HFEA Licence Committee Meeting

28 March 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 6

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD for an unnamed X-linked condition

Members of the Committee: Sue Price (professional) Chair Debbie Barber (professional) Jane Dibblin (lay) Andy Greenfield (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Stephen Hocking, Beachcroft LLP

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- PGD Application form

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers
- HFEA Pre-Implantation Diagnostic Testing (“PGD”) Explanatory Note For Licence Committee

Discussion

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied that the Centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

2. The Committee noted that the supporting documents with this application did not contain either a Peer Review or a Genetic Alliance Opinion. The Committee were satisfied that they had, in any event, sufficient information before them on which to make a decision.

3. The Committee noted that the Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(c) of schedule 2 of the Act, ie. 'to establish the sex of the embryo in case where there is a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness or serious medical condition'.

4. The Committee noted that this unnamed X-linked condition cannot be genetically tested for; therefore the aim of PGD is to exclude male embryos only where there is a high risk that the mother is a carrier from the family information.

5. The Committee noted that affected male children are born 'floppy' and pale, with an absence of reflexes and an inability to cry. There are malformations, and lung hypoplasia, with associated with myofibre hypotrophy, and congestive heart failure. There is a low heart rate, irregular respiration after suction, and fixed flexion deformities. Those with the condition die between 1 and 6 weeks of age.

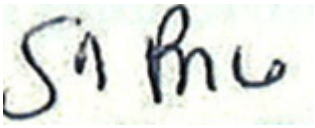
6. The Committee noted that the condition is undiagnosed, despite being akin to several other disorders for which the family have undergone testing and been found to be negative. The condition has been investigated by a neurology team and by geneticists and is an X-linked recessive condition, resulting in affected males dying in the neonatal period, following being born 'floppy', having an absence of reflexes and being unable to cry. The latest baby boy to die was in 2010 at Great Ormond Street Hospital, where no treatment could avoid it.

7. The Committee considered that the condition is serious because boys are either affected or unaffected and those who are affected die between 1 week and 6 weeks old. There is no effective treatment.

8. The Committee noted that the purpose for the proposed testing is to establish the sex of the embryo. It had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a male person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The Committee was therefore satisfied that the condition meets the criteria for testing for either and both of the purposes specified under paragraph 1ZA(1)(b) and (c) of Schedule 2 to the Act.

9. The Committee agreed to authorise the testing of embryos for this unnamed X-linked condition as described in the papers relating to this particular family.

Signed: Date: 15/04/2013



Sue Price (Chair)