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COLLECTION:
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Barbara Woolley
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FOLDER TITLE:
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2013-0365-F
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RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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

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b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

July 28, 1999

MEMORANDUM FOR CHRIS JENNINGS
BARBARA WOOLLEY

FROM: RACHEL LEVINSON RÉL

SUBJECT: **Information** - 7/29 PATIENTS' CURe STEM CELL BRIEFING

Patients' CURe has issued the attached media advisory, "Leading Congressional Conservatives to Speak in Favor of Stem Cell Research," in anticipation of other upcoming events regarding stem cell research.

In addition, *Science* magazine ran the attached story on NBAC's recommendations and the WH reaction.

Attachments

cc: Arthur Bienenstock
Jeff Smith

Patients' CURe
Patients' Coalition for Urgent Research

CONTACT: Joe Cerquone
(202) 293-2856

MEDIA ADVISORY

Leading Congressional Conservatives to Speak In Favor of Stem Cell Research at Media Roundtable

What: In anticipation of the release of the National Bioethics Advisory Commission's final report, the final NIH guidelines regarding federal funding stem cell research, and related activity on Capitol Hill, the Patients' Coalition for Urgent Research (Patients' CURe) will host a media roundtable briefing.

Who:

The Honorable Strom Thurmond (R-SC)
U.S. Senate

The Honorable Brian Bilbray (R-CA)
U.S. House of Representatives

Dan Perry, Chairman
Patients Coalition for Urgent Research

Dr. Robert Goldstein
Juvenile Diabetes Foundation

Joseph Bailey
ALS (Lou Gehrig's Disease) Patient

When: 10:00 a.m., Thursday, July 29, 1999

Where: U.S. Capitol Building, Room HC7

Refreshments will be served

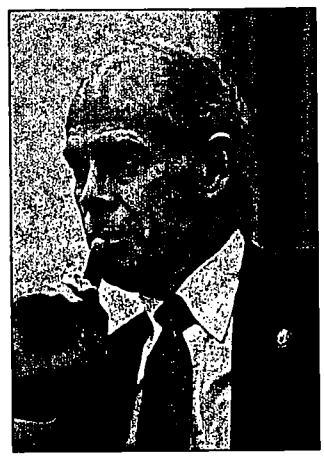
###

2021 K Street NW, Suite 305 ♦ Washington, DC 20006 ♦ Tel: 202-293-2856 ♦ Fax: 202-785-8574

BIOMEDICINE

Ethicists Back Stem Cell Research, White House Treads Cautiously

Research on a scientifically promising type of human cell received a vote of confidence last week. In a decision that Stanford University biologist Paul Berg calls "gutsy," the National Bioethics Advisory Commission (NBAC) recommended on 14 July that the federal government fund not only research on human embryonic stem cells but also the production of cell cultures—even if it means sacrificing embryos. In an official notice, NBAC, a presidential panel of 17 scholars and ethicists, says it will deliver its final report (not yet finished) to the president "very soon."



"I don't want to see NIH's funding wrapped up in an argument that to me is tangential."

—John Porter

The president's staff, however, didn't wait long to distance itself. On the same day that NBAC reached its decision, the White House released a note saying that the Administration's policy will be spelled out in guidelines being drawn up by the National Institutes of Health (NIH). It noted that the president has ruled out funding the creation of human embryos for research. Congress has gone further, for several years adding a general ban on funding embryo research to the NIH appropriation; the current law runs through 30 September. The White House concluded: "No other legal actions are necessary at this time because it appears that human embryonic stem cells will be available from the private sector," and research on these cells "is permissible under the current congressional ban."

With this, the Administration formally backed a policy adopted by NIH and the Department of Health and Human Services (HHS) in January. Their legal experts ruled that government funds may be spent to study, but not to derive stem cells from, embryos (*Science*, 22 January, p. 465). Under this policy, only private labs may develop human stem cells from embryos, but NIH-funded and other U.S.-backed researchers may use them. (The restriction on development doesn't apply to fetal tissue.) Even this plan is controversial, however, because some right-to-life activists have declared that *any* destructive use of an embryo is immoral.

Despite the legal clouds, many biomedical researchers think this field has a bright future. They say that stem cells derived from human embryos and fetal gonadal cells, which are capable of developing into a wide variety of specialized cells, may be a valuable source of transplant tissue. For the past 9 months, NBAC has been deliberating over ethical guidelines that might enable more rapid development of this biomedical technology by opening it to public funding. NBAC concluded that the potential benefits of stem cell research outweigh the disadvantages—provided the cells are drawn from embryos that would otherwise be discarded. NBAC recommended that only "spare" embryos from fertility clinics be used, and only when both donors give full consent. NBAC also said that the government should establish a watchdog committee to set ethical rules and enforce them.

NBAC's position could have an impact on debates on biomedical funding in Congress this summer and fall if right-to-life advocates seek to extend the congressional ban on embryo research and apply it explicitly to the derivation or use of embryonic stem cells. Representative John Porter, chair of the House appropriations subcommittee for Labor and HHS, which drafts the NIH budget, has tentatively set a meeting on 21 July to begin work on next year's appropriation. Although Porter told *Science* that he personally supports NIH's perspective, he said he didn't want this discussion to "overwhelm the funding process." Porter said: "I told [NIH director Harold] Varmus that we should fight the issue on the intellectual basis of what will happen with or without this kind of research. ... But I don't want to see NIH's funding wrapped up in an argument that to me is tangential."

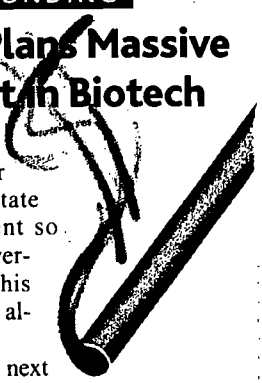
Other members of Porter's subcommittee —including Representative Jay Dickey (R–AR), a sponsor of the embryo research ban—reject both NBAC's view and the Administration's compromise position. "We believe that science should serve humans, not that humans should serve science," says Dickey. He does not think the current law permits federal research on embryonic stem cells, and says he will help take the fight to court, if necessary. He hasn't proposed any change in the embryo research ban.

But Berg, a spokesperson for the American Society for Cell Biology, says NBAC has developed a position that he hopes will make sense to scientists and the public. He calls NBAC's recommendations for monitoring the field "bureaucratic," but reasonable if they reassure the public that this research will be guided by ethical principles.

–ELIOT MARSHALL

RESEARCH FUNDING

Michigan Plans Massive Investment in Biotech



In what may be the largest windfall for research from a state tobacco settlement so far, Michigan Governor John Engler this week signed a bill allocating a stunning $1 billion over the next 20 years for a competitive biotechnology research fund for his state's scientists. The fund, to focus on aging and health, may be spent on a range of programs, from research grants for diabetes to building new bioinformatics databases.

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

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.

Condition	Americans Affected
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]

[1]Juvenile Diabetes Foundation
[2]Parkinson's Action Network
[3]National Coalition for Cancer Research
[4]American Heart Association
[5]National Osteoporosis Foundation
[6]Onhealth.com
[7]American Autoimmune Related Diseases Assn.
[8]American Paralysis Association
[9]March of Dimes
[10]The Alzheimer's Association

CARAVAN®

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%).

Janet Ulrich • 1-800-999-0213 *phone* • 1-800-759-5786 *fax* • OPINION RESEARCH CORPORATION INTERNATIONAL

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

Stem Cell

July 15, 1999

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.

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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.

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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,

American Academy of Allergy, Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Ophthalmology
American Association of Anatomists
American Burn Association
American College of Neuropsychopharmacology
American Medical Association
American Pediatric Society
American Society for Cell Biology
American Society for Clinical Nutrition
American Society for Investigative Pathology
American Society for Microbiology
American Society for Reproductive Medicine
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 Medical School Pediatric Department Chairs
Association of Professors of Medicine
Association of Subspecialty Professors
Citizens for Public Action on High Blood Pressure and Cholesterol
Coalition for American Trauma Care
East Carolina University School of Medicine
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The Endocrine Society
Eye Bank of America
Fred Hutchinson Cancer Research Center
Genetics Society of America
Joint Council of Allergy, Asthma, and Immunology
Juvenile Diabetes Foundation International
Krasnow Institute for Advanced Study
Massachusetts Institute of Technology
National Alliance for Eye and Vision Research
National Caucus of Basic Biomedical Science Chairs
National Childhood Cancer Foundation
National Coalition for Cancer Research
National Health Council
National Spinal Cord Injury Association
Oncology Nursing Society
Osteogenesis Imperfecta Foundation
Paralyzed Veterans of America
Research!America
Resolve, the National Infertility Association
Roswell Park Cancer Institute
Scleroderma Foundation
Society for the Advancement of Women's Health Research
Society for Pediatric Research
University of Florida
University of Washington

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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
Larry Stein
Dan Mendelson
Elena Kagan
David Beier
Chris Jennings
Barbara Woolley
Barry Toiv
Joe Lockhart

Draft 7/7/99

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.

Revised Draft 7/7/99 (incorporating John Podesta's 7/6/99 edits)

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.

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 will continue to insist 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 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.

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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.

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Draft 7/6/99

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

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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

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

b. / e stem cell issue

CLONING HUMAN EMBRYOS
June 14, 1999

Context: *Today's Washington Post reports that two separate companies, Geron Corporation and Advanced Cell Therapeutics, have started programs to create cloned human embryos. Geron Corp. is funding an unnamed American researcher to create human embryos by using somatic cell nuclear transfer with a human adult cell and a human egg. Advanced Cell Therapeutics is resuming earlier somatic cell nuclear transfer experiments using a human adult cell and a cow's egg. Both companies state that their purpose in creating cloned human embryos is for the isolation of embryonic stem cells, and not for 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. This article follows on a piece in yesterday's Post, in the Outlook section, on the religious perspective of the ethics of embryo research, which highlighted the lack of any consensus among different religious leaders on the acceptability of using early-stage embryos to derive stem cells. That article incorrectly stated that the National Bioethics Advisory Commission is planning to recommend that Congress ease the embryo research ban to permit Federal funding for the derivation of stem cells from excess IVF (in vitro fertilization) embryos. The Commission is still actively involved in discussion of this and other issues, and has not come to final agreement.*

General

- Two companies are separately funding research programs to create cloned human embryos for the purpose of deriving human embryonic stem cells that could be used therapeutically. The Post article voiced concern that this research brings us closer to cloning human beings.

