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THE WHITE HOUSE

WASHINGTON

July 26, 1999

MEMORANDUM FOR JOHN PODESTA

CC: DOUG SOSNIK
STEPHANIE STREETT
LORETTA UCELLI
LARRY STEIN
CHRIS JENNINGS
MARY BETH CAHILL
DAVID BEIER
DAN MENDELSON

FROM: NEAL LANE *John for NL*

SUBJECT: Stem Cell Event: Healthcare Advances for the 21st Century

Purpose

- The rationale for holding this event is to enable the President to associate his Administration with medical research that holds enormous promise for finding new treatments and cures for diseases that afflict approximately 128 million Americans, nearly half the population of the United States. "Such research," states Harold Varmus, head of the National Institutes of Health (NIH) "has the potential to revolutionize the practice of medicine." The ability of the NIH to fund research using human embryonic stem cells is being threatened by some in Congress who want to tighten the Congressional ban on human embryo research. A White House event that makes clear the President's position in support of human stem cell research *within the context of current law* will help conservative Members who support stem cell research hold the line against efforts to broaden the ban against such research.
- As has been widely reported, the White House, at this time, is endorsing a more moderate scope of research activities than NBAC has concluded should be eligible for federal funding. Nonetheless, by thanking NBAC for their report in a public ceremony, the White House can align itself with their core message, which is that stem cell research should proceed cautiously under appropriate ethical guidance. The President can use this event to take a strong stand that human stem cell research must be done according to the highest ethical standards, and direct that NIH put appropriate guidelines and oversight in place to ensure those standards are met. The President's efforts could be viewed as rolling up our sleeves and directing that fresh troops, namely, our nation's world-class Federally-funded medical research establishment, be fully dedicated to learning how to harness stem cells to treat people with diabetes, heart disease, Parkinson's disease, cancer, and spinal cord injuries.
- Seventy-four percent of Americans responded favorably to a public opinion poll on the use of Federal funds for research using human embryonic stem cells. A White House event that endorses that view, emphasizes the need to maintain high ethical standards, and directs NIH to move ahead with all deliberate speed, will resonate strongly with the majority of Americans who are desperately searching for cures and treatments for themselves and their loved ones.

Background

- On the political landscape, the use of human embryos in research has been a hot button topic for the last several years. The House Pro-Life Caucus was successful in attaching a rider to DHHS's appropriations bill for the last four years that prohibits federal funding for any research in which human embryos are created or destroyed. An HHS legal interpretation of this ban permits Federal funding for research that uses human embryonic stem cells (because stem cells are not embryos), but Representatives Dickey (R-AR) and Bliley (R-VA) oppose this research as well and have stated their intention to broaden the ban to include stem cells. The patient advocacy groups have been active in lobbying Congress very strongly to commit public funds and resources to allow such research. Their efforts apparently are paying off in that neither Dickey nor Bliley have acted on their statements to date. The timing of this event is critical. Holding it before Congress leaves will help spur the advocacy efforts of these patients groups during the month of August in Congressional Districts across the nation. A nationwide coalition of over 110 patient groups and professional and academic organizations have drafted a letter in support of Federal funding of stem cell research (attached), and it could be released in conjunction with this event.

Outline of event:

- The President meets briefly with the National Bioethics Advisory Commission, and then in the East Room, or the Rose Garden, accepts the Commission's report, briefly discusses the importance of stem cell research, and charges NIH to move ahead with all deliberate speed to put the necessary oversight process in place to ensure that Federally-funded stem cell research is conducted according to the highest ethical standards. Other speakers might include Secretary Shalala, Harold Varmus, or a parent with an ill child with a cell-failure disease.

President's suggested remarks:

- The control of human stem cells may open the door to the greatest medical discoveries since antibiotics. Every parent whose child has diabetes or any cell-failure disease is going to be riveted to this research, because it *is* the answer.
- The President would thank NBAC and acknowledge their efforts, discuss the importance of stem cell research, paint a vision of the future in which certain dreaded diseases could be defeated. Additionally, he would charge NIH to develop and implement an oversight process for stem cell research that will ensure that our ethics are as good as our science; and that our newest technologies must always incorporate our oldest values.
- Would also acknowledge the critical role of voluntary patient groups in raising public awareness regarding stem cells and their potential medical benefits.
- Would acknowledge the past and current Federal investments in science and technology that made this breakthrough possible, and urge Congress to provide full FY2000 funding for his Twenty-first Century Research Fund budget request.
- Would acknowledge Members of Congress and thank them for their support of biomedical research, and for holding the line so that stem cell research can proceed.

Attachments

Americans Affected by Diseases Stem Cell Research May Help

Stem cell research could help as many as 128 million Americans. Following are facts about the diseases that scientists say may be treated or cured with advancements in stem cell research.

<u>Condition</u>	<u>Americans Affected</u>
Cardiovascular Diseases	58,000,000
Autoimmune Diseases	30,000,000
Diabetes	16,000,000
Osteoporosis	10,000,000
Cancer	8,200,000
Alzheimer's	4,000,000
Parkinson's	1,500,000
Burns (Severe)	300,000
Spinal Cord Injuries	250,000
Birth Defects	150,000/ per year
Total Americans	128,400,000

- Diabetes kills one American every three minutes.¹
- Approximately 1.5 million Americans are afflicted with Parkinson's disease while roughly three million more have at-risk, pre-symptomatic dopamine cell loss.²
- Five Boeing 747 jumbo jets crashing *every day* for a year equals the 563,100 Americans who die each year from cancer.³
- Cardiovascular diseases remain the number one cause of death among Americans. They accounted for 41 percent of all deaths in 1996.⁴
- In the U.S. today, 10 million individuals already have osteoporosis and more than 18 million additional people have low bone mass, placing them at increased risk for the disease.⁵
- Every year in the United States two million people are burned, 300,000 of which are severe burns.⁶

- There are more than 80 known autoimmune diseases such as lupus, multiple sclerosis, rheumatoid arthritis and Graves' disease. Autoimmune diseases occur when the immune system attacks its own tissue.⁷
- By developing therapies for those who have spinal cord injuries and preventing injuries, the U.S. could save as much as \$400 billion on future direct and indirect lifetime spinal cord injury costs.⁸
- Birth defects are the leading cause of infant death and a major cause of disability in young people, affecting more than 150,000 babies each year.⁹
- About 2.7 million Americans care for people with Alzheimer's disease.¹⁰

¹Juvenile Diabetes Foundation

²Parkinson's Action Network

³National Coalition for Cancer Research

⁴American Heart Association

⁵National Osteoporosis Foundation

⁶Onhealth.com

⁷American Autoimmune Related Diseases Assn.

⁸American Paralysis Association

⁹March of Dimes

¹⁰The Alzheimer's Association

Stem Cell Research Polling Information

Opinion Research Corporation International was commissioned by Patients' Coalition for Urgent Research (Patients' CURE) to conduct polling on the subject of stem cell research. Several questions were included in our CARAVAN® Survey, a weekly omnibus telephone survey.

