**When Will “3-Parent Babies” Come to the U.S.?**

Action in the U.K. Parliament is raising questions about the future of a new reproductive technique in America

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The U.K. has taken a first step toward approval of a controversial technique that enables the birth of a child carrying genetic material from three parents. British legislators in the lower chamber of parliament green-lighted the procedure this week even as U.S. regulators have adopted a go-slow approach. The question now is how or if London’s action may influence U.S. plans about how to proceed with this complex reproductive method.

The approach, [mitochondrial replacement,](http://www.scientificamerican.com/article/making-babies-with-3-genetic-parents-gets-fda-hearing/)is designed to allow moms to give birth to genetically related offspring without passing on diseases that stem from rare mutations in maternal mitochondrial DNA. Mitochondria, the cell’s battery packs, contain a small amount of DNA inherited exclusively from the mother’s mitochondria present in her eggs. And mutations in that mtDNA, present in about one in 5,000 live births, can lead to [rare illnesses](http://ghr.nlm.nih.gov/mitochondrial-dna) that cause vision loss, seizures or even premature death.

The procedure takes place in a laboratory dish and involves genetic material from a mother, father and a female donor. The donor provides an egg that bears mutation-free mitochondrial DNA. The nucleus of that egg, however, will typically be extracted and the mom’s nuclear DNA—which, along with the father’s DNA, comprises the majority of the genetic instructions that shape a child—is inserted in its place. (Mitochondrial DNA makes up less than 0.1 percent of the entire human genome and contains just 37 genes.) The donor egg, which will be fertilized by dad’s sperm, bears both the mutation-free mitochondrial DNA and mom’s nuclear DNA. And as with other in vitro fertilization procedures, the fertilized egg is implanted in the mom.

**Unanswered questions**
So why should a procedure to address a serious genetic disorder be so controversial? Last year an [advisory board](http://fda.yorkcast.com/webcast/Play/20822bb6fae04813affd80d5c6853cb41d) to the U.S. Food and Drug Administration considered mitochondrial replacement and concluded that more studies must be performed before the procedure could be offered to aspiring mothers. The panel indicated there were still lingering scientific questions about the long-term effects of such procedures. Would, for instance, fragments of residual mutated mitochondrial DNA be inadvertent stowaways and cause health problems for future generations of kids?

Although nonhuman primates born via this method have survived into adulthood, no studies have yet tracked future generations of those offspring. “I really hope the U.K.’s move has a profound effect and hope it spurs our FDA to action,” says Susan Solomon, chief executive officer of the New York Stem Cell Foundation. Waiting for further animal data in the coming decades, she says, would be an unreasonably high bar that would rob mothers of the chance to be genetically related to their children without risking serious health consequences.

When it comes to reproductive technology, the U.K. already has a track record of paving the way for the U.S. to act, Solomon says. The U.K. was the first to allow in vitro fertilization in 1978, which cleared the way for millions of such births in the U.S. and elsewhere.

Much of the public furor, however, is still wrapped up in worries about designer babies. Opponents of the procedure argue that if clinicians can alter embryos in this way, who is to say it would not eventually lead to selection of other genetic material to make smarter, stronger, more attractive kids? “The FDA committee looked at the same evidence as the U.K. regulators saw and reached a very different conclusion,” Marcy Darnovsky, executive director of the Center for Genetics and Society and an opponent of the procedure said in an e-mail. The committee, she wrote, “concluded that the known risks and areas of disturbing uncertainty were too large to permit clinical trials to begin.”

Since the FDA advisory panel convened last February the federal agency asked the U.S. Institute of Medicine (IOM) to produce a consensus report exploring the ethical and social policy issues on the topic. The agency had its first [meeting last month](http://www.iom.edu/activities/research/mitoethics.aspx) and is expected to convene several more times in the coming months. Meanwhile, before the procedure becomes legal in the U.K., the House of Lords, its upper chamber of Parliament, still needs to pass the provision. Moreover, a U.K. regulatory agency, equivalent to the FDA, would regulate such action and review the science, says Evan Snyder, chair of the FDA’s Cellular, Tissue and Gene Therapies Advisory Committee. Even if mitochondrial transfer passes scientific muster with that agency, he says, it will be difficult to find a fertility clinic that could proceed with such procedures. “Only a handful of people in the world can do this so it can’t be done by fertility clinics throughout the world,” he says. Whether or not the U.K. action will spark speedier consideration in the U.S. or how heavily it will be weighed by the IOM, however, remains an ongoing question. For his part, Snyder expects that his panel will take up this issue again in two years, likely after the IOM has issued its own conclusions.