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Domestic Policy Council

Zinsmeister, W. Karl - Subject Files

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Folder Title:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Handwritten Note	[Notes]	2	N.D.	P5;
002	Handwritten Note	[Notes]	1	N.D.	P5;
003	Briefing	Meeting on Embryonic Stem Cell Research	2	06/20/2007	P5;
004	Speech	Remarks on Stem Cell Veto and Executive Order	4	06/20/2007	P5; P6/b6;
005	Handwritten Note	[Notes]	1	N.D.	P5;
006	Handwritten Note	[Notes]	1	N.D.	P5;
007	Briefing	PT Notes 6/18 S.C.	5	06/18/2007	P5;

COLLECTION TITLE:

Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

FOLDER TITLE:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

FRC ID:

14303

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]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
008	Draft	Expanding Approved Stem Cell Lines in Ethically Responsible Ways	4	N.D.	P5;
009	Speech	Remarks on Stem Cell Veto and Executive Order	4	06/20/2007	P5; P6/b6;
010	Email	Two Year Stem Cell Goal - To: Joel Kaplan - From: Karl Zinsmeister	1	06/15/2007	P5;
011	Draft	[Draft]	2	N.D.	P5;
012	Email	[Email] - To: Raul Yanes, et al. - From: Karl Zinsmeister	1	06/19/2007	P5;
013	Email	Stem Cell Speech - To: William McGurn, et al. - From: Karl Zinsmeister	1	06/08/2007	P5;

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014	Email	FW: - To: Christopher Papagianis, et al. - From: Karl Zinsmeister	1	06/15/2007	P5;

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Embryonic Stem Cell Registry

- What are stem cells?
- Can they cure diseases?
- Are there ethical issues?
- What is the N.I.H. policy?
- More FAQs
- Links to related resources

Stem Cell Registry

- Stem Cell Registry
- Current Research
- Upcoming Events
- Funding for Research
- Training Programs
- Scientific Literature

Cell

- Site Map
- Privacy
- Downloads
- Site Feedback

Frequently Asked Questions (FAQs)

1. Why has the name of the NIH Human Embryonic Stem Cell Registry been changed?
2. What is meant by the term "pluripotency"?
3. What are the properties of pluripotent stem cells?
4. Where do pluripotent stem cells come from?
5. How did NIH determine what standards should be used to establish a cell's pluripotency?
6. What kinds of pluripotent cell lines will now be added to the National Institutes of Health Human Pluripotent Stem Cell Registry?
7. How will NIH determine what cell lines meet these standards?
8. How can a scientist get her or his pluripotent cell lines listed on the NIH Human Pluripotent Stem Cell Registry?
9. Does a cell line need to be listed on the NIH Human Pluripotent Stem Cell Registry in order to be eligible for Federal Funding?
10. Will NIH be distributing the human pluripotent stem cell lines listed on the new NIH Human Pluripotent Stem Cell Registry?
11. What human subjects regulations and policies must I follow in order to have my pluripotent cell lines, whether derived from adult or fetal tissue, listed on the NIH Human Pluripotent Stem Cell Registry?
12. What kind of information will help NIH determine if cell lines can be included on the NIH Human Pluripotent Stem Cell Registry?
13. Who will be reviewing information about your cell line?

1. Why has the name of the NIH Human Embryonic Stem Cell Registry been changed?

President George W. Bush required that the name of the registry be changed in his [Executive Order #13435](#) (96.4 KB PDF; get [Adobe Reader](#)), issued on June 20, 2007. As a result of this Executive Order, the former National Institutes of Health Human Embryonic Stem Cell Registry will now be called the "National Institutes of Health Human Pluripotent Stem Cell Registry." The registry will now include both human embryonic stem cells that were derived consistent with the [President's policy of August 9, 2001](#) and human pluripotent stem cells derived from non-embryonic sources.

2. What is meant by the term "pluripotency"?

Pluripotency is defined as the ability of stem cells to give rise to all of the various cell types that make up the body.

