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Dec. 22, 1999

Director
Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products.

Dear Director:

Enclosed please find "Fact Sheet Re: Not Suitability of Ooplasm Transfer". The aim is to stop clinical malpractice to change natural human into artificial human by gene transfer on the germ cell and embryo level. This malpractice includes ooplasm transfer¹ and nuclear transfer² into a human oocyte. **It is dangerous and not appropriate to change human being by pseudo-sciences.**

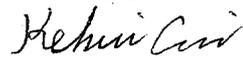
There is no techniques until now to perform gene therapy to change one or more bases at the correct location of DNA with correct number (or dosage) of bases. To use gene transfer to cure genetic diseases at the germ cell and embryo level will change human being rather than curing genetic diseases at the present time.

It is important to set up a guideline:

1. To restrict gene transfer in human germ cell and embryo level for the time being;
2. To restrict ooplasm transfer in human oocytes;
3. To restrict nuclear transfer in human oocytes.

Thank you for consideration.

Sincerely yours,



Ke-Hui Cui

1. Lancet 350, 186-187, 1997.
2. Supplement to Fertility and Sterility. S1, 1997.

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Fact Sheet Re: Not Suitability of Ooplasm Transfer

1. There is no evidence that women over 40 years old should only use ooplasm transfer to increase pregnancy. Some center can achieve to 40% pregnancy rate in women over 40 by better IVF techniques.
2. There is no evidence that the ooplasm in older women are all absent of mitochondria and need the supplement of mitochondria.
3. There is no evidence that the ooplasm aging is not related to other DNA aging, especially nuclear DNA aging.
4. There is no evidence that the HLA typing is not suitable at the oocyte level.
5. Transfer other source of protein (such as ooplasm) into oocyte will decrease the fertilization rate. For example: use medium with protein (purified Human Serum Albumin) for Intracytoplasm Sperm Injection will get lower fertilization rate than without using protein.
6. Ooplasm transfer will significantly increase costs.
7. **Ooplasm transfer will also produce gene transfer in oocyte (germ cell), i.e. mitochondria gene from donor ooplasm will be transferred to the recipient oocyte.**
8. **Ooplasm transfer will also produce chimera human. Thus it will change normal human into new species of human, and change natural human into artificial human. (Natural human contain genes from two people - mother and father. However, chimera human produced by ooplasm transfer contain genes from three people: mother, father and donor). Any practice to change natural human into artificial human on the germ cell and embryo level should be banned by our government, because it will generate artificial human offspring forever. It is not appropriate to change human being and human genetic structure by solving the simple problem of infertility.**

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