

Case Study: Stem Cell Research

Spring 2009

Created by:

Dr. Clark Wolf
Bioethics Program Director
Iowa State University

Michael A. Stanfield
Bioethics Program Assistant
Iowa State University

Introduction

In 1998, James Thomson of the University of Wisconsin-Madison derived the first human embryonic stem cell line. According to the National Institutes of Health, stem cells are “cells differ from other kinds of cells in the body. All stem cells—regardless of their source—have three general properties: they are capable of dividing and renewing themselves for long periods; they are unspecialized; and they can give rise to specialized cell types.” Stem cells are generally classified as either embryonic stem cells (ESC) or adult stem cells. Because of the unique nature of stem cells (as compared to other somatic cells), they have become of enormous importance in medical research, particularly as potential cures for life threatening diseases.

Human stem cell research, however, is extremely controversial. Especially in the case of embryonic stem cell research, serious ethical concerns have arisen. As a result, legislation providing for the use of stem cells in medical research has faced serious opposition.

The most recent legislation, introduced by the 110th session of the U.S. Congress regarding stem cell research, is S.5: Stem Cell Research Enhancement Act of 2007. This act was introduced on January 4, 2007, and passed by the Senate on April 11, 2007. The Act was passed by the House on June 7, 2007, but ultimately failed passage into law as a result of the June 20, 2007 presidential veto by then president, George W. Bush.

The 111th session of the U.S. Congress is now convening and its legislation is now subject to the veto power of the newly elected president, Barack H. Obama. Students are asked to consider the previously vetoed legislation and recommend a course of action:

- (1) Should the bill be reintroduced, in its current form, to the new Congress?
- (2) Should it be revised before being reintroduced to the Congress for consideration?
What revisions would your group recommend?
- (3) Should this issue be dismissed from consideration altogether?

Clearly explain and defend your group’s view about these questions.

Activity

You have been assigned to one of the interest groups below. For the purpose of this case study, you should consider yourself an advocate and representative for the group to which you have been assigned. You should aim to present that group's view in its strongest and most persuasive form.

This is a *role playing exercise*: You should strive, as much as possible, to adopt the perspective of a member of your interest group for the duration of this exercise whether or not you really do agree with the position your group would advocate.

These interest groups represent a variety of positions on stem cell research. Students should try to determine how their assigned group would respond to the above piece of legislation, and whether their interest group is likely to support it in its current form, suggest modifications to the bill, or move to dismiss the bill entirely.

Interest Groups

1) COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

According to its website, the Coalition is, “the nation's leading bipartisan pro-cures coalition. Comprised of more than 100 nationally recognized patient organizations, universities, scientific societies, and foundations, CAMR’s advocacy and education outreach focuses on developing better treatments and cures for individuals with life-threatening illnesses and disorders. CAMR is dedicated to being a national, collective voice on Capitol Hill and in the media for those who believe that regenerative medicine, including embryonic stem cell research, holds the key to providing American families with hope for the future.”

2) COALITION OF AMERICANS FOR RESEARCH ETHICS

Founded in 1999 by a coalition of professional medical doctors, academics, and religious orders personnel, the mission of CARE is “to advance the development of medical treatments and therapies that do not require the destruction of human life, including the human embryo; to educate and inform public policy makers and the general public regarding these ethically acceptable and medically promising areas of research and treatment; to support continuation of federal laws prohibiting the federal funding of research that requires the destruction of human life, including the human embryo.”

3) AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Founded in 1848, in its association with 262 affiliated societies and academies of science, “The American Association for the Advancement of Science (AAAS) is an international non-profit organization dedicated to advancing science around the world by serving as an educator, leader, spokesperson and professional association. In addition to organizing membership activities, AAAS publishes the journal *Science*, as well as many scientific newsletters, books and reports, and spearheads programs that raise the bar of understanding for science worldwide.”

4) CENTER FOR BIOETHICS AND HUMAN DIGNITY

The Center for Bioethics and Human Dignity is an organization conceived of by a group of Christian Bioethicists and produced as a result of a conference in May 1994 entitled, "The Christian Stake in Bioethics." The mission of the CBHD is, "to equip thought leaders to engage the issues of bioethics using the tools of rigorous research, conceptual analysis, charitable critique, leading-edge publication, and effective teaching. It is a national and international leader in producing a wide range of live, recorded, and written resources examining bioethical issues. Recognizing that biblical values have exercised a profound influence on Western Culture, the Center explores the potential contribution of such values as part of its work." The Center is a not-for-profit educational institution affiliated with Trinity International University.

Activity Schedule

1) First, read the text of the Stem Cell Research Enhancement Act (the next item in your packet), and the ISSCR Stem Cell Primer. Then study the materials associated with the interest group to which you have been assigned. (Note: You do not need to read material from all of the different interest groups, only the group to which you have been assigned.)

Write down the main claims that represent the view your interest group would take on stem cell research and the view you would expect your group to take with respect to the Stem Cell Research Enhancement Act. Be sure to identify the reasons that would be used by a member of your group to justify or defend these claims.

2) Get together with other class members who have been assigned to the same interest group, and discuss how you might best make the case for your group's perspective on this issue. As a group, you should work to put together a brief presentation (5 minutes or so) that will explain and justify your Interest Group's position. You should consider this to be in the spirit of a lobbyist presentation to the Senate: an effort to persuade members of the Senate to consider your position on the Stem Cell Research Enhancement Act of 2007.

In preparing your presentation, you should pay attention to the mission or the aim of the interest group you represent. You should consider the way in which the current version of the Act might promote or thwart the interest group's mission or broader objectives, and how (if possible) it could be improved.

3) After preparing their presentations, all groups will re-assemble. Each group will present its case to the other members of the workshop. Members of the audience will have a brief opportunity to pose questions or to raise objections after each presentation. In posing questions to members of other groups, you may either adopt the position of a member of the Senate, or a member of your own assigned interest group.

4) Case Study "Debriefing." Participants will have an opportunity to discuss the issue, the different interests and values involved, and the case study without constraints or adopted roles.

Nota Bene: I would like to invite you to give me advice on how this case study might be improved (even typos!). You may send suggestions to me at jwcwolf@iastate.edu.

Background Materials

1. The Stem Cell Research Enhancement Act of 2007
2. Stem Cell Primer, International Society for Stem Cell Research
3. NIH Stem Cell Primer (Optional)

Interest Group Materials

COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

1. Talking Points
http://www.camradvocacy.org/resources/SCNT_Talking_Points.pdf
2. Recent Developments and Alternatives
http://www.camradvocacy.org/resources/ESCR_Alternatives.pdf
3. A Catalyst for Cures: Embryonic Stem Cell Research White Paper
http://www.camradvocacy.org/resources/camr_wp.pdf

COALITION OF AMERICANS FOR RESEARCH ETHICS

1. Founding Statement
<http://www.stemcellresearch.org/statement/statement.htm>
2. Twelve Lessons About Stem Cell Research
<http://www.stemcellresearch.org/polisci/index.html>

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

1. Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research
<http://www.aaas.org/spp/sfrl/projects/stem/report.pdf>
2. AAAS Asked President Bush to Reconsider Veto
http://www.aaas.org/spp/cstc/docs/07_06_07stem_pres.pdf
3. AAAS Urges Senate Support for Expanding Federally Funded Stem Cell Research
http://www.aaas.org/spp/cstc/docs/07_04_09stemcell.pdf

CENTER FOR BIOETHICS AND HUMAN DIGNITY

1. Stem Cell Research Overview
<http://www.cbhd.org/resources/stemcells/overview.htm>
2. Position Statement
http://www.cbhd.org/resources/stemcells/position_statement.htm
3. The Interface Between Science and Ethics: Probing the Deeper Questions
http://www.cbhd.org/resources/stemcells/jones_2003-02-19.htm
4. Stem Cells and Our Moral Culture
http://www.cbhd.org/resources/stemcells/hollinger_2001-11-15.htm

BACKGROUND MATERIALS

RESOURCE 1: The Stem Cell Research Enhancement Act of 2007

HR 3 PCS
Calendar No. 6
110th CONGRESS
1st Session
H. R. 3

IN THE SENATE OF THE UNITED STATES

January 11, 2007
Received and read the first time

January 12, 2007
Read the second time and placed on the calendar

AN ACT

To amend the Public Health Service Act to provide for human embryonic stem cell research.
Be it enacted by the Senate and House of Representatives of the United States of America in
Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Stem Cell Research Enhancement Act of 2007'.

SEC. 2. HUMAN EMBRYONIC STEM CELL RESEARCH.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by
inserting after section 498C the following:

SEC. 498D. HUMAN EMBRYONIC STEM CELL RESEARCH.

- (a) In General- Notwithstanding any other provision of law (including any regulation or guidance), the Secretary shall conduct and support research that utilizes human embryonic stem cells in accordance with this section (regardless of the date on which the stem cells were derived from a human embryo).

(b) Ethical Requirements- Human embryonic stem cells shall be eligible for use in any research conducted or supported by the Secretary if the cells meet each of the following:

(1) The stem cells were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment.

(2) Prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.

(3) The individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation.

(c) Guidelines- Not later than 60 days after the date of the enactment of this section, the Secretary, in consultation with the Director of NIH, shall issue final guidelines to carry out this section.

(d) Reporting Requirements- The Secretary shall annually prepare and submit to the appropriate committees of the Congress a report describing the activities carried out under this section during the preceding fiscal year, and including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.'.

Passed the House of Representatives January 11, 2007.

Attest:

KAREN L. HAAS,
Clerk.
Calendar No. 6
110th CONGRESS
1st Session
H. R. 3

RESOURCE 2: Stem Cell Primer, Intl. Society for Stem Cell Research.

Full text: <http://www.public.iastate.edu/~jwcwolf/StemCellStudy/ISSCR.pdf>

Accessed: February 13, 2009

RESOURCE 3: NIH Stem Cell Primer (Optional)

Full text: <http://www.public.iastate.edu/~jwcwolf/StemCellStudy/NIH.pdf>

Accessed: February 13, 2009

COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

RESOURCE 1: Talking Points

Full text: http://www.camradvocacy.org/resources/SCNT_Talking_Points.pdf

Accessed: 02/02/2009

Somatic Cell Nuclear Transfer is about saving and improving lives, and is fundamentally different from human reproductive cloning. SCNT produces stem cells, not babies.

- In Somatic Cell Nuclear Transfer (SCNT), the nucleus of a donor's unfertilized egg is removed and replaced with the nucleus of a patient's own cells. These types of cells are called somatic cells.
- The goal of SCNT is to develop stem cells that will not be rejected or destroyed by the patient's immune system.
- No sperm is used in this procedure and the cells are not implanted into a womb.
- The unfertilized egg cells are stored in a petri dish to become a source of stem cells that can be used to treat life-threatening medical conditions.
- SCNT aims to treat or cure patients by creating tailor-made, genetically identical cells that their bodies won't reject. In other words, SCNT could allow patients to be cured using their own DNA.
- There are many different kinds of cloning, most of which are commonly used medical tools. The word "cloning" simply means making copies of a single molecule, cell, virus or bacterium.

Over the last decade, various types of cloning have allowed scientists and researchers to:

- Develop powerful new drugs;
- Produce insulin and useful bacteria in the lab;
- Track the origins of biological weapons;
- Catch criminals and free innocent people.

CAMR opposes reproductive cloning and implantation, which aims to create human beings by cloning human embryos.

SCNT could lead to dramatic new treatments and cures for now-incurable diseases and medical conditions. SCNT could be used to help nearly 100 million Americans suffering from cancer, Alzheimer's, Parkinson's, diabetes, heart disease, spinal cord injuries, ALS, and other devastating conditions for which treatments and cures must still be found.

SCNT is widely supported in the U.S. and a federal ban on SCNT would have devastating results. A ban would:

- cut off hope to millions of Americans with life-threatening diseases;

- run counter to our nation's history as a leader in biomedical research;
- make it illegal for U.S. citizens to seek SCNT treatment abroad. This means that a patient who may have little hope left could be thrown in jail upon re-entry to the U.S. if they went to another country to have treatment using SCNT, send a scientist to jail for developing SCNT therapies in a Petri dish, and make it illegal for U.S. scientists to import SCNT therapies that were developed in other countries.

In absence of forward-thinking federal policy, CAMR supports state efforts to create safe havens for critical medical research such as stem cells and SCNT, but it is no substitute for a supportive federal policy. State legislation that is pro-stem cell and SCNT helps attract top scientists / researchers to pursue this field of study and increases research activity. Increased research activity helps bring us closer to scientific advances that could lead to cures.

