# The American Voice 2004: A Pocket Guide to Issues and Allegations

# *Issues and Allegations: Human Stem Cell Research*

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# Background

Stem cells have been called "nature's blank slates". They are capable of developing into any of the nearly 200 cell types that make up the human body.

All stem cells have the ability to renew themselves through division. They do not have any tissue-specific structures that allow them to do things like pump blood through the body (like a heart muscle cell) or carry oxygen through the blood stream (like a red blood cell.) But they do have the potential to become cells with special functions, in a process called differentiation.[1]

The very earliest embryo is made up of stem cells that are capable of becoming all cells needed to support embryonic and fetal development, and all cells of the body. During fetal development, stem cells gradually become more likely ("committed") to become cells of a particular tissue type (e.g. only blood cells, only muscle cells, only skin cells, only nerve cells).

Stem cells exist in small numbers in some adult tissues -- bone marrow, blood, blood vessels, muscle, skin and brain. They generate replacements for cells lost through normal wear and tear, injury or disease. Cells that permit new skin growth are an example. Adult stem cells normally are specialized cells of the type of the tissue in which they reside. For example, blood stem cells can form all types of blood cells, but not muscle or skin cells.

Scientists work with both embryonic stem cells and adult stem cells. Research on adult stem cells (also called somatic stem cells) dates to the 1960s. Since then, adult stem cells have been used in bone marrow transplants and in treatments for inherited blood diseases and leukemia. They are also used to test drugs. Scientists grow a cell culture, apply the drug and look for abnormal reactions. In 1998, scientists were able for the first time to isolate and grow stem cells from human embryos.

Stem cells are isolated by transferring cell mass from the very early embryo called the blastocyst into a culture dish where they divide and spread over the surface of the dish. As the cells begin to crowd the culture dish, some are removed and placed into new culture dishes. This process, called subculturing, is repeated many times over many months.

# At a Glance...

#### The conservative view:

- An embryo is genetically unique human life. It is immoral to use them for research.
- Research on embryos turns them into commodities and devalues human life.
- Adult stem cells are at least as promising as embryonic stem cells.
- Research on adult stem cells has already provided medical treatments.
- The use of public funds for embryonic stem cell research gives public endorsement to research with disturbing moral and ethical considerations.

#### The liberal view:

- The promise of stem cell research outweighs the ethical problems involved in using embryos already created but not used for fertility treatments.
- Embryos created in the lab cannot develop into viable human life without technical intervention.
- Current restrictions on federal funding are holding back research in the field because there are few lines available and they are of lower quality than newly created lines
- Privately funded research will pursue profitable medical treatments; publicly funded research is important if we want to advance our basic understanding of human development.

Embryonic stem cells that have divided (or, proliferated) in a dish for six months or more without differentiating into specialized cells are called a stem cell line. Batches of the cells can be frozen and sent to other laboratories for further culture and experimentation.

Scientists are learning to control differentiation of embryonic stem cells by changing the culture medium (the substance in the dish that helps the cells proliferate), altering the surface of the culture dish, or inserting specific genes into the cells.

Embryonic stem cells are pluripotent; they can differentiate into any kind of cell in the body. Most scientists do not think adult stem cells are pluripotent. Instead, they can differentiate only into cells of the tissue type they come from. For example, stem cells from blood can become any kind of blood cell, but cannot become muscle cells.

Researchers most often obtain embryonic stem cells from blastocyst stage human embryos donated by couples who have undergone infertility treatment. Federal funds cannot be used to create stem cells in this way because current law prohibits federal funding for research that destroys or discards an embryo, or creates an embryo for research purposes.

Stem cells can also be obtained from 5 to 9 week old fetal tissue obtained after a pregnancy is terminated. The cells that will go on to become egg or sperm cells are isolated from the tissue and then grown in a laboratory culture. Fetal tissue research was banned in the 1980s and early 1990s by the Reagan and Bush administrations. In 1993, the Public Health Services Act was amended to allow federal funding for human fetal tissue research within NIH guidelines.

