



Scientifically Suspect Embryonic Stem Cell Research

March 9, 2009

STATUS

On Monday, March 9, 2009, President Obama reversed a Bush Administration policy which permitted federal funding of research using the more than 60 existing stem cell lines that have already been derived, while prohibiting the destruction of additional human embryos with federal funds. As was made clear in 2001, when President Bush announced this policy (and subsequent National Institutes of Health (NIH) guidelines), the embryos from which the existing stem cell lines were created had already been destroyed and no longer had the possibility of further development as human beings. President Obama's executive order would overturn the Bush policy and NIH guidelines, and allow federal funding to support destruction of human embryos, an act which many Americans find morally unconscionable.

BACKGROUND

Since President Bush's policy in 2001, significant strides have taken place in the field of non-embryonic stem cell research, leading to medical and scientific breakthroughs not previously seen in the field. *Adult* stem cells have been used in human applications for over two decades, and patients suffering from over [73 different diseases and disorders are being treated today](#) with experimental adult stem cell treatments (adult, cord blood, etc.). The National Institutes of Health have funded this research by spending \$203 million in FY08 on human non-embryonic stem cell research, and NIH projects funding for FY09 to be \$203 million.

Privately funded research on human embryonic stem cells has always been, and remained under the Bush Administration, legal. Furthermore, millions of dollars in the public and private sector are spent every year on human embryonic stem cell research, though there have yet to be successful human clinical trials or treatments for patients with life-threatening diseases.

Q & A

Is human embryonic stem cell research illegal because of the Bush policy? No. It is, and has always been legal in the U.S. to conduct human embryonic stem cell research and to destroy and conduct research on human embryos with private funds. Furthermore, embryonic stem cell research is currently receiving federal taxpayer funding under the Bush policy, which allowed funding for the existing human embryonic-derived stem cell lines to continue.

Does the NIH currently provide any money for human embryonic stem cell research? Yes. Even with the Bush policy in place, NIH has spent \$264 million on human embryonic stem cell research since FY04 (in FY08 alone the NIH provided \$88 million for such research).

Has human embryonic research ever produced a cure? No. Research using human embryonic stem cells has not treated or produced a cure for any human patient.

What has changed since 2001 in the way of ethical stem cell research? Science has eclipsed the debate and eliminated any perceived need for human embryonic stem cell research. Since 2001, there have been advances in non-embryonic stem cell research. Most recently, researchers discovered a

method of reprogramming adult cells into cells with the versatility and other properties of embryonic stem cells, without using embryos (“induced pluripotent stem cells” or “iPS cells”). Further advances have quickly followed to make this approach safer and more efficient, creating a new paradigm for stem cell research.

Did the FDA recently approve a clinical trial for human embryonic stem cells? Yes. The FDA recently approved a clinical safety trial using human embryonic stem cells for newly-injured spinal cord patients. However, it is important to note that this is not a treatment, but only approval to begin clinical trials on humans to test for safety. In addition, this development follows years of the FDA refusing to permit such trials due to embryonic stem cells’ propensity to form dangerous tumors (cancer) during animal trials.

COMMENTS FROM THE SCIENTIFIC COMMUNITY

“It is a step towards the practical use of reprogrammed cells in medicine, perhaps even eliminating the need for human embryos as a source of stem cells.”

–Dr. Keisuke Kaji of the Medical Research Council Centre for Regenerative Medicine, University of Edinburgh. *BBC News*, March 1, 2009.

“The creation of these ‘reprogrammed’ cells, known as induced pluripotent stem (iPS) cells, provides numerous advantages over stem cells sourced from human embryos and has ushered in a new paradigm in stem cell research for modeling human diseases, discovering and testing conventional pharmaceuticals and developing personalized cell replacement therapies.”

–New biotechnology company Fate Therapeutics, announcing that MIT’s researcher Dr. Rudolf Jaenisch has become a founding member of its scientific team exploring the potential of adult cell reprogramming. *Business Wire*, February 25, 2009.

Mr. Obama's anticipated reversal of policy “won’t be a boon the way some people might think ... time has moved on, and so has the field.”

–Arnold R. Kriegstein, director of the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research at the University of California at San Francisco. *The Chronicle of Higher Education*, February 4, 2009.

Dr. Yamanaka’s breakthrough [in producing iPS cells] “is absolutely changing the field ... it may be that we’ll be able to get away from embryonic stem cells completely. That’s something we’re all hoping will happen.”

–David T. Scadden, co-director of the Stem Cell Institute at Harvard University.

The following are statements made by University of Wisconsin researcher Dr. James Thomson, who led one of the two teams announcing the breakthrough in creating “induced pluripotent stem” [iPS] cells (and the first researcher, in 1998, to isolate embryonic stem [ES] cells by destroying human embryos):

“If human embryonic stem cell research does not make you at least a little bit uncomfortable, you have not thought about it enough. I thought long and hard about whether I would do it.”

“Now with the new technique, which involves adding just four genes to ordinary adult skin cells, it will not be long, he says, before the stem cell wars are a distant memory. ‘A decade from now, this will be just a funny historical footnote.’”

For questions or further information contact Sarah Makin at 6-2302.

The following is a U.S. News & World Report article authored by **Bernadine Healy, M.D.**, former head of the National Institutes of Health, the American Red Cross, and the College of Medicine and Public Health at Ohio State University. A cardiologist and author of two books, she spent more than 25 years practicing medicine. In this blog, she covers matters close to her heart, including cardiovascular disease and other important aspects of personal health and health policy.



