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A Long, Uncertain Path for New Cell Technique

By ANDREW POLLACK

While intriguing, a new approach for producing embryonic stem cells faces considerable hurdles before it can be used to develop medical treatments, executives from stem cell and other biotechnology companies said yesterday.

In particular, they said, the technique involves genetically altering cells, which could introduce new safety risks and make it harder to obtain regulatory approval.

“Once you muck around with the genome, all bets are off,” said Dr. Thomas B. Okarma, chief executive of Geron, a company trying to develop medical treatments from human embryonic stem cells. Dr. Okarma said getting approval from the Food and Drug Administration would become “enormously more complicated.”

In scientific papers published yesterday, scientists in the United States and Japan said that by inserting four genes into mouse skin cells, they could change those cells into what appear to be embryonic stem cells.

The method does not involve the destruction of embryos, thereby circumventing ethical issues that have led to restrictions on federal financing in the field. That controversy has also deterred some pharmaceutical and biotechnology companies.

Joydeep Goswami, vice president for stem cells and regenerative medicine at Invitrogen, a company that sells tools for stem cell research, said the new technique could get more companies interested in stem cells.

Not only does it eliminate the ethical issues, he said, but it also might provide a way around stem cell patents held by the University of Wisconsin that some scientists and corporate executives say have hindered work in the field.

Still, an even bigger hurdle for investors has been the uncertainty of whether stem cells can be turned into lucrative medical treatments. Some experts say this might take a decade or more, too long for many investors to wait.

“It takes a fair bit of faith that the science can work itself through the issues,” said Chris Christoffersen, a partner with Morgenthaler Ventures, a venture capital company. He said the new advance would have only a marginal effect in spurring investment in stem cells.

Dr. Okarma of Geron pointed out that after mouse embryonic cells were first isolated, it took about 18 years before human embryonic cells were similarly derived. Geron, based in Menlo Park, Calif., paid for the work with human cells at the University of Wisconsin and has exclusive commercial rights to certain types of tissues created from human embryonic stem cells.

Dr. Okarma also said it might not be desirable to use skin cells as a starting material because they might have been genetically mutated by exposure to ultraviolet radiation.

Still, the new technique could eventually provide a way to use a patient's own skin cells to produce other types of tissues that could be transplanted into the patient without being rejected by his or her immune system.

Scientists have been trying to do this using so-called therapeutic cloning, but that has proved difficult.

William M. Caldwell IV, chief executive of Advanced Cell Technology, said his company had not been able to obtain enough human eggs needed for therapeutic cloning. So the new approach, Mr. Caldwell said, is "a technology that everyone should take a hard look at."

Still, he said, the fact that the technique involves adding genes to the cells adds some uncertainty.

"From a clinical standpoint that's going to present a huge challenge," Mr. Caldwell said.