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Stem cell efforts hit state roadblock

Research limited by ban on buying eggs

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State laws that are aimed at putting California at the global forefront of stem cell science are stymieing a promising avenue of research by creating a shortage of human eggs.

The state's \$3 billion taxpayer initiative to fund stem cell research prohibits paying women to be egg donors. But to work on therapeutic cloning, an area of research that might make patient-specific therapies possible, scientists need human eggs.

“This is what I call the great stem cell debacle, and it's ridiculous,” said Dr. Samuel Wood, who founded Stemagen, a San Diego biotechnology company that is trying to create human embryonic stem cells through therapeutic cloning.

“The people of California passed Proposition 71 to fund billions of dollars worth of stem cell research including (therapeutic cloning) and then the legislators and leaders of the stem cell institute put guidelines in place that greatly hamper, or virtually eliminate, the possibility of this being successful.”

The institute has distributed \$614 million through 229 grants, but only one has involved therapeutic cloning. Several grant requests were denied after doubts were raised that the scientists would be able to obtain enough eggs, called oocytes, to conduct the research.



LAURA EMBRY / Union-Tribune
Dr. David Smotrich (left) used an ultrasound to help guide him as he extracted eggs from a donor.

"It's clear that without having access to resources, in this case human oocytes, we cannot move forward," said Shoukrat Mitalipov, a University of Oregon scientist considered a leader in therapeutic cloning.

Mitalipov led the only team known to have successfully conducted therapeutic cloning using monkey cells. He is a member of a San Diego-based team whose grant application proposing to translate his work into human cells was rejected.

Therapeutic cloning also is known as somatic cell nuclear transfer, which involves replacing the nucleus of an egg with genetic material from a somatic cell, or fully grown cell, of another individual.

Such a transplant reprograms the egg to have the DNA of the donor. The unfertilized egg is then developed into a blastocyst, a clump of about 150 to 200 cells, from which embryonic stem cells are derived.

No scientists have proved they can use this process to create a line of human embryonic stem cells. The team at Wood's company got as far as creating a blastocyst.

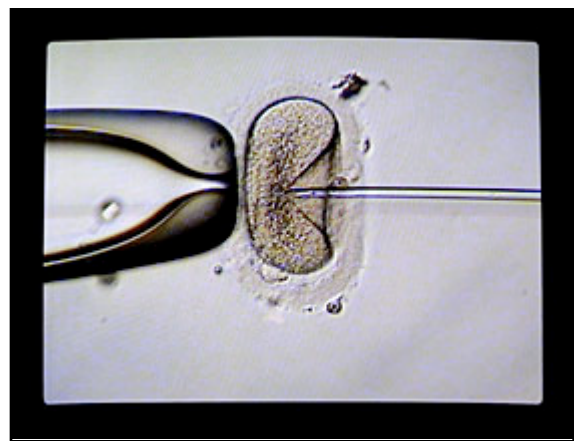
Human embryonic stem cells are the goal of this research because they are master cells that multiply and divide to become the more than 200 cell types in the human body. It is widely believed that they one day may be used to make therapies for disease, as well as human models for disease research and drug testing in a petri dish.

The state's rules regarding egg donations reflect the science and politics when Proposition 71 was passed in 2004. That included a cloud cast over embryonic stem cell research by a South Korean scientist's false claim of therapeutic cloning. In his ruse, the scientist violated ethical standards, including obtaining eggs from subordinates in his lab.

California's stem cell policymakers also were sensitive to concerns that by allowing compensation for egg donors, women would be coerced to take the health risks associated with the process, said Geoffrey Lomax, the institute's senior officer for medical and ethical standards.

However, no data were presented showing a high rate of problems or side effects. Fertility doctors who perform egg extractions, including Wood, said the risks are overstated.

Meanwhile, thousands of eggs are obtained each year for reproductive purposes in the United States. There is no law



LAURA EMBRY / Union-Tribune
A needle injects sperm into an unfertilized egg at La Jolla IVF.



LAURA EMBRY / Union-Tribune
Fertilized eggs are incubated in a small drop of fluid. At bottom, Dr. David Smotrich extracted eggs from a patient.



LAURA EMBRY / Union-Tribune
Dr. David Smotrich (left) used an ultrasound to help guide him as he extracted eggs from a donor.

preventing women from selling eggs to people who want to have children through in vitro fertilization.

