

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 *REL*

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

*Chris -
Can we talk about
this?
Rachel*



**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

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Korean science reform draws protests

Watching the brain decipher smells



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,

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 con-

troversial, 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 em-

bryo 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] Var- mus 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

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

—John Porter



a presidential panel of 17 scholars and ethicists, says it will deliver its final report (not yet finished) to the president "very soon."

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

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

*Scheduling
meeting at
4:00 in Loretta's
office*

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 *Plus for NL*

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

Purpose

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

Background

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

Outline of event:

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

President's suggested remarks:

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

Attachments

Americans Affected by Diseases Stem Cell Research May Help

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

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

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

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

¹Juvenile Diabetes Foundation

²Parkinson's Action Network

³National Coalition for Cancer Research

⁴American Heart Association

⁵National Osteoporosis Foundation

⁶Onhealth.com

⁷American Autoimmune Related Diseases Assn.

⁸American Paralysis Association

⁹March of Dimes

¹⁰The Alzheimer's Association

Stem Cell Research Polling Information

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

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

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

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

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

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

Date: TBD

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

Dear Representative _____:

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

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

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

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

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

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

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

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
Alliance for Aging Research
Alliance for Lung Cancer Advocacy, Support and Education
American Academy of Allergy, Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Ophthalmology
American Association for Dental Research
American Association of Anatomists
American Association of Dental Schools
American Association of Immunologists
American Autoimmune Related Diseases Association
American Burn Association
American College of Clinical Pharmacology
American College of Neuropsychopharmacology
American College of Obstetricians and Gynecologists
American College of Physicians - American Society of Internal Medicine
American Gastroenterological Association
American Medical Association
American Neurological Association
American Pediatric Society
American Physiological Society
American Society for Biochemistry and Molecular Biology
American Society for Bone and Mineral Research
American Society for Cell Biology
American Society for Clinical Nutrition
American Society for Investigative Pathology
American Society for Microbiology
American Society for Pharmacology and Experimental Therapeutics
American Society for Reproductive Medicine
American Society of Clinical Oncology
American Society of Hematology

American Society of Human Genetics
American Thoracic Society
American Veterinary Medical Association
Americans for Medical Progress
Association for Research in Vision and Ophthalmology
Association of Academic Health Centers
Association of American Cancer Institutes
Association of American Medical Colleges
Association of American Universities
Association of Chairs of Departments of Physiology
Association of Independent Research Institutes
Association of Medical and Graduate Departments of Biochemistry
Association of Medical School Pediatric Department Chairs
Association of Medical School Psychologists
Association of Professors of Medicine
Association of Subspecialty Professors
Association of Teachers of Preventive Medicine
Association of University Radiologists
Boston University School of Medicine
Cancer Research Foundation of America
Citizens for Public Action on High Blood Pressure and Cholesterol
Coalition for American Trauma Care
Columbia University
Cure for Lymphoma Foundation
Dartmouth Medical School
Duke University
East Carolina University School of Medicine
Easter Seals
The Endocrine Society
Eye Bank of America
Federation of American Societies for Experimental Biology
Fred Hutchinson Cancer Research Center
Genetics Society of America
Glaucoma Research Foundation
Harvard University
Interstitial Cystitis Association of America, Inc.
Johns Hopkins University
Joint Council of Allergy, Asthma, and Immunology
Juvenile Diabetes Foundation International
Krasnow Institute for Advanced Study
March of Dimes
Massachusetts Institute of Technology
Medical College of Wisconsin
Myasthenia Gravis Foundation of America, Inc.
Myositis Association of America, Inc.
National Alliance for Eye and Vision Research

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

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NOTE TO DAVID BEIER

CHRIS JENNINGS ✓

DAN MENDELSON

FROM: RACHEL LEVINSON *RL*

SUBJECT: WHITE HOUSE STATEMENT ON HUMAN STEM CELL RESEARCH

Late yesterday a decision was made to issue a statement in support of Federally-funded human stem cell research (attached). The statement responds to recommendations of the National Bioethics Advisory Commission that will be included in a report requested by the President (attached). We expect to receive the report in the next two weeks. The recommendations were discussed in a public meeting on Tuesday and Wednesday and we have received numerous press calls on the subject.

