

World's First Genetically-Modified Babies Born, Or Were They?

by Rebecca Taylor | LifeNews.com | 7/2/12 12:30 PM

Many people are talking about Michael Hanlon's piece in the [Daily Mail](#) about the first genetically modified babies being born. I want to discuss it because everything is not exactly how it seems.

Hanlon's undated piece discusses a technique IVF doctors have used to "rejuvenate" an infertile woman's eggs by injecting the cytoplasm of another woman's healthy egg. Factors inside the cytoplasm help the infertile woman's egg in fertilization. When doctors injected the cytoplasm of the healthy egg, it contained mitochondria from the donor egg. Those mitochondria have DNA from the woman who donated that egg. So the after that hybrid egg is fertilized, the resulting embryo has the DNA from 1 man, and 2 women. A genetic modification that any girl would pass onto her offspring since mitochondria are inherited from the mother only. The *Daily Mail* article reads:



The world's first genetically modified humans have been created, it was revealed last night.

The disclosure that 30 healthy babies were born after a series of experiments in the United States provoked another furious debate about ethics.

So far, two of the babies have been tested and have been found to contain genes from three 'parents'.

Fifteen of the children were born in the past three years as a result of one experimental programme at the Institute for Reproductive Medicine and Science of St Barnabas in New Jersey.

The babies were born to women who had problems conceiving. Extra genes from a female donor were inserted into their eggs before they were fertilised in an attempt to enable them to conceive.

Genetic fingerprint tests on two one-year- old children confirm that they have inherited DNA from three adults –two women and one man.

The fact that the children have inherited the extra genes and incorporated them into their 'germline' means that they will, in turn, be able to pass them on to their own offspring.

Altering the human germline – in effect tinkering with the very make-up of our species – is a technique shunned by the vast majority of the world's scientists.

Geneticists fear that one day this method could be used to create new races of humans with extra, desired characteristics such as strength or high intelligence.

Writing in the journal *Human Reproduction*, the researchers, led by fertility pioneer Professor Jacques Cohen, say that this 'is the first case of human germline genetic modification resulting in normal healthy children'.

A couple of readers have e-mailed this article to me so I went to the journal of *Human Reproduction* looking for the latest issue and found nothing from Jacques Cohen. I then found that Dr. Cohen is the [Laboratory Director at ART Institute of Washington at Walter Reed National Military Medical Center](#). Apparently he left Institute for Reproductive Medicine and Science of St Barnabas and works for a U.S. military hospital. (A fact that I find very disturbing.)

I scratched my head for a minute and dug deeper and think I have found the [original paper](#). It was from 2001, not 2012. The technique is called "cytoplasmic transfer." I did not start blogging until 2005, so I had no idea that this genetic engineering of embryos took place. I then found an in depth report in the [Washington Monthly](#) on the issue. Sharon Brownlee explains how the technique raised concerns at the Food and Drug Administration (FDA) and it seems they put a stop to cytoplasmic transfer in the United States:

In the mid-1990s, embryologist Jacques Cohen pioneered a promising new technique for helping infertile women have children. His technique, known as cytoplasmic transfer, was intended to "rescue" the eggs of infertile women who had undergone repeated, unsuccessful attempts at in vitro fertilization, or IVF. It involved injecting the cytoplasm found inside the eggs of a fertile donor, into the patient's eggs.

When the first baby conceived through cytoplasmic transfer was born in 1997, the press instantly hailed Cohen's technique as yet another technological miracle. But four years later, the real story has proven somewhat more complicated. Last year, Cohen and his colleagues at the Institute for Reproductive Medicine and Science of St. Barnabas, a New Jersey fertility clinic, set off alarm bells among bioethicists with the publication of a paper detailing the genetic condition of two the 17 cytoplasmic-transfer babies born through the clinic to date. The embryologists reported that they had endowed the children with extra bits of a special type of genetic material, known as mitochondrial DNA, or mtDNA, which came with the cytoplasm transferred from the donor eggs to the patient's.

Just how normal those children will turn out to be is anybody's guess. At a recent meeting in Europe, the New Jersey researchers reported that one of the children conceived through cytoplasmic transfer has been diagnosed with "pervasive developmental disorder," a catch-all term for symptoms that range from mild delays in speech to autism. Cohen's group maintained that it is extremely unlikely that cytoplasmic transfer and the resulting mishmash of mtDNA is to blame.

But geneticists have only begun to trace the connections between mtDNA and a host of diseases ranging from strange metabolic ailments to diabetes and Lou Gehrig's disease, and some experts argued that the child's disorder may well be caused by a mismatch between the

donor and mother's mtDNA. As Jim Cummins, a molecular biologist at Murdoch University in Western Australia, put it: "To deliberately create individuals with multiple mitochondrial genotypes without knowing the consequences is really a step into the dark."

Since 1998, the Food and Drug Administration (FDA) has argued that genetically manipulated embryos are a "biological product," and therefore subject to regulation, just like medical devices and drugs. But because of a quirk in federal law, the FDA's authority in this sphere is far from certain.

Last summer, FDA sent warning letters to six fertility centers threatening "enforcement action," and asserting its regulatory power over "therapy involving the transfer of genetic material by means other than the union of [sperm and egg.]" Cohen's clinic at St. Barnabas chose to stop performing cytoplasmic transfer. But at least two other recipients scoffed at the agency's threat: Panos Zavos, an embryologist at a Kentucky fertility clinic, and Brigitte Boisselier, the scientific director of Clonaid, the clinic set up by a group known as the Raelians, who believes human beings were genetically engineered by aliens. Both have announced their intentions to clone a human being.

Both also disputed the FDA's authority, and several bioethicists and legal scholars had to agree that the FDA could not prevent them from tinkering with human bioengineering. "It's a stretch for the FDA," says R. Alta Charo, a legal scholar and bioethicist at the University of Wisconsin, and former member of President Bill Clinton's Bioethics Advisory Committee.

So the children born using cytoplasmic transfer are indeed "genetically modified" but this is not a new development as the *Daily Mail* report suggests. Since it is not dated, I think the article came out in 2001 but is just making the rounds of the Internet now. So while still unethical, this is not a new technology that will be taking off as the new rage in infertility treatments.

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In fact, I could not find any information on who offers this technique or where. When asked, in 2009, where cytoplasmic transfer is legal, Dr. John David Gordon, the Co-Director of Dominion Fertility at The George Washington University and an expert that has been answering questions on high tech IVF for more than ten years, [replied](#), "I honestly have no idea..."

We should still be concerned, since there are questions about the FDA's authority to regulate the fertility industry in this regard. Which means it is even more critical that the United States join a host of other countries that have legally banned any germ-line genetic modifications and cloning in humans.

As the case of cytoplasmic transfer shows, scientists and doctors in the fertility industry will do anything that they are allowed to by law, even genetically modify embryos without real evidence that it is safe.