3. What are the properties of pluripotent stem cells?

Current scientific understanding of how to assess pluripotency is based on extensive studies of mouse embryonic stem (ES) cells. In mice, the gold standard test for the ability to form derivatives of all three germ layers (ectoderm, mesoderm, and endoderm) is injecting putative pluripotent cells (labeled to permit tracking of daughter cells) into a mouse blastocyst. If the injected cells are truly pluripotent, labeled daughter cells will be seen in tissues derived from all germ layers throughout the embryo. This method, however, is not practical in non-human primates, nor ethical when it involves the use of human cells or blastocysts. Consequently, scientists typically demonstrate the formation of all three germ layers by primate stem cells via teratoma formation. As our understanding of pluripotency and its molecular characteristics advances, alternative methods are likely to be developed and accepted.

4. Where do pluripotent stem cells come from?

At present, scientists are able to derive human pluripotent stem cells from the inner cell mass of a 5-day-old pre-implantation blastocyst-stage embryo obtained after in vitro fertilization; the cells derived in this manner are called human embryonic stem cells (hESCs). Recent publications report that scientists are now able to reprogram human adult skin cells to behave in many respects like hESCs. These reprogrammed human adult skin cells are known as induced pluripotent stem cells (iPSCs). Scientists continue to pursue additional ways to derive pluripotent human stem cells. NIH anticipates the need to continue to compare and evaluate new and existing sources of human pluripotent stem cells.

5. How did NIH determine what standards should be used to establish a cell's pluripotency?

The characterization of stem cells and the definition of pluripotency are under active investigation by scientists today. NIH examined the current literature for: 1) properties correlated with pluripotency; and 2) methods used to characterize human cells as pluripotent. The most commonly described properties were:

- ▶ Formation of a teratoma
- ▶ Unlimited self-renewal in culture
- ▶ Expression of a specific set of transcription factors (for example OCT4, SOX2, NANOG and POU5F1)
- ▶ Expression of a unique set of cell surface markers (such as SSEA-3, SSEA-4, TRA-1-60, and TRA-1-81)
- ▶ Formation of embryoid bodies
- ▶ A specific pattern of gene expression assayed by whole genome profiling
- ▶ A specific epigenetic profile

Two of these properties or methods were chosen as being most widely used and accepted as evidence of pluripotency: formation of a teratoma and unlimited self-renewal in culture. In addition, derivars should provide information on the expression of the transcription factors and cell surface markers that are widely used to characterize human pluripotent stem cells. NIH will update these criteria as additional and/or new standards are developed to establish pluripotency.

6. What kinds of pluripotent stem cell lines will now be added to the National Institutes of Health Human Pluripotent Stem Cell Registry?

Pluripotent cell lines derived from non-embryonic sources will be considered. Pluripotent cell lines derived from human embryos that meet the [eligibility criteria established by President George W. Bush on August 9, 2001](#) will also be considered. NIH will add cell lines to the new NIH Human Pluripotent Stem Cell Registry if derivars:

- ▶ Provide evidence that cells from the proposed cell line form a teratoma that contains cells from all 3 embryonic germ layers (endoderm, mesoderm, and ectoderm). This method was chosen because it is currently the gold standard for determining whether a human line is pluripotent. If cells from the line have not been demonstrated to form a teratoma, the derivars may provide alternative evidence of pluripotentiality for consideration by the NIH.
- ▶ Provide evidence that the cell line is capable of unlimited self-renewal.

7. How will NIH determine what pluripotent cell lines meet these standards?

The NIH Stem Cell Task Force has established a Pluripotency Standards Working Group that will evaluate submissions of cells and cell lines and assess them with respect to required properties. The Pluripotency Standards Working Group will also advise NIH on updating the criteria for establishing pluripotency as new science emerges. If appropriate, lines listed on the registry will be tested to determine that they meet the new standards.

8. How can a scientist get her or his pluripotent cell lines listed on the NIH Human Pluripotent Stem Cell Registry?

Scientists wishing to get their cell lines listed on the NIH Human Pluripotent Stem Cell Registry must submit evidence that their cells meet the minimum requirements listed in [FAQ #6](#), consider the items mentioned in [FAQ #12](#), and have the lines approved by the NIH Pluripotency Standards Working Group.

9. Does a pluripotent cell line need to be listed on the NIH Human Pluripotent Stem Cell Registry in order for the research on it to be eligible for Federal Funding?

Research using pluripotent stem cells derived from non-embryonic sources has been and continues to be eligible for Federal funds whether or not the cells are listed on the Registry. The August 9, 2001 policy limitation applies specifically to pluripotent stem cells derived from human embryos. Therefore, research using embryo-derived pluripotent stem cells is only eligible for Federal funding if it is listed on the NIH Human Pluripotent Stem Cell Registry.

