Britain Sets Out Plans for First '3-Parent' IVF Babies

By REUTERS   FEB. 27, 2014, 11:57 A.M. E.S.T.

LONDON — Britain proposed new regulations on Thursday that would make it the first country in the world to offer "three-parent" fertility treatments to families who want to avoid passing on incurable diseases to their children.

The move was praised by doctors and but feared by critics, who say the technique will lead to the creation of genetically modified designer babies.

The technique is known as three-parent in vitro fertilization (IVF) because the offspring would have genes from a mother, a father and from a female donor.

The British plans come as medical advisers in the United States began a series of public hearings this week to consider whether there is scientific justification for allowing human trials of the technique.

The treatment, only at the research stage in laboratories in Britain and the United States, would for the first time involve implanting genetically modified embryos into women.

The process involves intervening in the fertilization process to remove faulty mitochondrial DNA, which can cause inherited conditions such as fatal heart problems, liver failure, brain disorders, blindness and muscular dystrophy.

It is designed to help families with mitochondrial diseases - incurable conditions passed down the maternal line that affect around one in 6,500 children worldwide.

Mitochondria act as tiny energy-generating batteries inside cells.

"JUMPING THE GUN"

Announcing draft plans to allow the technique and launching a public consultation on them, Britain's chief medical officer Sally Davies said the proposed move would give women who carry severe mitochondrial disease the chance to have children without passing on devastating genetic disorders.
"It would also keep the UK in the forefront of scientific development in this area," she said in a statement.

But David King of the campaign group Human Genetics Alert accused the government of "jumping the gun" in laying out new laws before the treatments had been thoroughly investigated.

"If passed, this will be the first time any government has legalized inheritable human genome modification, something that is banned in all other European countries," he said in a statement. "Such a decision of major historical significance requires a much more extensive public debate."

Although some critics of mitochondrial transfer say it is akin to creating designer babies, replacing faulty mitochondria with healthy ones would not be genetic engineering in the usual understanding of the term. It would not make a child smarter, sportier, more attractive, or otherwise different from what his genome and environment would produce in the normal way.

Britain said the proposed new rules would be subject to public scrutiny and parliament's approval.

Many scientists, campaigners and medical experts welcomed the government's decision.

Jeremy Farrar, director of the Wellcome Trust international medical charity, urged the government to "move swiftly so that parliament could debate the regulations at the earliest opportunity and families affected by these devastating disorders can begin to benefit".

Peter Braude, a professor of obstetrics and gynecology at King's College London, welcomed the move, saying: "It is true that genetic alteration of disease risk is an important step for society and should not taken lightly."

"However the proposed changes to the regulations ensure it will be limited to informed couples, who understand from sad personal experience the significant effects of their disease, and are best placed to balance the risks of the technology with the possibility of having children without mitochondrial disease," he added.

Scientists are researching several three-parent IVF techniques.

One being developed at Britain's Newcastle University, known as pronuclear transfer, swaps DNA between two fertilized human eggs. Another, called maternal spindle transfer, swaps material between the mother's egg and a donor egg before fertilization.
A British ethics panel review of the potential treatments in 2012 decided they were ethical and should go ahead as long as research shows they are likely to be safe and effective.

Because Britain is in the vanguard of this research, ethical concerns, political decisions and scientific advances are closely watched around the world.

Britain’s public consultation on the draft regulations began on Thursday and was scheduled to run until May 21, 2014.

(Editing by Alison Williams)

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Britain Becomes First Nation to Legalize Three-Parent Babies

By Reuters, 24, 2015, 4:46 P.M. E.S.T.

LONDON — Britain will become the first nation to legalize a "three-parent" IVF technique which doctors say can prevent some inherited incurable diseases but which critics fear will effectively lead to "designer babies".

After more than three hours of debate, lawmakers in parliament's upper house voted on Tuesday for a change in the law to allow the treatments, echoing a positive vote in the lower house earlier this month.

The treatment, called mitochondrial transfer, is known as "three-parent" in vitro fertilization (IVF) because the babies, born from genetically modified embryos,
would have DNA from a mother, a father and from a female donor.

Although the techniques are still at the research stage in laboratories in Britain and the United States, experts say that now legal hurdles have been overcome, Britain's first 3-parent baby could be born as early as 2016.

Mitochondrial transfer involves intervening in the fertilization process to remove faulty mitochondrial DNA, which can cause inherited conditions such as heart problems, liver failure, brain disorders, blindness and muscular dystrophy.

Mitochondria act as tiny energy-generating batteries inside cells, and around 1 in 6,000 babies around the world are born with serious mitochondrial disorders.

