



Dawn Primarolo MP,  
Department of Health,  
Richmond House,  
79 Whitehall  
London SW1A 2NS

29 May 2008

Dear Ms Primarolo,

### **Clause 3ZA (5) of the HFE Bill**

The purpose of this letter is to explain our opposition to Clause 3ZA (5) of the HFE Bill, and to draw your attention to the fact that it creates an important loophole in the Bill's ban on the creation of genetically modified children. You have been at pains to reassure us that there is no need for our concern about the creation of genetically modified (GM) embryos since the Bill bans their implantation. The existence of this loophole destroys that reassurance, and perpetuates what David Drew MP referred to in the debate last week as his confusion about the Government's real intentions in this matter.

### **Nuclear transfer techniques**

We understand that the main purpose of Clause 3ZA (5) is to allow the Secretary of State to make regulations permitting the use of nuclear or cytoplasmic transfer techniques between oocytes to treat mitochondrial diseases. This in itself is highly problematic, because of the many ethical concerns about the use of such techniques.

As you will know, earlier work in the United States using cytoplasmic transfer had to be stopped in 2003, because it resulted in abnormalities in foetuses and children. If such an apparently innocuous manipulation of eggs can create abnormalities, it is very unlikely that the far greater disruption to the internal structures of eggs caused by transfer of nuclei will not also cause major problems. Despite all efforts to avoid such problems, the first children born using nuclear transfer between oocytes will be experiments, to which they cannot consent.

The technique is unnecessary, because there are obvious, safe alternatives. Firstly, women who carry mitochondrial conditions can use egg donation which is in any case necessary for the nuclear transfer techniques. All that they gain by using nuclear transfer would be that the child would be more strongly genetically related to them. Women who use egg donation would carry the child to birth and be its mother. For those who have strong feelings about a 'normal' genetic relationship with their child, the nuclear transfer technique creates a problem since the child will have mitochondria from a third genetic parent. It should also be noted that, strictly speaking, the pronuclei transfer technique being developed in Newcastle is a form of reproductive cloning.

Furthermore, for at least some mitochondrial conditions it seems likely that a form of qualitative preimplantation genetic diagnosis would be able to screen out embryos carrying too many mitochondria with the harmful mutation.

It seems highly unethical to submit a child to the risks of these techniques, for the sake of a non-medical gain (the increase in genetic relatedness, which is in any case compromised by the third genetic parent).

A further problem of these techniques is that they are arguably, in themselves a form of genetic manipulation of the human germ line, although they have different ethical implications to those raised by genetic modification. Once the nuclear transfer techniques were used they would undoubtedly be seen by some people as a precedent for human genetic modification (HGM), and the Government would face calls to permit HGM. We would like a clear statement from you that the Government would resist such calls. Our concern about this is especially strong given the drafting of Clause 3ZA (5), to which we now turn.

### **The loophole in Clause 3ZA (5)**

Although that clause has been drafted to allow the nuclear transfer techniques, the wording is so broad that it would allow the Secretary of State to authorise anything that might treat mitochondrial disease. Many mitochondrial diseases are caused by mutations in nuclear DNA; the attached documents provide some examples. Thus, as it stands, Clause 3ZA (5) would allow a future Secretary of State to authorise genetic modification to treat such conditions by using his/her power to create regulations. This is completely contrary to your assurances that the use of genetic modification for treatment purposes could only be authorised by a change in primary legislation. Once genetic modification for treatment of mitochondrial conditions was permitted, there would be no case for preventing its use for other genetic conditions, and this in turn would lead to the use of genetic modification for 'enhancement' purposes, either in the UK or abroad.

Despite our request in our initial letter, your letter to us of January 8 did not contain a clear statement about whether the Government views HGM as fundamentally unethical, or not: you merely state your intentions not to legalise it at present. However, intentions may change, as do Governments: the purpose of legislation is to set clear rules which cannot be broken by future Governments without the democratic scrutiny of Parliament. Your initial proposition to legalise HGM by way of regulations, and the obvious loophole in Clause 3ZA (5) continue to create uncertainty about the Government's real intentions. We would regard your willingness to close the loophole in Clause 3ZA (5) as a crucial test of your intention not to legalise HGM. Failure to do so will certainly make MPs less willing to support the legalisation of the creation of GM embryos.

In conclusion, we view Clause 3ZA (5) as opening the door to unnecessary and unethical practices. If the Government wishes to allow nuclear transfer techniques in future, given the major ethical issues they raise, there must be adequate Parliamentary and public debate, which is not generally possible when regulations are made. We therefore ask you to remove Clause 3ZA (5) and attendant clauses from the Bill. At the very least you should close the loophole which would allow a Secretary of State to legalise genetic modification of nuclear genes in order to treat mitochondrial conditions. Obviously, this matter is now very urgent, since the Bill is at Committee stage. We hope you will let us know how you will act in this matter in the next few days.

Yours sincerely,

Dr David King  
Director

cc David Drew MP, Michael Meacher MP