Amniotic still alive?
(with trying to keep alive)

fresh dead embryos

This is the primary for amniotic, cord blood

10. Will NIH be distributing the human pluripotent stem cell lines listed on the new NIH Human Pluripotent Stem Cell Registry?

No, these lines remain the property of the scientists and/or institutions that generated them. Scientists wishing to obtain these cells for their experiments should contact the Principal Investigator listed on the Registry.

11. What human subjects regulations and policies must I follow in order to have my pluripotent cell lines, whether derived from adult or fetal tissue, listed on the NIH Human Pluripotent Stem Cell Registry?

Certain Federal regulations and policies may apply to the derivation of pluripotent cell lines from adult or fetal tissue. The Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 apply to non-exempt human subjects research that is conducted or supported by HHS, and also may apply to non-exempt human subjects research that is performed at an institution that has agreed to apply HHS regulations to all of its human subjects research through its assurance of compliance with the Office for Human Research Protections (OHRP). The Food and Drug Regulations at 21 CFR parts 30 and 36 generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved products. Additional information on FDA regulations is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm>. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 160 and 164 Subparts A and E may also apply to certain health information used for research.

Investigators deriving pluripotent cell lines should consult their institutional review boards (IRBs) and/or Privacy Boards for specific guidance about whether and how Federal, state and local regulations and policies apply to their work. Additionally, since some of the same regulations and policies may apply to the use of the cell line for subsequent research, guidance about these requirements and later use of these cell lines should be sought from the local IRB and/or Privacy Board.

HHS Regulations:

Research involving the derivation of pluripotent cell lines from non-embryonic sources that is conducted or supported by the HHS or performed at an institution that has agreed to apply the HHS regulations to all of its human subjects research through its assurance of compliance with OHRP may be subject to the HHS regulations for the protection of human subjects (45 CFR part 46). The requirement for IRB review for derivation of the cell lines depends on whether the research involves human subjects, and if so, whether the human subjects research is exempt under 45 CFR 46.101(b). The HHS regulations for the protection of human subjects only cover human subjects research that is not exempt.

The HHS human subjects regulations define a human subject as follows:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

When using stored tissue or cells that were not collected specifically for the proposed derivation of pluripotent cell lines through an interaction or intervention with a living individual, and that retain no links to the identity of the individual from whom the tissue or cells were originally obtained, the derivation of the cell line is not considered human subjects research under the HHS regulations. Therefore, IRB approval and informed consent would not be required for the derivation of the cell line.

When using stored tissue or cells from a deceased donor, the derivation of the cell line would not be considered human subjects research under the HHS regulations because those regulations apply only to living individuals. However, state or local laws may apply (e.g., if material is obtained from autopsy).

When using stored tissue or cells that can be linked by the investigators to the identity of the individual from whom the tissue was obtained, the derivation of the cell line constitutes human subjects research under the HHS regulations. However, such human subjects research may be exempt under 45 CFR 46.101(b). Specifically, the exemption at 45 CFR 46.101(b)(4), which pertains to certain research involving the collection or study of existing data or specimens, may be applicable. If the derivation of the cell line involves non-exempt human subjects research, then IRB review and approval and informed consent would be required from the subject, unless the IRB determines that the criteria for a waiver of informed consent have been met. However, the derivation of the cell line may not constitute human subjects research if the stored tissues or cells are coded and certain other conditions are met. See the HHS Office for Human Research Protections (OHRP) [Guidance on Research Involving Coded Private Information or Biological Specimens](#), August 10, 2004.

When tissues or cells for cell line derivation are obtained specifically for the proposed derivation of pluripotent cell lines through an interaction or intervention with a living individual, IRB review is required and informed consent must be obtained, unless the IRB waives the requirement for obtaining informed consent in accordance with the requirements of the HHS regulations at 45 CFR 46.116(d).

When using tissues or cells from human fetal tissue, federal regulations (e.g. 45 CFR part 46, the FDA human subjects regulations, and/or the HIPAA Privacy Rule) and state and local laws must be followed, where applicable. In addition, Sections II. B. and Section III of the [NIH Guidelines for Research Using Human Pluripotent Stem Cells](#) also apply.