Between May 6-9 the survey of 1,005 adults was conducted. Chosen through a random-digit-sample, the adults included 503 men and 502 women 18 years of age or older, living in private households in the continental United States.

Prior to asking a question specifically addressing federal funding for stem cell research, a definition of the research was given. Following is the definition that was used:

As you may already know, a stem cell is the basic cell in the body from which all other cells arise. Medical researchers have been able to isolate stem cells from excess human embryos developed through *in vitro* fertilization and fetal tissue that has been donated to research. Medical researchers believe that human stem cells can be developed into replacement cells to cure diseases such as diabetes, Parkinson's, Alzheimer's, cancer, heart disease, arthritis, burns or spinal cord problems.

After hearing the definition, 74 percent of respondents said they favored the funding of stem cell research by the National Institutes of Health.

- Men are more likely than women to be in favor of the research funding (79% vs. 71%).
- Americans who have had at least some college education are more likely to favor the funding of research than those without any college education (78% vs. 71%).

Date: TBD

The Honorable _____
U.S. House of Representatives
Washington, DC 20515

Dear Representative _____:

This past February we wrote to you regarding our support for federal funding of research using human pluripotent stem cells. With the Appropriations process progressing we write now to reiterate that support and to urge you to allow this research to move forward.

Human pluripotent stem cells have enormous potential for treatment of disease because they have the ability to form into any type of cell in the body. But only a fraction of the work that will be necessary to transform this potential into reality has yet begun, and only a fraction of the biomedical research community has been able to participate because the federal government has not yet funded any of this work. The National Institutes of Health are in the process of completing guidelines that will permit and govern the use of these cells by federally funded investigators. Only when these guidelines are in place will it be possible to unleash the full capability of the biomedical research workforce toward bringing the remarkable potential of human pluripotent stem cells to fruition.

It is also clear that the American public supports federal funding of this research. A recent nationwide survey conducted by Opinion Research Corporation International has found that 74% of those polled favor funding of stem cell research by the NIH.

Some have argued that "adult" stem cells will be sufficient in our pursuit of treatments or cures of various diseases. While we believe that research in the area of adult stem cells is vital to the research effort, we are concerned that to restrict work to that area alone will prove insufficient and would be a grave mistake. The prospect of cutting off an avenue of research as promising as that with embryonic stem cells at this very early stage of discovery deeply troubles those of us who conduct and promote health research. Such a prohibition could delay possible treatments for diseases like diabetes, cancer, Alzheimer's and Parkinson's by years. Past work on animals has shown us that it is the embryonic stem cells that hold the greatest potential in their ability to be manipulated for treatments of disease.

We are also concerned by the argument that embryonic stem cell research can be left to the private sector. While it is clear that a few privately funded centers are working on pluripotent stem cell research, it is not generally the practice of private companies to conduct this kind of basic research into fundamental developmental processes. That is why it has been and remains the role of the federal government to make the lion's share of the investment in basic research, which has then been used by biotechnology and pharmaceutical companies to develop products used for treating diseases. And that is why we cannot rely on private industry to conduct the kind of basic research necessary to move the field of stem cell research from the laboratory bench to the clinic.

Our intent is simply to ensure that research on stem cell lines is not unduly restricted. With appropriate ethical safeguards, such as those being developed by the National Institutes of Health, we believe that a balance can be achieved, which respects both the moral status of the embryo and the public's sensitivity to this issue while ensuring progress in critical medical research. As we have said before, the government can play an important role of oversight so that our nation's federally funded scientists can conduct this critical work. Federal support will also increase the financial resources directed to this area of research, which will speed the pace of scientific discovery.

With the great hope pluripotent stem cell research provides to patients ailing or dying from devastating diseases we urge the Congress to allow this research to move forward with federal support.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
Alliance for Aging Research
Alliance for Lung Cancer Advocacy, Support and Education
American Academy of Allergy, Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Ophthalmology
American Association for Dental Research
American Association of Anatomists
American Association of Dental Schools
American Association of Immunologists
American Autoimmune Related Diseases Association
American Burn Association
American College of Clinical Pharmacology
American College of Neuropsychopharmacology
American College of Obstetricians and Gynecologists
American College of Physicians - American Society of Internal Medicine
American Gastroenterological Association
American Medical Association
American Neurological Association
American Pediatric Society
American Physiological Society
American Society for Biochemistry and Molecular Biology
American Society for Bone and Mineral Research
American Society for Cell Biology
American Society for Clinical Nutrition
American Society for Investigative Pathology
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 Human Genetics
American Thoracic Society
American Veterinary Medical Association
Americans for Medical Progress
Association for Research in Vision and Ophthalmology
Association of Academic Health Centers
Association of American Cancer Institutes
Association of American Medical Colleges
Association of American Universities
Association of Chairs of Departments of Physiology
Association of Independent Research Institutes
Association of Medical and Graduate Departments of Biochemistry
Association of Medical School Pediatric Department Chairs
Association of Medical School Psychologists
Association of Professors of Medicine
Association of Subspecialty Professors
Association of Teachers of Preventive Medicine
Association of University Radiologists
Boston University School of Medicine
Cancer Research Foundation of America
Citizens for Public Action on High Blood Pressure and Cholesterol
Coalition for American Trauma Care
Columbia University
Cure for Lymphoma Foundation
Dartmouth Medical School
Duke University
East Carolina University School of Medicine
Easter Seals
The Endocrine Society
Eye Bank of America
Federation of American Societies for Experimental Biology
Fred Hutchinson Cancer Research Center
Genetics Society of America
Glaucoma Research Foundation
Harvard University
Interstitial Cystitis Association of America, Inc.
Johns Hopkins University
Joint Council of Allergy, Asthma, and Immunology
Juvenile Diabetes Foundation International
Krasnow Institute for Advanced Study
March of Dimes
Massachusetts Institute of Technology
Medical College of Wisconsin
Myasthenia Gravis Foundation of America, Inc.
Myositis Association of America, Inc.
National Alliance for Eye and Vision Research

National Alliance for the Mentally Ill
National Association of State Universities and Land-Grant Colleges
National Caucus of Basic Biomedical Science Chairs
National Childhood Cancer Foundation
National Coalition for Cancer Research
National Health Council
National Osteoporosis Foundation
The National Pemphigus Foundation
National Psoriasis Foundation
National Spinal Cord Injury Association
New York University School of Medicine
Oncology Nursing Society
Osteogenesis Imperfecta Foundation
Paralyzed Veterans of America
Parkinson's Action Network
The Protein Society
Research!America
Resolve, the National Infertility Association
Roswell Park Cancer Institute
Scleroderma Foundation
Sjogren's Syndrome Foundation
Society for Investigative Dermatology
Society for Pediatric Research
Society for Reproductive Endocrinology and Infertility
Society for the Advancement of Women's Health Research
University of California
University of California, San Diego, School of Medicine
University of Florida
University of Illinois at Chicago
University of Michigan Medical School
University of Pittsburgh
University of Rochester Medical Center
University of Utah Health Sciences Center
University of Washington
University of Wisconsin-Madison
UPMC Health System
Vanderbilt University Medical Center
Yale University

