FOIA Number: 2013-0365-F

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Folder Title:
Stem Cell Issue [3]

Stack:	Row:	Section:	Shelf:	Position:
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Rachel Levinson to Barbara Woolley; re: 2 People to Add to the List (partial) (1 page)	04/12/1999	b(6)
002. list	re: Stem Cell Meeting - Attendees (partial) (1 page)	04/13/1999	b(6)
003. note	Cecile Coleman to Barbara Woolley; re: WH [White House] Clearance Information (partial) (1 page)	04/08/1999	b(6)
004. note	Tim Leshan to Barbara Woolley; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)
005. note	Marguerite Donoghue to Judy Park; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)
006. memo	Dave Moore to Barbara Woolley; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)

COLLECTION:
Clinton Presidential Records
Public Liaison
Barbara Woolley
OA/Box Number: 20953

FOLDER TITLE:
Stem Cell Issue [3]

2013-0365-F
jp3303

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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C. Closed in accordance with restrictions contained in donor's deed of gift.
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RR. Document will be reviewed upon request.

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February 19, 1999

The Honorable Tom Harkin
United States Senate
731 Hart Senate Office Building
Washington D.C. 20510

Dear Senator Harkin:

The undersigned organizations applaud the determination by the Department of Health and Human Services that current law permits the use of federal funds to support research utilizing human pluripotent stem cells.

Human pluripotent stem cells have the ability to give rise to other more specialized types of cells, such as muscle, skin, nerve, pancreas or blood cells. This ability to produce specialized cells opens a tremendous avenue of research with enormous potential for the treatment of many diseases. For example, human stem cells could be used to produce different kinds of specialized cells and tissues for use in transplantation to treat many diseases and conditions, including neurological disorders such as Parkinson's and Alzheimer's diseases, heart disease and stroke, diabetes, osteoarthritis, rheumatoid arthritis, and spinal cord injury.

Stem cell research also offers great promise for use in drug development and testing, to evaluate and understand both the beneficial and toxic effects of drugs on different human cell types, thus potentially reducing the need for animal studies and enabling fewer and more sharply focused human clinical trials. Research on human stem cells will open exciting new pathways by which to strengthen our understanding of normal human cell and tissue development. This, in turn, will accelerate our insights into the mechanisms of abnormal growth and development, and could lead to the discovery of radically new approaches to the prevention and treatment of birth defects and cancer.

The Federal government has an important role in funding and in overseeing the conduct of this research so that the talent and creativity of the nation's scientists -- both privately and federally funded -- can be applied to this valuable line of research. Federal involvement creates a more open research environment, promoting the free exchange of ideas and data among scientists, and ensuring greater public engagement and the protections of federal regulatory oversight. Federal support will also increase fiscal resources and expand the pool of well-trained investigators engaged in this area of research, both of which will speed the pace of scientific discovery.

We concur with the National Institutes of Health's plans to move forward to develop clear guidelines to address the special scientific, legal, and ethical issues surrounding this research. We are confident that this process will have appropriate public input, as well as the advice of the National Bioethics Advisory Commission and NIH's newly

established Council of Public Representatives. NIH has made clear that it will not support any research using human pluripotent stem cells until the appropriate guidelines have been developed and disseminated and an oversight process is in place.

Given the tremendous promise this research holds for millions of Americans, indeed all humankind, we strongly urge you to work with the NIH to ensure that this research can move forward with the support and oversight of the Federal government.

Sincerely,

Alliance for Aging Research
American Academy of Allergy, Asthma and Immunology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Association for Cancer Research
American Association for Dental Research
American Association for the Study of Liver Diseases
American Association of Colleges of Pharmacy
American Association of Dental Schools
American Association of Immunologists
American College of Cardiology
American Heart Association
American Lung Association
American Medical Association
American Pediatric Society
American Psychiatric Association
American Society for Biochemistry and Molecular Biology
American Society for Cell Biology
American Society for Microbiology
American Society for Pharmacology and Experimental Therapeutics
American Society for Reproductive Medicine
American Society of Clinical Oncology
American Society of Hematology
American Society of Tropical Medicine and Hygiene
American Thoracic Society
American Veterinary Medical Association
Americans for Medical Progress
America's Blood Centers
Association of Academic Departments of Otolaryngology - Head and Neck Surgery
Association of American Medical Colleges
Association of Independent Research Institutes
Association of Medical School Microbiology and Immunology Chairs
Association of Medical School Pediatric Department Chairs
Association of Professors of Dermatology

Citizens for Public Action
College on Problems of Drug Dependence
Cooley's Anemia Foundation
Cystic Fibrosis Foundation
East Carolina University School of Medicine
Emory University School of Medicine
Endocrine Society
Federation of American Societies for Experimental Biology
Federation of Behavioral, Psychological and Cognitive Sciences
Fred Hutchinson Cancer Research Center
Jeffrey Modell Foundation
Johns Hopkins University
Joint Council of Allergy, Asthma and Immunology
Juvenile Diabetes Foundation International
Krasnow Institute for Advanced Studies
Massachusetts Institute of Technology
National Alliance for Eye and Vision Research
National Alliance for the Mentally Ill
National Caucus of Basic Biomedical Science Chairs
National Health Council
National Organization for Rare Disorders
National Osteoporosis Foundation
National Spinal Cord Injury Association
New York University School of Medicine
Oklahoma Medical Research Foundation
Pharmaceutical Research and Manufacturers of America
ResearchIAmerica
Research Society on Alcoholism
RESOLVE, the National Infertility Association
Society for the Advancement of Women's Health Research
Society for Pediatric Research
Society for Reproductive Endocrinology and Infertility
The Genome Action Coalition
The Health, Safety and Research Alliance of New York State, Inc.
The Protein Society
Tourette Syndrome Association

THE AMERICAN SOCIETY FOR CELL BIOLOGY

NATIONAL OFFICE: 9650 Rockville Pike • Bethesda, Maryland 20814-3992
TEL: 301/530-7153 • FAX: 301/530-7139 • E-MAIL: ascbinfo@ascb.org • www.ascb.org/ascb

March 4, 1999

To the President of the United States and Members of the United States Congress:

We, the undersigned, urge you to support the decision to permit federally-funded biomedical scientists to conduct research with human "pluripotent" stem cells. This critical research can be advanced while simultaneously protecting the moral sensibilities of the American people.

