

What is a "Human Admixed Embryo"? March 2008

In the language of developmental biology, an "embryo" arises with the appearance, on the surface of the growing ball of cells created following conception, of a feature known as the "primitive streak". In effect, this is the point at which the cells display the characteristics of a vertebrate. In humans, this happens at about 14 days following fertilisation. Before then, the developing ball of cells is known as a "blastocyst". The *Human Fertilisation & Embryology Act 1990* (the "Act") made the word "embryo" include the blastocyst.

The controversial provisions concerning "embryo" research actually concern blastocysts. The "embryos" concerned are all created outside the womb and, because they are never implanted, can never develop beyond a very rudimentary stage. Indeed, a key reason for creating blastocysts for research is to derive the <u>most</u> rudimentary cells of all: embryonic stem cells.

The Human Fertilisation & Embryology Bill modifies the definition of "embryo" in the Act in important ways. First, it widens it to include embryos (i.e. blastocysts) created by means other than fertilisation. Having done so, it then excludes "human admixed embryos". This basic distinction sweeps these microscopic balls of cells containing non-human material away from any possible involvement with fertility treatment but permits their creation for purposes of medical research under licence. It is forbidden to implant such embryos in a woman or to keep them for more than 14 days. In fact, they rarely survive beyond 5 days, but this is long enough to derive valuable biological material, including stem cells.

Despite the hysteria and distortions of the Catholic church, the public appears wholly unrevolted by research using admixed embryos. Survey evidence adduced by the MRC to the parliamentary joint committee on the Bill (the "Joint Committee") showed that 70% of the public supported it. The BBC's Medical Correspondent told the Joint Committee that he was "not sure the public is really staying up late worrying about it".

The Bill provides for several different types of human admixed embryos:

 <u>Cytoplasmic hybrids</u> (also known as "cybrids") are created by removing the nucleus of an animal egg cell (which stops it becoming an animal) and replacing it with one from a human (which helps it to become human).

Why are they needed?

Mills & Reeve LLP is a limited liability partnership regulated by the Solicitors Regulation Authority and registered in England and Wales with registered number OC326165. Its registered office is at Fountain House, 130 Fenchurch Street, London, EC3M 5DJ, which is the London office of Mills & Reeve LLP. A list of members may be inspected at any of the LLP's offices. The term "partner" is used to refer to a member of Mills & Reeve LLP.

To compensate for a shortage of human eggs necessary for the production of embryonic stem cells and to prevent harm to women donors and their families. The Human Fertilisation & Embryology Authority (HFEA) has already granted two licences to produce cytoplasmic hybrids. This followed extensive public consultation and a report by the House of Commons Science and Technology Committee. The provision in the Act confirms the existing legal position.

Why are they controversial?

Although the egg has had its nuclear DNA removed so that it cannot develop into an animal, a very small amount of DNA remains in the enucleated egg. This DNA is found in, and codes for, microscopic units known as mitochondria, which provide the cell with power. Objectors claim that cytoplasmic hybrids mix human and animal DNA, but mitochondria are neither "animal" nor "human"; they are autonomous. They are descended from simple organisms that, many millions of years' ago, made a home for themselves within other cells, where they thrived to mutual benefit. They now live in all animal cells, including those of humans.

• <u>**True hybrids**</u> are created by combining human gametes (i.e. egg or sperm) with animal gametes.

Why are they needed?

The creation of human animal hybrids has been permitted under licence for many years under the *Human Fertilisation & Embryology Act 1990* in order to develop more effective techniques for determining the fertility and normality of sperm. However, "anything which forms" has to be destroyed no later than the two cell stage. This provision provides an extension of research possibilities, but is limited by the overall 14 day cap. The Joint Committee noted that, "We can see no clear reason why certain categories of inter-species embryo should be permitted under licence and 'true' hybrids proscribed".

Why are they controversial?

Objectors claim that mixing of human and animal cells is an affront to humanity. However, there is no question of the blastocyst being allowed to develop to the stage that biologists would recognise as an "embryo". The government's Chief Medical Officer, Sir Liam Donaldson, referred this as a "step too far as far as the public are concerned", - the Joint Committee observing wryly that, "Surprisingly, Sir Liam Donaldson gave no evidence of how he had ascertained the state of public opinion".

Human transgenic embryos are created by introducing animal DNA into one or more cells of a human embryo. This encompasses both nuclear and mitochondrial DNA.

Why are they needed?

Transgenic embryos are useful for a range of research purposes. The introduced DNA may well be identical to the DNA coded in human cells, although absent from the particular human cells under investigation. Typically, such inserted DNA will concern a DNA sequence which controls the expression of the DNA already in the human sample.

Why are they controversial?

Objections again dwell upon an unacceptable mixture of human and animal DNA. However, DNA is not intrinsically human or animal. Sections of DNA merely code for proteins, many of which are identical between animals, including humans.

Human animal chimeras are created by adding animal cells to a human embryo. A chimera is an organism comprised of cells from two or more genetically different organisms. A mouse-mouse chimera might, for example, be made by adding stem cells from a sandy-coloured mouse to the developing embryo of a black mouse. The resulting mouse is perfectly normal, but remarkable in having two genomes. In this example, the chimeric mouse might have black and sandy fur.

Why are they needed?

Chimeras provide powerful research tools for the observation of disease and treatments. In this case, the expectation is that the number of human cells outnumbers those from the animal and any ensuing blastocyst is not permitted to live beyond 14 days. The reverse case, where human cells are introduced into an animal embryo is addressed in other legislation.

Why are they controversial?

Again, the mixing of animal and human cells stirs powerful emotions for some, even though the cells cannot live beyond the blastocyst stage and have the potential to hasten cures for serious disease.

Anything specified by regulations

Why are they needed?

The law on embryo research has struggled to keep up with technological advance. This provision provides flexibility, but requires further legislation.

Why are they controversial?

Researchers feel that the proposal is not flexible enough, because of the requirement for further regulation. In their view, this is a matter well within the competence of the HFEA.

Julian Hitchcock Senior Solicitor for Mills & Reeve LLP 01223 222545 julian.hitchcock@mills-reeve.com

The contents of this document are copyright © Mills & Reeve LLP. All rights reserved. This document contains general advice and comments only and therefore specific legal advice should be taken before reliance is placed upon it in any particular circumstances. Where hyperlinks are provided to third party websites, Mills & Reeve LLP is not responsible for the content of such sites.