In August 2000, the NIH released guidelines for federally funded embryonic stem cell research, with the support of the Clinton Administration. The guidelines allowed research only on stem cells derived from embryos leftover from fertility treatments if they were donated with the consent of the couple and without profit to the fertility clinic.

On August 9, 2001, the Bush Administration announced new NIH guidelines. Federal funds could be used only for research on existing stem cell lines that are approved by the NIH. President Bush maintained that "more than 60 genetically diverse stem cell lines already exist". No federal funds can be used to derive new stem cell lines from human embryos, or for research on stem cell lines that are created after August 9, 2001. President Bush also created a new President's Council on Bioethics.[2]

To date, 17 stem cell lines are listed as available in the NIH Human Embryonic Stem Cell Registry.[3] The rest either belong to private companies or to institutions that do not have the capacity to grow and distribute them.

In March of 2002, the NIH issued a policy clarification, stating that researchers who receive federal funds can study new stem cell lines, and even derive new lines from human embryos, as long as the research is supported by private funds.[4]

Eight institutes at universities and private firms in the U.S. are currently using private funds for human embryonic stem cell research. In March 2004, a Howard Hughes Medical Institute researcher at Harvard announced the creation of 17 new embryonic stem cell lines that are freely available to researchers. Privately funded research is also underway at the University of Wisconsin, the University of Minnesota, and Stanford. New Jersey has given \$6.5 million to Rutgers University to create and study new stem cell lines, making it the first state to fund research. The November 2004 election in California includes a ballot-initiative to provide \$3 billion over 10 years for research at the University of California at San Francisco.

Some 33 states are currently considering 100 bills related to embryonic stem cell research.[5]

Laws on embryonic stem cell research vary in the rest of the world. China, Singapore, Australia and the U.K. all support it. The European Union finances embryonic stem cell research, but only in countries that allow it. This excludes France and Italy, both of which are predominantly Roman Catholic, where all research on human embryos is banned. Israel allows research on embryos.[6]

Stem cell research is one of those issues that cross party lines. For example, Senate Majority Leader Bill Frist, Senator Orrin Hatch, former First Lady Nancy Reagan and other Republicans support federal funding for stem cell research. Nevertheless, a clear conservative-liberal split still exists on the issue.

### The question

Should we encourage embryonic stem cell research?

### The conservative perspective

Conservatives argue that new human life begins at the moment the sperm cell fertilizes the egg. Once a new human life has been created, it deserves to be respected.[7] It should not be destroyed for research, no matter how potentially valuable the research may be.

The fact that embryos cannot feel pain or lack distinguishing characteristics is not relevant. Genetically, the embryos are human. Conservatives argue that "it is dangerous to begin to assign moral worth on the basis of the presence or absence of particular capacities and features, and [instead] we must recognize each member of our species from his or her earliest days as a human being deserving of dignified treatment."

Conservatives argue that frozen embryos are not simply leftovers that will be discarded anyway. Increasing numbers of frozen embryos are stored by fertility clinics, demonstrating that parents do not want to destroy them. Because the demand to adopt frozen embryos exceeds the supply, these embryos could still become children. Even though clinics are entitled to destroy embryos if the parents cannot be contacted for five years, most clinics do not do so.[8]

Conservatives argue that if we allow research on human embryos just because they cannot grant informed consent, it sets a dangerous precedent for research on humans.[9]

Conservatives warn that once scientists begin harvesting human life like a natural resource they will quickly move from using fertilization clinic embryos to creating embryos solely for research purposes. Embryos become commodities created for profit. This devalues human life.[10]

Conservatives argue that adult stem cells hold as much promise as embryonic stem cells, without the moral challenges. Human embryonic stem cells have yet to successfully treat any disease. Adult stem cells, on the other hand, already treat blood and liver diseases, strokes and leukemia.[11]