RESOURCE 2: Recent Developments and Alternatives

Full text: http://www.camradvocacy.org/resources/ESCR_Alternatives.pdf

Accessed: 02/02/2009

CAMR's ultimate mission is to help end the suffering of the 100 million Americans with diseases and conditions that may someday be treated or even cured through progress in the field of human embryonic stem cell research. CAMR supports all ethical research that unlocks the secrets of pluripotent cells -- cells that can develop into any cell type. The world's leading scientists assert that embryonic stem cell research remains the most promising key to demystifying these cells. The recent breakthroughs, while laudable, by no means obviate the need for further embryonic stem cell research. Embryonic stem cell research is more important now than ever. Therefore, CAMR will continue to work to enact the Stem Cell Research Enhancement Act.

This fact sheet contains summary descriptions of recent stem cell-related developments that have been in the news. The first, induced pluripotent stem cells (iPS), garnered the most attention as it reprogrammed adult cells to a pluripotent state. The second breakthrough, conducted by a company called Advanced Cell Technology, uses a controversial technique to remove cells from an early-stage embryo. Theoretically, this process does not harm the embryo but further research is needed to understand and effectively replicate this process. Finally, an announcement from the company Stemgen has refocused attention on somatic cell nuclear transfer (SCNT), a technique supported by CAMR. The announcement of any type of breakthrough is the beginning of a long process. Any development will require years of validation before it can reach the stage of progress we now have with human embryonic stem cell research.

Dr. James Thomson of the University of Wisconsin and Dr. Shinya Yamanaka of Kyoto University published studies in 2007 that offer a new approach for developing pluripotent cells, followed by similar studies from Harvard University. In all of the studies, genes were delivered via a virus agent to an adult cell. The genes reprogram the cell and "turn back the clock" -- reverting the cell to a pluripotent state that can be used to generate stem cell lines. Because iPS uses adult cells (one study used discarded tissue from newborn circumcisions) and does not

require a human egg or embryo, many assert that this research ends the need for embryonic stem cell research. However, there are several safety concerns about this technique such as the high frequency of tumor development and the hazards associated with using a virus to deliver the genes. Because of this, Thompson, Yamanaka and other scientists continue to see the need for embryonic stem cell research.

As Dr. George Daley, a member of the Harvard Stem Cell Institute's Executive Committee and President of the International Society for Stem Cell Research has noted, "despite success in generating iPS cells, we are not abandoning our efforts to derive new human stem cell lines by nuclear transfer. We are not yet certain which type of cell will prove most useful for medical applications. Besides, nuclear transfer is an experimental method that asks very important questions that will never be answered by reprogramming skin cells with defined genes." The iPS discoveries were derivatives of embryonic stem cell research. It is only because embryonic stem cell research was conducted first, that we have iPS now.

There are safety concerns associated with the iPS model. As Dr. Story Landis, chair of the NIH stem cell task force, said scientists working on iPS successfully reprogrammed these cells by using viruses to introduce the reprogramming genes, one of which is known to cause cancer, thereby making this method in its current form "absolutely" unsuitable for any kind of transplant. "So while this is a huge scientific step forward, there are many unanswered questions," she said. We do not know enough about pluripotent cells to know if the iPS versions are identical and it is unlikely that they will behave like exact copies.

Dr. Landis stated at the American Health Lawyers Association's (AHLA) annual conference (January 2008), "The game isn't over because we don't actually know that these cells [iPS] are identical to human embryonic stem cells. There are in fact differences," she said. "The likelihood and it is my personal belief, that you end up with something identical to that pristine human embryonic stem cell is about zero. We don't know. It's a very interesting question, and scientists are certainly looking at that."

Continued embryonic stem cell research is required to answer those questions. Rather than obviating the need for embryonic stem cell research, iPS provides another testament to the importance of such research. More work is needed to validate the iPS results. Dr. Kevin Eggan, a leading researcher at Harvard University stated in a *Science* article (February 2008) that "to validate iPS cells, scientists must make huge [numbers]...from many different people and compare them in a battery of tests with embryonic stem cells." Validating the results requires moving forward with embryonic stem cell research.

After his iPS announcement, Dr. Thomson asserted in an editorial co-authored by Dr. Alan Leshner (chief executive of the A.A.A.S. and executive publisher of the journal *Science*) that, "We hope Congress will override the president's veto of the Stem Cell Research Enhancement Act. Further delays in pursuing the clearly viable option of embryonic stem cells will result in an irretrievable loss of time, especially if the new approach fails to prove itself."

Writing in the journal *Cell Stem Cell*, Drs. Yamanaka, Konrad Hochedlinger (Harvard Stem Cell Institute's Principal Investigator) and Rudolf Jaenisch (MIT's Whitehead Institute) assert that

“We hold that research into all avenues of human stem cell research must proceed together. Society deserves to have the full commitment of scientific inquiry at its service. And science is a practice that works best when it is approached with an open and creative mind. Research into one approach can inspire new ideas in unpredictable and exciting ways.”

Dr. Landis’ comments at the AHLA conference further bolster this position: "We simply don't know where the advances are going to come from for any particular disease, and as an institute director, we're responsible for 600 diseases, common diseases, rare diseases, and to say that all the answers to neurogenerative diseases are going to come from adult stem cells or reprogrammed stem cells, I think that's just unreasonable."

In January 2008, a published study in the journal *Cell Stem Cell* announced that Advanced Cell Technology (ACT), a private company, created a pluripotent stem cell line from a single cell removed from an early stage embryo without causing harm to the embryo. This process of inducing a single cell to replicate is sometimes called “parthenogenesis.” The technique of removing an embryonic cell from a blastocyst prior to implantation is often used in fertility clinics for pre-implantation genetic testing and is controversial. While now growing in use and acceptance, the long-term effects of removing the single cell from an embryo prior to implantation are not known nor fully understood. Further research is needed to answer safety questions regarding this procedure.

Concerns about the ACT Study

- The results from the ACT study have not been replicated elsewhere. ACT is a privately held company and aspects of its work are not publicly available for scrutiny.
- The “Dickey-Wicker” amendment that has been included in the Labor-Health and Human Services-Education Appropriations bill for the past several years, severely limits research and experimentation on human embryos. This has prevented federally funded scientists from doing the long-term studies needed to confirm the safety of the technique.

In January 2008, private company Stemagen announced the first successfully performed technique called somatic cell nuclear transfer (SCNT), otherwise known as therapeutic cloning, on human cells. In SCNT an unfertilized human egg cell (oocyte) is used to develop pluripotent stem cell lines. The genetic material is removed from the egg, and genetic material from a donor is placed in the egg. Scientists are able to induce cellular division and create pluripotent stem cells. These stem cells are a perfect match to the genetic donor and have the potential to be used for a variety of treatments. CAMR fully supports SCNT and joins with the entire scientific and ethics communities in opposing human cloning, also called reproductive cloning.

In conclusion, CAMR supports all ethical research that will help end the suffering of the more than 100 million Americans with diseases and conditions that may someday be treated or even cured through progress in the field of embryonic stem cell research. Embryonic stem cell research remains the most promising avenue of research to cure diseases and end suffering. Other avenues of study, including iPS, are very new and will require years of validation before they can reach the stage of progress we now have with embryonic stem cell research. Too many patients and their families are suffering and we must not abandon the important work done to

date with embryonic stem cell lines. While CAMR supports all ethical research, it is imperative that the Stem Cell Research Enhancement Act (S.5), or similar legislation, be enacted, and the federal barriers to full funding for embryonic stem cell research be removed.

RESOURCE 3: A Catalyst for Cures: Embryonic Stem Cell Research

Full text: http://www.camradvocacy.org/resources/camr_wp.pdf

Accessed: 02/02/2009

On this 10th anniversary of the discovery that hES cells could be grown in culture, top U.S. stem cell scientists reflected on the promises and challenges of research with these extraordinary cells. These reflections lead to the unmistakable conclusion that in order to harvest the full rewards of the scientific successes thus far, the Federal government must resume its traditional role of full partner by lifting the restrictions imposed on Federal funding.

Access to hES cells is crucial to continued progress. These pluripotent cells that can self-renew are an unmatched research tool for understanding the body and what goes wrong in disease. Researchers refer to them as “the gold standard” because these are the cells with the greatest potential for making any cell type in the body. Study of these cells has led to the development of other potential sources of self-renewing cells, such as the reprogramming of adult skin cells to make induced pluripotent stem (iPS) cells. The ability to make iPS cells demonstrates the power of hES cell research to transform science and create new medical opportunities. Researchers will continue to test iPS cells against hES cells to determine their potential and limitations. Continued research on hES cells may reveal other ways to accomplish regenerative medicine, but the paradigm-shifting discoveries come when scientists have access to all avenues of exploration.

Federal restrictions are hindering collaborations and slowing research. Biotech firms that are eager to share cell lines with researchers to speed discoveries are restricted from doing so if those researchers are receiving Federal funding for that research. Seldom does the Federal government decline to fully support research that has such potential to solve major public health problems. Furthermore, the federally approved lines do not represent the diversity in our society, which is a critical part of ensuring that new medicines work for everyone.

Some firms are moving swiftly toward the clinic to test cell therapies in humans. For example, Geron Corporation and scientists from University of California, Irvine, are exploring the challenges of implanting hESC-derived glial cells in patients to repair acute spinal cord injuries. Researchers need the time and support to address safety concerns for using hESC-derived therapies in humans. To explore what happens to cells once they are transplanted, determine how the body reacts, reveal any health risks, and see how the therapy interacts with important medications. Based on hES cell research, scientists see great promise in efforts to improve therapies for diabetes, Parkinson’s disease, macular degeneration, cancer, spinal cord injuries, and heart disease. The time for removal of restrictions, expanded support, and implementation of relevant oversight guidelines is now.

In 1998, researchers imagined that hES cells could be made into any kind of cell in the body. Ten years ago, this was a hope. Today it is fact. Researchers have shown that stem cells from

embryos have the ability to become many of the roughly 210 cell types in the human body. They have coaxed hES cells to form heart cells, dopamine-producing brain cells, motor neurons, bladder tissue, kidney tissue, and others.

Two out of three major, early goals for hES cells have been met:

1. hES cells would be a vehicle for learning about tissue development and about the relationship of tissues and genes. They would lead to the discovery of the genes involved in self-renewal. Those promises have been realized.
2. hES cells would offer a path to new treatments. Now that scientists know how to make heart muscle and dopamine-producing cells, for example, the goals of cell therapies have moved from the theoretical to the concrete. hESC-derived cells are beginning to be used for early toxicity screening and new drug discovery, as well.
3. There would be widespread use and testing of these cells. Restrictive Federal policies severely diminished that expectation.

The scientific community is asking questions it would not have asked if it didn't have access to hES cells. hES cell studies led to the unexpected development of induced pluripotent stem (iPS) cells, adult cells that are reprogrammed to an embryonic stem cell-like state by being forced to express factors important for maintaining pluripotency. Now we even have proof that you can take a fully mature cell and put genes into it and drive it in a different direction. Pancreatic exocrine cells, for example, can be transformed to pancreatic beta cells, the cells that are destroyed in type 1 diabetes. All of these advances are a result of hES cell research. The big revolution in the next 10 years will focus on the ability to make the cell types that get sick and use them for drug discovery, removing the study of disease from people to a Petri dish. This has never been possible before—and it's one of the main reasons the drug pipeline has not been flowing with new, effective drugs.

The rise of serious heart risks from drugs that treat chronic conditions has become a top concern at the U.S. Food and Drug Administration (FDA). A potential solution comes from companies making panels of hES cells—cardiac, liver, kidney—to test new drugs for toxicities before they ever enter testing in patients. Only the most effective and safest candidates would move on to animal studies and later patient testing.

Unpleasant surprises during human studies are the biggest contributor to the cost of bringing a new drug to market. Improving predictive toxicology testing before new drugs are tested in people would have major consequences: "...a 10-percent improvement in predicting failures before clinical trials could save \$100 million in development costs per drug." Currently, predictive toxicology is limited to studies in rodents that are inbred. They don't come in the diversity that humans do. Even among humans, different populations metabolize drugs differently. A series of cells from different hES cell lines or iPS cell lines from humans of different genetic backgrounds would be extremely powerful. In addition, a drug may appear effective in mice, but not work in humans. And, there are drugs that failed in mice, but were effective in humans.

hES cells are an unbeatable research tool to understand the body and what goes wrong in disease.

hES cells offer unprecedented access to the human body. Scientists are using hES cells to grow limitless quantities of various tissues, such as heart muscle cells. It will be a vast improvement over today's studies of the physiology of the human heart, which rely on limited biopsy samples from sick hearts.