Human pluripotent stem cells are not embryonic cells because they cannot become a human being nor can they undergo embryological development. It is likely, however, that further research will reveal how to induce these cells to form certain specialized cell types that can be used for the treatment of human disease. A large body of successful work with mouse pluripotent stem cells encourages us to believe that as we progress to studies with human stem cells we will learn how to induce these cells to become bone marrow for treatment of cancer and other hematopoietic diseases, pancreatic cells for alleviating diabetes, and neuronal cells for treating Parkinson's disease, Alzheimer's and various forms of brain and spinal cord disorders. Treatments using these stem cells could be much more effective than existing therapies because they may be engineered to be less susceptible to rejection.

There are serious negative consequences of not allowing federally funded scientists to work with human pluripotent stem cells. The net effect will be to bar the majority of the Nation's most prominent researchers who are supported by the National Institutes of Health and the National Science Foundation at universities and non-profit institutions throughout the country from engaging in this critical research. Excluding these investigators will close off scientific opportunities to those most qualified to make dramatic advances towards using stem cells for the treatment of disease. Moreover, the new scientific understanding that emerges would not flow into the public domain and may be restricted to the commercial sector. Permitting peer-reviewed federal funds to be used for this research, combined with public

oversight of these activities, is our best assurance that research will be of the highest quality and performed with the greatest dignity and moral responsibility. We hope that the President and the Congress together will make the informed and courageous decision to guarantee that those scientists who are most prepared and qualified to conduct safe, ethical and invaluable stem cell research be enabled to do so.

Stem cell research has enormous potential for the effective treatment of human disease. There is, therefore, a moral imperative to pursue it. Those who seek to prevent medical advances using stem cells must be held accountable to those who suffer from horrible disease and their families, why such hope should be withheld.

Sincerely yours,

Kenneth J. Arrow
Professor of Economics and
Operations Research Emeritus
Stanford University
Nobel Prize in Economics, 1972

David Baltimore
President
California Institute of Technology
Nobel Prize in Physiology or Medicine, 1975

Baruj Benacerraf
Fabyan Professor of Comparative Pathology
Emeritus
Harvard Medical School
Nobel Prize in Physiology or Medicine, 1980

Paul Berg
Stanford University School of Medicine
Cahill Professor of Cancer Research
Department of Biochemistry
Nobel Prize in Chemistry, 1980

J. Michael Bishop
University Professor
Chancellor, University of California, San Francisco
Nobel Prize in Physiology or Medicine, 1989

Steven Chu
Professor of Applied Physics
Stanford University
Nobel Prize in Physics, 1997

Stanley Cohen
Distinguished Professor of Biochemistry
Vanderbilt School of Medicine
Nobel Prize in Physiology or Medicine, 1986

E. J. Corey
Professor of Chemistry
Harvard University
Nobel Prize in Chemistry, 1990

Edmund H. Fischer
Professor, Emeritus of Biochemistry
University of Washington
Nobel Prize in Physiology or Medicine, 1992

Robert Furchgott
University Distinguished Professor Emeritus
State University of New York
Health Science Center at Brooklyn
Nobel Prize in Physiology or Medicine, 1998

Alfred G. Gilman
Regental Professor and Chairman
University of Texas Southwestern Medical Center
Department of Pharmacology
Nobel Prize in Physiology or Medicine, 1994

Donald A. Glaser
Professor of Physics and of Neurobiology in the
Graduate School
University of California at Berkeley
Nobel Prize in Physics, 1960

Joseph L. Goldstein
Professor and Chairman
Department of Molecular Genetics
University of Texas Southwestern Medical Center
at Dallas
Nobel Prize in Physiology or Medicine, 1985

Roger Guillemin
Distinguished Research Professor
The Salk Institute for Biological Studies
Nobel Prize in Physiology or Medicine, 1977

Dudley Herschbach
Baird Professor of Science
Harvard University
Nobel Prize in Chemistry, 1986

ASCB Stem Cell Research Position/Page 3

David H. Hubel
John Franklin Enders University Professor of Neurobiology
Harvard Medical School
Nobel Prize in Physiology or Medicine, 1981

Arthur Kornberg
Professor of Biochemistry
Stanford University Medical Center
Nobel Prize in Physiology or Medicine, 1959

Edwin G. Krebs
Professor Emeritus
Department of Pharmacology
University of Washington
Nobel Prize in Physiology or Medicine, 1992

Joshua Lederberg
President Emeritus
The Rockefeller University
Nobel Prize in Physiology or Medicine, 1958

Leon M. Lederman
Pritzker Professor of Science
Illinois Institute of Technology
Nobel Prize in Physics, 1988

Ferid Murad
Professor and Chair, Department of Integrative Biology & Pharmacology
Director, Institute of Molecular Medicine
John Dunn Distinguished Chair in Medicine and Physiology
Regental Professor, University of Texas, Houston
Nobel Prize in Physiology or Medicine, 1998

Daniel Nathans
University Professor of Molecular Biology and Genetics
The Johns Hopkins University
Senior Investigator, the Howard Hughes Medical Institute
Nobel Prize in Physiology or Medicine, 1978

Marshall Nirenberg
Chief, Laboratory of Biochemical Genetics
National Heart Lung & Blood Institute
The National Institutes of Health
Nobel Prize in Physiology or Medicine, 1968

George Olah
Professor and Director
Loker Hydrocarbon Research Institute
University of Southern California
Nobel Prize in Chemistry, 1994

Douglas D. Osheroff
J.G. Jackson and C.S. Wood Professor of Physics
Stanford University
Nobel Prize in Physics, 1996

George Palade
Professor, Department of Medicine, Division of Cellular and Molecular Medicine
Dean, Scientific Affairs
University of California, San Diego School of Medicine
Nobel Prize in Physiology or Medicine, 1974

Burton Richter
Paul Pigott Professor of Physics
Stanford University
Nobel Prize in Physics, 1976

Richard J. Roberts
Research Director
New England Biolabs
Nobel Prize in Physiology or Medicine, 1993

Phillip A. Sharp
Professor and Head
Department of Biology
Massachusetts Institute of Technology
Nobel Prize in Physiology or Medicine, 1993

E. Donnall Thomas, M.D.
Member
Fred Hutchinson Cancer Research Center
Nobel Prize in Physiology or Medicine, 1990

James D. Watson
President
Cold Spring Harbor Laboratory
Nobel Prize in Physiology or Medicine, 1962

