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US weighs unknowns of 3-person embryo technique

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(AP)—Genetic experts cautioned the U.S. government Tuesday that it could take decades to confirm the safety of an experimental fertilization technique that would create babies from the DNA of three people, with the aim of preventing children from inheriting some debilitating diseases.

The Food and Drug Administration heard from supporters and opponents of the provocative technique at a two-day meeting, as the agency considers whether to greenlight testing in women who have defective genes linked to blindness, organ failure and many other inheritable diseases.

Preliminary testing in animals suggests that combining the DNA of two parents with that of a third female donor could allow prospective mothers to give birth to healthy children. But even experts in the field warned that researchers would have to follow the offspring for many years to see if they are truly healthy.

"The end of the experiment will come decades later," said Michigan State University's Keith Latham, in a presentation before the FDA and its advisory panel. "It's going to take us that long to figure out the health of the progeny produced from these procedures."

The FDA explicitly framed its public meeting as a "technical" discussion on the feasibility of safely testing the artificial fertilization technique in humans. In a statement read at the outset, FDA staffers acknowledged

the "ethical and social policy issues related to genetic modification of eggs and embryos," but said such issues were "outside the scope of this meeting."

Despite such disclaimers, more than a half-dozen public speakers urged the FDA to block any human testing of the DNA-swapping technique due to unknown medical, ethical and societal impacts. Several argued that it could be a slippery slope toward "designer babies"—allowing parents to customize traits like eye color, height and intelligence.

Marcy Darnovsky of the Center for Genetics and Society said that FDA-sanctioned testing would cross a "bright policy line" into altering genes that will be passed down to future generations.

"It could well be the first time any jurisdiction in the world had authorized intentional genetic modification of children and their descendants. And it would be making this decision with little or no input from the public or elected officials," said Darnovsky. Her group points out that 40 countries—including Germany and France—have laws banning human genetic changes that are passed on to future offspring.

Darnovsky and other speakers questioned the FDA's authority to authorize such testing, since the agency's jurisdiction mainly covers drugs and medical devices—not fertility techniques.

The bulk of Tuesday's discussion centered on the scientific aspects of gene replacement, with presentations by leading researchers in the field, including Shoukhrat Mitalipov's of the Oregon Health & Science University in Portland. Mitalipov and his staff have produced five healthy monkeys using his technique, which involves replacing defective DNA from a part of the cell called the mitochondria.

An estimated 1 in 4,000 U.S. children inherit diseases due to mutations

in their mitochondria, small energy-producing organs that float in the plasma around the cell. Unlike most DNA—located in the nucleus of the cell—mitochondrial DNA is only passed along by the mother, not the father.

Mitalipov's experimental technique, if approved for use, would involve removing the nucleus DNA from a healthy female donor's eggs and replacing it with the nucleus DNA of the prospective mother. After fertilization, the resulting child would inherit the mother's nucleus DNA—containing traits like hair color and height—but the donor's healthy mitochondrial DNA.

Discussions by FDA's panel of genetic experts on Tuesday suggested more long-term animal studies may be needed before human trials begin. Panelists questioned whether existing studies in monkeys, mice and cattle are relevant to the effects on human mothers and their children.

"There are so many aspects of mitochondrial disease that change over time and that we don't understand," said Dr. Katharine Wenstrom of Brown University. "We have to be very careful that we develop techniques to test these animals throughout the course of their entire lifespan."

The FDA is not required to follow the guidance of its experts, though it often does. On Wednesday the group is scheduled to discuss the specifics of a potential human trial of mitochondrial replacement.