- In 1997, President Clinton banned the use of Federal funds to clone a human being, and asked for a voluntary moratorium in the private sector (see below for text). The Administration also sent draft legislation to the Hill to outlaw reproductive cloning, however Congress did not act on it.

- The FDA has said that they have the authority to regulate the use of cloning as a reproductive method in the private sector.

Q. Are we closer to cloning a human being?

A. No. Two companies have announced that they are funding American researchers to create cloned human embryos for the purpose of isolating embryonic stem cells, which could then be used to treat disease. Neither company has reported a success. The possibility of using this technology for reproductive purposes remains uncertain.

Q. Are there any laws or regulations that would restrict the creation of cloned human embryos in the private sector?

A. No Federal funds may be used to create human embryos, either through cloning or the more conventional IVF technologies. Two years ago, the President issued a directive specifically banning Federal funds for cloning a human being, and requested a voluntary moratorium in the private sector, stating that the cloning technique of somatic cell nuclear transfer shouldn't be used to create human beings. At the same time, the President sent draft legislation to Congress to prohibit reproductive cloning in the private sector, however Congress did not act on that legislation. The FDA has stated that they have the authority to regulate the use of cloning as a reproductive method, and would prohibit its use on the basis of safety concerns.

Text of the President's March 4, 1997, Directive on Cloning:

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release March 4, 1997

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Prohibition on Federal Funding for Cloning of Human Beings

Recent accounts of advances in cloning technology, including the first successful cloning of an adult sheep, raise important questions. They potentially represent enormous scientific breakthroughs that could offer benefits in such areas as medicine and agriculture. But the new technology also raises profound ethical issues, particularly with respect to its possible use to clone humans. That is why last week I asked our National Bioethics Advisory Commission to thoroughly review the legal and ethical issues associated with the use of this technology and report back to me in 90 days.

Federal funds should not be used for cloning of human beings. The current restrictions on the use of Federal funds for research involving human embryos do not fully assure this result. In December 1994, I directed the National Institutes of Health not to fund the creation of human embryos for research purposes. The Congress extended this prohibition in FY 1996 and FY 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. However, these restrictions do not explicitly cover human embryos created for implantation and do not cover all Federal agencies. I want to make it absolutely clear that no Federal funds will be used for human cloning. Therefore, I hereby direct that no Federal funds shall be allocated for cloning of human beings.

WILLIAM J. CLINTON

# # #

Draft: Not Public till Thurs 10:00 AM

Patients' CURe
Patients' Coalition for Urgent Research

Patients' CURe Overview

The recent advances in stem cell research could lead to new treatments and even cures for diseases that affect millions of Americans. Doctors may one day be able to use stem cells to regenerate or replace damaged tissue in people who live with debilitating illnesses such as Parkinson's disease, cancer, heart disease, diabetes, Alzheimer's disease, spinal cord injuries, severe burns, osteoporosis and other diseases. Stem cell research will also allow scientists to study cell differentiation, which holds the key to a deeper understanding of birth defects and abnormal cell behavior, such as cancer.

Mission

The Patients' Coalition for Urgent Research (Patients' CURe) is a broad alliance of patients' groups dedicated to informing the public, media and policymakers about the extraordinary potential of this revolutionary research. In addition to educating, Patients' CURe is committed to ensuring stem cell research receives proper oversight and support through federal funding.

Coalition Members

Alliance for Aging Research
The ALS Association
American Autoimmune Related Diseases Assn.
American Cancer Society
American Parkinson Disease Association
Cancer Leadership Council
Christopher Reeve Paralysis Foundation
Citizens for Public Action on Blood Pressure & Cholesterol
Cure for Lymphoma Foundation
Glaucoma Research Foundation
Huntington's Disease Society of America
Juvenile Diabetes Foundation International
Kidney Cancer Association
National Coalition for Cancer Research
Nat'l Coalition of Autoimmune Patient Groups
National Health Council
National Marfan Foundation
National Osteoporosis Foundation
National Patient Advocate Foundation
National Spinal Cord Injury Association
Paralyzed Veterans of America
Parkinson's Action Network
Research!America
Resolve, The National Infertility Association
Society for the Advancement of Women's Health Research
Spina Bifida Assn. of America Foundation
Tourette's Syndrome Association, Inc.

Coalition Principles

- ***Gives Hope to Millions of Patients and their Families***
  No research in recent history has offered as much hope to as many as 128 million Americans suffering from debilitating and often fatal diseases. By studying tissues that would otherwise be discarded, researchers can potentially develop treatments and cures for our most intractable diseases, thereby saving and improving the lives of patients and their families.

- ***Lives will be Saved Faster***
  Early basic science is generally underfunded by the private sector because it does not produce marketable products quickly enough to make the investment worthwhile. Therefore, public funding is the only way to ensure stem cell research is thoroughly conducted. Government funding will allow many more scientists to study stem cells, which will hasten the discovery of effective therapies.

- ***Federal Funding Ensures Oversight and Public Accountability***
  Scientists who receive federal grants will be required to adhere to strict guidelines developed by the NIH with advice from ethicists, theologians and the public. It is important for this medical research to occur in the public domain with careful oversight and opportunities for evaluation.

2021 K Street NW, Suite 305 ◆ Washington, DC 20006 ◆ Tel: 202-293-2856 ◆ Fax: 202-785-8574

CARAVAN®

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.

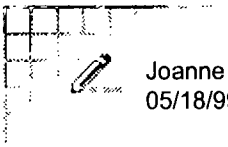
Prior to asking a question specifically addressing federal funding for stem cell research, a definition of the research was given. Following is the definition that was used:

> 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%).

Janet Ulrich • 1-800-999-0213 *phone* • 1-800-759-5786 *fax* • OPINION RESEARCH CORPORATION INTERNATIONAL



Joanne S. Tornow
05/18/99 01:27:45 PM

Record Type: Record

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

cc:
Subject: Patients' CURe meeting today

FYI

---------- Forwarded by Joanne S. Tornow/OSTP/EOP on 05/18/99 01:27 PM ----------

Penny Catterall <pcatterall@AGINGRESEARCH.ORG>
05/18/99 12:46:42 PM

Record Type: Record

To: Joanne S. Tornow/OSTP/EOP, Rachel E. Levinson/OSTP/EOP

cc: "Perry, Dan" <dperry@AGINGRESEARCH.ORG>
Subject: Patients' CURe meeting today

FYI - Dan Perry asked me to forward this notice which I sent out earlier today.

This is a notice that the Patients' CURe will be having its final press conference planning meeting this afternoon at 2:00 pm at the offices of Hill and Knowlton at 600 New Hampshire Avenue, Watergate complex, 6th floor. If you wish to participate by conference call, please call Krista Donahue at H&K at (202) 944-5108 this morning and give her your phone number.

Also, if your group is a patient member of the coalition and you wish to have a statement on the importance of stem cell research to your constituency included in the press packet that is mailed out to reporters tomorrow, please either bring it to the meeting or have it messengered to Hill and Knowlton before COB today. So far, we only have one statement from one group to include. If you cannot get a statement ready by today, please bring at least 50 copies on your letterhead to the press conference on Thursday morning and it will be put out on the press table at that time.

If endorsing groups (i.e. non-patient based) wish to put out a statement, your main thrust should be the endorsement of Patients' CURe and the coalition's focus and efforts, with lesser emphasis on stem cell research itself. Please contact Krista at H&K at kdonahue@hillandknowlton.com if you have any questions about the content of a statement.

Finally, for the information of those new groups signing on either as members or endorsers, the press conference to announce the coalition and strong national support for stem cell research will take place in the Capitol in room HC6 at 10:00 am on Thursday, May 20. We strongly urge ALL coalition groups to be represented at the press conference by at least one senior member of their organization. While you will not have to speak formally, your group may be asked questions by the media after the announcement, and we would like to have a very strong showing from all involved.

Thanks,
Penny

Penelope B. Catterall
Director, Corporate and Foundation Relations
Alliance for Aging Research
(202) 293-2856

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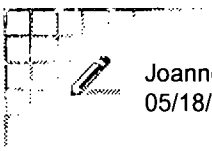

Joanne S. Tornow
05/18/99 12:31:08 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP@EOP

cc:
Subject: FWD: Patients' CURe

FYI, status of March of Dimes.
---------- Forwarded by Joanne S. Tornow/OSTP/EOP on 05/18/99 12:30 PM ----------

Dan Perry <dperry@AGINGRESEARCH.ORG>
05/18/99 11:25:23 AM

Record Type: Record

To: Joanne S. Tornow/OSTP/EOP

cc: relevinso@lngate.eop.gov
Subject: FWD: Patients' CURe

Note: Some recipients have been dropped due to syntax errors.
Please refer to the "$AdditionalHeaders" item for the complete headers.