Eric F. Wieschaus
Professor of Molecular Biology
Princeton University
Nobel Prize in Physiology or Medicine, 1995

Torsten Wiesel
President Emeritus
The Rockefeller University
Director, the Shelby White & Leon Levy Center for Mind Brain & Behavior
Nobel Prize in Physiology or Medicine, 1981

NATIONAL BIOETHICS ADVISORY COMMISSION

6100 Executive Blvd
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Rockville, MD
20892-7508

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Facsimile
301-480-6900
Website
www.bioethics.gov

March 9, 1999

Harold E. Varmus, M.D.
Director
National Institutes of Health
Building 1, Room 126
Bethesda, MD 20892

Dear Harold:

In my January 22nd letter to you I provided an outline of NBAC's plans for completing our report on research involving human stem cells, and our hope to provide the President (and others) with the benefit of any conclusions we might come to along the way. Given your own interest in NBAC's work, I wanted to share with you some of the commission's thinking at this point, even though no specific conclusions have been reached. This thinking is preliminary and is based on our most recent meeting (March 2-3), and reflects my views.

We seem to be coming to general agreement that federal funding for research involving the derivation and use of human embryonic stem (hES) cells should be permitted for at least the following categories of research: research using hES cells obtained from fetal tissue, and research using hES cells obtained from embryos in excess of those needed from infertility treatments. The commission is less close to agreement on the appropriateness of using federal funds to use (or derive) hES cells from embryos intentionally produced for research purposes (for example from somatic cell nuclear transfer), but I am confident that we will have something to say about this.

I am also enclosing a working draft, "Points to Consider," for your information. I had asked NBAC staff to prepare this document for two reasons: first, it may provide a useful summary of many of the ethical issues that might arise in research involving hES cells; second, it could, eventually, be included in our report as a suggestion for use (or adoption) by others. The commission has taken no position on this document at this time, but you may find it useful as you continue your thinking on how NIH will consider ethical issues. I recognize that this document reflects the model utilized by the Recombinant DNA Advisory Committee, but we took no position on whether it should be used by any particular group in that way.

We remain on target for completing our report by June, and I hope you will continue to follow our deliberations. I would be pleased to provide any clarification on any of these points.

Sincerely,

Harold T. Shapiro
Chair

168935

NBAC STAFF DRAFT

Points To Consider
In Evaluating Basic Research Involving Human Stem Cells

The following *Points to Consider* are presented not to prejudge the question whether human stem cell research should be conducted using federal funds. Rather, this document describes some of the ethical, clinical, scientific, and legal issues that could be considered when designing and/or reviewing studies that involve access to and use of human stem cells. These *Points to Consider* are only relevant for designing and evaluating studies where the role of the individual(s) who provide gametes, fetal tissue or embryos is limited to providing these materials for research that is intended to develop generalizable new knowledge. *These Points to Consider do not apply to situations in which an individual would be the recipient of a stem cell-based therapy, nor do they apply to studies involving human/animal hybrids.*

I. Scientific and Research Design Considerations

Several issues arise when designing research involving human stem cells, consideration of which would help ensure that research is well-designed, important, feasible, and timely. These issues are of particular significance given the nature of the materials.

A. The Source From Which The Human Stem Cells Will Be Obtained
   1. From existing cell lines (such as neuronal or hematopoietic stem cells)
   2. From aborted fetal tissue (following spontaneous or induced abortion or surgical termination of ectopic pregnancy)
   3. From stored/spare embryos obtained from infertility treatment
   4. From embryos produced for research purposes (including somatic cell nuclear transfer)

B. Previous Research Involving Animals

C. Alternatives To Using Human Stem Cells

D. Future Plans And Conservation Of Gametes, Fetal Tissue, and Embryos
   1. Will stem cells be produced and stored for later use?
   2. If a particular protocol is being proposed using stored embryos, does it use only the number of embryos necessary?
   3. What plans exist in the event that additional stem cells are needed?

E. The Research Setting
   1. Are the investigators scientifically qualified to carry out the proposed research?
   2. Is the research environment (including facilities) appropriate for the conduct of research involving stem cells?

II. Identification of Providers and Donors, Recruitment Practices, and Compensation

Several issues in identifying individuals (or couples) who may be asked to consider providing gametes, fetal tissue, or embryos for research involving human stem cells, consideration of these issues could help to ensure that no inappropriate burden, inducement or exploitation would occur.

A. Identification And Recruitment Practices
   1. Are potential donors or providers identified through advertisements to the general public? Are they identified through direct solicitation? Do they self-select?
   2. Is the selection of such individuals equitable and fair?

3. Are these individuals vulnerable to undue influence, coercion or exploitation? Does the recruitment method raise concerns about undue influence or coercion of the prospective donors? embryos?
4. Are the potential donors capable of giving an informed consent?
5. In which circumstances is it appropriate to identify and recruit an individual as well as his or her partner?

B. Compensation And Reimbursement

1. Will any financial compensation be paid to individuals (or couples) who provide source material ?
2. Does the compensation exceed the costs already being incurred (for example, the cost of embryo storage)? Will this fact be disclosed?
3. Does the compensation reimburse the individual (or couple) for specific services (e.g., gametes, infertility services)?
4. When is the offer of compensation made relative to individual's (or couple's) decision to make available the materials from which stem cells will be derived?

III. Informed Consent

Several issues arise in the process of informed consent (including the content of consent forms); considering these issues would help to ensure that ensure prospective donors or providers of source materials would receive timely, relevant and appropriate information to make informed and voluntary choices

A. General Considerations For Individuals (or Couples) Who Provide Gametes, Fetal Tissues or Embryos

1. Who will obtain informed consent? Will a clinician and researcher be available to answer questions?
2. Is it appropriate for others to participate in the consent process (e.g., partner or family member)?
3. Will psychological support mechanisms be in place when needed?
4. Are the purposes of stem cell research (in general) fully described?
5. If a specific research protocol is being contemplated with stem cells obtained, is the protocol fully described?
6. What are the possible risks to the woman (or partner) from the procedure to obtain stem cells, and how will these be minimized?
7. Will the consent form clearly disclose that stem cell research is not intended to benefit them directly?
8. Is it clear that decisions to consent to or refuse the procedures to obtain stem cells will not enhance the quality of care they will receive?
9. Will individuals be informed that no medical or genetic information about the gametes, fetal tissue, embryos, or stem cells derived from these sources will be provided?
10. What measures will be taken to protect the privacy and confidentiality of individuals who provide gametes, fetal tissue or embryos?
11. Is the source of funding for research (public, private, public/private, philanthropic) disclosed?
12. What known commercial benefits, if any, are expected to arise for the investigators seeking to obtain human stem cells?

