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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Memorandum	Embryonic Stem Cell Research - To: POTUS - From: Jay Lefkowitz	7	06/27/2001	P5;
002	Memorandum	Update on Embryonic Stem Cells - To: POTUS - From: Alan Gilbert	4	05/18/2004	P5;
003	Memorandum	Bioethics Agenda - To: POTUS - From: Yuval Levin	4	05/12/2005	P5;
004	Memorandum	Stem Cell Research - To: POTUS - From: Yuval Levin	3	07/10/2006	P5;

COLLECTION TITLE:

Staff Secretary, White House Office of the

SERIES:

Von Der Heydt, Thomas (Tommy) - Bush Record Policy Memos

FOLDER TITLE:

Stem Cells: A Timeline (2001 - 2008)

FRC ID:

13894

RESTRICTION CODES

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- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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STEM CELLS: A TIMELINE (2000–2008)

DOMESTIC POLICY COUNCIL

THE WHITE HOUSE

WASHINGTON

INFORMATION

MEMORANDUM FOR THE PRESIDENT

THROUGH: Karl Zinsmeister

FROM: Chris Papagianis and Vishal Amin

SUBJECT: Timeline of Your Stem Cell Policy

In 2001, President Bush established a policy on stem cell research that promotes scientific progress while respecting ethical boundaries. This policy is based on the President's firm belief that science and ethics need not be at odds, and that a balance can be struck between the natural desire for rapid scientific progress and the demands of conscience. Drawing careful distinctions between practices that avoid ongoing destruction of nascent human life and those that do not, the President's policy has allowed stem cell research to advance in rapid and promising ways—as the pages that follow will illustrate—without sacrificing the inherent dignity and matchless value of every human life.

Before President Bush took office, there was no federal funding for human embryonic stem cell research. The Clinton Administration had posted, but never implemented, preliminary guidelines for embryonic stem cell research funding. The Clinton Administration proposal, however, would have incentivized the destruction of human embryos for research, and thus failed to resolve the ethical controversy surrounding this issue.

Then on August 9, 2001, the President announced his decision to allow federal funds to be used for experiments on the embryonic stem cell lines that existed at the date of his announcement. To avoid encouraging further destruction of human embryos, no taxpayer funding could be expended on research using cell lines from embryos destroyed from that point forward. At this policy announcement, the President also stated his intention to establish a Council on Bioethics. The Council's role would be to provide advice to the President on bioethical issues that may emerge due to scientific and technological advancement.

The Decision-Making Process

“Months before his announcement, the President personally set in motion a highly unusual process of deliberation inside the White House. The process combined philosophical and scientific research with investigations into both the morality and the practicality of various policy options.”¹

¹ “Stem Cells and the President: An Inside Account.” *Jay P. Lefkowitz*. Commentary. New York: Jan 2008. Vol. 125, Iss. 1; pg. 19, 6 pgs

In early June 2001, the President began to hold semi-formal private sessions in the Oval Office to discuss the stem cell issue. The President consulted with members of Congress, researchers, physicians, members of his Cabinet, bioethicists, and friends.

It was in a meeting with Leon Kass of the University of Chicago and Daniel Callahan of the Hastings Center for Bioethics that the President started to conceive the outlines of this new policy. Jay Lefkowitz, Deputy Domestic policy advisor to the President at the time, reported that the discussion unfolded like this:

President: "I must confess I am wrestling with a difficult decision. It's a difficult issue for me. On one hand, it offers so much hope; on the other, so much despair. I worry about a culture that devalues life. I think my job is to encourage respect for life. On the other hand, I believe technologies and science will help solve many medical problems, and I have great hope for cures.

One of the two guests responded: You are not alone. There are a lot of people who, the more they know about this issue, the more complex they realize it is and the more ramifications it has.

There then ensued a broad discussion of the ethics of stem-cell research-in particular, the implications of utilizing the fruits of already destroyed embryos to try to develop cures for people suffering from truly deadly diseases. Kass averred: "We at least owe them [the frozen embryos] the respect not to manipulate them for our own purposes." After all, he continued, "We are dealing with the seeds of what could be the next generation." But then Bush asked what Kass thought of conducting research on stem cells that had already been extracted from embryos. Kass, who would later become chairman of Bush's Council on Bioethics, responded: "If you fund research on lines that have already been developed, you are not complicit in their destruction."²

In late July, the President constructed a tentative decision, and the speechwriters started drafting the remarks for the yet to be scheduled speech that would be delivered on August 9, 2001.

The Policy: Encouraging Ethical Advancements in Science

Over the years, the President's policy and new funding has produced considerable scientific investigation and progress. In total, more than \$170 million in Federal funds have been devoted to human embryonic stem cell research consistent with the President's policy. And, more than \$3.7 billion in Federal funds have gone to innovative research on all forms of stem cells, contributing to dozens of proven medical treatments. The President's Council on Bioethics also prepared several papers for the President on the state of stem cell research and the potential of emerging technologies.

In May of 2005, the President's Council on Bioethics issued a "White Paper" (entitled Alternative Sources of Human Pluripotent Stem Cells). The Paper examined the ethical, scientific, and practical prospects for a range of different approaches to derive pluripotent stem cells in non-destructive ways, and recommended specific investigations that could advance these techniques. The goal of all of these

² "Stem Cells and the President: An Inside Account." Jay P Lefkowitz. Commentary. New York: Jan 2008. Vol. 125, Iss. 1; pg. 19, 6 pgs

alternative approaches is to produce the functional equivalent of embryonic stem cells (or pluripotent stem cells), without harming embryos.

In the years since the Council's report, peer-reviewed studies on each of the approaches have been published in leading scientific journals, suggesting many opportunities for the ethical creation of new stem cell lines. This research reaffirmed the President's commitment to supporting non-destructive research methods.

Despite continued progress on alternative ethical methods to develop stem cells, Congress decided to send H.R. 810 to the President's desk, which would have overturned the President's careful and balanced stem cell policy. The bill would have, for the first time, used taxpayer money to fund the deliberate destruction of human embryos. On July 19, 2006 the President vetoed this bill.

Less than three weeks after this veto, Japanese scientists' successfully reprogrammed adult mouse cells to function like embryonic stem cells. This was an amazing breakthrough that demonstrated that there was the real possibility that the new alternative technologies could solve the moral dilemma in this area of research.

To promote this research even more, the President, in June 2007, signed an Executive Order to expand support for these non-destructive research methods and to make it more likely that exciting advances in this area would continue. Earlier that year, the White House released a report detailing the advances in stem cell research that do not destroy human life. In September 2007, the NIH announced a plan to implement the President's Executive Order. The plan includes a number of new or accelerated activities. The NIH Stem Cell Task Force will develop several funding opportunity announcements, including a Program Announcement (PA). The PA will ask for grant applications proposing research on human pluripotent stem cells derived from non-embryonic sources, such as somatic cells or cells found in amniotic fluid. In addition, the Stem Cell Task Force will create two supplement programs that will stimulate research in specific areas rapidly. They would be awarded to researchers already working in stem cell research to augment certain areas of their work that are of particular interest to NIH. In addition, the Task Force developed another FOA to rapidly stimulate research in human pluripotent stem cells from non-embryonic sources. This initiative will award additional funding to NIH-supported researchers already working in stem cell research to supplement certain areas of their work that are of particular interest to NIH.

Scientists continued to build upon the groundbreaking research that had already taken place, and in November 2007, several new studies showed the amazing potential of reprogramming adult cells, such as skin cells, to make them function like embryonic stem cells. University of Wisconsin researcher Dr. James Thomson, leading one of the two teams announcing the breakthrough (and the first researcher, in 1998, to isolate embryonic stem cells by destroying human embryos) made the following comments:

- "It is the beginning of the end of the controversy that has surrounded this field."³
- "The induced cells do all the things embryonic stem cells do. It's going to completely change the field."⁴

³ *The Boston Globe*, November 21, 2008.

www.boston.com/news/science/articles/2007/11/21/breakthrough_on_stem_cells?mode=PF

⁴ *Medical News Today*, November 26, 2008.

- “They are probably more clinically relevant than embryonic stem cells.”⁵

Dr. Ian Wilmut, the researcher who cloned “Dolly” the sheep, even announced that he was going to abandon the method the cloning method he pioneered:

“Ian Wilmut, the scientist responsible for cloning the first mammal, Dolly the sheep, has announced that he is abandoning the egg-hollowing, gene-replacing technique that made him a pioneer, noting that ‘changing cells from a patient directly into stem cells has got so much more potential.’ No embryos, no eggs, no hand-wringing over where the cells came from and whether it was ethical to make them in the first place.”⁶

With this advancement in adult cell reprogramming, scientists now have the technology to create pluripotent stem cells that are genetically identical to a prospective patient. In less than six years from the President’s announcement, research scientists had developed several distinct paths toward creating pluripotent stem cells – that did not destroy or harm human embryos. Charles Krauthammer – a one time opponent of the President’s stem cell policy, even published an op-ed in the *Washington Post* entitled “Stem Cell Vindication” after learning about the breakthrough.

In sum, it increasingly appears that the qualities researchers value in embryonic cells may also exist in other stem cells that are easier to procure, more stable to grow, safer to use in therapies, and free of the ethical violations of embryo destruction. There is a gathering consensus among experts, thanks to technical advances, that today’s heated controversies over research that harms embryos will fade in the future.

The Future of Stem Cells

The dramatic advances in stem cell research since 2001 are evidence that the President’s balanced policy worked. Scientists have shown they have the ingenuity and skill to pursue the potential benefits of embryonic stem cell research without endangering nascent human life in the process. In supporting these alternative approaches while maintaining longstanding bioethical guardrails which protect life and dignity, federal science-research funding can stay true to the ideals of a humane society. And with the research that has taken place, scientists are ready to take the next step. Instead of simply creating stem cells, scientists are now ready to put them into action, and an exciting new medical field is developing called regenerative medicine.

In April 2008, the Department of Defense announced the creation of the Armed Forces Institute for Regenerative Medicine (AFIRM), a new partnership between the Federal Government, Universities and the Private Sector. Regenerative medicine is a promising new field focused on the repair and replacement of tissues and organs, which has been made possible, in part, by progress in stem cell

www.medicalnewstoday.com/printerfriendlynews.php?newsid=89799

⁵ *Medical News Today*, November 26, 2008.

www.medicalnewstoday.com/printerfriendlynews.php?newsid=89799

⁶ *TIME*, December 3, 2008.

www.time.com/time/magazine/article/0,9171,1686833,00.html

research. On June 20, 2007, President Bush met one of the first patients to receive a bladder transplant that had been grown in the lab using her own stem cells.

Specific problems that the center plans to focus on include salvage and re-growth of functional digits and limbs, facial reconstruction, healing without scarring, burn repair, and other types of reconstruction, regeneration, or transplantation. The Center's goal is to take innovations out of the lab and make them a life-improving reality for our wounded warriors and other ordinary Americans.

In August 2008, scientists succeeded in directly reprogramming one type of an adult cell into another, without having to go through the intermediary step of reprogramming a cell back to a pluripotent or pseudo-embryonic state. This new research does not require embryos or even stem cells, and was done inside a living animal. Working with a diabetic mouse, the scientists reprogrammed regular pancreatic cells into beta cells (insulin producing cells) by inserting only three genes into regular adult pancreatic cells. After this reprogramming, the new beta cells in the mouse began to produce insulin, and the mouse's blood sugar levels were reduced. This new research builds upon the work that was reported in November 2007, in which researchers reprogrammed adult skin cells into pluripotent stem cells without harming or destroying human embryos. This new discovery demonstrates once again, that medical research can advance without compromising either high aims of science or the sanctity of human life.

STEM CELLS (2000-2008)

(TAB)

August 25, 2000

(1)

The Clinton Administration posts new guidelines for embryonic stem cell research funding in the Federal Register. The guidelines would incentivize the destruction of human embryos by making the stem cell lines that were derived from them eligible for federal funding.

April 6, 2001

(2)

A Memo is delivered to the President to consider a recommendation to rescind the Clinton Guidelines. The Memo discussed the compelling arguments for not allowing federal funding of embryonic stem cell research.

June 27, 2001

(3)

A Memo is delivered to the President that reviews the scientific background, ethical issues, legal questions, prior statements by the Administration. The Memo also presented a series of options, the respective pro's and con's to each. Options covered by the memo included: 1) permitting federal funding, but issuing stronger NIH guidelines; 2) permitting federal funding with strong NIH guidelines until a sufficient number of stem cell lines were created; 3) permitting federal funding with strong NIH guidelines, but only for research using existing stem cell lines; 4) adding federal oversight to any of the previous options; and 5) adding a robust adult stem cell initiative to any of the options above.

July 30, 2001

(4)

Press Statement: Administration Supports Passage of H.R. 2505 – "Human Cloning Prohibition Act of 2001"

August 9-12, 2001

(5)

The President defined the Administration's principled position on stem cell research and human cloning. Federal funds shall not be used to incentivize the destruction of human embryos; and are only to be used for research on existing embryonic stem cell lines. The President also announced that he would create a new President's Council on Bioethics (PCB) to monitor and provide feedback on innovations in the biomedical field.

Remarks by the President on Stem Cell Research

Fact Sheet: Embryonic Stem Cell Research

Radio Address on the Federal Role in Embryonic Stem Cell Research

Op-Ed: Stem Cell Science and the Preservation of Life (GWB)

November 28, 2001

(6)

The President issues an Executive Order establishing the PCB to advise him on emerging social, moral, and ethical issues in the biomedical field related to stem cells and cloning.

July 11, 2002

(7)

A Memo is delivered to the President on the first report of the PCB, which addresses human cloning for reproductive and research purposes. The report addressed two forms of human cloning. The first is cloning to produce children (what has been called "reproductive" cloning). All members of the Council recommended that reproductive cloning permanently be banned in the U.S. The second is cloning for biomedical research (what has been called "research" or therapeutic cloning). A majority of ten members recommended a four-year legal moratorium on research cloning, which would allow time for other areas of permissible research to proceed.

January 28, 2003

(8)

SOTU: President Urges Congress to Ban Human Cloning

February 26, 2003

(9)

A Statement on Administration Policy is issued in support of a measure (H.R. 534) to ban human cloning for both reproductive and research purposes.

January 14, 2004

(10)

President's Council on Bioethics Report: Monitoring Stem Cell Research (PDF)

February 12, 2004

(11)

The New York Times reports that Dr. Woo Suk Hwang, a South Korean scientist, and his team derived an embryonic stem cell line from the world's first cloned human embryo (see later reference that revealed this to be a fraud).

May 18, 2004

(12)

A Memo is delivered to the President that reviewed the number of embryonic stem cell lines that were available, the resources that NIH had devoted to the field, and the Congressional outlook. The Memo also presented some of the public criticisms of the Administration's policy and the plan to rebut the points.

May 10, 2005

(13)

Seeking to advance biomedical science while upholding ethical norms, the PCB issued a Paper reviewing the recent scientific advances that suggested that science itself might provide a way around the moral dilemma in this area. The Paper reports on four possible approaches to obtaining pluripotent stem cells (or those with the same functional abilities as embryonic stem cells) that do not involve creating, destroying, or harming human embryos. One of the approaches discussed is adult cell reprogramming.

May 12, 2005

(14)

A Memo is delivered to the President to update him on the progress of the Administration's bioethics agenda, in particular, efforts in defense of human dignity and nascent life. The Memo reviewed some of the key policies that the President had endorsed, including prohibitions on fetal farming, and the buying, selling and patenting of human embryos. The memo also recommended that the Administration launch a more energetic campaign to defend the current stem cell policy. This included an active promotion of innovative and experimental techniques for deriving embryonic-like stem cells without destroying human

embryos. (The President even underlined the specific techniques that were highlighted in the memo.) They included possibly using embryos that died in the process of thawing in fertility clinics rather than those that were killed for research, and reprogramming adult cells to behave like embryonic stem cells.

May 24, 2005

(15)

President Discusses Embryo Adoption and Ethical Stem Cell Research
Fact Sheet: Valuing Life Through Embryo Adoption and Ethical Stem Cell Research

December 20, 2005

(16)

The President Signs a Bill (H.R. 2520) creating a new Federal program to collect and store cord blood to further support adult stem cell research and therapies.

January 31, 2006

(17)

SOTU: President Urges Congress to Ban Human Cloning in All Its Forms

May 12, 2006

(18)

The New York Times reports that Dr. Woo Suk Hwang, the South Korean scientist, is indicted on fraud and embezzlement charges following an investigation concluding that he had not in fact cloned a human embryo.

July 10, 2006

(19)

A Memo is delivered to the President discussing upcoming legislative action relating to stem cell research, and providing an update on new research developments, including new non-destructive ways to derive embryonic-like stem cells. The Memo argued that the developments in stem cell research generally strengthened the case for ethical alternatives to embryo-destructive research, and for the President's policy. The Memo made clear that the public and political debates surrounding the issue often failed to reflect that.

July 17, 2006

(20)

A Memo is delivered to the President to discuss an upcoming meeting he was scheduled to have with key experts in the emerging field of alternative / non-destructive research techniques to derive pluripotent stem cells.

Setting the Record Straight: President Bush's Stem Cell Policy Is Working

July 19, 2006

(21)

Addressing an audience of children adopted as embryos (also known as "snowflake babies") and patients who benefited from adult stem cell treatments, the President reaffirms his Administration's ethical and moral guidelines on embryonic stem cell research.

The President signs into law S. 3504 which prohibits receipt of tissue from fetuses created for research purposes. He also vetoes H.R. 810 which would have allowed federal funding of embryonic stem cell research.

President Discusses Stem Cell Research Policy
President Vetoes H.R. 810, the "Stem Cell Research Enhancement Act of 2005"
Fact Sheet: President Bush's Stem Cell Research Policy
President Signs S. 3504, the "Fetus Farming Prohibition Act of 2006"

August 11, 2006

(22)

A Memo is delivered to the President reporting that Japanese scientists' successfully reprogrammed adult mouse cells to function like embryonic stem cells. The Memo noted that the President discussed this "switch-flipping" concept with one of the researchers that he met with the previous month. The Memo concluded that the this advance moved "us one step closer to dissolving the current stem-cell battle that pits scientific ambition against respect for human life."

January 8, 2007

(23)

The Washington Post reports that Dr. Tony Atala of Wake Forest University derives pluripotent stem cells from amniotic fluid in a non-destructive, non-harmful way.

January 9, 2007

(24)

The White House releases a report entitled "Advancing Stem Cell Science Without Destroying Human Life"⁷ that reviews the President's historical policy stance on embryonic stem cell research and support for alternative research methods.

April 11, 2007

(25)

The President releases a Statement expressing his opposition to the Stem Cell Research Enhancement Act of 2007 (S. 5), which would allow human embryonic stem cell research.

June 7, 2007

(26)

Statement: President Bush Disappointed in House Vote on Embryonic Stem Cell Bill

June 19, 2007

(27)

A Memo is delivered to the President recommending that he sign an Executive Order entitled "Expanding Approved Stem Cell Lines in Ethically Responsible Ways"). This EO directed HHS to take a series of actions to support the advancement of non-destructive, alternative stem cell research techniques.

June 20, 2007

(28)

A Memo is delivered to the President about an upcoming meeting he was scheduled to have with key experts in the emerging field of alternative / non-destructive research techniques to derive pluripotent stem cells.

⁷ An updated version of this report was released on April 2, 2007. Link: Advancing Stem Cell Science Without Destroying Human Life

The President vetoes the Stem Cell Research Enhancement Act of 2007 (S. 5) as previously promised on April 11, 2007. He also issues an executive order reaffirming his commitment to pluripotent stem cell research.

President Bush Discusses Stem Cell Veto and Executive Order

Fact Sheet: Advancing Stem Cell Research While Respecting Moral Boundaries

Message to the Senate on S. 5, the "Stem Cell Research Enhancement Act of 2007"

Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways

September 18, 2007

(29)

HHS/NIH Plan for Implementation of Executive Order 13435 (PDF)

November 20, 2007

(30)

The Press Secretary releases a Statement on behalf of the President applauding the discovery by American and Japanese scientists that pluripotent stem cells can be derived from adult human skin cells without the use of human embryos.

November 30, 2007

(31)

An Op-Ed by Charles Krauthammer in the Washington Post describes the recent scientific breakthrough in reprogramming as a vindication for the President's unwavering stem cell policy.

January 28, 2008

(XX)

SOTU: President Calls for Ban on Human Cloning and Hails Advances in Alternative Sources of Pluripotent Stem Cells

April 8, 2008

(XX)

Scientists in UK revert ordinary skin cells to their embryonic state to treat Parkinson's Disease in rats.

Boston Globe: 'Blank' Stem Cells Showing Promise

April 17, 2008

(XX)

The Administration launches a new "Armed Forces Institute for Regenerative Medicine (AFIRM)." This center for excellence will take advantage of recent scientific advancements, including in the stem cell area, to help develop treatments for wounded warriors and the general public.

April 18, 2008

(XX)

At the 2008 National Catholic Prayer Breakfast, the President acknowledged that in the recent advances in alternative research techniques, scientists have found a path that can lead beyond the divisive debates of the past -- and extend the healing potential of medicine without destroying human life.

Clinton Administration NIH Guidelines for Embryonic Stem Cell Funding

August 25, 2000

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). For purposes of these Guidelines, "human pluripotent stem cells" are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos. NIH research funded under these Guidelines will involve human pluripotent stem cells derived: (1) From human fetal tissue; or (2) from human embryos that are the result of in vitro fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed.

In accordance with 42 Code of Federal Regulations (CFR) 52.4, these Guidelines prescribe the documentation and assurances that must accompany requests for NIH funding for research using human pluripotent stem cells from: (1) Awardees who want to use existing funds; (2) awardees requesting an administrative or competing supplement; and (3) applicants or intramural researchers submitting applications or proposals. NIH funds may be used to derive human pluripotent stem cells from fetal tissue. NIH funds may not be used to derive human pluripotent stem cells from human embryos. These Guidelines also designate certain areas of human pluripotent stem cell research as ineligible for NIH funding.