OHRP information on how the HHS human subjects protection regulations apply to cells and specimens used for research is provided in:

- ▶ [Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles, March 19, 2002](#) (37.8 KB PDF; get [Adobe Reader](#))
- ▶ [Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004](#) (23.7 KB PDF; get [Adobe Reader](#))

The Health Insurance Portability and Accountability Act (HIPAA) Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) 45 CFR 160 and 164 Subparts A and E does not apply to specimens or cells per se, but may apply to information about individuals that is associated with the specimen or cells. The full text of the Privacy Rule can be found at the [HIPAA Privacy Website](#) of the Office for Civil Rights (OCR). Additional information about the Privacy Rule and research is available on the [NIH Privacy Rule website](#).

NIH Recombinant DNA Guidelines:

If the derivation of your pluripotent cell line involves recombinant DNA, you should consult the NIH Guidelines for Research Involving Recombinant DNA Molecules to determine whether they apply. The Guidelines are available for download at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.

12. What kind of information will help NIH determine if cell lines can be included on the NIH Human Pluripotent Stem Cell Registry?

For NIH to determine if your cell lines can be included on the Human Pluripotent Stem Cell Registry, NIH would be interested in knowing the following information:

Cell Line Information

- ▶ Cell line name or identifier
- ▶ Detailed protocol of derivation process and source of cell line
- ▶ Individual or institution who derived the cell line
- ▶ Individual or institution who owns the cell line
- ▶ Any published, peer-reviewed scientific journal article that includes experiments demonstrating the pluripotency of the human cell type or line being considered for inclusion on the NIH Human Pluripotent Stem cell Registry

Cell Characteristics

- ▶ Whether feeder cells were used during the isolation and the source of the feeder cells
- ▶ Passage number of the cell line
- ▶ Whether the cell line had normal or abnormal karyotype and the abnormality
- ▶ Whether the cells exhibit any of the following markers: SSEA-1, SSEA-3, SSEA-4, TRA-1-60, TRA-1-81, Oct-4, Alkaline Phosphatase, Nanog
- ▶ Whether a DNA fingerprint analysis of the cell line was performed

Demonstration of Pluripotency

- ▶ Whether or not your cells demonstrated the ability to give rise to a teratoma, ectoderm, mesoderm, endoderm, or other tissue type

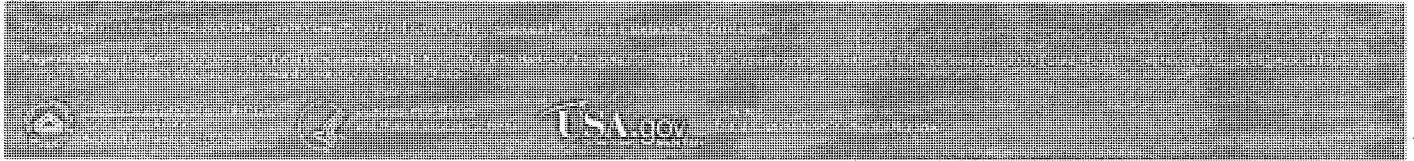
Demonstration of Self Renewal

- ▶ Whether your cell line is capable of dividing to produce more undifferentiated stem cells in culture, and the number of cell divisions the line has undergone

13. **Who will be reviewing information about your cell line?**

NIH Stem Cell Task Force
Human Pluripotent Stem Cell Registry Committee
31 Center Drive, Room 3C27, MSC (2320)
Bethesda, Maryland 20892-2320
Phone: 301-402-2313
Fax: 301-402-2265
E-mail: stemcell@mail.nih.gov

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Bush Will Pair Veto With New Cell Initiative

By SHERYL GAY STOLBERG

WASHINGTON, June 19 — President Bush will issue an executive order intended to encourage scientific advances in regenerative medicine, according to senior White House officials who said Mr. Bush would announce the initiative on Wednesday, just as he vetoes a measure promoting embryonic stem cell research.

The embryonic stem cell measure has widespread public support, and the veto would be the second time Mr. Bush has rejected it. By pairing the veto with a new scientific initiative, the White House clearly hopes to blunt the inevitable criticism that Mr. Bush will face from researchers, advocates for patients and politicians, including many in his own party.

