Written by <u>Steven J. DuBord</u> on August 20, 2009

Embryonic Stem-Cell Study Delayed

The first study of embryonic stem-cell therapy in human beings has been delayed by the Food and Drug Administration, Bloomberg News reported on August 18.

New American

The Geron Corporation said on August 18 that the FDA had halted the company's use of an embryonic stem-cell-based treatment for injured spinal cords in human beings. The treatment would involve injecting nerve cells made from embryonic stem cells near the site of a spinal injury. It is hoped that the stem cells would restore mobility to victims of paralysis.

The FDA had previously ordered a delay in May 2008, but that was lifted back in January. Joseph Pantginis, an analyst with the Merriman Curhan Ford Group in New York, believes the latest halt order was probably based on concern for safety, since Geron had submitted a new plan for administering a higher dose. "They are at the forefront, which a lot of times is a bit of a curse," Pantginis said. "They have to hit all the hurdles and be the first one to learn about how these cells behave."

Geron stated that it "will work closely with the F.D.A. to facilitate their review of the new data and to release the clinical hold." Company spokeswoman Anna Krassowska offered no further comment.

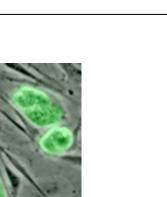
Bloomberg noted: "While thousands of patients around the world have been treated with adult stem cells and have shown mixed results, no humans have been given cells derived from embryos in an approved trial."

Bloomberg is perhaps a little too dismissive of adult stem-cell results. As recently as August 3, *Popular Science* told the story of University of Florida researchers who used adult stem cells to restore vision to blind mice. The researchers claim to be the first to turn adult stem cells into completely different kinds of cells through targeted gene manipulation. In this case, they transformed stem cells from bone marrow into retinal cells.

A virus with a new gene was introduced into blood stem cells extracted from the mouse's bone marrow. The gene caused the cells to produce a certain protein that is only present in retinal cells, essentially tricking the stem cells into becoming retinal cells. When the altered stem cells were injected back into the mouse, the mouse's body saw them as retinal cells, and they passed through the blood stream until they eventually settled in the mouse's eyes. Through 28 days of treatments, the stem cells gradually repaired the outer layer of the retina by replacing damaged cells.

After the four weeks, the formerly blind mice showed the same reaction to light as normal mice. The kind of blindness that was cured is similar to macular degeneration and diabetes-related blindness that occurs in human beings. As *Popular Science* put it, this is only the beginning for gene-manipulation therapy:

Macular degeneration is an age-related disease that affects almost 2 million people in the States alone; this could lead to the cure. But the groundbreaking process of tricking adult stem cells into







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becoming other cells could be even more beneficial, providing the flexible benefits of embryonic stem cells without the enduring controversy.

Now if only other scientists — including those at the Geron Corporation — would see the potential of adult stem cells to bring healing without taking the innocent life of an embryonic human being.



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