[Full Report truncated due to size; Full text located [here](#)]

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Memo to President to Rescind Clinton Administration Guidelines

April 6, 2001

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THE WHITE HOUSE
WASHINGTON

01 APR 6 P2:29

April 6, 2001

MEMORANDUM FOR THE PRESIDENT

FROM: ANNE PHELPS
THROUGH: MARGARET LAMONTAGNE
DATE: APRIL 6, 2001
RE: RECOMMENDATIONS ON EMBRYONIC STEM CELL RESEARCH

Background

Since fiscal year 1996, Congress has banned the use of federal funds in the annual appropriations bills for HHS (known as the Dickey amendment) for human embryo research in which an embryo is destroyed. The scientific advances in 1998, in which a stem cell was isolated from a human embryo, prompted HHS to issue a legal opinion stating that the use of embryonic stem cells did not violate the federal ban as long as federal funds are not used to *derive* the stem cell (as this process destroys the embryo). Therefore, private funds must be used for the extraction that kills the embryo and public funds could be used for the embryonic stem cell research. Following the HHS opinion, NIH issued guidelines for the conduct of embryonic stem cell research using federal funds. NIH has not yet funded embryonic stem cell research, but they are moving forward with the review of grant applications and will continue to receive new applications over the coming months. The initial review of grants will take place on April 25 in a public meeting at NIH; an announcement of the meeting will be placed in the Federal Register on April 10.

Following our initial discussions earlier this year, we have undertaken a review of the relevant issues and believe there are compelling arguments for not allowing federal funding of embryonic stem cell research.

While there is some question regarding the legality of the NIH guidelines, many believe the funding of embryonic stem cell research violates the spirit and intent of the current federal ban. Further, the scientific evidence regarding adult stem cell research has recently been shown to be very promising. Embryonic stem cell research is of uncertain potential at this time and raises serious ethical issues. While the pursuit of scientific knowledge and relief of human suffering is a high moral good, there is a greater moral concern about heading down the path of using federal funds for research that is the result of the experimentation on or destruction of human embryos.

Recommendation 1

We recommend issuing a temporary halt to the current review process and the accepting of new applications before the April 10 public announcement. According to the White House and HHS legal counsel, this may be accomplished through a letter from Secretary Thompson to the NIH Director. HHS is preparing to release a letter before the April 10 announcement.

Recommendation 2

Based on our review of the legal, scientific, and ethical issues regarding federal funding for embryonic stem cell research, we recommend moving forward with a permanent ban. Because this will result in a significant public outcry from the media and supporters of embryonic stem cell research, we recommend allowing some time for discussions with the relevant constituencies, particularly members of Congress, and preparation for a public announcement. We recommend making the announcement in May or early June.

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in staffing

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Staff Secretary, White House Office of the

SERIES:

Von Der Heydt, Thomas (Tommy) - Bush Record Policy Memos

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13894

OA Num.:

14457

NARA Num.:

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Administration Supports Passage of H.R. 2505 – "Human Cloning Prohibition Act of 2001"

July 30, 2001

The Administration supports a ban on the cloning of human beings by somatic cell nuclear transfer. The Administration unequivocally is opposed to the cloning of human beings either for reproduction or for research. The moral and ethical issues posed by human cloning are profound and cannot be ignored in the quest for scientific discovery.

At the same time, the Administration strongly approves of the development of cell and tissue-based therapies based on research involving the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans. To date, these scientific methods have enabled researchers to develop innovative drugs to treat research, such as breast cancer, or aid in treatment techniques for injury, such as cloning skin cells for skin grafts.

H.R. 2505, which prohibits human cloning by somatic cell nuclear transfer for any purpose, is consistent with the Administration's position. Although some technical issues may warrant further review, the Administration strongly supports the bill's overall intent and would welcome its passage by the House.

The Administration is strongly opposed to any legislation that would prohibit human cloning for reproductive purposes but permit the creation of cloned embryos for research. Thus, the Administration would strongly oppose any substitute amendment that is similar or identical to the language of H.R. 2608, which would permit human embryos to be created and developed solely for research purposes.

###

President Discusses Stem Cell Research

The Bush Ranch

Crawford, Texas

August 9, 2001

THE PRESIDENT: Good evening. I appreciate you giving me a few minutes of your time tonight so I can discuss with you a complex and difficult issue, an issue that is one of the most profound of our time.

The issue of research involving stem cells derived from human embryos is increasingly the subject of a national debate and dinner table discussions. The issue is confronted every day in laboratories as scientists ponder the ethical ramifications of their work. It is agonized over by parents and many couples as they try to have children, or to save children already born.

The issue is debated within the church, with people of different faiths, even many of the same faith coming to different conclusions. Many people are finding that the more they know about stem cell research, the less certain they are about the right ethical and moral conclusions.

My administration must decide whether to allow federal funds, your tax dollars, to be used for scientific research on stem cells derived from human embryos. A large number of these embryos already exist. They are the product of a process called in vitro fertilization, which helps so many couples conceive children. When doctors match sperm and egg to create life outside the womb, they usually produce more embryos than are planted in the mother. Once a couple successfully has children, or if they are unsuccessful, the additional embryos remain frozen in laboratories.

Some will not survive during long storage; others are destroyed. A number have been donated to science and used to create privately funded stem cell lines. And a few have been implanted in an adoptive mother and born, and are today healthy children.

Based on preliminary work that has been privately funded, scientists believe further research using stem cells offers great promise that could help improve the lives of those who suffer from many terrible diseases -- from juvenile diabetes to Alzheimer's, from Parkinson's to spinal cord injuries. And while scientists admit they are not yet certain, they believe stem cells derived from embryos have unique potential.

You should also know that stem cells can be derived from sources other than embryos -- from adult cells, from umbilical cords that are discarded after babies are born, from human placenta. And many scientists feel research on these type of stem cells is also promising. Many patients suffering from a range of diseases are already being helped with treatments developed from adult stem cells.

However, most scientists, at least today, believe that research on embryonic stem cells offer the most promise because these cells have the potential to develop in all of the tissues in the body.

Scientists further believe that rapid progress in this research will come only with federal funds. Federal dollars help attract the best and brightest scientists. They ensure new discoveries are widely shared at the largest number of research facilities and that the research is directed toward the greatest public good.

The United States has a long and proud record of leading the world toward advances in science and medicine that improve human life. And the United States has a long and proud record of upholding the highest standards of ethics as we expand the limits of science and knowledge. Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life. Like a snowflake, each of these embryos is unique, with the unique genetic potential of an individual human being.

As I thought through this issue, I kept returning to two fundamental questions: First, are these frozen embryos human life, and therefore, something precious to be protected? And second, if they're going to be destroyed anyway, shouldn't they be used for a greater good, for research that has the potential to save and improve other lives?

I've asked those questions and others of scientists, scholars, bioethicists, religious leaders, doctors, researchers, members of Congress, my Cabinet, and my friends. I have read heartfelt letters from many Americans. I have given this issue a great deal of thought, prayer and considerable reflection. And I have found widespread disagreement.

On the first issue, are these embryos human life -- well, one researcher told me he believes this five-day-old cluster of cells is not an embryo, not yet an individual, but a pre-embryo. He argued that it has the potential for life, but it is not a life because it cannot develop on its own.

An ethicist dismissed that as a callous attempt at rationalization. Make no mistake, he told me, that cluster of cells is the same way you and I, and all the rest of us, started our lives. One goes with a heavy heart if we use these, he said, because we are dealing with the seeds of the next generation.

And to the other crucial question, if these are going to be destroyed anyway, why not use them for good purpose -- I also found different answers. Many argue these embryos are byproducts of a process that helps create life, and we should allow couples to donate them to science so they can be used for good purpose instead of wasting their potential. Others will argue there's no such thing as excess life, and the fact that a living being is going to die does not justify experimenting on it or exploiting it as a natural resource.

At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lies at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages.

As the discoveries of modern science create tremendous hope, they also lay vast ethical mine fields. As the genius of science extends the horizons of what we can do, we increasingly confront complex questions about what we should do. We have arrived at that brave new world that seemed so distant in 1932, when Aldous Huxley wrote about human beings created in test tubes in what he called a "hatchery."

In recent weeks, we learned that scientists have created human embryos in test tubes solely to experiment on them. This is deeply troubling, and a warning sign that should prompt all of us to think through these issues very carefully.

Embryonic stem cell research is at the leading edge of a series of moral hazards. The initial stem cell researcher was at first reluctant to begin his research, fearing it might be used for human cloning. Scientists have already cloned a sheep. Researchers are telling us the next step could be to

clone human beings to create individual designer stem cells, essentially to grow another you, to be available in case you need another heart or lung or liver.

I strongly oppose human cloning, as do most Americans. We recoil at the idea of growing human beings for spare body parts, or creating life for our convenience. And while we must devote enormous energy to conquering disease, it is equally important that we pay attention to the moral concerns raised by the new frontier of human embryo stem cell research. Even the most noble ends do not justify any means.

My position on these issues is shaped by deeply held beliefs. I'm a strong supporter of science and technology, and believe they have the potential for incredible good -- to improve lives, to save life, to conquer disease. Research offers hope that millions of our loved ones may be cured of a disease and rid of their suffering. I have friends whose children suffer from juvenile diabetes. Nancy Reagan has written me about President Reagan's struggle with Alzheimer's. My own family has confronted the tragedy of childhood leukemia. And, like all Americans, I have great hope for cures.

I also believe human life is a sacred gift from our Creator. I worry about a culture that devalues life, and believe as your President I have an important obligation to foster and encourage respect for life in America and throughout the world. And while we're all hopeful about the potential of this research, no one can be certain that the science will live up to the hope it has generated.

Eight years ago, scientists believed fetal tissue research offered great hope for cures and treatments -- yet, the progress to date has not lived up to its initial expectations. Embryonic stem cell research offers both great promise and great peril. So I have decided we must proceed with great care.

As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made.

Leading scientists tell me research on these 60 lines has great promise that could lead to breakthrough therapies and cures. This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.

I also believe that great scientific progress can be made through aggressive federal funding of research on umbilical cord placenta, adult and animal stem cells which do not involve the same moral dilemma. This year, your government will spend \$250 million on this important research.

I will also name a President's council to monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation. This council will consist of leading scientists, doctors, ethicists, lawyers, theologians and others, and will be chaired by Dr. Leon Kass, a leading biomedical ethicist from the University of Chicago.

This council will keep us apprised of new developments and give our nation a forum to continue to discuss and evaluate these important issues. As we go forward, I hope we will always be guided by both intellect and heart, by both our capabilities and our conscience.

I have made this decision with great care, and I pray it is the right one.

Thank you for listening. Good night, and God bless America.

###

Fact Sheet: Embryonic Stem Cell Research

August 9, 2001

"As a result of private research, more than 60 genetically diverse stem cell lines already exist" I have concluded that we should allow federal funds to be used for research on these existing stem cell lines " where the life and death decision has already been made", This allows us to explore the promise and potential of stem cell research" without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."

-- George W. Bush

Federal funding of research using existing embryonic stem cell lines is consistent with the President's belief in the fundamental value and sanctity of human life. The President's decision reflects his fundamental commitment to preserving the value and sanctity of human life and his desire to promote vital medical research. The President's decision will permit federal funding of research using the more than 60 existing stem cell lines that have already been derived, but will not sanction or encourage the destruction of additional human embryos. The embryos from which the existing stem cell lines were created have already been destroyed and no longer have the possibility of further development as human beings. Federal funding of medical research on these existing stem cell lines will promote the sanctity of life " without undermining it " and will allow scientists to explore the potential of this research to benefit the lives of millions of people who suffer from life destroying diseases.

Federal funds will only be used for research on existing stem cell lines that were derived:

- (1) with the informed consent of the donors;
- (2) from excess embryos created solely for reproductive purposes; and
- (3) without any financial inducements to the donors.

In order to ensure that federal funds are used to support only stem cell research that is scientifically sound, legal, and ethical, the NIH will examine the derivation of all existing stem cell lines and create a registry of those lines that satisfy this criteria. More than 60 existing stem cell lines from genetically diverse populations around the world are expected to be available for federally-funded research.

No federal funds will be used for:

- (1) the derivation or use of stem cell lines derived from newly destroyed embryos;
- (2) the creation of any human embryos for research purposes; or
- (3) the cloning of human embryos for any purpose.

Today's decision relates only to the use of federal funds for research on existing stem cell lines derived in accordance with the criteria set forth above.

The President will create a new President's Council on Bioethics, chaired by Dr. Leon Kass, an expert in biomedical ethics and a professor at the University of Chicago, to study the human and moral ramifications of developments in biomedical and behavioral science and technology. The Council will study such issues as embryo and stem cell research, assisted reproduction, cloning, genetic screening, gene therapy, euthanasia, psychoactive drugs, and brain implants.

BACKGROUND

Embryonic stem cells. Embryonic stem cells, which come from the inner cell mass of a human embryo, have the potential to develop into all or nearly all of the tissues in the body. The scientific term for this characteristic is "pluripotentiality."

Adult stem cells. Adult stem cells are unspecialized, can renew themselves, and can become specialized to yield all of the cell types of the tissue from which they originate. Although scientists believe that some adult stem cells from one tissue can develop into cells of another tissue, no adult stem cell has been shown in culture to be pluripotent.

The potential of embryonic stem cell research. Many scientists believe that embryonic stem cell research may eventually lead to therapies that could be used to treat diseases that afflict approximately 128 million Americans. Treatments may include replacing destroyed dopamine-secreting neurons in a Parkinson's patient's brain; transplanting insulin-producing pancreatic beta cells in diabetic patients; and infusing cardiac muscle cells in a heart damaged by myocardial infarction. Embryonic stem cells may also be used to understand basic biology and to evaluate the safety and efficacy of new medicines.

The creation of embryonic stem cells. To create embryonic stem cells for research, a "stem cell line" must be created from the inner cell mass of a week-old embryo. If they are cultured properly, embryonic stem cells can grow and divide indefinitely. A stem cell line is a mass of cells descended from the original, sharing its genetic characteristics. Batches of cells can then be separated from the cell line and distributed to researchers.

The origin of embryonic stem cells. Embryonic stem cells are derived from excess embryos created in the course of infertility treatment. As a result of standard in vitro fertilization practices, many excess human embryos are created. Participants in IVF treatment must ultimately decide the disposition of these excess embryos, and many individuals have donated their excess embryos for research purposes.

Existing stem cell lines. There are currently more than 60 existing different human embryonic stem cell lines that have been developed from excess embryos created for in vitro fertilization with the consent of the donors and without financial inducement. These existing lines are used in approximately one dozen laboratories around the world (in the United States, Australia, India, Israel, and Sweden).

Therapies from adult and embryonic stem cell research. To date, adult stem cell research, which is federally-funded, has resulted in the development of a variety of therapeutic treatments for diseases. Although embryonic stem cell research has not yet produced similar results, many scientists believe embryonic stem cell research holds promise over time because of the capacity of embryonic stem cells to develop into any tissue in the human body.

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Radio Address by the President to the Nation

Federal Role in Embryonic Stem Cell Research

Bush Ranch

Crawford, Texas

August 11, 2001

THE PRESIDENT: Good morning. This week I made a decision on a complex and difficult issue, the federal role in embryonic stem cell research. Based on preliminary work, scientists believe these cells, which may have the ability to replace diseased or defective human tissue, offer great promise. They could help improve the lives of those who suffer from many terrible diseases -- from juvenile diabetes to Alzheimer's, from Parkinson's to spinal cord injuries.

While stem cells come from a variety of sources, most scientists, at least today, believe that research on stem cells from human embryos offers the most promise because these cells have the potential to develop into all the tissues of the body.

This research offers great hope for treatments and possible cures. Research on embryonic stem cells also raises profound ethical questions because extracting the stem cell destroys the embryo, and thus destroys the potential for life.

Some argue this small cluster of cells is not yet a human life because it cannot develop on its own. Yet an ethicist argued this is the same way you and I started our lives. One goes with a heavy heart if we use these, he said, because we are dealing with the seeds of the next generation.

At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lies at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages. As the genius of science extends the horizons of what we can do, we increasingly confront complex problems about what we should do.

In recent weeks we learned that scientists have created human embryos in test tubes solely to experiment on them. This is deeply troubling, and a warning sign that should prompt all of us to think through these issues very carefully. We recoil at the idea of growing human beings for spare body parts or creating life for our convenience. I strongly oppose cloning. And while we must devote enormous energy to conquering disease, it is equally important that we pay attention to the moral concerns raised by the new frontier of human embryo stem cell research. Even the most noble ends do not justify any means.

Embryonic stem cell research offers both great promise and great peril. So I have decided we must proceed with great care. As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines where the life and death decision has already been made.

Leading scientists tell me research on these 60 lines has great promise that could lead to breakthrough therapies and cures. This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.

I also believe that great scientific progress can be made through aggressive federal funding of research on umbilical cord, placenta, adult and animal stem cells, which do not involve the same moral dilemma. This year the government will spend \$250 million on this important research.

As we go forward, I hope we'll always be guided by both intellect and heart, by both our capabilities and our conscience. I have made this decision with great care, and I pray it is the right one.

Thank you for listening.

###

Stem Cell Science and the Preservation of Life

New York Times. George W. Bush

August 12, 2001

Some of the hardest ethical decisions pit good against good. In the case of stem cells, the promise of miracle cures is set against the protection of developing life. The conflict has left Americans divided, even in their own minds.

Stem cell research is still at an early, uncertain stage, but the hope it offers is amazing: infinitely adaptable human cells to replace damaged or defective tissue and treat a wide variety of diseases.

Yet the ethics of medicine are not infinitely adaptable. There is at least one bright line: We do not end some lives for the medical benefit of others. For me, this is a matter of conviction: a belief that life, including early life, is biologically human, genetically distinct and valuable. But one need not be pro-life to be disturbed by the prospect of fetal farming or cloning to provide spare human parts. Most Americans share a belief that human life should not be reduced to a tool or a means.

There are, however, two ways for the federal government to aggressively promote stem cell research without inviting ethical abuses.

First, we can encourage research on stem cells removed from sources other than embryos: adult cells, umbilical cords and human placentas. Many researchers see great potential in these cells -- and they have already been used to develop several new therapies.

Second, we can encourage research on embryonic stem cell lines that already exist. These cells can reproduce themselves in the laboratory, perhaps indefinitely. Stem cell lines at the University of Wisconsin have been producing cells for over two years. More than 60 of these cell lines now exist around the world. According to the National Institutes of Health, these lines are genetically diverse and sufficient in number for the research ahead.

Therefore my administration has adopted the following policy: Federal funding for research on existing stem cell lines will move forward; federal funding that sanctions or encourages the destruction of additional embryos will not. While it is unethical to end life in medical research, it is ethical to benefit from research where life and death decisions have already been made.

There is a precedent. The only licensed live chickenpox vaccine used in the United States was developed, in part, from cells derived from research involving human embryos. Researchers first grew the virus in embryonic lung cells, which were later cloned and grown in two previously existing cell lines. Many ethical and religious leaders agree that even if the history of this vaccine raises ethical questions, its current use does not.

Stem cell research takes place on a slippery slope of moral concern where much biomedical research is and will be conducted. We must keep our ethical footing. Government has a clear duty to promote scientific discovery -- and a duty to define certain boundaries:

Under my policy, existing stem cell lines, to be used in publicly supported research, must be derived (1) with the informed consent of donors, (2) from excess embryos created solely for reproductive purposes and (3) without any financial inducements to the donors.

I will direct the National Institutes of Health to establish a national human embryonic stem cell registry. This will ensure that ethical research standards are observed by all recipients of federal funding.

Soon I will appoint a Presidential Council on Bioethics, chaired by Dr. Leon Kass, to advise my administration on moral and scientific questions raised by biomedical research. My administration supports legislative efforts to prohibit the cloning of human beings for any purpose, and also to prohibit the production of human embryos solely to be destroyed in medical research.

As we enter the new territory of modern science, the choices will only grow more difficult. The new technologies we create -- with their potential to cure disease and relieve suffering -- may well define our age. But we will also be defined by the care and sense of self-restraint and responsibility with which we took up these new powers.

Power -- even technological power -- is always judged by its ends and its means. Seeking noble ends by any means is unacceptable when life itself is in the balance.

Biomedical progress should be welcomed, promoted and funded -- yet it can and must be humanized. Caution is demanded, because second thoughts will come too late. As we work to extend our lives, we must do so in ways that preserve our humanity.

###

Executive Order: Creation of the President's Council on Bioethics

November 28, 2001

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. There is established the President's Council on Bioethics (the "Council").

Sec. 2. Mission.

(a) The Council shall advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology. In connection with its advisory role, the mission of the Council includes the following functions:

- (1) to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology;
- (2) to explore specific ethical and policy questions related to these developments;
- (3) to provide a forum for a national discussion of bioethical issues;
- (4) to facilitate a greater understanding of bioethical issues; and
- (5) to explore possibilities for useful international collaboration on bioethical issues.

(b) In support of its mission, the Council may study ethical issues connected with specific technological activities, such as embryo and stem cell research, assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end of life issues. The Council may also study broader ethical and social issues not tied to a specific technology, such as questions regarding the protection of human subjects in research, the appropriate uses of biomedical technologies, the moral implications of biomedical technologies, and the consequences of limiting scientific research.

(c) The Council shall strive to develop a deep and comprehensive understanding of the issues that it considers. In pursuit of this goal, the Council shall be guided by the need to articulate fully the complex and often competing moral positions on any given issue, rather than by an overriding concern to find consensus. The Council may therefore choose to proceed by offering a variety of views on a particular issue, rather than attempt to reach a single consensus position.

(d) The Council shall not be responsible for the review and approval of specific projects or for devising and overseeing regulations for specific government agencies.

(e) In support of its mission, the Council may accept suggestions of issues for consideration from the heads of other Government agencies and other sources, as it deems appropriate.

(f) In establishing priorities for its activities, the Council shall consider the urgency and gravity of the particular issue; the need for policy guidance and public education on the particular issue; the connection of the bioethical issue to the goal of Federal advancement of science and technology; and the existence of another entity available to deliberate appropriately on the bioethical issue.

Sec. 3. Membership.

