February 18, 2014

Cellular, Tissue, and Gene Therapies Advisory Committee
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via email: gail.dapolito@fda.hhs.gov; rosanna.harvey@fda.hhs.gov

Dear Gail Dapolito and Rosanna Harvey,

I am writing to submit a sign-on letter for review by the members of the Cellular, Tissue, and Gene Therapies Advisory Committee Meeting in preparation for the February 25-26 public meeting to discuss oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility.

This letter was prepared by the Center for Genetics and Society (CGS) and the International Center for Technology Assessment, a project of the Center for Food Safety. Each of the 255 signatories filled out a form at the CGS website, or sent an email asking that their name be included.

Thank you for this opportunity to express the widespread concern regarding oocyte modifications that would constitute inheritable genetic modification.

Sincerely,

Marcy Darnovsky, PhD
Executive Director
February 18, 2014

To the FDA Cellular, Tissue and Gene Therapies Advisory Committee:

We are writing regarding the upcoming public meeting on “oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility.”

We strongly believe that clinical trials of oocyte modification for mitochondrial disease (also referred to as mitochondrial replacement techniques) should not be permitted because of the profound safety, efficacy, policy and social problems they would pose. We question the ethics of bringing children into existence by experimental techniques that have had developmentally poor outcomes in studies using both animal and human oocytes. We are also concerned about the contravention of widespread prohibitions against human germline genetic modification that approval of clinical trials would represent, and about the possible precedent such approval could set for additional human germline modifications.

Scientific understanding of the complex interaction between nuclear and mitochondrial DNA, and of the role of epigenetics on an individual’s phenotypic traits, is still at an early stage. Constructing an oocyte using one woman’s enucleated egg and the chromosomes from the egg of a second woman would be an evolutionarily unprecedented experiment that is more akin to somatic cell nuclear transfer than to conventional in vitro fertilization. Noted scientists have argued that it is unlikely that such an invasive procedure could be undertaken without causing unforeseen damage. Unintended harms could manifest at any point in the lives of resulting children; subsequent generations would be at risk as well.

We sympathize with women who place a high importance on having children genetically related to them. But we note that the number of women who would be candidates for the techniques in question is quite small. While about one in 5-10,000 people suffer from mitochondrial diseases, only about 15% of mitochondrial disease is caused solely by mitochondrial DNA mutations; the rest is associated with nuclear DNA variants and how they interact with mitochondria. Oocyte modification would be of no help in these cases.

Even for the handful of candidates for this procedure, a safer alternative exists. Because women can produce eggs with varying degrees of mitochondrial mutations, preimplantation genetic diagnosis (PGD) is proving to be effective for screening embryos resulting from in vitro fertilization to identify those with low risk.

Finally, oocyte modification should not proceed because it constitutes human germline modification. More than 40 countries, including those with the most highly developed biomedical sectors, have adopted policies on human germline modification, and all of these have prohibited it. This emerging global policy consensus has been supported by the major international biomedical and bioethical organizations and councils. We believe that it would be unconscionable for the United States to unilaterally cross this bright technical and policy line that has been observed internationally for decades.

We appreciate the distinction between the proposed techniques and attempts to control traits associated with nuclear DNA. However, many who have carefully examined these issues recognize that allowing one form of germline intervention could make it prohibitively difficult to prevent subsequent applications intended to modify cosmetic, behavioral, cognitive or other phenotypic traits. This
understanding, and the concern it raises about a new era of eugenic engineering, is the basis for the widespread agreement to forego human germline modification.

Considering and weighing the benefits of oocyte modification for mitochondrial disease to a small number of people who want a genetically related child, the existence of alternatives for them to achieve this, and the techniques’ significant safety risks and profoundly disturbing societal implications, we believe that the case for maintaining the current proscriptions on human germline genetic modification is clear. We strongly urge the FDA not to allow the techniques under consideration to move to human clinical trial.


Sincerely,

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Sandra Albanese, Indialantic, Florida
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