

THE TIMES

Medical potential of IPS stem cells exaggerated says world authority

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By Mark Henderson, Science Editor

The medical potential of reprogrammed stem cells that do not require the destruction of embryos has been exaggerated, according to the head of one of the world's leading regenerative medicine companies.

Thomas Okarma, the chief executive of Geron Corporation, told The Times that while so-called induced pluripotent stem (IPS) cells will be extremely useful in research, they are unlikely to be suitable for transplanting to patients to treat disease. IPS cells are made by genetically manipulating adult skin cells to give them the versatile properties of embryonic stem (ES) cells. They have caused excitement because they might provide a limitless source of replacement tissue for treating conditions such as spinal paralysis, Parkinson's disease and diabetes — without the need to destroy embryos.

As cells could be grown from a patient's own tissue they would be genetically matched, therefore minimising the risk of rejection by the immune system.

The technology was named as Breakthrough of the Year in 2008 by the journal *Science* and has caused some research funding to be diverted away from ES cell research.

Dr Okarma, whose company expects to begin the first patient trial of an ES cell therapy this summer, said that IPS cells had significant disadvantages to embryonic tissue if used in medical treatments. In an interview with The Times he said that the need to produce fresh IPS cells for every patient would make it uneconomical.

Regulatory issues will create further problems. Under current European and American rules, every new set of cells for each patient would have to be approved independently. ES cells

remain a far more attractive option because they can be standardised and mass-produced for thousands of patients.

"IPS cells have been talked up as therapy by people with no experience of developing therapies," Dr Okarma said. "There is simply no business model for getting treatments based on your own cells into your body. The degree of difficulty in getting regulatory approval is just too great when you're making new therapeutic cells from scratch every time. The product, whether it's IPS or ES, has to be scaleable. You've got to have something that can be stored and frozen, to provide thousands of doses, each one standardised and as good as the last. It's a stretch to imagine you could do that with IPS cells, while with ES cells we are there already."

IPS cells, Dr Okarma said, are still likely to have great value in medical research: they could provide powerful cell models for investigating genetic disease and developing drugs. "The science is sound and very exciting," he said. "The ultimate potential will be in identifying the mechanisms and pathways of genetic disease, and screening new treatments. That would be a huge success."

Professor Robin Lovell-Badge, of the National Institute for Medical Research in London, agreed that business and regulatory issues will limit the therapeutic potential of IPS technology. "In terms of typical pharmaceutical and biotech models, this doesn't really fit, but the biggest problem is the regulatory agencies. The regulators demand such a lot of evidence for every single cell line that's intended for therapy that it is totally impractical to have patient-specific IPS cells for treatment," he added.