- (a) The Council shall be composed of not more than 18 members appointed by the President from among individuals who are not officers or employees of the Federal Government. The Council shall include members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences.
- (b) The President shall designate a member of the Council to serve as Chairperson.
- (c) The term of office of a member shall be 2 years, and members shall be eligible for reappointment. Members may continue to serve after the expiration of their terms until the President appoints a successor. A member appointed to fill a vacancy shall serve only for the unexpired term of such vacancy.

Sec. 4. Administration.

- (a) Upon the request of the Chairperson, the heads of executive departments and agencies shall, to the extent permitted by law, provide the Council with information it needs for purposes of carrying out its functions.
- (b) The Council may conduct inquiries, hold hearings, and establish subcommittees, as necessary.
- (c) The Council is authorized to conduct analyses and develop reports or other materials.
- (d) Members of the Council may be compensated to the extent permitted by Federal law for their work on the Council. Members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701-5707), to the extent funds are available.
- (e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide the Council with administrative support and with such funds as may be necessary for the performance of the Council's functions.
- (f) The Council shall have a staff headed by an Executive Director, who shall be appointed by the Secretary of Health and Human Services in consultation with the Chairperson. To the extent permitted by law, office space, analytical support, and additional staff support for the Council shall be provided by the Department of Health and Human Services or other executive branch departments and agencies as directed by the President.

Sec. 5. General Provisions.

- (a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.), may apply to the Council, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines that have been issued by the Administrator of General Services.
- (b) The Council shall terminate 2 years from the date of this order unless extended by the President prior to that date.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

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Memo to President on First Report of the PCB

July 11, 2002

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THE WHITE HOUSE
WASHINGTON

July 11, 2002

MEMORANDUM FOR THE PRESIDENT

THROUGH: Margaret Spellings

FROM: Jay Lefkowitz

SUBJECT: Report of Bioethics Council on Human Cloning

Attached is a report of your Bioethics Council on the subject of human cloning. This is the first report issued by the Council, which is chaired by Dr. Leon Kass.

The report addresses two forms of human cloning. The first is cloning to produce children (what has been called "reproductive" cloning). All of the members of the Council recommended that reproductive cloning permanently be banned in the United States.

The second is cloning for biomedical research (what has been called "research" or "therapeutic" cloning). It involves the creation of cloned embryos that are then destroyed in order to derive stem cells. These embryos are virtual genetic copies of the donor. Research cloning offers the prospect—though entirely speculative at this point—of gaining knowledge about, and potentially treatment for, many diseases. A majority of ten members recommended a four-year legal moratorium on research cloning, which would allow time for other areas of permissible stem cell research, both adult and embryonic, to proceed. Such a moratorium would also allow those who believe that research cloning can never ethically be pursued to make their case, and those who believe that it can ethically be pursued to convince the nation that this is true by designing a responsible system of public oversight.

A minority of seven members recommended that research cloning be permitted, as long as significant regulations are in place.

The Council comprises a diverse group of scholars, and their lack of unanimity reflects the fact that Americans are deeply divided on this issue. However, the Council's majority recommendation of at least a four-year ban on all human cloning is consistent with your core position that no human cloning should be legal in the United States. Last year, the House of Representatives voted to ban all human cloning. You supported the House bill, and have stated your support for similar legislation sponsored by Senators Brownback and Landrieu.

THE PRESIDENT'S COUNCIL ON BIOETHICS
1801 Pennsylvania Avenue, NW
6th Floor
Washington, DC 20006

July 10, 2002

The President
The White House
Washington, D.C.

Dear Mr. President:

I am pleased to present to you the first report of the President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry*. The product of six months of discussion, research, reflection, and deliberation, we hope that it will prove a worthy contribution to public understanding of this momentous question.

Man's biotechnological powers are expanding in scope, at what seems an accelerating pace. Many of these powers are double-edged, offering help for human suffering, yet threatening harm to human dignity. Human cloning, we are confident, is but a foretaste—the herald of many dazzling genetic and reproductive technologies that will raise profound moral questions well into the future. It is crucial that we try to understand its full human significance.

We have tried to conduct our inquiry into human cloning unblinkered, with our eyes open not only to the benefits of the new biotechnologies but also to their challenges—moral, social, and political. We have not suppressed differences but sought rather to illuminate them, that all might better appreciate what is at stake. We have eschewed a thin utilitarian calculus of costs and benefits, or a narrow analysis based only on individual “rights.” Rather, we have tried to ground our reflections on the broader plane of human procreation and human healing, with their deeper meanings. Seen in this way, we find that the power to clone human beings is not just another in a series of powerful tools for overcoming unwanted infertility or treating disease. Rather, cloning represents a turning point in human history—the crossing of an important line separating sexual from asexual procreation and the first step toward genetic control over the next generation. It thus carries with it a number of troubling consequences for children, family, and society.

Although the Council is not unanimous, either in some of its ethical conclusions or its policy recommendations, we are unanimous in submitting the entire report as a fair and accurate reflection both of our views and of the state of the question. To summarize our findings briefly:

First. The Council holds unanimously that cloning-to-produce-children is unethical, ought not to be attempted, and should be indefinitely banned by federal law, regardless of who performs the act or whether federal funds are involved.

Second. On the related question of the ethics of cloning-for-biomedical research, the Council is of several minds and is divided in its policy preferences:

- Seven Members (a minority), eager to see the research proceed, recommend permitting cloning-for-biomedical-research to go forward, but only under strict federal regulation.
- Ten Members (a majority), convinced that no human cloning should be permitted at least for the time being, recommend instituting, by law, a four-year ban on cloning-for-biomedical-research, applicable to all researchers regardless of whether federal funds are involved.

Third. The same ten-Member majority recommends a federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field. A thorough federal review, during the moratorium, could help to clarify the issues and foster a public consensus about how to proceed, not just on cloning-for-biomedical-research but on all the related reproductive and genetic technologies. We think this Council is well situated to initiate such a review, and we have already begun it. But we also stand ready to assist any other body that may be established to take up this large and complex subject.

The extensive reasoning underlying these recommendations is given at length in the report and is well summarized in the Executive Summary, and so I shall not rehearse it here.

On behalf of my Council colleagues, and our fine staff, allow me to thank you, Mr. President, for the opportunity you have given us to serve the nation on this weighty subject.

Sincerely,



Leon R. Kass, M.D.
Chairman

###

SOTU: President Urges Congress to Ban Human Cloning

January 28, 2003

"By caring for children who need mentors, and for addicted men and women who need treatment, we are building a more welcoming society -- a culture that values every life. And in this work we must not overlook the weakest among us. I ask you to protect infants at the very hour of their birth and end the practice of partial-birth abortion. (Applause.) And because no human life should be started or ended as the object of an experiment, I ask you to set a high standard for humanity, and pass a law against all human cloning." – President George W. Bush

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Support of H.R. 534 – “Human Cloning Prohibition Act of 2003”

(Rep. Weldon (R) FL and 125 cosponsors)

February 26, 2003

The Administration strongly supports enactment of H.R. 534, which will ensure protection of human life as the frontiers of science expand. The Administration unequivocally is opposed to the cloning of human beings either for reproduction or for research. The moral and ethical issues posed by human cloning are profound and cannot be ignored in the quest for scientific discovery. Accordingly, the Administration strongly supports House passage of H.R. 534, a comprehensive ban against all human cloning.

The Administration is strongly opposed to any legislation that would prohibit human cloning for reproductive purposes but permit the creation of cloned embryos or development of human embryo farms for research, which would require the destruction of nascent human life. Thus, the Administration would strongly oppose any substitute amendment that would permit human embryos to be created, developed, and destroyed solely for research purposes.

At the same time, the Administration strongly supports the development of cell and tissue-based therapies based on research involving the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

To date, these scientific methods have enabled researchers to develop innovative drugs to treat diseases, such as

Report: Monitoring Stem Cell Research

The President's Council on Bioethics

January 14, 2004

Preface

Monitoring Stem Cell Research is a report of the President's Council on Bioethics, which was created by President George W. Bush on November 28, 2001, by means of Executive Order 13237.

The Council's purpose is to advise the President on bioethical issues related to advances in biomedical science and technology. In connection with its advisory role, the mission of the Council includes the following functions:

- To undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology.
- To explore specific ethical and policy questions related to these developments.
- To provide a forum for a national discussion of bioethical issues.
- To facilitate a greater understanding of bioethical issues.

The President left the Council free to establish its own priorities among the many issues encompassed within its charter, and to determine its own modes of proceeding.

Stem cell research has been of interest to, and associated in the public mind with, this Council since its creation. Taking up the charge given to us by President Bush in his August 9, 2001, speech on stem cell research, the Council has from its beginnings been monitoring developments in this fast-paced and exciting field of research. The first formal discussions of the science and ethics of stem cell research took place at our third meeting, in April of 2002, where presentations were made by two prominent stem cell researchers (John Gearhart of Johns Hopkins University and Catherine Verfaillie of the University of Minnesota) and an ethicist (Gene Outka of Yale University), at a time when we were still mostly engrossed in our discussions of human cloning. Over the course of the following year and a half, even as the Council was preparing the reports *Human Cloning and Human Dignity: An Ethical Inquiry* (July 2002) and *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003), it was gathering information on stem cell research and devoting increasing portions of its meeting agendas to this topic, which was ultimately discussed at six meetings (specifically, in April and July of 2002; and in June, July, September, and October of 2003).

The Council heard presentations from numerous experts in the relevant scientific, ethical, social, advocacy, and entrepreneurial arenas, and received public comment, oral and written. The Members engaged in serious deliberation throughout the process. All told, fourteen sessions, of ninety minutes each, were devoted to the subject at public meetings. Complete transcripts of all these sessions are available to the public on the Council's website at www.bioethics.gov.

The present monitoring report draws directly upon those sessions and discussions, as well as on written material prepared by Council members, staff, and consultants. As noted in Chapter 1, it is in the spirit of an "update" and contains no recommendations for policy.

We hope the report, with its overview chapters on the law, ethics, and science of stem cell research, and its extensive supporting material located in the appendices, will serve as a source of clear, intelligible, and useful information for both policymakers and the general public regarding the current state of this important research and of the debates that surround it.

In creating this Council, President Bush expressed his desire to see us

consider all of the medical and ethical ramifications of biomedical innovation. . . . This council will keep us apprised of new developments and give our nation a forum to continue to discuss and evaluate these important issues. As we go forward, I hope we will always be guided by both intellect and heart, by both our capabilities and our conscience.

It has been our goal in the present report, as in all of our work, to live up to these high hopes and noble aspirations.

[Full Report truncated due to size; Full text located [here](#)]

###

Cloning Creates Human Embryos

Gina Kolata
New York Times
February 12, 2004

Scientists in South Korea report that they have created human embryos through cloning and extracted embryonic stem cells, the universal cells that hold great promise for medical research.

Their goal, the scientists say, is not to clone humans but to advance understanding of the causes and treatment of disease.

But the work makes the birth of a cloned baby suddenly more feasible. For that reason, it is likely to reignite the fierce debate over the ethics of human cloning.

The work was led by Dr. Woo Suk Hwang and Dr. Shin Yong Moon of Seoul National University and will be published tomorrow in the journal *Science*. The paper provides a detailed description of how to create human embryos by cloning. Experts in the field not involved with the work said they found the paper persuasive.

"You now have the cookbook, you have a methodology that's publicly available," said Dr. Robert Lanza, medical director of a company, Advanced Cell Technology in Worcester, Mass., that had tried without success to do what the South Koreans did.

Although the paper was written in dense jargon and summarized its findings by saying, "We report the derivation of a pluripotent embryonic stem cell line (SCNT-hES-1) from a cloned human blastocyst," its import was immediately clear to researchers.

"My reaction is, basically, wow," said Dr. Richard Rawlins, an embryologist who is director of the assisted reproduction laboratories at the Rush University Medical Center in Chicago. "It's a landmark paper."

It is what patients with diseases like Parkinson's and diabetes had been waiting for, the start of so-called therapeutic cloning. The idea is to clone a patient's cells to make embryonic stem cells that are an exact genetic match of the patient. Then those cells, patients hope, could be turned into replacement tissue to treat or cure their disease without provoking rejection from the body's immune system.

Even though the new work clears a significant hurdle, scientists caution that it could take years of further research before stem cell science turns into actual therapies.

Even before the publication – reported last night by a South Korean newspaper, one day ahead of the embargo imposed by *Science* – the research was criticized by cloning opponents.

Dr. Leon R. Kass, chairman of the President's Council on Bioethics, called for federal legislation to stop human cloning for any purpose.

"The age of human cloning has apparently arrived: today, cloned blastocysts for research, tomorrow cloned blastocysts for baby-making," Dr. Kass wrote in an e-mail message. "In my opinion, and that of

the majority of the Council, the only way to prevent this from happening here is for Congress to enact a comprehensive ban or moratorium on all human cloning.”

The House has twice passed legislation that would ban all human cloning experiments, most recently in February 2003. But the bills have foundered in the Senate, where many members who oppose reproductive cloning do not want to ban it for medical research.

Dr. Hwang said he knew that the work would elicit strong responses but that the research was so important it should be done anyway, adding that there was strict oversight by an ethics committee.

“Of course,” he said, “we acknowledge that there will be controversy. But as scientists, we think it is our obligation to do this.”

The paper describes the successful process in detail, with precise information on how to start the embryos growing and what solutions are best to nourish them. That recipe appears to advance the likelihood of reproductive cloning. When fertility laboratories fertilize eggs, grow embryos to the same developmental stage as the embryo clones and implant them in a human uterus, 40 to 60 percent end up as babies.

The scientists stress that all the research was in the laboratory, in petri dishes. No embryo was implanted in a woman. The women who provided unfertilized eggs that were needed to start the cloning process were not paid.

The research was financed by the government of South Korea, where cloning to create a baby is illegal.

Dr. Hwang is an expert in animal cloning, and Dr. Moon is a medical doctor who trained in the late 1980’s at a leading American fertility center, the Jones Institute for Reproductive Medicine at the Eastern Virginia Medical School in Norfolk. That is one of the very few places where researchers have extracted human stem cells from embryos that were made the usual way, by using sperm to fertilize eggs.

Until now, no one had even come close to using cloning to create a human embryo or even a monkey embryo, to say nothing of extracting stem cells from one.

Stem cells are the research prize. They appear after an embryo has grown for five or six days, its cells subdividing within the hard casing of the egg. Although the embryo at this stage contains about 100 cells, it is still no bigger than the original egg, nearly invisible to the naked eye.

“If it was floating in water with light underneath, it might look like a speck of dust,” said Dr. William Gibbons, a professor of obstetrics and gynecology at Eastern Virginia.

The defining feature of a blastocyst is that it has a real structure, made of a ball of cells, the inner cell mass, encased in a sphere. The sphere becomes the placenta if the blastocyst is implanted in a woman’s uterus, and the inner cell mass becomes the fetus.

But at the blastocyst stage, the inner cell mass consists of cells that are still indeterminate, not yet committed to becoming any particular cell type. They are the stem cells, which can in theory develop into any of the body’s tissues and organs. Stem cells from a clone would be genetically identical to the person who contributed cells to make the embryo.

Some scientists want to use stem cells to study how genes cause disease. Others say they may one day use stem cells to grow replacement tissues that are identical to the patient's own cells.

But while most expected that cloning would one day be used to create human embryos for harvesting stem cells, the South Korean research elicited amazement from experienced investigators.

They were particularly surprised that the researchers had managed to assemble so many unfertilized human eggs, 247 in all.

Advanced Cell Technology, the lone American company that has tried to conduct similar research, went through a long and arduous debate with its ethics board before recruiting young women to donate eggs. The board eventually decided that a fair payment for a woman's time and effort would be \$4,000.

To donate eggs, women have to inject themselves with hormones to stimulate their ovaries, be monitored with ultrasound to see when the eggs are ready to emerge from the ovaries and then allow doctors to extract the eggs with a thin needle. Advanced Cell Technology advertised for donors and paid them the fee, but ended up with just 19 eggs. The company restarted its program in June, Dr. Lanza said, with "just a few donors."

In South Korea, Dr. Moon said in a telephone interview, there was no advertising for egg donors and no payments. The 16 women who donated the 242 eggs were "personal contacts," he said, declining to elaborate.

The Koreans are to discuss their findings today in Seattle, at the annual meeting of the American Association for the Advancement of Science.

The investigators selected 176 eggs that were in a developmental stage that made success seem most likely. To start the cloning, the team removed the genetic material from the eggs and replaced it with genetic material obtained from cumulus cells, the adult cells that cling to eggs. Cloning experiments with mice had indicated that the cells were especially amenable to the process.

Dr. Moon explained, "The cumulus cell is easy to get," because it is on the surface of the egg.

The abundance of eggs enabled the scientists to experiment with ways of having the egg cells start to divide and of growing the embryos in the laboratory.

"They had an incredible amount of eggs and an opportunity to perfect the protocols," said Dr. Jose B. Cibelli, formerly with Advanced Cell Technology and now a professor of animal biotechnology at Michigan State University. "They tried 14 different protocols."

Dr. Cibelli consulted with the Koreans toward the end of their work and is listed with them as an author of the paper in Science.

The researchers experimented with different timing, between adding the cumulus cell to an egg and activating the egg, making it start to divide with its cumulus cell genes.

"If they waited four hours instead of two hours, it didn't work," Dr. Hans Schöler, a professor of reproductive medicine at the University of Pennsylvania, said.

All along the way, Dr. Schöler added, such small variations in the procedure had marked effects.

"Marginal differences made it work," he said. "If you stepped a little bit to the right or a little bit to the left, it didn't work."

The resulting method yielded blastocysts 26 percent of the time. "That's amazing," Dr. Schöler said.

Eventually, Dr. Hwang, Dr. Moon and their colleagues ended up with 30 blastocysts, from which they were able to extract 20 inner cell masses. One grew into a line of stem cells.

The next step, Dr. Schöler said, will be to improve the success rate of obtaining stem cell lines from blastocysts.

Dr. Ron McKay, a stem cell scientist at the National Institute of Neurological Disorders and Stroke, said the work suggested that it might be easier than anyone thought to make cloned human embryos and extract stem cells from them.

"The next question takes you to the heart of the whole discussion," Dr. McKay said. "Why do it anyway? What's the point? Is there any point?"

Dr. McKay said that for him the point was that such cells could provide a unique opportunity to study human disease. He spoke of a scientist who had died in her 40's from breast cancer. What if her cells had been cloned to make embryonic stem cells and those cells had been directed to turn into breast tissue? That might give scientists a chance to examine how genes for breast cancer altered the cells' susceptibility and might explain how and why the cancer developed in the first place.

Dr. McKay said learning to make embryo clones for research could help people who want to make babies that are clones. But he added that scientists did not always do everything that is possible.

"I really don't want to comment on the slippery slope," he said.

Dr. Cibelli, too, focused on the Koreans' report.

"Now you have the demonstration that everyone was waiting for," he said. "Whether this approach will be applicable to making babies, I don't know. And I hope I never find out."

###

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Memorandum	Update on Embryonic Stem Cells - To: POTUS - From: Alan Gilbert	4	05/18/2004	P5;

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Staff Secretary, White House Office of the

SERIES:

Von Der Heydt, Thomas (Tommy) - Bush Record Policy Memos

FOLDER TITLE:

Stem Cells: A Timeline (2001 - 2008)

FRC ID:

13894

OA Num.:

14457

NARA Num.:

14246

RESTRICTION CODES

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White Paper: Alternative Sources of Pluripotent Stem Cells

The President's Council on Bioethics

May 10, 2005

Preface

Alternative Sources of Human Pluripotent Stem Cells is a White Paper of the President's Council on Bioethics, which was created by President George W. Bush on November 28, 2001, by means of Executive Order 13237.

The Council's purpose is to advise the President on bioethical issues related to advances in biomedical science and technology. In connection with its advisory role, the mission of the Council includes the following functions:

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The President left the Council free to establish its own priorities among the many issues encompassed within its charter and to determine its own modes of proceeding.

Stem cell research has been of interest to, and associated in the public mind with, this Council since its creation. Taking up the charge given to us by President Bush in his August 9, 2001, speech on stem cell research, the Council has from its beginnings been monitoring developments in this fast-paced and exciting field of research. In January 2004, the Council published a report, *Monitoring Stem Cell Research*, which provided an overview of the law, ethics, and science of stem cell research. That report was intended to serve as a source of clear, intelligible, and useful information for both policymakers and the general public regarding the current state of this important research and of the debates that surround it.

Much of the ethical controversy over stem cells derives from the fact that, until now, the only way to obtain human pluripotent stem cell lines has been to derive them from living human embryos by a process that necessarily destroys the embryos. If a way could be found to derive such stem cell lines without creating and destroying human embryos, a good deal of that ethical controversy would subside.

The present White Paper may be regarded as a new contribution to the stem cell discussions. It reports on some recent developments that deserve public notice because of their potential for finding a morally uncontroversial means of obtaining pluripotent human stem cells. Over the past six months, the Council has been looking into specific scientific proposals for obtaining pluripotent, genetically stable, and long-lived human stem cells by methods that would not involve destroying or endangering human embryos. In December 2004, the Council heard presentations of two such proposals, one by Drs. Donald Landry and Howard Zucker of the Columbia University College of Physicians and Surgeons, and the other by Dr. William Hurlbut of Stanford University (and a member of this Council). In March 2005, the Council

discussed a staff working paper in which these two proposals, as well as two others, were explained and analyzed.

That staff working paper, extensively revised and improved in light of Council discussions and member comments, is what the Council is now issuing as a White Paper, *Alternative Sources of Human Pluripotent Stem Cells*. In its present form, the White Paper has also benefited from expert review by three prominent scientists (Andrew Fire of the Stanford University School of Medicine, Markus Grompe of the Oregon Health & Science University, and Janet Rossant of the Samuel Lunenfeld Research Institute in Toronto, Ontario), as well as consultation with scientists at the National Institutes of Health.

The White Paper introduces the four proposals and begins an analysis of their strengths and weaknesses, ethical, scientific, and practical. Because the scientific and practical merits of these proposals are in large part empirical matters, not settled in advance by mere speculation, we give special weight to the ethical analysis. We also explore, in a preliminary way, whether these alternative avenues of deriving and using pluripotent stem cells are likely to be embraced by scientists or to become eligible for federal funding.

