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001. note	re: phone number (partial) (1 page)	06/30	P6/b(6)
002. form	re: Notice of Right to Sue (1 page)	07/20/2000	P6/b(6)
003. report	re: Banning Funding for Stem Cell Research (partial) (1 page)	01/20/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Heather Howard (Subject Files)
OA/Box Number: 21195

FOLDER TITLE:

Stem Cell Research

2012-0254-S

rc671

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

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

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

August 23, 2000

REMARKS BY THE PRESIDENT
UPON DEPARTURE FOR NEW JERSEY

The Rose Garden

See page 3

10:53 A.M. EDT

THE PRESIDENT: Before I leave for New Jersey today I want to make a brief announcement about some action we're taking to help consumers in southern California who have been hit very hard by skyrocketing electric bills. I want to thank Governor Davis, Senator Feinstein, Senator Boxer, and Congressman Filner for their leadership on this issue and their work with me.

The wholesale price of electricity has risen sharply in California this summer as a result of tight supplies and growing demand. This is having a particularly heavy impact where the price hikes are being passed on to consumers as they are in the San Diego region. Many families and small businesses in San Diego have seen their electric bills more than double. I've heard reports of senior citizens on fixed incomes being forced to choose between medicine and air-conditioning.

Today we're taking three new steps to help ease the burden. First, Secretary Richardson has asked the Federal Energy Regulatory Commission to expedite its investigation of the wholesale power markets, so we can better understand what is happening in California and provide policy-makers with the information they need to protect consumers in a timely fashion.

Second, I'm directing the Department of Health and Human Services and Secretary Shalala to release \$2.6 million in Low-Income Home Energy Assistance Program funds for the families of southern California. This doubles the amount of LIHEAP assistance in the San Diego region and will help to ensure that low-income families and senior citizens have the emergency help they need to pay their bills and stay cool.

Third, I'm directing the Small Business Administration to step up their efforts to inform small businesses about SBA loans to help cope with unusually high electric bills.

All of these are short-term steps to help families in southern California during the current power crunch. I also renew my call to Congress to work with us to build a better energy future over the long run, to take up my energy budget initiatives and the tax incentives to promote energy efficiency and conservation. I hope they will also pass a national comprehensive bill to foster a new era of the right kind of competition in the electric industry to establish a more competitive, efficient and reliable electric power system for our nation, and to beef up efforts to prevent utilities from abusing their market power to raise rates above competitive levels. This legislation would save our consumers about \$20 billion a year in power costs. We ought to do it, and we ought to do it this year.

Let me say once again to the people of southern California, we'll continue to keep a close eye on the situation. We'll do what we can to

help you get through this summer. Thank you very much.

Q Mr. President, do you think the power companies are profiteering in California?

THE PRESIDENT: Well, that's what FERC's going to investigate. Secretary Richardson and I talked about it. We want the FERC to look into it and see what the facts are. There is an unusual impact there, different from virtually any other place in America, and it needs to be examined. And I hope it will be. I hope the assistance we're giving in the meanwhile will help.

And, again, I will say, I believe that we could do an enormous amount if the Congress would pass the energy budget initiatives, the tax incentives to buy energy-efficient homes, vehicles, to retrofit businesses, and would pass the electric utility deregulation.

Let me remind you -- some of you may remember this -- I went out to the Inland Empire, east of LA, I believe it was in San Bernardino, to dedicate a housing project that was part of an effort with the National Home Builders and the Energy Department, for working people on modest incomes. And the homes that they built there lowered average electric rates by over 40 percent.

So we need to take some structural action here to empower the American people to solve this problem themselves, too. If we have deregulation and we give better incentives to people to build or retrofit their homes, their offices, and to buy other energy efficient appliances, we could make a big difference here in almost no time. So I hope that will happen.

Go ahead, Mark.

Q Sir, what do you think of Janet Reno's decision not to name a special counsel to investigate Al Gore's fundraising? Do you think it may look to some people like a whitewash?

THE PRESIDENT: I don't know any more about that than you do. I learned about it when I picked up the paper this morning.

Q Well, what are you hoping for from your meeting tomorrow with President-elect Fox of Mexico in terms of U.S. business potential and potential for the U.S. economy?

THE PRESIDENT: Well, first of all, I want to get to know him and I want to reaffirm the support of the United States, which I think is bipartisan, for good, strong relationships with Mexico, the need for us to work together to deal with the drug challenge, our common environmental challenges along the border, and to make our trade relationship work for both sides. And so, obviously, I hope that there will be long-term economic benefits.

I think he's quite serious about modernizing the Mexican economy and moving forward with our relationship. And I've been impressed with what I've seen and heard about him so far, and I'm anxious to meet him and do what I can to get our relationship off to a good start.

Q Mr. President, a lot of state Democratic chairs would like you to come out and do some targeted campaigning to help get out the base in November. Do you think that's a good idea? Is that something you intend to do?

THE PRESIDENT: Well, first of all, I think the most important thing is for me to do as much as I can for the American people in the job I have between now and January the 20th, and that's my main

priority. The second most important thing is for Al Gore and Joe Lieberman to go out and spread the message, engage in the debate and make sure the American people know what the choices are before them. And I think they're doing quite a good job of that.

Now, if I can help, of course, within those parameters, I will do that. I went to Michigan yesterday, I'm going to New Jersey today. I will do some work within the limits of my ability to do it. But the main thing is that the candidates carry the message, and I think they're doing a fine job.

Q Mr. President, on Colombia, you signed a waiver yesterday so that the aid could start flowing. There are still some problems of human rights violations and Congress has a lot of doubt. You're going to be there next Wednesday.

THE PRESIDENT: I did sign the waiver, but the Congress also passed the aid package and they expect it to go forward. I did it because I believe President Pastrana is committed to dealing with the human rights issues about which we're still very concerned. He has submitted legislation to the Colombian Parliament, for example, for civil trials, for allegations of military abuses of human rights. And we also have a system in place for specific case-by-case investigation of serious allegations.

So I think that we've protected our fundamental interest in human rights and enabled the Plan Colombia to have a chance to succeed, which I think is very, very important for the long-term stability of democracy and human rights in Colombia, and for protecting the American people and the Colombian people from the drug traffic.

Q Are you -- human rights in favor of the money?

THE PRESIDENT: No. No. First of all, the money is designed to help combat the drug-trafficking and to help alleviate a lot of the social problems, to help to develop alternative economic development, and also to build the civil institutions in Colombia which will help to protect human rights.

So what I did was to permit Plan Colombia to go forward and be implemented because I'm convinced that the President is committed to the proper course in human rights -- he submitted legislation which is evidence of that -- and because we haven't given up our ability to look into case-by-case allegations of human rights violations dealing with specific military units who can be kept from getting any of this assistance if they have, in fact, committed human rights violations.

Q Mr. President, can you talk about your administration's decision to support federally-funded stem cell research, and are you worried about the controversy involved in that?

THE PRESIDENT: Well, I believe if people will actually -- Secretary Shalala and I had a long talk about this before we came out this morning -- I think if the public will look at, first of all, the potentially staggering benefits of this research -- everything from birth defects to Parkinson's to Alzheimer's to diabetes -- profoundly important there -- to certain kinds of cancers, spinal cord injuries, burns, anything kind of regeneration of cells that's required, the potential to change the future, the health future for Americans and for people around the world is breathtaking.

Secondly, these guidelines were not put out without a rigorous scientific review. And human embryo research deals only with those embryos that were, in effect, collected for in-vitro fertilization that never will be used for that. So I think that the protections are there;

the most rigorous scientific standards have been met. But if you just -- just in the last couple of weeks we've had story after story after story of the potential stem cell research to deal with these health challenges. And I think we cannot walk away from the potential to save lives and improve lives, to help people literally to get up and walk, to do all kinds of things we could never have imagined, as long as we meet rigorous ethical standards. And I'm convinced, and Secretary Shalala is convinced, that that has been done.

Q Mr. President -- talked about open borders between the United States and Mexico. Generally speaking, sir, do you support that concept even over the long-term, and do you expect it to be a dominant part of your meeting tomorrow?

THE PRESIDENT: Well, I want to hear what he has to say about it, and how we would go about dealing with the problems that we have with the trade arrangement we have now, whether they would be amplified. In general, I think there will be increasing interdependence of the world's economies over the next decade, increasing interdependence in our region.

I think -- I believe we should have done more with South America. We've got the Caribbean Basin Trade Initiative, which I think is good. We've got the relationship with Mexico, which I think has been a net plus for the United States, both economically and politically. We didn't extend our trade agreements to the rest of South America and I think that the Europeans have benefitted at our expense. So I think there will be more interdependence and the United States has to be a part of that.

But, like everything else, the devil is always in the details here, so I want to talk to him about it and see what he has in mind. I would imagine most of this work would have to be done by the next administration.

Q -- U.S. doing to convince OPEC nations to increase output, and will you be discussing this issue with Nigeria when you go?

THE PRESIDENT: OPEC nations? I'm sorry. Well, as you know, we have done what we could -- I was actually -- I was reviewing the situation last night, and, yes, I will discuss it with Nigeria. But we have to look at where there is excess capacity.

Part of this a question of whether the OPEC nations can increase their production. Part of the problem is coming because there's now renewed economic growth elsewhere in the world. And it seems to me, just looking at all the numbers over the long run, we're going -- we'll get some benefit out of that. That is, I expect you'll see a significant increase in American exports over the next six months to two years because of the increasing growth in other parts of the world, but as a result of that, it's putting more pressure on the oil supplies that are available.

So I'm going to do what I can to keep these prices moderated and to continue to argue to all the OPEC nations that if the price gets too high they will cause recession in other countries and then the purchases will drop dramatically and for a longer period of time. They're much better off with a price that's below where it is now, but one that can be sustained. They don't want to go down to \$13-\$15 a barrel again, but we don't need it -- it needs to be, I think, in the low \$20s somewhere. I think that's -- low to mid '20s is a more sustainable rate. And so I will clearly discuss it with President Obasanjo and with others in the weeks ahead.

