Scientists predict huge impact on human life

New possibilities open up in medical treatment of diseases and injuries

By Tim Friend
USA TODAY

Scientists now have their chance to learn the secrets of that tiny, pale dot of cells that many believe holds the power to regenerate a human being. The U.S. government will fund research on human embryonic stem cells.

Supporters of the research say President Bush's decision, announced Thursday night in a televised address to the nation, will have a profound effect on how well scientists can spend their winning years. If scientists can learn to harness the natural ability of embryonic stem cells to become any type of cell in the human body, then it may be possible for the first time to develop treatments for spinal cord injuries and diseases such as Alzheimer's, Parkinson's and cancer.

The most immediate impact of Bush's decision is that it will pull research on human embryonic stem cells from behind the walls of private laboratories for the first time and places it squarely in the public spotlight.

Many feared that without funding, the research would be developed solely by private interests without ethical safeguards and that it would be driven overseas. The Bush decision permits funding for human embryonic stem-cell research. Some scientists had predicted a brain drain or exodus of leading stem-cell researchers to the more favorable research climate of the United Kingdom.

Experts also say that without public funding in the USA, the research would surely have progressed at a much slower rate. The British government, which has a lower overall level of research funding, now has a competitive climate that could make it easier to attract researchers.

But leading stem-cell scientists were baffled by Bush's decision to fund research on an existing 60 stem-cell lines. Bush said he would not permit funding on newly created cells.

A stem-cell line represents a colony of continuously dividing cells derived from a single early-stage embryo. To create a stem-cell line, an embryo must be destroyed. But existing stem-cell lines can produce an in which researchers are able to work so early in the process may well be detrimental, say some research scientists.

Melton and Van Etten said they were also concerned about whether the decision is good news or bad news, even if they are right. The decision has been made over the past few years, including some who believe that the stem-cell lines are of poor quality.

Peter Van Etten, president of the Juvenile Diabetes Research Foundation, said, "We are very concerned about whether this is sufficient to get the work done."

The biotechnology industry agrees.

Carl Feldbaum, president of the Biotechnology Industry Organization, said, "The President's decision is major step forward for patients and the biotechnology industry. The decision is good news for all those who believe that the stem-cell lines are of poor quality."

Thomas Okarma, CEO of Geron, said Thursday that it would ensure open access to its stem-cell lines. Melton, however, said he fears Geron and other companies will place restrictions on access to their stem cells.

Bush's decision to fund research only on the existing stem-cell lines was an attempt to address the moral concerns many people have about the research. Obtaining stem cells for research destroys embryos. Many people, including Bush, say they believe that destroying embryos is immoral. Because of the overriding public benefit that might come from the research, Bush said the government would fund studies on cell lines that had already been created.

Bioethicist Thomas Murray of the Hastings Center in Garrison, N.Y., said Bush's decision "showed appropriate regard for the moral considerations of both sides of the stem cell debate."

"I think we all have to recognize that this is a very difficult issue and a very complex issue," said Van Etten. "We have to respect the time and effort the president has made to balance these issues."

"Van Etten says the 1 million children in the USA with juvenile diabetes may be among the first people to benefit from the research. Just last week, a team in Israel, using human embryonic stem cells developed by scientists at the University of Wisconsin and Geron found that the cells began producing insulin.

It is unclear whether the cell lines Bush will provide funding for meet ethical guidelines developed by the National Bioethics Advisory Commission and the Catholic University. "There is no guarantee that they will be eligible," said Van Etten.

The NIH has funded research on so-called adult stem cells for years and adult stem research on animals has been conducted for decades. But adult stem cells are found in certain organs and tissues from birth through adulthood. They may act as reservoirs for naturally regenerating tissues. An NIH assessment of stem-cell research, developed for Bush, stated that adult stem cells also show great promise but may not be as versatile as embryonic stem cells.

The current budget on adult stem cells is an indication of the level of funding for research on human embryonic stem cells, the amount will be significant.

Last year, NIH allocated $256 million for adult stem-cell research. Harold Varmus, former director of the NIH, said Thursday that he predicts initial levels of funding for human embryonic stem-cell research could be in the tens of millions of dollars.

Bush's announcement "meals all the world to us. We are thrilled with the decision," said Wendy Schmidt, whose 17-year-old son, Tom, has juvenile diabetes. "Now we have the right to do things that will be fair and ethical."

Contributing: Richard Willing
Embryonic vs. adult stem cells

Politics aside, it's too early to tell which type works better.

Answers to some common questions about stem cells:

Q: What are stem cells?
A: Stem cells are master cells that have the ability to transform themselves into other cell types, including those in the brain, heart, bone, muscles and skin.

Q: What are embryonic stem cells?
A: Embryonic stem cells are cells contained in embryos that have the ability to transform themselves into virtually any other type of cell in the body. They are not used by the fertility clinic. These can serve as the source for derive stem cells as long as it involves removing the blastocyst's inner cells and destroying the embryo.

