



**DO NO
HARM**

The Coalition of Americans
for Research Ethics

FOUNDING MEMBERS

Kevin Fitzgerald, S.J., Ph.D.

Dr. Lauler Professor for Catholic
Health Care Ethics;
Associate Professor of Oncology,
Georgetown University,

C. Christopher Hook, M.D.

Hematology/Medical Oncology,
The Mayo Clinic (MN);
Chair, Mayo Clinical Ethics Council,
Mayo Reproductive Medicine Advi-
sory
Board and DNA Research Committee

Ralph Miech, M.D., Ph.D.

Associate Professor (Emeritus)
of Pharmacology
Brown University School of Medicine

Robert D. Orr, M.D.

Director of Ethics, FAHC
University of Vermont
College of Medicine

David Prentice, Ph.D.

Senior Fellow for Life Sciences
Family Research Council
Visiting Professor
Center for Clinical Bioethics
Georgetown University

Frank E. Young, M.D., Ph.D.

Former Commissioner,
U.S. Food and Drug Administration;
Dean Emeritus,
School of Medicine and Dentistry,
University of Rochester;
Director, Reformed Theological
Seminary, Metro Washington

Joseph Zanga, M.D.

Jefferson-Pilot Distinguished Professor
in Primary Care; Assistant Dean for
Generalist Programs; Professor of
Pediatrics, Brody School of Medicine
East Carolina University

1100 H Street, NW
Suite 700
Washington, DC 20005

PH: 202-347-6840
Fax: 202-347-6849
www.stemcellresearch.org

“As to diseases ,make a habit of two things —
to help, or at least *do no harm.*”

— Hippocrates, *The Epidemics* —

WHERE'S THE BEEF?

Hint: Not with Embryonic Stem Cells

Senator Arlen Specter (PA) says that embryonic stem cell research “could result in a veritable fountain of youth by replacing diseased or damaged cells” (Congressional Record, March 16, 2005, p. S2764).

The Alliance for Aging Research says that embryonic stem cell research allows us to “imagine a world without debilitating costly diseases such as Parkinson's, heart disease and diabetes” (“Stem Cells: Small in Size, Big in Hope” (online at http://www.agingresearch.org/living_longer/spring_99/science.htm).

As for other avenues of stem cell research, such as adult and cord blood? The Coalition for the Advancement of Medical Research says “they have yet to be proven” in comparison to embryonic stem cells, “which we know work” (“Coalition for the Advancement of Medical Research Says Passage of H.R. 810 Critical for Patients and Science,” 7/13/05, online at http://www.stemcellfunding.org/camr_news.aspx?rid=0002).

A fountain of youth...a world without debilitating disease... all this from embryonic stem cells “which we know work.”

WOW!

So how are embryonic stem cells helping human patients now?

“Not a single embryonic stem cell has ever been tested in a human being, for any disease.” (Diana Kapp, “The \$3 Billion Cell Job,” *San Francisco*, January, 2005).

But they have shown great progress in experiments using animals, right?

Well, not quite: “Embryo stem cells entered the world in 1981...[with] cells isolated from early mouse embryos...Even in the mouse system itself, where both authentic ES cells and virtually unlimited genetically compatible subjects had been available since 1981, **there had been essentially no progress in curing or even palliating disabling conditions for which mouse ‘models’ existed, such as diabetes, spinal cord injury, Parkinson’s and so forth.**” (Stuart Newman, Professor of Cell Biology and Anatomy, New York Medical College, “Averting the Clone Age: Prospects and Perils of Human Developmental Manipulation,” *J. Contemporary Health Law and Policy*, Vol.19:2003, pp.446-447)

Nonetheless, breakthroughs in using embryonic stem cells to treat any number of diseases are imminent, aren’t they?

“‘No one in human embryonic-stem cells will tell you that therapies are around the corner,’ said a spokeswoman for the Howard Hughes Medical Institute. The caution is widely shared. ‘Two years ago, [the embryo-stem-cell field] was hype, hype, hype,’ said [University of Florida scientist Michael] Atkinson, the gene-therapy advocate. ‘It is still that way in California, but I think that field has hit a bit of a wall,’ he told *National Journal*.” (Neil Munro, “Charitable Choices,” *National Journal*, 1/22/05).

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Well, if not right around the corner, then when can we reasonably expect some real developments from this avenue of research that Congress now wants to direct more money and resources to?

“Gone are the allusions to healing such afflictions as spinal cord injuries and Parkinson's and Alzheimer's diseases that dominated the 2004 campaign for Proposition 71. In fact, scientists say, **there is no guarantee of cures -- certainly not any time soon** -- from the measure that was optimistically titled the California Stem Cell Research and Cures Act....the draft plan is clear: **‘It is unlikely that [the California Institute of Regenerative Medicine] will be able to fully develop stem cell therapy for routine clinical use during the 10 years of the plan.’** Instead, the top goal is to establish, in principle, that a therapy developed from human embryonic stem cells can ‘restore function for at least one disease.’” (Mary Engel, “Reality Check for Stem Cell Optimism,” *Los Angeles Times*, December 3, 2006); emphasis added).

“[University of Michigan researcher Dr. Jose] Cibelli...said he gives the same answer to anyone asking how long it will take for a [embryonic stem cell-based] therapy to be ready. ‘My answer is five years,’ he said. ‘It’s the same thing as saying I have no idea.’” (Jonathan Bor, “Stem Cells: A Long Road Ahead,” *The Baltimore Sun*, 3/8/04; N. B.: Cibelli is a leading advocate of research cloning and embryonic stem cell research).

What might be some of the reasons for this?

