

Three's a Crowd. FDA Says No to Three Parent Babies



By Julianna LeMieux — August 8, 2017



Letters [1]

Just because you did something once last year in Mexico does not mean you can do it here. That is the message the US Food and Drug Administration (FDA) is sending to a physician in New York.

Dr. John Zhang runs the [New Hope Fertility Center](#) [2]. The center, located in a high rent district of Manhattan, is in the business of infertility treatments which are generally not a problem. It is, specifically, fertility treatments using mitochondrial DNA (mtDNA) replacement therapy (MRT) that were banned. Dr. Zhang started marketing this type of treatment through the website of his company Darwin Life (the website was not available at the time of this writing.)

These procedures are intended to allow women with heritable diseases caused by faulty mitochondria to spare their children from their condition. Last fall, Dr. Zhang used this technique to create an embryo in the United States which was sent to Mexico where it was implanted into the mother. The couple had a healthy baby boy.

Mitochondrial disease is caused by a mutation in the DNA found in the cells' mitochondria. The DNA in mitochondria is different from the DNA in the nucleus. So, if you want to pass down the traits found in your DNA, but, don't want to pass down your mitochondrial disease, an embryo can be created that has the nuclear DNA from the mother and father and a third person's mitochondria (from a donor.) The baby has been called a "three-parent baby" for this reason.

The problem is that Dr. Zhang has been marketing the mitochondrial transfer procedure - a treatment not approved in the United States - in the United States. FDA sent a letter last week instructing him to stop:

"Your April 2016 letter further informed FDA that "until an effective IND is in place, and a clinical trial is authorized by FDA, Darwin [L]ife will not use its spindle transfer technology again within the United States to support ex-US studies or procedures." Despite that commitment, you continue to market MRT to prevent the transmission of mitochondrial disease and to treat infertility"

The bigger question may be, why is MRT still illegal in the United States? MRT is incredibly useful in cases when the mother has one of the 200 known mitochondrial diseases - which manifests itself in one in 5,000-10,000 children each year. With the exception of people's general discomfort with the concept of creating designer babies, MRT stands to help a lot of individuals, and there is not a lot of risks.

A [report from the National Academy of Medicine](#) [3] published last year, at FDA's request, analyzed the ethical, social, and policy considerations of the procedure. In the end, the agency was mostly in support of the practice - as long as certain regulatory steps are followed. It concluded, "*the most germane issues could be avoided if the use of these techniques were restricted by certain conditions, rather than prohibiting them altogether.*"

Examples of the restrictions on clinical investigations are limiting clinical investigations to:

1. Women who are at risk of passing on a serious mitochondrial disease to her offspring
2. Cases where the mitochondrial DNA's mutation is known to cause disease
3. Cases where clinical presentation of the disease is predicted to be severe by causing early death or substantial impairment in the child
4. Permitting only male embryos to be transferred to a woman for a possible pregnancy to stop any possible passing down of a disease (mitochondrial disease is only passed down from a female.)

If the above situations apply, the group concludes that it is ethical to test this approach. On top of that, the technique is available in the UK, although highly regulated.

So, even though experts agree that this approach should be tested in the United States, this technique seems to be at a standstill for the moment. Until further notification, Dr. Zhang will have to stay north of the border unless he's on vacation.

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[3] <http://www.nationalacademies.org/hmd/Reports/2016/Mitochondrial-Replacement-Techniques.aspx>