It remains to be seen whether any of these proposals will succeed scientifically, and more discussion is surely required on some of the ethical issues we have identified. Nevertheless, having conducted this "preliminary hearing," we believe that several of these possibilities have sufficient merit to commend them now to wider public attention and further scientific investigation. People of all moral and political persuasions should be pleased to learn that scientists and others are creatively seeking morally unproblematic and uncontroversial ways to advance this promising area of scientific research.

In creating this Council, President Bush expressed his desire to see us

consider all of the medical and ethical ramifications of biomedical innovation. . . . This council will keep us apprised of new developments and give our nation a forum to continue to discuss and evaluate these important issues. As we go forward, I hope we will always be guided by both intellect and heart, by both our capabilities and our conscience.

It has been our goal in the present White Paper, as in all of our work, to live up to these high hopes and noble aspirations.

[Full report truncated due to size; Full text located [here](#)]

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President Discusses Embryo Adoption and Ethical Stem Cell Research

The East Room

May 24, 2005

THE PRESIDENT: Thank you all. Please be seated. Good afternoon, and welcome to the White House. I have just met with 21 remarkable families. Each of them has answered the call to ensure that our society's most vulnerable members are protected and defended at every stage of life.

The families here today have either adopted or given up for adoption frozen embryos that remained after fertility treatments. Rather than discard these embryos created during in vitro fertilization, or turn them over for research that destroys them, these families have chosen a life-affirming alternative. Twenty-one children here today found a chance for life with loving parents. (Applause.)

I believe America must pursue the tremendous possibilities of science, and I believe we can do so while still fostering and encouraging respect for human life in all its stages. (Applause.) In the complex debate over embryonic stem cell research, we must remember that real human lives are involved -- both the lives of those with diseases that might find cures from this research, and the lives of the embryos that will be destroyed in the process. The children here today are reminders that every human life is a precious gift of matchless value. (Applause.)

I appreciate Mike Leavitt, Department of Health and Human Services, for being here. He's the Secretary of the Department of Health and Human Services. I picked a really good man to take on this assignment. He's doing a fine job. (Applause.)

I want to thank the Executive Director of Nightlight Christian Adoptions, Ron Stoddart, for joining us today. Welcome. (Applause.) I want to thank Lori Maze, the Director of Snowflakes Frozen Embryo Adoption program. Welcome, Lori. Thank you for coming. (Applause.) And thank you all for being here.

The rapid advance of science presents us with the hope of eventual cures for terrible diseases, and with profound moral and ethical dilemmas. The decisions we make today will have far-reaching consequences. So we must aggressively move forward with medical research, while also maintaining the highest ethical standards.

Research on stem cells derived from human embryos may offer great promise, but the way those cells are derived today destroys the embryo. I share the hope of millions of Americans who desperately want to find treatments and cures for terrible diseases such as juvenile diabetes and Parkinson's disease. That is why my administration completing -- completed the doubling of the NIH budget to \$29 billion a year, to encourage research. I also made available for the first time federal funds for embryonic stem cell research in order to explore the potential of these cells.

But I also recognize the grave moral issues at stake. So, in August 2000 first -- 2001, I set forward a policy to advance stem cell research in a responsible way by funding research on stem cell lines derived only from embryos that had already been destroyed. This policy set a clear standard: We should not use public money to support the further destruction of human life. (Applause.)

Under this policy we have supported a great deal of ethical research. About 600 shipments of eligible stem cell lines are already being used by researchers across the country, and over 3,000 more shipments are still available. We've increased funding for all forms of stem cell research by more than 80 percent since I took office. A tremendous amount of both public and private research is underway in America on embryonic, as well as adult stem cells, and stem cells from umbilical cord blood.

Today the House of Representatives is considering a bill that violates the clear standard I set four years ago. This bill would take us across a critical ethical line by creating new incentives for the ongoing destruction of emerging human life. Crossing this line would be a great mistake.

Even now researchers are exploring alternative sources of stem cells, such as adult bone marrow and umbilical cord blood, as well as different ethical ways of getting the same kind of cells now taken from embryos without violating human life or dignity. With the right policies and the right techniques, we can pursue scientific progress while still fulfilling our moral duties.

I want to thank Nightlight Christian Adoptions for their good work. Nightlight's embryo adoption program has now matched over 200 biological parents with about 140 adoptive families, resulting in the birth of 81 children so far, with more on the way. (Applause.)

The children here today remind us that there is no such thing as a spare embryo. Every embryo is unique and genetically complete, like every other human being. And each of us started out our life this way. These lives are not raw material to be exploited, but gifts. And I commend each of the families here today for accepting the gift of these children and offering them the gift of your love. (Applause.)

Thank you for coming today. By the way, we're having a little birthday gathering just in a second for Tanner and Noelle. You all are invited to partake in a little birthday cake. (Laughter.) In the meantime, may God bless you and your families, and may God continue to bless our country. Thank you. (Applause.)

###

Fact Sheet: Valuing Life Through Embryo Adoption and Ethical Stem Cell Research

May 24, 2005

Today's Presidential Action

Today, President Bush Will Deliver Remarks On Embryo Adoption And Ethical Stem Cell Research Policy At The White House. To recognize this life-affirming alternative, the President will meet with 21 families that have adopted children as embryos and will reiterate his opposition to using taxpayer money to promote research that takes life.

Background: Embryo Adoption And Ethical Stem Cell Research

President Bush Supports Embryo Adoption As A Life-Affirming Alternative. Embryo adoption provides an option for the survival and development of embryos frozen in fertility clinics, giving them a chance at life and giving infertile couples the opportunity to build a family.

- **Frozen Embryos Do Not Have To Be Destroyed In Research Or Discarded.** There are alternatives to destroying or discarding embryos stored after fertility treatment. They can be donated for adoption to other couples through efforts like the Snowflakes Frozen Embryo Adoption program, which has connected donating families with adoptive families, resulting in the birth of 81 children to date with more on the way.
- **The President Supports Efforts To Increase Public Awareness Of Embryo Adoption.** Administration officials have voiced support of embryo adoption and have worked to inform doctors and infertile couples of this option. In 2002, President Bush signed a bill granting \$1 million per year for HHS grants to publicize embryo adoption programs.

Embryo Adoption Shows The Human Face Behind The Debate On Stem Cell Research. The debate over government funding of embryonic stem cell research is not just about science. It is about human life.

- **Taxpayer Money Should Not Promote Research That Destroys Life.** While the President's policy does not ban, limit, or restrict stem cell research of any kind, it does not provide federal funding for stem cell research that would require the destruction of human embryos.
- **Other Kinds Of Stem Cell Research Hold Great Promise Without Ethical Concerns.** Stem cell research involving blood from umbilical cords or adult bone marrow has already led to medical advances and offers enormous potential for many more. Such research never requires the destruction of human life. In addition, researchers are exploring ways to obtain the same kind of cells now derived from embryos without harming or taking life.
- **President Bush Delivered The First Ever Federal Funding For Embryonic Stem Cell Research.** From 2001 to 2004, the Administration provided \$54 million for human embryonic stem cell research pursued within clear moral bounds. During this same period of time, federal funding for non-embryonic stem cell research exceeded \$1.7 billion.

- **Many Opportunities For Stem Cell Research Exist.** Seventy-eight derivations of human embryonic stem cells have been found eligible for federal funding. With federal funding, scientists are developing these lines; so far, 22 have been made available as fully developed lines. Because stem cell lines replicate themselves, eligible lines can be used by many individual researchers. Hundreds of experiments are underway at facilities around the country.

###



President Signs "Stem Cell Therapeutic and Research Act of 2005"

Cord Blood Bill

December 20, 2005

On December 20, 2005, the President has signed into law:

H.R. 2520, the "Stem Cell Therapeutic and Research Act of 2005", which creates a new Federal program to collect and store cord blood, and expands the current bone marrow registry program to also include cord blood.

#

SOTU: President Urges Congress to Ban Human Cloning in All Its Forms

January 31, 2006

“A hopeful society has institutions of science and medicine that do not cut ethical corners, and that recognize the matchless value of every life. Tonight I ask you to pass legislation to prohibit the most egregious abuses of medical research: human cloning in all its forms, creating or implanting embryos for experiments, creating human-animal hybrids, and buying, selling, or patenting human embryos. Human life is a gift from our Creator -- and that gift should never be discarded, devalued or put up for sale.” – President George W. Bush

###

Cloning Scientist Is Indicted in South Korea

Choe Sang-Hun

International Herald Tribune/New York Times

May 12, 2006

Hwang Woo Suk, the disgraced cloning expert, was indicted on fraud and embezzlement charges today, months after an investigative panel determined that he had fabricated evidence to prove that he had cloned human cells.

Prosecutors blamed the scandal, one of the most notorious cases of science fraud in recent years, on a combination of elements: a junior scientist who fabricated lab tests to please his boss, and Mr. Hwang himself, a charismatic head researcher who was blind to the scam but also ordered more fabrications to speed up the publication of his papers.

Junior researchers knew about the alleged wrongdoing but could not challenge Mr. Hwang, said a prosecutor, Lee In Kyu, during a nationally televised news conference. Five of Mr. Hwang's associates were also indicted.

Reconfirming the earlier findings by Hwang's school, Seoul National University, Mr. Lee said that Hwang had never cloned embryonic stem cells from patients. Mr. Hwang's now-discredited claim had raised hopes that doctors one day would grow genetically matching tissues from embryonic stem cells to repair damaged organs or treat diseases like Alzheimer's.

The prosecutors, however, failed to clarify what role South Korean government officials had played in the dramatic rise of Mr. Hwang as a national hero and as the government's first "supreme scientist," a title created for him that granted him millions of dollars in research funds. Critics called for a parliamentary investigation.

"Prosecutors spent all those months in investigation, and yet they don't say anything about how much the government was involved and responsible," said Song Sang Yong, chairman of the Asia Bioethics Association. From President Roh Moo Hyun to his science minister and aides, the government has fervently supported Hwang.

Mr. Hwang was charged with fraud for accepting 2 billion won, or \$2.1 million, in private donations based on his falsified research. He also was accused of embezzling at least 800 million won out of the estimated 37 billion won he had received in government and private research funds.

Mr. Hwang used part of the money to make donations to politicians, the prosecutor said. He was also charged with using part of the funds to buy human eggs for his research in violation of the country's bioethics law.

If convicted, Mr. Hwang could serve up to 10 years in jail.

The scandal raised doubt about the feasibility and ethics of one of science's most cutting-edge research fields: cloning human embryos and then destroying them to extract stem cells.

Lessons from the cloning scandal will become a major topic at conferences by the World Congress of Bioethics, the Society for Social Studies of Science, and the European Association for the Study of

Science and Technology later this year, Song said. Unesco is working to revise and strengthen its 30-year-old code of conduct for scientists.

By raising false expectations, Mr. Hwang "indelibly hurt the people as well as the families and patients of hard-to-cure diseases," Mr. Lee said. "Some scientists abused the people's high expectations and a lack of peer reviews and disregarded ethics of research to attain their own goals."

Mr. Hwang and the five associates indicted today on similar charges were not arrested.

About 300 supporters of Mr. Hwang staged an overnight candlelit vigil in front of the prosecutor's office, accusing them of conducting a witch hunt and demanding that Mr. Hwang be reinstated to continue his research. When the results were announced, some wept or smashed their cell phones on the pavement in anger.

Calls to Mr. Hwang were not returned, but his lawyer, Mun Hyong Sik, told local reporters that Mr. Hwang will dispute the charges. Mr. Hwang has earlier said that he was the victim of a conspiracy to discredit him.

No one in recent years has galvanized South Korea's national pride as Mr. Hwang did. In a paper published in the periodical Science in 2004, his team said it had cloned the first human embryo and extracted stem cells from it. In a technology called "nuclear transfer," Mr. Hwang transplanted a woman's DNA into her egg to clone an embryo. In 2005, Mr. Hwang's team published another paper in Science saying that it repeated the procedure with DNA from patients' body cells and the eggs of unrelated donors.

Mr. Hwang's fame began crumbling last year when news media and scientists began scrutinizing his papers and found evidence of fabrication. Science retracted both his papers.

According to prosecutors, it was unclear whether the stem cell line Mr. Hwang said his team created in its 2004 paper was produced by embryonic cloning or was just a human egg induced to develop by parthenogenesis, a process that does not involve cloning and is known as virgin birth because no sperm is used.

But Mr. Hwang's lab lost the cell colony during a test. Hwang nonetheless ordered the fabricating of DNA data and cell photographs and published his landmark 2004 paper, prosecutors said.

###

Withdrawal Marker

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Memorandum	Stem Cell Research - To: POTUS - From: Yuval Levin	3	07/10/2006	P5;

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COLLECTION:

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SERIES:

Von Der Heydt, Thomas (Tommy) - Bush Record Policy Memos

FOLDER TITLE:

Stem Cells: A Timeline (2001 - 2008)

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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Memo to President on Meeting with Stem Cell Experts

July 17, 2006

THE WHITE HOUSE

WASHINGTON

July 17, 2006

THE PRESIDENT HAS SEEN

7/18/06

INFORMATION

MEMORANDUM FOR THE PRESIDENT

THROUGH: Karl Zinsmeister

FROM: Yuval Levin

SUBJECT: Stem Cell Research Meetings

Purpose

To discuss the state and future prospects of stem cell research with your Administration's key experts, and to discuss emerging alternatives to the destruction of embryos with outside experts.

Background

This week the Senate will consider three bills on stem cell research: a bill overturning your 2001 funding policy, a bill prohibiting the practice of "fetal farming," and a bill supporting alternative routes to embryonic-like cells without the destruction of embryos.

Administration Experts – Discussion of the State of Stem Cell Science

The first meeting will be with your Administration's chief biomedical research and bioethics experts. It will focus on the state of stem cell research, the efforts of your Administration, and the key ethical issues.

Dr. Elias Zerhouni, Director of the National Institutes of Health, will speak briefly about the efforts of the NIH to implement and administer your funding policy. Under your policy, the NIH has spent more than \$90 million on embryonic stem cell research in ways that avoid the further destruction of embryos. The results have been impressive, but rarely remarked upon in the midst of the ongoing debate. Dr. Zerhouni will discuss the facts and figures regarding shipments of lines they have made available, the kinds and quantity of projects they have supported, and the state of the science as he sees it. He may also briefly discuss some scientists' concerns about the currently approved lines. Dr. Zerhouni has said in the past that from a purely scientific perspective, an expanded policy would allow more research to move forward, but that the policy takes the shape it does for ethical, not purely scientific, reasons and that it is not his role to comment on those. He will be prepared to answer questions about the nature of the research now ongoing, latest developments, and prospects or concerns for the future.

Dr. Edmund Pellegrino has served as Chairman of your Bioethics Council since 2003 and is a professor of medicine and medical ethics at Georgetown University. He is one of the founders of American bioethics, and has been a leader in the field for decades. He will address the ethical issues surrounding stem cell research, speak to how developments may bear on fundamental

ethical questions, and discuss the importance of seeing this issue and the ethical principles involved in the context of related and no less complex bioethical challenges the Nation will likely confront in the years ahead. Dr. Pellegrino is personally opposed to the destruction of embryos for research, and supports your funding policy. He will also be prepared to discuss the arguments often made in the public debate about stem cell research.

Secretary Leavitt will also participate in this briefing.

Outside Experts – Discussion of Emerging Ethical Alternatives

The second meeting with key outside experts will focus on the emerging alternative technologies to develop cells just like those derived from embryos but without destroying human embryos. If they prove successful, these approaches could offer a way around the ethical concerns with embryonic stem cell research.

Dr. Markus Grompe is director of the Oregon Stem Cell Center and a professor of Molecular and Medical Genetics at Oregon Health & Science University in Portland. He is also on the Board of Directors of the International Society for Stem Cell Research and is a prominent researcher in the field. He has been personally involved in the development of techniques to produce embryonic-like stem cells through the reprogramming of adult cells to function like embryonic stem cells without the need for embryos (the most scientifically and ethically appealing of the proposed alternatives). He will speak about that technique as well as other potential alternative avenues. Dr. Grompe is personally opposed to the destruction of embryos for research, but works to develop these new technologies with many scientists who do not share his moral views but share his belief that these new approaches could provide a promising way forward. He will address the state of these techniques, accomplishments in proving their validity and effectiveness, and his sense of future prospects. He will be prepared to answer questions about the scientific aspects of these emerging alternatives.

Dr. Robert George—the McCormick Professor of Jurisprudence at Princeton University and a highly regarded scholar of moral philosophy—has been active in bioethics for decades. He is also a member of your Bioethics Council. Dr. George is the preeminent expert in the ethical issues surrounding the new alternative technologies, has written widely about them, and is well steeped in both the technical details and the prospects they offer for a way around the ethical dilemmas of stem cell research. Dr. George supports your funding policy and the two Senate bills you have supported, and will discuss in particular the significance of the Specter-Santorum bill to fund research into alternative methods of deriving embryonic-like cells without destroying embryos. He will also be prepared to answer questions.

###



Setting the Record Straight: President Bush's Stem Cell Policy Is Working

July 17, 2006

TIME Magazine: "The 'presidential lines' were of limited value; there were not nearly as many as scientists initially thought would be available - more like 21 than 62, and they were old, in some cases damaged and most likely contaminated with the mouse feeder cells and calf serum used to grow them." (Nancy Gibbs, Alice Park, Mike Allen, and Massimo Calabresi, "What A Bush Veto Would Mean For Stem Cells," *TIME*, 7/24/06)

The Washington Post: "When Mr. Bush announced that he would permit the use of existing stem cell lines almost five years ago, that compromise made sense. But instead of the 78 lines originally foreseen by the administration, only 22 are available, and some of those are deteriorating or contaminated." (Editorial, "Stem Cell Showdown," *The Washington Post*, 7/17/06)

President Bush's Stem Cell Policy Is Significantly Advancing Research In An Ethical Way

President Bush Is The First President To Ever Fund Embryonic Stem Cell Research. Over \$90 million in Federal funding has been devoted to research on approved lines since 2001.

President Bush's Stem Cell Policy Has Made Federally Funded Stem Cell Lines Widely Available To Scientists. The NIH has sent more than 700 shipments of cells to researchers, and has thousands more available upon request.

85 Percent Of All The Human Embryonic Stem Cell Science Done In The World Has Been Done With The Lines Now Approved For Funding By The NIH. (Jason Owen-Smith and Jennifer McCormick, "An International Gap In Human ES Cell Research," *Nature Biotechnology*, April 2006)

- **The Vast Majority Of This Work Has Been In The Past Five Years.**

The Eligible Lines Are Not Contaminated, And Are Very Widely Used By Researchers. The use of mouse cells is standard scientific practice. As the FDA has indicated, the resulting stem cell lines can be carefully screened to ensure they are safe for use in any future clinical trials. Drug and biological products are routinely co-cultured with animal cells with no adverse consequences for the millions of people who have benefited from them. The FDA has proven itself time and again to be fully capable of ensuring the safety and efficacy of such products.

- **Tom Okarma, CEO Of The Stem Cell Company Geron:** "So the stuff you hear published that all of those lines are irrevocably contaminated with mouse materials and could never be used in people - hogwash. If you know how to grow them, they're fine." (Steven Edwards, "Scrutinizing A Stem Cell Trial," *Wired News*, 3/29/06)

Several Scientific Publications Have Now Demonstrated Techniques For Removing All Animal Materials From The Existing Cell Cultures. This helps further alleviate concerns about animal material issues. (James Thomson et al., "Derivation Of Human Embryonic Stem Cells In Defined Conditions," *Nature Biotechnology*, February 2006)

Even *TIME* Magazine Says The "Science Has Outrun The Politics" And Adult Stem Cells May Be More Valuable Than Previously Thought. "The good news for all sides is that over the course of this long argument, researchers have learned more about how stem cells work, and the science has outrun the politics. Adult cells, such as those found in bone marrow, were thought to be less valuable than embryonic cells, which are 'pluripotent' master cells that can turn into anything from a brain cell to a toenail. But adult cells may be more elastic than scientists thought, and could offer shortcuts to treatment that embryonic cells can't match." (Nancy Gibbs, Alice Park, Mike Allen, and Massimo Calabresi, "What A Bush Veto Would Mean For Stem Cells," *TIME*, 7/24/06)

###

President Discusses Stem Cell Research Policy

The East Room

July 19, 2006

THE PRESIDENT: Good afternoon. Congress has just passed and sent to my desk two bills concerning the use of stem cells in biomedical research. These bills illustrate both the promise and perils we face in the age of biotechnology. In this new era, our challenge is to harness the power of science to ease human suffering without sanctioning the practices that violate the dignity of human life. (Applause.)

In 2001, I spoke to the American people and set forth a new policy on stem cell research that struck a balance between the needs of science and the demands of conscience. When I took office, there was no federal funding for human embryonic stem cell research. Under the policy I announced five years ago, my administration became the first to make federal funds available for this research, yet only on embryonic stem cell lines derived from embryos that had already been destroyed.

My administration has made available more than \$90 million for research on these lines. This policy has allowed important research to go forward without using taxpayer funds to encourage the further deliberate destruction of human embryos.

One of the bills Congress has passed builds on the progress we have made over the last five years. So I signed it into law. (Applause.) Congress has also passed a second bill that attempts to overturn the balanced policy I set. This bill would support the taking of innocent human life in the hope of finding medical benefits for others. It crosses a moral boundary that our decent society needs to respect, so I vetoed it. (Applause.)

Like all Americans, I believe our nation must vigorously pursue the tremendous possibility that science offers to cure disease and improve the lives of millions. We have opportunities to discover cures and treatments that were unthinkable generations ago. Some scientists believe that one source of these cures might be embryonic stem cell research. Embryonic stem cells have the ability to grow into specialized adult tissues, and this may give them the potential to replace damaged or defective cells or body parts and treat a variety of diseases.

