"As to diseases ,make a habit of two things —
to help, or at least *do no harm*."
— Hippocrates, *The Epidemics* —

DO NO HARM
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Juvenile Diabetes Patients Need Real Hope, Not Hype and False Promises
Embryonic Stem Cells Not The Path To Cures; Adult Stem Cells Give Real Hope

The Juvenile Diabetes Research Foundation (JDRF) is aggressively lobbying on Capitol Hill to overturn President Bush's policy on research with human embryonic stem cells (ESCs).

Under the President's policy, 22 existing embryonic stem cell lines are now available for federally funded research, with 3500 vials of cells waiting to be shipped. In addition, 39 more lines are still in the freezer, not yet thawed for use in experiments. Under the President's policy, federal funds are not used for research that requires destroying more human embryos for stem cells.

Patients and Members of Congress should have the real facts when evaluating the claim that ESCs offer the only or best approach to curing juvenile diabetes.

Embryonic stem cells have produced disappointing results for juvenile diabetes.

Several studies have claimed to turn ESCs into insulin-producing cells, and even to temporarily benefit diabetic mice. But pro-ESC scientist Doug Melton of Harvard has published two recent papers casting significant doubts on such studies (Hansson M *et al.*, "Artifactual insulin release from differentiated embryonic stem cells", *Diabetes* 53, 2603-2609, October 2004; Rajagopal J *et al.*; "Insulin staining of ES cell progeny from insulin uptake"; *Science* 299, 363; 17 Jan 2003). Researchers from the University of Calgary have also found that the insulin-producing cells derived from ESCs are not actually the "beta cells" needed to reverse diabetes. While the cells produced some insulin, they did not do so in response to changes in glucose levels; when placed in mice they did not reverse diabetes but formed teratomas (tumors) (Sipione S *et al.*, "Insulin expressing cells from differentiated embryonic stem cells are not beta cells", *Diabetologia* 47, 499-508, March 2004).

This pattern -- false hope, followed by a sobering dose of reality – has become a common feature of efforts to use ESCs for diabetes. Because of the difficulty of getting ESCs to form desired tissues, the risk of tumor formation, genetic instability of ESCs in culture, and other problems, ESCs cannot be expected to provide treatments for juvenile diabetes anytime soon.

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ADULT islet cells have reversed juvenile diabetes in hundreds of patients in clinical trials.

The "Edmonton protocol," using *adult* pancreatic islet cells from cadavers, has already helped hundreds of patients throw their insulin needles away (M. Duenwald, "Progress Seen in Transplants for Diabetes," *The New York Times*, Feb. 16, 2005, A18; D. Wahlberg, "New islet cells put into liver," *The Atlanta Journal- Constitution*, June 1, 2003, at www.ajc.com/health/content/health/special/0603/01exdiabetic_sidebar.html).

A recent report shows that islet cells can now be donated from live donors for patients, opening up many more possibilities for transplants. Using this technique, a mother donated cells for her diabetic daughter, alleviating the diabetic symptoms (Matsumota S *et al.*, "Insulin independence after living-donor distal pancreatectomy and islet allotransplantation," *The Lancet*, 365, 1642-1644, 7 May 2005.)

ADULT stem cells can form insulin-secreting cells and alleviate diabetes symptoms

In a new report, researchers have discovered that a diabetes patient may be able to serve as his or her own donor (Sapir T *et al.*, "Cell-replacement therapy for diabetes: generating functional insulin-producing tissue from adult human liver cells," *Proceedings of the National Academy of Sciences USA* 102, 7964-7969, published online May 17, 2005). They converted human liver cells into insulin-secreting pancreatic cells, and showed that these newly-formed cells could relieve diabetes in mice. The scientists note that this new technique would allow "the diabetic patient to be the donor of his own insulin-producing tissue. This approach may circumvent the shortage in tissue availability, the need for antirejection treatment and the ethical issues associated with the use of fetal or embryonic stem cells for this purpose."

Researchers at Massachusetts General Hospital have used adult cells from the spleen to regenerate insulin-producing cells and show "permanent reversal of diabetes" in mice (R. Mishra, "Juvenile diabetes cured in lab mice," *The Boston Globe*, November 14, 2003, p. A2; S. Kodama et al., "Islet Regeneration During the Reversal of Autoimmune Diabetes in NOD Mice," *Science* 302, 1223-1227; 14 Nov 2003). Essentially the spleen cells "retrain" the body's immune system to stop attacking its own islet cells, and new cells then naturally regenerate from the spleen cells and the body's own cells, eliminating the need for any further cell transplant. The Harvard team, headed by Dr. Denise Faustman, now has FDA approval for clinical trials in human juvenile diabetes patients.

These and other advances promise new approaches to treating diabetes that require no destruction of human embryos, and offer real hope to diabetic patients.

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