In California, the average rate is \$3,000 to \$5,000 plus expenses, although more is sometimes paid to women with certain physical attributes or high intelligence, said David Smotrich, who runs La Jolla IVF, a fertility practice.

The process involves two weeks of multiple, daily drug and hormone injections to stimulate the ovaries to create more than the one egg typically produced in month. The process can cause mood swings, fatigue, bloating and cramping. There are no statistics available on long-term effects.

At the end of the cycle, the woman undergoes an invasive procedure, under general anesthesia, to remove the eggs. Along with the risks associated with anesthesia, there is a possibility of bleeding and ovary hyperstimulation, which causes a dangerous loss of fluid and requires hospitalization.

Wood, who also runs a fertility practice in San Diego, conducted a survey of women who were egg donors for fertility purposes and found that 60 percent would consider doing so for research. All but one would expect to be compensated, at a rate of at least \$3,000, he said. Wood hopes the survey will help change state law.

Proposition 71 states that the institute's board can change its policy and standards, allowing it to evolve with science and public opinion, Lomax said.

And institute leaders recognize it may be time to reconsider its rules.

At meetings of the institute's board in February and June, President Alan Trounson brought up the issue.

But at the June meeting, the board turned down several grant requests from scientists seeking to create new stem cell lines using therapeutic cloning. Among other things, grant reviewers were concerned about the availability of eggs.

Among the applicants rejected were two San Diego companies: Stemagen, which could obtain eggs through Wood's fertility practice; and Cascade LifeScience, which said it had access to eggs from voluntary donors through Smotrich's IVF practice.

The state stem cell institute remains committed to therapeutic cloning, said chief scientist Marie Csete. The institute's standards committee will meet in February to discuss egg payments, Csete said.

Wood plans to attend. He wants to talk about using excess eggs obtained for fertilization. Another option, Wood said, would be to use grants to reimburse fertility doctors who would reduce their rates to women donating eggs for research.

In the United Kingdom, regulators overcame the egg shortage by allowing women to receive in vitro fertilization for half the normal price if they agreed to give half of their eggs to research.

That alleviates concerns about coercion because the women already were planning to have the procedure. It also makes in vitro fertilization available to couples who otherwise could not afford the procedure, which can cost about \$20,000 in the United States.

Institute officials don't believe there is enough wiggle room in the law for such changes.

"People voted for Proposition 71 with the understanding that eggs would not be paid for," said Jeff Sheehy, an AIDS activist and member of the institute's board. "We can't suddenly say that the words and law don't mean what we thought they meant."

In 2006, the Legislature passed a law prohibiting payment for oocytes donated for research that is not funded by the institute. For that reason, the Legislature should address the issue, said Sheehy, a member of the institute's standards committee. Elected leaders could give the institute direction, he said.

Meanwhile, Sheehy would like to see the institute fund therapeutic cloning projects submitted by teams that say they can get enough donated eggs.

“We've never demonstrated that there's an egg shortage because we never funded any of the applications,” Sheehy said.

Amid the debate, some scientists think therapeutic cloning may not be worth the trouble. Besides the egg shortage, the procedure is technically difficult. Also, in the past year, an alternative procedure for producing patient-specific stem cells has developed rapidly.

Called induced pluripotency, or IPS, the technique uses chemicals and gene manipulation to move a human skin cell backward down the development chain until it becomes embryolike or pluripotent, meaning it has the potential to grow into many cell types.

IPS cells cannot be used in humans because the chemicals and gene manipulation cause cancer. They can be used to make models of human disease, Csete said. Scientists expect to be able to devise a method for inducing pluripotency without posing a cancer risk.


State grant reviewers approved 10 grants for IPS research, which also is eligible for funding from federal agencies. That was in the same round of grants in which Stemagen and Cascade LifeScience were turned down for therapeutic cloning, which cannot be funded with federal dollars under restrictions ordered by President Bush.

Investment in therapeutic cloning could make the process easier and cheaper, said Sophia Khaldoyanidi, chief scientist at Cascade. Khaldoyanidi believes it is necessary to pursue all methods for creating embryolike stem cells.

“What's interesting about therapeutic cloning is that it uses the oocyte's natural ability to reprogram itself,” said Mitalipov, the Oregon researcher. “Unlocking the magic in the egg should tell scientists how they can successfully perform induced pluripotency without the cancer-causing genes and chemicals. And when we know how to do that, we might not need eggs or embryos for this work and be rid of what's controversial.”

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