Yet we must also remember that embryonic stem cells come from human embryos that are destroyed for their cells. Each of these human embryos is a unique human life with inherent dignity and matchless value. We see that value in the children who are with us today. Each of these children began his or her life as a frozen embryo that was created for in vitro fertilization, but remained unused after the fertility treatments were complete. Each of these children was adopted while still an embryo, and has been blessed with the chance to grow up in a loving family.

These boys and girls are not spare parts. (Applause.) They remind us of what is lost when embryos are destroyed in the name of research. They remind us that we all begin our lives as a small collection of cells. And they remind us that in our zeal for new treatments and cures, America must never abandon our fundamental morals.

Some people argue that finding new cures for disease requires the destruction of human embryos like the ones that these families adopted. I disagree. I believe that with the right techniques and the right policies, we can achieve scientific progress while living up to our ethical responsibilities. That's what I sought in

2001, when I set forth my administration's policy allowing federal funding for research on embryonic stem cell lines where the life and death decision had already been made.

This balanced approach has worked. Under this policy, 21 human embryonic stem cell lines are currently in use in research that is eligible for federal funding. Each of these lines can be replicated many times. And as a result, the National Institutes of Health have helped make more than 700 shipments to researchers since 2001. There is no ban on embryonic stem cell research. To the contrary, even critics of my policy concede that these federally funded lines are being used in research every day by scientists around the world. My policy has allowed us to explore the potential of embryonic stem cells, and it has allowed America to continue to lead the world in this area.

Since I announced my policy in 2001, advances in scientific research have also shown the great potential of stem cells that are derived without harming human embryos. My administration has expanded the funding of research into stem cells that can be drawn from children, adults, and the blood in umbilical cords, with no harm to the donor. And these stem cells are already being used in medical treatments.

With us today are patients who have benefited from treatments with adult and umbilical-cord-blood stem cells. And I want to thank you all for coming. (Applause.)

They are living proof that effective medical science can also be ethical. Researchers are now also investigating new techniques that could allow doctors and scientists to produce stem cells just as versatile as those derived from human embryos. One technique scientists are exploring would involve reprogramming an adult cell. For example, a skin cell to function like an embryonic stem cell. Science offers the hope that we may one day enjoy the potential benefits of embryonic stem cells without destroying human life.

We must continue to explore these hopeful alternatives and advance the cause of scientific research while staying true to the ideals of a decent and humane society. The bill I sign today upholds these humane ideals and draws an important ethical line to guide our research. The Fetus Farming Prohibition Act was sponsored by Senators Santorum and Brownback -- both who are here. (Applause.) And by Congressman Dave Weldon, along with Nathan Deal. Thank you, Congressmen. (Applause.) This good law prohibits one of the most egregious abuses in biomedical research, the trafficking in human fetuses that are created with the sole intent of aborting them to harvest their parts. Human beings are not a raw material to be exploited, or a commodity to be bought or sold, and this bill will help ensure that we respect the fundamental ethical line.

I'm disappointed that Congress failed to pass another bill that would have promoted good research. This bill was sponsored by Senator Santorum and Senator Arlen Specter and Congressman Roscoe Bartlett. Thanks for coming, Roscoe. (Applause.) It would have authorized additional federal funding for promising new research that could produce cells with the abilities of embryonic cells, but without the destruction of human embryos. This is an important piece of legislation. This bill was unanimously approved by the Senate; it received 273 votes in the House of Representatives, but was blocked by a minority in the House using procedural maneuvers. I'm disappointed that the House failed to authorize funding for this vital and ethical research.

It makes no sense to say that you're in favor of finding cures for terrible diseases as quickly as possible, and then block a bill that would authorize funding for promising and ethical stem cell research. At a moment when ethical alternatives are becoming available, we cannot lose the opportunity to conduct

research that would give hope to those suffering from terrible diseases, and help move our nation beyond the current controversies over embryonic stem cell research.

We must pursue this research. And so I direct the Secretary of Health and Human Services, Secretary Leavitt, and the Director of the National Institutes of Health to use all the tools at their disposal to aid the search for stem cell techniques that advance promising medical science in an ethical and morally responsible way. (Applause.)

Unfortunately, Congress has sent me a bill that fails to meet this ethical test. This legislation would overturn the balanced policy on embryonic stem cell research that my administration has followed for the past five years. This bill would also undermine the principle that Congress, itself, has followed for more than a decade, when it has prohibited federal funding for research that destroys human embryos.

If this bill would have become law, American taxpayers would, for the first time in our history, be compelled to fund the deliberate destruction of human embryos. And I'm not going to allow it. (Applause.)

I made it clear to the Congress that I will not allow our nation to cross this moral line. I felt like crossing this line would be a mistake, and once crossed, we would find it almost impossible to turn back. Crossing the line would needlessly encourage a conflict between science and ethics that can only do damage to both, and to our nation as a whole. If we're to find the right ways to advance ethical medical research, we must also be willing, when necessary, to reject the wrong ways. So today, I'm keeping the promise I made to the American people by returning this bill to Congress with my veto.

As science brings us ever closer to unlocking the secrets of human biology, it also offers temptations to manipulate human life and violate human dignity. Our conscience and history as a nation demand that we resist this temptation. America was founded on the principle that we are all created equal, and endowed by our Creator with the right to life. We can advance the cause of science while upholding this founding promise. We can harness the promise of technology without becoming slaves to technology. And we can ensure that science serves the cause of humanity instead of the other way around.

America pursues medical advances in the name of life, and we will achieve the great breakthroughs we all seek with reverence for the gift of life. I believe America's scientists have the ingenuity and skill to meet this challenge. And I look forward to working with Congress and the scientific community to achieve these great and noble goals in the years ahead.

Thank you all for coming and may God bless. (Applause.)

###

Message to the House of Representatives (Veto of H.R. 810)

July 19, 2006

TO THE HOUSE OF REPRESENTATIVES:

I am returning herewith without my approval H.R. 810, the "Stem Cell Research Enhancement Act of 2005."

Like all Americans, I believe our Nation must vigorously pursue the tremendous possibilities that science offers to cure disease and improve the lives of millions. Yet, as science brings us ever closer to unlocking the secrets of human biology, it also offers temptations to manipulate human life and violate human dignity. Our conscience and history as a Nation demand that we resist this temptation. With the right scientific techniques and the right policies, we can achieve scientific progress while living up to our ethical responsibilities.

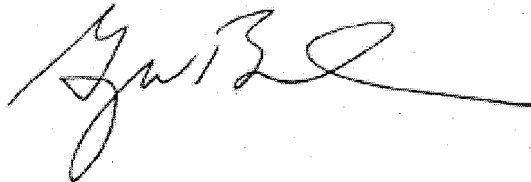
In 2001, I set forth a new policy on stem cell research that struck a balance between the needs of science and the demands of conscience. When I took office, there was no Federal funding for human embryonic stem cell research. Under the policy I announced 5 years ago, my Administration became the first to make Federal funds available for this research, but only on embryonic stem cell lines derived from embryos that had already been destroyed. My Administration has made available more than \$90 million for research of these lines. This policy has allowed important research to go forward and has allowed America to continue to lead the world in embryonic stem cell research without encouraging the further destruction of living human embryos.

H.R. 810 would overturn my Administration's balanced policy on embryonic stem cell research. If this bill were to become law, American taxpayers for the first time in our history would be compelled to fund the deliberate destruction of human embryos. Crossing this line would be a grave mistake and would needlessly encourage a conflict between science and ethics that can only do damage to both and harm our Nation as a whole.

To the House 7-19-06

Advances in research show that stem cell science can progress in an ethical way. Since I announced my policy in 2001, my Administration has expanded funding of research into stem cells that can be drawn from children, adults, and the blood in umbilical cords with no harm to the donor, and these stem cells are currently being used in medical treatments. Science also offers the hope that we may one day enjoy the potential benefits of embryonic stem cells without destroying human life. Researchers are investigating new techniques that might allow doctors and scientists to produce stem cells just as versatile as those derived from human embryos without harming life. We must continue to explore these hopeful alternatives, so we can advance the cause of scientific research while staying true to the ideals of a decent and humane society.

I hold to the principle that we can harness the promise of technology without becoming slaves to technology and ensure that science serves the cause of humanity. If we are to find the right ways to advance ethical medical research, we must also be willing when necessary to reject the wrong ways. For that reason, I must veto this bill.



THE WHITE HOUSE,

July 19, 2006.

###

Fact Sheet: President Bush's Stem Cell Research Policy

July 19, 2006

Today, The President Signed A Bill That Draws A Clear Line Against One Of The Most Egregious Abuses In Biomedical Research And Vetoed A Bill That Attempts To Overturn His Balanced Stem Cell Research Policy:

- **The President Signed The "Fetus Farming Prohibition Act," Which Prohibits Trafficking In Human Fetuses That Are Created With The Sole Intent Of Aborting Them To Harvest Their Parts.**
- **The President Vetoed H.R. 810, Which Would Overturn The Balanced Policy On Embryonic Stem Cell Research That The Administration Has Followed For The Past Five Years.** This bill would also reverse the principle that Congress itself has followed for more than a decade, when each year it has prohibited Federal funding for research that destroys human embryos.
 - **If This Bill Were To Become Law, American Taxpayers Would For The First Time In Our History Be Compelled To Fund The Deliberate Destruction Of Human Embryos.** The President has made it clear to Congress he will not allow our Nation to cross this moral line. If we are to find the right ways to advance ethical medical research, we must also be willing to reject the wrong ways when necessary.
- **President Bush Is Disappointed Congress Failed To Pass A Bill That Would Have Authorized Additional Federal Funding For Promising New Research That Could Produce Cells With The Abilities Of Embryonic Cells, But Without The Destruction Of Human Embryos.** This bill was unanimously approved by the Senate and received 273 votes in the House of Representatives, but it was blocked by a minority in the House using procedural maneuvers.
 - **It Makes No Sense To Say You Are In Favor Of Finding Cures For Terrible Diseases As Quickly As Possible And Then Block A Bill That Would Provide Funding For Promising And Ethical Stem Cell Research.**
 - **The President Is Directing The HHS Secretary And NIH Director To Use All The Tools At Their Disposal To Aid The Search For Stem Cell Techniques That Advance Promising Medical Science In An Ethical And Morally Responsible Way.**

President Bush Is The First President To Provide Federal Funding For Embryonic Stem Cell Research

In 2001, President Bush Set Forth A New Policy On Stem Cell Research That Struck A Balance Between The Needs Of Science And The Demands Of Conscience. In this new era, our challenge is to harness the power of science to ease human suffering without sanctioning practices that violate the dignity of human life.

- **When The President Took Office, There Was No Federal Funding For Human Embryonic Stem Cell Research.**
- **Under The Policy Announced Five Years Ago, This Administration Became The First To Make Federal Funds Available For This Research.** Federal funding was made available for research only on human embryonic stem cell lines derived from embryos that had been destroyed before the announcement of the President's policy. The Administration has made available more than \$90 million for research on these lines, allowing important research to go forward without using taxpayer funds to encourage the further deliberate destruction of human embryos.

Finding New Cures For Disease Does Not Require Destroying Human Embryos

Today, The President Met With Children Who Began Their Lives As Frozen Embryos Created For In Vitro Fertilization. These children were adopted while still embryos, and have been blessed with the chance to grow up in a loving family. They remind us of what is lost when embryos are destroyed in the name of research, that we all began our lives as a small collection of cells, and that America must never abandon our fundamental moral principles in our zeal for new treatments and cures.

Embryonic Stem Cells Come From Human Embryos That Are Destroyed For Their Cells. Each of these human embryos is a unique human life, with inherent dignity and matchless value.

With The Right Techniques And Policies, We Can Achieve Scientific Progress While Living Up To Our Ethical Responsibilities. America was founded on the principle that we are all created equal, and endowed by our Creator with the right to life. We can advance the cause of science while upholding this founding principle.

Since The President Announced His Policy In 2001, Advances In Scientific Research Have Also Shown The Great Potential Of Stem Cells That Are Derived Without Harming Human Embryos. The Administration has expanded the funding of research into stem cells that can be drawn from children, adults, and the blood in umbilical cords, with no harm to the donor - and these stem cells are already being used in medical treatments.

Researchers Are Now Also Investigating New Techniques That Could Allow Doctors And Scientists To Produce Stem Cells Just As Versatile As Those Derived From Human Embryos Without Requiring The Destruction Of These Embryos. One technique scientists are exploring would involve "reprogramming" an adult cell - for example, a skin cell - to function like an embryonic stem cell.

President Bush's Balanced Approach To Stem Cell Research Has Worked

The President's Policy Has Allowed Science To Explore The Potential Of Embryonic Stem Cells - And It Has Allowed America To Continue To Lead The World In This Area. Under the President's policy, 21 human embryonic stem cell lines are currently available for Federal funding, and are in use. Each of these lines can be replicated many times. As a result, the National Institutes of Health have helped make more than 700 shipments to researchers since 2001.

There Is No Ban On Embryonic Stem Cell Research. To the contrary, even critics of the President's policy concede that these Federally funded lines are being used in research every day by scientists across the world.

According To The Most Recent Data, From 1998 To 2004, 85 Percent Of Publications On Human Embryonic Stem Cell Research Involved The Use Of Lines Approved For Funding By NIH. (Jason Owen-Smith and Jennifer McCormick, "An International Gap In Human ES Cell Research," *Nature Biotechnology*, April 2006)

According To The Most Recent Data, From 1998 To 2004, 46 Percent Of All Human Embryonic Stem Cell Studies Published Have Been Done In American Institutions. (Jason Owen-Smith and Jennifer McCormick, "An International Gap In Human ES Cell Research," *Nature Biotechnology*, April 2006)

The President Believes We Must Continue To Explore Hopeful Alternatives And Advance The Cause Of Scientific Research While Staying True To The Ideals Of A Decent And Humane Society. At a moment when ethical alternatives are becoming available, we cannot lose the opportunity to conduct research that would give hope to those suffering from terrible diseases and help move our Nation beyond the current controversies over embryonic stem cell research.

###

President Signs S. 3504, the "Fetus Farming Prohibition Act of 2006"

On Wednesday, July 19, 2006, the President signed into law:

S. 3504, the "Fetus Farming Prohibition Act of 2006," which prohibits the solicitation or acceptance of tissue from fetuses gestated for research purposes.

###



Memo to President on Stem Cell Breakthrough

August 11, 2006

THE WHITE HOUSE

WASHINGTON

August 11, 2006

THE PRESIDENT
HAS SEEN

8/11-12/06

INFORMATION MEMORANDUM FOR THE PRESIDENT

FROM: Karl Zinsmeister

SUBJECT: Stem Cell Research

This week has seen an important new advance in efforts to produce stem cells without ethical controversy. In a study published today in the leading journal *Cell*, a team of Japanese scientists reports success in efforts to reprogram an adult mouse cell to function like an embryonic stem cell without the need for an embryo. (You discussed this "switch-flipping" concept with Dr. Markus Grompe in our July 18th briefing.)

Building on an earlier effort by scientists at Harvard University, the Japanese team determined that by exposing an adult cell to just four chemical factors in the right proportion, they could reprogram the cell into one that has the ability to grow into different kinds of body tissue (as an embryonic stem cell does), while retaining the genetic makeup of the adult cell (making it a perfect match for the donor, a great advantage over any stem cell produced from some embryo line).

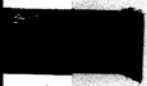
This result needs to be tested, refined, and proved further, and borne out with human as well as mouse cells. But this provides one more powerful reason to believe that the research and eventually therapeutic benefits of stem cells may be achievable without the ethical problems and medical drawbacks of deriving them from embryos.

Recall that during the stem cell debate last month, a bill that would have funded "alternative" research like the above was passed by the Senate but failed to garner the needed two-thirds vote in the House. You stated in your stem cell speech that your Administration would act on its own to encourage such research, seeking an ethical way forward in stem cell science.

A draft Executive Order instructing the National Institutes of Health to provide assistance and encouragement to such work has now been produced. In the coming days your advisers and the relevant agencies will finalize the details of that proposed order and prepare it for your review. This will allow your Administration to establish a system for encouraging, prioritizing, and funding non-embryo-destroying research.

That leaves us one step closer to dissolving the current stem-cell battle that pits scientific ambition against respect for life.

###



Scientists See Potential In Amniotic Stem Cells

They Are Highly Versatile And Readily Available

Rick Weiss, Washington Post

January 8, 2007

A type of cell that floats freely in the amniotic fluid of pregnant women has been found to have many of the same traits as embryonic stem cells, including an ability to grow into brain, muscle and other tissues that could be used to treat a variety of diseases, scientists reported yesterday.

The cells, shed by the developing fetus and easily retrieved during routine prenatal testing, are easier to maintain in laboratory dishes than embryonic stem cells -- the highly versatile cells that come from destroyed human embryos and are at the center of a heated congressional debate that will resume this week.

Moreover, because the cells are a genetic match to the developing fetus, tissues grown from them in the laboratory will not be rejected if they are used to treat birth defects in that newborn, researchers said. Alternatively, the cells could be frozen, providing a personalized tissue bank for use later in life.

The new cells are adding credence to an emerging consensus among experts that the popular distinction between embryonic and "adult" stem cells -- those isolated from adult bone marrow and other organs -- is artificial.

Increasingly, it appears there is a continuum of stem cell types, ranging from the embryonic ones that can morph into virtually any kind of tissue but are difficult to tame, up to adult ones that can turn into a limited number of tissues but are relatively easy to control.

The newly analyzed fetal stem cells, scientists said, have many of the advantages of both.

"They grow fast, as fast as embryonic stem cells, and they show great pluripotentiality," meaning they can become many kinds of tissues, said study leader Anthony Atala, director of the Institute for Regenerative Medicine at Wake Forest University School of Medicine in Winston-Salem, N.C. "But they remain stable for years without forming tumors," he added, something that embryonic cells are not very good at.

Atala and other scientists emphasized that they don't believe the cells will make embryonic stem cells irrelevant.

"There's not going to be one shoe that fits all," said Robert Lanza, scientific director at Advanced Cell Technology in Worcester, Mass. "We're going to have to see which ones are most useful for which clinical conditions."

George Daley, a Harvard stem cell researcher, echoed that sentiment. "They are not a replacement for embryonic stem cells," he said.

But in the past, even hints that non-embryonic cells might have medical potential similar to embryonic ones have complicated the political push to expand federal funding for the controversial field. And accordingly, opponents quickly pounced on the new results.

"This is wonderful news," said Richard Doerflinger, deputy director of pro-life activities at the U.S. Conference of Catholic Bishops, which opposes research that depends on embryo destruction. "It doesn't require harming anyone or destroying life at any stage."

Last year, President Bush vetoed a bill that would have allowed federal funding of research on stem cells from embryos discarded by fertility clinics. The newly Democratic Congress has promised to send the same or a similar bill to Bush's desk with even greater majorities early this term, with the House slated to vote on the matter this week.

The new work, described in yesterday's online edition of the journal *Nature Biotechnology*, shows that "amniotic fluid-derived stem cells" can be isolated as early as 10 weeks after conception from fluid extracted during tests widely done to detect birth defects.

In the laboratory, the amniotic cells can mature into all of the major types of cells, dividing at the impressive clip of once every 36 hours yet never showing signs of aging and never becoming tumors -- even after living for more than two years in the lab.

With co-workers from Wake Forest and from Children's Hospital in Boston, Atala coaxed the cells to become brain cells and injected them into the skulls of mice with diseased brains. The new cells filled in diseased areas and appeared to make new connections with nearby healthy neurons.

When coaxed to become bone cells and seeded onto a gelatin scaffold that was then implanted in a mouse, the cells calcified and turned into dense, healthy bone.

Under other conditions they became muscle, fat, blood vessel and liver cells.

Atala said that if 100,000 women donated their amniotic cells to a bank, that would provide enough cells of sufficient genetic diversity to provide immunologically compatible tissues for virtually everyone in the United States. With more than 4 million U.S. births a year, it would not take long to collect that many specimens, he said -- especially because the cells can be found not only in amniotic fluid but also in the placenta, which is discarded after birth.

The rights to certain patent claims relating to the cells have been licensed to Plureon Corp. of Winston-Salem, a privately held company on whose board of directors Atala sits.

Although several stem cell experts applauded the work, some questioned the novelty of the newly described cells. Similar cells have been under study for years with little fanfare, they noted. And though Atala's careful characterization of them is better than any previously done, they said, it is not clear that his cells are truly different than ones others have in hand.

At Children's Hospital in Boston, for example, Dario Fauza, a pediatric surgeon, has been cultivating similar cells and getting them to grow into cartilage, which he has used to repair defective windpipes in newborn sheep. He has also grown the cells into tendon tissue that was used to repair defective diaphragms in sheep.

Fauza is seeking Food and Drug Administration permission to try the method in children diagnosed with birth defects while in the womb. He hopes to grow replacement tissues from their own amniotic cells and use those tissues to repair their defects after birth.

"Typically, you don't do anything until the child is born, and then you are scrambling to fix it," Fauza said. "Why not take out some amniotic fluid, which we do routinely anyway, and engineer a tissue in parallel during the remainder of gestation so he or she will have a tissue by the time he or she is born?"

###

Advancing Stem Cell Science Without Destroying Human Life

White House Domestic Policy Council

January 9, 2007

Executive Summary

In 2001, President Bush established a policy on stem cell research that promotes scientific progress while respecting ethical boundaries. This policy is based on the President's firm belief that science and ethics need not be at odds, and that a balance can be struck between the natural desire for rapid scientific progress and the demands of conscience. Drawing careful distinctions between practices that avoid ongoing destruction of nascent human life and those that do not, the President's policy has allowed stem cell research to advance in rapid and promising ways—as the pages that follow will illustrate—without sacrificing the inherent dignity and matchless value of every human life.

Before President Bush took office, there was no federal funding for human embryonic stem cell research. Then on August 9, 2001, the President announced his decision to allow federal funds to be used for experiments on the embryonic stem cell lines that existed at the date of his announcement. To avoid encouraging further destruction of human embryos, no taxpayer funding could be expended on research using cell lines from embryos destroyed from that point forward.

