

# **The Human Fertilisation and Embryology Bill 2008 - a commentary**

**Dr David King**  
**Director, Human Genetics Alert**

In November 2008 the UK Parliament finally passed The Human Fertilisation and Embryology (HFE) Bill, thereby completing a process which began formally in 2005, but was foreshadowed for at least five years before that. Although the Labour government hesitated for a long while before tabling the legislation, apparently through fear of the pro-life lobby, the final result has been warmly greeted by scientific organisations, and was an almost complete victory for the science lobby.

The debate over the Bill was marked by the usual polarisation of positions between the science and pro-life camps, and it was extremely difficult for organisations such as Human Genetics Alert (which have a position which is pro-choice but critical of many trends in reproductive technologies) to be heard in the debate. This problem was exacerbated by the fact that the 1990 legislation contains provisions on abortion, so passage of the Bill allowed amendments to the 1967 Abortion Act by both sides of the debate. At the latter stages this issue came to overshadow all others, resulting in a farcical final session of debate in the House of Commons, in which both sides “talked out” all the other important issues in the Bill, in order to avoid having to discuss abortion, upon which both sides had too much to lose.

A further major problem was the decision by the Government not to allow a free vote for members of the Labour Party on most issues on the Bill. In 1990, and all subsequent debates on this legislation members of all parties were allowed to vote according to their conscience, rather than under usual party discipline, because the ethical differences that are raised by reproductive technology do not follow party lines. The Brown Government’s decision to restrict conscience voting to only four issues (‘saviour siblings’, human animal hybrids, the need for IVF doctors to consider the child’s need for a father and abortion) was a compromise forced by a major campaign against its original decision to allow no conscience votes at all. The lack of free voting made it very difficult to change provisions of the Bill covering issues such as genetic modification of human embryos.

One general aspect of the Bill which raises severe concerns is the power it gives to future Governments to change the rules without a full parliamentary debate. The Government’s policy, which is known as “future proofing” is designed to make it easy for future governments to adapt the legislation quickly to advances in science. Whilst this may seem reasonable, future governments will be able to change important rules with only the minimum of debate, and with no opportunity for amendments. Most disturbingly a future government would be able to change the basic definitions of eggs, sperm and embryos: it is hard to imagine any other legislation in which a government may change the basic definitions of what the legislation is about without full debate. The Bill is littered with such powers, which may in future even permit the legalisation of full scale Human Genetic Modification and cloning without proper parliamentary debate.

## **Genetic Modification of Human Embryos**

The Bill improves the 1990 Act’s prohibition on creation of a genetically modified child but with a major loophole (see below). However, the Bill legalises the creation of genetically modified human embryos for research purposes only; like all research embryos these

would have to be destroyed by fourteen days at the latest. Although many countries have no legislation on human genetic modification (HGM) this Bill marks an important milestone, since it may be the first time that any government has officially permitted the creation of GM embryos. This may be the beginning of officially-sanctioned efforts to develop safe technology for the eventual creation of GM children. This was of great concern to Human Genetics Alert, which was first founded in 2000 because of the threat of HGM, and we therefore devoted most of our efforts on this Bill to alerting MPs to this threat.

It is worthwhile to recount some of the history of British Government policy on this issue, in order to clarify how this position was arrived at. As early as 1990 there was concern that scientists might try to create a GM baby, and the 1990 Act contains a prohibition on doing so. However Britain has never signed the European Convention on Biomedicine and Human Rights which contains a more comprehensively worded ban. British government policy statements have always tended to emphasise that HGM would be unethical because of the risks of harming the child, and have never taken a firm ethical stance against allowing it under any circumstances. Thus, there has always been a suspicion that the government might approve HGM if technology which rendered it safe were developed. In 2005 the report of the Parliamentary Science and Technology Committee for the first time openly advocated the genetic modification of embryos in order to develop safe technologies for HGM. (It will be recalled that this report which took a strongly libertarian approach to the regulation of reproductive and embryonic technologies, was so controversial that the Committee was completely split, and was only able to issue a report because of the Chair's casting vote). When the Government issued the consultation document preparing the way for the Bill, later in that year, it clearly supported the Committee's recommendation and cited the possibility of curing genetic conditions through HGM as the only reason for permitting the genetic modification of embryos. That document also floated the possibility that the legalisation of full scale HGM could eventually happen through the passing of regulations, which typically allow only 90 minutes of debate in Parliament. In 2006, the White Paper which stated the Government's firm policy proposals for the legislation thankfully stepped back from this latter proposal, but still suggested that research on GM embryos could further the eventual possibility of HGM.