Why Embryonic Stem Cells Are Obsolete

March 04, 2009 11:52 AM ET | [Bernadine Healy, M.D.](#)

Scientists may be growing impatient, but President Obama has been rightly taking his time in addressing a campaign promise to lift the ban on federal funding for research using new lines of stem cells to be taken from human embryos. Even for strong backers of embryonic stem cell research, the decision is no longer as self-evident as it was, because there is markedly diminished need for expanding these cell lines for either patient therapy or basic research. In fact, during the first six weeks of Obama's term, several events reinforced the notion that embryonic stem cells, once thought to hold the cure for Alzheimer's, Parkinson's, and diabetes, are obsolete. The most sobering: a report from Israel published in *PLoS Medicine* in late February that shows embryonic stem cells injected into patients can cause disabling if not deadly tumors.

The report describes a young boy with a fatal neuromuscular disease called ataxia telangiectasia, who was treated with embryonic stem cells. Within four years, he developed headaches and was found to have multiple tumors in his brain and spinal cord that genetically matched the female embryos used in his therapy.

His experience is neither an anomaly nor a surprise, but one feared by many scientists. These still-mysterious cell creations have been removed from the highly ordered environment of a fast-growing embryo, after all. Though they are tamed in a petri dish to be disciplined, mature cells, research in animals has shown repeatedly that sometimes the injected cells run wildly out of control—dashing hopes of tiny, human embryos benignly spinning off stem cells to save grown-ups, without risk or concern.

That dream was still alive only a few weeks before this report. Within days of Obama's inauguration, the Food and Drug Administration approved its first-ever embryonic stem cell study in humans: the biotech company Geron's plan to inject highly purified human embryonic cells into eight to 10 patients with acute spinal cord injuries. (The cells are from a stem cell line approved by Bush because it predated his ban.) The FDA should now be compelled to take another look: Are eight to 10 patients enough, or one year of monitoring sufficient, to assess safety? And doctors who participate in the trial will have to ask what every doctor must ask before performing research on a human subject: Were I this patient, would I participate? Would I encourage my loved ones to do so?

Even as the future of embryonic stem cells has dimmed, adult stem cell research has scored major wins evident just in the past few months. These advances involve human stem cells that are not derived from human embryos. In fact, adult stem cells, which occur in small quantities in organs throughout the body for natural growth and repair, have become stars despite great skepticism early on. Though this is a more difficult task, scientists have learned to coax them to mature into many cell types, like brain and heart cells, in the laboratory. (Such stem cells can be removed almost as easily as drawing a unit of blood, and they have been used successfully for years in bone marrow transplants.)

To date, most of the stem cell triumphs that the public hears about involve the infusion of adult stem cells. We've just recently seen separate research reports of patients with spinal cord injury and multiple sclerosis benefiting from adult stem cell therapy. These cells have the advantage of being the patient's natural own, and the worst they seem to do after infusion is die off without bringing the hoped-for benefit. They do not have the awesome but dangerous quality of eternal life characteristic of embryonic stem cells.

A second kind of stem cell that has triumphed is an entirely new creation called iPS (short for induced pluripotent stem cell), a blockbuster discovery made in late 2007. These cells are created by reprogramming DNA from adult skin. The iPS cells are embryonic-like in that they can turn into any cell in the body—and so bypass the need for embryos or eggs. In late February, scientists reported on iPS cells that had been transformed into mature nerve cells. While these cells might become a choice for patient therapy in time, scientists are playing this down for now. Why? These embryonic-like cells also come with the risk of cancer.

James Thompson, the stem cell pioneer from the University of Wisconsin who was the first to grow human embryonic stem cells in 1998, is an independent codiscoverer of iPS cells along with Japanese scientists. Already these reprogrammed cells have eclipsed the value of those harvested from embryos, he has said, because of significantly lower cost, ease of production, and genetic identity with the patient. They also bring unique application to medical and pharmaceutical research, because cells cultivated from patients with certain diseases readily become laboratory models for developing and testing therapy. That iPS cells overcome ethical concerns about creating and sacrificing embryos is an added plus.

The importance of stem cells for medical research has never been greater, and the scientific and public clamor for unimpeded research is fully understandable. But it's important that Obama and everyone supporting a lifting of the ban be clear with the public on what is involved in this decision; it's more complex than advertised. The ban Bush became famous for restricted the use of federal research dollars just to adult stem cells and embryonic stem cells already in existence at the time of his executive order. Lifting this ban so that researchers can use frozen embryos that would otherwise be discarded—they've been donated by couples who have had in vitro fertilization treatments—has drawn wide and bipartisan support from Congress. It's an easy lift.

The more ethically charged decision—less understood by the public and one Congress has avoided—involves the ban on *creating* human embryos in the laboratory solely for research purposes. In fact, President Clinton is the one who balked at allowing scientists to use government money for embryo creation and research on stem cells harvested from such embryos; Bush only affirmed the Clinton ban. The scientific community has been able to attract nonfederal money for such work, and it is going on all the time in stem cell institutes. Scientists want relief from the inconvenience and expense of keeping that work and the money that supports it separate from federal dollars.

Reversing the executive orders of two prior presidents on embryo creation, which even the Congress has been unwilling to tackle, is a far bigger issue than lifting the ban on the use of IVF embryos slated for destruction. Obama stands for transparency, and it's important for him to make sure the public understands his decision, including that all stem cells are not the same or created equally.