B. Issues Specific To Consenting To The Use of Fetal Tissue

1. Is there a description of what is usually done with fetal tissue at the institution at which individuals are undergoing termination of pregnancy? Is this information available in written form and provided to the individuals?
2. Is there a description that the decision to permit research will entail that research may begin immediately.

C. Issues Specific To Consenting To The Use of Embryos Obtained From Infertility Treatments

1. Is there a description of what is usually done with spare embryos at the institution at which individuals are undergoing infertility treatment? Is this information available in written form and provided to the individuals?
2. Will information be made available about whether the spare embryo was viable and normal or non-viable and abnormal?
3. Is there a description of options available (e.g., permit material to be used in research, cryopreserve, discard, donate to another couple for infertility treatment)?
4. Is it clear that the embryos used in research will not, under any circumstances, be transferred to any woman's uterus?
5. Is it clear that the research will result in the destruction of the embryo? Is the method described?

D. Issues Specific To Consenting To The Use of Gametes[1]

1. Will individuals be informed whether embryos will be produced with the gametes (e.g., using *in vitro* fertilization, or somatic cell nuclear transfer?)
2. Is there a description of what is usually done at this institution with gametes not used for research?
3. Is there a description of options available (e.g., permit materials to be used in research, cryopreserve, discard, donate to another couple for fertilization and transfer)?
4. Is it clear that the embryos produced for research purposes (whether by IVF or somatic cell nuclear transfer) will not, under any circumstances, be transferred to any woman's uterus?

IV. Review Issues

Several issues arise in the review and oversight of research involving human stem cells; consideration of these issues will provide assurance that, regardless of the source of funding, appropriate compliance with applicable regulations, guidelines and other standards will occur. These considerations would supplement, not replace, applicable federal and state regulations.

A. Applicability of Relevant Regulations

1. What current guidelines, regulations, rule, or policies apply to the conduct of this research?
2. What mechanisms are in place to assure compliance with these regulations?

B. Applicability of Professional Practice Standards

C. IRB Review

D. Submission of Research Findings for Publication

E. Other Responsibilities of Investigators and Collaborating Clinicians

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[1] Note: For persons who provide sperm anonymously, the details of the consent form and the specificity of the informed consent process may vary—EMM 2/15/99

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Rachel E. Levinson 04/12/99 05:39:00 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: 2 people to add to the list

Pat white's info: Francis P. White, dob: (b)(6) SSN: (b)(6)

He will definitely be there.

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 04/12/99 05:37 PM ----------

Rachel E. Levinson 03/31/99 04:09:52 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: 2 people to add to the list

Harley Thomas
Associate Legislative Director, Paralyzed Vets Association
202-872-1300

Pat White
American Association of Immunologists
301-571-0643

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EVENT: Stem Cell Meeting
DATE: April 13, 1999
TIME: 3- 4PM
SPONSORING OFFICE: opl

LAST NAME	FIRST NAME	DOB	SSN	CITIZEN? (Y/N)	COUNTRY CODE
Lipner	Robyn	(b)(6)	(b)(6)	Y	US
Ludlam	Charles			Y	US
Melanson	Jess			Y	US
Guarducci	Mara			Y	US
Kerr	Eleanor			Y	US
Chow	Ida			Y	US
Weinberg	Nina			Y	US
Dougherty	Pamela			Y	US
Tipton	Sean			Y	US
Perry	Daniel			Y	US
Soler	Lawrence			Y	US
Milo	Sara			Y	US
Leshan	Timothy			Y	US
Moore	Dave			Y	US
Hendricks	Karen			Y	US

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C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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Alliance for Aging Research

2021 K Street, NW • Suite 305 • Washington, D.C. 20006 • 202/293-2856 • FAX 202/785-8574

WHITE HOUSE CLEARANCE INFORMATION

TO: Barbara Woolley - 456-6218
Office of the Press Secretary

FROM: Cecile Coleman
Executive Assistant

RE: WH Clearance Information

Ms. Woolley,

Dan is out of the office on business, however, he has received your message and will be able to participate at a stem cell research briefing at the White House. He is available for Tuesday, April 13 at 3 pm (Rm 100 OEOB).

As you requested, listed below is Dan's personnel information for clearance. Please do not hesitate to contact me at (202) 293-2856 if I can be of further assistance.

Daniel P. Perry (Dan)
Executive Director, Alliance for Aging Research

Date of Birth: (b)(6) [003]

Social Security: (b)(6)

Driver License: 560-62-7960 (expiry 3/31/2000)

Business address/tel/fax: Alliance for Aging Research
2021 K Street, NW, Suite 305
Washington, DC 20006
T: 202/293-~~2840~~ 2856 - F: 202/785-8574

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004. note	Tim Leshan to Barbara Woolley; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)

COLLECTION:
Clinton Presidential Records
Public Liaison
Barbara Woolley
OA/Box Number: 20953

FOLDER TITLE:
Stem Cell Issue [3]

2013-0365-F
jp3303

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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THE AMERICAN SOCIETY FOR CELL BIOLOGY

9650 Rockville Pike, Bethesda, MD 20814-3992

TO: Barbara Wooley	From: Tim Leshan
Number of Pages including cover: 1 / Date: 4/7/99	Telephone Number: 301-530-7153
Fax Number: 202-456-6218	Fax Number: 301-530-7139
Subject: Stem Cell Meeting	E-mail: ascbinfo@ascb.org

Barbara - Thank you for inviting me to the Stem Cell meeting on April 13 at 3:00 p.m. in room 100 of the Old Executive office building. I have just learned that one of our scientist, Dr. Larry Goldstein, who has testified before Congress on this issue will be in town that day. Would it be appropriate to bring him along? If not that is fine, but if so I will see if he could make the meeting.

Please also invite Mike Clayes to the meeting from the Parkinson Action Network at 1-800-850-4726. If you have any other questions please let me know.

