

U.S. Food and Drug Administration
Cellular, Tissue and Gene Therapies Advisory Committee
10903 New Hampshire Avenue
Silver Spring, MD 20993
Attn: Gail Dapolito
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On October 22 and 23 the Cellular, Tissue and Gene Therapies Advisory Committee will meet to discuss oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility. I am writing to you at this time to provide you with information I trust the committee will find relevant.

First, I draw to your attention that this activity is legally prohibited in Canada in the *Assisted Human Reproduction Act 2004*. Section 5(1) stipulates that "No person shall knowingly ... (f) alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants."

Second, when this matter was being discussed in the United Kingdom, there was a discussion of the science and ethics on national radio in Canada. The participants were Robin Lovell-Badge (head of the Division of Stem Cell Biology and Developmental Genetics at the National Institute for medical research in London), Jacques Cohen (founder of Reprogenetics and director of Typo-Galileo Research Laboratories) and myself, Françoise Baylis, (Professor and Canada Research Chair in Bioethics and Philosophy). The podcast is available at <http://www.cbc.ca/thecurrent/episode/2012/09/19/three-parent-in-vitro-fertilization/>

Third, I have canvassed a number of the ethical issues in a recent publication in Reproductive BioMedicine Online [http://www.rbmojournal.com/article/S1472-6483\(13\)00132-6/fulltext](http://www.rbmojournal.com/article/S1472-6483(13)00132-6/fulltext). A copy is attached. I conclude that the various ethical objections to this transgressive science are cause for serious concern.

Please make this letter and the attached article available to the committee. If there are questions about my research, I would be pleased to address these.

Sincerely,



Françoise Baylis, PhD, FRSC, FCAHS
Professor and Canada Research Chair in Bioethics and Philosophy