Joanne,
Here is the message I received from Jess Melanson who has been representing the March of Dimes at our weekly strategy meetings. This states where we stand with MOD and Marina Weiss' current position. Help from your folks could be decisive here.
--Dan

===== Original Message from "Melanson, Jess" <JMelanson@modimes.org> at 5/17/99 4:12 pm
>Original Recipient(s):
>To: TLESHAN <TLESHAN@ascb.org>
> dperry <dperry@AGINGRESEARCH.ORG>
>
>I have some unfortunate news regarding our efforts to include the March of
>Dimes as a member of Patients' CURe. Marina just informed me that her
>meeting today with our President, Research Director, and Medical Director
>was canceled, and we can take no action until they meet.
>
>I pushed the idea of the March of Dimes simply signing on as a member before
>the press conference and defining our role at a later date, but she

>maintains that the foundation will take no action until we have a clear
>strategy that has been endorsed by key members of the organization.
>
>I will attend tomorrow's meeting, but any further questions on this matter
>will have to be directed toward Marina as this is now out of my hands. I'll
>keep you posted of any further developments.
>
>
>Jess Melanson
>Associate Director of State Affairs
>March of Dimes
>1901 L St., NW, Ste. 200
>Washington, DC 20036
>(202) 659-1800

Dan Perry
Executive Director
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(202) 293-2856
(202) 785-8574 (fax)
dperry@agingresearch.org

dperry @ AGINGRESEARCH.ORG
04/16/99 04:44:00 PM

Record Type: Record

To: Barbara D. Woolley

cc:
Subject: stem cell coalition

Rachel,
I found your email address, at last, so I can pass on these thoughts on major patient groups where we need help in getting commitments to the stem cell coalition. We currently have 15 groups signed on, the latest being the Sprina Bifuda Association Foundation. I believe you have the others on a list.

The top targets still outstanding are: 1) American Heart Association; 2) ~~American Cancer Society~~; 3) Alzheimer Association; Arthritis Foundation; and the Multiple Sclerosis Society. These are all high profile, important patient groups for diseases that likely will be approached far more effectively because of what we will learn from stem cell research.

It was also just announced this week that two groups have merged to form the Christopher Reeve Paralysis Foundation. I don't have to tell you how valuable that name is. Two other groups I have not mentioned because I am sure they will agree to the coalition without further pressure are the March of Dimes Birth Defects Foundation and the Paralyzed Veterans of America.

I would be happy to talk with anyone about the status of approaches to these groups. Calls from the right people in the Clinton Administration could be decisive in bringing these names to our coalition.

Incidentally, I just learned that our message testing strategy will be in the field next Thursday with two focus groups in Lansing, MI, followed the next Wednesday by two groups in Nashville, TN.

Let me know how I can support your good efforts.

--Dan

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	To Barbara Woolley; re: Appointment Request (partial) (1 page)	04/12/1999	b(7)(C), b(7)(E), b(6)

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

FOLDER TITLE:
Stem Cell Issue [2]

2013-0365-F
jp3302

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

WAVES_CONF @ PMDF.EOP.GOV
04/12/99 07:15:16 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: WAVES Confirmation

ADDRESSEES: BARBARA_D._WOOLLEY
SUBJECT: CONFIRMATION: APPT. REQUEST FOR WOOLLEY, BARBARA
FROM: WAVES OPERATIONS CENTER - (b)(6), (b)(7)c, (b)(7)e
Date: 04-12-1999
Time: 18:13:09
This message serves as confirmation of an appointment for the visitors listed below.
Please note: Appointment confirmation for visitor names you requested and not listed below may be forthcomming.
Appointment With: WOOLLEY, BARBARA
Appointment Date: 4/13/99
Appointment Time: 2:30:00 PM
Appointment Room: 100
Appointment Building: OEOB
Appointment Requested by: WOOLLEY BARBARA
Phone Number of Requestor: 62155
WAVES APPOINTMENT NUMBER: U70270
If you have any questions regarding this appointment, please call the WAVES Center at 456-6742 and have the appointment number listed above available to the Access Control Officer answering your call.

[redacted]

16

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TOTAL NUMBER OF NAMES SUBMITTED FOR ENTRY : 15
TOTAL NUMBER OF NAMES OF CLEARED FOR ENTRY: 14

****

CHOW, IDA
DOUGHERTY, PAMELA
GUARDUCCI, MARA
HENDRICKS, KAREN
KERR, ELEANOR
LESHAN, TIMOTHY
LIPNER, ROBYN
LUDLAM, CHARLES
MELANSON, JESS
MILO, SARA
MOORE, DAVE
SOLER, LAWRENCE
TIPTON, SEAN
WEINBERG, NINA

[redacted]

[redacted]

[redacted]

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. email	To Barbara Woolley; re: Appointment Request (partial) (1 page)	04/12/1999	b(7)(C), b(7)(E), b(6)

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

FOLDER TITLE:
Stem Cell Issue [2]

2013-0365-F
jp3302

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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)]

b(1) National security classified information [(b)(1) of the FOIA]
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b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

MAILMGT @ A1
04/12/99 06:28:00 PM

Record Type: Record

To: Barbara D. Woolley

cc:
Subject: CONFIRMATION: APPT. REQUEST FOR WOOLLEY

FROM: WAVES OPERATIONS CENTER - [redacted] [002]
Date: 04-12-1999
Time: 18:25:18

This message serves as confirmation of an appointment for the visitors listed below.

Appointment With: WOOLLEY
Appointment Date: 4/13/99
Appointment Time: 2:30:00 PM
Appointment Room: 100
Appointment Building: OEOB
Appointment Requested by: WOOLLEY BARBARA
Phone Number of Requestor: 62155

WAVES APPOINTMENT NUMBER: U70270

If you have any questions regarding this appointment, please call the WAVES Center at 456-6742 and have the appointment number listed above available to the Access Control Officer answering your call.

****

TOTAL NUMBER OF NAMES SUBMITTED FOR ENTRY : 2
TOTAL NUMBER OF NAMES OF CLEARED FOR ENTRY: 2

****

TURNER, SAM
WHITE, FRANCIS

[redacted] [002]

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. email	To Barbara Woolley; re: Appointment Request (partial) (1 page)	04/12/1999	b(7)(C), b(7)(E), b(6)

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

FOLDER TITLE:
Stem Cell Issue [2]

2013-0365-F
jp3302

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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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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b(1) National security classified information [(b)(1) of the FOIA]
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b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

WAVES_CONF @ PMDF.EOP.GOV
04/12/99 07:23:56 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: WAVES Confirmation

ADDRESSEES: BARBARA_D._WOOLLEY
SUBJECT: CONFIRMATION: APPT. REQUEST FOR WOOLLEY, BARBARA
FROM: WAVES OPERATIONS CENTER [redacted] (b)(6), (b)(7)c, (b)(7)e [003]
Date: 04-12-1999
Time: 18:16:41
This message serves as confirmation of an appointment for the visitors listed below.
Appointment With: WOOLLEY, BARBARA
Appointment Date: 4/13/99
Appointment Time: 2:30:00 PM
Appointment Room: 100
Appointment Building: OEOB
Appointment Requested by: WOOLLEY BARBARA
Phone Number of Requestor: 62155
WAVES APPOINTMENT NUMBER: U70270
If you have any questions regarding this appointment, please call the WAVES Center at 456-6742 and have the appointment number listed above available to the Access Control Officer answering your call.

26

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TOTAL NUMBER OF NAMES SUBMITTED FOR ENTRY : 15
TOTAL NUMBER OF NAMES OF CLEARED FOR ENTRY: 15

****

CHOW, IDA
DOUGHERTY, PAMELA
GUARDUCCI, MARA
HENDRICKS, KAREN
KERR, ELEANOR
LESHAN, TIMOTHY
LIPNER, ROBYN
LUDLAM, CHARLES
MELANSON, JESS
MILO, SARA
MOORE, DAVE
PERRY, DANIEL
SOLER, LAWRENCE
TIPTON, SEAN
WEINBERG, NINA

[redacted] (b)(6)

[003]

Rachel E. Levinson 04/13/99 12:47:49 PM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP, Jennifer M. Luray/WHO/EOP, Devorah R. Adler/OPD/EOP

cc:
Subject: stem cell meeting at 3 today - updated agenda and list of attendees

Human Stem Cell Research
April 13, 1999, 3 p.m.
OEOB, Room 100

Agenda

1. Introductions — Attendees
2. Opening Remarks — Chris Jennings

Jennifer Luray

Welcome. Describe point in Weekly Standard that GOP may be planning to raise human stem cell research and tightening of the Congressional ban on embryo research as part of anti-choice movement. We convened this meeting to convey this information, to touch base once again with groups who are following this issue and have been helpful to us in the past, and to hear what they have been working on to ensure that important biomedical research is not constrained unnecessarily.

The President has already stated very clearly the "promising significant medical benefits" of human stem cell research (Nov. 14 letter to NBAC). We have been working very closely with Harold Varmus and others at HHS to ensure that such research would be carried out under appropriate oversight and in accordance with the highest ethical standards.

4. Brief Reports on Status of Relevant Activities

- National Bioethics Advisory Commission
  Rachel Levinson

The Commission is preparing a report to the President in response to his Nov. 14 request and has reached a degree of consensus in support of the use of human stem cells derived from aborted fetuses and from embryos left over from infertility treatment. There is concern on the part of at least one commissioner regarding HHS' determination that the embryo research ban does not apply to use of stem cells. Alex Capron agrees with this conclusion but feels that use of the cells cannot be decoupled from derivation of the cells from embryos. The Commission hopes to have a report completed around June or July.

- NIH Ad Hoc Advisory Panel — Lana Skirboll

On April 8, Harold Varmus convened an ad hoc panel in a public forum to help NIH develop an oversight process and guidelines for the ethical use of human stem cells in federally-funded research. This meeting was a first step in a deliberative process. Once the panel finishes their draft guidelines, NIH plans to

publish them for a 60-day public comment period. A final version must be approved by Dr. Varmus' advisory committee before he will consider moving ahead to fund human stem cell research. During a public comment session, a representative of the House Pro-Life Caucus reiterated earlier Congressional statements that Federal funding of human stem cell research violates the Congressional ban on human embryo research.

5. Report on Congressional Activity and Meetings
Attendees
Several groups have been active in meetings with Hill staff. Patient advocacy groups and scientific and professional societies met in February to discuss legislative strategy for forestalling a tightening of the ban on federally-funded human embryo research. While some advocate using stem cells as tool for attacking the ban altogether (AAMC and American Society for Reproductive Medicine), others are uncomfortable with this approach and fear that it might provoke a backlash in the form of a more restrictive ban via HHS approps.