The President's policy and new funding has produced considerable scientific investigation and progress. Over the past six years, more than \$130 million of federal money has been devoted to human embryonic stem cell research consistent with the President's policy. Overall, more than \$3 billion has gone to innovative research on all forms of stem cells, contributing to dozens of proven medical treatments.

In May of 2005, the President's Council on Bioethics issued a "White Paper"¹ reviewing possible non-destructive sources for additional stem cell lines in the future. *Alternative Sources of Human Pluripotent Stem Cells* examined the ethical, scientific, and practical prospects for a range of different approaches, and recommended specific investigations that could advance these techniques. The goal of all of these alternative approaches is to produce the functional equivalent of embryonic stem cells, without harming embryos.

In the months since the Council's report, peer-reviewed studies on each of the approaches have been published in leading scientific journals, suggesting many opportunities for ethical creation of new stem cell lines. One of the most promising possibilities is adult-cell reprogramming. Recent work by two research teams—Kevin Eggan and Chad Cowan of the Harvard Stem Cell Institute, and Shinya Yamanaka and Kazutoshi Takahashi at Japan's Institute for Frontier Medical—suggests that it may be possible to use chemical and genetic factors to reprogram an adult cell to function like an embryonic stem cell. This approach could prove capable of creating cell lines for the study and treatment of disease without the many ethical dilemmas associated with the creation and destruction of embryos.

In January 2007, another very promising approach was outlined in the journal *Nature Biotechnology*. Dr. Anthony Atala of the Institute for Regenerative Medicine at Wake Forest University School of Medicine reported² that he and his colleagues had discovered a new and readily available source of stem cells in the amniotic fluid that cushions babies in the womb.³ While the research is still developing, Dr. Atala and his team believe that these amniotic stem cells may be fully as flexible as embryonic stem cells, while having additional medical advantages: they are easier to grow than human embryonic stem

cells, and they do not form tumors (a problem that has plagued embryonic stem cell use)⁴. And since amniotic stem cells can be collected without destroying human life, they avoid the ethical dilemmas.⁵

In sum, it increasingly appears that the qualities researchers value in embryonic cells may also exist in other stem cells that are easier to procure, more stable to grow, safer to use in therapies, and free of the ethical violations of embryo destruction. There is a gathering consensus among experts, thanks to technical advances, that today's heated controversies over research that harms embryos could fade in the future.⁶

The dramatic advances in stem cell research since 2001 are evidence that the President's balanced policy is working. Scientists have shown they have the ingenuity and skill to pursue the potential benefits of embryonic stem cell research without endangering nascent human life in the process. In supporting these alternative approaches while maintaining longstanding bioethical guardrails which protect life and dignity, federal science-research funding can stay true to the ideals of a humane society. [Truncated due to size. Full report [here](#)]

###



Statement by the President on Stem Cell Research

April 11, 2007

Scientists believe that stem cells have the potential for medical breakthroughs in treating debilitating medical diseases and disorders. However, the advancement of science and medicine need not conflict with the ethical imperative to protect every human life. I am a strong supporter of scientific research – which is why I authorized the first federal funding for research on embryonic stem cells, under careful safeguards, starting in 2001.

My policy unleashed an unprecedented scientific effort using the stem cell lines my policy approved for funding. While encouraging – not banning – research, my policy also ensures that federal funds are not used to create incentives to destroy, or harm, or create living human embryos for purposes of research.

The Senate today voted in support of legislation to overturn these safeguards. I believe this will encourage taxpayer money to be spent on the destruction or endangerment of living human embryos – raising serious moral concerns for millions of Americans.

Research using human embryonic stem cells is still at an early stage, and it will be years before researchers know how much promise lies in therapeutic applications. I believe this early stage is precisely when it is most important to develop ethically responsible techniques, so the potential of stem cells can be explored without violating human dignity and life.

S.5 is very similar to legislation I vetoed last year. This bill crosses a moral line that I and many others find troubling. If it advances all the way through Congress to my desk, I will veto it.

Meanwhile, exciting and significant scientific advances have been reported over the past few years on uses of stem cells that do not involve the destruction of embryos. These advances using adult and other forms of stem cells are exciting. Some have even produced effective therapies and treatments for disease – all without the destruction of human life.

The second bill that passed the Senate today, the Hope Act, builds on this ethically appropriate research by encouraging further development of these alternative techniques for producing stem cells without embryo creation or destruction. I strongly support this bill, and I encourage the Congress to pass it and send it to me for my signature, so stem cell science can progress, without ethical and cultural conflict.

###



President Bush Disappointed in House Vote on Embryonic Stem Cell Bill

June 7, 2007

Today, the United States House of Representatives, with its vote on the embryonic stem cell bill, chose to discard existing protections on human life. This bill puts scientific research and ethical principle into conflict, rather than supporting a balanced approach that advances scientific and medical frontiers without violating moral principles.

My Administration has sought to understand the dilemmas of stem cell research not as a choice between science and ethics, but as a challenge to advance medicine while meeting our solemn obligation to defend human life. That is why in 2001 I authorized the first federal funding for research on embryonic stem cells, under careful safeguards. This policy encouraged ethical research, while requiring taxpayer funds not be used to support the creation, destruction, or harming of living human embryos.

Recent scientific developments have reinforced my conviction that stem cell science can progress in ethical ways. Researchers have been investigating innovative techniques that could allow doctors and scientists to produce stem cells just as versatile as those derived from human embryos, but without harming life, and the House vote on this bill took place just after significant advances in stem cell research were reported in leading scientific journals. These reports give us added hope that we may one day enjoy the potential benefits of embryonic stem cells without destroying human life.

I am disappointed the leadership of Congress recycled an old bill that would simply overturn our country's carefully balanced policy on embryonic stem cell research. If this bill were to become law, American taxpayers would for the first time in our history be compelled to support the deliberate destruction of human embryos. Crossing that line would be a grave mistake. For that reason, I will veto the bill passed today.

###

Memo to the President on E.O. 13435

June 19, 2007



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

June 19, 2007

THE DEPUTY DIRECTOR

MEMORANDUM FOR THE PRESIDENT

FROM: Stephen S. McMillin *Stephen S. McMillin*
Deputy Director #13435

SUBJECT: Proposed Executive Order entitled "Expanding Approved Stem Cell Lines in Ethically Responsible Ways"

SUMMARY: This memorandum forwards for your consideration a proposed executive order that was prepared by the White House Domestic Policy Council. The proposed order would direct the Secretary of Health and Human Services (Secretary) to take certain actions in connection with research on stem cells that are capable of producing all or almost all cell types of the developing body (pluripotent stem cells or stem cells), but are derived without creating, destroying, or harming human embryos.

BACKGROUND: In your July 19, 2006, speech on stem cell research, you discussed the emergence of new techniques that may allow for the development of stem cells just like those derived from the destruction of human embryos, but without harming or destroying human embryos. You also directed the Secretary and the Director of the National Institutes of Health (Director) to use all of the tools at their disposal to aid the search for stem cell techniques that advance promising medical science in an ethically and morally responsible way.

The proposed executive order would formalize that commitment. It would direct the Secretary to conduct and support research on the isolation, derivation, production, or testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of, or treatments for, diseases and other adverse health conditions, but are derived without creating, destroying, or harming human embryos.

It would direct the Secretary, after consultation with the Director, to issue a plan within 90 days to conduct and support research on stem cells, prioritize research with the greatest potential for clinical benefit, and take into account techniques outlined by the President's Council on Bioethics.

The proposed order would also direct the Secretary to report to the President, not later than December 31st of each year, on the activities carried out under the order.

VIEWS OF AFFECTED AGENCIES AND STAFF: The following executive departments, agencies, and offices do not object to the proposed executive order: (a) the Departments of Justice and Health and Human Services; (b) the EOP Offices of the Chief of Staff, Communications and Speechwriting, Legislative Affairs, Cabinet Affairs, Strategic

WHS/MS/jm 6-20-2007
To: President 6-21-2007

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Initiatives, Intergovernmental Affairs, Presidential Personnel, White House Counsel, and HSC, DPC, USTR, NEC, CEQ, ONDCP, OSTP, CEA, and OA; and (c) the Office of the Vice President.

RECOMMENDATION: I join the Assistant to the President for Domestic Policy in recommending that you sign the proposed executive order.

Attachments

THE PRESIDENT HAS SEEN

6/18/07

EXECUTIVE ORDER

13435

EXPANDING APPROVED STEM CELL LINES
IN ETHICALLY RESPONSIBLE WAYS

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to provide leadership with respect to research on pluripotent stem cells derived by ethically responsible techniques so that the potential of pluripotent stem cells can be explored without violating human dignity or demeaning human life, it is hereby ordered as follows:

Section 1. Research on Alternative Sources of Pluripotent Stem Cells. (a) The Secretary of Health and Human Services (Secretary) shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus.

(b) Within 90 days of this order, the Secretary, after such consultation with the Director of the National Institutes of Health (Director) as the Secretary determines appropriate, shall issue a plan, including a request for proposals, to implement subsection (a) of this section that:

(i) specifies and reflects a determination of the extent to which specific techniques may require additional basic or animal research to ensure that any research involving human cells using these techniques is clearly consistent with the standards established under this order and applicable law;

(ii) prioritizes research with the greatest potential for clinical benefit;

(iii) takes into account techniques outlined by the President's Council on Bioethics, and any other appropriate techniques and research, provided they clearly meet the standard set forth in subsection (a) of this section;

(iv) renames the "Human Embryonic Stem Cell Registry" the "Human Pluripotent Stem Cell Registry"; and

(v) adds to the registry new human pluripotent stem cell lines that clearly meet the standard set forth in subsection (a) of this section.

(c) Not later than December 31 of each year, the Secretary shall report to the President on the activities carried out under this order during the past fiscal year, including a description of the research carried out or supported by the Department of Health and Human Services, including the National Institutes of Health, and other developments in the science of pluripotent stem cells not derived from human embryos.

Sec. 2. Policy. The activities undertaken and supported by and under the direction of the Secretary shall be clearly consistent with the following policies and principles:

(a) the purposes of this order are (i) to direct the Department of Health and Human Services, including the National Institutes of Health, to intensify peer reviewed research that may result in improved understanding of or treatments for diseases and other adverse health conditions, and (ii) to promote the derivation of human pluripotent stem cell lines from a variety of alternative sources while clearly meeting the standard set forth in subsection 1(a) of this order;

(b) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity;

(c) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another;

(d) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and

(e) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries.

Sec. 3. Interpretation of this Order. (a) For purposes of this order, the term "human embryo" shall mean any organism, not protected as a human subject under 45 CFR 46 as of the date of this order, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

(b) For purposes of this order, the term "subjecting to harm a human embryo" shall mean subjecting such an embryo to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)) as of the date of this order.

(c) Nothing in this order shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by somatic cell nuclear transfer, or any other research not specifically authorized by this order, or to forbid the use of existing stem cell lines deemed eligible for other federally funded research in accordance with the presidential policy decision of August 9, 2001, for research specifically authorized by this order.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the

United States, its departments, agencies, or entities, its
officers, employees, or agents, or any other person.

THE WHITE HOUSE,

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President Meets with Leading Scientists and Researchers on Alternative Sources of Pluripotent Stem Cells

June 20, 2007

COPY
FROM ORM

THE WHITE HOUSE
WASHINGTON

MEETING ON EMBRYONIC STEM CELL RESEARCH

Wednesday, June 20, 2007

2:00 p.m. - 2:20 p.m.

Oval Office

Karl Rove / Candida Wolff / Karl Zinsmeister

I. PURPOSE

To meet with scientists and researchers from outside the Administration who are pursuing alternative sources of pluripotent stem cells.

II. BACKGROUND

Congress has sent you a bill, S. 5, that would overturn your policy on embryonic stem cell research. This bill would reverse the principle that Congress has followed for more than a decade to prohibit Federal funding for research that encourages the destruction of human embryos. S. 5 is very similar to the measure that you vetoed on July 17, 2006.

This year when you veto S. 5, you will have an opportunity to sign an Executive Order that directs the Secretary of Health and Human Services and the Director of the National Institutes of Health to use all of the tools at their disposal to further aid the search for stem cell techniques that advance promising medical science in an ethically and morally responsible way.

Before you announce the veto and the Executive Order, three of the leading researchers behind alternative stem cell techniques will provide a background briefing on the latest scientific developments. In January 2007, Dr. Tony Atala led the first team of researchers who isolated pluripotent stem cells in amniotic fluid. He is also a leader in regenerative medicine and tissue regeneration, focusing on growing new human cells and tissues, including bladder, kidney, pancreas, and others. Dr. Bill Hurlbut is the pioneer behind a proposed technological solution that involves reprogramming and either gene addition or deletion to directly produce pluripotent stem cells without creating or destroying embryos. Since 2002, he has also served on your Council on Bioethics. Dr. Don Landry is coauthor of a research project on rescuing live stem cells from embryos that have naturally died. The primary work needed to finalize this approach is building a consensus and legal framework on clear medical definitions (analogous to establishing the concept of brain death back at the time respirators were invented).

III. PARTICIPANTS

Administration Official

Secretary Mike Leavitt, Department of Health and Human Services

VIPs

Dr. Tony Atala [AH-tall-ah], Director, Wake Forest Institute for Regenerative Medicine (Winston-Salem, North Carolina)

Dr. Bill Hurlbut [HERL-but], Professor of Neurology, Stanford Medical Center; Member, President's Council on Bioethics (Stanford, California)

Note: Dr. Hurlbut has served on your Council on Bioethics since 2002.

Dr. Don Landry [LAYN-dree], Professor of Medicine, Columbia University Department of Medicine; Director, Division of Nephrology, Columbia University Department of Medicine; Director, Division of Clinical Pharmacology & Experimental Therapeutics, Columbia University Department of Medicine (New York, New York)

White House Staff Attending

Joshua Bolten, Chief of Staff

Joel Kaplan, Deputy Chief of Staff for Policy

Tony Snow, Press Secretary

Candida Wolff, Assistant to the President for Legislative Affairs

Karl Zinsmeister, Assistant to the President for Domestic Policy

Dr. Jack Marburger, Director, Office of Science and Technology Policy

Tim Goeglein, Deputy Director, Office of Public Liaison

Chris Papagianis, Associate Director, Domestic Policy Council

Working Contacts

Matt Shilling, Associate Director, Office of Public Liaison

Elise Stefanik, Executive Assistant, Domestic Policy Council

IV. PRESS PLAN

Closed

V. SEQUENCE OF EVENTS

Note: There will be a pre-brief in the Oval Office led by Karl Zinsmeister and Candi Wolff. Joshua Bolten and Tim Goeglein will attend.

- You greet guests into the Oval Office.
- You participate in the meeting at your discretion.
- You conclude meeting.

Note: Upon conclusion of the meeting, participants will be escorted to the East Room for your remarks. Dr. Hurlbut and Dr. Landry will be on stage for your remarks.

VI. ATTACHMENT

Background Information on Meeting Participants

BACKGROUND INFORMATION ON MEETING PARTICIPANTS

Dr. Tony Atala [AH-tall-ah], Director, Wake Forest Institute for Regenerative Medicine (Winston-Salem, North Carolina)

Dr. Atala is a surgeon in the area of pediatric urology and a researcher in the area of regenerative medicine and tissue engineering. His current work focuses on growing new human cells, tissues and organs (including kidney, blood vessels, cartilage, muscle, bladder, pancreas, and others) to repair or replace tissues or organs damaged by age, cancer, trauma, or abnormal development. In January 2007, he led the team of researchers who first reported the isolation of pluripotent stem cells from the amniotic fluid that surrounds developing embryos.

Dr. Bill Hurlbut [HERL-but], Professor of Neurology, Stanford Medical Center; Member, President's Council on Bioethics (Stanford, California)

Dr. Hurlbut's main areas of interest involve the ethical issues associated with advancing biotechnology and neuroscience, and the integration of philosophy of biology with theology. Since 2002, he has served on your Council on Bioethics. He is the author of *Altered Nuclear Transfer*, a proposed technological solution to the moral controversy over embryonic stem cell research. This proposal would utilize the power of reprogramming and/or gene addition or deletion in combination with basic nuclear transfer technology to directly produce pluripotent stem cells without generating and subsequently destroying embryos.

Dr. Don Landry [LAYN-dree], Professor of Medicine, Columbia University Department of Medicine; Director, Division of Nephrology, Columbia University Department of Medicine; Director, Division of Clinical Pharmacology & Experimental Therapeutics, Columbia University Department of Medicine (New York, New York)

Dr. Landry has worked as a NIH Physician-Scientists and his subspecialty training is in Nephrology. In 1991 he established a laboratory at Columbia University to investigate medical applications of artificial enzymes. His laboratory in Experimental Therapeutics focuses on organic chemical solutions to intractable medical problems. Dr. Landry is one of the co-authors of a research project that proposes to use and apply the ethical framework for obtaining essential organs from deceased persons for transplantation to the harvesting of live stem cells from "dead human embryos."

TAB B

THE WHITE HOUSE

WASHINGTON

REMARKS ON EMBRYONIC STEM CELL RESEARCH

Wednesday, June 20, 2007

2:25 p.m. – 2:55 p.m.

East Room

Karl Rove / Candida Wolff / Karl Zinsmeister

I. PURPOSE

To deliver remarks on your reasons for vetoing S. 5, which would encourage the destruction of embryos for research and to outline recent advances in alternative stem cell therapies.

II. BACKGROUND

Your remarks follow your meeting with experts on embryonic stem cell research.

III. PARTICIPANTS

Administration Officials

Secretary Mike Leavitt, Department of Health and Human Services

Admiral John Agwunobi, Assistant Secretary, Department of Health and Human Services

Members of Congress

Senator Norm Coleman (R, MN)

Senator Saxby Chambliss (R, GA)

Senator Johnny Isakson (R, GA)

Minority Leader John Boehner (R, OH-08)

Congressman Chris Smith (R, NJ-04)

Congressman Roscoe Bartlett (R, MD-06)

Congressman Dave Weldon (R, FL-15)

Congressman Joe Pitts (R, PA-16)

Congressman Randy Forbes (R, VA-04)

Congressman Mike Pence (R, IN-06)

Congressman Trent Franks (R, AZ-02)

Congressman Phil Gingrey (R, GA-11)

Congresswoman Marsha Blackburn (R, TN-07), and daughter Mary Morgan Ketchel

Congressman Charles Boustany (R, LA-07)

Congressman Jeff Fortenberry (R, NE-01), and wife Celeste Gregory

Congressman Dan Lungren (R, CA-03)

Stage Participants

Carol Franz, Stem Cell Patient; Retired; Former Employee, IBM Corporation (Oswego, New York)

Dr. Bill Hurlbut, Professor of Neurology, Stanford Medical Center; Member, President's Council on Bioethics (Stanford, California)

Note: Dr. Hurlbut will participate in the meeting on embryonic stem cells in the Oval Office prior to your remarks.

Dr. Don Landry, Professor of Medicine, Columbia University Department of Medicine; Director, Division of Nephrology, Columbia University Department of Medicine; Director, Division of Clinical Pharmacology & Experimental Therapeutics, Columbia University Department of Medicine (New York, New York)

Note: Dr. Landry will participate in the meeting on embryonic stem cells in the Oval Office prior to your remarks.

Kaitlyne [Kate-Lynn] McNamara (age 18), Stem Cell Patient, and father Mike, mother Tracy, and brother Ian (age 16) (Middletown, Connecticut)

White House Staff Attending

Tony Snow, Press Secretary

Karl Zinsmeister, Assistant to the President for Domestic Policy

Jay Hein, Deputy Assistant to the President and Director of the Office of Faith-Based Community Initiatives

Working Contacts

Matt Shilling, Associate Director, Office of Public Liaison

Elise Stefanik, Executive Assistant, Domestic Policy Council

IV. PRESS PLAN

Open

V. SEQUENCE OF EVENTS

- You arrive into the Blue Room and are met by Carol Franz and Kaitlyne, Mike, Tracy, and Ian McNamara (2 clicks).

Note: The greeters will be escorted onto the stage with Dr. Hurlbut and Dr. Landry.

- You are announced into the East Room and proceed to the podium.
- You deliver remarks.
- Upon conclusion of your remarks, you depart.

VI. REMARKS

Provided by Speechwriting

VII. ATTACHMENT

Background Information of Stage Participants

BACKGROUND INFORMATION ON STAGE PARTICIPANTS

McNamara Family (Middletown, Connecticut)

Kaitlyne [Kate-Lynn], stem cell patient (18 years)

Tracy, mother

Mike, father

Ian, brother (age 16)

Kaitlyne McNamara was born with spina bifida, as well as a diseased bladder. She failed all medical therapy and her kidneys were at risk of failing (due to her high bladder pressures). Doctors took a small piece of her bladder, less than half the size of a postage stamp, isolated her bladder-specific normal stem cells, expanded their number, and then used them to cover a bladder-shaped mold in the laboratory. The cells formed new bladder tissue that was then implanted back into Kaitlyne. The organ was made with her own cells, so there was no rejection. She is now benefiting from her new bladder and her kidneys are no longer at risk. Kaitlyne, 18, will be joined on stage by her parents and her 16-year-old brother.

Carol Franz, Stem Cell Patient; Retired; Former Employee, IBM Corporation (Oswego, New York)

In December 2002, Carol was diagnosed with an aggressive form of multiple myeloma cancer. After six months of chemotherapy, Carol received an adult stem cell transplant from the cells in her own blood stream. After her transplant, Carol's immune system strengthened significantly and for three years, she was cancer free. In May 2006, Carol learned that the cancer had returned and she underwent additional treatment, including another adult stem cell transplant. Today, her cancer is once again in full remission. Carol has done numerous press interviews and has traveled the country to share her story.

Dr. Bill Hurlbut, Professor of Neurology, Stanford Medical Center; Member, President's Council on Bioethics (Stanford, California)

Dr. Hurlbut's main areas of interest involve the ethical issues associated with advancing biotechnology and neuroscience, and the integration of philosophy of biology with theology. He has served on your Council on Bioethics since 2002. He is the author of *Altered Nuclear Transfer*, a proposed technological solution to the moral controversy over embryonic stem cell research. This proposal would utilize the power of reprogramming and/or gene addition or deletion in combination with basic nuclear transfer technology to directly produce pluripotent stem cells without generating and subsequently destroying embryos.

