

03 April 2008

*Wellington House
133-155 Waterloo Road
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Dear Dr Middleton,

Human Fertilisation and Embryology Bill – Embryo testing and selection

Thank you for attending the meeting on the 19th March at the Department of Health to discuss donor and embryo selection provisions in the Human Fertilisation and Embryology Bill. We are grateful to you and the other attendees that took the time to share their views with us.

The intention of the meeting was to help to clarify the intention behind the proposed new section 13(9) of the Human Fertilisation and Embryology Act 1990 (the 1990 Act) as introduced by clause 14(4) of the Bill. We found the meeting very helpful and we hope that you and the other attendees did too.

This letter aims to summarise the Department's position as well as addressing the specific action points that came out of the meeting.

Embryo testing and selection

May I say at the outset that the provisions in the Bill about embryo testing and donor selection do not reflect a view on the value of people with any medical condition or disability and the Department of Health did not wish to cause any offence to the deaf community by the language used in the Explanatory Notes.

It is our view that embryo testing should only be permitted where the intention is to avoid a serious medical condition, serious illness or disability. The provisions in the Bill directly mirror the Human Fertilisation and Embryology Authority (HFEA) policy on licensing preimplantation genetic diagnosis (PGD). A licence is granted for PGD for a particular condition when there is a 'significant risk of a serious genetic condition'. The HFEA have previously licensed PGD to avoid an inherited form of deafness and therefore, based on that, we took the position that the embryo testing provisions in the Bill may also include deafness.

We understand that many people in the Deaf community do not consider deafness to be a serious medical condition or a disability and we respect the rights of those people to hold those views. However, some people would like to

use PGD to avoid passing on an inherited deafness and if the specific inherited condition meets the criteria in the Bill, as applied by the HFEA and their code of practice, it is our view that this would be an appropriate use of the technology.

It is not appropriate, if it were possible, to use the technology to select for positive attributes such as athleticism, intelligence or hair colour. The provisions in the Bill do not enable testing for such attributes. Equally, if deafness is considered by an individual couple to be a positive attribute, it would also not be appropriate to use the technology to select for this attribute.

New section 13(9) of the 1990 Act as introduced by clause 14(4) of the Bill

As discussed at the meeting, the word 'preferred' is used in this clause to ensure that there is some flexibility to allow for appropriate clinical decision-making within the legislative framework. Whilst the purpose of the Bill has to be to avoid the use of this technology for anything other than where people wish to screen out serious medical conditions or disabilities, there may be some circumstances where replacing an embryo that has condition would be appropriate. This would be subject to decision making within the clinic and other guidance such as the HFEA's Code of Practice and professional guidelines.

An example of this could be where a woman had undergone successful treatment for an inherited form of breast cancer. Prior to treatment, she had frozen embryos with her partner. As a result of the treatment the woman's only option to have a child genetically related to her would be by using the stored embryos. They decided to test the embryos for the presence of the gene that results in an increased chance of developing breast cancer. Of the three available embryos all of the viable ones (i.e. the ones that would be likely to result in a pregnancy) have the gene that was tested for. In this case, the couple may decide that it would be appropriate to use one of these embryos because it is their only chance of having a child that is genetically related to them both.

In the example above, the Bill would not prevent choosing to use those embryos that are affected because it would not involve preference of an affected one to an unaffected one. If there were only two embryos: one affected and one unaffected, and you wanted to use one you would have to put back the one unaffected embryo. However, if it were appropriate to transfer two embryos, both could be placed in the woman because the affected one is not being preferred to the unaffected one. This would be subject to other considerations such as the welfare of any resulting child.

In the meeting summary, you also mention other more complex situations where perhaps multiple embryos are at risk of different conditions. It is our view, where a condition that is considered to be a serious medical condition, (which is a requirement in order for testing to be carried out) is identified in an embryo, the embryo with that condition should not be preferred to those that do not have it. If there are some embryos affected by one condition but not another, and no totally unaffected embryos, it would be a clinical decision to choose which of the affected embryos to replace in any given circumstance.

Explanatory note

At the meeting, we agreed to redraft the explanatory note for clause 14(4) in order to remove all reference to deafness. It currently refers to a couple who specifically selected a deaf sperm donor to increase their chance of having a child who was also deaf. The explanatory notes have already been published for the Bill in the House of Commons, however at the first opportunity we intend to update the notes. Below is the re-drafted text for the explanatory note.

“Clause 14(4) contains a provision that relates to the provisions on embryo testing (see note on clause 11). New sections 13(8) to (11) amend the 1990 Act to make it a condition of a treatment licence that embryos that are known to have an abnormality (including a gender-related abnormality) are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. This would prevent assisted reproduction technology being used to deliberately select an embryo that would result in a child with a serious medical condition or select a donor to increase the chance of a child having a serious medical condition.”

Equality scheme

A link to the Department of Health Single Equality Scheme is below http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_075463

I will also provide hard copies of the document if you give me with your postal addresses. Please note that this document is currently being updated and a new version of this will be published towards the end of April 2008.

Specific action points from the meeting

1. The DH team promised to find out what consultation had been done for the Deaf community and also promised to look into future consultation involving the Deaf community in BSL.

The Department of Health undertook a public consultation on the review of the 1990 Act in 2005. The views expressed by those that attended the meeting were reflected in some of the consultation responses. Some respondents were in favour of screening in certain characteristics or impairments.

We apologise if members of the deaf community feel that they were not given adequate opportunity to feed into the discussion. The meeting summary and the response to the meeting will be available in BSL.

2. The DH team promised to find out if Explanatory Note 109 could be revised, thus not singling out deafness in relation to Clause 14(4)(9).

We agree to amend the text in the Explanatory Notes and they will be updated at the first opportunity – see above.

3. The DH promised to clarify use of the word 'preferred' and make it explicit that it would be possible to implant a deaf embryo or other embryo with a genetic condition if this is what the parents wanted as long as it was not preferred to an unaffected embryo. This would also need to be within the context of other guidance and professional guidelines.

This has been addressed in the text above.

4. The DH said they would discuss the issue of equality and choice and get back to the other group members. More specifically, whether it was feasible to make comment about equality of reproduction – either to allow both deaf and hearing couples to use the technology or neither.

The Bill provides that embryo testing can only be carried out to avoid a serious medical condition, serious illness or disability and that an embryo with such a condition must not be preferred to a viable, unaffected embryo.

It is our view that the Government's policy is appropriate with regards to balancing the wishes of the parents to choose a disabled child or a child with a serious illness or condition and the need to ensure the welfare of any child who is born.

5. The DH team said they would discuss the issue of policy change about reference to donors and get back to the other group members.

The Department of Health recognise the concerns raised at the meeting regarding donors. If a donor with a genetic abnormality was being selected because there was no other suitable donor, the Bill would not prohibit such a choice. This would be subject to other professional guidance.

6. The DH said they would re-draft the explanatory notes and circulate to the attendees at the meeting. They also said they would provide a note for further clarification of how the clause in the Bill might be interpreted in practice. This will be made available in BSL.

This response should address these points. The summary of the meeting and the response to the meeting are available in BSL on the StopEugenics website (<http://stopeugenics.org/>).

This letter has been copied to the other attendees at the meeting. Please feel free to share it more widely if you wish.

Yours Sincerely

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