6. List of Attendees

Robyn Lipner, Bass and Howes Inc., Parkinson's Disease
Charles Ludlam, BIO
Jess Melanson, March of Dimes
Mara Guarducci, Pharmaceutical Research and Manufacturers of America
Victoria Blattner, Merck
Ida Chow, Society for Developmental Biology
Nina Weinberg, National Health Council
Pamela Dougherty, American Cancer Society
Sean Tipton, American Society for Reproductive Medicine
Daniel Perry, Alliance for Aging Research
Lawrence Soler, JDF International
Sara Milo, NCCR
Timothy Leshan, American Society for Cell Biology
Dave Moore, Association of American Medical Colleges
Karen Hendricks, American Academy of Pediatrics
Harley Thomas, Paralyzed Vets Association
Pat White, American Association of Immunologists
Sam Turner, Geron

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

National Institutes of Health
Department of Health and Human Services
March 30, 1999

FACT SHEET ON STEM CELL RESEARCH

The Department of Health and Human Services (DHHS) has concluded that current law permits federal funds to be used for research utilizing human pluripotent stem cells. The National Institutes of Health (NIH) plans to move forward in a careful and deliberate fashion to develop rigorous guidelines that address the special ethical, legal, and social issues relevant to this research. The NIH will not fund research using human pluripotent stem cells until guidelines are developed and widely disseminated to the research community and an oversight process is in place.

The Promise of Stem Cell Research

Scientists have recently isolated and successfully cultured human pluripotent stem cells[1]. These human pluripotent stem cells have an unlimited capacity to divide, and the ability to develop into most of the specialized cells or tissues in the body.

This advance represents a major step forward in human biology and has generated much enthusiasm and interest among scientists and the public, particularly patients and their families. Because these cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, blood cells, and others, they are enormously important to science and hold great promise for advances in health care. For example, further research using pluripotent stem cells may help us:

- Generate cells and tissue that could be used for transplantation. Pluripotent stem cells may be stimulated to develop into many different specialized cells of the body, which may someday be used as replacement cells and tissue to treat many diseases and conditions including Parkinson's disease, spinal cord injury, stroke, burns, heart disease, diabetes, and arthritis.

- Improve our understanding of the complex events that occur during normal human development and also help us understand what goes wrong to cause diseases and conditions such as birth defects and cancer.

- Change the way we develop drugs and test them for safety and potential efficacy. New medications could be tested using human pluripotent stem cells, such as liver cells or skin cells; only the drugs which are both safe and appear to have a beneficial effect would graduate to human testing.

Legal Issues

These human pluripotent stem cells were isolated using two different methods. One group of

---

[1]Michael Shamblott, et al, Derivation of pluripotent stem cells from cultured human primordial germ cells. PNAS, 95: 13726-13731, Nov. 1998.

James Thomson, et al, Embryonic stem cell lines derived from human blastocysts. Science, 282: 1145-1147, Nov. 6, 1998.

scientists derived the pluripotent stem cells from early-stage embryos donated by people who were undergoing fertility treatment in an *in vitro* fertilization (IVF) clinic. Another group of scientists isolated the pluripotent stem cells from non-living fetuses obtained from pregnancies that had been terminated. In both cases, all of the individuals gave full informed consent for the embryos or fetal tissue to be used in research. Neither research project utilized federal funds. Because of the regenerative capacity of pluripotent stem cells, a single culture of human pluripotent stem cells could supply numerous other researchers.

Federal law currently prohibits the DHHS from funding human embryo research. In light of this legislative ban, the Director of the NIH sought a legal opinion from the DHHS Office of the General Counsel on whether DHHS funds may be used for research utilizing human pluripotent stem cells.

After a thorough analysis of the law, DHHS concluded that the congressional prohibition on the use of DHHS funds for certain types of human embryo research does not apply to research utilizing human pluripotent stem cells because such cells are not embryos. The legal opinion also clarified that human pluripotent stem cells derived from non-living fetuses would fall within the legal definition of human fetal tissue and are, therefore, subject to certain Federal restrictions on the use of such tissue.

Thus, research using pluripotent stem cells derived from human embryos can be funded by DHHS. Research that generates and uses pluripotent stem cells from non-living fetuses can also be supported by DHHS, subject to existing law and regulation.

NIH Support

In view of the scientific and medical benefits that may result from research using pluripotent stem cells, the NIH plans to fund research using these cells. It is essential that the Federal government play a role in funding and overseeing the conduct of this research, so that all scientists--both privately and federally funded--have the opportunity to pursue this important line of research. Federal funding will provide oversight and direction that would be lacking if this research were the sole province of industry and academe.

The NIH understands and respects the compelling ethical, legal, and social issues relevant to pluripotent stem cell research and is sensitive to the need for stringent oversight of this research that goes beyond the traditional NIH scientific peer review process. In light of these issues, the NIH plans to move forward in a careful and deliberate way, prior to funding any research utilizing pluripotent stem cells.

In an effort to ensure that any research utilizing human pluripotent stem cells is appropriately and carefully conducted, the NIH will convene a 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, at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814, on April 8, 1999. The meeting will begin at approximately 9:00 a.m. and end at approximately 5:30 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. The working group will meet in public session and will be composed of scientists, patients and/or their families, ethicists, clinicians and

lawyers. They will be asked to consider advice from the National Bioethics Advisory Commission (NBAC), the public, and the Congress. Once developed, guidelines for research utilizing human pluripotent stem cells will be published in the Federal Register for public comment. Until both the guidelines and the oversight process are in place, interested investigators have been notified, via the NIH web site, NIH program staff, and the Deputy Director for Intramural Research that they cannot use DHHS funds to conduct research using human pluripotent stem cells.

Congress of the United States

Washington, DC 20515

February 11, 1999

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

Last month the General Counsel at HHS, Harriet Rabb, issued a memorandum to Dr. Harold Varmus, Director of the National Institutes of Health (NIH), supporting the claim that taxpayer funds may be used for research on stem cells taken from living human embryos. Shortly thereafter, and using the Rabb memo as a basis, Dr. Varmus announced that NIH will reverse current federal policy and begin funding research which relies on the mutilation and destruction of human embryos.

We wish to express to you, in the strongest possible terms, our objection to Ms. Rabb's memo and to Dr. Varmus's decision. Any NIH action to initiate funding of such research would violate both the letter and spirit of the federal law banning federal support for research in which human embryos are harmed or destroyed.[1] Rather than providing guidance on how best to implement the law that Congress passed and the President signed, the memorandum appears to be a carefully worded effort to justify transgressing that law.

In her memorandum Ms. Rabb makes significant errors on the way to her conclusion that it would be permissible for NIH to fund research using stem cells harvested from human embryos. We call upon you to correct the General Counsel's interpretation and to reverse Dr. Varmus's decision.

---

[1] Since January 1996, Congress has included in the annual Labor, Health and Human Services, Education Appropriations Act a section prohibiting funding for this type of research. Section 511 of the most recently enacted research funding bill, Public Law 105-277, provides (in part) that--

> (a) None of the funds made available in this Act may be used for--
> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

PRINTED ON RECYCLED PAPER

The Honorable Donna E. Shalala
February 11, 1999

At the start of her analysis, the General Counsel unilaterally narrows the meaning of "research in which a human embryo or embryos are destroyed" and states that it prohibits only direct federal funding of the specific act of destroying the embryo. In this way she limits the scope of the law passed by Congress. While the *act* of destroying or injuring an embryo would certainly be ineligible for Federal funding, the law has a broader application. It also bars the use of tax dollars to fund research which follows or depends upon the destruction of or injury to a human embryo.

Congress could have structured paragraph (2) of subsection (a) of the law like paragraph (1) and simply prohibited the use of funds for the destruction or discarding of human embryos. We did not do that, and by established rules of statutory construction, HHS may not construe the law's provision on "research in which" embryos are destroyed as narrowly as its provision on the creation of embryos.[2] Instead, we prohibited the funding of research projects in which the lethal dissection or harmful manipulation of living human embryos is a necessary prerequisite, including projects where the material used in the experiments is obtained by destruction of an embryo that would not otherwise be done (or not otherwise done in the same way). In congressional testimony, Dr. Varmus has confirmed that it is impossible to obtain stem cells from embryos for these experiments without destroying the embryos.

The Rabb memo also ignores the policy reflected in current law on fetal tissue transplantation research using tissue from intentionally aborted children. While that law is itself open to criticism, it at least bans the use of fetal tissue in federally funded research if abortion was induced for the purpose of providing the tissue. Under current law, federal funds may not be used for fetal tissue transplantation experiments following an abortion if the timing and method of the abortion were altered solely for the purpose of providing usable tissue for research. Yet, in the embryonic stem cell research which NIH proposes to fund, the timing, method and procedures for destroying the embryonic child would be determined solely by the federally funded researcher's need for usable stem cells.

Finally, both Ms. Rabb's memorandum and Dr. Varmus's testimony before a Senate subcommittee present a new definition of "human embryo" that would undermine both the congressional rider on embryo research, and the President's own 1994 directive against using federal funds to create human embryos for research purposes. They now say that an entity is an "embryo" only if one can show that it is capable, if implanted in the womb, of becoming a born "human being." This narrow definition has no support whatsoever in federal law.

---

[2]When a law has two parallel clauses, one of which is deliberately written in broader terms than the other, it may not be interpreted to have the same meaning as the narrower clause. See *Russello v. United States*, 464 U.S. 16, 23 (1983), and cases cited therein.

Nevertheless, researchers are already offering to use damaged human embryos in their destructive research, or even to engineer lethal defects in advance into the embryos they create for such research, in order to take advantage of this Administration cover and ignore the congressional and presidential directives altogether.

For more than 20 years, Federal laws and regulations have protected the human embryo and fetus from harmful experimentation at the hands of the Federal government – regardless of whether the embryo is "perfect" or damaged, wanted or unwanted, intended for abortion or intended for live birth. This area of law has provided a bulwark against government's misuse and exploitation of human beings in the name of medical progress. It would be a travesty for this Administration to attempt to unravel this accepted ethical standard.