THE WHITE HOUSE

WASHINGTON

July 6, 1999

MEMORANDUM FOR JOHN PODESTA

FROM: NEAL LANE 
SUBJECT: Human Stem Cell Research Update

Background: In November 1998, human embryonic stem cells were successfully isolated and cultured in two privately funded laboratories. Human embryonic stem cells are primitive cells, which themselves lack a specific function but have the capacity to develop into any specialized type of cell found in the human body (such as nerve, bone, blood, or muscle cells). While this announcement stirred great excitement in the biomedical research community, because of the tremendous potential that stem cells have for treating human disease, the source of these cells (human embryos and aborted fetuses) generated a great deal of controversy. The isolation of stem cells from human embryos (but not fetuses) currently cannot be done using public funds because of the Congressional ban on the use of Federal funds for human embryo research, which has been attached to the HHS appropriations bill for the last four years. On November 14, 1998, the President asked his National Bioethics Advisory Commission (NBAC) for a "thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations." In January 1999, HHS General Counsel Harriet Rabb issued a decision that the human embryo research ban did not include human embryonic stem cells, because stem cells are not themselves embryos, and so research using these cells would be eligible for Federal funds. The House Pro-Life Caucus has objected strenuously to this decision. However, Senators Specter and Harkin of the Senate Appropriations Committee strongly support NIH funding of human stem cell research (they held three hearings on this issue in late 1998), as does Congressman Porter of the House Appropriations Committee.

Present Status: NBAC is examining the ethics of research on stem cells derived from fetuses, embryos left over from fertility treatments, and embryos produced for research, either from fusing donated eggs and sperm or via cloning methods. They are also considering the ramifications of Federal funding of each of these activities. The Commissioners unanimously agree that the *use* of human embryonic stem cells for research is ethically defensible and should be eligible for Federal funding. However, there is still considerable debate over the ethics of *deriving* cells from the different sources, and the use of Federal funds for such research. Even though NBAC generally agrees that deriving cells from embryos left over from fertility treatments is ethically acceptable, some Commissioners may recommend against using public funds to support such a controversial activity. At this point, it appears that the Commission will not recommend Federal funding for research using stem cells derived from embryos produced for research purposes using either cloning or IVF technologies, which is consistent with the President's 1994 position opposing the creation of human embryos for research purposes. NBAC expects to finalize their report shortly after they meet next week (July 13-14) in Cambridge, MA.

NIH has drafted a set of guidelines describing the steps investigators must complete to receive NIH funds for research involving the *use* of human stem cells, to be published in the *Federal Register* for a 60-day public comment period, once they have received departmental clearance. The guidelines will parallel existing regulations covering fetal tissue transplantation research. NIH will not fund research that would include the *destruction* of human embryos as this would violate the Congressional embryo research ban.

Possible Administrative Action: The release of the NBAC report and/or the publication of the draft NIH guidelines are opportunities for an Administration statement. Two draft statements are attached, which express support for funding research using human embryonic stem cells, but emphasize the need for this research to be done using the highest ethical standards. Because valuable research can proceed using stem cells that are derived using private funds, there is no need at this time to push for a relaxation of the current Congressional ban on human embryo research.

Attachments

Tab A Draft Statement for Neal Lane and/or Joe Lockhart

Tab B Draft Statement for POTUS

cc: Bruce Reed
Dan Mendelson
Elena Kagan
David Beier
Chris Jennings
Barbara Woolley
Barry Toiv
Joe Lockhart

Draft 7/6/99

Draft Statement for Neal Lane or Joe Lockhart when NIH Guidelines are Published/NBAC Report is Nearing Completion

Last November, the President asked his National Bioethics Advisory Commission to undertake a thorough review of all of the ethical and medical considerations associated with human stem cell research. In the ensuing months, a national dialogue took place highlighting the potential applications of stem cells for treating people with diabetes, heart disease, Parkinson's disease, cancer, and spinal cord injury. Ethical issues were also central to this debate, including a wide range of religious and philosophical views that are a part of the fabric of our democratic culture. NBAC has nearly completed its deliberations and appears ready to endorse the medical promise and ethical acceptability of certain types of human stem cell research.

The Clinton Administration recognizes that human stem cell technology's potential medical benefits are compelling and worthy of pursuit, so long as the research is conducted according to the highest ethical standards. NIH is putting in place guidelines and an oversight system that will ensure that the cells are obtained in an ethically sound manner. The President's 1994 ban on the use of Federal funds for the creation of human embryos for research purposes will remain in effect. Because it appears that human stem cells will be available from the private sector, such research is permissible under the current Congressional ban on human embryo research and no other legal actions are necessary at this time.

Draft 7/6/99

Draft Statement for POTUS when NIH Guidelines are Published/NBAC Report is Released

Back in November, when I asked my National Bioethics Advisory Commission to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes. (Juvenile Diabetes Foundation, Alliance for Aging Research, Paralyzed Vets or other members of the Patients' Coalition for Urgent Research may be invited.)

But I also understand that stem cell research raises ethical concerns that need to be addressed, and the national dialogue has highlighted a range of opinions that must be respected. First, I want to restate the ban I issued in 1994 prohibiting the use of Federal funds for the creation of human embryos for research purposes. Second, I hereby direct that any Federally-supported human stem cell research be held to the highest ethical standards. The NIH guidelines, with input from NBAC, will be the principal mechanism to ensure this outcome, while helping scientists turn the promise of stem cell technology into reality.

THE WHITE HOUSE

WASHINGTON

July 19, 1999

MEMORANDUM FOR JOHN PODESTA

CC: STEPHANIE STREETT

FROM: NEAL LANE 

SUBJECT: Human Stem Cell Event

This memo responds to your request for an outline of a possible human stem cell/biomedical ethics event. In short, the script might go as follows: the President meets briefly with the National Bioethics Advisory Commission and discusses their report. Then they move to the Rose Garden where the President accepts the Commission's report, discusses the importance of stem cell research, and charges the National Institutes of Health (NIH) to put the necessary oversight process in place or, alternatively, announces that NIH is going to publish guidelines that will, when finalized, ensure that Federally-funded stem cell research will be conducted according to the highest ethical standards.