Some opposed to hESC research have argued that we don't need hES cells anymore, now that iPS cells have been developed. But if we have learned anything in the history of stem cell research, it is that we have not been very good at predicting which cells are most useful for which applications. To devise new therapies, research must continue with all types of stem cells. If we allow research on hES cells to wither, who knows how many other breakthroughs, like adult cell reprogramming, will go undiscovered. Although iPS cells show great promise, preliminary studies indicate they are not identical to hES cells and may not be as useful for some applications. And there appears to be significant variation between iPS cell lines, probably more so than between human ES cell lines. In terms of safety, iPS cells are much further from the clinic than are ES cells. At present, they are made with genes and viruses that can cause cancer.

Every study of iPS cells requires hES cells for controls and comparisons. These comparisons are crucial for moving the iPS field forward. Researchers must test the safety and efficacy of iPS cells against hES cells. Continued research on hES cells and others may reveal other ways to accomplish regenerative medicine. But we are not there yet.

Finally, and importantly, Federal restrictions on hES cell lines are a social justice issue. The Federal lines do not represent the diversity in our society. If hES cells have the potential to change the future of medicine, our Federal government has imposed restrictions that might lead to minorities being left out of that future. The same Federal government that insists on enrolling diverse patients in any clinical trial to ensure that new medicines work in everyone, insists that researchers do all work on hES cells that are from a small number of sources.

What about adult stem cells? So far, adult stem cells have only successfully been used in a very narrow area: blood system reconstitution, including bone marrow transplant, umbilical cord transplant, and peripheral blood transplant. "The argument that there are 60 to 70 diseases that can be cured with adult stem cells was never credible" says Sean Morrison, University of Michigan.

Somatic cell nuclear transfer (SCNT) is another example of a technology with promise that has faced unexpected challenges. Oocyte availability, for example, has been problematic. Yet, "SCNT is the only known procedure for completely and normally reprogramming a cell," says John Gearhart, University of Pennsylvania. Because SCNT is more efficient than iPS cell technology for reprogramming cells, and can be done without inserting new genes, continued studies of SCNT could help scientists find the linchpin to make reprogramming factors more efficient and effective. SCNT will also provide fundamental insights into how an egg reprograms that will teach a great deal about basic biology.

The bottom line is, all areas of stem cell research should remain open. "It's not our job to guess right now what we will need in the future and how," says Sean Morrison, University of Michigan. "This is a war against disease and it needs to be fought with all weapons." Federal

restrictions are hindering collaborations and slowing research, and they are discouraging young, fresh minds from being able to safely enter an extremely exciting field. U.S. companies are going to foreign researchers for collaborations. In addition, researchers setting up their first lab are less likely to go into a politically controversial field where NIH funding is questionable, when they are under pressure to get grants and achieve tenure.

“Embryonic research is not the unregulated ‘wild west’ of science,” says Sean Morrison. Guidelines for the ethical oversight and ongoing monitoring of stem cell research have been developed by the National Academies and the International Society for Stem Cell Research. Many institutions have already adopted these guidelines, which require each institution conducting stem cell research to have a protocol-by-protocol ethical review of the work by a committee of ethicists, scientists, legal experts, and community members. These so-called ESCRO (Embryonic Stem Cell Research Oversight) committees are focused specifically on the ethical implications of using human embryonic stem cell lines in scientific research. Additional supervision is afforded by other pre-existing federally mandated oversight committees, such as institutional review boards in the case of human subjects research, animal care committees, and committees on biological safety. If Federal policies change, there is already a framework in place to devise Federal guidelines on the use of these materials.

Public opinion strongly favors embryonic stem cell research. Nearly three-quarters (73%) of Americans believe that President Obama should keep his pledge to lift existing Federal restrictions on embryonic stem cell research, according to a national poll conducted for CAMR in January 2009 by Opinion Research Corporation. November 2008’s U.S. election, Michigan voters decided to let scientists derive new human embryonic stem cell lines from embryos donated by couples getting fertility treatments. Michigan had one of the country’s most restrictive laws on embryonic stem cell research and the ballot proposal to loosen restrictions succeeded despite an extremely well-funded opposition campaign. A Colorado measure that would define a fertilized egg as a human being was also defeated.

Scientists need the time and support to overcome safety concerns for using ES cells in patients. There won’t be products for patients unless scientists can devise ways to eliminate risk. Parkinson’s researcher Ole Isacson is sorting stem-cell derived neural cells to remove those that have tumor-cause potential. This isn’t headline-grabbing, but it’s critical science. Researchers need to explore what happens to cells once they are transplanted, determine the immune system’s reaction to the cells, and see if there are cancer risks. Researchers are also studying ES cells, close cousins to cancer cells, to learn how cancer cells replicate. ES cells may be used as a drug target for cancer cells. They may also be used to personalize cancer therapies. Before a cancer patient takes a chemotherapy regimen that is extremely toxic, doctors could take a skin cell from the patient, and through the iPS process, create liver cells and heart cells. The chemotherapy could be tested first on those patient’s “own” cells. A new drug regimen would only be given to the patient after it is clear that the drugs will kill the cancer, not the patient.

In conclusion, in order to harvest the full rewards of the scientific successes thus far, the Federal government must resume its traditional role of full partner by lifting the restrictions imposed on Federal funding for human embryonic stem cell research.

COALITION OF AMERICANS FOR RESEARCH ETHICS

RESOURCE 1: C.A.R.E. Founding Statement

Full text: <http://www.stemcellresearch.org/statement/statement.htm>

Accessed: 02/02/2009

Recent scientific advances in human stem cell research have brought into fresh focus the dignity and status of the human embryo. These advances have prompted a decision by the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to fund stem cell research which is dependent upon the destruction of human embryos. Moreover, the National Bioethics Advisory Commission (NBAC) is calling for a modification of the current ban against federally funded human embryo research in order to permit direct federal funding for the destructive harvesting of stem cells from human embryos. These developments require that the legal, ethical, and scientific issues associated with this research be critically addressed and articulated. Our careful consideration of these issues leads to the conclusion that human stem cell research requiring the destruction of human embryos is objectionable on legal, ethical, and scientific grounds. Moreover, destruction of human embryonic life is unnecessary for medical progress, as alternative methods of obtaining human stem cells and of repairing and regenerating human tissue exist and continue to be developed.

In November 1998, two independent teams of U.S. scientists reported that they had succeeded in isolating and culturing stem cells obtained from human embryos and fetuses. Stem cells are the cells from which all 210 different kinds of tissue in the human body originate. Because many diseases result from the death or dysfunction of a single cell type, scientists believe that the introduction of healthy cells of this type into a patient may restore lost or compromised function. Now that human embryonic stem cells can be isolated and multiplied in the laboratory, some scientists believe that treatments for a variety of diseases—such as diabetes, heart disease, Alzheimer's, and Parkinson's—may be within reach. While we in no way dispute the fact that the ability to treat or heal suffering persons is a great good, we also recognize that not all methods of achieving a desired good are morally or legally justifiable.

One of the great hallmarks of American law has been its solicitous protection of the lives of individuals, especially the vulnerable. Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being. Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being. Likewise, the international structure of human rights law—one of the great achievements of the modern world—is founded on the conviction that when the dignity of one human being is assaulted, all of us are threatened. The duty to protect human life is specifically reflected in the homicide laws of all 50 states. Furthermore, federal law and the laws of many states specifically protect vulnerable human embryos from harmful experimentation. Yet in recently publicized experiments, stem cells have been harvested from human embryos in ways which destroy the embryos.

Despite an existing congressional ban on federally-funded human embryo research, the Department of Health and Human Services (HHS) determined on January 15, 1999 that the government may fund human embryonic stem cell research. The stated rationales behind this

decision are that stem cells are not embryos (which itself may be a debatable point) and that research using cells obtained by destroying human embryos can be divorced from the destruction itself. However, even NBAC denies this latter claim, as is evident by the following statement in its May 6, 1999 Draft Report on Stem Cell Research:

Whereas researchers using fetal tissue are not responsible for the death of the fetus, researchers using stem cells derived from embryos will typically be implicated in the destruction of the embryo. This is true whether or not researchers participate in the derivation of embryonic stem cells. As long as embryos are destroyed as part of the research enterprise, researchers using embryonic stem cells (and those who fund them) will be complicit in the death of embryos.

If the flawed rationales of HHS are accepted, federally-funded researchers may soon be able to experiment on stem cells obtained by destroying embryonic human beings, so long as the act of destruction does not itself receive federal funds. However, the very language of the existing ban prohibits the use of federal funds to support “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death....” Obviously, Congress’ intent here was not merely to prohibit the use of federal funds for embryo destruction, but to prohibit the use of such funds for research dependent in any way upon such destruction. Therefore, the opinion of HHS that human embryonic stem cell research may receive federal funding clearly violates both the language of and intention behind the existing law. Congress and the courts should ensure that the law is properly interpreted and enforced to ban federal funding for research which harms, destroys, or is dependent upon the destruction of human embryos.

It is important to recognize also that research involving human embryos outside the womb—such as embryos produced in the laboratory by in vitro fertilization (IVF) or cloning—has never received federal funding. Initially, this was because a federal regulation of 1975 prevented government funding of IVF experiments unless such experiments were deemed acceptable by an Ethics Advisory Board. This regulation was rescinded by Congress in 1993, and the Human Embryo Research Panel recommended to the National Institutes of Health (NIH) that certain kinds of harmful nontherapeutic experiments using human embryos receive federal funding. However, these recommendations were rejected in part by President Clinton and then rejected in their entirety by Congress. Further, it is instructive to note that the existing law which permits researchers to use fetal tissue obtained from elective abortions requires that the abortions are performed for reasons which are entirely unrelated to the research objectives. This law thus prohibits HHS from promoting the destruction of human life in the name of medical progress, yet medical progress is precisely the motivation and justification offered for the destruction of human life that occurs when stem cells are obtained from human embryos.

Current law against funding research in which human embryos are harmed and destroyed reflects well-established national and international legal and ethical norms against the misuse of any human being for research purposes. Since 1975, those norms have been applied to unborn children at every stage of development in the womb, and since 1995 they have been applied to the human embryo outside the womb as well. The existing law on human embryonic research is a reflection of universally accepted principles governing experiments on human subjects—principles reflected in the Nuremberg Code, the World Medical Association’s Declaration of Helsinki, the United Nations Declaration of Human Rights, and many other statements.

Accordingly, members of the human species who cannot give informed consent for research should not be the subjects of an experiment unless they personally may benefit from it or the experiment carries no significant risk of harming them.

It may strike some as surprising that legal protection of embryonic human beings can co-exist with the U.S. Supreme Court's 1973 legalization of abortion. However, the Supreme Court has never prevented the government from protecting prenatal life outside the abortion context, and public sentiment also seems even more opposed to government funding of embryo experimentation than to the funding of abortion. The laws of a number of states—including Louisiana, Maine, Massachusetts, Michigan, Minnesota, Pennsylvania, Rhode Island, and Utah—specifically protect embryonic human beings outside the womb. Most of these provisions prohibit experiments on embryos outside the womb. We believe that the above legally acknowledged protections against assaults on human dignity must be extended to all human beings—irrespective of gender, race, religion, health, disability, or age. Consequently, the human embryo must not be subject to willful destruction even if the stated motivation is to help others.

The prospect of government-sponsored experiments to manipulate and destroy human embryos should make us all lie awake at night. That some individuals would be destroyed in the name of medical science constitutes a threat to us all. Recent statements claiming that human embryonic stem cell research is too promising to be slowed or prohibited underscore the sort of utopianism and hubris that could blind us to the truth of what we are doing and the harm we could cause to ourselves and others. Human embryos are not mere biological tissues or clusters of cells; they are the tiniest of human beings. Thus, we have a moral responsibility not to deliberately harm them.

An international scientific consensus now recognizes that human embryos are biologically human beings beginning at fertilization, and acknowledges the physical continuity of human growth and development from the one-cell stage forward. Both the Human Embryo Research Panel and the National Bioethics Advisory Commission describe the human embryo from its earliest stages as a living organism and a “developing form of human life.” The claim that an early human embryo becomes a human being only after 14 days or implantation in the womb is therefore a scientific myth.