We urge you to review this issue carefully, and to put a stop to a proceeding which so clearly does violence to the meaning and intent of Federal law.

Sincerely,

JAY DICKEY, M.C.

SPENCER BACHUS, M.C.

HENRY J. HYDE, M.C.

RON PACKARD, M.C.

JOE BARTON, M.C.

DAN BURTON, M.C.

DUNCAN HUNTER, M.C.

W.J. (BILLY) TAUZIN, M.C.

SENT BY:

The Honorable Donna E. Shalala
February 11, 1999

JOSEPH R. PITTS, M.C.

GARY G. MILLER, M.C.

RON LEWIS, M.C.

TODD TIAHRT, M.C.

ROBERT B. ADERHOLT, M.C.

CHIP PICKERING, M.C.

PETER T. KING, M.C.

JOHN SHIMKUS, M.C.

JIM RYUN, M.C.

STEPHEN E. BUYER, M.C.

BOB SCHAFFER, M.C.

RON PAUL, M.C.

PETER HOEKSTRA, M.C.

PETE SESSIONS, M.C.

The Honorable Donna E. Shalala
February 11, 1999

JOHN T. DOOLITTLE, M.C.

JOHN HOSTETTLER, M.C.

DAVID M. McINTOSH, M.C.

RICK HILL, M.C.

HELEN CHENOWETH, M.C.

JAMES A. BARCIA, M.C.

CHARLES T. CANADY, M.C.

CHRISTOPHER H. SMITH, M.C.

NICK J. RAHALL II, M.C.

STEVE LARGENT, M.C.

RICHARD K. ARMEY, M.C.
Majority Leader

RONNIE SHOWS, M.C.

TOM A. COBURN, M.C.

LINCOLN DIAZ-BALART, M.C.

The Honorable Donna E. Shalala
February 11, 1999

CHRIS JOHN, M.C.

KEVIN BRADY, M.C.

ASA HUTCHINSON, M.C

PHIL ENGLISH, M.C.

PAUL RYAN, M.C.

TOM TANCREDO, M.C.

ROBERT W. NEY, M.C.

JIM TALENT, M.C.

JACK METCALF, M.C.

DONALD A. MANZULLO, M.C.

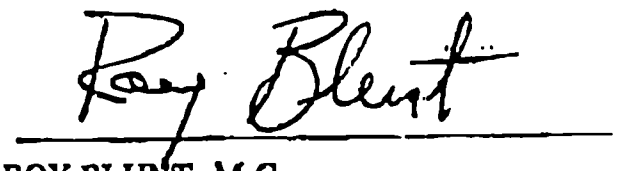
JIM DeMINT, M.C.

DAVE WELDON, M.C.

RAY LaHOOD, M.C.

TOM LATHAM, M.C.

The Honorable Donna E. Shalala
February 11, 1999



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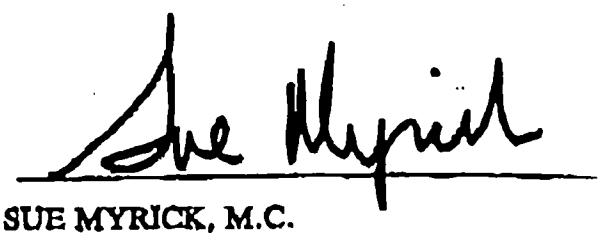

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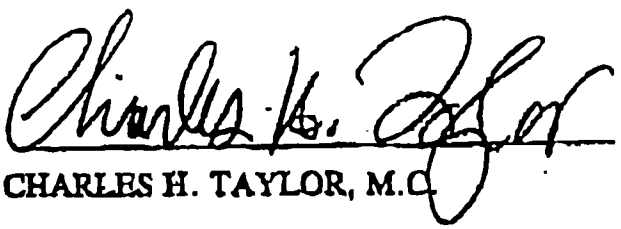

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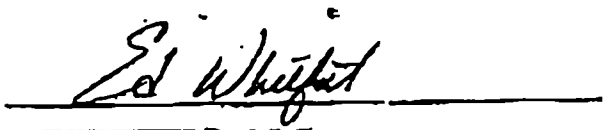

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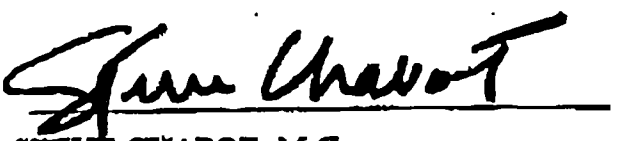

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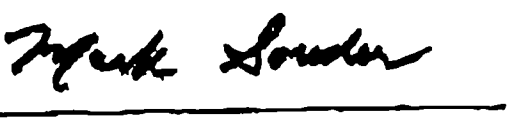
MICHAEL P. FORBES, M.C.



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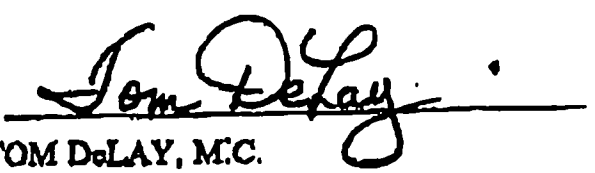
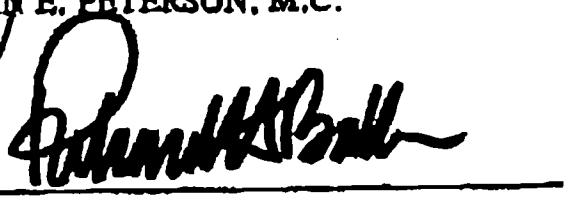
JOHN E. PETERSON, M.C.



TOM DeLAY, M.C.
Majority Whip



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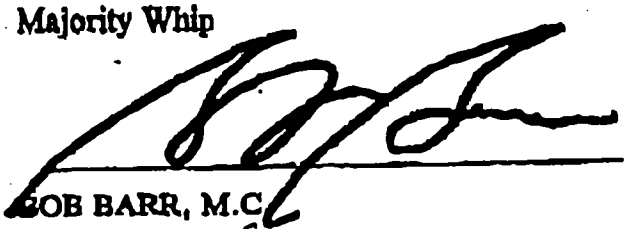

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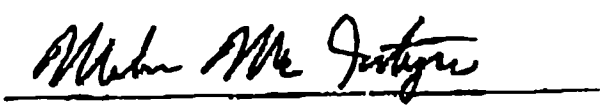

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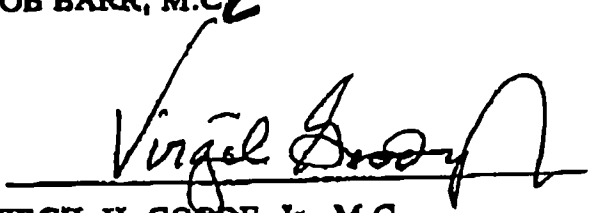

VIRGIL H. GOODE, Jr., M.C.

The Honorable Donna E. Shalala
February 11, 1999

DAVID D. PHELPS, M.C.

LINDSAY O. GRAHAM, M.C.

IKE SKELTON, M.C.

ERNEST J. ISTOOK, Jr., M.C.

SOLOMON P. ORTIZ, M.C.

J.C. WATTS, Jr., M.C.
Republican Conference Chairman

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 23 1999

The Honorable Jay Dickey
U.S. House of Representatives
2453 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Dickey:

Thank you for your letter dated February 11, 1999, concerning the recent announcement by the Director of the National Institutes of Health (NIH) regarding federal funding for research utilizing human pluripotent stem cells. As you know, this research has the potential to lead to great progress in our treatment of debilitating and deadly diseases, our understanding of human development and our ability to develop and test new drugs. Stem cell research is richly promising, yet raises important ethical issues. Therefore, Dr. Varmus and his colleagues at the National Institutes of Health (NIH) will proceed with great caution to ensure that the highest standards are set before moving forward in this area.

In keeping with the important ethical concerns that must be considered, the NIH plans to proceed in a careful and deliberate fashion to develop rigorous guidelines. A working group of the Advisory Committee to the Director of NIH will develop guidelines for the conduct of research using pluripotent stem cells and will recommend an oversight mechanism for protocol review. The National Bioethics Advisory Commission is studying these issues and will provide us with advice that – together with counsel from outside experts, Congress and other interested parties – will help ensure appropriate oversight.

First and foremost, these guidelines will ensure that any research funded in this area is consistent with the prohibition on federal funding for human embryo research contained in section 511 of the HHS appropriations law. Since this prohibition was first enacted in 1996, the Department of Health and Human Services (HHS) has conscientiously adhered to its strictures. For example, we have included the restriction on the use of funds in the NIH Grants Policy Statement and have issued notices reminding NIH intramural staff and the extramural research community that they must observe the prohibition. When necessary, we have not and will not hesitate to take appropriate enforcement action. I am firmly committed to our continued adherence to the law.

Your letter makes specific inquiries regarding a legal memorandum on this subject from the HHS General Counsel. You suggest that the legal analysis is problematic because it relies on a new definition of human embryo that would undermine the Congressional prohibition. In fact, the memorandum relies on the definition provided in the statute itself. The statute defines human embryo as "any organism ... that is derived ... from one or more human gametes or diploid cells."

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The legal memorandum, relying on the scientific definition of the word "organism", concludes that the stem cells at issue are not organisms and therefore cannot be considered human embryos under section 511 of the HHS appropriations law.

The prohibition on federal funding for human embryo research bars the expenditure of federal funds for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded or knowingly subject to greater than minimal risk. You suggest that this provision should be read to also bar federal funding for research which follows or depends upon the destruction of or injury to a human embryo. The plain language of the statute supports the opinion issued by the General Counsel. The law applies by its terms to research in which "a human embryo or embryos are destroyed, discarded" or subjected to more than minimal risk, and not to research preceding or following such research projects. Moreover, I have been advised that there is nothing in the legislative history to suggest that the provision was intended to prohibit funding for research in which embryos -- organisms -- are not involved.