Note: Dr. Hurlbut will participate in the meeting on embryonic stem cells prior to your remarks.

Dr. Don Landry, Professor of Medicine, Columbia University Department of Medicine; Director, Division of Nephrology, Columbia University Department of Medicine; Director, Division of Clinical Pharmacology & Experimental Therapeutics, Columbia University Department of Medicine (New York, New York)

Dr. Landry has worked as a NIH Physician-Scientist and his subspecialty training is in Nephrology. In 1991, he established a laboratory at Columbia University to investigate medical applications of artificial enzymes. His laboratory in Experimental Therapeutics focuses on organic chemical solutions to intractable medical problems. Dr. Landry is one of the co-authors of a research project that proposes to use and apply the ethical framework for obtaining essential organs from deceased persons for transplantation to the harvesting of live stem cells from "dead human embryos."

Note: Dr. Landry will participate in the meeting on embryonic stem cells prior to your remarks.

###

President Bush Discusses Stem Cell Veto and Executive Order

East Room

June 20, 2007

THE PRESIDENT: Welcome. I'm glad you're here. America is a nation that leads the world in science and technology. Our innovative spirit is making possible incredible advances in medicine that could save lives and cure diseases. America is also a nation founded on the principle that all human life is sacred -- and our conscience calls us to pursue the possibilities of science in a manner that respects human dignity and upholds our moral values.

I appreciate the fact that we're joined by a lot of folks who share the deep desire to advance science, and at the same time, uphold our moral values. I appreciate the fact that Mike Leavitt is here, Secretary of the Department of Health and Human Services. I want to thank the members of the United States Congress and Senate who have joined us. I thank you for taking your time to be here on this important announcement today.

I'm joined on stage by two good docs, really smart, capable people: Dr. Bill Hurlbut, Professor of Stanford University Medical Center; Dr. Don Landry, Professor at Columbia University Department of Medicine -- actually, he's the Chairman of the Department. The reason they're here is these are brilliant biologists who are seeking new ways to develop stem cell lines without violating human life. And these are smart folks, and I cannot thank them enough for coming to the Oval Office to share with me their wisdom and their vision.

I'm also up here with Carol Franz; she has whipped cancer twice by using adult stem cells. In other words, adult stem cells have saved her life. She's a determined woman who believes strongly that there are different alternatives available to use stem cells other than those which are created as the result of destruction of human life.

And, finally, I'm up here with the McNamara family -- Kaitlyne is with us -- I'm going to talk about her in a second.

I do want to thank the other stem cell patients and researchers and advocates who are here with us today. If you're not in any of those categories you're welcome, too. (Laughter.)

In 2001, I announced a policy to advance stem cell research in a way that is ambitious, ethical, and effective. I became the first President to make federal funds available for embryonic stem cell research -- and my policy did this in ways that would not encourage the destruction of embryos. Since then, my administration has made more than \$130 million available for research on stem cell lines derived from embryos that had already been destroyed. We've provided more than \$3 billion for research on all forms of stem cells -- including those from adult and other non-embryonic sources.

This careful approach is producing results. It has contributed to proven therapeutic treatments in thousands of patients with many different diseases. It's opening the prospect of new discoveries that could transform lives.

Congress has sent me a bill that would overturn this policy. If this legislation became law, it would compel American taxpayers -- for the first time in our history -- to support the deliberate destruction of human embryos. I made it clear to Congress and to the American people that I will not allow our nation

to cross this moral line. Last year, Congress passed a similar bill -- I kept my promise by vetoing it. And today I'm keeping my word again: I am vetoing the bill that Congress has sent. (Applause.)

Destroying human life in the hopes of saving human life is not ethical -- and it is not the only option before us. We're already seeing remarkable advances in the science and therapeutic uses of stem cells drawn from adults and children, and the blood from umbilical cords -- with no harm to the donor. Researchers value embryonic stem cells because they are pluripotent -- which means that they have the potential to develop into nearly all the cell types and tissues in the body. Researchers are now developing promising new techniques that offer the potential to produce pluripotent stem cells -- without having to destroy human life.

For example, several new studies released earlier this month showed the potential of reprogramming adult cells -- such as skin cells -- to make them function like embryonic stem cells. It's exciting new research taking place in the United States of America. Scientists from all over the country hailed this as an important breakthrough. And I'm pleased to report to you that my administration and the NIH helped fund this exciting work. The taxpayers' dollars are going to new kinds of therapies, new kinds of science, new kinds of work that do not cross a moral and ethical line.

A few months earlier, scientists discovered that cells extracted from amniotic fluid and placentas could also provide stem cells that seem to do what embryonic cells can. Still other researchers are investigating how to combine reprogramming and other innovative techniques to produce stem cells with the abilities of embryonic stem cells -- without creating or destroying embryos. There's a lot of interesting work going on that's ethical and moral. Scientists are exploring ways to collect stem cells in the same manner that doctors now rescue organs from patients who have died.

With us today are patients who are benefiting from ethical stem cell research -- including Kaitlyne McNamara. Kaitlyne was born with spina bifida, a disease that damaged her bladder. None of the treatments her doctor tried had worked; she was in danger of kidney failure. Then her doctors took a piece of her bladder, isolated the healthy stem cells, and used them to grow a new bladder in a laboratory -- which they then transplanted into her. And here she stands, healthy. (Applause.) Scientific advances like this one are important and should give us hope that there's a better way forward than scientific advances that require the destruction of a human life.

The researchers pursuing these kinds of ethically responsible advances deserve our support, and there is legislation in Congress to give them that support. Recently, the United States Senate passed a bill sponsored by Norm Coleman and others that would authorize additional federal funding for alternative stem cell research. The bill was approved with the backing of 70 United States senators. The House leaders need to pass similar legislation that would authorize additional funds for ethical stem cell research. That would be an important advancement. It would be an important statement. Because we can't lose the opportunity to conduct research that would give hope to those suffering from terrible diseases -- and help this country move beyond the controversies over embryo destruction.

We have a good chance to put aside all the politics and focus on a good piece of legislation that advances science and doesn't cross an ethical line. Norm, I want to thank you and Johnny Isakson for sponsoring that piece of legislation. (Applause.)

In the meantime, my administration is taking immediate action to increase our support for researchers in their vital work. Earlier today, I issued an executive order to strengthen our nation's commitment to

research on pluripotent stem cells. This order takes a number of important steps. The order directs the Department of Health and Human Services and the NIH to ensure that any human pluripotent stem cell lines produced in ways that do not create, destroy, or harm human embryos will be eligible for federal funding.

The order expands the NIH Embryonic Stem Cell registry to include all types of ethically produced human pluripotent stem cells. The order renames the registry -- calls it this, the Pluripotent Stem Cell Registry -- so it reflects what stem cells can do, instead of where they come from. The order invites scientists to work with the NIH, so we can add new ethically derived stem cell lines to the list of those eligible for federal funding. I direct Secretary Leavitt to conduct an assessment of what resources will be necessary to support this important new research.

This science which does not cross ethical lines requires money. I believe it is a good use of taxpayers' money to spend money on this kind of science and research. And Michael is going to expedite it, that's what that means -- it's a fancy paragraph for saying he's going to get it done. (Laughter.)

With these steps, we'll encourage scientists to expand the frontiers of stem cell research. We want to encourage science. We want to say, we stand on your side in an ethically responsible way. Scientists have recently shown they have the ingenuity and skill to pursue the potential benefits of pluripotent stem cell research. Here's two of them right here. That's why they're standing here, they have showed what's possible. I have confidence in their abilities to continue to develop new techniques. With our expanded support of non-destructive research methods, we'll make it more likely that these exciting advances continue to unfold.

Technical innovation in this difficult area is opening up new possibilities for progress without conflict or ethical controversy. So I invite policymakers and scientists to come together to speed our nation toward the destination we all seek -- where medical problems can be solved without compromising either the high aims of science or the sanctity of human life.

Thank you all for coming. May God bless. (Applause.)

###

Fact Sheet: Advancing Stem Cell Research While Respecting Moral Boundaries

*President Bush Takes Action To Support Ethical Research, Vetoes Bill
Overturning Balanced Stem Cell Policy*

June 20, 2007

Today, President Bush Signed An Executive Order To Strengthen Our Nation's Commitment To Research On Pluripotent Stem Cells. Scientists have recently shown they have the ingenuity and skill to pursue the potential benefits of pluripotent stem cell research - research on cells that have the potential to develop into nearly all the cell types and tissues in the body - without endangering human life in the process. By expanding support for non-destructive research methods, this Executive Order will make it more likely that these exciting advances continue to unfold.

- **President Bush Also Vetoes A Bill That Would Overturn His Careful, Ethical Approach To Stem Cell Research.** If this legislation became law, it would compel American taxpayers - for the first time in our history - to support the deliberate destruction of human embryos. The President has made it clear to Congress and the American people that he will not allow the Nation to cross this moral line.

In August 2001, President Bush Announced A Policy To Advance Stem Cell Research In A Way That Is Ambitious, Ethical, And Effective. President Bush was the first president to make Federal funds available for human embryonic stem cell research - and his policy did this in ways that would not encourage the destruction of embryos.

- **The President Believes We Must Pursue The Possibilities Of Science In A Manner That Respects Human Dignity And Upholds Our Moral Values.** Destroying human life in the hopes of saving human life is not ethical, and it is not the only option before us. Technical innovation in this difficult area is opening up new possibilities for progress without conflict or ethical controversy.
- **The President's Careful Approach Is Producing Results.** Since 2001, the Administration has made \$130 million dollars available for research on stem cell lines derived from embryos that had already been destroyed before the President's policy was announced. It has also provided more than \$3 billion in Federal funding for research on all forms of stem cells, including those from adult and other non-embryonic sources. This funding has contributed to proven therapeutic treatments in thousands of patients with many different diseases, and it is opening the prospect of new treatments and cures that could transform countless lives.

Recent Scientific Breakthroughs Are Showing Stem Cell Science Can Progress While Respecting Moral Boundaries

There Have Been Advances In Therapies That Use Stem Cells Drawn From Adults, Children, And The Blood From Umbilical Cords - With No Harm To The Donor.

Researchers Are Now Developing Promising New Techniques That Offer The Potential To Produce Pluripotent Stem Cells - Without Having To Destroy Human Life.

- This month, several new studies showed the potential of reprogramming adult cells, such as skin cells, to make them function like embryonic stem cells.

- In January 2007, scientists discovered that cells extracted from amniotic fluid and placentas could also provide stem cells that seem to do what embryonic stem cells can - without creating or destroying embryos.

The Administration Is Taking Immediate Action To Increase Our Support For These Researchers In Their Vital Work

Today, President Bush Issued An Executive Order To Strengthen Our Nation's Commitment To Research On Pluripotent Stem Cells. The Order:

- Directs the Department of Health and Human Services and the National Institutes of Health to ensure that any human pluripotent stem cell lines produced in ways that do not create, destroy, or harm human embryos will be eligible for federal funding.
- Expands the NIH's Embryonic Stem Cell registry to include all types of ethically produced human pluripotent stem cells.
- Renames the registry the Pluripotent Stem Cell Registry - so that it reflects what the stem cells can do, instead of where they come from.
- Invites scientists to work with the NIH, so we can add new ethically derived stem cell lines to the list of those eligible for Federal funding.

President Bush Calls On Congress To Pass Legislation That Would Authorize Additional Funds For Ethical Stem Cell Research So He Can Sign It Into Law. The Senate recently passed a bill that would authorize additional Federal funding for alternative stem cell research, and the President calls on the House to pass similar legislation.

###

Message to the Senate on S.5

June 20, 2007

TO THE SENATE OF THE UNITED STATES:

I am returning herewith without my approval S. 5, the "Stem Cell Research Enhancement Act of 2007."

Once again, the Congress has sent me legislation that would compel American taxpayers, for the first time in our history, to support the deliberate destruction of human embryos.

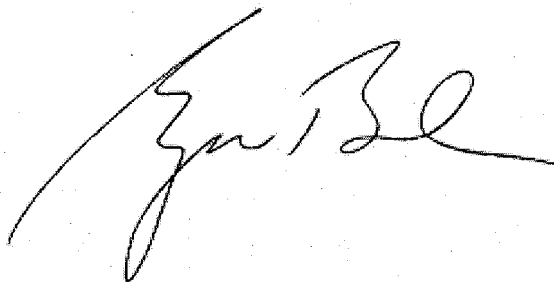
In 2001, I announced a policy to advance stem cell research in a way that is ambitious, ethical, and effective. I became the first President to make Federal funds available for embryonic stem cell research, and my policy did this in ways that would not encourage the destruction of embryos. Since then, my Administration has made more than \$130 million available for research on stem cell lines derived from embryos that had already been destroyed. We have also provided more than \$3 billion for research on all forms of stem cells, including those from adult and other non-embryonic sources.

This careful approach is producing results. It has contributed to proven therapeutic treatments in thousands of patients with many different diseases. And it is opening the prospect of new discoveries that could transform lives. Researchers are now developing promising new techniques that offer the potential to produce pluripotent stem cells, without having to destroy human life -- for example, by reprogramming adult cells to make them function like stem cells.

Technical innovation in this difficult area is opening up new possibilities for progress without conflict or ethical controversy. Researchers pursuing these kinds of ethically responsible advances deserve support, and there is legislation in the Congress to give them that support. Bills supporting alternative research methods achieved majority support last year in both the House and the Senate. Earlier this spring another

bill supporting alternative research won overwhelming majority support in the Senate, and I call on House leaders to pass similar legislation that would authorize additional funds for ethical stem cell research. We cannot lose the opportunity to conduct research that would give hope to those suffering from terrible diseases and help move our Nation beyond the controversies over embryo destruction. I invite policymakers and scientists to come together to solve medical problems without compromising either the high aims of science or the sanctity of human life.

S. 5, like the bill I vetoed last year, would overturn today's carefully balanced policy on stem cell research. Compelling American taxpayers to support the deliberate destruction of human embryos would be a grave mistake. I will not allow our Nation to cross this moral line. For that reason, I must veto this bill.



THE WHITE HOUSE,
June 20, 2007.

###

Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways

June 20, 2007

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to provide leadership with respect to research on pluripotent stem cells derived by ethically responsible techniques so that the potential of pluripotent stem cells can be explored without violating human dignity or demeaning human life, it is hereby ordered as follows:

Section 1. Research on Alternative Sources of Pluripotent Stem Cells. (a) The Secretary of Health and Human Services (Secretary) shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions, but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus.

(b) Within 90 days of this order, the Secretary, after such consultation with the Director of the National Institutes of Health (Director), shall issue a plan, including such mechanisms as requests for proposals, requests for applications, program announcements and other appropriate means, to implement subsection (a) of this section, that:

(i) specifies and reflects a determination of the extent to which specific techniques may require additional basic or animal research to ensure that any research involving human cells using these techniques is clearly consistent with the standards established under this order and applicable law;

(ii) prioritizes research with the greatest potential for clinical benefit;

(iii) takes into account techniques outlined by the President's Council on Bioethics, and any other appropriate techniques and research, provided they clearly meet the standard set forth in subsection (a) of this section;

(iv) renames the "Human Embryonic Stem Cell Registry" the "Human Pluripotent Stem Cell Registry;" and

(v) adds to the registry new human pluripotent stem cell lines that clearly meet the standard set forth in subsection (a) of this section.

(c) Not later than December 31 of each year, the Secretary shall report to the President on the activities carried out under this order during the past fiscal year, including a description of the research carried out or supported by the Department of Health and Human Services, including the National Institutes of Health, and other developments in the science of pluripotent stem cells not derived from human embryos.

Sec. 2. Policy. The activities undertaken and supported by and under the direction of the Secretary shall be clearly consistent with the following policies and principles:

(a) the purposes of this order are (i) to direct the Department of Health and Human Services, including the National Institutes of Health, to intensify peer reviewed research that may result in improved understanding of treatments for diseases and other adverse health conditions, and (ii) to promote the derivation of human pluripotent stem cell lines from a variety of alternative sources while clearly meeting the standard set forth in section 1(a) of this order;

(b) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity;

(c) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another;

(d) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and

(e) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries.

Sec. 3. Interpretation of this Order. (a) For purposes of this order, the term "human embryo" shall mean any organism, not protected as a human subject under 45 CFR 46 as of the date of this order, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

(b) For purposes of this order, the term "subjecting to harm a human embryo" shall mean subjecting such an embryo to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)) as of the date of this order.

(c) Nothing in this order shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by somatic cell nuclear transfer, or any other research not specifically authorized by this order, or to forbid the use of existing stem cell lines deemed eligible for other federally funded research in accordance with the presidential policy decision of August 9, 2001, for research specifically authorized by this order.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

###

HHS/NIH Plan for Implementation of Executive Order 13435: *Expanding Approved Stem Cell Lines in Ethically Responsible Ways*

September 18, 2007

I. EXECUTIVE SUMMARY

On June 20, 2007, President George W. Bush issued Executive Order 13435. The Executive Order requires that *"The Secretary of Health and Human Services shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions, but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus."*

The Secretary of the Department of Health and Human Services (HHS) has tasked the National Institutes of Health (NIH) with the responsibility to develop a plan to implement the Executive Order. A summary of the implementation plan is described below.

1. Issue Funding Opportunity Announcements (FOA)

The NIH Stem Cell Task Force will develop several Agency-wide Funding Opportunity Announcements (FOAs) to accelerate research on human pluripotent stem cells (hPSCs) from non-embryonic sources. The FOAs will include a Program Announcement (PA) soliciting research applications proposing research on hPSCs from non-embryonic sources, such as reprogramming somatic cells, deriving cells from amniotic fluid and other sources for developing pluripotent stem cells.

Another FOA will propose Administrative Supplements to add funds to an existing grant. One Supplemental Program will support research on creating hPSCs from non-embryonic sources through the application of technology developed using animal cells. A second Supplemental Program will support research to establish pluripotency of existing human cell lines.

2. Rename the NIH Stem Cell Registry as the Human Pluripotent Stem Cell Registry

The NIH will rename the NIH Human Embryonic Stem Cell Registry as the NIH Human Pluripotent Stem Cell Registry. Consistent with applicable law, the NIH Stem Cell Task Force will develop an NIH definition of —pluripotency|| and will use this definition to determine which lines are eligible to be added to the Registry. The Task Force will assess recent advances in stem cell characterization and specify additional criteria as it deems necessary. Scientists interested in having their cell lines included on the Registry can apply to the NIH for consideration.

3. Consider Alternative Sources of Pluripotent Stem Cells

NIH will explore research on alternative sources of pluripotent stem cells, including specifically those techniques outlined in a 2005 white paper by the President's Council

on Bioethics (PCOB) entitled —Alternative Sources of Human Pluripotent Stem Cells.¶

This report discusses four potential sources of pluripotent stem cells: —dead¶ embryos, altered nuclear transfer (ANT), single cell biopsy, and cellular reprogramming. In addition to these methods, other potential sources of pluripotent stem cells should be considered that are consistent with the Executive Order and applicable law and policy.

4. Undertake Comprehensive Portfolio Analysis

NIH will conduct a comprehensive review of its research portfolio to determine if research is currently being conducted on any of the techniques mentioned above. This portfolio analysis will assist NIH in determining which alternative methods represent unmet research opportunities. NIH will then work to address these unmet research opportunities by including these methods in a PA.

5. Convene State-of-the-Science Workshop

NIH will convene a workshop to evaluate the state of the science of the various ways to derive hPSC lines, identify knowledge gaps and determine what specific techniques/methods may require additional basic or animal research to ensure that any research involving human cells using these techniques is consistent with the standards established under the Executive Order and applicable law and policy. The outcome of the workshop will inform the NIH as to needs for additional FOAs.

6. Hold Human Pluripotent Stem Cell (hPSC) Research Symposium to Prioritize Research with the Greatest Potential for Clinical Benefit

The NIH will convene a symposium on the current state of basic and clinical pluripotent stem cell biology to help NIH prioritize research with greatest potential for clinical benefit. This symposium will enable NIH to determine which areas of high priority research need to be emphasized and then to develop additional FOAs to increase research in these areas.

[Full report truncated due to size; Full text located [here](#)]

###

Stem Cells Taken From Cloned Monkey Embryos

Gina Kolata
New York Times
November 14, 2007

Researchers in Oregon are reporting today that they used cloning to produce early monkey embryos and then extracted stem cells from those embryos.

Not only is this the first time such cells have been produced in any animal other than a mouse, but the method, the researchers say, should also work in humans.

(A report in 2004, by researchers from South Korea, claiming stem cells from cloned human embryos, turned out to be fraudulent.)

"We hope the technology will be useful for other labs that are working on human eggs and human cells," said the group's lead researcher, Shoukhrat Mitalipov at Oregon Health and Science University in Beaverton. "I am quite sure it will work in humans."

The monkey stem cells were genetically identical to an adult monkey whose cells were cloned. They are a sort of universal cell that can, in theory, develop into any sort of tissue or organ

Medical researchers and patient advocacy groups have long hoped to use human embryonic stem cells to study diseases and supply replacement cells to treat them. So far, though, stem cell research has not yielded cures and many obstacles lie ahead.

Cloning adds even more interest to stem cells, scientists say. One advantage is that the stem cells would genetically match a patient's cells, making it unnecessary to suppress the immune system if the stem cells are used in treatment. Another is that it would be possible to produce stem cells that genetically match patients with complex diseases, like Alzheimer's. That might allow scientists to study those cells in the laboratory and understand how the diseases progress.

Now, with the work on monkeys, some researchers say cloned human embryonic stem cells seem more feasible. There is no way to know, of course, whether it will be harder or easier to repeat the work with humans. But scientists are hopeful.

"I'm very enthusiastic," said Dr. Leonard Zon, director of the stem cell program at Harvard's Children's Hospital. "The next step is definitely doing it in humans."

But groups that oppose human cloning and the destruction of human embryos to extract stem cells say the report makes it more urgent than ever to draw a moral line.