The last century and a half has been marred by numerous atrocities against vulnerable human beings in the name of progress and medical benefit. In the 19th century, vulnerable human beings were bought and sold in the town square as slaves and bred as though they were animals. In this century, the vulnerable were executed mercilessly and subjected to demeaning experimentation at Dachau and Auschwitz. At mid-century, the vulnerable were subjects of our own government's radiation experiments without their knowledge or consent. Likewise, vulnerable African-Americans in Tuskegee, Alabama were victimized as subjects of a government-sponsored research project to study the effects of syphilis. Currently, we are witness to the gross abuse of mental patients used as subjects in purely experimental research. These experiments were and are driven by a crass utilitarian ethos which results in the creation of a “sub-class” of human beings, allowing the rights of the few to be sacrificed for the sake of potential benefit to the many. These unspeakably cruel and inherently wrong acts against human beings have resulted in the enactment of laws and policies which require the protection of human rights and liberties, including the right to be protected from the tyranny of the quest for scientific

progress. The painful lessons of the past should have taught us that human beings must not be conscripted for research without their permission—no matter what the alleged justification—especially when that research means the forfeiture of their health or lives.

We are aware that a number of Nobel scientists endorse human embryonic stem cell research on the basis that it may offer a great good to those who are suffering. While we acknowledge that the desire to heal people is certainly a laudable goal and understand that many have invested their lives in realizing this goal, we also recognize that we are simply not free to pursue good ends via unethical means. Of all human beings, embryos are the most defenseless against abuse. A policy promoting the use and destruction of human embryos would repeat the failures of the past. The intentional destruction of some human beings for the alleged good of other human beings is wrong. Therefore, on ethical grounds alone, research using stem cells obtained by destroying human embryos is ethically proscribed.

Integral to the decision to use federal funds for research on human embryonic stem cells is the distinction between stem cells and embryos. HHS has stated that federal funds may be used to support human embryonic stem cell research because stem cells are not embryos. A statement issued by the Office of the General Counsel of HHS regarding this decision asserts that “The statutory prohibition on the use of [government] funds...for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. [Moreover, because] pluripotent stem cells do not have the capacity to develop into a human being, [they] cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term.”

Research on human embryonic stem cells is objectionable due to the fact that such research necessitates the prior destruction of human embryos; however, the HHS’s claim that stem cells are not, and cannot develop into, embryos may itself be subject to dispute. Some evidence suggests that stem cells cultured in the laboratory may have a tendency to reaggregate and form an aggregate of cells capable of beginning to develop as an embryo. In 1993, Canadian scientists reported that they successfully produced a live-born mouse from a cluster of mouse stem cells. While it is true that these stem cells had to be wrapped in placenta-like cells in order to implant in a female mouse, it seems that at least some doubt has been cast on the claim that a cluster of stem cells is not embryonic in nature.

If embryonic stem cells do indeed possess the ability to form or develop as a human embryo (without any process of activation which affects the transformation of the cell into a human embryo), research on such stem cells could itself involve the creation and/or destruction of human life and would thereby certainly fall under the existing ban on federally-funded embryo research. It would be irresponsible for the HHS to conduct and condone human embryonic stem cell research without first discerning the status of these cells. Their use in any research in which they could be converted into human embryos should likewise be banned.

While proponents of human embryonic stem cell research lobby aggressively for government funding of research requiring the destruction of human embryos, alternative methods for repairing and regenerating human tissue render such an approach unnecessary for medical progress. For instance, a promising source of more mature stem cells for the treatment of disease

is hematopoietic (blood cell-producing) stem cells from bone marrow or even from the placenta or umbilical cord blood in live births. These cells are already widely used in cancer treatment and in research on treating leukemia and other diseases. Recent experiments have indicated that their versatility is even greater than once thought. For example, given the right environment, bone marrow cells can be used to regenerate muscle tissue, opening up a whole new avenue of potential therapies for muscular dystrophies. In April 1999, new advances were announced in isolating mesenchymal cells from bone marrow and directing them to form fat, cartilage, and bone tissue. Experts in stem cell research believe that these cells may allow for tissue replacement in patients suffering from cancer, osteoporosis, dental disease, or injury.

An enormously promising new source of more mature stem cells is fetal bone marrow, a source which is many times more effective than adult bone marrow and umbilical cord blood. It appears that fetal bone marrow cells do not provoke immune reactions to the same degree as adult or even newborn infant cells. This is true whether the unborn child is the donor or the recipient—that is, fetal cells can be used to treat adults, or adult bone marrow cells can be used to treat a child in the womb without the usual risk of harmful immune reactions. Such cells would not need to be derived from fetuses who were intentionally aborted, but could instead be obtained from spontaneously aborted fetuses or stillborn infants.

In 1999, unprecedented advances were also made in isolating and culturing neural stem cells from living human nerve tissue and even from adult cadavers. Such advances render it quite possible that treatment of neural diseases such as Parkinson's and Alzheimer's, as well as spinal cord injuries, will not depend upon destructive embryo research.

Earlier claims that embryonic stem cells are uniquely capable of "self-renewal" and indefinite growth can also now be seen as premature. For example, scientists have isolated an enzyme, telomerase, which may allow human tissues to grow almost indefinitely. Although this enzyme has been linked to the development of cancer, researchers have been able to use it in a controlled way to "immortalize" useful tissue without producing cancerous growths or other harmful side effects. Thus, cultures of non-embryonic stem cells may be induced to grow and develop almost indefinitely for clinical use.

One of the most exciting new advances in stem cell research is the January 1999 announcement that Canadian and Italian researchers succeeded in producing new blood cells from neural stem cells taken from an adult mouse. Until recently, it was believed that adult stem cells were capable of producing only a particular type of cell: for example, a neural stem cell could develop only into cells belonging to the nervous system. Researchers believed that only embryonic stem cells retained the capacity to form all kinds of tissue in the human body. However, if stem cells taken from adult patients can produce cells and tissues capable of functioning within entirely different systems, new brain tissue needed to treat a patient with Parkinson's disease, for example, might be generated from blood stem cells derived from the patient's bone marrow. Conversely, neural stem cells might be used to produce needed blood and bone marrow. Use of a patient's own stem cells would circumvent one of the major obstacles posed by the use of embryonic stem cells—namely, the danger that tissue taken from another individual would be rejected when transplanted into a patient. Thus, in commenting on this finding, the *British Medical Journal* remarked on January 30, 1999 that the use of embryonic stem cells "may soon be eclipsed by the more readily

available and less controversial adult stem cells.” Given that the function of the adult stem cells was converted without the cells first having to pass through an embryonic stage, the use of such cells would not be subject to the ethical and legal objections raised by the use of human embryonic stem cells. The Director of the NIH has pointed out that evidence that adult stem cells can take on different functions has emerged only from studies on mice. However, his own claim that human embryonic stem cell research can produce treatments for diabetes and other diseases is also based solely on experimental success in mice.

One approach to tissue regeneration that does not rely on stem cells at all, but on somatic cell gene therapy, is already in use as an experimental treatment. A gene that controls production of growth factors can be injected directly into a patient’s own cells, with the result that new blood vessels will develop. In early trials, this type of therapy saved the legs of patients who would have otherwise undergone amputation. It was reported in January 1999 that the technique has generated new blood vessels in the human heart and improved the condition of 19 out of 20 patients with blocked cardiac blood vessels. Such growth factors are now being explored as a means for growing new organs and tissues of many kinds.

The above recent advances suggest that it is not even necessary to obtain stem cells by destroying human embryos in order to treat disease. A growing number of researchers believe that adult stem cells may soon be used to develop treatments for afflictions such as cancer, immune disorders, orthopedic injuries, congestive heart failure, and degenerative diseases. Such researchers are working to further research on adult, rather than embryonic, stem cells. In light of these promising new scientific advances, we urge Congress to provide federal funding for the development of methods to repair and regenerate human tissue which do not require the destruction of embryonic human life. However, even if such methods do not prove to be as valuable in treating disease as are human embryonic stem cells, use of the latter in the name of medical progress is still neither legally nor ethically justifiable for the reasons stated in this document.

We believe that an examination of the legal, ethical, and scientific issues associated with human embryonic stem cell research leads to the conclusion that the use of federal funds to support any such research that necessitates the destruction of human embryos is, and should remain, prohibited by law. Therefore, we call on Congress to:

- (1) maintain the existing ban against harmful federally-funded human embryo research and make explicit its application to stem cell research requiring the destruction of human embryos and
- (2) provide federal funding for the development of alternative treatments which do not require the destruction of human embryonic life.

RESOUCCE 2: Twelve Lessons About Stem Cell Research

Full text: <http://www.stemcellresearch.org/polisci/index.html>

Accessed: 02/02/2009

Lesson 1: The fountain of youth

- **Political:** “Stem cell research could result in a veritable fountain of youth by replacing diseased or damaged cells” Sen. Arlen Specter, PA, 2005.
- **Science:** “Pluripotent stem cells are hard to rein in. 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” Glenn McGee, U. of Pennsylvania, 2001.
- **Science:** “We think there are advantages to using adult stem cells. For example, with embryonic stem cells, a significant number become cancer cells, so the cure could be worse than the disease” Brian Butcher, Tulane University, 2004.

Lesson 2: Remember not to tell fairy tales about Alzheimer’s

- **Political:** “This issue is especially poignant given President Reagan’s passing. Embryonic stem cell research might hold the key to a cure for Alzheimer’s and other terrible diseases” Sen. Dianne Feinstein, CA, 2004.
- **Science:** “The infrequently voiced reality, stem cell experts confess, is that, of all the diseases that may someday be cured by embryonic stem cell treatments, Alzheimer’s is among the least likely to benefit...Given the lack of any serious suggestion that stem cells themselves have practical potential to treat Alzheimer’s, the Reagan-inspired tidal wave of enthusiasm stands as an example of how easily a modest line of scientific inquiry can grow in the public mind to mythological proportions. It is a distortion that some admit is not being aggressively corrected by scientists ‘To start with, people need a fairy tale,’ said Ronald D.G. McKay, a stem cell researcher at the National Institute of Neurological Disorders and Stroke. ‘Maybe that’s unfair, but they need a story line that’s relatively simple to understand,’” Rick Weiss, “Stem Cells An Unlikely Therapy for Alzheimer’s,” *The Washington Post*, June 10, 2004.

Lesson 3: Pay attention to your own scientists’ results

- **Political:** Explaining why adult and umbilical cord blood stem cells are inferior to embryonic stem cells, Christopher Reeve testified to Congress on April 26, 2000: “Those are cells that have significantly differentiated; that is, they are no longer pluripotent or capable of transforming into other cell types. For the true biological miracles that researchers have only begun to foresee, medical science must turn to undifferentiated stem cells.”
- **Science:** “Pluripotent stem cells have been detected in multiple tissues in the adult, participating in normal replacement and repair, while undergoing self renewal.” - First sentence of a scientific study funded by the Christopher Reeve Paralysis Foundation, submitted for publication March 31, 2000. The authors cite 11 earlier studies in support of this statement, and conclude that mesenchymal stem cells from adult bone marrow would have significant advantages over embryonic stem cells in treating a variety of neurologic diseases.

Lesson 4: The myth of the 400,000 embryos

- **Political:** “There are estimated to be more than 400,000 IVF embryos, which are currently frozen and will likely be destroyed if not donated, with informed consent of the couple, for research,” Letter from 200 House members to President Bush, April 28, 2004.
- **Science:** From the research study that provided the estimate of 400,000 frozen embryos in the U.S.: “Patients have designated only 2.8 percent (about 11,000 embryos) for research. The vast majority of frozen embryos are designated for future attempts at pregnancy. “From those embryos designated for research, perhaps as many as 275 stem cell lines (cell cultures suitable for further development) could be created. The actual number is likely to be much lower,” The RAND Law and Health Initiative, 2003.
- **Science:** In short, over 200 House members based their support for the expanded destruction of human embryos on a factual claim that is 97% false. The frozen embryos potentially available for research are enough for current laboratory research and animal trials – but then, so are the cell samples available under the Bush policy (many of which have not been turned into ongoing cell lines because they are not yet needed). Treatment of any major human disease, however, would require projects in human cloning, or the creation and destruction of vast numbers of new embryos carefully chosen to match the genetic diversity of the population. The myth of the 400,000 embryos is used to mask the fact that the campaign for “spare” embryos is useless in and of itself, and is only a transitional step to a broader agenda.

Lesson 5: Juvenile comments about diabetes

- **Political:** “Stem cell research offers the greatest potential for curing ... diabetes.” Rep. Mark Kirk, IL, 2005.
- **Science:** “Is the use of embryonic stem cells close to being used to provide a supply of islet cells for transplantation into humans?” No. The field of embryonic stem cells faces enormous hurdles to overcome before these cells can be used in humans. The two key challenges to overcome are making the stem cells differentiate into specific viable cells consistently, and controlling against unchecked cell division once transplanted. Solid data of stable, functioning islet cells from embryonic stem cells in animals has not been seen.” Autoimmune Disease Research Foundation, “Q & A,” 2005.