In interviews on Tuesday, two senior administration officials said Mr. Bush would direct his health and human services secretary to promote research into producing cells with properties akin to those of human embryonic stem cells, without destroying embryos in the process. Mr. Bush has said embryo destruction is a moral line that he will not cross.

The officials said Mr. Bush wanted the National Institutes of Health to capitalize on recent scientific advances, including a study published this month involving skin cells in mice, that had the potential to sidestep the ethical controversies surrounding embryonic stem cell experiments. The White House has been consulting with scientists in recent weeks on the plan, they said.

"This is the product of a lot of really hard, earnest work on this policy," said Karl Zinsmeister, a domestic policy adviser to Mr. Bush who helped develop the initiative. "It is a real sincere effort to open up a new scientific solution to a vexing problem."

But the effort appears largely symbolic — there is no money at-

tached — and some scientists were instantly skeptical. Two leading stem cell researchers, interviewed Tuesday evening, said the recent work was no substitute for embryonic stem cell research. One, Douglas A. Melton of Harvard University, said he had become aware recently that the White House was trying to reach out to some of his colleagues who are pursuing the skin cell research, which has not been replicated in humans.

"It should be pursued just as actively as we pursue human embryonic stem cell research," Dr. Melton said of the recent studies. "I'm not trying to say there's nothing to this," he continued, "but it doesn't need any special attention from the White

Looking for avenues less problematic than embryonic stem cells.

House. All we've ever asked is let human embryonic stem cell research vie for public funding like all other research."

Tony Fratto, deputy White House press secretary, said the new initiative was "not about politics. It's about achieving effective policy."

Controversy over human embryonic stem cell studies has been a theme in the Bush presidency. The cells are considered valuable because they are "pluripotent," meaning they can develop into any type of tissue in the body, and might therefore yield treatments and cures. In August 2001, Mr. Bush said he would allow taxpayers to finance the research, but only on stem cell colonies, called lines, that already existed.

Scientists and advocates for pa-

tients have been pressing Mr. Bush to lift those restrictions. On Tuesday, two senior administration officials, speaking anonymously because the president had not yet announced his new initiative, summoned a reporter to the White House to share details of the alternative plan.

They said the initiative had three parts.

First, Mr. Bush will announce that the registry of embryonic stem cell lines eligible for research with federal tax dollars will be reconfigured as the "human pluripotent stem cell registry," a change intended to allow other types of stem cells to become eligible for federal financing if they have the same properties as embryonic stem cells.

Mr. Bush will also order Michael O. Leavitt, secretary of health and human services, to "support alternative techniques," the officials said. He will instruct Mr. Leavitt to come up with a plan describing how scientists and researchers who want to get new stem cell lines approved for the registry might do so.

The officials said the White House was particularly encouraged by several new avenues of research, including studies involving stem cells obtained from amniotic fluid, and efforts to extract stem cells from embryos that had been declared "clinically dead."

But scientists said those studies could be as ethically problematic as the ones Mr. Bush already opposes. John Gearhart, a stem cell researcher at Johns Hopkins University, said no one had figured out when an embryo could be declared clinically dead. The White House officials said it would be up to the health institutes to develop standards.

"It is not an alternative for embryonic stem cell research, because some of these alternative procedures still have ethical issues associated with them," Dr. Gearhart said, adding, "Who is the god that says the embryo is dead?"

Preservation Copy

Bush Moving to Bolster Stem Cell Alternatives

Embryonic Harvesting Remains Off-Limits

By MICHAEL A. FLETCHER
and DAVID BROWN
Washington Post Staff Writers

President Bush, under increasing pressure to relax his restrictions on embryonic stem cell research, plans to issue an executive order today to encourage government agencies to support research that offers the promise of creating medically useful stem cells without destroying human embryos, according to senior administration officials.

The order, which Bush plans to outline in a speech at the White House today, would require the Department of Health and Human Services to develop guidelines for funding alternative approaches over the next three months.

Bush is to issue his order as he vetoes legislation that would loosen his six-year-old restrictions on federal funding for embryonic stem cell research. The bill passed by comfortable — but not veto-proof — margins in the House and Senate. Bush has opposed research with stem cells derived in a process that destroys human embryos, which he calls immoral.

White House officials acknowledge that the executive order is less a change in policy than “a kick in the pants” for the government to make clear that it is willing to fund promising stem cell research. Recent advances have increased optimism that stem cells with potential for treating diseases or even developing into human organs for transplants can be developed from skin cells, amniotic fluid or even cells salvaged from dead embryos.