Timothy E. Leshan
DOB
SS# (b)(6)

[004]

email - tleshan@ascb.org

FAX COVER PAGE

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. note	Marguerite Donoghue to Judy Park; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)

COLLECTION:
Clinton Presidential Records
Public Liaison
Barbara Woolley
OA/Box Number: 20953

FOLDER TITLE:
Stem Cell Issue [3]

2013-0365-F
jp3303

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The N•C•C•R

A coalition of cancer organizations joining together to advocate for cancer research

426 C STREET, N.E.
WASHINGTON, D.C. 20002
(202) 544-1880
(202) 543-2565 FAX

April 7, 1999

To: Judy Park
White House Office of Public Liaison

From: Marguerite Donoghue
Executive Director, NCCR

Subject: Stem Cell Meeting

Judy, thanks so much for the invitation to the strategy meeting on Stem Cells. The NCCR has been active on this issue and is in the process of disseminating our position statement to offices on Capitol Hill. Unfortunately, I will be out of town at the AACR meetings, but one of my colleagues will be attending for me. Her information is as follows:

Sara Milo
DOB: (b)(6)
SS#

[005]

Judy, if you could just let me know where in the OEB the meeting will be held so that I can let Sara know that would be great. You can call and leave a message at (202) 544-1880 or email me at md@capitolassociates.com. Thanks so much.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006. memo	Dave Moore to Barbara Woolley; re: Stem Cell Meeting (partial) (1 page)	04/07/1999	b(6)

COLLECTION:
Clinton Presidential Records
Public Liaison
Barbara Woolley
OA/Box Number: 20953

FOLDER TITLE:
Stem Cell Issue [3]

2013-0365-F
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ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2450 N STREET, NW, WASHINGTON, DC 20037
PHONE 202-828-0400 FAX 202-828-1125
HTTP://WWW.AAMC.ORG

Memorandum [via fax]

April 7, 1999

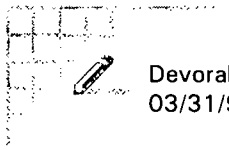
To: Barbara Woolley

From: Dave Moore

Subj: April 13 Stem Cell Meeting

I will attend the meeting on Tuesday, April 13, at 3 p.m. in room 100 of the Old Executive Office Building. (b)(6) (b)(6)

[a06]



Devorah R. Adler
03/31/99 10:11:31 AM

Record Type: Record

To: Rachel E. Levinson/OSTP/EOP, Jennifer M. Luray/WHO/EOP, Barbara D. Woolley/WHO/EOP

cc: Kelley L. O'Dell/WHO/EOP, Sarah A. Bianchi/OVP @ OVP, Teresa M. Jones/OPD/EOP
Subject: stem cell

Hello --

I guess we are now working on a time next week for Chris, Jennie, Barbara, and Rachel to talk to the research and disease groups to forewarn them that stem cell research is likely to play a prominent part in the Republican's anti-choice agenda, and that they should be vigilant in this area.

Chris would like to get a general sense from Jennie and Rachel what his message to them should be -- are there specific members they should lobby? is there something we want them to do that they are not doing? what do we want to send them off to do?

When we schedule the meeting with the groups, we should add 15 minutes on the front end for him to talk about these issues with you, rather than schedule a separate meeting to brief him.

Thanks a lot.

Devorah

Rachel E. Levinson 04/01/99 01:28:10 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: stem cell

have you/are you going to respond to Devorah's e:mail about scripting this for Chris? Should we talk again about how to brief him on Tuesday before the meeting? I am assuming that he will run it - is that a correct assumption? I think he would just reiterate the President's statements on the importance of stem cell reseach and our hope that the embryo research ban will not be tightened to stop such research. Then what we've heard about GOP activity and ask what others have heard about potential Hill action and efforts to allow stem cell research to proceed.

I believe that Neal Lane is available to attend/drop by the meeting. Can I go ahead and get this on his calendar?

I have been busy clearing Qs and As directed toward Shalala and Varmus following approps hearings. They continue to support and further define the HHS GC's interpretation of the ban to NOT apply to USE of human stem cells. Questions came from Specter (supportive), Kyl (investigatory) and Istook (inflammatory).

I

email

(REVISED)

ROLLOUT STRATEGY FOR STEM CELL ISSUE

Congressional

A List

Senate:

- Frist
- Hatch
- Domenici
- Bennett (*)
- Jeffords (*)
- Mack (*)
- Specter (*)
- Thurmond (*)
- Daschle (*)
- Harkin (*)
- Kennedy (*)

B List

Senate:

- Campbell (*)
- Chafee (*)
- Collins (*)
- Roth (*)
- Smith (*)
- Snowe (*)
- Voinovich (*)
- Breaux (*)
- Feinstein
- Hollings (*)
- Lieberman (*)
- Robb (*)
- Wellstone (*)

A List

House:

- Bilirakis
- Ganske
- Greenwood
- Bilbray
- Porter
- Bonilla
- Miller (FL)
- Johnson (CT)
- Gephardt
- Dingell
- Waxman
- Brown (OH)
- Klink
- Obey
- Lowey

B List

House:

- Upton
- Stearns
- Lazio
- Northup
- Gekas
- Nethercutt
- Hoyer
- Pelosi
- Delauro
- Pallone

Academicians/Industry/Patients Groups/Ethicists

- AAMC – Dave Moore 828-0400 (7) – Paul Berg
- American Society of Cell Biology – Elizabeth Marincola 301-530-7153 (4)
- PhARMA Barry Cal... 835-3480 (3)
- BIO Carl Feldbaum (1)
- Alzheimer's Association
- Juvenile Diabetes Foundation Bill Schaut 2 371-9746 (1)
- Cystic Fibrosis Foundation
- National Multiple Sclerosis Society
- American Lung Association
- American Heart Association Diane Cannova
- National Organizatin for Rare Disorders
- Paralyzed Veterans of America
- National Council on Spinal Cord Injuries
- National Alliance for the Aging – Dan Berry (5)
- National Health Council 785 Steph Marshall (2)

– Visits on phone calls

* Possible visits

1900 (6) ~~Steve Tiptek~~ ~~347-3454~~

619-424-4000 X 2208

alheime not active

Haro I
Boo ethics
Tuesday

dept we can fund
research ... NIH
embryo internal validi
den cells w/out violati
call Cong Ban on Em R
cells reg

Not embro 2 be

letter to Administ

Frist
Jeffords
Kennedy
Specter
Harkin
Hatch - ?
Porter
Bengall
Bia...