Lesson 6: The hard sell on cell lines

- **Political:** “When Bush announced his Executive Order limiting federal funding to studies on existing stem-cell lines, he declared that private research had produced more than 60 genetically diverse lines that would be eligible. Researchers now say the number is more like 22, and even those are contaminated with mouse DNA, making them ill-suited for use on humans,” quoted from “Why Bush’s Ban Could Be Reversed,” CNN.com, 2005.
- **Science:** This confusion is based on a failure to understand the difference between a cell sample derived from an embryo, and the ongoing *cell line* that may be developed over time from that sample. The Bush policy allows federally funded research on cell lines developed *after* August 9, 2001, as long as the original cells were *derived from an embryo* by that date. Several dozen cell samples remain potentially eligible for federally funded research; the number now available in the form of self-perpetuating *cell lines* is 22 and growing. Many other samples, now in frozen storage, are available for future use if the currently active cell lines deteriorate or become inadequate for basic research. And

many of these “cell lines not yet available for shipping” (the 16 samples now in storage at Göteborg University, for example) were isolated *without* animal feeder cells, and could be cultured on human cell layers now that this technique has been developed.

- **Science:** Ironically, the charges launched against the Bush administration’s cell lines by its critics are far *more* true of the new cell lines those critics insist should receive federal funding. For example, the cell lines created at Harvard last year with private funding from the Juvenile Diabetes Research Foundation soon developed serious genetic abnormalities -- because they were not kept in frozen storage until needed, but were immediately induced to start growing and mutating. C. Cowan et al., “Derivation of Embryonic Stem-Cell Lines from Human Blastocysts,” 350 *New England Journal of Medicine* (2004): 1353-6 at 1355. Recent research suggests that *all* actively developing human embryonic stem cell lines may spontaneously accumulate genetic abnormalities associated with cancer: J. Draper et al., “Recurrent gain of chromosomes 17q and 12 in cultured human embryonic stem cells,” *Nature Biotechnology*, 2003. And *all* of Harvard’s new cell lines are “contaminated” with mouse feeder cells.

Lesson 7: It’s not political hype that will get people walking again.

- **Political:** “If we do the work that we can do in this country, the work that we will do when John Kerry is president, people like Christopher Reeve are going to walk, get up out of that wheelchair and walk again,” Sen. John Edwards, vice-presidential candidate, on embryonic stem cells, 2004.
- **Science:** “It appears though, at the moment, that embryonic stem cells are effective in treating acute injuries and are not able to do much about chronic injuries,” Christopher Reeve, chronic spinal cord injury patient, interview in October 2004 *Reader’s Digest*.
- **Science:** Moreover, adult stem cells from patients’ own nasal cavity (olfactory mucosa) have already been used in Portugal to benefit dozens of chronic spinal cord injury patients – including several Americans who began to walk with braces after years of chronic paralysis. They have told their story in congressional testimony and on the PBS-TV program *Miracle Cell*. Unlike embryonic stem cell research, this approach is not receiving federal funds in the U.S.

Lesson 8: Bloody nonsense

- **Political:** “Well, let me make it very clear about adult stem cells or cord blood. There’s not a researcher of any renown out there whatsoever, who believes that they can do anything more than help with blood related diseases. As a matter of fact 14 of the 15 diseases that people most die from in the United States of America can never be addressed by adult stem cells.” Rep. Michael Castle, DE, 2005.
- **Science:** Adult stem cells “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: The official National Institutes of Health resource for stem cell research,” FAQ.

Lesson 9: Making a difference?

- **Political:** “These extraordinary [embryonic stem] cells can generate a new heart muscle for those who have suffered cardiac damage, and new pancreas cells for diabetics, new brain cells for those with Parkinson's disease,” Sen. Edward Kennedy, MA, 2002.
- **Science:** Human embryonic stem cells do have the ability to form every tissue in the body — when they are left to grow and differentiate as part of an intact human embryo. But in the lab, researchers have not succeeded in turning embryonic stem cells into pure cultures of specific, viable tissue types -- the essential first step if these cells are to have any therapeutic application. Even after 20 years of experience with mouse embryonic stem cells they have been unable to do this. “Scientists know this is a thorny problem,” the *New York Times* reported in 2001, “but their views were not widely heard when the public and politicians seemed to assume that it was easy to grow any tissue type desired from embryonic stem cells. In fact, no one has been able to do this even with mouse cells...The science is not even close,” G. Kolata, “A Thick Line Between Theory and Therapy, as Shown with Mice,” *New York Times*, 2001.

Lesson 10: You can't advance science by denying science

- **Political:** Said on the Senate floor regarding the human embryo: “If in fact it is a human life -- it is not, by the way...” – Sen. Richard Durbin, IL, 2005.
- **Science:** The early embryo is not only “alive” in the sense that all human cells are, but is *a* human life, the first stage in the development of any human being. To deny this, in order to justify destroying human embryos for research, is to deny science to advance an ideology. “Zygote. This cell results from the union of an oocyte and a sperm during fertilization. A zygote is the beginning of a new human being (i.e., an embryo).” Moore, Keith, Persaud, *The Developing Human: Clinically Oriented Embryology*, 2003.
- **Science:** “Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote)... The time of fertilization represents the starting point in the life history, or ontogeny, of the individual.” Carlson, Bruce M. *Patten's Foundations of Embryology*. 6th edition. New York: McGraw-Hill, 1996.

Lesson 11: Not months or days, but decades

- **Political:** “People are dying from diseases and medical conditions that might be cured through embryonic stem-cell research. For these people, every month matters. And every day of delay by the Senate has life-and-death consequences.” Sen. Tom Harkin, IA, 2005.
- **Science:** “Much of the California electorate was sold last year on the idea that human embryonic stem cells might be turned into amazing cures for incurable diseases, propelling Proposition 71 to easy victory in the Nov. 2004 election. Now, it's increasingly clear that stem cell transplants for diabetes or Parkinson's or Alzheimer's are nowhere close, maybe decades away.” Science writer Carl T. Hall, “Stem Cell leaders to talk strategy at conference,” *The San Francisco Chronicle*, Sept. 30, 2005.

Lesson 12: Don't throw away the future

- **Political:** “There are also cord blood stem cells. But the real opportunity for medical advance lies in the flexible embryonic stem cells...” – Sen. Arlen Specter, PA, 2005.
- **Science:** Umbilical cord blood stem cells can now help suffering patients with six dozen illnesses, and show promise in treating many more. Due to a lack of national coordination

and funds for cord blood banking, 4 million samples of cord blood are discarded in hospital nurseries every year – a tragedy that Washington-area Channel 4 News calls “throwing away the future.”

- **Science:** “Writing in the *New England Journal of Medicine*, researchers at Duke University Medical Center reported that infants born with a fatal nerve disorder have been helped -- and perhaps even saved -- by treatment with stem cells taken from the umbilical cords of healthy babies... The target in this case was Krabbe’s disease, a devastating enzyme disorder that prevents the nerve fibers in babies’ brains from developing the myelin insulation they need, leading to blindness, deafness, cognitive deterioration and death before age 2.... ‘Our oldest survivor is 6 1/2,’ says [lead author Dr. Maria] Escolar. ‘She’s now running, jumping and doing well in school,’” “Stem Cells Save Babies,” *TIME*, May 30, 2005..

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

RESOURCE 1: Monitoring the Frontiers of Biomedical Research

Full text: <http://www.aaas.org/spp/sftrl/projects/stem/report.pdf>

Accessed: 02/06/2009

Findings and Recommendations

Human stem cell research holds enormous potential for contributing to our understanding of fundamental human biology. Although it is not possible to predict the outcomes from basic research, such studies will offer the real possibility for treatments and ultimately for cures for many diseases for which adequate therapies do not exist.

The benefits to individuals and to society gained by the introduction of new drugs or medical technologies are difficult to estimate. The introductions of antibiotics and vaccines, for example, have dramatically increased life spans and improved the health of people all over the world. Despite these and other advances in the prevention and treatment of human diseases, devastating illnesses such as heart disease, diabetes, cancer, and diseases of the nervous system such as Alzheimer's disease present continuing challenges to the health and well-being of people everywhere. The science leading to the development of techniques for culturing human stem cells could lead to unprecedented treatments and even cures for these and other diseases.

As with all research, our ability even to contemplate the possibilities offered by stem cell derived therapies is a result of many years of research. The science of stem cells dates to the mid-1960s, and many papers have been published on the isolation and laboratory manipulation of stem cells from animal models. While these models are imperfect, they are accepted in the scientific community as good initial predictors of what occurs in human beings.

There already exists evidence from animal studies that stem cells can be made to differentiate into cells of choice, and that these cells will act properly in their transplanted environment. In human beings, transplants of hematopoietic stem cells (the cells which eventually produce blood) following treatments for cancer, for example, have been done for years now. Further, somewhat cruder experiments (e.g., the transplantation of fetal tissue into the brains of Parkinson's patients) indicate that the expectation that stem cell therapies could provide robust treatments for many human diseases is a reasonable one. It is only through controlled scientific research that the true promise will be understood.

This research raises ethical and policy concerns, but these are not unique to stem cell research.

Innovative research and new technologies derived from such research almost always raise ethical and policy concerns. In biomedical research, these issues include the ethical conduct of basic and clinical research as well as the equitable distribution of new therapies. These issues are relevant to discussions about stem cell research and its eventual applications; however, they are part of a constellation of ethical and policy concerns associated with all advances in biomedical research.

Guidelines or policies for the use of human biological materials have been issued at many levels, from internal review boards to the National Bioethics Advisory Commission, which recently released a detailed report on the use of such materials. Existing policies cover all aspects of research, from the use of cell lines in laboratories, to human subjects protections, that will surface in the consideration of stem cell research.

It is essential that there be a public that is educated and informed about the ethical and policy issues raised by stem cell research and its applications. Informed public discussion of these issues should be based on an understanding of the science associated with stem cell research, and it should involve a broad cross-section of society.

It is essential for citizens to participate in a full and informed manner in public policy deliberations about the development and application of new technologies that are likely to have significant social impact. The understanding of the science is particularly important for discussing ethical and policy issues. Ideally, scientists should communicate the results of their research in ways that will be readily understandable to a diverse audience, and participate in public discussions related to stem cell research. The ethical and policy issues raised by stem cell research are not unique, but this research has received a significant amount of public attention and there is much to gain by open reflection on the implications of this sensitive area of research. Congressional hearings, public meetings by government agencies, and media coverage have pushed stem cell research issues into a spotlight. There should be continued support for the open manner that has allowed all those interested to observe or participate in these processes and for a sustained dialogue among scientists, policy makers, ethicists, theologians, and the public to consider issues that emerge with the advancement of stem cell research.

Existing federal regulatory and professional control mechanisms, combined with informed public dialogue, provide a sufficient framework for oversight of human stem cell research.

The appearance of new technology can evoke apprehension and engender uncertainty among segments of the population about its uses. Where these concerns are related to issues having important ethical and social implications, certain levels of oversight are appropriate. But it is important to create new oversight mechanisms or regulatory burdens only when there are compelling reasons for doing so.

Federal funding would automatically trigger a set of oversight mechanisms now in place to ensure that the conduct of biomedical research is consistent with broad social values and legal requirements. While basic laboratory research with personally non-identifiable stem cells does not pose special ethical or oversight challenges, an elaborate system of review is in place for research involving human subjects, ranging from procurement issues to the conduct of clinical trials. The Federal Common Rule governing human subjects research provides for local and federal agency review of research proposals in such circumstances, weighing risks against benefits and requiring involved and voluntary consent. The Food and Drug Administration (FDA) has the authority to regulate the development and use of human stem cells that will be used as biological products, drugs, or medical devices to diagnose, treat or cure a disease or underlying condition. Further, states should adopt the Federal Government's *Model Program for the Certification of Embryo Laboratories*.

Complementing these regulatory mechanisms are the National Bioethics Advisory Commission (NBAC), which has demonstrated its legitimate claim to respect for its efforts as a national body to promote public input into social policy related to advances in biomedical research, and the Recombinant DNA Advisory Committee (RAC), which currently has a mandate to review the ethical and policy issues associated with gene therapy and could be authorized to change its mission to broaden its purview. These federal bodies should work with interested stakeholders in the conduct of stem cell research—professional organizations, patient disease groups, religious communities, the Congress, funding agencies and private foundations, industry, and others—so that the public can be assured that appropriate safeguards are in place as this research evolves. Thus, at the present time, no new regulatory mechanisms are needed to ensure responsible social and professional control of stem cell research in the United States.