At this point, Human Genetics Alert began publicly campaigning to draw attention to the threat of beginning research on HGM. At this time the Government's public position on the reason for allowing genetic modification for embryos appeared to change: instead of being for the purpose of development of HGM, the Government now emphasised the use of genetic modification in basic biomedical research. Around the same time, many scientific organisations began campaigning to reverse the Government's position against the creation of human-animal hybrid embryos (see below) and this introduced a further complication to the legal equation. Following the change of the Government's position on this issue, the version of the Bill that was finally introduced to Parliament deals with the issue of genetic modification in two separate ways. Firstly, it deleted the ban in the 1990 Act on genetic modification of embryos, but did not introduce any new text specifically permitting genetic modification, which meant that many people were not aware that a major change had been made. Secondly, human embryos containing animal genes were specifically defined as a type of hybrid embryo, whose creation for research purposes was permitted.

Despite strenuous efforts, it proved very difficult to awaken the interest both of either MPs or the media in the issue of genetic modification, because of the many other controversial issues in the Bill, and the framing of the debates as science versus religion. This persisted even when HGA broke the news of the creation of the first genetically modified human

embryo (*Sunday Times* May 11<sup>th</sup> 2008) on the eve of the first House of Commons debate. Because of the legal complications and the Government policy to permit a free vote only on the issues of human-animal hybrids, etc, tabled amendments to restore the ban in the 1990 Act on genetic modification of embryos were not voted on at the most important session of debate.

The Bill then moved to Committee stage. At this point it became clear that there was a major loophole in the Bill's prohibition on implantation of any genetically modified, or even cloned embryos. The crucial clause in the Bill which controls which embryos can be implanted contains a very broadly-worded exemption, which concerns embryos created in order to prevent transmission of mitochondrial genetic conditions. In the US and elsewhere; children have been born after embryos were manipulated to prevent these conditions, scientists in Newcastle are currently researching methods to improve these techniques, which themselves have been found to lead to congenital problems in the children born through them. The techniques involve various slightly different nuclear transfer methods which place the nuclear DNA of a woman who has genetic problems with her mitochondria into a donor egg from a woman who is healthy. These techniques have sometimes been referred to as a form of HGM, since the resulting embryo has DNA from two different women, and since its genome comprises both the nuclear and mitochondrial DNA, it can be argued that this is a case of artificial modification of the human genome. Permitting this would appear to set a precedent for allowing conventional genetic modification of human beings; however, these techniques do not offer the possibility of targeted 'enhancement' of specific human characteristics in the way that conventional genetic modification does, and so they do not appear to raise the same major ethical and social concerns that have lead us to oppose HGM.

The major problem with the wording of the exemption clause in the Bill is that it gives the Government powers to authorise any technique for treating mitochondrial conditions including genetic modification and cloning. Genetic modification would not be used to treat genetic conditions originating in the mitochondrial DNA; however, because many proteins in mitochondria are encoded by nuclear genes, many mitochondrial conditions have their origin in nuclear DNA, and the nuclear transfer techniques that the Government hopes to permit could not be used to prevent the transmission of such conditions. Once the nuclear transfer techniques were in use, there would then undoubtedly be calls to permit the use of genetic modification to treat the conditions involving nuclear mutations, and the Bill gives the Government powers to permit this, by means of the passing of regulations, which receive only the briefest Parliamentary debate. Thus the Bill opens a major loophole in the protection against full-scale HGM. Following HGA's efforts to alert MPs to this point, several members of the Committee forcefully urged the Government to close the loophole. However, despite promises to look again at the issue, the Government eventually refused to change the Bill, and rejected efforts by MPs to close the loophole in the final debating session on the Bill in October 2008.

This final session was effectively pointless, since both sides of the debate simply made lengthy speeches in order to avoid having to deal with controversial amendments on abortion, which were put to the end of the agenda. An HGA amendment which would have permitted genetic modification of embryos for basic research purposes, but prohibited research designed to develop techniques for HGM was not debated or voted upon because of this. The farcical nature of this final session was a fitting conclusion to a parliamentary process which utterly failed to come to terms with the seriousness of the issue being debated.

## **Reproductive Cloning.**

As noted above the loophole concerning mitochondrial conditions opens the possibility that a future Government could legalise reproductive cloning with very little parliamentary debate. The Bill supersedes the 2001 Reproductive Cloning Act, which has a clear ban on reproductive cloning.

## **Human Animal Hybrid Embryos.**

The Bill legalises the creation of several different types of human animal hybrid embryos, for research purposes only. Following the consultation process in preparation for the Bill, the Government decided to prohibit the creation of such embryos due to the strong public opposition, and because previous Government committees had opposed the creation of such embryos and stated that they would be of little value for research. This decision provoked an outcry from the scientific community, led by two groups of scientists, from Newcastle and London, had already submitted applications to the HFEA to begin such research. The groups wished to create embryos by inserting the nucleus of a human cell into a cow or rabbit egg, in the hope of creating embryonic stem cells from them. Such 'cytoplasmic hybrid' embryos became the main focus of the public debate on the Bill.