Q: What are the possible medical uses for stem cells?
A: Scientists hope to harness the transdifferentiation abilities of stem cells to derive treatments for a variety of diseases affecting millions of people worldwide. Because stem cells can turn into many other cell types with the right prompting, doctors might be able to replace tissues and organs damaged by disease or injury to restore function.

Q: What is the controversy?
A: For some people, the destruction of any embryo is tantamount to murdering a human being. Leaders of the Roman Catholic Church and some other religious and political figures hold this view.

Q: Has the federal government ever funded research involving human embryonic stem cells?
A: No, it has not. Human embryonic stem cells were isolated in 1998. A law passed in 1995 banned federal funding for research in which a human embryo is destroyed, discarded or knowingly subject to injury. In 2001, the Department of Health and Human Services decided not to issue a legal opinion that the earlier law did not apply to stem cells derived from embryonic tissue because the stem cells themselves were not embryos and the destruction of the embryos was not financed by the government.

Q: What other medical uses are possible?
A: Using stem cells, researchers would be able to test drugs that prevent or cure diseases. This is already happening in human tissue such as a laboratory animal as a proxy. In addition, scientists could harvest and package stem cells to deliver gene therapy to specific targets within the body to treat genetic problems.

Q: Are embryonic stem cells better than adult stem cells?
A: It is too early to say. Embryonic stem cells boast far more important qualities: They can become almost anything in the body, and they can be grown in culture in an unlimited quantity. The disadvantages are that a patient's immune system might reject transplants of embryonic stem cells, that transplants are rejected, and that the immunity of embryonic stem cells could produce tumors.

Q: Embryonic stem cells vs. adult stem cells
A: Embryonic stem cells are isolated from embryos, which are destroyed to obtain them. Adult stem cells are harvested from mature tissues and can be obtained from people of all ages. The United States currently regulates stem cell research so that anything created from human embryos, or any cells that could develop into an embryo, is not allowed to be used in research. This includes derived stem cells. However, the National Institutes of Health have allowed research on adult stem cells, which are not embryos. The United States currently regulates stem cell research so that anything created from human embryos, or any cells that could develop into an embryo, is not allowed to be used in research. This includes derived stem cells. However, the National Institutes of Health have allowed research on adult stem cells, which are not embryos.

Bush's political compromise

By Walter Shapiro

He bet the ranch.

At his vacation home in Crawford, Texas, George W. Bush made a decision that he most fateful domestic-policy choice of his administration. Even before the president spoke to the nation Thursday night, Republican political consultant Scott Reed, who had been Bob Dole's 1996 campaign manager, called it "the biggest decision since Bush picked Dick Cheney."

With his intentions shrouded in secrecy that is emblematic of this closed, nonscrutinized administration, the president, who privately had weighed science, morality, and politics, knowing full well that any choice had consequences that would transcend next month's poll numbers.

Would Bush follow the scientific mainstream and belatedly ratify Bill Clinton's decision, made nearly a year ago, to take a permissivist view of government funding on embryonic stem cells? Or would he hold anti-abortion president, heading a public appeal made by the Pope just last month, cleave to the position that morality forbade the destruction of human embryos? Or was there somehow a scientifically credible middle ground?

Tension built during the 10-minute speech as Bush argued that, while researchers should be encouraged to explore the pros and cons of federally funded stem-cell research, there were moments when he seemed, even as Bush's eyes darted from line to line of the speech in the teleprompter, that the president was having a debate with himself, and the outcome of that internal wrestling match was still up for grabs. Rarely, if ever, has a president displayed both the self-confidence and vulnerability necessary to show the nation a leader on the cusp of both moral and scientific uncertainty.

And, yet, in the end, Bush took a political risk. He bet the ranch on the ultimate success of his proposal, because he is betting that the American people will tell him that his approach was the right one.

Reuters

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The stem cell hard sell
Would public be more receptive with more knowledge?

By Tim Friend
USA TODAY

A recent USA TODAY/CNN poll found that most Americans do not understand even
the basics of human embryonic stem cell
research. One reason is that details of the
privately funded research in the USA have
been shrouded in secrecy. The technology
companies and academic institutions in
isolated labs conduct experiments on early-
stage human embryos and extract stem
cells for medical research.

A review of the National Institute of
Health report on stem cell research com-
piled for President Bush, to be released
Wednesday, suggests only seven studies on
human embryonic stem cells have been
published since 1989, when the first paper
announcing that stem cells had been isolated
from human embryos appeared in Science.
The level of detail scientists are accus-
tonning to have to evaluate new fields of
study is lacking for what is regarded as one
of the most promising fields of research. The
NIH report lists 110 studies, most of which
are based on mice.

Supporters say human embryonic stem cell
research offers the greatest hope for de-
veloping treatments for diseases such as
Alzheimer’s and Parkinson’s disease. But the
number of laboratories conducting studies on
human embryonic stem cells is unknown. Lawrence Soler, chairman of the
Coalition for the Advancement of Medical
Research, says more studies would have
been published if the research were pub-
licly funded. The Bush administration is de-
iding whether to fund the research with

"This is not science fiction. By the time
we get old and have kidney disease, we
will take a skin cell and grow you up a
new kidney."