Thank you.

Q Mr. President, how -- look for your legal defense fund?

Q Are you back in the spotlight? (Laughter.)

THE PRESIDENT: I'm going to New Jersey.

END 11:08 A.M. EDT

Editorial



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August 25, 2000

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Sensible Rules for Stem Cell Research

The Clinton administration issued guidelines this week that would at long last allow federal funding of research on stem cells derived from human embryos. This avenue of inquiry offers the potential for breathtaking medical breakthroughs. Even so, the guidelines are sure to be challenged by pro-life members of Congress who have vowed to block the needed funding.

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The research involves taking cells from a human embryo when it is only a week old and still just a microscopic clump of cells. The expectation is that scientists will learn to manipulate these versatile cells to produce the specialized tissue needed to treat such diseases as diabetes, Parkinson's, Alzheimer's, spinal cord injuries, burns, heart disease, cancer and other maladies.

Yet progress has been stymied for years by Congressional opponents who consider the clumps of embryonic cells a form of life that must be protected. Although stem cell research is allowed in the private sector, Congress has banned federal funding.

The new guidelines have been written with great care to answer many of the criticisms. The stem cells will be taken from frozen human embryos that would otherwise be discarded after treating infertile couples. The cells will be obtained by private companies rather than by the researchers who receive government funds, in an effort to skirt Congressional prohibitions on funding research in which embryos are destroyed or discarded. And there will be multiple scientific and ethical reviews.

Evidence has been emerging that in some circumstances adult stem cells might be used to achieve the same medical benefits, thus avoiding the need to use embryos. But no one yet knows which approach will work best with which diseases. It makes sense to give researchers the broadest possible arsenal to cope with some of the most devastating human diseases.

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6/30

Project A.L.S.

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NIH guidelines

going through animal use to address safety concerns.

[001]

P6/(b)(6)

Compassionate use⁴ of cells -

- interim before human trials

let it be used for people suffering
from ALS

meeting w/ FDA

NIH Stem Cell Guidelines Released
August 23, 2000

Context: The final version of guidelines governing human stem cell research was put on display today at the Federal Register by the National Institutes of Health (NIH), the principal biomedical research funding agency of the Federal government. The Washington Post, L.A. Times, Wall Street Journal, NPR and CNN carried accurate, balanced reports anticipating the Guidelines' release.

Background: Stem cells are cells that have the potential to form a wide variety of cell types and are candidates for treating or even curing almost any medical condition that requires replacement of missing or defective cells. Included in the list of such conditions are Parkinson's disease, Alzheimer's, diabetes, stroke, arthritis, multiple sclerosis, spinal cord injury, burns, and heart disease. Stem cell research is controversial because fetuses and embryos are sources for human "pluripotent" (meaning able to form many cell types) stem cells. Appropriations language prohibits NIH funding for any research that would harm or destroy embryos. The HHS General Counsel has determined that Federal funds may be used to support research in which stem cells are used, provided that the actual derivation is conducted *without* public funds.

The NIH Guidelines prescribe the conditions under which NIH can ensure that stem cell research is conducted in an ethical and legal manner. NIH will require investigators to document that the cells were obtained from frozen embryos that were created for the purpose of fertility treatment and were in excess of clinical need. Embryos may not be created for research purposes, in accordance with the President's 1994 ban. Informed consent of embryo donors must be obtained, with a clear separation between the fertility treatment and the decision to donate embryos for research. Donors may not be induced to donate for financial rewards or to procure treatment for a potential stem cell recipient. If the stem cells might be used for transplantation, information linking donated embryos to the donor would be retained. In such cases, the donor must be informed of that possibility.

Question: Why should the Federal government support stem cell research?

Answer: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards.

Question: New research reports show that adult stem cells might be used instead of the more objectionable cells derived from embryos. Why should the government fund the most controversial research?

Answer: Some adult organs are known to contain stem cells but it is not known whether these cells have the same potential for forming new cell types as those derived from embryos and fetuses. In addition, not all organs may contain suitable stem cells or ones that can be obtained without damage to a patient, such as brain cells.

Question: These Guidelines govern Federally-funded research. What restrictions are there on stem cell research that is conducted in the private sector without public funds?

Answer: Private entities that provide stem cells to publicly-funded investigators must follow the Guidelines in obtaining the cells in an ethical manner. Although we would hope that the same procedures would be followed for *all* stem cell research, the Guidelines do not extend to private sector research. Should the stem cells be used for transplantation, FDA regulations and oversight for product safety and efficacy would pertain.

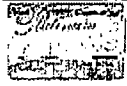
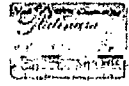
Question: Rep. Dickey and others claim that it is not legal for NIH to fund research using stem cells derived from human embryos because the embryos are destroyed in the derivation process. Can NIH legally fund such research?

Answer: We believe that the law is clear. It permits the use of Federal funds to conduct stem cell research, and prohibits the use of Federal funds to derive stem cells from human embryos. Stem cells are not embryos and do not have the capability to become a child. We will abide by existing law.

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Help

U.S. to Issue New Rules for Research on Embryo Cells

By Rick Weiss
Washington Post Staff Writer
Wednesday, August 23, 2000; Page A01

Stepping into a politically delicate issue that has pitted antiabortion activists against ailing patients, the Clinton administration today is scheduled to release long-awaited guidelines that will, for the first time, allow federally funded scientists to conduct research on human embryo cells.

The guidelines spell out in great detail the ethical and scientific criteria that the National Institutes of Health will weigh as it considers the first applications for federal grant money to study human embryonic stem cells.

Those cells, which could be obtained from embryos donated by patients at fertility clinics, are widely believed to carry the potential to treat a range of diseases, including diabetes and neurological disorders such as Alzheimer's and Parkinson's. Opponents say the research is unacceptable because the only way to acquire the cells is by destroying human embryos.

The guidelines will insist that federal research be conducted only on cells taken from frozen embryos that were destined to be discarded anyway, sources briefed on the plan said. Moreover, federal money could not be used for the destruction of embryos to get the cells. That job would have to be done by privately funded researchers who could then pass the useful cells to federally supported scientists, creating a separation of responsibility for the embryo's destruction that opponents have criticized as morally meaningless.

The new rule will disallow payments to embryo donors and will preclude donors from specifying who should receive their embryo's stem cells. Those provisions aim to discourage the creation of a market in embryo cells and block any incentive for a woman to create fresh embryos just to provide a potential treatment for a sick relative.

Special Report

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Patient support groups immediately hailed the new rule, which was held up for more than a year after the NIH was flooded with public comments on an earlier draft. One source close to the process said those comments had at first run strongly against allowing such research, but that patient advocacy groups later caught up and helped turn the tide.

"We're very supportive of this research," said Robert Goldstein of the Juvenile Diabetes Foundation in New York. "We'd like to see work go forward in this field, which we think has extraordinary promise."

But others, citing recent evidence that certain cells from adults may hold much of the curative potential previously believed unique to embryo cells, threatened to derail the research funding effort.

"It's becoming harder and harder to argue that embryonic cells have uses that adult cells do not," said Richard Doerflinger, associate director of the Secretariat for Pro-life Activities at the National Conference of Catholic Bishops. "I think the decision to release this during [congressional] recess is deliberate. They hope the flak will die down by Labor Day."

Members of Congress vowed to pick up the issue when they returned.

"I don't think that they by law should be allowed to do this," said Rep. Jay Dickey (R-Ark.), who for the past four years has co-sponsored an amendment to the NIH appropriations bill precluding federal funding of any research that results in the destruction of human embryos--a provision that Health and Human Services Department lawyers last year determined did not preclude stem cell research.

"We're talking about dismembering a living being, according to our interpretation," said Dickey, adding that he would consider filing a legislative amendment to clarify his position.

Scientists countered that embryos are not "dismembered" to get stem cells because retrieval is conducted when the embryo is still a one-week-old microscopic ball of undifferentiated cells, long before any organs or limbs have developed. They noted that just last week a British government advisory commission came out in favor of far more permissive human embryo research rules. They would allow scientists there to create cloned human embryos from scratch for research as long as they are destroyed within 14 days, when the first evidence of nerve cells appears.

According to one source who participated in an NIH briefing late yesterday, the agency plans to appoint an advisory committee of scientists and ethicists, called the human pluripotent stem cell review group, to review all embryo cell grant applications submitted to the NIH's Office of Science Policy. That committee will have its first

meeting in December.

Applications that pass first muster will be forwarded to the NIH scientific review advisory committee, which is scheduled to have its next meeting in January and which can forward promising applications to the grant-judging committees within the NIH's individual funding institutes. That means the first awards could be announced late next year at the earliest, the source said--assuming that Congress or the next president do not interfere with the process.

The final rule closely tracks the wording of last year's draft rule, sources said, but has added provisions to address public concerns. That includes stronger language to ensure that donors fully understand that their embryos will not survive the procedure and that cells from their embryos may be kept alive indefinitely and may be made into tissues that could ultimately be transplanted into patients.

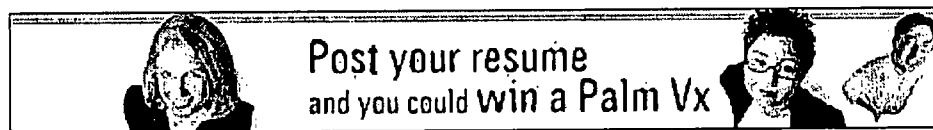
The rules state that federally funded researchers who want to conduct research on stem cells would have to arrange for someone else to retrieve those cells, and would have to certify to the NIH that they were retrieved in accordance with federal rules.

"It would be very tough for the public to take argument with this rule-making process, which has reached out to ethicists, religious leaders, scientists, patient groups, physicians and others in a very sincere attempt to provide a mechanism to exploit what may be the biggest breakthrough in medicine in the past 10 years," said Daniel Perry, chairman of Patients' Coalition for Urgent Research, created last year to support stem cell research.