Such an event benefits us in multiple ways. First, this is a good time to make clear our position in support of human stem cell research and signal resistance to a tightening of the Congressional ban on human embryo research. HHS will appreciate our support for their incremental approach. [However, Varmus would like to discuss sending a hint of disapproval of the ban, but that is risky right now.] The presence of members like Senator Specter would send a strong message to Representative Dickey or others who oppose any stem cell research. Second, the July 14 White House statement puts at arm's length a central NBAC recommendation, i.e., allowing the use of Federal funds to derive stem cells that destroy embryos in the process. The Commission has labored long and hard for the President and deserves a show of support. In thanking them, we can align ourselves with their core message, which is: stem cell research should proceed cautiously under appropriate ethical constraints. Seventy-four percent of Americans responded favorably to a public opinion poll on stem cell research. Third, the event would be an ideal opportunity to bring in the leaders of the large patient advocacy groups that have joined Patients' Coalition for Urgent Research (CURE), the coalition supporting stem cell research, as well as others still on the fence. Patients' CURE estimates that 128 million Americans could be treated or cured with by stem cell-based therapies including those with cardiovascular disease, diabetes, cancer, Alzheimer's and Parkinson's disease.

President's suggested remarks:

The President would thank NBAC and acknowledge their efforts, briefly discuss the importance of stem cell research, and charge NIH to develop and implement an oversight process that will ensure that our ethics are as good as our science.

Would also acknowledge the critical role of voluntary patient groups in raising public awareness regarding stem cells and their potential medical benefits.

Would acknowledge the Federal investments in science and technology that made this breakthrough possible, and urge Congress to provide full funding for his FY2000 R&D budget request.

Would acknowledge the support of key members of Congress, and thank them for their support of biomedical research and for holding the line so that stem cell research can proceed.

Attachments:

- 1) Scheduling Proposal
- 2) Americans Affected by Diseases Stem Cell Research May Help

THE WHITE HOUSE

WASHINGTON

Schedule Proposal: The President

Date: July 19, 1999

_____ACCEPT

_____REGRET

_____PENDING

TO: Stephanie Streett

FROM: Neal Lane 

REQUEST: A Rose Garden ceremony with President Clinton, the National Bioethics Advisory Commission (NBAC), and DHHS, upon delivery of the Commission's report "The Ethical Use of Human Stem Cells in Research."

PURPOSE: To recognize and thank NBAC for their dedicated efforts in producing the report on human stem cells, and to charge NIH/DHHS to put in place an oversight process so that publicly funded stem cell research can begin under highest ethical standards.

BACKGROUND: President Clinton established NBAC in 1995 to consider bioethical issues arising from research on human biology and behavior. OSTP staffed this initiative. Last November, in response to the announcement that human embryonic stem cells had been successfully isolated in the private sector, the President asked NBAC to undertake a thorough review of all of the ethical and medical considerations associated with human stem cell research. In the ensuing months, a national dialogue took place highlighting the potential applications of stem cells for treating people with diabetes, heart disease, Parkinson's disease, cancer, and spinal cord injury. Ethical issues were also central to this debate, including a wide range of religious and philosophical views.

NBAC is nearing completion of their report to the President, expected in the next two weeks. The Commission will recommend that the use of human embryonic stem cells for research, as well as their derivation, be eligible for Federal funding. The use of NIH funds for the derivation of stem cells from human embryos is currently prohibited under the Congressional ban on

human embryo research. The Commission opposes the creation of human embryos for research purposes.

The development of NBAC's report has been a particularly controversial and high-profile process. The Commission has put in back-breaking work and long hours to respond to this and other special POTUS requests. A meeting would be very helpful in signifying White House appreciation.

NIH convened an advisory panel to draft guidelines and an oversight process to ensure the ethical use of human stem cells in NIH-funded research. The draft guidelines will be ready to publish for public comment in the next two weeks.

PREVIOUS

PARTICIPATION:

President Clinton held a Rose Garden ceremony with NBAC on June 9, 1997, upon receipt of their report "Cloning Human Beings"

DATE & TIME:

July 29, a.m.

BRIEFING TIME:

30 minutes

LOCATION:

Rose Garden

PARTICIPANTS:

NBAC Chairman Dr. Harold Shapiro and other members of
Commission
HHS Secretary Donna Shalala
NIH Director Harold Varmus
Science Advisor Neal Lane

INVITEES:

Senator Arlen Specter
Senator Tom Daschle
Senator Tom Harkin
Senator Ted Kennedy
Senator Bill Frist
Senator Connie Mack
Senator Jim Jeffords
Senator Barbara Mikulski
Senator Dianne Feinstein
Senator Richard Durbin
Senator Christopher Dodd
Senator Strom Thurmond
Senator Paul Wellstone
Representative John Porter
Representative Nita Lowey

Patient Advocacy groups (Patients' CURE, March of Dimes, Alzheimer's Association, American Heart Association)

CONTACT: Jeff Smith, Executive Assistant for Policy & Intergovernmental Affairs, OSTP, X66047

Americans Affected by Diseases Stem Cell Research May Help

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Total Americans	128,400,000

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- Five Boeing 747 jumbo jets crashing *every day* for a year equals the 563,100 Americans who die each year from cancer.³
- Cardiovascular diseases remain the number one cause of death among Americans. They accounted for 41 percent of all deaths in 1996.⁴
- In the U.S. today, 10 million individuals already have osteoporosis and more than 18 million additional people have low bone mass, placing them at increased risk for the disease.⁵
- Every year in the United States two million people are burned, 300,000 of which are severe burns.⁶

- There are more than 80 known autoimmune diseases such as lupus, multiple sclerosis, rheumatoid arthritis and Graves' disease. Autoimmune diseases occur when the immune system attacks its own tissue.⁷
- By developing therapies for those who have spinal cord injuries and preventing injuries, the U.S. could save as much as \$400 billion on future direct and indirect lifetime spinal cord injury costs.⁸
- Birth defects are the leading cause of infant death and a major cause of disability in young people, affecting more than 150,000 babies each year.⁹
- About 2.7 million Americans care for people with Alzheimer's disease.¹⁰

¹Juvenile Diabetes Foundation

²Parkinson's Action Network

³National Coalition for Cancer Research

⁴American Heart Association

⁵National Osteoporosis Foundation

⁶Onhealth.com

⁷American Autoimmune Related Diseases Assn.

⁸American Paralysis Association

⁹March of Dimes

¹⁰The Alzheimer's Association

THE WHITE HOUSE

WASHINGTON

June 17, 1999

MEMORANDUM FOR JOHN PODESTA

FROM: NEAL LANE 
SUBJECT: Human Stem Cell Research Update

I want to alert you to two upcoming events regarding oversight of human stem cell research and discuss actions that we might take regarding human stem cell research and cloning for the purpose of human reproduction.

NIH Guidelines -- NIH expects to send a human stem cell research oversight plan and draft guidelines to DHHS next week. Once cleared, the guidelines will be published in the *Federal Register* for a 60-day public comment period. The guidelines are expected to describe the steps investigators must complete in order to receive NIH funds for research involving the use of human stem cells. The guidelines will parallel existing regulations covering fetal tissue transplantation research. NIH will not fund research that would include the destruction of human embryos as this would violate the Congressional embryo research ban.

