FDA intensifies discussions on medical and ethical issues of mitochondrial replacement therapy

On January 27, 2015, a newly appointed committee of the Institute of Medicine (IOM) will hold the first in a series of meetings to fulfill the FDA's request to consider the ethical and social policy issues raised by "genetic modification of eggs and zygotes to prevent transmission of mitochondrial disease." The meeting is the first public event in an FDA-sponsored study that will take place over approximately the next 14 months.

The background: In February 2014, the FDA's Cellular, Tissue, and Gene Therapies Advisory Committee held a public meeting to consider the scientific, technologic, and clinical issues related to "3-person IVF." The FDA called this procedure "oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility."

This experimental procedure would combine the nuclear DNA from one woman's egg or embryo with mitochondria from another woman's egg or embryo; the hoped-for result would be a disease-free child with DNA from two women and one man. The term "3-person IVF" is imperfect terminology for multiple reasons, but hopefully gets the point across quickly.

At the time of the FDA meeting, many scientists and public interest advocates raised technical and safety concerns about the techniques, including the lack of proof-of-concept studies, the specific health risks of pregnancy to women who have mitochondrial disease (and who are supposed to benefit from the technique), and serious known and unknown health risks to any resulting children caused by epigenetic harm from nuclear transfer or nuclear/mitochondrial mismatch. The committee concluded that significantly more data was needed prior to a clinical trial in humans (let alone introduction into fertility clinics, as now proposed in the UK).

Read full, original article: Institute of Medicine to Study the Social Policy and Ethics of "3-Person IVF"