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Statement by The New York Stem Cell Foundation on the UK Parliament's Debate on Mitochondrial Donation

New York, NY (January 30, 2015) – "The New York Stem Cell Foundation (NYSCF) praises the United Kingdom's active role in bringing mitochondrial replacement therapy to patients. The UK Parliament's upcoming debate regarding the regulations of mitochondrial donation represents an important step forward in the prevention of devastating diseases. NYSCF strongly supports mitochondrial donation and advocates for the UK parliament to pass the government's proposed regulations that would allow for mitochondrial donation in the UK," said Susan L. Solomon, CEO and Co-Founder of The New York Stem Cell Foundation.

Termed mitochondrial donation or mitochondrial replacement therapy (MRT), this technique will allow for healthy children to be born to mothers who have mitochondrial disease. Since 2007, the UK has employed an excellent process for analyzing the ethical and scientific risks and benefits of this technique and we applaud their efforts on this matter.

At this point, a woman with a family history of mitochondrial diseases or a child with such a disease has few options if she wants to have healthy children. She may elect to have no future children, or she can undergo an egg retrieval process at an in-vitro fertilization (IVF) clinic, in which preimplantation genetic diagnosis selects eggs with the lowest number of mutant mitochondrial DNA to reduce—but it cannot fully eliminate—risk of the child developing mitochondrial disease. Alternatively, she can use the egg of a donor, although her child will not be genetically related to her.

According to a study published this week in the *New England Journal of Medicine*, approximately 12,423 women in the United States are between the ages of 15 and 44 and are at risk of passing mitochondrial diseases to their children. It is not acceptable to sit idly as new techniques that have been developed by scientists from The New York Stem Cell Foundation and other institutions that allow for the prevention of these diseases from being passed on to future generations are becoming available. This new technique brings patients with mitochondrial disease one step closer to being able to having healthy children that are genetically related to them.

Mitochondrial replacement therapy has undergone three scientific reviews by the HFEA in 2011, 2013, and 2014, an ethical review by the Nuffield Council on Bioethics, and a public consultation by the HFEA found that people in the UK were broadly supportive of MRT. This comprehensive approach by the UK government can help guide implementation of MRT elsewhere, including in the United States.

In vitro fertilization (IVF) is a field that has undergone significant advances and transformations since it's advent in 1978 with the birth of Louise Brown. Various improvements to IVF have been made and this is one more example of exemplary scientific work that is being translated to medical practice to prevent diseases.

We commend the work of the HFEA for their years of work in assessing the safety and support of mitochondrial donation. We also applaud the Wellcome Trust for their active role in educating the public about mitochondrial diseases and mitochondrial donation. If successful, this would be a tremendous illustration of how proper regulation working in accordance with medical science and greater society allows for the development and implementation of new treatments and cures.

About The New York Stem Cell Foundation

The New York Stem Cell Foundation (NYSCF) is an independent organization founded in 2005 to accelerate cures and better treatments for patients through stem cell research. NYSCF employs over 45 researchers at the NYSCF Research Institute, located in New York, and is an acknowledged world leader in stem cell research and in developing pioneering stem cell technologies, including the NYSCF Global Stem Cell ArrayTM. Additionally, NYSCF supports another 60 researchers at other leading institutions worldwide through its Innovator Programs, including the NYSCF – Druckenmiller Fellowships and the NYSCF – Robertson Investigator Awards. NYSCF focuses on translational research in a model designed to overcome the barriers that slow discovery and replaces silos with collaboration. For more information, visit <u>www.nyscf.org</u>