The White House sees the emerging research as a way out of a difficult and emotional debate. Shortly after becoming president, Bush banned federal funding of stem cell research that involves the destruction of human embryos, which have long been seen as the most promising source of stem cells. It was a position cheered by many conservative Christians and others who equate embryos with human lives.

Opponents said the ban was slowing the pace of potentially life-saving research, which is now being pursued with private and some state funding. In addition, opponents said the embryos from which stem cells are derived are slated for

“This disabuses us of this notion that there is this fundamental conflict between science and ethics,” Karl Zinsmeister, Bush’s top domestic policy adviser, said of the new research.

Scientists can receive federal funding only for work on embryonic stem cells obtained from roughly 20 colonies already in existence when Bush’s ban went into effect. In his speech, Bush is expected to express the hope that the recent advances will quickly expand the number of cell colonies compatible with federal funding.

There is some evidence that cells with the capacity to divide and grow into many different tissues exist in the placenta, umbilical cord blood and bone marrow. Winnowing them from other cells and successfully pushing them down a path toward medically useful purposes, however, has been difficult.

Part of the problem is that some of these “adult” stem cells are not as primitive and potent as those extracted from an embryo when it is at the stage of a barely visible ball of cells.

This month, three research teams announced that they were able to coax skin cells from mice to revert into more primitive and potent cells — the equivalent of going back in time. This raises the possibility that everyone may possess the raw material to make stem cells with the same therapeutic potential as ones from embryos.

Other researchers recently showed they could make healthy mouse stem cells from eggs with severe genetic abnormalities by removing the damaged chromosomes and putting in normal ones. If that could be done with some of the tens of thousands of chromosomally abnormal fertilized eggs routinely discarded by fertility clinics, it might be a source of ethically acceptable embryonic stem cells, some experts believe.

But translating research from lab to clinic, and from animals to humans, requires huge amounts of research. At least some of that work is what Bush apparently now wants to support more vigorously.

“The president supports and encourages stem cell research — including using embryonic lines — as long as it does not involve creating, harming or destroying embryos,” said White House spokesman Tony

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
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COLLECTION:

Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

FOLDER TITLE:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

FRC ID:

14303

OA Num.:

14165

NARA Num.:

14062

FOIA IDs and Segments:

2017-0029-F

2014-0503-F

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]
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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a(5) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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Records Not Subject to FOIA

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Briefing	Meeting on Embryonic Stem Cell Research	2	06/20/2007	P5;

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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."



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For Immediate Release
Office of the Press Secretary
June 20, 2007

Message to the Senate of the United States

[Fact Sheet: Advancing Stem Cell Research While Respecting Moral Boundaries](#)

[Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways](#)

[White House News](#)

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.

GEORGE W. BUSH

THE WHITE HOUSE,

June 20, 2007.



THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

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For Immediate Release
Office of the Press Secretary
June 20, 2007

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

[Message to the Senate of the United States](#)

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[White House News](#)

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.

GEORGE W. BUSH

THE WHITE HOUSE,

June 20, 2007.

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Zinsmeister, Karl

From: Papagianis, Christopher C.
Sent: Wednesday, June 20, 2007 3:38 PM
To: Troy, Tevi D.; Zinsmeister, Karl
Cc: Stefanik, Elise M.
Subject: FW: NRLC praises Bush veto and executive order on stem cell research

National Right to Life Commends President Bush for Executive Order and Veto, Advancing Research While Respecting Human Life

The following statement was released by the National Right to Life Committee (NRLC) in Washington, D.C., on Wednesday, June 20, 2007, at 3 PM EDT. For further information, send an e-mail to Legfederal@aol.com or call 202-626-8820.

WASHINGTON (June 20, 2007) -- The National Right to Life Committee (NRLC) today expressed strong approval of President Bush's veto of legislation (S. 5) that would mandate federal funding of the type of stem cell research that requires the killing of human embryos. NRLC also commended the President for issuing an executive order to promote more federal funding for promising types of stem cell research that do not require harming human embryos.

