

## WRITTEN MINISTERIAL STATEMENT

### DEPARTMENT OF HEALTH

#### Government response to consultation on regulations to allow mitochondrial donation

Tuesday 22 July 2014

**The Parliamentary Under-Secretary of State, Department of Health (Jane Ellison):** We are today publishing the Government response to the consultation about draft regulations to allow mitochondrial donation to prevent the transmission of serious mitochondrial disease from mother to child.

Mitochondrial disease is passed from mother to child through faults in the mitochondrial DNA. It is estimated that 1 in 6,500 children are born every year in the UK with a serious mitochondrial DNA disorder. Serious mitochondrial disease can have a devastating effect on families, including the premature death of children, painful debilitating and disabling suffering, long-term ill-health and low quality of life.

The consultation ran between 27 February and 21 May 2014. The consultation reached a wide audience and received 1857 responses from research bodies, patient bodies, professional organisations, faith organisations, parliamentarians and a large number of individuals. We have carefully considered all responses in deciding how to move forward with the regulations, recognising that there is a broad spectrum of widely different views.

Although the purpose of the consultation was to invite views on the detail of the draft regulations, four out of five respondents simply expressed a view for or against the principle of mitochondrial donation. Where comments were made about the detail of the regulations, respondents were generally positive about the proposed individual provisions. The Government has taken the view that our policy position on the key issues remains the correct one. As such, we will:

- retain the principle behind the definition of the mitochondrial donation techniques as currently set out in the draft regulations;
- retain the provision that the Human Fertilisation and Embryology Authority (HFEA) would have to be satisfied that there is both a particular risk of mitochondrial abnormality and a significant risk that a person with that abnormality would have or develop a serious physical or mental disability, a serious illness or other serious medical condition;
- retain the provision that the HFEA will consider each application on a case-by-case basis; and
- retain the provision that the HFEA will release only non-identifying information about the mitochondrial donor to people born following mitochondrial donation when they reach age 16.

We will also include additional provisions in the regulations to clarify the consent requirements around the use and storage of eggs and embryos used in the mitochondrial donation techniques.

Alongside the consultation exercise, the Department also asked the HFEA to reconvene the expert panel to undertake a further, third, review of the efficacy and safety of the mitochondrial donation techniques. A report of that review was published in June 2014. The report found that the techniques of maternal spindle transfer and pro-nuclear transfer are potentially useful for a specific and defined group of patients and that the evidence does not suggest that these techniques are unsafe. The panel was of the view that research has progressed well since its previous two reviews, although it recommended that further experiments should be completed before clinical treatment is offered.

The Government has decided to proceed with putting regulations before Parliament, subject to giving further consideration to the expert panel's recommendations, refining the draft regulations to take account of changes identified during the consultation, and discussion with the HFEA about an appropriate approval process. The Government will consider the timing of the regulations in the light of these actions.

The regulations will be subject to full scrutiny by the public and Parliament through the affirmative procedure.

*Mitochondrial Donation: Government response to the consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child* has been placed in the Library. Copies are available to hon Members from the Vote Office and to noble Lords from the printed Paper Office.