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

1/10/08

Dear Dawn,

Genetic modification in the HFE Bill

We would like to take up with you some concerns about genetic modification in the HFE Bill. Firstly, we will briefly state the position as we understand it.

The Bill has removed the pre-existing prohibition on genetic modification of embryos, but has improved, in some respects the prohibition against the use of genetic modification in treatment. We have two main concerns: firstly that there is a significant loophole in the ban on genetic modification in treatment (Clause 3ZA (5)); secondly, that the aim of removing the ban on genetic modification in research is to allow scientists to develop technology which will eventually be used for treatment purposes, following legalisation by a future government.

1. Clause 3ZA (5)

We understand that several members raised concerns about the regulation-making power in this Clause during the deliberations of the Public Bill Committee on June 3rd, but you have decided to take no action on this. In your comments during that meeting you repeatedly emphasised that this Government would never consider making regulations to allow either reproductive cloning or genetic modification for treatment. Like others, we have no trouble in accepting that assertion. However, it must be pointed out that in 2005, the Consultation Document issued by the Government envisaged the legalisation of genetic modification in treatment, and even proposed to take this enormous step by way of regulations. The Government has clearly stepped back from that position now, but it it is by no means inconceivable that a future government might, as a matter of expediency, utilise the regulation-making power in Clause 3ZA (5). Similarly, the way that the Bill repeals the 2001 Reproductive Cloning Act, yet leaves open the theoretical possibility that regulations might legalise it as a treatment for mitochondrial conditions raises severe concerns.

We understand that the Government wishes to 'future proof' the legislation, so that it is flexible enough to accommodate advances in science. However, if it does not at the same time make very sure that regulation-making powers cannot be used to do things that would be ethically and socially undesirable,

there is a risk that 'future-proofing' will disturb the delicate balance between our desire to make treatments readily available to patients, and the need to properly consider the ethical and social consequences of advances in reproductive and genetic technology. Legislation should set clear rules which cannot be broken by future governments without the democratic scrutiny of Parliament.

Although the possibility of genetic modification might seem, at this point, remote, once regulations provided for the use of nuclear transfer techniques to treat mitochondrial conditions, the situation would look very different. As you may know the first paper describing the use of mitochondrial donation referred to the techniques used as, 'the first case of human germline genetic modification', (Human Reproduction Vol 16 pp 513-516), and some people might agree with that claim. Once mitochondrial donation was permitted it would appear logical to some people, and a very small step, to allow genetic modification of nuclear genes. Thus, Clause 3ZA (5) looks like a slippery slope in preparation. Members of the Committee on June 3 drew a strong distinction between mitochondrial and nuclear DNA; however that distinction might not survive the passage of regulations permitting mitochondrial donation, unless it is very firmly put on the face of the Bill.

We draw your attention to amendment 41 which we submitted for Report stage of the Bill. Please let us know if there are any drafting problems with this amendment, which would interfere with treatments for mitochondrial conditions.

You have emphasised in debates how much the Government has been prepared to listen to criticisms and suggestions during the process of preparation of the Bill, and we agree that this has improved the Bill. We understand that you may feel that, given the Government's clearly stated intentions not to allow genetic modification or cloning, that such changes may be unnecessary. However, given the importance of having a water tight ban in the legislation on germline genetic engineering and cloning, and in the spirit of willingness to accept improvements, we would argue that the onus is upon you to show that making such an amendment would be positively harmful. We think you will find no opposition in the House to such amendments.

We will briefly address three points made in justification of your position, in a letter from Mr Ted Webb to Dr David King of Human Genetics Alert, which Dr King has shown us. We take these to be the only reasons for your decision not to close the loophole. If that is the case, they are clearly inadequate.

1. You argue that, 'As the precise process by which mitochondrial diseases may be treated is not yet clear, an amendment to the regulation-making power runs the risk of inadvertently reducing the scope for processes or treatments to be allowed'. We accept the need not to inadvertently limit the scope of possible methods for preventing the transmission of mitochondrial disease. However, amendment 41 has been narrowly drafted and designed to only prohibit those things that the Government says it wants to prohibit.

2. You argue that, ‘The regulation-making power is limited to the treatment of mitochondrial disease only, which will not involve the ‘reproductive cloning’ of a person’. In fact, as the Department has admitted in press statements, reproductive cloning could theoretically be used to prevent the transmission of mitochondrial conditions, and since you cannot control the behaviour of future governments, it is futile to assert that it ‘will not’ be used.

3. You argue that, ‘Making the regulations would include public consultation and then debate in Parliament, which will enable any concern about the regulations to be clearly brought out, discussed and robustly challenged’. This seems to suggest that you think that Parliamentary debate over regulations would be adequate to deal with the issues raised by genetic modification and cloning. We note, however, your comments in the Committee on the June 3rd , concerning the use of artificial gametes in treatment (Dawn Primarolo, Public Bill Committee session 2, Column 45-6). You said that it would be wrong to legalise their use in treatment through regulations since artificial gametes raise such important ethical issues, which cannot be adequately discussed in the time allotted to debates on regulations. Surely the same point is true, with even greater force with regard to genetic modification and cloning?

2. The purpose of GM embryo research

Our second concern is about the reason for removing the prohibition on genetic modification in research. The Government says that the Bill provides for a permanent ban on genetic modification in treatment. If that is the case, it would be illogical to legalise research intended to develop germline genetic modification techniques for eventual use in treatment. Is it is the case that the Government's reason for allowing genetic modification in research is purely to allow basic biomedical research, (for example on the early stages of development of serious diseases), and not in order to allow the development of techniques for germline genetic modification? This is a critical distinction upon which we would like to get some clarity from the Government.

We look forward to your response at your earliest possible opportunity.

Best wishes,

David Drew
Michael Meacher
David Taylor