Perry said the potential medical benefits for desperately ill children and adults outweigh any ethical reservations about embryo cell research.

"What the patient groups have been saying all along is, 'Get on with it. We want this for our loved ones.' "

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News Release

Contacts: In Seattle, Jennifer Hahn at (206) 465-1931;
National media, call Douglas Gould & Co. (914) 833-7093

Embargo: July 19, 2000
10:00 A.M. PDT

PLANNED PARENTHOOD FILES UNPRECEDENTED

SEX DISCRIMINATION LAWSUIT:

Employers' Refusal to Provide Insurance Coverage for Contraceptives Unlawful and Unfair

July 19, 2000 - Seattle, WA — In an unprecedented legal strategy that may affect the lives of millions of women across the United States, Planned Parenthood of Western Washington (PPWW) and Planned Parenthood Federation of America (PPFA) filed a class action lawsuit in federal court in Seattle today. The case, brought under Title VII of the Civil Rights Act, sues an employer who provides a private insurance plan that does not pay for contraceptives. The lawsuit asks the court to order the health plan that Bartell Drug Co. provides its employees to include coverage for prescription contraceptives.

Erickson v. Bartell Drug Co. is a landmark lawsuit that contends it is sex discrimination for a private employer to exclude prescription contraception services from a health insurance plan that covers other prescription drugs. Such exclusion singles out women and forces them to pay for basic and essential health care from their own pockets, or risk unplanned pregnancies.

The first-of-its-kind suit was filed by Jennifer Erickson, a pharmacist at Bartell Drug Co. in Seattle. Ms. Erickson, who is being represented by PPWW and PPFA, is bringing the lawsuit on her own behalf, and on behalf of all other non-union female employees at her company. Her employer, Bartell Drug Co., a large, self-insured employer with 45 drugstores in the state of Washington, has more than \$135 million in annual revenues.

The *Erickson* case was filed under a federal law known as Title VII of the Civil Rights Act. The law prohibits employers with 15 or more employees from making decisions — including decisions about health care benefits — on the basis of gender or pregnancy, or for other discriminatory reasons. In her case, Ms. Erickson states that prescription contraception is a basic health need, but her current insurance fails to pay for her prescription. Since women are the sole users of prescription contraceptives, the employer's refusal to cover them constitutes sex discrimination.

According to Gloria Feldt, President of Planned Parenthood Federation of America, the American public overwhelmingly supports contraceptive use because they understand it prevents unintended pregnancy and reduces the number of abortions. Ms. Feldt said that the failure of employers to provide coverage is an issue of gender equity.

Media contact: Douglas Gould & Co., 914-833-7093
Information available at www.covermypills.org

*Planned Parenthood
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"It is sex discrimination when male employees get their basic health care needs covered by insurance, but women are forced to pay for theirs," said Ms. Feldt.

Legal Remedy Sought to Prevent Employers' from Skirting Coverage

Thirteen states have laws that require contraceptive coverage, but Washington is not among them. But even these laws are not fully adequate and do not apply to self-insured companies. Federal legislation has been introduced in Congress that would require all health plans nationwide to cover contraception, but it has stalled in committee despite substantial bipartisan support. This suit, and other suits in formation around the country, would establish equity in basic health coverage for millions of American women using federal anti-discrimination law.

Prior to this filing, Seattle-based industry giant Microsoft responded to requests to change its insurance plan to offer prescription coverage. Additionally, one of the nation's largest unions, the Screen Actors Guild, has done the same.

The plaintiff is asking the court to order Bartell's to begin immediately covering all FDA-approved methods of contraception in the health insurance plan offered to employees. "This lawsuit is about fairness – not just for me – but also for millions of American women like me who are being discriminated against," she said.

Ms. Erickson, who is 26 years old and married, said she would like to have children some day, but is not ready yet. She believes that it is not fair that she has to pay over \$300 per year for prescription contraceptives, even though she has health insurance. Her position in the health care industry has enabled her to witness this discrimination first-hand. She has grown increasingly troubled when she has to tell female customers that their health insurance does not cover one of their most basic and fundamental health care needs. All female employees at Bartell Drug are subject to the same discriminatory insurance coverage.

"As a pharmacist, I see firsthand that contraceptives are central to women's health care," said Ms. Erickson. "That's why I'm taking this stand against the unfair singling out of contraception from insurance."

Polls Show Public Support for Contraceptive Use and Coverage

A recent nationwide poll of privately insured adults revealed that 73 percent support coverage of full contraceptive services in their health insurance plans, even if it would increase their own costs by \$5 per month (Princeton Survey Research for Kaiser Family Foundation). Nonetheless, many private health plans in the U.S. still do not provide the coverage. According to the most comprehensive study of this issue, half of all traditional indemnity plans do not cover oral contraceptives or condoms. Even among HMOs, which offer the most comprehensive contraceptive coverage, 7 percent do not cover prescription contraceptives and only 39 percent cover all five types of contraception.

Roberta Riley of PPWW, the lead attorney in the case, stressed that the courts must reverse blatantly unfair and discriminatory policies. She noted the historic nature of the suit, explaining that it was filed on behalf of the 60 million American women who are of reproductive age.

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"This is truly a landmark occasion," said Ms. Riley. "Until today, no one has asked the court to stop this discrimination that blocks women's access to basic health care."

Planned Parenthood counsel will establish that it is illegal sex discrimination for this employer to single out prescription contraception from its employee health plans. "A victory in this case will directly benefit Bartell's employees and set legal precedent for all women," said Ms. Riley.

Contraception is Basic Health Care for Women

All of those bringing the lawsuit pointed out that contraception is a basic health care need. Seven in 10 American women in their childbearing years are sexually active and do not wish to become pregnant. Without insurance coverage, however, some women use less effective and less reliable contraceptive methods, risking more unplanned pregnancies.

Providing full contraceptive coverage in employee health plans would not be expensive. According to the Alan Guttmacher Institute, providing such coverage would cost employers \$21.40 per employee per year, if employers paid the full cost of coverage.

Recent studies have also shown that contraception is critical to improving maternal and child health. The United States has alarmingly high infant mortality and low-birthweight rates, both of which are associated with unintended conception. Women who carry unintended pregnancies to term are less likely than other women to receive adequate prenatal care, resulting in greater risks to their health and poorer birth outcomes.

Ms. Erickson is represented in this case by Roberta Riley, Planned Parenthood of Western Washington; Eve Gartner, Planned Parenthood Federation of America; and the Seattle law firm of Keller Rohrback. The National Women's Law Center is of counsel on the case.

Planned Parenthood® of Western Washington has 17 medical clinics providing reproductive health services to more than 58,000 men and women throughout Western Washington.

Planned Parenthood® Federation of America is the world's largest and most trusted voluntary family planning organization. It is comprised of 129 affiliates that operate 875 health centers nationwide, which serve nearly five million Americans annually.

The National Women's Law Center is a non-profit organization based in Washington, DC that has been working since 1972 to advance and protect women's legal rights.

For more information online, please visit www.plannedparenthood.org or www.covermypills.org.

Seattle media, contact Jennifer Hahn at (206) 465-1931 or Marilyn Knight at (206) 328-7735; National media, call Douglas Gould & Co. (914) 833-7093.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

JENNIFER ERICKSON, on behalf of herself
and all others similarly situated,

Plaintiff,

THE BARTELL DRUG COMPANY,

Defendant

No. C00-1213L

COMPLAINT – CLASS ACTION

Plaintiff Jennifer Erickson, through her undersigned attorneys, brings this Class Action Complaint against the Bartell Drug Company ("Bartell") and in support thereof states the following upon information and belief:

I. Introduction

1. This is an employment discrimination action, arising under the Civil Rights Act of 1964 as amended, 42 U.S.C. § 2000e et seq. ("Title VII"), and specifically as amended by the Pregnancy Discrimination Act of 1978, 42 U.S.C. § 2000e(k) (the "PDA").

2 Bartell singles out female employees for disadvantageous treatment by excluding

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1 prescription contraceptives from an employee benefit plan while including benefits for other
2 preventive medical services, including other preventive prescription medications and devices.
3 Prescription contraception, which is available for use only by women, is basic medical care for
4 women who have the potential to become pregnant but who wish to control that potential by
5 reversible means. The failure to provide coverage for prescription contraception treats medication
6 needed for a pregnancy-related condition less favorably than medication needed for other medical
7 conditions, it therefore constitutes facial sex discrimination.

9 3. In addition, Bartell's exclusion of prescription contraception has an adverse disparate
10 impact on Ms. Erickson and other members of the proposed class. Because prescription
11 contraceptives are available for use only by women, Bartell's failure to provide coverage for
12 prescription contraception forces its female employees to choose between paying their own out-of-
13 pocket prescription costs, or bearing the physical, emotional and financial costs of unplanned
14 pregnancy.

16 4. As a result of Bartell's decision to exclude contraceptives from its non-union employee
17 benefit plan, Ms. Erickson and other members of the proposed class are being discriminated against
18 in the terms and conditions of employment, which includes the receipt of benefits under fringe
19 benefit programs, because of their potential for pregnancy. This violates Title VII.

21 5 To remedy this discrimination, Ms. Erickson and the Class she represents seek equitable,
22 declaratory and injunctive relief against Bartell.

23 II. Jurisdiction and Venue

24 6. Jurisdiction is conferred on this Court by 28 U.S.C. § 1331 (federal question); and 42
25 U.S.C. § 2000e-5(f)(3) (Title VII).

26 COMPLAINT - 2

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1 7. Ms. Erickson's claim for declaratory and injunctive relief is authorized by 28 U.S.C. §§
2 2201 and 2202 and by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general
3 legal and equitable powers of this Court

4 8. Venue is appropriate under 28 U.S.C. § 1391(b) and (c), and 42 U.S.C. § 2000e-5(f)(3)
5 because the unlawful employment practices giving rise to this claim were committed in this district
6 and Bartell resides in this district.

