Mitochondrial donation has captured the public imagination with the promise—or threat—of three-parent children. The technique was described in shocking terms of how genetic therapies would alter the genomes of the resulting children. If governments were to allow these “designer babies,” where will medical science end?

The reality is much less sensational. While the mitochondria have their own DNA, the donor’s DNA does not affect the appearance or the overall genetics of the resulting children. While this process has not yet been approved in the United States, in October 2015 the United Kingdom became the first country in the world to permit the use of mitochondrial donation in fertility treatment.

The new technique, developed through British research, offers parents with defective mitochondrial DNA the chance to conceive their own genetic children without passing on debilitating diseases. The advance to using this technique in treatment does break new ground legally as well as medically, requiring the U.K. Parliament to remove the existing legal bar against the use of artificially manipulated human embryos in fertility treatment.

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What Is Mitochondrial Donation?

Often described as the “batteries of the cell,” mitochondrial DNA is responsible for creating energy within the cells that make up the human body. If any of the 37 genes found in a person’s mitochondria are faulty, this can have a seriously detrimental effect on his or her health and life. Individuals who suffer from mitochondrial disorders can experience a range of symptoms, including neurological issues; strokes; dementia; heart, liver, kidney, or respiratory disease; immune system problems; and premature death.

Mitochondrial disease is largely untreatable as it subsists at the cellular level. Damaged mitochondria are passed down matrilineally, meaning that if a woman carries defective mitochondria, she will pass the defect on to her future children (and her daughters to their children).

Each year, one in 6,500 children in the United Kingdom is thought to be born with serious mitochondrial disorders, and in the United States it is estimated that every year 1,000 to 4,000 children are born with mitochondrial disease.

Due to the complexity of mitochondrial disease, the reproductive options previously have been limited. In most cases, the only preventive solution has been egg donation, but this denies these mothers the opportunity to have their own genetic child. Mitochondrial donation offers an alternative solution, in which the faulty mitochondrial DNA from the egg of an affected mother is replaced with healthy mitochondrial DNA from a donor (or, using a slightly different method, healthy mitochondrial DNA is swapped...
into a fertilized embryo). Crucially, the nuclear DNA from the mother (which carries all of her significant genetic identity) is retained, but the cell (and therefore all the other cells that replicate from it as a baby grows) are healthy. This enables a woman with faulty mitochondrial DNA to conceive a (healthy) genetic child, while removing the risk that mitochondrial disease will be passed to her children and future generations.

Scientists estimate that the number of women likely to be eligible for the procedure will be around 150 per year in Britain. In the United States, if the treatment were available, the number of women eligible would likely be near 800 each year. Although the number of people needing this treatment will be small, the impact on those families will be life-changing.

**Legal Background**

The United Kingdom has a long and proud history of being at the forefront of scientific progress on assisted reproduction, and its law has had to keep pace. The first in vitro fertilization (IVF) baby in the world was born in the United Kingdom in 1978, prompting the enactment of a comprehensive regulatory system for licensing U.K. embryo research and fertility treatment, which came into effect in 1991. In accordance with this system, any person carrying out fertility treatment or embryo research in the United Kingdom must hold a license—issued by the Human Fertilisation and Embryology Authority (HFEA)—and must comply with all the statutory and regulatory conditions of that license, including regular inspections and a myriad of ethical and safety rules. This regulatory system has promoted a liberal environment for embryo research in the United Kingdom, which has arguably enabled ethically sensitive techniques like mitochondrial donation to be developed with public confidence.

While the HFEA could license the research into mitochondrial donation, it did not have the power to license the next step—the use of modified embryos in treatment. This required a change to the law, and so a decision from the U.K. Parliament.

**The Public Debate on “Three-Parent Babies”**

In preparation for a decision on legal change, the HFEA and a number of other professional bodies (such as the Nuffield Council on Bioethics) conducted an extensive public consultation from 2012 onward, including focus groups, interviews with stakeholders, surveys, and public engagement. Understandably there was considerable public and media interest, and the consultation process was educative and helped ensure that the debate was of a high quality.

One matter that grabbed the imagination of the U.K. public and the press was the idea that the children born using mitochondrial donation might have three parents. Although the media focused heavily on this issue, the science was made clear: the woman who donates her mitochondria is giving a gift of health rather than life. She passes on no meaningful personal characteristics or traits, just the power to help the cells function normally and keep the child free of mitochondrial disease. As a result, mitochondrial donation is better described as “three-person IVF” than “three-parent IVF,” and the mitochondrial donor should not be treated in the same way as other gamete donors whose nuclear DNA is passed to children conceived.

There are interesting conceptual and ethical issues here. Like gamete donation, mitochondrial donation offers a couple the opportunity to conceive a baby, but the real goal is to find a cure for an illness rather than to enable conception. It not only allows the couple in question to conceive an otherwise unobtainable healthy genetically linked child, but also eradicates the threat of mitochondrial disease for future generations of that family.