X invite
Dave AAMC

Rich Tarplin
we dont think
itself is a
good idea
1 800 800 7759

Paul Berg — Cell
Dan Perry — Alliance
Bell — SDS
Claudia — ANA
Steph — NHC
Judy — Ohana
Dave — AAMC
Bio - chuck
~~Greg Mueller~~

Dr. Varmus mtg Tues. Announce.
* do have auth to fund CS line research. Set up review process.
Not immed. fund.

Rachel E. Levinson 02/12/99 05:53:59 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP, Barbara D. Woolley/WHO/EOP, Arthur Bienenstock/OSTP/EOP, Clifford J. Gabriel/OSTP/EOP

cc:
Subject: Adhoc: Stem Cell Letter

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/12/99 05:53 PM ----------

David Moore <Dbmoore @ aamc.org>
02/12/99 04:46:57 PM

Please respond to David Moore <Dbmoore@aamc.org>

Record Type: Record

To: adhoc @ aamcinfo.aamc.org

cc:
Subject: Adhoc: Stem Cell Letter

To: Organizations Interested in Medical Research

Note: This notice has been sent to the Ad Hoc Group for Medical Research Funding list serve. The Ad Hoc Group has taken no position on this issue, and use of this list serve does not imply a position on this issue.

We are still seeking endorsements for the following letter to all members of the House and Senate supporting the administration's decision on stem cell research. The deadline for signing this letter has been extended to the close-of-business on Thursday, February 18. If your organization wishes to sign this letter, please e-mail me at <dbmoore@aamc.org>.

Dave Moore
Associate Vice President
Office of Governmental Relations
Association of American Medical Colleges
202-828-0525
FAX 202-862-6218
dbmoore@aamc.org

****

that this research can move forward with the support and oversight of the Federal government.

Sincerely,

Alliance for Aging Research
American Academy of Allergy, Asthma and Immunology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Association for Cancer Research
American Association of Colleges of Pharmacy
American Association of Immunologists
American Association for the Study of Liver Diseases
American Heart Association
American Lung Association
American Pediatric Society
American Society for Biochemistry and Molecular Biology
American Society for Cell Biology
American Society for Microbiology
American Society for Pharmacology and Experimental Therapeutics
American Society of Hematology
American Society of Tropical Medicine and Hygiene
American Thoracic Society
American Veterinary Medical Association
Association of Academic Departments of Otolaryngology - Head and Neck Surgery
Association of American Medical Colleges
Association of Medical School Microbiology and Immunology Chairs
Association of Medical School Pediatric Department Chairs
Association of Professors of Dermatology
Citizens for Public Action
Cooley's Anemia Foundation
Cystic Fibrosis Foundation
East Carolina University School of Medicine
Federation of American Societies for Experimental Biology
Fred Hutchinson Cancer Research Center
Jeffrey Modell Foundation
Johns Hopkins University
Joint Council of Allergy, Asthma and Immunology
Juvenile Diabetes Foundation International
Krasnow Institute for Advanced Studies
Massachusetts Institute of Technology
National Alliance for Eye and Vision Research
National Alliance for the Mentally Ill
National Health Council
National Organization for Rare Disorders
National Spinal Cord Injury Association
Research!America
RESOLVE, the National Infertility Association
Society for Pediatric Research
The Genome Action Coalition

The Honorable _____
United States Senate
Washington D.C. 20510

Dear Senator _____:

The undersigned organizations applaud the determination by the Department of Health and Human Services that current law permits the use of federal funds to support research utilizing human pluripotent stem cells.

Human pluripotent stem cells have the ability to reproduce themselves indefinitely and to give rise to other more specialized types of cells, such as muscle, skin, nerve, pancreas or blood cells. This ability to produce specialized cells opens a tremendous avenue of research with enormous potential for the treatment of many diseases. For example, human stem cells could be used to produce different kinds of specialized cells and tissues for use in transplantation to treat many diseases and conditions, including neurological disorders such as Parkinson*s and Alzheimer*s diseases, heart disease and stroke, diabetes, osteoarthritis, rheumatoid arthritis, and spinal cord injury.
Stem cell research also offers great promise for use in drug development and testing, to evaluate and understand both the beneficial and toxic effects of drugs on different human cell types, thus potentially reducing the need for animal studies and enabling fewer and more sharply focused human clinical trials. Research on human stem cells will open exciting new pathways by which to strengthen our understanding of normal human cell and tissue development. This, in turn, will accelerate our insights into the mechanisms of abnormal growth and development, and could lead to the discovery of radically new approaches to the prevention and treatment of birth defects and cancer.

It is essential that the Federal government play a primary role in funding and overseeing the conduct of this research so that the talent and creativity of all our scientists -- both privately and federally funded -- can be applied to this important line of research. Federal involvement creates a more open research environment, promoting the free exchange of ideas and data among scientists, and ensuring greater public engagement and the protections of federal regulatory oversight. Federal support will also increase fiscal resources and expand the pool of well-trained investigators engaged in this area of research, both of which will speed the pace of scientific discovery.

We concur with the National Institutes of Health*s plans to move forward to develop clear guidelines to address the special scientific, legal, and ethical issues surrounding this research. We are confidant that this process will have appropriate public input, as well as the advice of the National Bioethics Advisory Commission and NIH*s newly established Council of Public Representatives. NIH has made clear that it will not support any research using human pluripotent stem cells until the appropriate guidelines have been developed and disseminated and an oversight process is in place.