National Bioethics Advisory Commission Report -- NBAC will meet on June 28-29 to discuss human stem cell research. The Commission expects to complete its report shortly after their meeting on July 13-14, in Cambridge, MA. The report will respond to the President's Nov. 14, 1998 request for a "thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations." NBAC is examining the ethics of conducting research on stem cells derived from fetuses, and embryos left over from fertility treatments, embryos produced from donated eggs and sperm or via cloning methods. They are also considering the ramifications of Federal funding of each of these activities.

Although the Commission has not yet completed its deliberations, it appears that they will support Federal funding for research using stem cells derived from fetuses or excess embryos. A majority of Commissioners do not draw an ethical distinction between the use and the derivation of stem cells and are comfortable with the practice of deriving stem cells from excess embryos for research purposes. Despite news reports to the contrary, however, NBAC has not concluded that they will recommend that the Congressional ban be eased to allow Federally-funded research involving the destruction of human embryos to obtain stem cells. Even without an ethical basis, some Commissioners may recommend against using public funds to support such a controversial activity. At this point, it appears that the Commission will not recommend Federal funding for research using stem cells derived from embryos produced for research purposes using cloning or IVF technologies.

Recent News Reports

It was reported in the June 14 Washington Post that two separate companies, Geron Corporation and Advanced Cell Therapeutics, have launched programs to produce human embryos using cloning technology. In the June 15 New York Times, Geron denied that it was producing human embryos but was, instead, using somatic cell nuclear transfer to learn about factors produced in the egg that turn back the developmental clock in an adult nucleus. The company may, in fact, be producing human embryos. Advanced Cell Technology is resuming earlier somatic cell nuclear transfer experiments using a human adult cell and a cow egg. Both companies state that their purpose is the isolation of embryonic stem cells, and not human reproduction (i.e., therapeutic, not reproductive, cloning). In 1994, President Clinton banned the use of Federal funds to create embryos for research purposes (this ban was broadened by Congress in 1995 to include all research using human embryos), and in 1997 banned Federal funding for the use of cloning to reproduce a human being. None of these bans apply to the private sector, although some companies have said that they will comply with the President's voluntary moratorium.

Hill Activity

The Congressional ban on human embryo research will be debated in the HHS appropriations process. Patient advocacy groups have formed an active coalition (Patients' CURE) that has been very effective in making the case of the importance of stem cell research in developing treatments for diseases such as diabetes, heart disease, Parkinson's and cancer. Rachel Levinson, of my staff, Chris Jennings, David Beier, and Barbara Woolley, met with the coalition on April 13 to hear about their message development efforts. Chris reiterated the Administration's position as articulated in the President's and Harold Varmus' statements on the potential medical benefits of stem cell research.

Senators Specter and Harkin have indicated strong support for NIH funding of human stem cell research. Senate markup of the Labor/HHS appropriations bill could come as early as July 1, but that is unlikely.

Rep. Porter supports the Administration's position on stem cell research. House Labor/HHS appropriations staff have said that they don't envision a tightening of the embryo research ban in order to prohibit stem cell research. However, something along these lines can always slip in, especially if there is an Omnibus bill.

Last month, Rep. Bliley announced that he would hold a hearing in response to press reports that NBAC would recommend easing the ban to allow public sector research deriving stem cells. No stem cell hearings have been scheduled.

Possible Administrative Actions

Publication of the NIH guidelines and/or release of the NBAC report are opportunities for an Administration statement, in the event one is called for. However, I do not see a compelling reason to make a new statement at this time. We are on record supporting human stem cell

research as a promising avenue of biomedical research. We have already stated the need for stringent ethical oversight and publication of the NIH guidelines will reinforce this message.

In the event that NBAC recommends in mid-July that the government fund research involving the destruction of human embryos in order to obtain stem cells, I would advise against working toward relaxation of the current Congressional ban. Harold Varmus says valuable research can proceed using stem cells that are derived using private funds and there is no need to go across this line for the time being. Although fertility research could be enhanced if the ban were lifted, the incremental approach appears to be more prudent at this juncture. Going further might lose the support of some of the patient groups (Paralyzed Vets, e.g.) because it would bring the debate closer to the abortion issue.

We drafted a bill to prohibit reproductive cloning (June 97) while protecting biomedical research but it was never introduced. We could call on Congress once again to address this real area of concern—rather than restricting biomedical research.

Additionally, we should work with FDA to clarify their regulatory authority to prevent private sector use of cloning technology to produce a child. We might also explore other administrative oversight options.

Given that our current positions on stem cell research and reproductive cloning are clear and enjoy the support of patient groups and the biotechnology and pharmaceutical industries, we need not issue new statements until we see what develops in the appropriations process.

cc: Bruce Reed
Elena Kagan
David Beier
Chris Jennings
Barbara Woolley

Human Stem Cell Research

June 26, 1999

- Q. The National Bioethics Advisory Commission recommended that the government fund research using human stem cells, *and* research in which the stem cells are taken out of embryos, destroying the embryos in the process. But you (and NIH) are proposing to fund only the former. Why is this?**
- A. Dr. Varmus assures me that there will be sufficient human stem cells available from the private sector to begin to answer the most pressing scientific questions. The NIH guidelines will ensure that these cells are obtained according to the highest ethical standards.
- Q. The National Bioethics Advisory Commission has recommended that the Congressional ban on human embryo research be partially lifted to allow Federal funding for research in which stems cells are isolated from human embryos. The Commission also recommended that the Federal government fund research using human stem cells from aborted fetuses or from human embryos left over from fertility treatments. The Commission recommended against Federal support for research in which stem cells are obtained from embryos created solely for research purposes. What is your position on the Commission's recommendations?**
- A. When scientists defeated the technical barriers that had prevented them from growing human stem cells in their laboratories, I was heartened by the possibility that this technology might be used to create replacement muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes. At the same time, I realized that even talking about cells that come from human embryos and fetuses makes people uncomfortable. So I asked my National Bioethics Advisory Commission to think long and hard about all the ethical issues that are raised by human stem cell research along with the medical applications and they are close to finishing/have just sent me their report.

In 1994 I said that I was opposed to the creation of human embryos for research purposes and I have not changed my views. The Commission agrees with that position. When I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research, and the scientific results that have come out in just the past few months only strengthen my commitment, so long as the research is conducted according to the highest ethical standards. NBAC agrees with this opinion.

When NBAC says that the government should also fund the derivation of stem cells, I have to think about what this would mean to all the American people, all the people who might be helped one day by cell transplants, as well as those who are troubled by research based on cells that come from the earliest forms of life. I think that this course of action demonstrates respect for the wide range of views that is part of our democratic culture. It

seems to me that the prudent course is to see what results can be learned from these studies before we consider any expansion.

It is against current law to use Federal funds for human embryo research including isolating stem cells. Dr. Varmus tells me that the human stem cells that scientists want to use will be available in large quantities from the private sector where they will be isolated and grown without using any public money. NIH is putting in place guidelines and an oversight system that will ensure that the cells are obtained in an ethically sound manner. I don't see that there is an immediate need to address the ban so long as there is a sufficient supply of human stem cells to begin to answer the most pressing scientific questions. One of these is likely to be learning the difference, if any, between stem cells from fetuses and from embryos.