In response to the scientists' campaign, the House of Commons Science and Technology Committee organised an inquiry in early 2007, and as might be expected from the previous record of this Committee, fully backed the claims being made that such embryos were vital for medical research and were ethically unproblematic. The Committee made it clear that such research was necessary in order that Britain "retain its lead in stem cell research". At this point the Government performed a U-turn, and decided, on the principle of 'in for a penny, in for a pound' that it would also legalise the creation of all other possible types of human-animal hybrid embryo: chimaeras (mixtures of human and animal cells), genetically modified human embryos containing animal genes, 'full hybrid embryos' (embryos containing a full set of human and animal chromosomes), and any other type of embryo that scientists might like to create in the future. This was a completely opportunistic decision, since there had been essentially no public debate about these later types of embryo and even the major scientific organisations could think of little scientific use for them. In the case of full hybrids, their designation as human embryos (which was necessary for their inclusion within this legislation, which deals only with human embryos) is scientifically indefensible, since, by definition, they are 50% human and 50% animal.

By this stage, however, it became apparent that scientific indefensibility was no barrier to the crusade mounted by supporters of this research. Neither was the scientific community deterred by the publication in mid-2007 of the first paper on Induced Pluripotent Stem Cells, which are an obviously superior alternative to hybrid cells. In fact, as HGA's briefing showed ([www.hgalert.org/topics/HFEBill/hybrid\\_embryos\\_main\\_briefing.pdf](http://www.hgalert.org/topics/HFEBill/hybrid_embryos_main_briefing.pdf)), cytoplasmic hybrid embryos are likely to be so biologically abnormal that it is extremely unlikely they would survive to the stage that stem cells could be extracted, and if any stem cells were produced, they would also be so abnormal that any results obtained with them would be likely to mislead scientists. HGA wrote to three Nobel Prize-winning British scientists who supported this research, none of whom were able to refute our arguments. In my nearly 20 years involvement in public debates on biotechnology, including the GM food campaign, this campaign in support of human-animal hybrid embryos has been without doubt the most scientifically misleading and mendacious that I have experienced. Despite continuing public opposition, Parliament decided to trust the arguments of the scientific

establishment, and although there was a free vote, most Labour MPs supported the Government largely because the pro-life lobby opposed it.

In early 2009, the critiques which HGA has made of the scientific case for the use of cytoplasmic hybrid embryos were clearly vindicated by the rejection of research funding applications to use such embryos, by both the Medical Research Council and the Biotechnology and Biological Sciences Research Council.

### **PGD, 'saviour siblings' and sex selection.**

The Bill amends the 1990 Act by creating specific criteria for PGD, which was not even mentioned specifically in the 1990 Act. These criteria essentially enshrine in law the HFEA's existing guidelines on PGD, and do not make the situation any worse than it was previously. However, the crucial criteria for allowing PGD, that the condition in question is 'serious' has already been shown to be almost infinitely flexible. The HFEA has for example, already allowed PGD for late-onset cancers where the lifetime risk is still uncertain and much less than 100% and where preventative monitoring and prophylaxis is available. It has even consented to the use of PGD to avoid a condition which results in a severe squint.

The 'saviour siblings' issue was widely discussed, but the Government refused to accept any amendments designed to increase even slightly the protection given to such children, or to restrict the range of conditions in the sick child for which this process is to be allowed. Thus, the law will permit parents to have a 'saviour sibling' child in order to treat a child whose condition is not invariably fatal, and the second child may be submitted to bone marrow donation or even, potentially, whole organ donation.

The one bright spot in the Bill was the creation of a clear ban on sex selection, either by PGD, or by sperm sorting.

### **The 'Deaf Genes' Fiasco.**

One of the least-noticed aspects of the Bill concerned the possibility that Deaf couples might use PGD or choose a Deaf sperm donor, in order to have a Deaf child. The disgraceful behaviour the Government and the unfortunate reaction of the Deaf community over this issue is a parable of the pitfalls of the politics of genetics in the 21<sup>st</sup> century, and deserves close attention by all those who wish to see responsible control of genetics, in order that this episode is not repeated.

The affair began with the insertion into the Bill of a clause which prohibits couples using either PGD or the choice of a gamete donor in order to positively select for a child which will suffer from a genetic condition. It should be noted that this clause does not specifically mention deafness, even though it was clearly motivated by the celebrated case in the USA, in which a Deaf lesbian couple chose a Deaf sperm donor in order to have a Deaf child. This case was mentioned in explanatory notes to the Bill and also by a Government spokesperson when presenting the Bill in the House of Lords.