8 III. Parties

9 9. Jennifer Erickson has been employed on a full-time basis by Bartell as a licensed
10 pharmacist since February, 1999. As part of the terms and conditions of her employment, Ms.
11 Erickson receives health insurance coverage, including coverage of prescription drugs and devices.
12 Ms. Erickson sues on her own behalf and as a representative of the proposed class of employees who
13 are discriminated against by the exclusion of contraception from Bartell's benefit plan.

14 10 Ms. Erickson is 26 years old, has been married for one year, and has no children. She
15 and her husband plan to have children some day, but they are not yet ready to do so. In order to
16 avoid unplanned pregnancy, Ms. Erickson uses a reversible contraceptive: birth control pills (also
17 known as oral contraceptives). Because prescription contraceptives are excluded by Bartell's non-
18 union employee health plan, Ms. Erickson must pay out-of-pocket for her prescription contraceptives,
19 or risk the physical, emotional and financial costs of an unplanned pregnancy.

20 11. On or about June 30, 1999, Ms. Erickson wrote to Bartell's Benefits Department asking
21 about insurance coverage for contraception. She received a letter back indicating that contraception
22 was not part of the Prescription Benefit Plan.

23 12 On December 29, 1999, Ms. Erickson filed a charge with the EEOC in Seattle,
24

25 COMPLAINT - 3
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1 Washington alleging that Bartell's failure to provide her with health insurance coverage for
2 prescription contraceptives constitutes unlawful discrimination on the basis of sex.

3 13. On July 10, 2000, Ms. Erickson received a right-to-sue letter from the EEOC. A copy of
4 that letter is annexed hereto as Exhibit A.

5 14 Bartell is a corporation organized under the laws of Washington, with its principal place
6 of business in Seattle, Washington. On information and belief, Bartell employs approximately 1,380
7 individuals.
8

9 IV. Bartell's Health Plan

10 15. As a term and condition of her employment, Bartell offers Ms. Erickson the opportunity
11 to enroll in one of two health plans. Upon information and belief, Bartell self-insures and controls
12 all of the terms and conditions of these plans. Both health plans offered by Bartell are administered
13 by Regence Blue Shield. Both plans exclude prescription drugs other than those provided on an
14 inpatient basis. However, as a term and condition of her employment, Bartell also offers Ms.
15 Erickson the opportunity to enroll in the Bartell Drug Prescription Benefit Plan for Non-Union
16 Employees, which is the only outpatient prescription coverage available to her as a non-union
17 employee of Bartell. Upon information and belief, Bartell self-insures and controls all of the terms
18 and conditions of the Bartell Drug Prescription Benefit Plan for Non-Union Employees
19 ("Prescription Benefit Plan"). The Prescription Benefit Plan requires employees to fill all
20 prescriptions at a Bartell Pharmacy (unless an emergency arises when the employee is out of the
21 service area served by Bartell).
22

23 16. As of May 1, 1999, Ms. Erickson enrolled in one of the Regence-administered health
24 plans and the Bartell Drug Prescription Benefit Plan for Non-Union Employees (together, the
25
26

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1 "Health Plan"). Under the Health Plan, Ms. Erickson's benefits include coverage of many
2 preventive services, including but not limited to coverage of routine exams, immunizations, well
3 child care, cancer screenings, routine hearing and vision exams, preventive and diagnostic dental
4 services, smoking cessation care, blood-pressure and cholesterol-lowering prescription drugs, and
5 hormone replacement therapy to prevent osteoporosis.
6

7 17. Despite covering other preventive medical services and prescriptions, the Health Plan
8 does not cover prescription drugs and devices used by women to prevent pregnancy. The written
9 Bartell Drug Prescription Benefit Plan for Non-Union Employees lists "contraceptive devices
10 (including birth control pills)" as a "non-covered item."
11

12 18. If Ms. Erickson were to become pregnant, the Health Plan would cover the costs of either
13 an abortion or continuing the pregnancy to term - whichever she chose to do.

14 V. Harm to Ms. Erickson and Other Class Members

15 19. As a result of Bartell's failure to cover contraception to avoid pregnancy, Ms. Erickson
16 must pay for her monthly supply of birth control pills on an out-of-pocket basis, or risk unintended
17 pregnancy.

18 20. If contraception were treated on an equal basis with other prescriptions under the Health
19 Plan, Ms. Erickson and other class members would pay a co-pay of either \$5 (generic) or \$10 (brand
20 name) for a 34-day supply of contraception.
21

22 VI. Factual Framework

23 21. Contraception is a drug or device that prevents pregnancy. Contraceptives work either by
24 preventing fertilization of a woman's ovum or by preventing implantation of the blastocyst in the
25 uterine wall.
26

COMPLAINT - 5

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22 The Food and Drug Administration (FDA) has approved five methods of prescription contraception: oral contraception; Norplant; Depo-Provera; intra-uterine device ("IUD"); and the diaphragm. Only women can use these methods of prescription contraception.

23 The consequence of failure to use contraception is pregnancy. Because women bear all of the physical burdens of pregnancy, contraception is basic to women's health and well-being.

24. Because of the significant physiological, bio-chemical and anatomical changes that a woman undergoes during pregnancy, the preexisting medical conditions of many women are exacerbated by pregnancy. Among these are: certain blood diseases, including sickle-cell disease, heart disease; endocrine disorders such as diabetes; diseases of the nervous system such as epilepsy; kidney and liver diseases; connective tissue disorders such as systemic lupus erythematosus and rheumatoid arthritis; chronic hypertension; respiratory disease including asthma and pneumonia; and HIV present in the blood stream.

25. Moreover, even in an otherwise healthy woman, pregnancy poses medical risks that are significantly greater than the risks of using contraception. In any given year, the risk of death from pregnancy is 1 in 11,000 while the risk of death from contraception is much less. 1 in 63,000 for non-smoking oral contraception users; 1 in 100,000 for IUD users; and no risk of death for diaphragm users.

26. The morbidity rate during pregnancy is high as well. Twenty-two percent of all pregnant women are hospitalized before delivery because of complications.

27. If no method of contraception were used, the average woman would be expected to have between 12 and 15 pregnancies in her lifetime. The physical, financial and emotional burdens of such childbearing would, in many cases, cause serious harm to the woman, her family, and society.

COMPLAINT - 6

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1 28. Due to the wide variation in effectiveness, cost, and medical appropriateness of available
2 forms of contraception, choice of contraceptive method is essential to successful pregnancy
3 prevention. Other factors that contribute to what type of contraception a woman chooses to use are
4 whether the woman intends to delay, space, or entirely prevent future childbearing.

5 29. Women with medical conditions that require pregnancy avoidance, in particular, require a
6 full range of contraceptive options because their medical conditions often preclude the use of one or
7 more contraceptive methods. For example, birth control pills are medically contraindicated for
8 women who are at risk of cardiovascular problems, such as stroke, heart attack, blood clots, and
9 hypertension, as well as women who have, or are at risk of, depression or hepatic adenomas.
10 Women who smoke, particularly women over 35 who smoke, increase their risk of heart attack,
11 stroke, and blood clots by using birth control pills.

12 30. Inadequate insurance coverage of contraception has substantial economic consequences
13 for the 67% of American women of reproductive age who rely on employer-sponsored health
14 insurance coverage. These women pay 68% more in out-of-pocket expenditures for health care
15 services than men, and reproductive health services account for much of that difference. Almost 5
16 million privately insured women have out-of-pocket expenditures for health care services in excess
17 of 10% of their income.

21 VII. Statutory Framework

22 31. Title VII provides that: "It shall be an unlawful employment practice for an employer to
23 . . . discriminate against any individual with respect to his compensation, terms, conditions, or
24 privileges of employment, because of such individual's . . . sex." 42 U.S.C. § 2000e-2(1).

25 32 In 1978, Congress enacted the Pregnancy Discrimination Act ("PDA") which provides
26

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1 that the term "because of sex" in Title VII includes, but is not limited to, "because of or on the basis
2 of pregnancy, childbirth, or related medical conditions." 42 U.S.C. § 2000e(k) The PDA further
3 states that "women affected by pregnancy, childbirth, or related medical conditions shall be treated
4 the same for all employment-related purposes, including receipt of benefits under fringe benefit
5 programs as other persons not so affected but similar in their ability or inability to work." Id. Thus,
6 Title VII specifically mandates that employers may not single out employees for disadvantageous
7 treatment based on "pregnancy, childbirth, or related medical conditions."

9 33. Contraception is "pregnancy-related" within the meaning of the PDA because it is
10 medical treatment that provides women with the ability to control their potential to become pregnant.
11 Exclusion of contraception from a health plan is sex discrimination in violation of the PDA because
12 it treats women differently on the basis of their potential to become pregnant. The exclusion of
13 contraception from the Health Plan is, therefore, sex discrimination on its face in violation of Title
14 VII, as amended by the PDA.

16 34. The exclusion of contraception from the Health Plan also has an adverse disparate impact
17 on women in violation of Title VII because it forces them either to pay for prescription
18 contraceptives out of pocket, despite having prescription insurance coverage, or to bear the physical,
19 emotional and financial burdens of unplanned pregnancy. Bartell's policy of excluding
20 contraceptive coverage cannot be justified as job-related and consistent with business necessity.

22 VIII. Class Action Allegations

23 35 Pursuant to Fed. R. Civ. P. 23(b)(2), Ms. Erickson seeks declaratory and injunctive relief
24 on behalf of herself and all other persons similarly situated, defined as:

25 All female employees of Bartell who at any time after December 29,
26 1997 were enrolled in Bartell's prescription benefit plan for non-union

COMPLAINT - 8

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employees while using prescription contraceptives.