"I certainly think that this represents a new threshold in the entire discussion," said the Rev. Tad Pacholczyk, director of education at the National Catholic Bioethics Center. "At this point, it becomes essential to ask a question as a society: Are there ever going to be circumstances where it is morally justifiable to clone human beings?"

The cloned monkey stem cells have features indicating they are universal cells, Dr. Mitalipov said. When the investigators grew them in petri dishes, they turned the stem cells into monkey heart cells and

nerve cells. They also grew the stem cells in mice where the cells turned into a wide array of monkey cell types.

The stem cells, Dr. Mitalipov said, “can contribute to any cell of the body.”

In their research, which is to be published in the Nov. 22 issue of *Nature* (the journal released the paper today), the scientists began by cloning. They removed skin cells from a 9-year-old adult male rhesus macaque monkey and inserted those cells, along with all of their genes, into monkey eggs whose genetic material had been removed.

The monkey egg, in a part of the cloning process that is still mysterious, reprogrammed the genes from the skin cells, bringing them back to the state they were in when embryo development first begins. Those reprogrammed genes then took over the development of the eggs. The result was monkey embryos that were clones of the adult male monkey — they were genetically identical. A few days later, the researchers extracted stem cells from the embryo clones, destroying the embryos in the process.

Most of their attempts failed — the researchers started with 304 egg cells and ended up with two stem cell lines. One of the stem cell lines had an abnormal Y chromosome. The other, Dr. Mitalipov said, appeared normal.

But, he speculates, one reason the scientists succeeded at all was that they discovered a gentle way to take the genetic material out of monkey eggs. In their previous attempts, the researchers used a method that worked well in mice — they would mark the egg’s chromosomes with a dye that glowed under an ultraviolet light. That let them see the chromosomes and be sure they were removed before they inserted the adult cell with its genes into the egg.

The dye and the ultraviolet light, the Oregon researchers surmised, might be damaging the egg. So they used a new method that shines polarized light through the egg, allowing them to see the chromosomes directly, without using dyes.

Randall Prather, professor of reproductive biotechnology at the University of Missouri, said he had similar problems with the dyes and ultraviolet light when he tried to clone pigs. In that situation, he said, his group succeeded by going in blindly and plucking the nuclei out of the pigs’ eggs.

“Each system has a quirk to make it work,” Dr. Prather said.

Dr. Mitalipov said that once his group decided to use its modified methods of producing the cloned embryos, it took just a few months to get the stem cells.

“Publication took a lot longer,” he said. *Nature* received his paper in May and accepted it in October. And in publishing it, the journal included a paper by David S. Cram and his colleagues at Monash University in Melbourne, Australia, independently confirming that the stem cells were indeed genetically identical to the adult monkeys that were cloned.

Dr. Mitalipov said his group’s next project would be to use its new method to try to create cloned monkeys that carry genes for human diseases. The researchers would add human disease genes to adult skin cells before starting the cloning process. The result would be cloned monkeys that had the human disease gene in every one of their cells. Scientists could study those monkeys to understand the causes and treatment of the disease.

“We hope to model every known human disease,” Dr. Mitalipov said.

###

Statement by the Press Secretary on Promise of Advances in Ethical Stem Cell Research

November 20, 2007

President Bush is very pleased to see the important advances in ethical stem cell research reported in scientific journals today. By avoiding techniques that destroy life, while vigorously supporting alternative approaches, President Bush is encouraging scientific advancement within ethical boundaries.

President Bush was the first president to make federal funds available for human embryonic stem cell research -- and his policy did this in ways that would not encourage the destruction of embryos. In July 2006, the President highlighted research into the possibility of reprogramming adult skin cells into pluripotent stem cells without intruding on human embryos or eggs. The President's Executive Order issued in June 2007 was intended to accelerate precisely the kind of research being reported today. One of the studies announced today was funded in part by the National Institutes of Health operating under the President's stem cell policy.

The President believes medical problems can be solved without compromising either the high aims of science or the sanctity of human life. We will continue to encourage scientists to expand the frontiers of stem cell research and continue to advance the understanding of human biology in an ethically responsible way.

###

Stem Cell Vindication

Charles Krauthammer
Washington Post

November 30, 2007

"If human embryonic stem cell research does not make you at least a little bit uncomfortable, you have not thought about it enough."

-- James A. Thomson

A decade ago, Thomson was the first to isolate human embryonic stem cells. Last week, he (and Japan's Shinya Yamanaka) announced one of the great scientific breakthroughs since the discovery of DNA: an embryo-free way to produce genetically matched stem cells.

Even a scientist who cares not a whit about the morality of embryo destruction will adopt this technique because it is so simple and powerful. The embryonic stem cell debate is over.

Which allows a bit of reflection on the storm that has raged ever since the August 2001 announcement of President Bush's stem cell policy. The verdict is clear: Rarely has a president -- so vilified for a moral stance -- been so thoroughly vindicated.

Why? Precisely because he took a moral stance. Precisely because, to borrow Thomson's phrase, Bush was made "a little bit uncomfortable" by the implications of embryonic experimentation. Precisely because he therefore decided that some moral line had to be drawn.

In doing so, he invited unrelenting demagoguery by an unholy trinity of Democratic politicians, research scientists and patient advocates who insisted that anyone who would put any restriction on the destruction of human embryos could be acting only for reasons of cynical politics rooted in dogmatic religiosity -- a "moral ayatollah," as Sen. Tom Harkin so scornfully put it.

Bush got it right. Not because he necessarily drew the line in the right place. I have long argued that a better line might have been drawn -- between using doomed and discarded fertility-clinic embryos created originally for reproduction (permitted) and using embryos created solely to be disassembled for their parts, as in research cloning (prohibited). But what Bush got right was to insist, in the face of enormous popular and scientific opposition, on drawing a line at all, on requiring that scientific imperative be balanced by moral considerations.

History will look at Bush's 2001 speech and be surprised how balanced and measured it was, how much respect it gave to the other side. Read it. Here was a presidential policy pronouncement that so finely and fairly drew out the case for both sides that until the final few minutes of his speech, you had no idea where the policy would end up.

Bush finally ended up doing nothing to hamper private research into embryonic stem cells and pledging federal monies to support the study of existing stem cell lines -- but refusing federal monies for research on stem cell lines produced by newly destroyed embryos.

The president's policy recognized that this might cause problems. The existing lines might dry up, prove inadequate or become corrupted. Bush therefore appointed a President's Council on Bioethics to oversee ongoing stem cell research and evaluate how his restrictions were affecting research and what means might be found to circumvent ethical obstacles.

More vilification. The mainstream media and the scientific establishment saw this as a smoke screen to cover his fundamentalist, obscurantist, anti-scientific -- the list of adjectives was endless -- tracks. "Some observers," wrote The Post's Rick Weiss, "say the president's council is politically stacked."

I sat on the council for five years. It was one of the most ideologically balanced bioethics commissions in the history of this country. It consisted of scientists, ethicists, theologians, philosophers, physicians -- and others (James Q. Wilson, Francis Fukuyama and me among them) of a secular bent not committed to one school or the other.

That balance of composition was reflected in the balance in the reports issued by the council -- documents of sophistication and nuance that reflected the divisions both within the council and within the nation in a way that respectfully presented the views of all sides. One recommendation was to support research that might produce stem cells through "de-differentiation" of adult cells, thus bypassing the creation of human embryos.

That Holy Grail has now been achieved. Largely because of the genius of Thomson and Yamanaka. And also because of the astonishing good fortune that nature requires only four injected genes to turn an ordinary adult skin cell into a magical stem cell that can become bone or brain or heart or liver.

But for one more reason as well. Because the moral disquiet that James Thomson always felt -- and that George Bush forced the country to confront -- helped lead him and others to find some ethically neutral way to produce stem cells. Providence then saw to it that the technique be so elegant and beautiful that scientific reasons alone will now incline even the most willful researchers to leave the human embryo alone.

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SOTU: President Calls For Ban on Human Cloning and Hails Advances in Alternative Sources of Pluripotent Stem Cells

January 28, 2008

“On matters of life and science, we must trust in the innovative spirit of medical researchers and empower them to discover new treatments while respecting moral boundaries. In November, we witnessed a landmark achievement when scientists discovered a way to reprogram adult skin cells to act like embryonic stem cells. This breakthrough has the potential to move us beyond the divisive debates of the past by extending the frontiers of medicine without the destruction of human life. – President George W. Bush

President George W. Bush receives applause at the State of the Union Address Monday, Jan. 28, 2008, at the U.S. Capitol. Vice President Dick Cheney and Speaker of the House Nancy Pelosi are seen back right. So we're expanding funding for this type of ethical medical research. And as we explore promising avenues of research, we must also ensure that all life is treated with the dignity it deserves. And so I call on Congress to pass legislation that bans unethical practices such as the buying, selling, patenting, or cloning of human life.” – President George W. Bush

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'Blank' Stem Cells Showing Promise

Could quiet debate on embryos
Colin Nickerson, Boston Globe

April 8, 2008

Cambridge scientists have used stem cells that were "reprogrammed" from ordinary skin cells to alleviate symptoms of Parkinson's disease in rodents, illustrating the vast medical potential of this new type of stem cell.

In the study, rats whose midbrains were damaged in a way to closely mimic Parkinson's received transplants of healthy neurons cultivated from reprogrammed stem cells. These are basically biological "blank slates" that are believed to have the same capacity as embryonic stem cells to be turned into nerves, organs, bloods, bone, or any other cell type.

The brain-damaged rats had wandered in uncontrollable circles. After the treatment, however, eight of the nine test rats "showed markedly less or even no circling," according to Marius Wernig, a scientist at the Whitehead Institute for Biomedical Research and lead author of the research.

"This is the first demonstration that reprogrammed cells can integrate into the neural system or positively affect neurodegenerative disease," Wernig said.

The work, published yesterday in the journal *Proceedings of the National Academy of Sciences*, has political as well as medical significance since it may add weight to the argument - made by President Bush, among other religious conservatives - that there is no compelling reason to use human embryos to make stem cells. Reprogrammed cells are created from ordinary tissue without harming embryos. The work at the Whitehead, a Cambridge-based center loosely affiliated with the Massachusetts Institute of Technology, was done with rats, but the principle applies to humans.

"This shows that [reprogrammed] cells are able to function in the therapeutic manner that people have ascribed to them," said Rudolf Jaenisch, the pioneering Whitehead and MIT stem cell scientist who oversaw the work. "These cells are more readily available and much less controversial than embryonic stem cells. But they seem to have identical potential."

Jaenisch's lab has already achieved success in using reprogrammed cells to treat sickle cell anemia, a blood disease, in lab rodents.

"The basic idea is to use [reprogrammed] stem cells to make custom-designed healthy cells that will not be rejected by a patient," said Jaenisch. Since the new cells can be reprogrammed from the patient's own tissue, they are genetically identical.

But researchers concede that the direct therapeutic use in humans remains problematic because the reprogrammed cells are forged in a process that relies on potent regulator genes that are linked to cancer - raising the potential that they might trigger tumors in patients.

"In a human, we'd use the same process - taking adult cells, reprogramming it to the [stem cell] stage, then differentiating it into the cells we need," said Jaenisch. "But human work is a long way off. Science moves step by step."

Last year saw a series of breakthroughs in the creation of embryonic-like stem cells without making or destroying human embryos, winning applause from religious conservatives who had opposed the use of stem cells derived from cloned or frozen embryonic tissue.

The research from the Whitehead offers dramatic evidence that so-called IPS cells - for induced pluripotent stem cells - hold medical potential equal to the fanfare that greeted their appearance as an alternative to embryonic stem cells.

"This is a big step forward," said Margaret Sutherland, a program director at the National Institute of Neurological Disorders and Strokes. "IPS cells are still in their infancy. But this shows their use [in human medicine] could be near for things like drug screening" or in diagnosing patients.

The day is fast nearing when skin cells, for example, could be taken from a patient and quickly transformed into stem cells that can be used to test the efficiency of a specific medicine against a given disease - an individual's own flesh and blood, in the form of tissue made from reprogrammed cells, could be used to see if it is responsive to particular medicine or other therapy.

Parkinson's disease is a degenerative disorder caused by insufficient levels of a key brain signaling chemical, called dopamine. As many as 1 million Americans suffer from the disease, which results in loss of motor control.

The research at Whitehead was similar to work done earlier in the decade by Harvard Medical School and McLean Hospital in Belmont that used "pure" embryonic stem cells to relieve symptoms of Parkinson's disease in rats. The efficacy of true embryonic stem cells has been recognized for years, but reprogrammed cells are still uncharted territory.

The Whitehead researchers started with adult mouse skin cells, which were treated with four genes to regress into an embryonic stem cell-like state. In lab dishes, these cells were then coaxed into becoming brain tissue. This is the neural matter that was implanted into the brains of Parkinson's-afflicted rats - raw material from mice works fine in rats, at least in this experiment.

Within eight weeks of the transplant, the neurons generating dopamine were established in the rats' brains, alleviating symptoms of the disease.

"This is a proof-of-principle for using reprogrammed . . . cells for treating disease," said George Q. Daley, a prominent stem cell researcher at Children's Hospital Boston.

The revolutionary reprogramming technique, introduced using human cells only last year by scientists in Japan and the United States, uses genetic alteration to turn back the clock on adult cells, making them regress to an embryonic-like state. Then the time machine process can be reversed, with the cells coaxed to take on the form and function of any developed cell.

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Announcement of the New Armed Forces Institute for Regenerative Medicine

April 17, 2008

MR. FRATTO: Today at 1:30 p.m., the Department of Defense, in partnership with the Veterans Administration and the National Institutes of Health and some of America's finest research institutions will announce the creation of the Armed Forces Institute for Regenerative Medicine. This isn't the kind of thing we usually announce from here, but it is an exciting thing that the Armed Forces are working on, and the economic -- I'm sorry, the health researchers are working on.

Regenerative medicine is a promising new field focused on the repair and replacement of tissues and organs, which has been made possible in part by progress in stem-cell research. The center will use regenerative medicine to improve the lives of our wounded warriors and other Americans. The creation of this center for excellence is another important step by the administration to help the men and women who have protected our nation recover from injuries and to lead healthy lives. If you'd like to cover this event, please contact the Department of Defense.

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President Gives Remarks at the 2008 National Catholic Prayer Breakfast

April 18, 2008

THE PRESIDENT: Thank you for the gracious welcome. Austin, thanks for your kind introduction. Thanks for giving me this unusual speaking opportunity. I understand that this program builds up to another speech. (Laughter.) It's not every day you get to be the warm-up act to the Holy Father. (Laughter.) I'm honored to be here. I do thank Austin for his leadership for the Catholic Prayer Breakfast. I thank the Board of Directors for having me. I thank Archbishop Gomez, tejano, for being here. And I want to thank Bishop Finn, members of the clergy. Thank you for serving our country. Thank you for being men of faith.

I'm proud to be here with the Chief Justice of the Supreme Court, John Roberts. (Applause.) He's always looking for a free breakfast. (Laughter.) Proud to be here with members of the United States Senate and Congress. Thank you all for being here. Solicitor General Paul Clement is with us today. (Applause.) Members of my administration, members of the Diplomatic Corps and distinguished guests.

This has been a joyous week. (Applause.) It's been a joyous time for Catholics -- and it wasn't such a bad week for Methodists, either. (Laughter.) The excitement was just palpable. The streets were lined with people that were so thrilled that the Holy Father was here. And it was such a privilege to welcome this good man to the United States.

For those of you on the South Lawn -- who saw the South Lawn ceremony live, it was -- what an unbelievable -- it was just such a special moment. (Applause.) And it was a special moment to be able to visit with the Holy Father in the Oval Office. He is a humble servant of God. He is a brilliant professor. He is a warm and generous soul.

He is courageous in the defense of fundamental truths. (Applause.) His Holiness believes that freedom is the Almighty's gift to every man, woman and child on Earth. He understands that every person has value, or to use his words, "each of us is willed, each of us is loved, [and] each of us is necessary." (Applause.)

The Holy Father strongly believes that to whom much is given much is required -- and he is a messenger of God's call to love our neighbors as we'd like to be loved ourselves.

I've seen how American Catholics are guided by these truths. One of the blessings of being the President is I get to see firsthand how people are motivated by the fundamental truths articulated by the Holy Father. I've watched you live out the Gospel through countless acts of compassion and courage. I've joined with you in striving to heed the Scriptures' noble calling: to see God's image in all mankind, and to uphold the dignity of each human being on Earth. (Applause.)

Together, over the nearly seven and a half years we've worked to uphold the dignity of human life. Over the last -- over the last years, my administration has put a stop to U.S. tax dollars funding foreign groups that perform or promote abortions. (Applause.) We've worked together to protect unborn victims of violence, and to end the barbaric practice of partial-birth abortion. (Applause.) *We have stood fast in*

our belief that promising medical advances can co-exist with ethical medical practices. (Applause.)
Last November, scientists discovered a way to reprogram adult skin cells to act like embryonic stem cells. This is a significant breakthrough, because science -- scientists have found a path that can lead beyond the divisive debates of the past -- and extend the healing potential of medicine without destroying human life. (Applause.)

Together, we've worked to strengthen America's lifelines of learning -- including our nation's Catholic schools. The Catholic Church has a proud educational tradition dating back centuries, and one of the Holy Father's priorities has been maintaining this tradition in the United States. Today, America's Catholic schools serve thousands of students -- both Catholic and non-Catholic -- in some of our nation's poorest neighborhoods. They help minority students narrow the achievement gap. They prepare children for lives of character and purpose and success. And yet these schools are closing at an alarming rate: nearly 1,200 Catholic schools have shut their doors since the year 2000.

In my State of the Union address this January, I proposed a new \$300 million program called Pell Grants for Kids. And the reason I did so is because I want to help low-income children in underperforming public schools be able to attend a private or parochial school of their choice. (Applause.) I am concerned about the loss of a major national asset, and that is the decline of Catholic schools, particularly in inner-city America. And to this end, next week we're having a White House Summit on Inner-City Children and Faith-Based Schools. (Applause.) And the purpose of the summit is to highlight the lack of educational options facing low-income urban students. And we're going to bring together educators and clergy and philanthropists and business leaders, all aiming to urge there to be reasonable legislation out of Congress and practical solutions to save these schools -- and more importantly, to save the children. (Applause.)

And some of the people trying to save America's Catholic schools are here at this prayer breakfast, and I can't thank you enough for your efforts. (Applause.)

Together, we've worked to foster a culture of tolerance and peace. We believe that religion should be a source of understanding and grace -- not a source of extremism and violence. On his visit and throughout his time as the Holy Father, the Pope has worked to foster inter-religious dialogue, and to heal the wounds of religious conflict. I strongly support the Pope's call for religious freedom around the world. I share his concern for Christians in the Middle East, and his desire to see a peaceful and independent Lebanon. I respect his scholarship, which demonstrates that faith and reason can co-exist. And I join him in praying for a world at peace, where Christians and Muslims and Jews, believers and non-believers, can live side by side. And I thank all of you here who work to make this hopeful vision a reality. (Applause.)

Together, we've worked to bring comfort to troubled souls. We believe that where hearts are burdened by destitution and disease and despair, we must answer with hope and love and faith. We know that [no] government program can answer the call like our armies of compassion can -- but we also know that government programs can support, and must support, their work. And so I've been a strong believer in faith-based and community based effort to bring healing and hope to people who wonder whether or not there's a bright tomorrow.

I don't know if you really realize this, but in 2006, 3,000 direct federal grants totaling more than \$2 billion were made to faith-based organizations -- including many Catholic organizations. (Applause.) And the reason why is because Catholic organizations provide shelter to the homeless in very effective and loving ways. They tutor at-risk youth. They help children of prisoners, while at the same time they work tirelessly to help prisoners get back on their feet. These groups seek out our society's most vulnerable and fulfill Christ's promise that "the last shall be first."

Abroad, Catholic organizations are a vital part, an integral part of our effort to fight hunger and disease from Latin America to the continent of Africa. In these places, Catholic groups have a hand in what some call the "Lazarus Effect," where whole communities that once lay dying are brought back to life.

Oftentimes people ask me, why is it that you're so focused on helping the hungry and diseased in strange parts of the world? My answer is, we're a wealthy enough nation to take care of people at home and to help those abroad; it is in our moral interests that when we find people suffering that we do all we can do to help ease the burden; it's in our national interests -- (applause) -- and it's in our national interests that we defeat the ideologues of hate with an ideology of hope.

During these -- as President I've seen some of the great wonders of compassion as a result of our Catholic citizens. I've seen them here in Washington, with the Little Sisters of the Poor. (Applause.) Laura and I had the honor of visiting with the Little Sisters and, you know, I was struck by how hard they worked to ask [for] money to care for the old and sick, so that the old and sick don't have to beg for money.

I've seen these wonders of Catholic love on the Gulf Coast. I'm struck by the Catholic educators that in the face of unprecedented disaster worked night and day to provide good and stable schools for the children, and provide comfort for, you know, people that were just wondering whether or not there was going to be a good tomorrow.

I've seen wonders on the Sea of Galilee during my recent trip to the Middle East. On a recent visit my guides were joyful Catholic nuns who preserve the holy sites for all mankind -- even as they struggle with the dangers to the region's Christian minority.

I've seen these wonders in Africa, in an emergency -- in a hospital supported by PEPFAR. In February, I saw a 9-year-old girl who is HIV-positive, who had lost both her parents to AIDS. And for the last year, Catholic Relief Services had been paying for the girl to receive treatment at the clinic. I want to tell you what her grandmother said: "As a Muslim, I never imagined that a Catholic group would help me like that." She went on to say, "I am so grateful to the American people." And I am grateful for those who provide love and compassion in America and around the world. (Applause.)

This is a prayer breakfast. And this is a perfect place for me to say how much I appreciate the prayers of the people for me and Laura. I can't thank our fellow citizens enough for taking time out of their lives to lift us up for prayer. I have finally begun to understand the story of the calm and the rough seas -- (laughter) -- and I believe -- I believe in my heart of hearts that it's because of the prayers of my fellow citizens.

And today with the trust in the Lord's wisdom and goodness, I offer prayers of my own: for each gathered in the room, for the safety and success of the Holy Father's visit, and for God's continued blessings on our great land. Thank you. (Applause.)

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