Firstly, it should be clear that this clause is definitely eugenic, both in motivation and effect. Research has shown that the number of cases in which positive selection for a genetic impairment might occur is likely to be very small: the issue is far more academic than real. The fact that the Government and its scientific and medical advisers see the issue as important enough to require legislation on shows their horror at the idea that someone

might deliberately choose to have a disabled child. Clearly, attitudes towards the birth of disabled children have not changed that much: although it is to some extent unavoidable, and parents' decisions over abortion are not supposed to be coerced, deliberately choosing to have a disabled child is still beyond the pale. What I find even more alarming is that this is the first time in many decades that the State has broken the unwritten agreement established after World War II, that it should not directly intervene or legally coerce parents' reproductive genetic decision making. It would be far better for these decisions to be left in the hands of parents and their genetic counselors, although it is noticeable that the clinical genetics profession made little protest to the Government on this important point. It should also be noted that, because legislation is such a clumsy tool, the law now sets up a situation which may cause severe difficulties in the IVF clinics. Situations may arise where the only choice is between implanting an embryo carrying a genetic impairment or one which has no impairment, but is of very poor quality, and therefore unlikely to create a successful pregnancy. Clinicians will be obliged to implant the latter embryo, which makes little sense.

The reaction of the Deaf community to news of the Government's plans was predictable, but very unfortunate. Petitions and emails began circulating and a "Stop Eugenics" campaign was launched. The campaign was supported by the British Deaf Association and other Deaf organisations and called on the Government to withdraw the offending clause. However, although the Stop Eugenics campaign stated that it was not actively advocating the use of PGD to select for deafness, this point was, not surprisingly, ignored by the media, which simply represented the issue as one of Deaf people wanting to have Deaf children in this way. This perception was not merely an invention of the media, since it became clear that many Deaf people did support the idea, and the one Deaf couple which was prepared to be interviewed by the media openly said that they would like to have a Deaf child in this way.

The result of the campaign was a meeting between Deaf organisations and the Department of Health at which the Government refused to remove the clause from the Bill, but agreed to remove the specific references to deafness in the explanatory notes, on the grounds that it could be seen as discriminatory to single out a particular group. Eventually the Bill was passed with the clause on positive selection intact.

Thus, although the Deaf campaign was not successful, it had the extremely unfortunate effect of providing support to the cause of reproductive libertarianism, and of providing the libertarians with the ideological cover that they were merely fighting for the rights of an oppressed group. I personally remonstrated with the Stop Eugenics campaigners about this point, and argued that their campaign only made sense within a broader campaign of disabled people. Unfortunately, the main thrust of Deaf politics in Britain is to argue that Deaf people are not disabled, so it was difficult to create such an alliance of Deaf and disabled people. It should also be pointed out in fairness that there was very little visible campaigning by disabled people against eugenic aspects of the Bill. I pointed out that for the last 40 years the major threat has not been state eugenics but free-market eugenics and that their campaign ran the risk of increasing that threat. Sadly, my predictions were borne out: the only non-Deaf organisation to support the campaign was the Progress Educational Trust, which, as anyone familiar with the British political debate on these issues will know, is one of the most pro-technology and libertarian voice in the debate.

This whole episode is an example of how, paradoxically, free-market eugenics can be advanced by the identity politics of oppressed groups. Such groups, which are naturally focussed on their own interests, can find it difficult to see the broader political imperative

for everyone of opposing free-market eugenics. It is vital that organisations working for responsible control of genetics make efforts to ensure that this pattern is not repeated.

## **Conclusion**

The new Human Fertilisation and Embryology Act is definitely a step in the wrong direction, although none of the changes it makes are, in themselves, disastrous. The most worrying aspect is the opening of the door to research on Human Genetic Modification. In my view the creation of cytoplasmic hybrid embryos will prove to be a scientific dead end, but there is considerably more scope for the creation of chimeras, and this is likely to become an important issue over the next few years.

In many ways, the experience of trying to effect some positive changes in the legislation was much more distressing than the legislation itself. The inability of both politicians and the media to critically scrutinise the bullish pronouncements of the science lobby, or to grasp properly the real significance of many aspects of the legislation is extremely depressing. In the absence of a strong and well organised critical movement, it is widely assumed that any concerns about the direction in which this technology is taking us must come from a religious root and this is enough for concerns to be dismissed by the majority. This fundamental structuring of the debate, and the determination of the Government to steamroller through its policies, meant that it was difficult to achieve much useful change to the Bill.

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