Attachments

cc: Jeff Smith
Devorah Adler

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release
July 14, 1999

Contact 202/456-6047

Statement by the Press Secretary

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 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. No other legal actions are necessary at this time, because it appears that human embryonic stem cells will be available from the private sector. Publicly funded research using these cells is permissible under the current Congressional ban on human embryo research.

The President acknowledges the hard work of Chairman Dr. Harold Shapiro and other members of the National Bioethics Advisory Commission in their thoughtful consideration of a complex and sensitive matter.

Recommendation 1

Research involving the derivation and use of human embryonic germ cells from cadaveric fetal tissue should continue to be eligible for federal funding. In addition, relevant statutes and regulations should be amended to make clear that existing ethical safeguards apply to the derivation and use of embryonic germ cells for research purposes.

Recommendation 2

Research involving the derivation and use of human embryonic stem cells from embryos remaining after infertility treatments should be eligible for federal funding. An exception should be made to the present statutory ban on federal funding of embryo research to permit federal agencies to fund research involving the derivation of human embryonic stem cells from this source, under appropriate regulations that include public oversight and review (See Recommendations 8 and 9)

Recommendation 3

Federal agencies should not fund research to generate or use human embryonic stem cells derived from embryos made via IVF solely for research purposes.

spell out

Recommendation 4.

Federal agencies should not fund research to generate or use human embryonic stem cells derived from embryos made via somatic cell nuclear transfer into oocytes solely for research purposes.

Recommendation 5

Prospective donors of embryos remaining after infertility treatments should receive timely, relevant, and appropriate information to make an informed and voluntary choice regarding disposition of the embryo. Prior to considering the potential research use of the embryos, the prospective donor should have been presented with the options of storing the remaining embryos, donating them to another woman, or

discarding them. If the prospective donor chooses to discard the embryos, the options of donating to research may be presented during which presentation the person seeking the donation should:

- X disclose that the embryonic stem cell research is not intended to provide medical benefit to the donor,
- X make clear that consenting or refusing will not affect the quality of any future care provided to the prospective donor,
- X describe the general research area and the specific research protocol, if known,
- X disclose the source of funding and expected commercial benefits of the research, *if known*
- X make clear that embryos used in research will not be transferred to any woman's uterus, and
- X make clear that the research will involve the destruction of the embryos.

Recommendation 6

In federally funded research involving embryos remaining after infertility treatments, the donor may not restrict the patient-subjects who will receive the cells derived from the embryos.

Commentary—fetal tissue parallel

Recommendation 7

Cadaveric fetal tissue and embryos should ~~may~~ not be bought and sold.

In commentary – mention profit/cost issues, costs incurred in infertility treatments are not the same.

Recommendation 8

The Department of Health and Human Services should establish a National Oversight and Review Panel to ensure that all federally funded research involving the derivation and use of human embryonic stem

cells and embryonic germ cells is conducted in conformance with the ethical principles and recommendations provided in this report. The Panel should have a broad, multidisciplinary membership, including members of the public. The responsibilities of the Panel shall include:

- ^{general} reviewing protocols for the derivation of human embryonic stem cells and human embryonic germ cells and approving those that meet the requirements described in this report
- certifying ES/EG cell lines that result from approved protocols
- maintaining a Public Registry of ^{approved, certified} ES/EG cell lines (See recommendation 9) ^{→ and related information}
- collecting from sponsoring federal agencies descriptions of all protocols that use or derive such cells, with any available information concerning research outcomes, including published papers. The private sector is encouraged to submit similar, non-proprietary data.
- establishing a database—which should be linked to the Public Registry—to be used by the Panel to track the history and ultimate use of certified cell lines for the purpose of policy development.
- establishing requirements for and provide guidance to sponsoring agencies on the social and ethical issues that should be considered in the review of research protocols that derive or use such cells.
- providing an annual report to the DHHS Secretary which would include an assessment of the current state of the science for both derivation and use of embryonic stem cells and embryonic germ cells, a review of recent developments in the broad category of human stem cell research, a summary of any emerging ethical or social concerns associated with this research, and a review of the adequacy and currency of the recommendations addressed in this report.