Federal funding for stem cell research is necessary in order to promote investment in this promising line of research, to encourage sound public policy, and to foster public confidence in the conduct of such research.

Realizing the potential health benefits of stem cell technology will require a large and sustained investment in research. The federal government is the only realistic source for such an infusion of funds. For those who are challenged daily by serious diseases that could in the future be relieved by therapies gained through stem cell research, public funding holds the greatest promise for sooner rather than later research results that can be transferred from the bench to the bedside. Without the stimulus of public funding, new treatments could be substantially delayed.

The commitment of federal funds also offers a basis for public review, approval, and monitoring through well established oversight mechanisms that will promote the public's interest in ensuring that stem cell research is conducted in a way that is both scientifically rigorous and ethically proper. Additionally, public funding contributes to sound social policy by increasing the probability that the results of stem cell research will reflect broad social priorities that are unlikely to be considered if the research is carried out in the private sector alone. There are segments of American society that disagree on moral grounds with using public monies to support certain types of stem cell research. However, public policy in a pluralistic society cannot resolve all the differences that arise in national debates on sensitive social issues. In the context of stem cell research, this leads to three practical conclusions. One is a willingness to permit individuals, whether they are researchers or embryo or fetal tissue donors, to act in conformity with their own moral views on these matters. A second is the commitment to public involvement in research support when this research is related to the promotion and protection of public health, including the acquisition of new molecular and cellular insights into basic human developmental biology. A third is respect for opposing views, especially those based on religious grounds, to the extent that this is consistent with the protection and promotion of public health and safety.

Public and private research on human stem cells derived from all sources (embryonic, fetal, and adult) should be conducted in order to contribute to the rapidly advancing and changing scientific understanding of the potential of human stem cells from these various sources.

There are three primary sources of stem cells, each with different characteristics as to how many different developmental paths they can follow and how much they can contribute to our

understanding of a functioning organism. Embryonic stem cells (ES cells), derived from a very early embryo, and embryonic germ cells (EG cells), collected from fetal tissue at a somewhat later stage of development, have particular promise for a wide range of therapeutic applications because, according to our present knowledge, they are capable of giving rise to virtually any cell type. Research on these primordial cells will also provide a unique opportunity to study human cell biology.

Adult stem cells, obtained from mature tissues, differentiate into a narrower range of cell types. As a result, many cells of medical interest cannot currently be obtained from adult-derived stem cells. It is also less feasible to develop large-scale cultures from adult stem cells. However, it is important to note that, at this time, it is only adult human stem cells that are well-enough understood that they can be reliably differentiated into specific tissue types, and that have proceeded to clinical trials. Because the study of human stem cells is at an early stage of development, it is difficult to predict outcomes and findings at this point in time. As more research takes place, the full developmental potential of different kinds of stem cells will become better understood.

In view of the moral concerns surrounding the uses of embryonic and fetal tissue voiced by a segment of the American population, strengthening federally and privately funded research into alternative sources and/or methods for the derivation of stem cells, including further initiatives on adult stem cells, should be encouraged. Human stem cell research can be conducted in a fully ethical manner, but it is true that the extraction of embryonic stem cells from the inner mass of blastocysts raises ethical questions for those who consider the intentional loss of embryonic life by intentional means to be morally wrong. Likewise, the derivation of embryonic germ cells from the gonadal tissue of aborted fetuses is problematic for those who oppose abortion. In contrast, adult stem cell research is more broadly acceptable to the American population.

Public funding should be provided for embryonic stem cell and embryonic germ cell research, but not at this time for activities involved in the isolation of embryonic stem cells, about which there remains continuing debate. This approach will allow publicly-funded researchers to move more quickly toward discoveries that will lead to alleviating the suffering caused by human disease.

Although the derivation of human stem cells can be done in an ethical manner, there is enough objection to the process of deriving stem cells to consider recommending against its public funding. Further, for the foreseeable future there will be sufficient material isolated by researchers not using public funding that this exclusion will not have a negative impact on research.

There are many individuals who believe that any use of human embryos other than for achieving a pregnancy is unethical, believing that the embryo is a full human being from the earliest moments in the conception process. However, many religious traditions take a “developmental” view of personhood, believing that the early embryo or fetus only gradually becomes a full human being and thus may not be entitled to the same moral protections as it will later; others hold that while the embryo represents human life, that life may be taken for the sake of saving and preserving other lives in the future. The dialogue about these issues is ongoing in the United

States, but these concerns need not exclude publicly-funded research activities on cell lines that have already been established.

Embryonic stem cells should be obtained from embryos remaining from infertility procedures after the embryo's progenitors have made a decision that they do not wish to preserve them. This decision should be explicitly renewed prior to securing the progenitors' consent to use the embryos in ES cell research.

The most ethical source of human primordial stem cells is embryos produced for the process of in vitro fertilization whose progenitors have decided not to implant them and have given full and informed consent for the use of these embryos for research purposes. Two appropriate potential sources of donation are embryos with poor quality that makes them inappropriate for transfer and embryos remaining when couples have definitely completed their family and do not wish to donate the excess embryos to others. Informed consent requires that the woman or couple, with substantial understanding and without controlling influences, authorize the use of their spare embryos for research purposes. Because assisted reproduction can be a stressful process, informed consent should be secured in two stages. The two-stage process would also maintain a separation between personnel working with the woman or couple who hope to get pregnant and personnel requesting embryos for stem cell research.

At the beginning of the process, personnel working with the woman or couple who hope to become pregnant should ascertain their preferences as to the future of embryos remaining after the assisted reproduction process. These options should include consent for embryo donation to another couple, consent for donation for research, and consent for destruction of the spare embryos. Once a couple has definitely decided that it has completed its family, then the couple should be approached a second time to secure an explicit consent to use the embryos in ES cell research.

Persons considering donating their excess embryos for research purposes should be afforded the highest standards of protection for the informed consent and voluntariness of their decision.

Securing embryos for the purpose of harvesting stem cells must proceed in a careful fashion for several reasons. These are to protect the interests of the gamete donors, to reassure the public that important boundaries are not being overstepped, to enable those who are ethically uncomfortable with elements of this research to participate to the greatest extent possible, and to ensure the highest quality of research and outcomes possible. Consonant with good research practice, policies on the procurement of embryos should include at least the following points: (1) Women should not undergo extra cycles of ovulation and retrieval in order to produce more "spare" embryos in the hope that some of them might eventually be donated for research; (2) Analogous with our current practice for organ donation, there should be a solid "wall" between personnel working with the woman or couple who hope to get pregnant, and personnel requesting embryos for stem cell purposes; (3) Women and men, as individuals or as couples, should not be paid to produce embryos, nor should they receive reduced fees for their infertility procedures for doing so; and (4) Consent of both gamete donors should be obtained.

Where appropriate, guidelines that can attract professional and public support for conducting stem cell research should be developed.

At present, stem cell research raises no unique ethical or policy issues. As research advances issues may emerge that challenge acceptable ethical practices and public policy. Hence, there should be opportunities for public reconsideration of the need for guidelines specifically targeted to human stem cell research. Such efforts should be informed by the most current scientific evidence and should occur through a process that encourages broad involvement by all sectors of society.

Almost two decades of experience with the Recombinant DNA Advisory Committee's (RAC) oversight of recombinant DNA research suggest that the RAC could be an effective institutional focal point within the federal government to facilitate the type of public dialogue on stem cell research proposed here, and to coordinate efforts to develop new guidelines, where needed. The RAC has a proven track record of providing an open forum for sorting out complex ethical issues and of defusing conflict. Furthermore, it has acquired a degree of legitimacy among scientists in both the public and private sectors, with its widely accepted *Points to Consider* in the design and conduct of gene therapy.

In order to allow persons who hold diverse moral positions on the status of the early embryo to participate in stem cell research to the greatest degree possible without compromising their principles, and also to foster sound science, stem cells (and stem cell lines) should be identified with respect to their original source.

Patients and researchers should be able to avoid participating in stem cell use if the cells were derived in a way that they would consider to be unethical. As a matter of good scientific practice, records are routinely maintained on the sources of biological materials. It is of utmost importance that documentation of the original source of the stem cells can be made readily available to researchers and to potential recipients of stem cell therapies.

Special efforts should be made to promote equitable access to the benefits of stem cell research.

The therapeutic potential for treating and possibly curing many serious diseases constitutes a major rationale for large-scale investments of public and private resources in human stem cell research. To justify funding stem cell research on the basis of its potential benefits, particularly the use of public resources, however, requires some assurance that people in need will have access to the therapies as they become available. Several factors make it unlikely that there will be equitable access to the benefits of this research. Unlike other western democracies, the United States does not have a commitment to universal health care. More than 44 million people lack health insurance and therefore do not have reliable access even to basic health care. Others are underinsured. Moreover, if stem cell research were to result in highly technological and expensive therapies, health insurers might be reluctant to fund such treatments. Overcoming these hurdles and assuring equitable access to the benefits of stem cell research in this country will be a politically and financially challenging task. It is therefore appropriate to begin considering how to do so now in advance of the development of applications. The federal government should consider ways to achieve equitable access to the benefits derived from stem cell research.

Intellectual property regimes for stem cell research should set conditions that do not restrict basic research or encumber future product development.

The U.S. Patent and Trademark Office (PTO) has already stated that purified and isolated stem cell products and research tools meet the criteria for patentable subject matter. When research is funded by the private sector, as is currently the case with stem cell research, and is patented, it is a private matter whether and under what terms new intellectual property is obtainable for research purposes or development. This is of particular concern because the private sector will not invest resources in potential applications that they consider to lack commercial value, but that may have considerable therapeutic promise.

Given the promise of stem cell research, it is important to encourage the development of broadly beneficial therapeutic products with widespread access. This objective could be achieved in a variety of ways. Government investment in promising areas of research would enable federal agencies and laboratories to hold patents and to exercise them in ways that enhance development and contribute to the dissemination of this stem cell technology. Congress or the PTO should define a strong research exemption that would give third parties access to stem cell products and research tools for research purposes without having to obtain permission from the patent holder. Another possibility is to require compulsory licensing under limited and clearly defined circumstances.

The formation of company-based, independent ethics advisory boards should be encouraged in the private sector.

Private sector research has played a crucial part in the advancement of research on stem cells. The leadership exhibited by the company that has sponsored all of the published human embryonic and germ cell research to date in establishing an external Ethics Advisory Board to develop guidelines for the ethical conduct of such research is laudable. While these private sector boards are not a substitute for public oversight and guidance, they can be a positive influence on the way that industry-funded stem cell research proceeds.

The credibility and impact of such ethics advisory boards will be enhanced if they review ethical issues at the start-up phase of the research, have multidisciplinary membership, including representatives from the local community, give minimum, if any, financial compensation for service, and share their own findings and recommendations with other companies. The latter provision could be especially helpful in developing a “case law” in the private sphere that would inform public efforts to develop national guidelines.

Resource 2: AAAS Asked President Bush to Reconsider Veto

Full text: http://www.aaas.org/spp/cstc/docs/07_06_07stem_pres.pdf

Accessed: 02/06/2009

The Honorable George W. Bush
President of the United States
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

June 7, 2007

Dear Mr. President:

Once again, the U.S. Congress has voted to support the Stem Cell Research Enhancement Act, which would expand federal support for embryonic stem cell research. And once again, we hope that you will consider this measure with an open mind and open heart and then sign it into law.

Like the majority of the American people, the American Association for the Advancement of Science (AAAS), the world's largest general scientific society, recognizes the great potential in human embryonic stem cell research. The scientific consensus is that embryonic stem cell research is an extremely promising field of research that may lead to the development of more effective treatments for devastating conditions like diabetes, spinal cord injuries, and Parkinson's disease.

We believe all avenues of stem cell research should be explored. But the science is still young. Recent developments in alternative methods do not change the fact that stem cells derived from early-stage human embryos appear to hold great therapeutic promise. This bill would allow, under strict ethical guidelines, the use of cell lines derived from the embryos left over from *in vitro* fertilization techniques. There are some 400,000 such embryos in clinics around the country, many of which will be discarded. It would serve a high moral purpose for the federal government to take full advantage of their availability for research to help improve and save lives.

We see the Stem Cell Research Enhancement Act as an affirmation of life and the potential of scientific and medical research to improve the human condition. We stand with a broad coalition of Americans that spans all parties and faiths who urge you to approve this bill in the interest of alleviating suffering and advancing human progress.