On June 7, House Speaker Nancy Pelosi (D-Ca.) said that "science has taken us to a place that is biblical in its power to cure -- and that is the embryonic stem cell research." NRLC Legislative Director Douglas Johnson commented, "Since not a single human being has benefited from any procedure using embryonic stem cells, Pelosi's statement is yet another demonstration that the congressional Democratic leadership is more interested in demagoguery than in supporting the most promising types of stem cell research, which do not require killing human embryos."

A close vote is expected in the Senate on whether to override the veto, which would require the votes of two-thirds of the sworn senators who are present and voting. If the Senate votes to override, S. 5 would return to the House of Representatives. The House has already voted on the issue twice this year -- on January 11 (253-174, on passage of H.R. 3, which is very similar to S. 5), and on June 7 (247-176, on passage of S. 5). There were different absentees on each occasion, but every House member voted on at least one of those two occasions, and if all House members had voted on June 7, the margin of passage would have been 35 votes short of a two-thirds margin. Contrary to some claims by Congresswoman Diana DeGette (D-Co.), there was no movement in either direction between the January and June roll calls.

According to a report in *Roll Call* (June 20), Senators Tom Harkin (D-Iowa) and Arlen Specter (R-Pa.) also intend to insert language in the appropriations bill for the Department of Health and Human Services, which they proclaim as a "compromise," but

which in reality would overturn the President's policy. NRLC's Johnson commented, "Such grandstanding won't overturn the President's pro-life policy, but it could result in the entire appropriations bill being vetoed." Indeed, the *Roll Call* article reports, "But one Senate Democratic source said the addition of the stem-cell provision will help divert attention from the price tag of the bill, which is expected to be far more expensive than the president requested."

On May 3, President Bush sent Senate Majority Leader Harry Reid (D-Nv.) and House Speaker Pelosi letters in which he said, "I will veto any legislation that weakens current Federal policies and laws on abortion, or that encourages the destruction of human life at any stage." More than one-third of the members of the House have signed a letter to the President, pledging that they will vote to sustain such vetoes. To view or download these letters, go to http://www.nrlc.org/press_releases_new/Release050307.html

To read NRLC's April 2 letter to House members in opposition to S. 5, go to: http://www.nrlc.org/killing_embryos/NRLCLettertoSenateS5andS30.html

To read a recent essay from National Review Online highlighting examples of widely disseminated misinformation about embryonic stem cell research, click [here](#).

For more information on human embryo research, human cloning, human fetus farming, and related issues, see: http://www.nrlc.org/killing_embryos/index.html and <http://www.stemcellresearch.org/>

If you do not wish to receive occasional updates from NRLC on issues such as this, simply REPLY to this e-mail with the word REMOVE in the body of your reply. Thank you.

See what's free at AOL.com.

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.

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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."

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Speech	Remarks on Stem Cell Veto and Executive Order	4	06/20/2007	P5; P6/b6;

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Records Not Subject to FOIA

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

Advancing Stem Cell Research While Respecting Moral Boundaries

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

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.

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Handwritten Note	[Notes]	1	N.D.	P5;

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COLLECTION:

Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

FOLDER TITLE:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

FRC ID:

14303

OA Num.:

14165

NARA Num.:

14062

FOIA IDs and Segments:

2017-0029-F

2014-0503-F

RESTRICTION CODES

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

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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Briefing	PT Notes 6/18 S.C.	5	06/18/2007	P5;

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Oregon scientist reports first ES cells from cloned primate embryos

By Natalie DeWitt and Monya Baker

The Niche-blog hosted by Nature Reports Stem Cells

http://blogs.nature.com/reports/theniche/2007/06/oregon_scientist_reports_first.html

Monkey embryonic stem cells have, for the first time, been created through somatic cell nuclear transfer (SCNT). All attempts to make human embryonic stem cells through nuclear transfer so far have failed, but Jamie Thomson got the recipe for human embryonic stem cells by first doing so in monkeys, so researchers will likely be going to Shoukhrat Mitalipov of Oregon National Primate Research Center for advice. Mitalipov made his announcement Monday at the International Society for Stem Cell Research in Cairns, Australia, in a special add-on presentation. This finding represents a proof of principle that therapeutic cloning to create patient-specific ES cell lines could work in primates.