There is no way scientists know of -- short of fetus farming – to transform embryonic stem cells into pure tissue types suitable for transplant: “Although embryonic have been shown to have the potential to turn into virtually any cell type found within the body, no studies have demonstrated the controlled generation of a uniform cell type.” (Harvard Medical School Professor Charles Vacanti, “In tissue engineering, embryonic stem cells may not be the way to go”; *Science*, Vol. 18, #22, 9/22/04)

Embryonic stem cells are characterized by a tendency to form tumors – often lethal ones: “‘The emerging truth in the lab is that pluripotent [embryonic] stem cells are hard to reign in,’ University of Pennsylvania bioethicist Glenn McGee told MIT’s Technology Review. ‘The potential that they would explode into a cancerous mass after a stem cell transplant might turn out to be the Pandora’s box of stem cell research.’” (“Stemming the Tide: Hard Cell,” *The Wall Street Journal Europe*, 8/3/01).

But adult and cord blood stem cells are certainly no better – they are, after all “unproven.” Like embryonic stem cells, they haven’t shown any benefits to human patients either, right?

Well, no -- But don’t take our word for it:

“Adult stem cells such as blood-forming stem cells in bone marrow (called hematopoietic stem cells or HSCs) are currently the only type of stem cell commonly used to treat human diseases...The clinical potential of adult stem cells has also been demonstrated in the treatment of other human diseases that include diabetes and advanced kidney cancer” (National Institutes of Health, “Stem Cell Information: Frequently Asked Questions (FAQs): Basic Questions # 2,” online at <http://stemcells.nih.gov/info/faqs.asp#success>; accessed 7/16/06).

“Meanwhile, forward steps continue to be made in the field of adult stem cell therapy. One estimate is that there are currently over 80 therapies and around 300 clinical trials underway using such cells. Hematopoietic stem cell transplants are routine clinical practice and more than 300 patients with type I diabetes have now undergone transplants of islet cells using the so-called Edmonton protocol, with a significant proportion staying off insulin injections for several years” (Editorial, “Proceed with Caution,” *Nature Biotechnology* 23, 763, July 2005).

“When asked about this adult-cell-versus-embryo-cell dispute, [Juvenile Diabetes Research Foundation (JDRF) President and CEO Peter] Van Etten acknowledged the surprising advances made by the adult-stem-cell faction.”

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“There have been more promising results in adult stem cells than there have been in embryonic-stem cells ...” (Neil Munro, “Charitable Choices,” *National Journal*, 1/22/05). (N.B. The Juvenile Diabetes foundation is one of the nation’s leading advocates of embryonic stem cell research).

“Preliminary Study Suggests Use of Stem Cell Transplantation is Beneficial Treatment of Type 1 Diabetes” (American Medical Association news release on an adult stem cell trial, April 10, 2007; <http://pubs.ama-assn.org/media/2007j/0410.dtl#3>)

“In research to be published in today's *Journal of the American Medical Association*, scientists from Brazil and the United States showed that adult stem cells may indeed help cure diabetes. In that study, 14 of 15 patients with early-onset Type 1 diabetes, once known as juvenile diabetes, could stop taking insulin after undergoing a procedure that partially destroyed their immune and blood systems and then reconstituted those systems with the help of stem cells that had been isolated from their blood in advance.”(Rick Weiss, “Senate Revisits Debate on Stem cell Research,” *Washington Post*, 4/11/07.

What about experiments in animal models?

In addition to already providing some therapeutic benefits to human patients, research in animal models using adult and cord blood stem cells have matched or surpassed results achieved with embryonic stem cells:

Spinal Cord Injury:

“These results are the most dramatic functional and histological repair yet achieved after complete spinal cord transection in mammals, and they open new avenues in the search for treatment of spinal cord injuries in other mammals, **including humans.**” (“Cells in Patients’ Nose Hold Potential To Restore Function In Spinal Cord Injury,” *Federation of American Societies for Experimental Biology*, 4/24/02; <http://www.sciencedaily.com/releases/2002/04/020424073621.htm>) (N.B.: A clinical study showing benefits to human SCI patients from adult olfactory stem cells was published June 24, 2006, in the peer-reviewed *Journal of Spinal Cord Medicine*).

Diabetes:

“Three groups of scientists report today that they independently replicated a controversial finding: severely diabetic mice can recover on their own if researchers squelch an immune system attack that is causing the disease...If the findings applied to humans, they might mean reversing a disease that had seemed incurable. The findings also gave rise to questions about using embryonic stem cells as replacement cells for diabetics, a method that is the focus of intense interest. If it is possible, in mice, for the pancreas to cure itself, and if the same finding holds true in humans — which, so far, is entirely unknown — adding embryonic stem cells as the source of new pancreas cells might provide little added benefit, if any. In any event, scientists are not yet ready to treat diabetic patients with embryonic stem cells; they first have to prod the cells to turn into insulin-secreting pancreas cells” (Gina Kolata, “A Controversial Therapy for Diabetes is Verified,” *New York Times*, 3/24/06).

Parkinson’s:

“Injection of growth protein into brains of Parkinson's rats caused their neural stem cells to grow, migrate to the site of damage, and begin to replace missing nerve cells. Eighty percent (80%) of the rats received a benefit from the treatment, with no tumor formation (J. Fallon et al.; "In vivo induction of massive proliferation, directed migration, and differentiation of neural cells in the adult mammalian brain," (*Proc. Natl. Acad. Sci. USA* 97, 14686-14691; December 19, 2000).

So why do so many in the Senate want to pass S.5, which will direct more money and resources to an avenue of research that has proven very productive of hype, but very paltry in tangible results?

That’s a good question we don’t have a good answer for.

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(4/07)