I have reviewed our Department's position and am reassured that proceeding cautiously with research on existing pluripotent stem cell lines is both legal and appropriate. Further, it will allow the NIH to foster world-class research on stem cells, assure appropriate oversight, and bring together the finest minds and facilities to further medical and scientific advances. Allow me to assure you that the NIH understands and respects the deep convictions of people in the research, academic and religious communities, and in Congress, and intends to seek the advice and comment of those communities as we move ahead. I look forward to working with you to ensure that the legal and ethical issues involved in this extremely promising area of research are addressed.

Sincerely,

Donna E. Shalala

United States Senate

WASHINGTON, DC 20510

February 12, 1999

The Honorable Donna E. Shalala
The Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

SPECIAL

Dear Secretary Shalala:

We are deeply concerned with what appears to be a unilateral attempt on your part to effectively undermine congressional intent, by circumventing the current federal funding ban on embryo research.

Of particular concern to us is testimony Dr. Varmus gave on January 26, 1999, during a hearing before the Appropriations Subcommittee on Labor, Health and Human Services and Education. During Dr. Varmus' testimony he stated, "Dr. Thomson and his co-workers derived pluripotent stem cells from the blastocyst stage of an early embryo — the embryos used were donated by couples who were receiving infertility treatment; this derivation of stem cells from the embryo does fall under the ban on Federal funding." The contention being made is that once the stem cells are derived, federal funding of research which directly relies on such destruction is acceptable. We disagree.

Also of concern to us is Dr. Varmus' response to a statement by some researchers that human pluripotent stem cells may come together in culture to begin developing as an embryo. If this does occur, then NIH would be directly violating the congressionally imposed ban by funding embryonic stem cell research. Dr. Varmus stated that he was unsure if it does occur, and that it would be "grossly unethical" to try to find out because that would involve implantation. If the director of the National Institutes of Health is unsure, then the proper course of action would be to take no action. Better to err on the side of preserving congressional intent than destroying it.

Congress never intended for the National Institutes of Health to give incentives for the killing of human embryos for the purpose of stem cell research. We are very interested in any further insight you might provide on this issue and look forward to hearing from you soon.

Sincerely,

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Jon Kyl
JON KYL

Bob Smith

Jesse Helms

Michael B. Enzi
MICHAEL B. ENZI

John Ashcroft

SPECIAL

02-17-99-0011

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 2 1999

The Honorable Don Nickles
United States Senate
133 Hart Senate Office Building
Washington, DC 20510

Dear Senator Nickles:

Thank you for your letter dated February 11, 1999, concerning the recent announcement by the Director of the National Institutes of Health (NIH) regarding federal funding for research utilizing human pluripotent stem cells. As you know, this research has the potential to lead to great progress in our treatment of debilitating and deadly diseases, our understanding of human development and our ability to develop and test new drugs. Stem cell research is richly promising, yet raises important ethical issues. Therefore, Dr. Varmus and his colleagues at the National Institutes of Health (NIH) will proceed with great caution to ensure that the highest standards are set before moving forward in this area.

In keeping with the significant ethical concerns that must be considered, the NIH plans to proceed in a careful and deliberate fashion to develop rigorous guidelines. A working group of the Advisory Committee to the Director of NIH will develop guidelines for the conduct of research using pluripotent stem cells and will recommend an oversight mechanism for protocol review. The National Bioethics Advisory Commission is studying these issues and will provide us with advice that -- together with counsel from outside experts, Congress and the public -- will help ensure appropriate oversight.

First and foremost, these guidelines will ensure that any research funded in this area is consistent with the prohibition on federal funding for human embryo research contained in section 511 of the HHS appropriations law. Since this prohibition was first enacted in 1996, the Department of Health and Human Services (HHS) has conscientiously adhered to its strictures. For example, we have included the restriction on the use of funds in the NIH Grants Policy Statement and have issued notices reminding NIH intramural staff and the extramural research community that they must observe the prohibition. When necessary, we have not and will not hesitate to take appropriate enforcement action. I am firmly committed to our continued adherence to this law.

You have asked whether pluripotent stem cells may come together in culture to begin developing as an embryo. The scientific knowledge base about pluripotent stem cells comes from years of experience in animal research. Mouse pluripotent stem cells grown in a petri dish can give rise to specialized cells and tissues which sometimes form an aggregated structure, similar to certain tumors of the ovary and testis, termed an "embryoid body." These mouse embryoid bodies, however, are not embryos. Similarly, in one report on the derivation of human pluripotent stem cells, researchers observed that the human pluripotent stem cells can form embryoid bodies that are similar in structure to mouse embryoid bodies, which, as noted above, are not embryos.

168409

I have reviewed our Department's position and am reassured that proceeding cautiously with research on existing pluripotent stem cell lines is both legal and appropriate. Further, it will allow the NIH to foster world-class research on stem cells, assure appropriate oversight of such research, and bring together the finest minds and facilities to further medical and scientific advances. I assure you that the NIH understands and respects the deep convictions of people in the academic, religious and bioethics communities, and in Congress, and intends to seek the advice and comment of those communities as we move ahead. I look forward to working with you to ensure that the legal and ethical issues involved in this extremely promising area of research are addressed.

Sincerely,

Donna E. Shalala

Congress of the United States

Washington, DC 20515

SPECIAL

March 15, 1999

99 MAR 16 PM 4:32

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

Thank you for responding so quickly to our February 11 letter concerning federal funding of research in which human embryos are destroyed. Unfortunately, your letter was not responsive to our concerns but only raises further questions.

Consequently, we once again are compelled to point out that well-established rules of statutory construction have been ignored by the HHS General Counsel's memorandum reinterpreting current law on embryo research. The Supreme Court of the United States, as we noted in our earlier correspondence, has ruled that two parallel clauses of a law may not be interpreted in the same way if Congress expresses one provision narrowly and the other broadly. Had Congress intended only to ban the use of funds for the specific act of destroying or discarding embryos, Congress would have done that. Instead, Congress prohibited funding of "research in which" embryos are destroyed or discarded. For this reason, your contention that "the plain language of the statute supports the opinion issued by the General Counsel" remains unconvincing.

In fact, your conclusion that the ban was not intended to cover "research preceding or following" such destruction contradicts NIH's own policy and practice ever since the funding ban was first enacted. In 1997, for example, researcher Mark Hughes was found to be in violation of this law and dismissed from NIH. His violation was that he had used NIH-funded equipment to analyze genetic material obtained from human embryos. NIH funds were used in research which followed the harvesting of a cell from an embryo; in cases where a genetic defect was found, the analysis may also have preceded the discarding of an embryo. There was never any indication that the NIH equipment was used to destroy embryos. Yet in testimony before the House Commerce Subcommittee on Oversight and Investigations on June 19, 1997, NIH Director Harold Varmus agreed that the ban had been violated -- and he assured Congress that NIH had taken "several steps to further diminish the risk of subsequent violations." Now HHS proposes that these types of violations become the norm.

We would also point out that the context in which the funding ban was enacted supports NIH's enforcement of the law from its enactment in January 1996 until Dr. Varmus's announcement in January 1999. Congress passed the law in response to a 1994 report from the NIH Human Embryo Research Panel. The panel recommended taxpayer support of "research involving the development of embryonic stem cells" as part of its recommendations on funding of

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"various areas of research involving the ex utero preimplantation human embryo." The panel treated embryonic stem cell research as a form of embryo research because it knew that the cells would have to be obtained by destroying embryos. When Congress rejected the recommendations of the NIH panel by enacting the current funding ban, it did not make any exceptions. It rejected this form of experimentation as well.

In this context, it is remarkable that your February 23 letter proposes the Advisory Committee to the Director of NIH as the body that will ensure respect for ethical and legal standards in this research. This committee unanimously endorsed the original recommendations of the Human Embryo Research Panel -- including proposals for special creation of embryos for research purposes that were immediately rejected by President Clinton. This same committee openly planned a lobbying campaign to prevent Congress from enacting the ethical protections that remain in law today. Thus we are more concerned than ever that HHS's current course is less a good-faith interpretation of the law than an attempted end-run by those who have always opposed the law.

With regard to the definition of human embryo[1], we are not troubled at all by HHS's use of a scientific definition of the word "organism." As the HHS General Counsel rightly states, an "organism" includes any "individual constituted to carry out all life functions," including a one-celled individual. Rather, we are troubled by the paragraph in which she completely ignores this definition and states that "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." Ms. Rabb declares on behalf the Department, with an appeal to no authority in science or law, that virtually no one considers a human embryo to actually be a living human being. This position simply contradicts the definitions which Ms. Rabb used a few lines before this in her memo to establish that a human embryo is an organism, and, as such, is an "individual constituted to carry out all life functions" of a human being. In other words, an embryo is a human being.

Ms. Rabb's statement that certain cells "do not have the capacity to develop into a human being, even if transferred to a uterus" leaves a doubt in our mind as to the point in biological development when Ms. Rabb considers a "human being" to come into existence, or whether she considers any child before birth to be a "human being." This is not an insignificant point. If the potential or capability of something "to develop... into a living human being" is the standard used to determine whether an organism is a human embryo, and HHS does not consider a "human being" to exist before live birth, then the entire law on embryo research, as well as President Clinton's directive against special creation of research embryos, is undermined. Scientists have already offered to conduct their destructive experiments on damaged embryos not expected to survive to live birth, or to engineer lethal defects into embryos in advance, so that the human embryos they create for purposes of destructive research will not legally be "embryos" at all.

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[1] Current law provides that, "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."

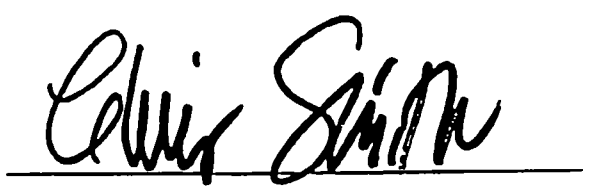
This new and arbitrary use of the term "human being" also contradicts the entire history of federal regulations on human experimentation which, since 1975, have treated the child in the womb at every stage of development as a "human subject" to be protected from harmful research. In commissioning studies of ethical issues in genetics, Congress has urged respect for "the essential equality of all human beings, born and unborn" (42 USC §300v-1). Clearly, in science and law, a human embryo has no need to "develop into" a human being because it already is a human being. The fact that a particular embryo may ultimately have a longer or shorter life span is irrelevant in this regard. It would be akin to HHS claiming that a seriously ill infant is not really an infant because he or she most likely will not "develop into" a live adult.