Mitalipov and his colleagues used a classic nuclear transfer procedure, where a somatic cell nucleus (in this case from a skin biopsy from a ten year old adult rhesus monkey), was inserted into an enucleated egg. The egg was prodded to start dividing, and developed into a blastocyst (a hollow ball consisting of a few hundred cells). Then Mitalipov teased out the cells of the inner cell mass, a thickening in the ball that would have eventually formed the embryo proper if left undisturbed. Once they placed the cells into a culture dish, the cells began to divide, forming the world's first cloned primate ES cells.

The Oregon scientists isolated two separate monkey ES cell lines from 20 blastocysts, and went on to show that the ES cells showed the genetic hallmarks of a true cloned cell line, containing the mitochondrial DNA of the egg and the nuclear DNA of the somatic donor cell (which in this case was a male, making it easier to rule out the possibility that it was a parthenote.) The cells behaved like ES cells are supposed to do-- self renewing, differentiating into cardiac and neuronal lineages in vitro, and forming teratomas after injection into mice testes.

Mitalipov attributes his success to avoiding the use of a DNA stain to visualize the nucleus of the oocyte during its removal. Instead he combined microscopy with a visualization software that allowed him to see and remove the nucleus. The presumption is that this technique leaves some reprogramming factors in the egg undamaged, allowing them to transform the nucleus of a specialized cell.

"This is the first time this has been done in primates. It's something we've been looking for," said Alan Trounson of Monash University, adding that the data have not yet been published and the work not replicated and advising due caution.

Posted by Natalie DeWitt on June 18, 2007

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Draft	Expanding Approved Stem Cell Lines in Ethically Responsible Ways	4	N.D.	P5;

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Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

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OA Num.:

14165

NARA Num.:

14062

FOIA IDs and Segments:

2017-0029-F

2014-0503-F

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

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WHITE HOUSE STAFFING MEMORANDUM

Date: 6/18/07 7:00 P.M. ACTION / CONCURRENCE / COMMENT DUE BY: 6/19/07 10:00 A.M.

Subject: CLOSE HOLD - REMARKS ON STEM CELL VETO AND EXECUTIVE ORDER

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	SNOW	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SULLIVAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input type="checkbox"/>	<input type="checkbox"/>	TOWNSEND	<input type="checkbox"/>	<input type="checkbox"/>
FIELDING	<input checked="" type="checkbox"/>	<input type="checkbox"/>	WOLFF	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HADLEY	<input type="checkbox"/>	<input type="checkbox"/>	WRIGHT	<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	YANES	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HUBBARD	<input type="checkbox"/>	<input type="checkbox"/>	ZINSMEISTER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
KAPLAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input type="checkbox"/>
LAZEAR	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
MARBURGER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
MCBRIDE	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
MCGURN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
PORTMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS DIRECTLY TO MELISSA CARSON, EXT. 6-2180 / FAX 6-2983, BY TUESDAY, JUNE 19, 2007, AT 10:00 A.M., WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

KZ
CP

Assistant to the President
and Staff Secretary
Ext. 62702
FAX Ext. 62215

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Speech	Remarks on Stem Cell Veto and Executive Order	4	06/20/2007	P5; P6/b6;

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COLLECTION:

Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

FOLDER TITLE:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

FRC ID:

14303

OA Num.:

14165

NARA Num.:

14062

FOIA IDs and Segments:

2017-0029-F

2014-0503-F

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Email	Two Year Stem Cell Goal - To: Joel Kaplan - From: Karl Zinsmeister	1	06/15/2007	P5;

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Draft	[Draft]	2	N.D.	P5;

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Email	[Email] - To: Raul Yanes, et al. - From: Karl Zinsmeister	1	06/19/2007	P5;

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- A. Closed by Executive Order 13526 governing access to national security information.
- B. Closed by statute or by the agency which originated the document.
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Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Records Not Subject to FOIA

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Withdrawal Marker

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Email	Stem Cell Speech - To: William McGurn, et al. - From: Karl Zinsmeister	1	06/08/2007	P5;

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COLLECTION:

Domestic Policy Council

SERIES:

Zinsmeister, W. Karl - Subject Files

FOLDER TITLE:

Stem Cells 2007: Stem Cell Veto 2007 and Executive Order [1]

FRC ID:

14303

OA Num.:

14165

NARA Num.:

14062

FOIA IDs and Segments:

2017-0029-F

2014-0503-F

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]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Email	FW: - To: Christopher Papagianis, et al. - From: Karl Zinsmeister	1	06/15/2007	P5;

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