Commentary:

Give the panel a name.

Discuss the membership of the panel and need to be a FACA committee.

Discussion of proprietary information can be done in closed session.

Recommendation 9

The National Oversight and Review Panel shall establish a Public Registry, the functions of which shall include:

- Maintaining a record of all protocols approved by the Panel
- Maintaining a list of certified cell lines derived from these approved protocols.

merged w/ Rec 8

Recommendation 10 9

Protocols involving the derivation of embryonic stem cells and embryonic germ cells must be reviewed and approved by an appropriately constituted and convened local review body prior to consideration by the National Oversight and Review Panel (See Recommendation 8).

IRB ?

Commentary: explanatory text about 45 CFR 46.

New Rec. 11 10

IRB ?

The local review body described in Recommendation 10 should ensure compliance with any requirements established by the Panel, including confirming that institutions (in the United States or abroad) that supply embryos or fetuses have obtained them in accordance with the requirements established by the Panel.

Recommendation 12 11

~~When reviewing research protocols using embryonic stem cells and embryonic germ cells,~~ all federal agencies should ensure that their review processes comply with any requirements established by the National Oversight and Review Panel (See Recommendation 8), paying particular attention to the adequacy of the justification for using such cell lines.

Recommendation 13 12

For privately funded research on ES/EG cells that would otherwise be eligible for federal funding, NBAC encourages researchers and sponsors

voluntarily to adopt the recommendations of this report that apply to such research, This includes submitting protocols to the National Oversight and Review Panel for the derivation of embryonic stem cells and embryonic germ cells for review and for the certification of such cell lines. (See Recommendations 8 and 9).

Recommendation 14 3

For research projects that involve deriving ES/EG cells that would not be eligible for federal funding under Recommendations 3 and 4 in this report, NBAC recommends that:

- (a) professional societies and trade associations develop and promulgate ethical safeguards and standards consistent with the principles underlying this report;
- (b) privately funded researchers conducting this research (and their sponsors) should voluntarily comply with these safeguards and standards.

Recommendation 15 4

The National Oversight and Review Panel and the Public Registry described in Recommendations 8 and 9 should sunset after a period of five years, and the process and substance of their activities independently evaluated to determine whether these mechanisms have adequately fulfilled their functions.

Will be rewritten but retain this substance

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FROM: RACHEL LEVINSON *RL*

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spellout

Recommendation 4.

Federal agencies should not fund research to generate or use human embryonic stem cells derived from embryos made via somatic cell nuclear transfer into oocytes solely for research purposes.

Recommendation 5

Prospective donors of embryos remaining after infertility treatments should receive timely, relevant, and appropriate information to make an informed and voluntary choice regarding disposition of the embryo. Prior to considering the potential research use of the embryos, the prospective donor should have been presented with the options of storing the remaining embryos, donating them to another woman, or

discarding them. If the prospective donor chooses to discard the embryos, the options of donating to research may be presented during which presentation the person seeking the donation should:

- X disclose that the embryonic stem cell research is not intended to provide medical benefit to the donor,
- X make clear that consenting or refusing will not affect the quality of any future care provided to the prospective donor,
- X describe the general research area and the specific research protocol, if known,
- X disclose the source of funding and expected commercial benefits of the research, *if known*
- X make clear that embryos used in research will not be transferred to any woman's uterus, and
- X make clear that the research will involve the destruction of the embryos.

Recommendation 6

In federally funded research involving embryos remaining after infertility treatments, the donor may not restrict the patient-subjects who will receive the cells derived from the embryos.