Conservatives maintain that there is evidence adult stem cells could be changed into cells of any type in the body. Studies of adult stem cells from bone marrow and blood, for example, have shown the potential to become liver cells and muscle cells. Canadian scientists are working on a technique to turn skin cells into brain cells for use in treating neurological disorders such as Parkinson's and Alzheimer's. Researchers at Massachusetts General Hospital used adult stem cells from the spleen to cure juvenile diabetes in mice. **[12]** 

Conservatives argue that if public money is used to create new stem cell lines, it publicly endorses a technique with profoundly disturbing moral and ethnical implications. "(P)roviding taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life", according to President Bush, would constitute "crossing a fundamental moral line".[13]

Some conservatives, including the U.S. Conference of Catholic Bishops, oppose all embryonic stem cell research, including research on the lines approved for federal funding under the Bush Administration's decision. They argue that federal funding for any kind of embryonic stem cell research removes the ethical stigma. It provides seed money for the basic research that leads to demand for further research and more stem cell lines, which means more embryos will inevitably be destroyed.[14]

# The liberal perspective

Liberals maintain that the enormous medical promise of stem cell research far outweighs the ethical problems involved. They argue that a 5-day-old human embryo's several hundred stem cells have not begun to become body cells of any kind. The embryo lacks a nervous system, has no head-to-toe orientation and has no capacity for pain. It has not even reached the stage when it would divide into two if it were going to become twins.

Liberals argue that a human embryo created in a laboratory should not be considered a life in that it does not have the potential to develop without additional technical intervention.

Liberals note that there are more than 400,000 embryos in frozen storage in U.S. fertility clinics. One study presented to the President's Council on Bioethics anticipates that if all of the embryos currently in storage were processed, it would yield about 275 stem cell lines for research.[15]

These embryos are left over from couples who have undergone fertility treatment. Many of these embryos were put into storage because they did not have a strong chance of becoming children. They cannot be stored indefinitely. To use them in ways that could be beneficial to some one who is sick rather than destroy them would be ethically moral and socially beneficial.

Liberals point to recent research in which scientists were unable to replicate the findings of previous research using adult stem cells.**[16]** They say that evidence from this and other research leads scientists to believe that adult stem cells are not as flexible as embryonic stem cells. According to James Thomson, the lead scientist in the research that first grew stem cells from human embryos, "The debate regarding whether adult stem cells or embryonic stem cells are 'better' is a creation of politics and the press, not of the scientific community. I know of no credible stem cell scientist that does not believe that both should be studied; human medicine will suffer if either is excluded."**[17]** 

Liberals, and other supporters of embryonic stem cell research, say that the compromise put forth by the Bush Administration is holding back progress in the field.

Of the "more than 60" stem cell lines that were to be available for publicly funded research, only 15 are available today. A recent NIH summary report says that the "best case scenario" is for 23 lines to eventually be available for public funding.[18]

Scientists say that the pre-August 9, 2001 stem cell lines are not as useful for research as more recently developed lines. They were developed in the early days of research on embryonic stem cells, when scientists were just beginning to learn techniques. These early lines are unstable and difficult to work with. Scientists in different labs cannot maintain the lines in the same way, making it difficult to repeat experiments for verification of results.**[19]** 

More importantly, scientists say that it may not be possible to use these lines for human therapies. Early stem cell lines were grown using a culture medium of irradiated mouse cells. Scientists worry that treating humans with stem cells grown in this way could introduce mouse viruses into humans. Today, scientists can grow stem cell lines without the use of any animal materials, and without any biological culture medium at all. These are less risky to use, and make it easier to obtain FDA approval of clinical trials for therapies.[20]

Liberals argue that privately funded research will not advance knowledge of the field as quickly as publicly funded research. Private firms use intellectual property laws to protect their research. They do not spread the research widely through the scientific community, where other researchers can learn from it. When access to privately funded research is granted, it requires agreements on royalties and licensing fees. This limits the free-flow of information that allows scientists to advance the field by learning from and testing the work of others. They point out that intellectual property protection is one reason there are so few lines available through the NIH directory of approved lines.[21]