Sincerely,

(signed)

Alan I. Leshner

Resource 3: AAAS Urges Senate Support for Expanding Federally Funded Stem Cell Research

Full text: http://www.aaas.org/spp/cstc/docs/07_04_09stemcell.pdf

Accessed: 02/06/2009

The Honorable Harry Reid
United States Senate
Washington, DC 20510

April 9, 2007

Dear Senator Reid,

On behalf of the American Association for the Advancement of Science (AAAS), we urge your support for S. 5, which would expand the current federal policy to permit researchers to gain greater access to new embryonic stem cell lines, when the Senate once again debates the subject of human embryonic stem cell research.

The scientific consensus is that embryonic stem cell research is an extremely promising field of research that may lead to the development of more effective treatments for devastating conditions like diabetes, spinal cord injuries, and Parkinson's disease.

Last year AAAS testified before the Senate Labor-HHS Appropriations Subcommittee on emerging techniques proposed as alternatives to human embryonic stem cells. These new approaches are still in the early stages of development and are already eligible for NIH funding, thus S. 30 is not a substitute for S. 5. AAAS strongly believes that it is only through federal support of diverse avenues of stem cell research that we may better understand the potential value and limitations of each approach, and S. 5 is the best bill to help scientists achieve this goal.

AAAS, the world's largest multi-disciplinary science society, representing the interests of ten million scientists worldwide, and publisher of the prestigious peer-reviewed journal *Science*, has a longstanding interest and expertise in stem cell research. We issued recommendations in 1999 for the ethical conduct of stem cell science and continue to work to provide resources to Congress, scientists, and the public on this important topic.

AAAS stands ready to work with you and the U.S. Congress in addressing this complex subject. If you have any questions, please do not hesitate to contact me.

Sincerely,

(signed)

Alan I. Leshner

CENTER FOR BIOETHICS AND HUMAN DIGNITY

Resource 1: Stem Cell Research Overview

Full text: <http://www.cbhd.org/resources/stemcells/overview.htm>

Accessed: 02/06/2009

In November of 1998, scientists reported that they had successfully isolated and cultured human embryonic stem cells—a feat which had eluded researchers for almost two decades. This announcement kicked off an intense and unrelenting debate between those who approve of embryonic stem cell research and those who are opposed to it. Some of the most prominent advocates of the research are scientists and patients who believe that embryonic stem cell research will lead to the development of treatments and cures for some of humanity's most pernicious afflictions (such as Alzheimer's disease, Parkinson's disease, heart disease, and diabetes). Among the most vocal opponents of the research are those who share the desire to heal, but who object to the pursuit of healing via unethical means. CBHD's view is that because human embryonic stem cell research necessitates the destruction of human embryos, such research is unethical—regardless of its alleged benefits. Ethical alternatives for achieving those benefits should be actively pursued.

What are human embryonic stem cells and how are they obtained?

Human embryonic stem cells are the cells from which all 200+ kinds of tissue in the human body originate. Typically, they are derived from human embryos—often those from fertility clinics who are left over from assisted reproduction attempts (e.g., in vitro fertilization). When stem cells are obtained from living human embryos, the harvesting of such cells necessitates destruction of the embryos.

How are adult stem cells different from embryonic stem cells?

Adult stem cells (also referred to as “non-embryonic” stem cells) are present in adults, children, infants, placentas, umbilical cords, and cadavers. Obtaining stem cells from these sources does not result in certain harm to a human being.

Is it ethical to obtain stem cells from human fetuses and umbilical cords?

Fetal stem cell research may ethically resemble either adult or embryonic stem cell research and must be evaluated accordingly. If fetal stem cells are obtained from miscarried or stillborn fetuses, or if it is possible to remove them from fetuses still alive in the womb without harming the fetuses, then no harm is done to the donor and such fetal stem cell research is ethical. However, if the abortion of fetuses is the means by which fetal stem cells are obtained, then an unethical means (the killing of human beings) is involved. Since umbilical cords are detached from infants at birth, umbilical cord blood is an ethical source of stem cells.

Have scientists been successful in using non-embryonic stem cells to treat disease?

Yes. In contrast to research on embryonic stem cells, non-embryonic stem cell research has already resulted in numerous instances of actual clinical benefit to patients. For example, patients suffering from a whole host of afflictions—including (but not limited to) Parkinson’s disease, autoimmune diseases, stroke, anemia, cancer, immunodeficiency, corneal damage, blood and liver diseases, heart attack, and diabetes—have experienced improved function following administration of therapies derived from adult or umbilical cord blood stem cells. The long-held belief that non-embryonic stem cells are less able to differentiate into multiple cell types or be sustained in the laboratory over an extended period of time—rendering them less medically-promising than embryonic stem cells—has been repeatedly challenged by experimental results that have suggested otherwise. (For updates on experimental results, access www.stemcellresearch.org.)

Have scientists been successful in using embryonic stem cells to treat disease?

Though embryonic stem cells have been purported as holding great medical promise, reports of actual clinical success have been few. Instead, scientists conducting research on embryonic stem cells have encountered significant obstacles—including tumor formation, unstable gene expression, and an inability to stimulate the cells to form the desired type of tissue. It may indeed be telling that some biotechnology companies have chosen not to invest financially in embryonic stem cell research and some scientists have elected to focus their research exclusively on non-embryonic stem cell research.

What is the relationship between embryonic stem cell research and "therapeutic" cloning?

Another potential obstacle encountered by researchers engaging in embryonic stem cell research is the possibility that embryonic stem cells would not be immunologically compatible with patients and would therefore be “rejected,” much like a non-compatible kidney would be rejected. A proposed solution to this problem is to create an embryonic clone of a patient and subsequently destroy the clone in order to harvest his or her stem cells. Cloning for this purpose has been termed “therapeutic” cloning—despite the fact that the subject of the research—the clone—is not healed but killed.

Why should we value the human embryo?

Underlying the passages of Scripture that refer to the unborn (Job 31:15; Ps. 139:13-16; Lk. 1:35-45) is the assumption that they are human beings who are created, known, and uniquely valued by God. Genesis 9:6 warns us against killing our fellow human beings, who are created in the very image of God (Gen. 1:26-27). Furthermore, human embryonic life—as well as all of creation—exists primarily for God’s own pleasure and purpose, not ours (Col. 1:16).

8. Shouldn't it be ethical to allow the destruction of a few embryos in order to help the millions of people who suffer from diseases such as Parkinson's and heart disease?

Many proponents of human embryonic stem cell research argue that it is actually wrong to protect the lives of a few unborn human beings if doing so will delay treatment for a much larger number of people who suffer from fatal or debilitating diseases. However, we are not free to

pursue gain (financial, health-related, or otherwise) through immoral or unethical means such as the taking of innocent life (Deut. 27:25). The history of medical experimentation is filled with horrific examples of evil done in the name of science. We must not sacrifice one class of human beings (the embryonic) to benefit another (those suffering from serious illness). Scripture resoundingly rejects the temptation to “do evil that good may result” (Rom. 3:8).

What does the law say and can I have a voice?

No forms of stem cell research or cloning are prohibited by federal law, though some states have passed partial bans. Private funds can support any practice that is legal, whereas federal funds cannot be used for research on embryonic stem cell lines unless they existed before August 9, 2001. You can object to all forms of human cloning and research that destroys human embryos, as well as encourage adult stem cell research, by writing, telephoning, or emailing your U.S. Senators and Representatives. Contact information for Congress is available at www.senate.gov or www.house.gov, and through the Capitol switchboard at (202) 224-3121. Also contact your state legislators. You can stay informed via the web sites www.cbhd.org and the CBHD-maintained stem cell web site: www.stemcellresearch.org.

Resource 2: Position Statement

Full text: http://www.cbhd.org/resources/stemcells/position_statement.htm

Accessed: 02/06/2009

Recent scientific advances in human stem cell research have brought into fresh focus the dignity and status of the human embryo. These advances have prompted a decision by the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to fund stem cell research which is dependent upon the destruction of human embryos. Moreover, the National Bioethics Advisory Commission (NBAC) is calling for a modification of the current ban against federally funded human embryo research in order to permit direct federal funding for the destructive harvesting of stem cells from human embryos. These developments require that the legal, ethical, and scientific issues associated with this research be critically addressed and articulated. Our careful consideration of these issues leads to the conclusion that human stem cell research requiring the destruction of human embryos is objectionable on legal, ethical, and scientific grounds. Moreover, destruction of human embryonic life is unnecessary for medical progress, as alternative methods of obtaining human stem cells and of repairing and regenerating human tissue exist and continue to be developed.

Human Embryonic Stem Cell Research Violates Existing Law & Policy

In November 1998, two independent teams of U.S. scientists reported that they had succeeded in isolating and culturing stem cells obtained from human embryos and fetuses. Stem cells are the cells from which all 210 different kinds of tissue in the human body originate. Because many diseases result from the death or dysfunction of a single cell type, scientists believe that the introduction of healthy cells of this type into a patient may restore lost or compromised function.

Now that human embryonic stem cells can be isolated and multiplied in the laboratory, some scientists believe that treatments for a variety of diseases-such as diabetes, heart disease, Alzheimer's, and Parkinson's-may be within reach. While we in no way dispute the fact that the ability to treat or heal suffering persons is a great good, we also recognize that not all methods of achieving a desired good are morally or legally justifiable. If this were not so, the medically accepted and legally required practices of informed consent and of seeking to do no harm to the patient could be ignored whenever some "greater good" seems achievable.

One of the great hallmarks of American law has been its solicitous protection of the lives of individuals, especially the vulnerable.⁸ Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being.⁹ Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being. Likewise, the international structure of human rights law-one of the great achievements of the modern world-is founded on the conviction that when the dignity of one human being is assaulted, all of us are threatened. The duty to protect human life is specifically reflected in the homicide laws of all 50 states. Furthermore, federal law and the laws of many states specifically protect vulnerable human embryos from harmful experimentation. Yet in recently publicized experiments, stem cells have been harvested from human embryos in ways which destroy the embryos.

Despite an existing congressional ban on federally-funded human embryo research, the Department of Health and Human Services (HHS) determined on January 15, 1999 that the government may fund human embryonic stem cell research. The stated rationales behind this decision are that stem cells are not embryos (which itself may be a debatable point) and that research using cells obtained by destroying human embryos can be divorced from the destruction itself. However, even NBAC denies this latter claim, as is evident by the following statement in its May 6, 1999 Draft Report on Stem Cell Research:

Whereas researchers using fetal tissue are not responsible for the death of the fetus, researchers using stem cells derived from embryos will typically be implicated in the destruction of the embryo. This is true whether or not researchers participate in the derivation of embryonic stem cells. As long as embryos are destroyed as part of the research enterprise, researchers using embryonic stem cells (and those who fund them) will be complicit in the death of embryos.

If the flawed rationales of HHS are accepted, federally-funded researchers may soon be able to experiment on stem cells obtained by destroying embryonic human beings, so long as the act of destruction does not itself receive federal funds. However, the very language of the existing ban prohibits the use of federal funds to support "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death...."¹⁸ Obviously, Congress' intent here was not merely to prohibit the use of federal funds for embryo destruction, but to prohibit the use of such funds for research dependent in any way upon such destruction. Therefore, the opinion of HHS that human embryonic stem cell research may receive federal funding clearly violates both the language of and intention behind the existing law. Congress and the courts should ensure that the law is properly interpreted and enforced to ban federal funding for research which harms, destroys, or is dependent upon the destruction of human embryos.

It is important to recognize also that research involving human embryos outside the womb—such as embryos produced in the laboratory by in vitro fertilization (IVF) or cloning—has never received federal funding. Initially, this was because a federal regulation of 1975 prevented government funding of IVF experiments unless such experiments were deemed acceptable by an Ethics Advisory Board. Following the failure of the first advisory board to reach a consensus on the matter, no administration chose to appoint a new board. After this regulation was rescinded by Congress in 1993, the Human Embryo Research Panel recommended to the National Institutes of Health (NIH) that certain kinds of harmful nontherapeutic experiments using human embryos receive federal funding. However, these recommendations were rejected in part by President Clinton and then rejected in their entirety by Congress.

Further, it is instructive to note that the existing law which permits researchers to use fetal tissue obtained from elective abortions requires that the abortions are performed for reasons which are entirely unrelated to the research objectives. This law thus prohibits HHS from promoting the destruction of human life in the name of medical progress, yet medical progress is precisely the motivation and justification offered for the destruction of human life that occurs when stem cells are obtained from human embryos.