Given the tremendous promise this research holds for millions of Americans, indeed all humankind, we strongly urge you to work with the NIH to ensure

Rachel E. Levinson 02/12/99 05:53:04 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP, Christopher C. Jennings/OPD/EOP

cc: Arthur Bienenstock/OSTP/EOP, Clifford J. Gabriel/OSTP/EOP, Joanne S. Tornow/OSTP/EOP

Subject: Meeting of the Adhoc group re: stem cells

Yesterday the Ad hoc group met to discuss next steps in a legislative strategy for stem cells. While many would like to see the embryo research ban disappear, most of the people felt that going after the ban would be a mistake and might create a backlash. This could happen if, as predicted, the reproductive rights groups renew this battle. A few felt that it would be more intellectually consistent to attack the ban. There was more support for ensuring that the ban is not extended to include stem cells and some went so far as to say that their organizations were not prepared to join in a battle to lift the ban. There was some debate about whether it would be better to seek explicit authority to conduct stem cell research using cells created in the private sector, vs. simply holding the line against an express prohibition. Another suggestion was to urge that this issue not be addressed in an appropriations bill, although the potential downside is that the group might have less infleunce with the authorizing committee. The meeting ended without resolution except to look for potential champions (with clout) and continue to educate members about the potential benefits of stem cell research and the distinctions between the cells and embryos. They are sending around a letter in preparation for NIH's approps hearings beginning Feb. 22. I will forward the letter.

I did speak to Dave Moore about the patients' bill of rights. He said that the members of the Ad hoc had discussed this issue but did not have consensus. Because of their heterogeneity, some members could get behind parts of some bills but there was no common denominator. This is not surprising given that the group includes representatives of patients, payors and providers. It might be better to try to get together with Marguerite Donohue from Capital Associates as she represents a number of patient groups.

Tony Mazzaschi <Tmazzaschi @ aamc.org>
03/31/99 01:04:52 PM

Please respond to Tony Mazzaschi <Tmazzaschi@aamc.org>

Record Type: Record

To: adhoc @ aamcinfo.aamc.org

cc:
Subject: Adhoc: Meeting of Stem Cell Working Group Announced

The NIH has announced a public meeting of the ACD working group on research involving human pluripotent stem cells on April 8 in Bethesda. During the meeting, the working group is making time available for public testimony. The NIH notice follows.

Fri afternoon
mon Tues

Tony Mazzaschi
AAMC

The Working Group of the Advisory Committee to the Director (ACD), NIH to advise
the ACD on guidelines and oversight for research involving human pluripotent
stem cells, will meet in public session at the Bethesda Marriott, 5151 Pooks
Hill Road, Bethesda, Maryland 20814, on April 8, 1999, 9:00 a.m.-5:50 p.m.

The goal of the Working Group is to provide advice to the ACD about the
scientific, ethical, legal, and social issues relevant to guidelines for the
conduct of research utilizing human pluripotent stem cells (cells that can form
most of the cells and tissues of the body) and to consider oversight options for
this research.

A limited amount of meeting time will be allotted for public testimony.
Individuals who wish to give five minute public testimony may sign up at the
meeting site the morning of the meeting on a first come, first served basis.
Written testimony may be submitted to: the Office of Science Policy, Bldg. 1,
Room 218, NIH, 9000 Rockville Pike, Bethesda, 20892.

Attendance may be limited to seat availability.

Leg
Chris
Elena
Mary Beth
Rachel
Jenny
Rachel

Disease / Medical
Women's

Pump
our plan

Abs
Sean
Man
AAA
AAU
JP
Bio
Pharm
Dunleavy
Moore
Paley

Statement of Daniel Perry

Executive Director, Alliance for Aging Research

National Bioethics Advisory Commission

January 19, 1999

Members of the Committee:

Thank you for the opportunity to discuss recent discoveries involving human embryonic stem cells. I am here to provide a view of some of the clinical and ethical issues of human stem cells that reflect the thinking of my organization, and that of many other groups of health care consumers and patients who will one day benefit from this research.

I wish to begin by applauding the important and historic statement made here today by Dr. Harold Varmus. The Director of the National Institutes of Health has conveyed the opinion of the Clinton Administration that research on pluripotent stem cell lines is clinically and ethically a different proposition from currently prohibited direct experiments on human embryos. It is vitally important that the view expressed by Dr. Varmus today should prevail in federal policy. If that view does prevail, it is likely many of the best prepared and best equipped research scientists in the nation will move quickly to begin revealing new insights into human cellular biology, made possible by some of the most important discoveries of our time.

Americans, and people everywhere, will be well served as public as well as private funding becomes available to advance understanding of fundamental biological mechanisms, by looking through the "window" opened by these special cells that rejuvenate and retain the ability to become any cell or tissue in the human body.

As the head of a not-for-profit group eager to find cures and preventions for the diseases related to the aging process, and committed to overall better health and vitality for people as they age, my views are formed by a recognition of the medical needs of the growing population of older people. The Alliance for Aging Research, which I represent, works to stimulate academic, governmental, and privately-sponsored research into the chronic diseases of human aging. We anticipate there will be concerns in some quarters regarding embryonic stem cells, which to date have been derived either from fetal tissue or from portions of donated *in vitro* fertilized reproductive cells. However, it is the position of the Alliance, which I hope the Commission will share, that this research is too momentous, its potential benefits too overwhelming, to impede, to slow, or to stop.

The United States, along with much of the world, is experiencing a profound and wholly unprecedented demographic shift toward greater longevity for human beings. Every day in the United States, another 6,000 people celebrate a 65th birthday. Meanwhile, America's Baby Boomers are entering their 50s in even greater numbers, about 10,000 a day.

Understandably, there was great excitement in recent months with the first reports of long-lived cultures of human stem cells. These cells have the potential to become a full array of transplant material for people who cannot find suitable donors. The Commission has already heard the details of that research from the scientists involved, presented with great detail and authority.

We understand that, before the full pay-off of stem cell technology is ready for patients, it could take many years of further research, and major technical hurdles must be overcome. It also will likely take millions, if not billions, of dollars to realize the full therapeutic potential. However, from the perspective of health advocates and patients, here is what we believe is in the offing.

We believe stem cell technology will bring a deeper understanding by scientists into how and why cells multiply and divide, grow, age and die. Unraveling the processes by which cells form into different cell types, with different functions, offers a unique platform to understand and harness nature's mechanisms of cell development, tissue growth and repair. This will advance the critical field of development biology and could be the basis of innovative new medical therapies.

Secondly, this technology could allow some to produce unlimited quantities of normal human differentiated cells *in vitro*. These laboratory cultures of human cells then could be used for highly specific drug screening and testing, and for drug toxicology studies. This would be far more efficient and accurate than current testing and extrapolations taken from testing on animal tissues. Greater efficiencies in new drug development will mean more effective new medicines getting to patients faster.