— Robert Lanza, Advanced Cell Technology
medical director

taxpayer money. Opponents led by the
Catholic Church believe destroying embry-
ons for research is against the sanctity of life.

Janet Thompson pioneered research on
human embryonic stem cells at the Univer-
sity of Wisconsin-Madison. At WCCL Re-
search Institute, a not-for-profit company
formed by the Wisconsin Alumni Research
Foundation that will begin clinical trials. After about five
colonies of stem cells, known as cell
lines, from human embryos. WARF spokes-
man Andy Cohen says WCCL sells vials of
the cells for $5,000 to scientists or laborato-
ries. He said the vials currently are sold at a
loss. He estimated that 30 shipments of the
cells have been made to other facilities, but
he refuses to disclose the names of scien-
tists or labs.

We have more than 100 requests for the
stem cells and we have more than enough to
accommodate all requests if public fund-
ing is approved," Cohen says.

Without scientific publication or even
knowledge of which laboratories are con-
ducting research, the public cannot expect
to understand the debate over embryonic
stem cell research. But given what we
know, here is a primer that may shed light
on what stem cells are, where they come
from and how they are being used.

The body’s building blocks

Human embryonic stem cells are the raw
materials that will build a human body. In
their nascent form in a newly developing embryo, the
stem cells await instructions to begin forming organs,
bone and all of the specialized tissues and cells that
make a human. Scientists are hopeful that they can
learn to harness the power of these cells to develop
cellular replacement therapies for aging and diseased
people. But to achieve this goal, they must take apart
embryos at an early stage of development known as
the blastocyst and remove the stem cells. This de-
sroyes the embryo.

After a sperm fertilizes an egg, a new single
nucleus cell will begin dividing. These
multiplying cells form a blastocyst, a ball the
size of a pinhead. On about the sixth day after concep-
tion, the ball begins to form an outer layer that will

become the placenta, and an inner mass of cells
that will become the embryo.

If everything goes right during the initial cell divi-
sions, the ball of cells will attach to the uterus and
implant itself. Then it begins to form anatomic fea-
tures, the first of which is known as a primitive streak
and becomes the spinal cord. Scientists say blastocysts
often do not survive past the first two weeks of
development. Because of that, some scientists and
religious groups do not regard blastocysts with
the same respect as embryos that are in the womb and
have begun developing anatomic features.

Research reported so far on human embryos has
focused only on the blastocyst stage. The prize inside
the blastocyst is the inner cell mass because the cells
have not yet begun to differentiate into a spinal
cord, organs and other tissues.

Different methods, different interpretations

So far, scientists have revealed three different
means of obtaining human embryonic stem
cells for research. The methods each cross dif-
f erent moral, ethical and, perhaps soon, legal
lines. The colonies of cells currently used in re-
search are reported to be extracted from frozen
human embryos from fertility clinics. These
blastocysts are the leftovers from fertility pro-
cedures and are donated by the couples who
had them generated. The embryos are thawed
and the inner cell mass is removed, a procedure that
destroy the embryo.

Scientists then use techniques, which are not pub-
lished in any detail, to trick the cells into dividing
and forming colonies. The goal is to get the cells to be
have in mind a strategy in the past to
consider whether he believes it is moral or ethical to
done an embryo of himself and harvest the clone stem

The National Institutes of Health has not ad-
ressed the ethics of therapeutic cloning, but ACT has pub-
lished papers on its view of ethics in the journal of

Ethical questions aside, this research is underway.
Congress, however, is considering two bills to ban
cloning. One bill would allow the therapeutic
cloning and ban only reproductive cloning. The other
bill would ban both types.

But even if the United States bars therapeutic clon-
ing, the research will proceed in Britain, where it was
approved by Parliament last year. The brave new
world of medical research has arrived. It will proceed
with or without the USA.
How stem cell technology works and the ethical questions it raises

Stem cells come from embryos, which are obtained three ways:

**Frozen embryo**
Spare frozen embryos come from fertility clinics, donated by infertile couples who no longer need them for pregnancy. Ethical guidelines recommend research only on these.

**Fresh embryo**
Fresh embryos are being created specifically for research by at least one fertility clinic. Ethical guidelines ban public funding of research on these.

**Cloned embryo**
Embryos can be created by cloning human cells. Cloning for research is legal in England; the United States is considering banning it.

1. A human embryo at five days of development after fertilization is called a blastocyst. It is a ball of cells the size of a pinhead.

2. At Day 6, the inner cell mass begins to form. This mass contains the stem cells desired for research. These cells give rise to virtually all cells of the human body. If implanted in a womb, they would transform into a fetus.

3. Stem cells are extracted from the blastocyst and put into cultures. The process destroys the embryo, raising moral and ethical concerns.

4. Scientists say they can trigger stem cells to grow into many different types of tissues, including heart cells that beat in a petri dish.

5. The goal of stem cell research is to one day use them as sources of replacement cells to treat diseases such as heart failure, Alzheimer's, Parkinson's, diabetes and cancer.

Source: Research by Tim Friend, USA TODAY
By Julie Snider, USA TODAY