nuclear genetic material has been altered by genetic modification, or whose nucleus has been replaced by the nucleus of a somatic cell, to be a permitted egg or a permitted embryo.

() In this section, "genetic modification" includes the alteration of the nuclear genetic material of an egg or embryo by –

- (a) recombinant nucleic acid techniques which change the DNA sequence of nuclear chromosomes of the egg or one or more cells of the embryo, or,
- (b) the introduction into the egg or into one or more cells of the embryo of a stably-maintained artificial chromosome, virus or plasmid."

This amendment would stop future Governments passing regulations permitting reproductive cloning or genetic modification as a way to prevent the transmission of mitochondrial conditions. The Government has emphasised that the Bill provides comprehensive protection against the creation of cloned or genetically modified children, which is banned in most countries since it would inevitably be used to create 'enhanced', 'designer' babies. The Government says that this could only be permitted in future by a change in primary legislation, not by regulations. **However, Clause 3ZA (5) is so broadly worded that it would allow a future Secretary of State to override the protections in Clauses 3ZA (2-4), through regulations (1).** The Minister acknowledged during the Committee stage that regulations do not allow for adequate Parliamentary debate about the huge ethical and social issues raised by allowing cloning or genetic modification. She promised to re-examine this issue, but has decided not to close the loophole.

The main aim of Clause 3ZA (5) is to allow (subject to the passing of regulations) the donation of healthy mitochondria, in order to prevent transmission of mitochondrial conditions, where there is a harmful mutation in the patient's mitochondrial DNA. This would be done by nuclear- or cytoplasmic-transfer techniques (see attached diagrams). However, many conditions that affect mitochondria are the result of a mutation in nuclear DNA (mitochondria contain hundreds of proteins but only 37 genes). Once nuclear transfer techniques were allowed, there would be pressure to allow the alteration of nuclear DNA by genetic modification, in order to prevent transmission of mitochondrial conditions arising from nuclear genes. **This could lead to legalisation of the creation of GM children through regulations.** Members of the Committee drew a strong distinction between altering mitochondrial and nuclear DNA, but that distinction might not be maintained in the future, unless it is very firmly put on the face of the Bill.

We accept the Government's reassurances that it would never pass such regulations. However, it cannot control the behaviour of successor governments, and it is prudent to ensure that cloning and genetic modification cannot be legalised via the back door. The Government may argue that this is not necessary, but given the huge ethical and social consequences of cloning and genetic modification, the onus should be on the Government to show that the above amendment is harmful. It has been drafted in order not to interfere with mitochondrial donation techniques, but only to prevent the legalisation of techniques which there is a strong public and international consensus against.

**Note:** it has been necessary to define genetic modification in order to make a clear distinction between that and the nuclear transfer techniques for preventing transmission of mitochondrial conditions, which, it could be argued, also 'alter nuclear DNA' (by replacing the nuclear DNA of an egg or embryo, with that of a different egg or embryo).

1. http://www.timesonline.co.uk/tol/news/politics/article4133539.ece