Most promising of all, from the vantage point of the patient, is the advances this is likely to bring to transplantation medicine. The potential therapeutic impact of human embryonic stem cells in replacing cells and tissues damaged by disease or aging is enormous. We have heard from scientists close to this field that self-renewing cells and tissues derived from stem cells could conceivably replace damaged heart muscle cells that normally do not proliferate during adult life. Congestive heart failure is the single greatest cause of hospitalization among American's after age 65, affecting some 5 million people. Another 1.5 million people in the U.S. each year experience a heart attack which damages heart muscle. About one-third of heart attack victims die immediately. Of those who survive, damaged heart cells from an ischemic attack raise risks for later attacks and premature death. Transplants of stem cell derived heart muscle tissue have already been performed on mice and dogs, showing exciting potential for replacing damaged tissue. Similar use of stem cells and tissues as therapy for heart disease in humans seems very promising for the future.

Increasingly medical researchers tell us that stem cells one day will be able to produce youthful cells that won't be rejected by the host, and which could produce, for instance, dopamine, the brain chemical that is not produced in Parkinsons sufferers. Stem cells could be used to replicate healthy Islet cells in the pancreas, and thus produce insulin needed by diabetics. Further speculation suggests applications of this technology for the relief of age-related blindness, atherosclerosis, cancer, spinal cord injuries, Alzheimers disease, and for the promotion of wound healing. Despite the time and money it will take

In the decade of life between ages 50 and 60, the risks to the average person of being diagnosed with hypertension, arthritis, or diabetes more than triples. In the next three decades, the United States population over age 65 will double to more than 70 million people. As of today, the risk those over 65 being diagnosed with a chronic, age-related disease doubles every five to seven years. Adding up the costs of just eight major diseases of aging – osteoporosis, stroke, depression, arthritis, diabetes, Alzheimer's disease, cancer and heart disease— approaches $600 billion in the U.S. annually. The incidence of the diseases of aging and the costs of treating those diseases will not decrease unless new discoveries from biomedical research allow us to delay or prevent these debilitating conditions. Without making such discoveries and putting them to work for people as they age, the burden on Medicare and private insurance will be crushing as the baby boom moves into its high-risk years.

The alternative to aggressive pursuit of biomedical research, is to let the population age under the same conditions as now exist and watch as the diseases of aging and their associated costs grow exponentially. If, in the absence of real breakthroughs from research, we are left to rely on nursing homes and today's medicines that treat only the outward manifestations of disease, we will surely overwhelm our financial and social resources in caring for a burgeoning population of disabled elders.

Fortunately, there is a wiser, less expensive and more humane alternative to the path we are on. The alternative, and, I believe, proper course, is to encourage rapid advances and applications from our medical research infrastructure to hasten the discovery of the means to forestall the declining health status that we now commonly associate with old age.

Even a brief delay in the onset of age-related disability translates into dramatic savings for our economy. For example, the Alliance calculates that postponing physical dependency among older Americans by just one month would save the U.S. at least $5 billion a year in health care and nursing costs. Postponing the average onset of Alzheimer's disease by five years would, over time, save $50 billion a year in health care costs. A five-year delay in the beginnings of cardiovascular disease could save $69 billion a year. These are just a few examples from a long list of potential savings.

But then we must then ask: What kind of magic will it take to fine tune the aging process so that we can actually delay the ravages of age-related diseases by months or even years? Can people actually hope that diseases of aging might be put on hold? Is it reasonable to think that scientific understanding of aging at the level of cells and genes might buy many people several additional years of active life expectancy, with overall time of sickness and disability at the end of life reduced to a bare minimum? That is indeed the promise that is raised by the advances that are emerging from many scientific disciplines in the field of human aging. This research is being supported by universities, by government, by the pharmaceutical industry, by biotechnology companies large and small, and by private philanthropy.

Combined with better geriatric health care management from the behavioral sciences and medical effectiveness research, and better training of doctors and nurses in geriatrics, the benefits for today's aging population could be enormous.

to realize some or all of these applications, it is understandable that there is so much hope among patients and their families, and such urgency that the research move ahead with all appropriate speed and support.

To deny older citizens, as well as younger people with chronic disease, the opportunity to benefit from this research, would be a tragic reversal of dramatic recent biomedical progress, and a great frustration for public expectations. While some may oppose federal participation and financing of stem cell research, they must know they cannot stop it altogether from going forward. A lack of federal funding would only affect a segment of the overall research effort, albeit a significant portion of the total U.S. research initiative. Stem cell research will go forward -- in the United States, using non-governmental funding, and in other countries, using both public and private funding. The effect of a denial of federal funding would be to deny government agencies, especially the NIH, the oversight we believe they should have. The bell of stem cell research cannot be un-rung. It will continue apace in the private sector and will produce remarkable discoveries for the foreseeable future. If federal government funding is available, then appropriate federal oversight and review will be available and this will serve to better manage the research while assuring that appropriate ethical guidelines are followed.

With increasing understanding of the mechanisms of aging and increasing interest in aging, continued support of this type of research is vital to the effort to uncover new discoveries that will increase the health and independence of a growing number of older Americans. If stem cell research is allowed to proceed, with the guidance and oversight of NIH and other appropriate governmental and scientific organizations, our society will be better able to develop much-needed cures for aging-related diseases and conditions.

The vast majority of Americans strongly support the advancement of biomedical research through the application of their tax dollars. Surveys consistently show Americans want to see greater efforts against serious and life-threatening diseases. That public support helped biomedical research advocates in Congress substantially increase this year's appropriated budget for the NIH. Many in Congress and many of us in the public are eager to see the NIH budget double over a period of five years. This is an audacious, but vitally important national goal. These increases in medical research funding should be used wisely and without arbitrary restrictions. Heightened opportunities to find new preventive and curative measures will be seriously undercut if inappropriate obstacles are placed against this enterprise for political or ideological purposes.

We agree that policymakers, ethicists, scientists, and patient groups must continue to discuss and evaluate advances in science that increasingly will touch upon the fundamental mechanisms that create and define human life. In the end, it is imperative that promising biomedical research go forward without inappropriate bars. The present dramatic breakthroughs in the life sciences, and the profound implications of what we are learning, will inevitably raise public concerns, but we are confident that most Americans will recognize that there could be nothing more unethical than impeding the effort to find help for those patients and their families in greatest need.

On behalf of the Alliance for Aging Research I thank you for the opportunity to present the views of my organization on this important consideration.