36 This action is properly maintainable as a class action under Fed. R. Civ. P. 23(a).

a Plaintiff is informed and believes that the class is so numerous that joinder of all members is impracticable. Bartell employs approximately 1,380 people in Washington State, about one-half of whom are non-union employees eligible to participate in the prescription benefit plan at issue in this case. Given the number of qualifying employees and the well-documented utilization rates for prescription contraceptive drugs and devices, plaintiff is informed and believes that the class consists of at least 100 persons.

b. There are questions of law or fact common to the class, including: whether Bartell's conduct violates Title VII as amended by the Pregnancy Discrimination Act, which prohibits discrimination based on "pregnancy, childbirth or related medical conditions"; whether Bartell's conduct has an adverse disparate impact on a protected class in violation of Title VII; whether Bartell's conduct is justified by any recognized legal defense; the nature and scope of injunctive relief necessary to prevent further violations of federal law; the nature and scope of equitable relief appropriate to complement the injunctive relief awarded by the Court; and the nature and scope of declaratory relief appropriate in this case.

c. The claims of the representative parties are typical of the claims of the class. Ms. Erickson was enrolled in Bartell's prescription benefit plan for non-union employees during the class period. A health care professional prescribed contraceptives for Ms. Erickson's use. Like every other member of the class, Ms. Erickson has been denied benefits of her employment based on a pregnancy-related medical condition. Furthermore, the Bartell contraception exclusion has had an adverse disparate impact on her, as it has on other female employees of Bartell.

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1 d. Ms. Erickson will fairly and adequately protect the interests of the class. She will
2 pursue this litigation with diligence and vigor, and she has retained counsel experienced in Title VII
3 and other class action litigation. Ms. Erickson has exhausted administrative remedies on behalf of
4 herself and the class.

5
6 37. This action is properly maintainable as a class action under Fed. R. Civ. P. 23(b)(2)
7 because Bartell has acted or refused to act on grounds generally applicable to the class, thereby
8 making declaratory, injunctive and other equitable relief appropriate for the class as a whole.

9 IX. First Claim for Relief: Disparate Treatment

10 38. Plaintiff hereby incorporates by reference Paragraphs 1 through 37 above.

11 39. By providing Ms. Erickson and the Class with health insurance benefits that selectively
12 exclude all FDA-approved prescription contraception, Bartell discriminates on the basis of sex in
13 violation of Title VII as amended by the PDA.
14

15 X. Second Claim for Relief: Disparate Impact

16 40. Plaintiff hereby incorporates by reference Paragraphs 1 through 39 above.

17 41. By providing Ms. Erickson and the Class with health insurance benefits that selectively
18 exclude all FDA-approved prescription contraception, Bartell engages in an employment practice
19 that has an adverse disparate impact on Ms. Erickson and the Class, thus constituting illegal
20 employment discrimination on the basis of sex in violation of Title VII as amended by the PDA.
21

22 XI. Prayer for Relief

23 42. On behalf of herself and all other persons similarly situated, Jennifer Erickson seeks the
24 following relief:

25 a) That an order be entered certifying the Class pursuant to Fed. R. Civ. P. 23(b)(2).

26 b) That a declaratory judgment be entered declaring that Bartell has violated the civil

COMPLAINT - 10

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rights of Ms. Erickson and the Class she represents as guaranteed by 42 U.S.C. § 2000e.

- c) That a permanent injunction be entered prohibiting Bartell from engaging in the illegal and discriminatory conduct alleged herein and requiring Bartell to issue and disseminate to all eligible employees a revised prescription coverage plan that covers all FDA-approved prescription contraceptive drugs and devices.
- d) That the Court award equitable relief to Ms. Erickson and the Class in the form of nominal damages, incidental monetary relief, back pay, attorneys fees and costs.
- e) That the Court award Ms. Erickson and the Class their attorneys' fees and costs pursuant to 42 U.S.C. § 2000e-5(k).
- f) That the Court award such other and further relief as it deems just and proper under the circumstances.

DATED this 19th day of July 2000.

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*Application to appear *pro hac vice* submitted herewith

COMPLAINT - 11

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COMPLAINT - 12

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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]

INFORMATION RELATED TO FILING SUIT UNDER THE LAWS ENFORCED BY THE EEOC

(This information relates to filing suit in Federal or State court under Federal law. If you also plan to sue claiming violations of State law, please be aware that time limits and other provisions of State Law may be shorter or more limited than those described below.)

PRIVATE SUIT RIGHTS — Title VII of the Civil Rights Act, the Americans with Disabilities Act (ADA), or the Age Discrimination in Employment Act (ADEA):

In order to pursue this matter further, you must file a lawsuit against the respondent(s) named in the charge within 90 days of the date you receive this Notice. Therefore, you should keep a record of this date. Once this 90-day period is over, your right to sue based on the charge referred to in this Notice will be lost. If you intend to consult an attorney, you should do so promptly. Give your attorney a copy of this Notice, and its envelope, and tell him or her the date you received it. Furthermore, in order to avoid any question that you did not act in a timely manner, it is prudent that your suit be filed within 90 days of the date this Notice was mailed to you (as indicated where the Notice is signed) or the date of the postmark, if later.

Your lawsuit may be filed in U.S. District Court or a State court of competent jurisdiction. (Usually, the appropriate State court is the general civil trial court.) Whether you file in Federal or State court is a matter for you to decide after talking to your attorney. Filing this Notice is not enough. You must file a "complaint" that contains a short statement of the facts of your case which shows that you are entitled to relief. Your suit may include any matter alleged in the charge or, to the extent permitted by court decisions, matters like or related to the matters alleged in the charge. Generally, suits are brought in the State where the alleged unlawful practice occurred, but in some cases can be brought where relevant employment records are kept, where the employment would have been, or where the respondent has its main office. If you have simple questions, you usually can get answers from the office of the clerk of the court where you are bringing suit, but do not expect that office to write your complaint or make legal strategy decisions for you.

PRIVATE SUIT RIGHTS — Equal Pay Act (EPA):

EPA suits must be filed in court within 2 years (3 years for willful violations) of the alleged EPA underpayment: backpay due for violations that occurred more than 2 years (3 years) before you file suit may not be collectible. For example, if you were underpaid under the EPA for work performed from 7/1/96 to 12/1/96, you should file suit before 7/1/98 -- not 12/1/98 -- in order to recover unpaid wages due for July 1996. This time limit for filing an EPA suit is separate from the 90-day filing period under Title VII, the ADA or the ADEA referred to above. Therefore, if you also plan to sue under Title VII, the ADA or the ADEA, in addition to suing on the EPA claim, suit must be filed within 90 days of this Notice and within the 2- or 3-year EPA backpay recovery period.

ATTORNEY REPRESENTATION — Title VII and the ADA:

If you cannot afford or have been unable to obtain a lawyer to represent you, the U.S. District Court having jurisdiction in your case may, in limited circumstances, assist you in obtaining a lawyer. Requests for such assistance must be made to the U.S. District Court in the form and manner it requires (you should be prepared to explain in detail your efforts to retain an attorney). Requests should be made well before the end of the 90-day period mentioned above, because such requests do not relieve you of the requirement to bring suit within 90 days.

ATTORNEY REFERRAL AND EEOC ASSISTANCE — All Statutes:

You may contact the EEOC representative shown on your Notice if you need help in finding a lawyer or if you have any questions about your legal rights, including advice on which U.S. District Court can hear your case. If you need to inspect or obtain a copy of information in EEOC's file on the charge, please request it promptly in writing and provide your charge number (as shown on your Notice). While EEOC destroys charge files after a certain time, all charge files are kept for at least 6 months after our last action on the case. Therefore, if you file suit and want to review the charge file, please make your review request within 6 months of this Notice. (Before filing suit, any request should be made within the next 90 days.)

IF YOU FILE SUIT, PLEASE SEND A COPY OF YOUR COURT COMPLAINT TO THIS OFFICE.

Project A.L.S.

PHOTOCOPY
PRESERVATION

THE WHITE HOUSE
WASHINGTON

June 23, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: HEATHER HOWARD
CC: MELANNE VERVEER
ANN O'LEARY
SUBJECT: STEM CELL RESEARCH

As you know, stem cell research holds tremendous promise for advancements in medical science. Embryonic stem cells, which are derived from fertilized eggs created by in vitro fertilization, can regenerate many types of human cells and may be able to replace tissue that has been damaged by disease or injury, offering hope of new treatments for many diseases. Per your request, following is an update on the status of stem cell research:

Since 1995, federal law has banned the use of federal funding for human embryo research. However, in January 1999, the U.S. Department of Health and Human Services issued a legal memorandum which concluded that the ban against funding for the scientific use of embryos does not extend to stem cell research, as long as federal funding is not used to destroy embryos in order to derive the stem cells. That is so, HHS reasoned, because stem cells, unlike the embryos from which they are derived, lack the potential to grow into a human being.

In September 1999, the President's National Bioethics Advisory Commission (NBAC) delivered its report entitled "Ethical Issues in Human Stem Cell Research." The Commission recommended that public funding of stem cell research be permitted. It also recommended a process that would allow researchers to derive the cells from unused embryos donated by couples who seek in vitro fertilization – embryos that otherwise would be discarded. A copy of the report is attached.

In December 1999, HHS issued proposed guidelines for stem cell research funded by NIH. The proposed guidelines would require that for research involving stem cells derived from human embryos, NIH funds could be used only if the cells were from "surplus" embryos created for infertility treatment. Until the guidelines are finalized, no federally-funded stem cell research will be conducted, but of course the private sector does not operate under any restrictions. The proposed guidelines are in comment period now.