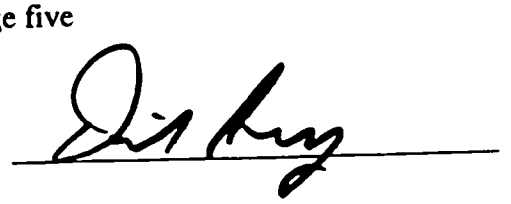
Even if HHS's arbitrary definition were valid, the General Counsel's statement that pluripotent stem cells "do not have the capacity to develop into a human being, even if transferred to a uterus" is open to question. On January 26, Dr. Varmus testified that he does not know whether these stem cells may sometimes recongregate in culture to begin developing as a human embryo. He added that it would be "grossly unethical" to transfer these cells into a woman's uterus to try to answer this question. Would it not also be grossly unethical to simply ignore this question and pursue such embryonic stem cell research, particularly if NIH admits that it may violate the law?

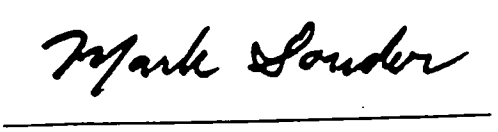
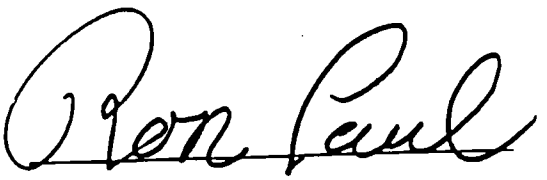
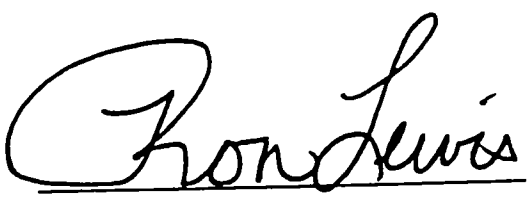
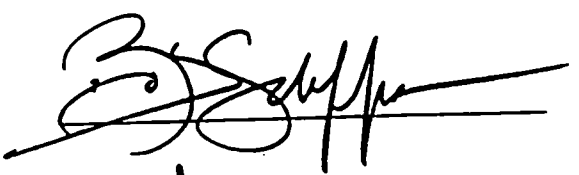
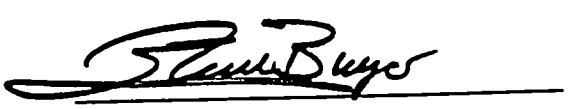
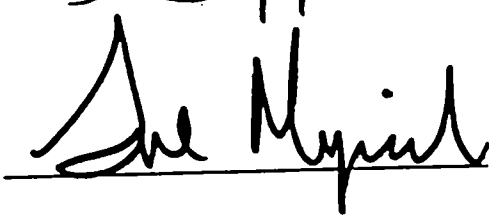
Finally, your letter makes no reference to the precedent established by current law on the use of fetal tissue from induced abortions. Under this law, which also specifically covers cells and tissue obtained from embryos, the harvesting procedure itself must not destroy prenatal life, and the timing and method for taking life must not be influenced solely by the needs of the federally funded research project. These principles are violated by the Administration's proposal for stem cell research.

Madam Secretary, because these are complex and important issues, we urge you once again to address our very serious concerns. For three years the ban on taxpayer funding of harmful research involving human embryos was enforced clearly and appropriately. The change in policy proposed by Dr. Varmus, based on the faulty reasoning in your General Counsel's memo, would violate the funding ban and mark a tragic step backward in federal standards for research involving human subjects.

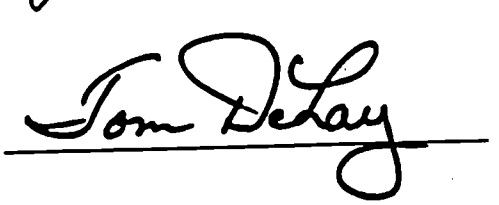
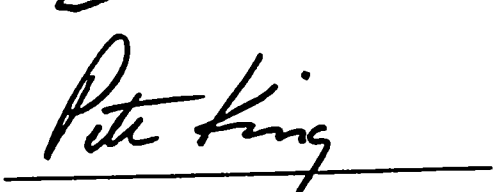
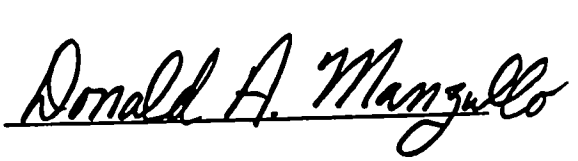
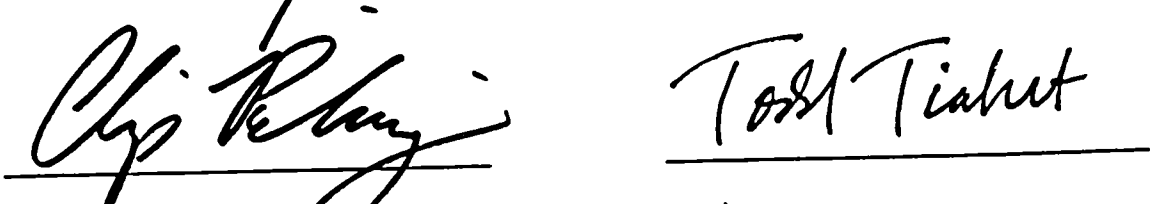
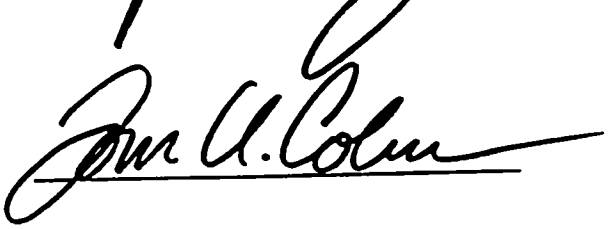
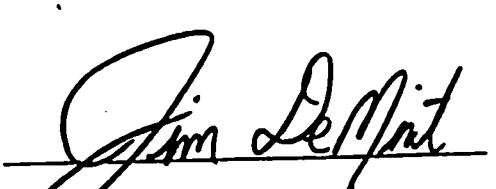
Sincerely,