Commentary—fetal tissue parallel

Recommendation 7

Cadaveric fetal tissue and embryos should ~~may~~ not be bought and sold.

In commentary – mention profit/cost issues, costs incurred in infertility treatments are not the same.

Recommendation 8

The Department of Health and Human Services should establish a National Oversight and Review Panel to ensure that all federally funded research involving the derivation and use of human embryonic stem

cells and embryonic germ cells is conducted in conformance with the ethical principles and recommendations provided in this report. The Panel should have a broad, multidisciplinary membership, including members of the public. The responsibilities of the Panel shall include:

- *general* reviewing protocols for the derivation of human embryonic stem cells and human embryonic germ cells and approving those that meet the requirements described in this report
- certifying ES/EG cell lines that result from approved protocols
- maintaining a Public Registry of *approved, certified* ES/EG cell lines (See recommendation 9) *→ and related information*
- collecting from sponsoring federal agencies descriptions of all protocols that use or derive such cells, with any available information concerning research outcomes, including published papers. The private sector is encouraged to submit similar, non-proprietary data.
- establishing a database—which should be linked to the Public Registry—to be used by the Panel to track the history and ultimate use of certified cell lines for the purpose of policy development.
- establishing requirements for and provide guidance to sponsoring agencies on the social and ethical issues that should be considered in the review of research protocols that derive or use such cells.
- providing an annual report to the DHHS Secretary which would include an assessment of the current state of the science for both derivation and use of embryonic stem cells and embryonic germ cells, a review of recent developments in the broad category of human stem cell research, a summary of any emerging ethical or social concerns associated with this research, and a review of the adequacy and currency of the recommendations addressed in this report.

Commentary:

Give the panel a name.

Discuss the membership of the panel and need to be a FACA committee.

Discussion of proprietary information can be done in closed session.

Recommendation 9

The National Oversight and Review Panel shall establish a Public Registry, the functions of which shall include:

- Maintaining a record of all protocols approved by the Panel
- Maintaining a list of certified cell lines derived from these approved protocols.

merged w/ Rec 8

Recommendation 10 9

Protocols involving the derivation of embryonic stem cells and embryonic germ cells must be reviewed and approved by an appropriately constituted and convened local review body prior to consideration by the National Oversight and Review Panel (See Recommendation 8).

IRB ?

Commentary: explanatory text about 45 CFR 46.

New Rec. 11 10

IRB ?

The local review body described in Recommendation 10 should ensure compliance with any requirements established by the Panel, including confirming that institutions (in the United States or abroad) that supply embryos or fetuses have obtained them in accordance with the requirements established by the Panel.

Recommendation 12 11

~~When reviewing research protocols using embryonic stem cells and embryonic germ cells,~~ all federal agencies should ensure that their review processes comply with any requirements established by the National Oversight and Review Panel (See Recommendation 8), paying particular attention to the adequacy of the justification for using such cell lines.

Recommendation 13 12

For privately funded research on ES/EG cells that would otherwise be eligible for federal funding, NBAC encourages researchers and sponsors

voluntarily to adopt the recommendations of this report that apply to such research, This includes submitting protocols to the National Oversight and Review Panel for the derivation of embryonic stem cells and embryonic germ cells for review and for the certification of such cell lines. (See Recommendations 8 and 9).

Recommendation 14 3

For research projects that involve deriving ES/EG cells that would not be eligible for federal funding under Recommendations 3 and 4 in this report, NBAC recommends that:

- (a) professional societies and trade associations develop and promulgate ethical safeguards and standards consistent with the principles underlying this report;
- (b) privately funded researchers conducting this research (and their sponsors) should voluntarily comply with these safeguards and standards.

Recommendation 15 4

The National Oversight and Review Panel and the Public Registry described in Recommendations 8 and 9 should sunset after a period of five years, and the process and substance of their activities independently evaluated to determine whether these mechanisms have adequately fulfilled their functions.

Will be rewritten but retain this substance

The attached reflects John Podesta's 7/6/99 edits.

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.

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

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FROM: NEAL LANE 
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