The debate in Congress this year is likely to focus on whether the current human embryo research ban covers stem cell research. Last year, Sen. Specter intended to clarify that stem cell research was not covered by the ban, but in exchange for dropping the matter, Sen. Specter secured a promise from Sen. Lott to have a vote this year. Sen. Specter, along with Sen. Harkin,

introduced legislation that would permit funding for research on human embryos for the limited purpose of generating embryonic stem cells, and would codify HHS's decision to allow federally-funded stem cell research. It is unclear whether Sen. Lott will allow a vote on Sen. Specter's bill (or why he would do so, since it would probably pass). There may be amendments on the issue, or on fetal tissue research, in the Senate during consideration of Labor-HHS appropriations next week. You should know that federally-funded fetal tissue research is allowed, although federal law prohibits the sale of fetal tissue for profit, and a woman's abortion decision must be made before she consents to donating the fetal tissue.

Project A.L.S.

FINDING AND FUNDING
TREATMENTS AND A CURE
FOR ALS

MISSION STATEMENT

Project A.L.S., Inc., is a non-profit organization that raises awareness and significant funds toward effective treatments and a cure for ALS. Project A.L.S. distributes funds raised through its charitable efforts to the most exciting ALS and related research worldwide. In addition to fundraising, Project A.L.S. will continue to increase public awareness of ALS, which has remained under-funded and poorly understood since it was first described in 1869. It is our goal that the public come to recognize ALS for what it really is: a fatal neuromuscular disease that is not rare (ALS is diagnosed with roughly the same frequency as multiple sclerosis) and that does not discriminate on the basis of age, gender or ethnicity. Project A.L.S. intends to transform ALS into a matter of urgent national concern.

WHAT IS ALS?

A college student becomes uncharacteristically clumsy as she rehearses for her ballet recital.

An investment banker and father of four starts slurring his words.

A restaurant manager has trouble turning the key in her car ignition.

These people are experiencing some of the first symptoms of ALS (amyotrophic lateral sclerosis). Also known as Lou Gehrig's disease, ALS attacks the body's motor neurons, or nerve cells, and proves fatal within an average of two to five years. As motor neurons are destroyed, a person with ALS loses his or her ability to walk, speak, swallow and breathe. Unless we do something, 300,000 seemingly healthy Americans living now will die from ALS. It is a fact that, if we solve the mystery of ALS, we will learn what we need to know about other devastating brain diseases including Alzheimer's, Parkinson's and Huntington's, which afflict over six million people. To date, there exists not one effective treatment to improve the lifestyle of some

one with ALS. Project A.L.S. is working to find and fund treatments and a cure for a disease that has been stamped untreatable for almost 150 years.

ABOUT PROJECT A.L.S.

Founded in 1998, Project A.L.S. has already funded investigations into neural stem cell replacement, high throughput drug screening, functional genomics, and accelerated drug trials—approaches that may well extend the lives of those with ALS. When she was diagnosed with the disease at the age of thirty-five—upon learning that there were no drugs or treatments—Jenifer Estess, her sisters and friends formed Project A.L.S. Drawing upon her experience and expertise as a producer, Estess united the



Actor Julianna Margulies, in front of an electronic mural of Jenifer Estess, performs at a Project A.L.S. event. The entertainment and corporate communities have joined the fight for effective treatments.

corporate and entertainment communities in the interest of raising significant research funds. In June, 1998, Project A.L.S. held its inaugural benefit at New York's famed Roseland Ballroom. The event raised over \$500,000 and enjoyed the support and participation of First Lady Hillary Rodham Clinton, Sarah The Duchess of York, Jane Alexander, Fiona Apple, William Baldwin and Ben Stiller. In February, 1999, Project A.L.S. hit Los Angeles for a gala that raised over \$750,000. Sponsored by Saks Fifth Avenue and AOL MovieFone, hosted by Ben Stiller and Kristen Johnston, the evening featured performances by Melissa Etheridge and Randy Newman, and appearances by Helen Hunt, Greg Kinnear, Camryn Manheim, Julianna Margulies, Penelope Ann Miller, Brooke Shields, Julie Moran, Marisa Tomei, Rob Morrow and Gina Gershon. Most recently, Project A.L.S. returned to New York for a gala at the Hammerstein Ballroom which netted

over \$1.2 million for research. Sponsors included AOL MovieFone, Bloomberg L.P., Citigroup, Plaza Construction Corporation, Wasserstein Perella Group and Vogue Magazine. Participants included Ben Stiller, Kristen Johnston, Janeane Garofalo, Jon Stewart, Nathan Lane and Kevin Spacey. Please contact Project A.L.S. for more information on the next Los Angeles benefit on April 10, 2000 and events throughout the coming year.

Last spring, Saks Fifth Avenue launched the David Yurman Project A.L.S. Angel Pin, which is being sold in Saks Fifth Avenue stores nationwide for one year. Mr. Yurman and Saks Fifth Avenue have donated 100% of the proceeds to Project A.L.S. As of this printing, Project A.L.S. is negotiating several other cross-marketing and promotion opportunities that will net significant funds for research.

In addition to its fundraising efforts, Project A.L.S. is creating a public service campaign for print and television, and an original television movie for CBS.



Janeane Garafalo, Ben Stiller, Kristen Johnston, Brooke Shields and Jon Stewart step up for a Project A.L.S. event in New York, September 27, 1999.

RESEARCH

In one year, Project A.L.S. has emerged as a new model for fundraising and disease research. As a result of its aggressive, streamlined approach, Project A.L.S. has moved scientists significantly closer to developing treatments for ALS. Because Project A.L.S. enjoys minimal overhead, it applies the majority of funds raised to research.

Under the advisement of its medical advisory board, and its board of directors, Project A.L.S. targets the most promising investi-

gations, then distributes funds quickly, on a rolling basis.

From there, Project A.L.S. places corporate expectations on its scientist-partners. Those scientists who are funded by Project A.L.S. are required to commit to time and action lines, and to complete their work with all due diligence and speed.

Project A.L.S. believes that working collaborations

between excellent scientists is crucial. Therefore, it has constructed a growing ALS "center without walls." Each Project A.L.S. research initiative unites the best thinkers and doers, regardless of academic or corporate affiliation.

One such collaboration is the first ever investigation into **neural stem cell replacement in ALS**. The principal investigator is Evan Y. Snyder, M.D., Ph.D., Children's Hospital, Boston/Harvard Medical School. Collaborators include Robert H. Brown, M.D., D. Phil., Massachusetts General Hospital/Harvard Medical School, Jeffrey D. Rothstein, M.D., Ph.D., Johns Hopkins University, Richard Sidman, M.D., Ph.D., Harvard University, and Thomas Jessell, Ph.D., Columbia University.

If successful, neural stem cell replacement will act as a "cell transplant" for those with ALS—replacing damaged motor neurons with new ones. The neural stem cell collaboration, which Project A.L.S. is funding in its entirety, is under way in all aspects, so that we may be assured of the fastest possible human trial.

In adjunct experiments, select members of this same team are investigating **the rescue of motor neurons responsible for respiration**.

Additionally, Project A.L.S. is funding Dr. Robert Brown's **discovery of genes associated with ALS**. In 1991, Dr. Brown and colleagues located the first genetic

mutation associated with ALS (SOD1), and he is now zeroing in on other strong possibilities. Project A.L.S. is also driving the collaboration between Dr. Brown and Steven Gullans, Ph.D., Brigham and Women's Hospital, and their study of ALS and the human genome. The **functional genomics** project applies cutting-edge technology in the identification of new genetic pathways in ALS.

Project A.L.S. is fully funding accelerated experiments of small molecule compounds called **immunophilins**. At Johns Hopkins, Dr. Jeffrey Rothstein is nearing completion of a second round of accelerated experiments to test the ability of these compounds to protect motor neurons and stimulate their regrowth.

In a year and a half, Project A.L.S. has moved researchers closer to solving the mystery and devastation that is ALS—and to providing treatments for a disease that has been stamped untreatable for 150 years.



Project A.L.S. is funding investigations into the replacement, protection, and regrowth of motor neurons.

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For more information or to make a
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Project A.L.S.

511 Avenue of the Americas, PMB 341
New York, New York 10011
or call 1-800-603-0270 or 212-969-0329
email: projectals@aol.com

visit the Project A.L.S. website
www.project-als.org

InStyle

volume 7, number 6, june 2000



sweet charity Big talent with big hearts (pictured at left, including George Clooney, Julianna Margulies and co-hosts Kristen Johnston and Ben Stiller) came to lend support at the second annual Night & Day benefit on April 10 in Los Angeles. The daylong event began with a golf tournament and ended with a glittering gala at the Hollywood Palladium, co-sponsored by *In Style*. In all, more than \$1 million was raised to aid Project ALS, an organization that works to find a cure for the neurological ailment commonly known as Lou Gehrig's disease.



The second annual Project ALS fund-raiser at the Hollywood Palladium



George Clooney & Sheryl Crow



Helen Hunt & Hank Azaria



Emcees Ben Stiller & Kristen Johnston

get with the project

Jenifer Estess fights ALS with a little help from her famous friends

"This is a night to celebrate survival," George Clooney said at the L.A. benefit for Project ALS. And celebrate he did. For despite the tragic effects of amyotrophic lateral sclerosis (aka Lou Gehrig's disease), Ben Stiller and Kristen Johnston welcomed guests at the Hollywood Palladium to an evening of fund-raising (more than \$1 million), education and, of course, non-stop entertainment. The celebrity hosts are close friends of the charity's founder, Jenifer Estess, whose own career was cut short by ALS after she co-founded the renowned New York theater company Naked Angels. "We all know it's sad," said David Spade, whose uncle has the disease. "But we still want to make the night fun." Thanks to an announcement of new medical breakthroughs and the show's finale—a rocking set from Sheryl Crow—that's all the crowd wanted to do. —Honor Brodie



Julianna Marquies & David Spade



Dana Kind & Jane Krakowski



"I was very forward-thinking about planning my life," says Estess (with sister Alison and their niece Kate in Manhattan). "I still am."