Current law against funding research in which human embryos are harmed and destroyed reflects well-established national and international legal and ethical norms against the misuse of any human being for research purposes. Since 1975, those norms have been applied to unborn children at every stage of development in the womb, and since 1995 they have been applied to the human embryo outside the womb as well. The existing law on human embryonic research is a reflection of universally accepted principles governing experiments on human subjects—principles reflected in the Nuremberg Code, the World Medical Association's Declaration of Helsinki, the United Nations Declaration of Human Rights, and many other statements. Accordingly, members of the human species who cannot give informed consent for research should not be the subjects of an experiment unless they personally may benefit from it or the experiment carries no significant risk of harming them. Only by upholding such research principles do we prevent treating people as things—as mere means to obtaining knowledge or benefits for others.

It may strike some as surprising that legal protection of embryonic human beings can co-exist with the U.S. Supreme Court's 1973 legalization of abortion.²⁹ However, the Supreme Court has never prevented the government from protecting prenatal life outside the abortion context, and public sentiment also seems even more opposed to government funding of embryo experimentation than to the funding of abortion. The laws of a number of states—including Louisiana, Maine, Massachusetts, Michigan, Minnesota, Pennsylvania, Rhode Island, and Utah—specifically protect embryonic human beings outside the womb. Most of these provisions prohibit experiments on embryos outside the womb. We believe that the above legally acknowledged protections against assaults on human dignity must be extended to all human beings—irrespective of gender, race, religion, health, disability, or age. Consequently, the human embryo must not be subject to willful destruction even if the stated motivation is to help others. Therefore, on existing legal grounds alone, research using stem cells derived from the destruction of early human embryos is proscribed.

Human Embryonic Stem Cell Research Is Unethical

The HHS decision and the recommendations of NBAC to federally fund research involving the destruction of human embryos would be profoundly disturbing even if this research could result in great scientific and medical gain. The prospect of government-sponsored experiments to manipulate and destroy human embryos should make us all lie awake at night. That some individuals would be destroyed in the name of medical science constitutes a threat to us all. Recent statements claiming that human embryonic stem cell research is too promising to be slowed or prohibited underscore the sort of utopianism and hubris that could blind us to the truth of what we are doing and the harm we could cause to ourselves and others. Human embryos are not mere biological tissues or clusters of cells; they are the tiniest of human beings. Thus, we have a moral responsibility not to deliberately harm them.

An international scientific consensus now recognizes that human embryos are biologically human beings beginning at fertilization, and acknowledges the physical continuity of human growth and development from the one-cell stage forward. In the 1970s and 1980s, some frog and mouse embryologists referred to the human embryo in its first week or two of development as a "pre-embryo," claiming that it deserved less respect than embryos in later stages of development. However, some embryology textbooks now openly refer to the term "pre-embryo" as a scientifically invalid and "inaccurate" term which has been "discarded" and others which once used the term have quietly dropped it from new editions. Both the Human Embryo Research Panel and the National Bioethics Advisory Commission have also rejected the term, describing the human embryo from its earliest stages as a living organism and a "developing form of human life." The claim that an early human embryo becomes a human being only after 14 days or implantation in the womb is therefore a scientific myth. Finally, the historic and well-respected 1995 Ramsey Colloquium statement on embryo research acknowledges that:

The [embryo] is human; it will not articulate itself into some other kind of animal. Any being that is human is a human being. If it is objected that, at five days or fifteen days, the embryo does not look like a human being, it must be pointed out that this is precisely what a human being looks like--and what each of us looked like--at five or fifteen days of development.

Therefore, the term "pre-embryo," and all that it implies, is scientifically invalid.

The last century and a half has been marred by numerous atrocities against vulnerable human beings in the name of progress and medical benefit. In the 19th century, vulnerable human beings were bought and sold in the town square as slaves and bred as though they were animals. In this century, the vulnerable were executed mercilessly and subjected to demeaning experimentation at Dachau and Auschwitz. At mid-century, the vulnerable were subjects of our own government's radiation experiments without their knowledge or consent. Likewise, vulnerable African-Americans in Tuskegee, Alabama were victimized as subjects of a government-sponsored research project to study the effects of syphilis. Currently, we are witness to the gross abuse of mental patients used as subjects in purely experimental research. These experiments were and are driven by a crass utilitarian ethos which results in the creation of a "sub-class" of human beings, allowing the rights of the few to be sacrificed for the sake of potential benefit to the many. These unspeakably cruel and inherently wrong acts against human beings have resulted in the enactment of laws and policies which require the protection of human

rights and liberties, including the right to be protected from the tyranny of the quest for scientific progress. The painful lessons of the past should have taught us that human beings must not be conscripted for research without their permission-no matter what the alleged justification-especially when that research means the forfeiture of their health or lives. Even if an individual's death is believed to be otherwise imminent, we still do not have a license to engage in lethal experimentation-just as we may not experiment on death row prisoners or harvest their organs without their consent.

We are aware that a number of Nobel scientists endorse human embryonic stem cell research on the basis that it may offer a great good to those who are suffering. While we acknowledge that the desire to heal people is certainly a laudable goal and understand that many have invested their lives in realizing this goal, we also recognize that we are simply not free to pursue good ends via unethical means. Of all human beings, embryos are the most defenseless against abuse. A policy promoting the use and destruction of human embryos would repeat the failures of the past. The intentional destruction of some human beings for the alleged good of other human beings is wrong. Therefore, on ethical grounds alone, research using stem cells obtained by destroying human embryos is ethically proscribed.

Human Embryonic Stem Cell Research Is Scientifically Questionable

Integral to the decision to use federal funds for research on human embryonic stem cells is the distinction between stem cells and embryos. HHS has stated that federal funds may be used to support human embryonic stem cell research because stem cells are not embryos. A statement issued by the Office of the General Counsel of HHS regarding this decision asserts that "The statutory prohibition on the use of [government] funds...for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. [Moreover, because] pluripotent stem cells do not have the capacity to develop into a human being, [they] cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term."

It is important to note that the materials used in an experiment, as well as the methods of experimentation, are considered to be part of scientific research. When a scientific study is published, the first part of the article details the methods and materials used to conduct the research. Ethical and scientific evaluation of an experiment takes into account both the methods and materials used in the research process. Therefore, the source of stem cells obtained for research is both a scientifically and ethically relevant consideration.

Research on human embryonic stem cells is objectionable due to the fact that such research necessitates the prior destruction of human embryos; however, the HHS's claim that stem cells are not, and cannot develop into, embryos may itself be subject to dispute. Some evidence suggests that stem cells cultured in the laboratory may have a tendency to reaggregate and form an aggregate of cells capable of beginning to develop as an embryo. In 1993, Canadian scientists reported that they successfully produced a live-born mouse from a cluster of mouse stem cells. While it is true that these stem cells had to be wrapped in placenta-like cells in order to implant in a female mouse, it seems that at least some doubt has been cast on the claim that a cluster of stem cells is not embryonic in nature. If embryonic stem cells do indeed possess the ability to

form or develop as a human embryo (without any process of activation which affects the transformation of the cell into a human embryo), research on such stem cells could itself involve the creation and/or destruction of human life and would thereby certainly fall under the existing ban on federally-funded embryo research. It would be irresponsible for the HHS to conduct and condone human embryonic stem cell research without first discerning the status of these cells. Their use in any research in which they could be converted into human embryos should likewise be banned.

Methods of Repairing and Regenerating Human Tissue Exist Which Do Not Require the Destruction of Human Embryos

While proponents of human embryonic stem cell research lobby aggressively for government funding of research requiring the destruction of human embryos, alternative methods for repairing and regenerating human tissue render such an approach unnecessary for medical progress.

For instance, a promising source of more mature stem cells for the treatment of disease is hematopoietic (blood cell-producing) stem cells from bone marrow or even from the placenta or umbilical cord blood in live births. These cells are already widely used in cancer treatment and in research on treating leukemia and other diseases. Recent experiments have indicated that their versatility is even greater than once thought. For example, given the right environment, bone marrow cells can be used to regenerate muscle tissue, opening up a whole new avenue of potential therapies for muscular dystrophies. In April 1999, new advances were announced in isolating mesenchymal cells from bone marrow and directing them to form fat, cartilage, and bone tissue. Experts in stem cell research believe that these cells may allow for tissue replacement in patients suffering from cancer, osteoporosis, dental disease, or injury.

An enormously promising new source of more mature stem cells is fetal bone marrow, a source which is many times more effective than adult bone marrow and umbilical cord blood. It appears that fetal bone marrow cells do not provoke immune reactions to the same degree as adult or even newborn infant cells. This is true whether the unborn child is the donor or the recipient—that is, fetal cells can be used to treat adults, or adult bone marrow cells can be used to treat a child in the womb without the usual risk of harmful immune reactions. Such cells would not need to be derived from fetuses who were intentionally aborted, but could instead be obtained from spontaneously aborted fetuses or stillborn infants.

In 1999, unprecedented advances were also made in isolating and culturing neural stem cells from living human nerve tissue and even from adult cadavers. Such advances render it quite possible that treatment of neural diseases such as Parkinson's and Alzheimer's, as well as spinal cord injuries, will not depend upon destructive embryo research.

Earlier claims that embryonic stem cells are uniquely capable of "self-renewal" and indefinite growth can also now be seen as premature. For example, scientists have isolated an enzyme, telomerase, which may allow human tissues to grow almost indefinitely. Although this enzyme has been linked to the development of cancer, researchers have been able to use it in a controlled way to "immortalize" useful tissue without producing cancerous growths or other harmful side

effects. Thus, cultures of non-embryonic stem cells may be induced to grow and develop almost indefinitely for clinical use.

One of the most exciting new advances in stem cell research is the January 1999 announcement that Canadian and Italian researchers succeeded in producing new blood cells from neural stem cells taken from an adult mouse. Until recently, it was believed that adult stem cells were capable of producing only a particular type of cell: for example, a neural stem cell could develop only into cells belonging to the nervous system. Researchers believed that only embryonic stem cells retained the capacity to form all kinds of tissue in the human body. However, if stem cells taken from adult patients can produce cells and tissues capable of functioning within entirely different systems, new brain tissue needed to treat a patient with Parkinson's disease, for example, might be generated from blood stem cells derived from the patient's bone marrow. Conversely, neural stem cells might be used to produce needed blood and bone marrow. Use of a patient's own stem cells would circumvent one of the major obstacles posed by the use of embryonic stem cells—namely, the danger that tissue taken from another individual would be rejected when transplanted into a patient. Thus, in commenting on this finding, the *British Medical Journal* remarked on January 30, 1999 that the use of embryonic stem cells "may soon be eclipsed by the more readily available and less controversial adult stem cells." Given that the function of the adult stem cells was converted without the cells first having to pass through an embryonic stage, the use of such cells would not be subject to the ethical and legal objections raised by the use of human embryonic stem cells. The Director of the NIH has pointed out that evidence that adult stem cells can take on different functions has emerged only from studies on mice. However, his own claim that human embryonic stem cell research can produce treatments for diabetes and other diseases is also based solely on experimental success in mice.

One approach to tissue regeneration that does not rely on stem cells at all, but on somatic cell gene therapy, is already in use as an experimental treatment. A gene that controls production of growth factors can be injected directly into a patient's own cells, with the result that new blood vessels will develop. In early trials, this type of therapy saved the legs of patients who would have otherwise undergone amputation. It was reported in January 1999 that the technique has generated new blood vessels in the human heart and improved the condition of 19 out of 20 patients with blocked cardiac blood vessels. Such growth factors are now being explored as a means for growing new organs and tissues of many kinds.

The above recent advances suggest that it is not even necessary to obtain stem cells by destroying human embryos in order to treat disease. A growing number of researchers believe that adult stem cells may soon be used to develop treatments for afflictions such as cancer, immune disorders, orthopedic injuries, congestive heart failure, and degenerative diseases. Such researchers are working to further research on adult, rather than embryonic, stem cells. In light of these promising new scientific advances, we urge Congress to provide federal funding for the development of methods to repair and regenerate human tissue which do not require the destruction of embryonic human life. However, even if such methods do not prove to be as valuable in treating disease as are human embryonic stem cells, use of the latter in the name of medical progress is still neither legally nor ethically justifiable for the reasons stated in this document.

Conclusion

We believe that an examination of the legal, ethical, and scientific issues associated with human embryonic stem cell research leads to the conclusion that the use of federal funds to support any such research that necessitates the destruction of human embryos is, and should remain, prohibited by law. Therefore, we call on Congress to (1) maintain the existing ban against harmful federally-funded human embryo research and make explicit its application to stem cell research requiring the destruction of human embryos and (2) provide federal funding for the development of alternative treatments which do not require the destruction of human embryonic life. If anything is to be gained from the cruel atrocities committed against human beings in the last century and a half, it is the lesson that the utilitarian devaluation of one group of human beings for the alleged benefit of others is a price we simply cannot afford to pay.