6-23-99

Patients and Abortion Foes Clash on Stem-Cell Research

By LAURIE MCCINLEY and ANN FAWCETT
Staff Writers of THE WALL STREET JOURNAL
WASHINGTON—Sen. Charles Grassley often touts the need for more research into diseases such as Alzheimer's, Parkinson's and osteoporosis. "I hope research will lead to a day when no one has to live with a debilitating condition," he says.

Nevertheless, the Iowa Republican opposes federal funding of experiments that may hold bright promise for treating the afflictions: research on embryonic stem cells. These cells have the potential to develop into most of the body's specialized tissues, including those of the brain, heart, liver and blood. This raises prospects that they could be used someday to rehabilitate organs damaged by disease or accident.

But the research also requires destruction of the embryos. "It's the manipulation of a living organism and the destruction of that organism," says Sen. Grassley, chairman of the Senate Aging Committee and an abortion advocate.

The senator's views point up the challenge facing Daniel Perry, chairman of Patients' Coalition for Urgent Research, made up of more than 30 groups pressing for government funding of stem-cell work. The coalition, which includes the American Parkinson's Disease Association, the Juvenile Diabetes Foundation International and the Christopher Reeve Paralysis Foundation, is rallying patients to promote the potential breakthroughs offered by stem-cell research. And it's trying to play down the hot-button abortion politics that are inevitably part of the debate.

"Clearly, there will be an effort to bring this into the very sad and worn debate on abortion," says Mr. Perry, who is also executive director for the nonprofit Alliance for Aging Research. "But the patients will be heard, and we think the members of Congress will make their decisions based on that." The strategy was displayed at a recent coalition press conference. Michelle Pucynski, a 15-year-old resident of Toledo, Ohio, said she was diagnosed with juvenile diabetes when she was just 13 months old and since then has "taken 16,300 injections of insulin just to survive."

But antiabortion groups are mobilizing their own troops for the increasingly emotional battle. Funding embryo stem-cell research "would forge new ground for active government support of research that takes human life," says Richard Doerflinger, spokesman for the National Conference of Catholic Bishops' antiabortion secretariat. "This violates human experimentation norms because it destroys one member of the human family to help another."

The fight is bound to intensify. The National Bioethics Advisory Commission, in coming weeks, is expected to call for federal funding of some embryo research, including stem-cell studies. There is now a congressional ban on federal funding of research that results in harm to an embryo, although there's a heated dispute about whether that ban extends to stem cells.

The Clinton administration argues that

the stem-cell research can be funded, as long as the stem cells are obtained from private sources and federal researchers don't destroy the embryos themselves. The National Institutes of Health is developing guidelines to be proposed soon, to pave the way for such funding. But dozens of members of Congress sharply criticize the administration's position.

"It's an outrageous interpretation of this law," say New Hampshire Sen. Robert Smith, Republican candidate for president. Dozens of lawmakers, led by GOP Rep. Jay Dickey of Arkansas, have protested. They're planning to add an explicit ban on funding of embryonic stem-cell research to this year's spending bill for the National Institutes of Health, which is part of the Department of Health and Human Services.

The congressional embryo-research ban has been approved each year since 1996, but new scientific breakthroughs promise to turn this year's debate into a major brouhaha. Last fall, researchers from the University of Wisconsin-Madison and Johns Hopkins University reported that they had succeeded in isolating and culturing embryonic stem cells—something scientists had been attempting for more than a decade. The work, the University of Wisconsin trumpeted at the time, "opens the door to growing from scratch everything from heart muscle to bone marrow and brain tissue."

But the research also raises the tricky question of the source of the stem cells. The Johns Hopkins scientists derived the cells from aborted fetuses; the Wisconsin researchers got them from leftover embryos. stem cells? Is it alright to create embryos for the research, or only to use embryos that are being discarded anyway? Is a scientist who uses stem cells complicit with the act of destroying embryos?

Despite the difficulty of the issue, Dr. Cox believes the pendulum is swinging toward allowing federally funded research, because of the tremendous potential of embryonic stem cells.

That view may be right, says Republican Rep. John Porter of Illinois, chairman of the House appropriations subcommittee that handles NIH funding. Rep. Porter, who supports federal funding, doesn't believe that Rep. Dickey and his allies will be able to muster the votes to stop it.

To build support for federal funding, Tim Leschman, director of public policy for the American Society for Cell Biology, has been urging research and patient organizations to call members of Congress. In addition, he has organized briefings for con-

gressional staffers to explain exactly what embryonic stem cells are—and why they're important. "I thought that had a tremendous effect," he says.

The feelings are running high on both sides. Consider a recent exchange of letters in the newspaper Roll Call, which covers Congress. Rep. Dickey wrote, "Just because the embryo, to which I attribute the same moral status as a live human baby, is so young that it has not yet developed legs and arms and eyes, an individual does not have the right to kill that embryo to derive stem cells for research purposes."

But Joseph Bailey, a resident of Alexandria, Va., replied that his life has been devastated by amyotrophic lateral sclerosis, or "Lou Gehrig's Disease." As far as the leftover embryos at fertility clinics, he wrote, "No life will ever come from these sources, except perhaps mine and more than 100 million other Americans suffering from fatal and chronic diseases."

donated by couples who had gone through in vitro fertilization at private fertility clinics. Scientists estimate there are tens of thousands of such extra embryos stored in liquid nitrogen in private clinics.

It was in the wake of the groundbreaking research that HHS issued a legal ruling earlier this year saying that NIH could fund stem-cell research. GOP California Rep. Brian Bilbray believes such research is badly needed. "Literally, it's a breakthrough that can put people back on their feet," he says.

But opponents argue that funding embryo stem-cell research isn't necessary. New studies, they note, suggest that adult stem cells may be able to do some of the same things as embryonic stem cells. "Why engage in the legality or illegality, morality or immorality of it when it's just not necessary?" says Sen. Sam Brownback, a Kansas Republican. Mr. Perry counters that establishing a "no-fly zone" in which adult cells could be used by scientists, but not embryo cells, would stifle research.

The complex ethical questions involved in the research are stirring debate across the country. David Cox, professor of genetics and pediatrics at Stanford University, says the central questions include: How should the medical potential of the stem cells be balanced against the requirement that embryos be destroyed to get the cells? What are acceptable sources for human

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THE WALL STREET JOURNAL

MONDAY, JUNE 21, 1999

THE WHITE HOUSE

WASHINGTON

June 17, 1999

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his
John

MEMORANDUM FOR JOHN PODESTA

FROM:

NEAL LANE *neal*

SUBJECT:

Human Stem Cell Research Update

I want to alert you to two upcoming events regarding oversight of human stem cell research and discuss actions that we might take regarding human stem cell research and cloning for the purpose of human reproduction.