All for One

When Jenifer Estess got sick, she and her sisters got mad—then they got motivated • *by Christina Cheakalos*

Nearly three years ago, Jenifer Estess, then 35, was, as she wryly puts it, "the perfect—and perfectly neurotic—New York girl": a successful Manhattan theater producer who loved her work but felt it was time to work on love. She was seeing a shrink and exercising with a per-

sonal trainer—the better to be psyched *and* toned when she met Mr. Right. But on one of her first dating forays, her life plan was inexorably altered. "His elevator was broken, and it was a four-flight walk-up," says Estess, now 38. "I was literally having trouble pulling myself up the stairs. By the time I

got to his floor, I was covered in sweat."

In March 1997, Estess was diagnosed with amyotrophic lateral sclerosis—the fatal illness known as Lou Gehrig's disease. Among its barbaric characteristics, ALS destroys the cells that control muscles, robbing sufferers of the ability to move, speak, swallow and, finally, to breathe. There are about 30,000 Americans with ALS, 80 percent of whom will die within five years of diagnosis. The disease has already robbed Estess of her ability to walk, roll over, hug her nieces and nephews, even lift a cup of coffee. "But I can still speak," she says. "And while I can, I'll make sure no one



The stars (ABC Entertainment president Jamie Tarses, left, Ben Stiller and Kristen Johnston) came out to raise funds at a gala for Estess's cause last February in L.A.

she's in a wheelchair," says Ben Stiller, who was cohost at one of the events with *3rd Rock from the Sun*'s Kristen Johnston. "She doesn't have an ounce of self-pity."

Growing up with three sisters and a brother (Noah, now 34, lives in San Diego) in the comfortable New York City suburb of Harrison, Estess's first life-isn't-fair lesson came at 13, when her stockbroker father, Gene, left the household. He and Estess's mother, Marilyn, were divorced soon after. The family was forced to move to a smaller home, and Marilyn went to work as a real estate agent. "I point to that experience," says Estess, who has no contact with her father, "as when we sisters learned that if we came together we would get a lot done." She grew especially close to Valerie and Meredith, working with them after school at local doughnut shops to help make ends meet. "Jennifer was the most coveted doughnut girl," says Valerie, teasing. "She was chosen to work the grill."

"They have always been one for all and all for one," says their mother. "I am in awe of them." They see themselves more like "the sisters in *Sense and Sensibility*—only Jewish," says Estess. "Or *The Godfather*," quips Meredith, as the sisters burst into rapid-fire banter about which of them is Don Corleone.

That would be Jennifer, says Jaqui Lividini, a high school classmate and now vice president of public relations for Saks Fifth Avenue, a Project A.L.S. corporate sponsor. "Even then, Jennifer had a presence," she says. "She quietly commanded that you see her." At New York University, Estess studied acting, graduating in 1984 with a bachelor of fine arts degree in theater. But it was with *Naked Angels* that her real gift emerged. "She would convince corporations and major magazines to support a start-up theater they'd never even heard of—and make them feel good about it," says Hoffenberg, 33, who joined the company in 1988.

In 1996, Estess began to experience involuntary twitches in her leg muscles and overall weakness, symptoms she wrote off to strenuous exercise and the stress of planning the first New York Women's Film Festi-

else has to hear that there is no hope and no cure. That's absolutely unacceptable."

So, too, was the notion that she would fight her battle alone. Within months of her diagnosis, her sisters Meredith Estess, 36, a fashion executive, and Valerie Estess, 40, an advertising writer—both married with young children—quit their jobs to be with her. (Oldest sister Alison Estess, 41, a civil litigator for New York City, also married with children, helps out.) Six months later, the trio, with Jennifer's friend Julianne Hoffenberg—who eventually put her career as a theatrical producer on hold and moved in with Estess—created the nonprofit Project A.L.S., headquartered in the bedroom of Estess's Greenwich Village apartment. Two splashy benefits generated \$1.25 million in donations and drew big-name stars, including Calista Flockhart, Helen Hunt and Dylan McDermott.

Estess honed her powerhouse fund-raising skills—and famous friendships—a decade ago, as producing director of *Naked Angels*, the

Off-Broadway theater troupe that has boasted Marisa Tomei, Matthew Broderick and Fisher Stevens among its members. "Whenever I call her up, because of her spirit, I forget



"I came to Jennifer for all my advice," says Meredith (helping her sister at home).

PHOTOGRAPH BY JEFFREY M. HARRIS

● family

val. Initial examinations turned up nothing. But after a neurologist ran a muscle nerve test, she was told she had motor neuron disease, another name for ALS. The diagnosis was confirmed two months later by ALS pioneer Dr. Lewis P. Rowland at Columbia-Presbyterian Medical Center. "He asked me to sit on the floor," Estess recalls. "Then he told me to get up. I couldn't."

At first, Estess and her family were immobilized by shock and grief. But when specialists had nothing better to offer than suggesting that she eat all the junk food she wanted or max out her credit cards, the sisters grew furious. "Can you imagine?" says Estess. "I've got a fatal disease, and I want a McDonald's or a little black dress!"

Instead, they formed Project A.L.S. and became self-taught experts, "researching the researchers and their research," says Valerie. Several times each month, Estess adds proudly, her sisters and Hoffenberg

hit the road and "go to Harvard and Johns Hopkins and storm the hallowed halls." "We don't storm," corrects Meredith. Valerie settles the dispute: "We *demurely* storm. When you sit down with the ability to write a check for \$100,000 and talk to them in their own language, suddenly you are not a stressed-out chick who should go see a psychiatrist. You are taken seriously."

As Dr. Jeffrey Rothstein can attest. "They grill the hell out of me," says Rothstein, 44, an associate professor of neurology and neuroscience at Johns Hopkins and a recipient of two \$100,000 Project A.L.S. grants. "But they're right to do that. This is a really horrible disease that doesn't stop you from thinking, smelling, feeling while you're trapped in your body. Jenifer," he adds, "is probably the first patient who brought me to tears with her intense and moving questions" about life and love and children. Says Estess: "The whole area of dressing up and putting on

makeup, of romance and being with men, that has all been turned upside down. I can't even brush my hair."

Though her breathing is growing labored and she now requires round-the-clock nursing care (paid for by Medicaid and Social Security), Estess spends 12-hour days working from her bed or wheelchair. Her sisters, like sentries, are always nearby, making and taking calls on their cell phones, crossing and uncrossing Estess's legs, holding a cup to her mouth. The circle of support grows on weekends—husbands, a new baby in a bassinet and older nieces and nephews who can't get enough of their Aunt Jen-Jen. Friends, famous and not-so, drop by. "Jenifer has always been a magnet," says Valerie. "She was the one who would make it, the one with the Malibu beach house that we'd all sponge off of. That's still the plan."

● With reporting by Kelly Carter in Los Angeles



"They are amazing grace in action," says Marilyn Estess of her tireless daughters (from left, Meredith, Jenifer and Valerie).

NEW YORK, WEDNESDAY, JANUARY 27, 1999

Immobilized, and Energized, by an Illness

By JOYCE WADLER

JENIFER ESTESS was working on the New York Film Festival when she noticed involuntary trembling in her legs. The therapist she was seeing for help to get the six-figure salary, to get married, to make her — as Ms. Estess says with view-from-the-wheelchair amusement — “the perfect New York girl,” told her the trembling was stress-related. Perfection is viewed differently when in two years’ time you go from being a high-powered “Equinox girl” to a 37-year-old woman who lacks the strength to cut up her food.

The specialists Ms. Estess consulted, after a diagnosis of amyotrophic lateral sclerosis, the fatal illness commonly known as Lou Gehrig’s disease, also often failed her.

“I saw a doctor at John Hopkins who said: ‘Your motor neurons are dying; they will never be regenerated. You are in a worse situation than Christopher Reeve,’” Ms. Estess says in her Greenwich Village apartment, her speech still clear but her hands curled inward, her legs immobile. “It’s just such a fast-moving, terrible disease, and there is nothing for it.”

The battle cry:

“If you have A.L.S. you’re just expected to sit there and die, and that is unacceptable.”

A request to her sister, Valerie, who with another sister, Meredith, and a roommate, Julianne Hoffenberg, is in the room:

“Can you cross my leg for me?”

Amyotrophic lateral sclerosis, or A.L.S., is a degenerative muscular disease, affecting about 30,000 Americans. Life expectancy is two to five years; there is little treatment and no cure.

Ms. Estess and her three sisters — “think ‘Pride and Prejudice,’ a Jewish ‘Pride and Prejudice,’” Ms. Estess says — decline to accept that. Valerie Estess, 39, and Meredith Estess, 35, quit their jobs (Valerie was in advertising, Meredith in fashion) when Ms. Estess received the diagnosis of A.L.S. two years ago. Working with Ms. Estess, Ms. Hoffenberg and Alison Estess, another sister who is a lawyer, they have formed Project A.L.S. In the group’s first fund-raising event, last June, they raised more than a half-million dollars. They have also been bringing doctors together, trying to speed up research.

“I’m saying to them — and coming to them with large cash gifts — that if they come to this disease with a new way of thinking, we might make progress,” says Valerie, who met with Project A.L.S. researchers a few weeks ago. “It’s not chump



Frances Roberts for The New York Times

Jenifer Estess, despite her illness, is a fervent fund-raiser for research.

change. We gave grants of \$100,000.”

“My sister can speak at a level with the doctors,” puts in Meredith, in the overlapping conversation of the Estess sisters.

“I feel if the doctors reorient themselves, are infused with passion...” says Jenifer.

“There’s research, but it seems to me some of it has been too scattered, too academic,” Valerie says. “I feel like someone needs to bring these doctors together and light a fire under their...”

She completes the sentence, but there’s a reproachful look from Meredith. Then the sisters are laughing.

Ask the Estess sisters about their father and there is a momentary silence — not because the sisters are shy, but because two of the three present are crinkling their noses.

“Estranged,” says one.

“And strange,” says another.

THE Estess sisters (there is also a brother) grew up in Harrison, N.Y. Their father was a stockbroker, their mother a “real 50’s housewife type” who became a real estate agent after her divorce. Jenifer Estess studied acting at New York University. After college she was a co-founder and a producer of the Off Broadway company the Fallen Angels, which included the actors Rob Morrow and Marisa Tomei.