Responding to the vote, Jeremy Farrar, director of the Wellcome Trust medical charity commended lawmakers for a "considered and compassionate decision".

"Families who know what it is like to care for a child with a devastating disease are the people best placed to decide whether mitochondrial donation is the right option," he said.

Mark Downs, chief executive of the Society of Biology, hailed "a great day for UK science" and said the landmark decision "will ensure mothers who carry faulty mitochondria can have healthy children free from the devastating conditions."

But Marcy Darnovsky, director of the campaign group The Center for Genetics and Society, called the move a "historic mistake" which turns children into biological experiments and will "forever alter the human germline".

"The techniques ... are relatively crude and will not in and of themselves create so-called designer babies," she said.

"However, they will result in children with DNA from three different people in every cell of their bodies, which will impact a large range of traits in unknowable ways and introduce genetic changes that will be passed down to future generations."

(Editing by Janet Lawrence)
GAITHERSBURG, Md. — The Food and Drug Administration is weighing a fertility procedure that involves combining the genetic material of three people to make a baby free of certain defects, a therapy that critics say is an ethical minefield and could lead to the creation of designer babies.

The agency has asked a panel of experts to summarize current science to determine whether the approach — which has been performed successfully in monkeys by researchers in Oregon and in people more than a decade ago — is safe enough to be used again in people.

The F.D.A. meeting, on Tuesday and Wednesday, is meant to address the scientific issues around the procedure, not the ethics. Regulators are asking scientists to discuss the risks to the mother and the potential child and how future studies should be structured, among other issues. The meeting is being closely watched. The science of such therapies has advanced significantly in recent years, and many scientists are urging federal regulators to ease requirements for study in humans.

The procedure in question involves mitochondria, the power producers in cells that convert energy into a form that cells can use. Mitochondria with defects that could be passed to a fetus are replaced with healthy mitochondria from another woman. This is done either before or after an egg is fertilized.
Scientists have already experimented with combining genetic material from cells of three people. In 2001, researchers in New Jersey did so using material from the cytoplasm, the material that surrounds the nucleus of the egg and directs its development after fertilization, from fertile women into the eggs of infertile women. More than 17 babies have been born this way in the United States.

The practice raised questions and eventually led the F.D.A. to tell researchers that they could not perform such procedures in humans without getting special permission from the agency. Since then, studies have been confined to animals.

But a researcher in Oregon, Shoukhrat Mitalipov, has performed the mitochondrial procedure in monkeys and has said that it is ready to be tried in people.

Such genetic methods have been controversial in the United States, where critics and some elected officials wonder how far scientists plan to go in their efforts to engineer humans, and question whether these methods might create other problems.

“Every time we get a little closer to genetic tinkering to promote health — that’s exciting and scary,” said Dr. Alan Copperman, director of the division of reproductive endocrinology and infertility at Mount Sinai Medical Center in New York. “People are afraid it will turn into a dystopian brave new world.”

“The most exciting part, scientifically,” he said, “is to be able to prevent or fix an error in the genetic machinery.”

But others have sounded alarm bells. Jeremy Gruber, president of the Council for Responsible Genetics, a bioethics advocacy group, said it was premature to try the procedure in people. He said it could cause new, unforeseen genetic abnormalities and that more animal studies were needed to determine whether that might happen.

“There’s a step missing here,” he said. “The basic research is still unresolved.”

Dr. Mitalipov presented his work at the meeting, and some
participants asked whether he had tried to create a real-life environment that
would be typical for a pregnant woman.

“What kind of diet did you have these monkeys on?” said Dr. David L. Keefe, a
professor in the department of obstetrics and gynecology at New York
University School of Medicine. “Did you give them on a McDonald’s super-size
stress test?”

Dr. Mitalipov said he had plans for more work with the monkeys. Dr. Celia
Witten, director of the office of Cellular, Tissue and Gene
Therapies at the F.D.A., gave few clues to the agency’s thinking.

“We haven’t made any decision about whether clinical trials will be
allowed to proceed,” she said.

**Correction: February 27, 2014**

An article on Wednesday about a Food and Drug Administration hearing on a
fertility method involving genetic material from three people misspelled, in some
copies, the surname of the director of an office at the agency. She is Dr. Celia
Witten, not Whitten.

A version of this article appears in print on February 26, 2014, on page A15 of the New York edition with the
headline: F.D.A. Weighs Fertility Method That Raises Ethical Questions.

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wedded to tradition, and not known for taking a revolutionary stance. Yet its members have just made a groundbreaking decision, one that no other legislature has so far been willing to contemplate.