NIH Guidelines -- NIH expects to send a human stem cell research oversight plan and draft guidelines to DHHS next week. Once cleared, the guidelines will be published in the *Federal Register* for a 60-day public comment period. The guidelines are expected to describe the steps investigators must complete in order to receive NIH funds for research involving the *use* of human stem cells. The guidelines will parallel existing regulations covering fetal tissue transplantation research. NIH will not fund research that would include the destruction of human embryos as this would violate the Congressional embryo research ban.

National Bioethics Advisory Commission Report -- NBAC will meet on June 28-29 to discuss human stem cell research. The Commission expects to complete its report shortly after their meeting on July 13-14, in Cambridge, MA. The report will respond to the President's Nov. 14, 1998 request for a "thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations." NBAC is examining the ethics of conducting research on stem cells derived from fetuses, and embryos left over from fertility treatments, embryos produced from donated eggs and sperm or via cloning methods. They are also considering the ramifications of Federal funding of each of these activities.

Although the Commission has not yet completed its deliberations, it appears that they will support Federal funding for research using stem cells derived from fetuses or excess embryos. A majority of Commissioners do not draw an ethical distinction between the use and the derivation of stem cells and are comfortable with the practice of deriving stem cells from excess embryos for research purposes. Despite news reports to the contrary, however, NBAC has not concluded that they will recommend that the Congressional ban be eased to allow Federally-funded research involving the destruction of human embryos to obtain stem cells. Even without an ethical basis, some Commissioners may recommend against using public funds to support such a controversial activity. At this point, it appears that the Commission will not recommend Federal funding for research using stem cells derived from embryos produced for research purposes using cloning or IVF technologies.

Recent News Reports

It was reported in the June 14 Washington Post that two separate companies, Geron Corporation and Advanced Cell Therapeutics, have launched programs to produce human embryos using cloning technology. In the June 15 New York Times, Geron denied that it was producing human embryos but was, instead, using somatic cell nuclear transfer to learn about factors produced in the egg that turn back the developmental clock in an adult nucleus. The company may, in fact, be producing human embryos. Advanced Cell Technology is resuming earlier somatic cell nuclear transfer experiments using a human adult cell and a cow egg. Both companies state that their purpose is the isolation of embryonic stem cells, and not human reproduction (i.e., therapeutic, not reproductive, cloning). In 1994, President Clinton banned the use of Federal funds to create embryos for research purposes (this ban was broadened by Congress in 1995 to include all research using human embryos), and in 1997 banned Federal funding for the use of cloning to reproduce a human being. None of these bans apply to the private sector, although some companies have said that they will comply with the President's voluntary moratorium.

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Rep. Porter supports the Administration's position on stem cell research. House Labor/HHS appropriations staff have said that they don't envision a tightening of the embryo research ban in order to prohibit stem cell research. However, something along these lines can always slip in, especially if there is an Omnibus bill.

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Possible Administrative Actions

Publication of the NIH guidelines and/or release of the NBAC report are opportunities for an Administration statement, in the event one is called for. However, I do not see a compelling reason to make a new statement at this time. We are on record supporting human stem cell

research as a promising avenue of biomedical research. We have already stated the need for stringent ethical oversight and publication of the NIH guidelines will reinforce this message.

In the event that NBAC recommends in mid-July that the government fund research involving the destruction of human embryos in order to obtain stem cells, I would advise against working toward relaxation of the current Congressional ban. Harold Varmus says valuable research can proceed using stem cells that are derived using private funds and there is no need to go across this line for the time being. Although fertility research could be enhanced if the ban were lifted, the incremental approach appears to be more prudent at this juncture. Going further might lose the support of some of the patient groups (Paralyzed Vets, e.g.) because it would bring the debate closer to the abortion issue.

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Additionally, we should work with FDA to clarify their regulatory authority to prevent private sector use of cloning technology to produce a child. We might also explore other administrative oversight options.

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cc: Bruce Reed
Elena Kagan
David Beier
Chris Jennings
Barbara Woolley

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

December 2, 1994

Statement by the President

The Director of the National Institutes of Health has received a report regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions as well as issues concerning the appropriate allocation of federal funds. I appreciate the work of the committees that have considered this complex issue and I understand that advances in in vitro fertilization research and other areas could derive from such work. However, I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research. In order to ensure that advice on complex bioethical issues that affect our society can continue to be developed, we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

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THE WHITE HOUSE

WASHINGTON

November 14, 1998

Dr. Harold Shapiro
Chair
National Bioethics Advisory Commission
Suite 3C01
6100 Executive Boulevard
Bethesda, Maryland 20892-7508

Dear Dr. Shapiro:

This week's report of the creation of an embryonic stem cell that is part human and part cow raises the most serious of ethical, medical, and legal concerns. I am deeply troubled by this news of experiments involving the mingling of human and non-human species. I am therefore requesting that the National Bioethics Advisory Commission consider the implications of such research at your meeting next week, and to report back to me as soon as possible.

I recognize, however, that other kinds of stem cell research raise different ethical issues, while promising significant medical benefits. Four years ago, I issued a ban on the use of federal funds to create human embryos solely for research purposes; the ban was later broadened by Congress to prohibit any embryo research in the public sector. At that time, the benefits of human stem cell research were hypothetical, while the ethical concerns were immediate. Although the ethical issues have not diminished, it now appears that this research may have real potential for treating such devastating illnesses as cancer, heart disease, diabetes, and Parkinson's disease. With this in mind, I am also requesting that the Commission undertake a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations.

I look forward to receiving your reports on these important issues.

Sincerely,

Bill Clinton



February 9, 1998
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 1601 - Human Cloning Prohibition Act

(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to create a human being through cloning. The President believes that using somatic cell nuclear transfer cloning techniques to create a human being is untested, unsafe, and morally unacceptable. The Administration, however, believes S. 1601, as introduced, is too far-reaching because it would prohibit important biomedical research aimed at preventing and treating serious and life-threatening diseases. Therefore, the Administration would not support passage of the bill in its current form. The Administration looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

- Include a five-year sunset on the prohibition on human somatic cell nuclear transfer technology. The sunset provision would ensure a continuing examination of the risks and benefits of this, while being free from the concern that someone will use it prematurely.
- Permit somatic cell nuclear transfer using human cells for the purpose of developing stem cell (unspecialized cells capable of giving rise to specific cells and tissue) technology to prevent and treat serious and life-threatening diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries and for basic research that could lead to such treatments.
- Strike the bill's criminal penalties and instead make any property, real or personal, derived from or used to commit violations of the Act subject to forfeiture to the United States.
- Strike the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would needlessly duplicate the mission of the President's National Bioethics Advisory Commission.