Private firms are also less likely to advance the basic science of the field. Many scientists believe that the most important thing to come from embryonic stem cell research is a greater understanding of how humans develop, and why the cells in our bodies do things that make us healthy or sick. Private firms generally prefer a situation where scientists at publicly funded institutions do basic research, and private firms develop treatments based on this research. They do not like to invest in basic research that will not quickly lead to a marketable product.[22]

Liberals support the NIH decision, endorsed by the Bush Administration, to allow federally financed researchers to study new stem cell lines as long as they do so only with private money. But they say there are still concerns that the ban on federal funding will discourage the brightest young scientists from entering the field. According to Dr. Douglas Melton, the Harvard researcher whose lab has created 17 new lines with private funds, they will be put off by "the enormous amount of administrative headaches on the one hand, combined with the controversy on the other."[23]

# Notes and Sources

#### Note on internet citations

[1] For more background information, see: **Statement of Harold Varmus**, **M.D.**, Director, National Institutes of Health before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies. December 2,1988.

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[2] The full text of President Bush's 9 August 2001 statement is available at http://www.whitehouse.gov/news/ releases/2001/08/20010809-2.html

[3] NIH. Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells.

[4] See Stem Cells Information: FAQs at http://stemcells.nih.gov/faqs.asp - 21

[5] Dan Vergano. "New stem cell lines available." USA Today. March 3, 2004.

[6] Times Higher Education Supplement. "A Dilemma in the Way of Science." New York Times. July 18, 2003.

[7] U.S. Conference of Catholic Bishops. Secretariat for Pro-Life Activities. Stem Cell Reality Check #4.

**[8]** Laura Antkoviak. *Understanding Stem Cell Research.* National Right to Life Committee. Accessed April 23, 2004. "Some See New Route to Adoption in Clincs Full of Frozen Embryos." *The New York Times.* February 24, 2001.

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[10] Richard M. Doerflinger. *Farming Humans for Fun and Profit.* U.S. Conference of Catholic Bishops.; Smith, Wesley J. "Where Frist Comes Down." *National Review Online.* July 20, 2001.

**[11]** A list of successful treatments using adult stem cells is available from the U.S.C.C.B Secretariat for Pro-Life Activities. *Current Clinical Use of Adult Stem Cells to Help Human Patients*.

[12] U.S. Conference of Catholic Bishops. Secretariat for Pro-Life Activities. *Scientific Experts Agree: Embryonic Stem Cells are Unnecessary for Medical Progress.* 

[13] The full text of President Bush's August 9, 2001 statement is available at http://www.whitehouse.gov/news/ releases/2001/08/20010809-2.html

[14] U.S. Conference of Catholic Bishops. Secretariat for Pro-Life Activities. President Bush's Stem Cell Decision.

[15] Farhad Manjoo. "Thou shalt not make scientific progress." Salon. March 25, 2004.

[16] Sabin Russel. "Adult stem cell transplants fail in two studies." The San Francisco Chronicle. March 22, 2004.

In two separate articles in the journal *Nature*, scientists described research efforts in which they were unable to replicate earlier studies that seemed to show that adult stem cells could be coaxed into making new heart muscle.

[17] Dan Vergano. "New stem cell lines available." USA Today. March 3, 2004.

**[18]** Justin Gillis and Rick Weiss. "NIH: Few Stem Cell Colonies Likely Available for Research; of Approved Lines, Many are Failing." *The Washington Post.* March 3, 2004.

[19] Farhad Manjoo. "Thou shalt not make scientific progress." Salon.com. March 25, 2004.

[20] ibid.

See also FDA Letter to Senator Edward M. Kennedy Regarding Stem Cells. September 5, 2001.

[21] Sheryl Gay Stolberg. "Ruling by U.S. Widens Study of Stem Cells." The New York Times. August 7, 2002.

[22] ibid.

[23] ibid.

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