They approved legislation that makes Britain the first country to allow the creation of what many call “three-parent babies.” Supporters say the procedure will enable women to avoid passing on certain severe and even deadly genetically inherited diseases. But many regard the new law as an unwise, even immoral, move — the first step toward the creation of “designer babies.” Some even see it as a new experiment in eugenics.

“Three-parent babies” is a sensationalized term to describe a special form of in vitro fertilization, or I.V.F., that is better labeled “mitochondrial transfer.”

Every human cell comprises two main parts: the nucleus and the cytoplasm. The nucleus contains the DNA, the genetic code that helps shape inherited traits. The cytoplasm is the workshop of the cell, where most day-to-day functions occur. Among its constituent parts are mitochondria, tiny organelles (organlike units within a cell) whose job it is to provide energy. Each mitochondrion contains tiny amounts of its own DNA, some 37 genes compared with the 20,000 or so in the nucleus. (It is thought that back in evolutionary history, a free living bacterium became trapped in a host cell, where it boosted the cell’s capacity to produce energy; over time, it evolved into an organelle, an intimate part of the cell, but retained its
own DNA.)

Mitochondrial DNA plays no part in determining an individual’s inherited traits, such as those that shape appearance or talents. But if it malfunctions, it can cause terrible conditions like muscle weakness, seizures, blindness, deafness, organ failure and even death. There are more than 50 mitochondrial diseases, affecting at least one in every 8,000 children (some suggest the figure is much higher). There are currently no cures.

In mitochondrial transfer, the healthy nucleus of an egg with damaged mitochondria is transferred into the body of a healthy donor egg from which the nucleus has been removed. When that egg is fertilized, it will have its normal complement of genes from the mother and father, together with a tiny amount of mitochondrial DNA from the healthy third-party egg into which the nucleus was transferred. (The law also permits a more complex alternate technique, in which both eggs are first fertilized in vitro, and then the nucleus of the egg with defective mitochondria is transferred to the healthy donor egg, from which the nucleus has been removed.)

Hence the notion of a “three-parent baby” — misleading though the term is. None of the socially or ethically important characteristics of the child will derive from the “third parent.”

What makes you “you” depends upon far more than your genes, but insofar as genes play a role in personality or talent or physical attributes, they all derive from the nucleus. In the case of mitochondrial transfer, such genes will come, not from the woman who donated the egg with working mitochondria, but from the nucleus of the woman with faulty mitochondria and from the sperm of her partner. Those two are truly the child’s only parents.

The best analogy for mitochondrial transfer is that of an organ transplant. Transplanting healthy mitochondria is little different from transplanting a healthy kidney or heart into a person with a diseased organ — and should be no more ethically troubling. If the term “three-parent baby” does not describe the reality of the process, it does raise the specter of scientists “playing God” and of championing supposedly unnatural methods.

The belief that scientists or doctors should not play God has always struck me as odd. Playing God — in the sense of interfering in the natural course of events so as to improve human lives — is precisely what doctors are required to do every day of the
year. Whether transplanting naturally faulty hearts, or delivering a baby by cesarean section when natural birth may be impossible or dangerous, the very essence of medicine is to right the wrongs of nature.

Even less tenable is the claim made that the process creates “designer babies.” A designer baby is one whose genes have been altered to change, or improve, certain characteristics. Today, we can perform in vitro screening of embryos for certain genetic defects or characteristics such as sex. But we are a long way from the kind of genetic modification implied by the notion of designer babies.

Whatever the moral arguments about the desirability or otherwise of such modifications, these are irrelevant to the issue of mitochondrial transfer. There is no genetic interference or redesign.

It is true that the donor’s mitochondrial DNA will (if the child is a girl) be passed on to the next generation. That should make us cautious to ensure that no problems are passed down the generations by the process. But this does not make the process inherently problematic from an ethical standpoint.

Imagine a situation in which a woman with mitochondrial abnormalities conceives naturally, rather than through mitochondrial transfer. In this case, too, mitochondrial DNA would be passed down the generation. The only difference is that future generations would inherit faulty, rather than working, DNA. Why should it be ethical to pass on faulty DNA, but unethical to impart healthy DNA?

The opponents cast the debate as one between amoral science, intent on progress at any cost, and those who seek to place scientific advancement within a moral framework. But what is moral about causing unnecessary misery by preventing medical advance?

For once, Britain’s Parliament embraced the future and made the ethical decision.

Kenan Malik, a writer, lecturer and broadcaster, is the author, most recently, of “The Quest for a Moral Compass: A Global History of Ethics.”

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