The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

* * * * *



January 15, 1999

TO: Harold Varmus, M.D.
Director, NIH

FROM:

Harriet S. Rabb

SUBJECT: Federal Funding for Research Involving Human Pluripotent Stem Cells

The Office of the General Counsel of the U.S. Department of Health and Human Services (HHS) has prepared the following in response to your request for a legal opinion on whether federal funds may be used for research conducted with human pluripotent stem cells derived from embryos created by *in vitro* fertilization or from primordial germ cells isolated from the tissue of non-living fetuses. This inquiry arises from the recently reported research of: (1) Dr. James A. Thomson of the University of Wisconsin-Madison, who isolated pluripotent stem cells from embryos donated for research by persons undergoing fertility treatment¹; and (2) Dr. Michael Shambloott of the Johns Hopkins University School of Medicine, who derived pluripotent stem cells from primordial germ cells from non-living fetuses.² The research described in these two published reports was not funded by HHS.

Summary Answer

The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. To the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to the statutory prohibition on sale for valuable consideration, the restrictions on fetal tissue transplantation research that is conducted or funded by HHS, as well as to the federal criminal prohibition on the directed donation of fetal

¹ James A. Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocysts, Science, vol. 282, November 6, 1998, pp. 1145-1147.

² Michael J. Shambloott et al., Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells, 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).

and do not have the capacity to develop into an organism that could perform all the life functions of a human being — in this sense they are not even precursors to human organisms.⁴ They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin producing cells.

Moreover, a human embryo, as that term is virtually universally understood, has the potential to develop in the normal course of events into a living human being. The scientific definition of embryo, as described in McGraw-Hill, is "[t]he product of conception up to the third month of human pregnancy."⁵ Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus.⁶ Therefore, in addition to falling outside of the legal definition provided by statute, pluripotent stem cells cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term. Thus, based on

collection of unicells, but a multicellular cooperative with the emergent properties of 'whole organism.'

⁴ At a December 2, 1998, stem cell research hearing before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee, Senator Tom Harkin asked five scientists, two bioethicists, and a theologian testifying before the committee if, in their view, stem cells were organisms. All of the experts who responded concluded that human pluripotent stem cells are not organisms. Use of Fetal Tissue in Brain Stem Cell Research: Hearing Before the Subcomm. on Labor, Health and Human Services, and Education of the Senate Appropriations Comm., 105th Cong. (December 2, 1998) available in LEGISLATE, Transcript No. 983360015 [hereinafter Stem Cell Hearing] (statement of Dr. Harold Varmus, Director, National Institutes of Health; Dr. John Gearhart, Johns Hopkins University School of Medicine; Dr. James Thomson, Wisconsin Primate Research Center, University of Wisconsin; Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System; and Mr. Richard Doerflinger, Associate Director for Policy Development, Secretariat of Pro-Life Activities, National Conference of Catholic Bishops). One expert, Dr. Eric Meslin, Executive Director of the National Bioethics Advisory Commission, stated that he could not speak on behalf of the Commission because it had not considered the question. Stem Cell Hearing, supra (statement of Dr. Eric Meslin).

⁵ McGraw-Hill Dictionary, supra note 3, at 673.

⁶ See Letter from the Chair of the National Bioethics Advisory Commission, to the President of the United States, response to question no. 2, November 20, 1998; National Institutes of Health, Report of the Human Embryo Research Panel, Sept. 1994, p. 26. See also Stem Cell Hearing, supra note 4, (statements of Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; and Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System).

prohibition unless the scientist providing the materials sought payment in excess of the expenses included in the statutory definition of "valuable consideration."

In addition, the law places some restrictions on federal support for research on the transplantation of fetal tissue. Section 498A of the Act provides that the Secretary may conduct or support research on the "transplantation of fetal tissue for therapeutic purposes," only if certain statutory requirements are met. 42 U.S.C. 289g-1. These requirements include obtaining: (1) the informed consent of the woman donating the tissue; (2) a statement by the attending physician regarding the woman's consent and the method of obtaining the tissue; (3) a statement by the researcher regarding his or her understanding of the source of the tissue, that such information has been conveyed to the donee, and that the researcher has not participated in any decision regarding termination of the pregnancy.

Finally, section 498B(b) of the Act provides that it shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation into another person if the tissue will be or is obtained pursuant to an induced abortion, and there is a promise to the donor: (1) to transplant the tissue into a person specified by the donor; (2) the tissue will be transplanted into a relative of the donor; or (3) the donee of the tissue has provided valuable consideration for the costs associated with the abortion. 42 U.S.C. 289g-2(b). The Act provides criminal penalties for violation of the prohibition on directed donations.

III. Federal Restrictions on Fetal Research

Federal regulation provides that activities involving cells, tissues, or organs excised from a non-living fetus shall be conducted only in accordance with any applicable state or local law. 45 CFR 46.210, Subpart B. This regulation would apply to certain human pluripotent stem cells, including those derived from the primordial germ cells of non-living fetuses.

IV. Prohibition on Federal Funding for Cloning of Human Beings

In a March 4, 1997, memorandum to the heads of executive departments and agencies, the President directed that no federal funds will be used for the cloning of human beings and that federal funds shall not be allocated for that purpose.⁹ There are myriad uses for human pluripotent stem cells that are completely unrelated to cloning. However, to the extent such stem cells were to be used for human cloning, the prohibition on the use of federal funds for that purpose would apply.

⁹ Memorandum from the President of the United States to Heads of Executive Departments and Agencies (March 4, 1997).

Human Embryo Research – Fact Sheet

Since FY 96, Congress has prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" (P.L.104-99, sect. 128). The President's FY 97, 98 and 99 budgets proposed deleting this language and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source, and goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

The second provision applies to embryos the same standards that are currently in place for research involving human fetuses which is governed under DHEW 45 CFR part 46.208(a), "No fetus in utero may be involved as a subject in any activity covered by this subpart unless:

- (2) The risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means."
- (b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Taken in sum, both phrases prohibit virtually all human embryo research that might be conducted with Federal funds under other circumstances. Due to the large demand for in vitro fertilization to circumvent certain male and female causes of infertility, there is considerable work under way in this area in the private sector, funded by patients. There are no standards in place governing such procedures, other than FDA requirements for approval of the component drugs and devices.

A preimplantation human embryo exists from a few days after conception until about 3 weeks, at which time implantation occurs. The NIH Human Embryo Research Panel highlighted research involving up to 14-day old embryos because it is at this time that the "primitive streak" appears; a line of cells that will eventually form the nervous system. Prior to development of the primitive streak, the embryo is a disc-shaped collection of cells. The outer cells will form the placenta and amniotic sac for a developing fetus. The cells forming the inner cell mass are referred to as embryonic stem cells and will differentiate into all the body's cells but cannot develop into an embryo without the help of the outer cells. This multi-function potential makes stem cells especially valuable in the development of a wide range of therapeutic agents for leukemia, sickle cell anemia, Parkinson's disease, diabetes, and spinal cord injury. This field is emerging as one with significant potential to understand human biology and address illness and disease affecting millions of Americans.