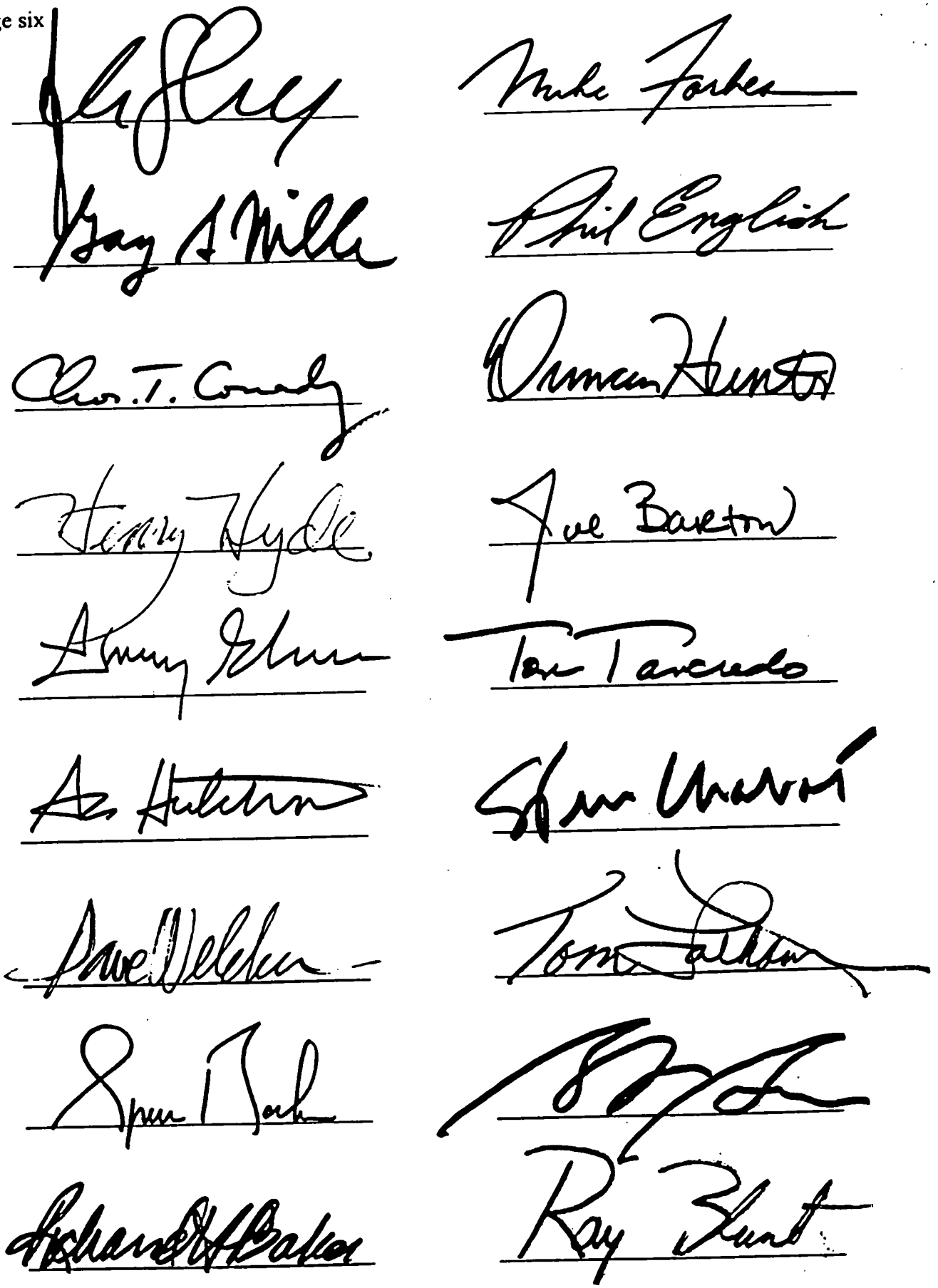


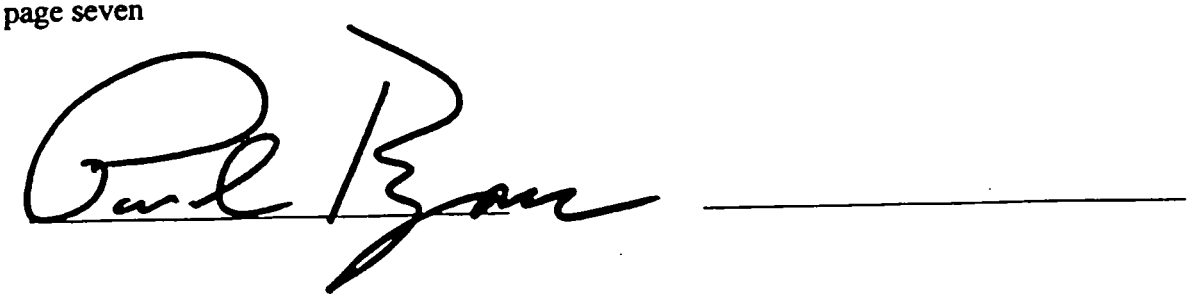








SPECIAL

03-16-99-0062

Congress of the United States
Washington, DC 20515

Statement of Members of the House of Representatives
to the Working Group of the Advisory Committee to the Director of the National Institutes of Health
APRIL 8, 1999

When Dr. Harold Varmus announced in January that he would reverse current policy and begin using taxpayer funds for research on stem cells taken from living human embryos, we -- together with many of our colleagues -- wrote to Health and Human Services Secretary Donna Shalala to protest. As the ban on such funding originated in Congress, and has been consistently opposed by this Administration, we believe we have something to contribute to today's proceedings, particularly with regard to the legality of Dr. Varmus's plan.

Put simply, any NIH action to initiate funding of research which relies on the mutilation and destruction of human embryos would violate both the letter and spirit of the federal law banning federal support for research in which human embryos are harmed or destroyed. We believe the memorandum from HHS General Counsel Harriet Rabb to Dr. Varmus supporting the claim that taxpayer funds may be used for experiments on embryonic stem cells is wrong. Rather than providing guidance on how best to implement the law that Congress passed and the President signed, the memorandum appears to be a carefully worded effort to justify transgressing that law.

The General Counsel unilaterally narrows the meaning of "research in which a human embryo or embryos are destroyed" and states that it prohibits only direct federal funding of the specific act of destroying the embryo. While the *act* of destroying or injuring an embryo would certainly be ineligible for federal funding, the law has a broader application. It also bars the use of tax dollars to fund research which follows or depends upon the destruction of or injury to a human embryo.

Congress could have structured paragraph (2) of subsection (a) of the law like paragraph (1) and simply prohibited the use of funds for the destruction or discarding of human embryos. We did not do that, and by well-established rules of statutory construction, HHS may not construe the law's provision on "research in which" embryos are destroyed as narrowly as its provision on the creation of embryos. The Supreme Court of the United States has ruled that two parallel clauses of a law may not be interpreted in the same way if Congress expresses one provision narrowly and the other broadly. Had Congress intended only to ban the use of funds for the specific act of destroying or discarding embryos, Congress would have done that. Instead, Congress prohibited funding of "research in which" embryos are destroyed or discarded.

In fact, the Secretary's conclusion that the ban was not intended to cover "research preceding or following" such destruction contradicts NIH's own policy and practice ever since the funding ban was first enacted. In 1997, for example, researcher Mark Hughes was found to be in violation of this law and dismissed from NIH because he had used NIH-funded equipment to analyze genetic material obtained from human embryos. NIH funds were used in research which followed the harvesting of a cell from an embryo; in cases where a genetic defect was found, the analysis may also have preceded the discarding of an embryo. There was never any indication that the NIH equipment was used to destroy embryos. Yet in testimony before the House Commerce Subcommittee on Oversight and Investigations on June 19, 1997, NIH Director Varmus agreed that the ban had been violated, and he assured Congress that NIH had taken "several steps to further diminish the risk of subsequent violations." Now NIH proposes that these types of violations become the norm.

We would also point out that the context in which the funding ban was enacted supports NIH's enforcement of the law from its first enactment in January 1996 until Dr. Varmus's announcement in January 1999. Congress passed the law in response to a 1994 report from the NIH Human Embryo Research Panel. The panel recommended taxpayer support of "research involving the development of embryonic stem cells" as part of its recommendations on funding of "various areas of research involving the ex utero preimplantation human embryo." The panel treated embryonic stem cell research as a form of embryo research because it knew that the cells would have to be obtained by destroying embryos. When Congress rejected the recommendations of the NIH panel by enacting the current funding ban, it did not make any exceptions. It rejected this form of experimentation as well.

Even members of the National Bioethics Advisory Commission (NBAC) criticized Ms. Rabb's memo as "disingenuous" for attempting to draw a line between actually destroying embryos for research purposes and using the cells derived from that destruction.

According to a news report, NBAC member Alex Capron, co-director of the Center for Health Policy and Ethics at University of Southern California, was quoted as saying, "I don't believe use and derivation can be separated." John Fletcher, a biomedical ethicist from the University of Virginia expressed the belief that HHS and NIH were relying on an excessively legalistic interpretation and said the legal argument "is not an ethical argument. It is an opinion that use can be separated from derivation, as if derivation is not relevant." He continued, "As a moral construct I think that is very weak and evasive." (Source: *Washington FAX*, March 4, 1999)

Dr. Varmus's plan and the Rabb memorandum also ignore the policy reflected in current law on fetal tissue transplantation research using tissue from intentionally aborted children. While that law is itself open to criticism, it at least bans the use of fetal tissue in federally funded research if abortion was induced for the purpose of providing the tissue. Under current law, which also specifically covers cells and tissue obtained from embryos, federal funds may not be used for fetal tissue transplantation experiments following an abortion if the timing and method of the abortion were altered solely for the purpose of providing usable tissue for research. Yet, in the embryonic stem cell research which NIH proposes to fund, the timing, method and procedures for destroying the embryonic child would be determined solely by the federally funded researcher's need for usable stem cells.

Finally, both Ms. Rabb's memorandum and Dr. Varmus's testimony before a Senate subcommittee present a new definition of "human embryo" that would undermine both the congressional funding ban on embryo research, and the President's own 1994 directive against using federal funds to create human embryos for research purposes. Ms. Rabb states that "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." She declares on behalf the Department of Health and Human Services, with an appeal to no authority in science or law, that virtually no one considers a human embryo to actually be a living human being. This position simply contradicts the definitions which Ms. Rabb used a few lines before this in her memo to establish that a human embryo is an organism, and, as such, is an "individual constituted to carry out all life functions" of a human being. In other words, an embryo is a human being.

The position that an entity is an "embryo" only if one can show that it is capable, if implanted in the womb, of becoming a born "human being" has no support whatsoever in federal law. Nevertheless, researchers are already offering to use damaged human embryos in their destructive research, or even to engineer lethal defects in advance into the embryos they create for such research, in order to take advantage of this Administration cover and ignore the congressional and presidential directives altogether.

This new and arbitrary use of the term "human being" also contradicts the entire history of federal regulations on human experimentation which, since 1975, have treated the child in the womb at every stage of development as a "human subject" to be protected from harmful research. In commissioning studies of ethical issues in genetics, Congress has urged respect for "the essential equality of all human beings, born and unborn" (42 USC §300v-1). Clearly, in science and law, a human embryo has no need to "develop into" a human being because it already is a human being. The fact that a particular embryo may ultimately have a longer or shorter life span is irrelevant in this regard. It would be akin to HHS claiming that a seriously ill infant is not really an infant because he or she most likely will not "develop into" a live adult.

Even if HHS's arbitrary definition were valid, the General Counsel's statement that pluripotent stem cells "do not have the capacity to develop into a human being, even if transferred to a uterus" is open to question. On January 26, Dr. Varmus testified that he does not know whether these stem cells may sometimes recongregate in culture to begin developing as a human embryo. He added that it would be "grossly unethical" to transfer these cells into a woman's uterus to try to answer this question. Would it not also be grossly unethical to simply ignore this question and pursue such embryonic stem cell research, particularly if NIH admits that it may violate the law?

For more than 20 years, Federal laws and regulations have protected the human embryo and fetus from harmful experimentation at the hands of the Federal government -- regardless of whether the embryo is "perfect" or damaged, wanted or unwanted, intended for abortion or intended for live birth. This area of law has provided a bulwark against government's misuse and exploitation of human beings in the name of medical progress. It would be a travesty for this Administration to attempt to unravel this accepted ethical standard.

We urge you to recommend that the Director rescind his decision to begin funding research involving the manipulation and destruction of living human embryos and continue to enforce the embryo research funding ban as Congress intended.

Respectfully,

The Honorable Jay Dickey, M.C.
The Honorable Christopher H. Smith, M.C.
The Honorable Rick Hill, M.C.
The Honorable Steve Largent, M.C.
The Honorable Ron Lewis, M.C.
The Honorable Kevin Brady, M.C.
The Honorable Mark E. Souder, M.C.
The Honorable Bob Ney, M.C.
The Honorable Gary G. Miller, M.C.
The Honorable Ron Paul, M.C.
The Honorable Tom A. Coburn, M.C.
The Honorable John T. Doolittle, M.C.
The Honorable Richard H. Baker, M.C.
The Honorable Bob Schaffer, M.C.
The Honorable Jim Ryun, M.C.