Arguments about the “slippery slope” of genetic manipulation were also carefully addressed. Mitochondrial donation is about treating disease, not about developing techniques to create designer babies, and there would be careful legal and regulatory controls.

**Making Legal Change**

The debates laid the groundwork for legal change in the United Kingdom; it is arguable that without them, Parliament would not have had the confidence to support the use of modified techniques like mitochondrial donation, arguably enabled ethically sensitive in the United Kingdom, which has environment for embryo research, ethical and safety rules. This regulatory system has promoted a liberal for licensing U.K. embryo research and fertility treatment, which came into effect in 1991. In accordance with this system, any person carrying out fertility treatment or embryo research in the United Kingdom must hold a license—issued by the Human Fertilisation and Embryology Authority (HFEA)—and must comply with all the statutory and regulatory conditions of that license, including regular inspections and a myriad of ethical and safety rules. This regulatory system has promoted a liberal environment for embryo research in the United Kingdom, which has arguably enabled ethically sensitive techniques like mitochondrial donation to be developed with public confidence.

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**Making Legal Change**

The debates laid the groundwork for legal change in the United Kingdom; it is arguable that without them, Parliament would not have had the confidence
to approve the new regulations, as it ultimately did so comfortably. On February 3, 2015, the House of Commons voted overwhelmingly to approve the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. The United Kingdom became the first country in the world where mitochondrial donation was both scientifically possible and legally permitted.

There are two different donation techniques that are allowed under U.K. law: pronuclear transfer (PNT) and maternal spindle transfer (MST). These involve slightly different medical procedures although both achieve the same result. PNT involves a scientific procedure in which the intended parent’s embryo is altered, resulting in a reconstructed embryo which contains nuclear DNA from the intended parent and healthy mitochondria from the donor. Alternatively, MST simply involves altering the eggs of the intended mother and the donor. This results in an egg containing nuclear DNA from the mother and healthy mitochondrial DNA from the donor. This egg can then be fertilized with sperm from the intended father. In both cases, the resulting embryo can then develop unaffected by mitochondrial disease. Both are allowed under the law in the United Kingdom, as scientists have not yet determined the best and most efficient way to carry out mitochondrial donation.

Following an implementation period, the regulations came into force on October 29, 2015, and the HFEA has now started to license and regulate mitochondrial donation in treatment services in the United Kingdom.

Guidelines have recently been produced that set out exactly how the HFEA will assess clinics considering offering mitochondrial donation to families. Treatment centers will first need to follow a two-stage licensing process to become able to offer the procedure. If successful, they will subsequently need to obtain authorization from the HFEA for each and every patient they plan to treat, based on making a case in respect of the individual circumstances. The center will need to establish that there is a particular risk that the egg or embryo has a mitochondrial abnormality, and then assess whether there is a significant risk that a child born will have or develop a serious mitochondrial disease. This will need to be supported by confirmation of a family history of mitochondrial disease and additional scientific evidence.

The legislation has also made the donor’s position in law very clear: she is neither a parent nor an egg donor, but simply a contributor of donated tissue. This means that she has no legal or financial responsibilities with respect to any child conceived. It also means that her details are not recorded on the HFEA’s Register of Information to be available to any person conceived as a result of her donation. Under U.K. law, children conceived through egg donation have statutory rights to access information about their donor (with nonidentifying information available to the child before he or she reaches the age of 18 and identifying information accessible after the age of 18; information about genetic siblings conceived with the help of the same donor is also available). These rules will not apply in respect of mitochondrial donors, who will remain permanently anonymous to any children conceived. Mitochondrial donors will, in essence, be treated in the same way as blood and organ donors.

**What’s Next?**

It is not yet clear when we will see the first baby born in the United Kingdom through mitochondrial donation, but the path ahead is now clear. With affected families waiting for the new technique to become lawful, it seems unlikely it will be long before the new regulations are put into practice.

There are, perhaps, international lessons to be learned from the careful and sensitive approach the United Kingdom has taken, which has enabled practical application of a new scientific technique that might otherwise have been considered controversial or ethically sensitive. Ethics and safety are of course always important considerations in any new scientific advance, but decisions should be made on the basis of evidence, and facts and debates should be informed. The United Kingdom’s approach and courage is to be applauded, given the significant impact this stands to have on real families who suffer from the terrible debilitating conditions caused by mitochondrial disease.

Ultimately, is it not a fundamental part of the human condition that we solve our problems through science and technology? Where that gives us the ability to prevent suffering, do we not have an obligation to do so? We are proud that the United Kingdom is leading the world by debating intelligently, helping families, and backing progress.

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**Endnotes**


5. Id.