Jenifer Estess’s problem was diagnosed in April 1997. After a discouraging series of visits with specialists (one suggested Ms. Estess “max out” her credit card and eat junk food), the sisters briefly tried

alternative methods.

“The Estesses are Western girls for the most part,” Jenifer Estess says. “But we were desperate.”

By 13 months after the diagnosis, she was forced to use a wheelchair. She resisted as long as possible.

“I took the worst falls,” she says.

Now Ms. Estess cannot dress herself or brush her hair or walk or roll over in bed or cut her own food or hold a cup of coffee if it is more than half full. The progression of the disease, she will tell you, is well charted. She can recite it without losing too much emotional control:

First there is loss of motor function, beginning either with limbs or with speech. There is progressive loss of muscle, which robs one of the ability to walk, speak and eat. It is usually the loss of the muscles of the diaphragm, which controls breathing, that brings on death.

Recently, Ms. Estess started to feel some difficulty forming words. She does not take antidepressants or tranquilizers. She works 18 hours a day. The next benefit for A.L.S. will be in Los Angeles early next month, with Saks as the corporate sponsor and dozens of stars, including Ms. Estess’s old friends Ms. Tomei, Mr. Morrow and William Baldwin.

“Work is the way I get to hold out against the disease,” Ms. Estess says. “Like Chekhov said in ‘The Three Sisters,’ when the sisters are falling apart, when they’ve lost all their money and their dad died, the oldest sister says: ‘We have to return to our work. We still have our work.’”

Project A.L.S.

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Meredith Estess
Valerie Estess
Julianne Hoffenberg

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June 14, 2000

Mrs. Hillary Rodham Clinton
First Lady
West Wing
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mrs. Clinton:

It was our honor and privilege to speak with you this morning and I am sending the enclosed materials as background information before we meet again.

As a follow-up to our conversation today, the enclosed articles and summaries convey the mission of Project A.L.S. and our organization's potential impact on millions of Americans living with brain diseases and spinal cord injury.

In only two years, Project A.L.S. has become the new paradigm for disease research. Not only has our group mobilized the entertainment and corporate communities for fundraising and awareness purposes, we have energized the science community in a whole new way. Project A.L.S. has made exponential progress in finding effective treatments for a uniformly fatal disease by imposing corporate expectations on scientists. We leverage the world's leading neuroscientists with significant funding and we require that these men and women - who have previously been fierce competitors--work together in true collaboration. Our medical team includes Evan Snyder of the Children's Hospital at Harvard Medical School, Jeffrey Rothstein and Thomas Jessell both of Johns Hopkins University. We also unite investigators from a variety of disciplines, many of whom have not worked together before, and insist that they adhere to strict time and action schedules.

The Project A.L.S. program *Neural Stem Cell Replacement in ALS* will likely result in history's first human trials involving neural stem cells. Project A.L.S. is currently in negotiations with the Food and Drug Administration to bring these powerful cells to those who desperately need them. If successful, neural stem cells will mean treatments and, ultimately, cures, for Alzheimer's, Parkinson's, stroke, multiple sclerosis and spinal cord injury.

page two

As you know, the issue of stem cell research has become one of hot political debate. Along with Christopher Reeve, my sister, Jenifer Estess, recently testified before the Arlen Specter chaired Senate Subcommittee on Labor, Health and Education. (Senator Specter is sponsoring a bill calling for federal funding of embryonic stem cell research.) Meanwhile, senators like Sam Brownback (R-Kansas), who testified at those same hearings has equated embryonic stem cell research with "Nazi experimentation during World War II."

We cannot allow so-called pro-life forces to define this research or to sidetrack our efforts to bring stem cells, which have been earmarked as the most revolutionary therapy of this century, to the Americans who are fatally ill.

Jenifer Estess and Project A.L.S. look forward to discussing with you the ways in which we might work together to galvanize support for embryonic stem cell research and for *Neural Stem Cell Replacement in ALS*.

Conversely, Project A.L.S. has an amazing list of New York supporters, a big Wall Street constituency. We will do everything we can to mobilize these forces for your candidacy. We are with you all the way. Today was thrilling for Jenifer. Thank you for caring for our fight.

I hope we can set up a meeting in the near future to fit into your schedule in New York.

Sincerely yours,

Valerie Estess

A handwritten signature in black ink, appearing to read "Valerie Estess". The signature is fluid and cursive, with the first name "Valerie" written in a larger, more prominent script than the last name "Estess".

cc: Kathie Berlin
Enclosures: confidential medical updates,
bios, etc.

THE WHITE HOUSE

June 19, 2000

Valerie and Jennifer Estess
Project A.L.S.
511 Avenue of the Americas
PMB #341
New York, New York 10011

Dear Valerie and Jennifer:

It was a pleasure meeting you the other day and to have a chance to learn more about the important work you are doing at Project A.L.S.. You are lucky to have Kathie in your corner. She is a fiercely protective and tenacious friend – I know!

I will read the materials and share them with my domestic policy staff. I hope that a meeting will be possible someday soon. Until then, I wish you the best of luck with

THE WHITE HOUSE

June 19, 2000

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Valerie and Jennifer Estess

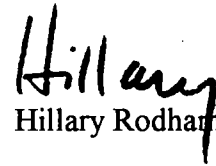
June 19, 2000

Page Two

your efforts to promote and fund stem cell research and I look forward to seeing you again soon.

With warm regards, I remain

Sincerely yours,

A handwritten signature in black ink, appearing to read "Hillary", with a stylized flourish at the end.

Hillary Rodham Clinton

cc: Patti Solis Doyle, Director of Scheduling
Heather Howard, Domestic Policy

Project A.L.S.

Research

In under two years, Project A.L.S. has emerged as a new paradigm for disease research. As a result of its aggressive, streamlined approach, Project A.L.S. has moved scientists significantly closer to developing treatments and a cure for ALS and a deeper understanding of the related diseases Alzheimer's, Parkinson's and Huntington's.

Project A.L.S. awards significant funding on a rolling basis to the most promising research worldwide. It then forges and maintains true working collaborations between excellent scientists from a variety of disciplines. The result is history's first ALS "center without walls," which unites the best thinkers and doers, regardless of academic or corporate affiliation.

1) Neural Stem Cell Replacement in ALS

Description:

This historic collaboration unites Evan Y. Snyder, M.D., Ph.D. (Boston Children's Hospital/Harvard Medical School), John D. Gearhart, Ph.D. and Jeffrey D. Rothstein, M.D., Ph.D., Robert H. Brown, Jr., M.D., D. Phil. (Massachusetts General Hospital/Harvard Medical School), Thomas M. Jessell, Ph.D. (Howard Hughes Medical Institute, Columbia University) and Marc Tessier-Lavigne, Ph.D. (Howard Hughes Medical Institute, University of California, San Francisco). Dr. Snyder has shown that neural stem cells migrate to the area of injury in the diseased spine and brain, that they "engraft" or take hold, and then transform into the kinds of neurons or support cells that have been destroyed depending on the given disease or injury. Project A.L.S. has funded the first ever investigation of Dr. Snyder's cells in laboratory models of ALS, including cell culture, and *in vivo*, in SOD-1 mutated mice and primates. The first human trials are in the design phase.

Potential:

First data suggest that neural stem cells could effectively treat and cure a range of neurologic disorders, including Alzheimer's and Parkinson's, multiple sclerosis and epilepsy, stroke and spinal cord injury.

2) Gene Chip Discovery in ALS

Description:

Unites the eminent ALS geneticist Robert H. Brown, Jr., M.D., D. Phil (Massachusetts General Hospital/Harvard Medical School) with Steven Gullans, Ph.D. (Brigham and Women's Hospital, Boston), in an investigation into the identification of new genetic clues about ALS pathways and therapies. The pilot phase of the work, in which RNA from human ALS tissue has been measured against what we know of the human genome in the form of "gene chips," has just been completed. We now have promising new leads on genes that may be turned off and on in the cascade of events that comprise ALS.

Potential:

To date, there has been one genetic mutation identified with the familial form of ALS (which strikes approximately 5% of the ALS population). This collaboration will home in on new genes which may be players in the ALS and on therapies to fix those problems.

3) Creation of Microassays for High Throughput Drug Screening in ALS

Description:

Traditionally, drug testing has been a slow, painstaking process--one compound tested on one disease model at a time. Technology has now afforded us the chance to test potential efficacy of hundreds of thousands of compounds in a matter of hours. However, there exists no predictive panel of microassays--or approximations of ALS--for the purpose of this high throughput drug screening. Project A.L.S. has funded the creation of the first microassay for this purpose in ALS. Dr. Robert H. Brown, Jr. M.D., D.Phil. (Massachusetts General Hospital/Harvard Medical School) has generated a cell-death microassay in a 96-well plate (soon to be translated into a 364-well format) that is already giving us our first "high throughput" look at compounds that may work in ALS.

Potential:

The creation of a predictive panel of microassays for drug screening in ALS assures an exponential leap forward in the area of drug discovery.

4) Rescue of Respiratory Motor Neurons in ALS

Description:

The loss of the muscles responsible for breathing, primarily the diaphragm, is the fatal component of ALS. This investigation examines our potential for saving those motor neurons responsible for stimulating breathing muscles specifically. Project A.L.S. has funded Yang D. Teng, M.D., Ph.D. (Boston Children's Hospital/Harvard Medical School) and the Evan Y. Snyder Lab to test targeted families of compounds in the rescue of respiratory motor neurons in ALS. Dr. Teng has already reported effective methods of this type of rescue in models of spinal cord injury. Project A.L.S. has recruited him to do the same in ALS. Dr. Teng and his colleagues are currently testing the targeted compounds in SOD-1 ALS mice.

Potential:

If effective, these compounds, some of which are FDA approved for other indications, will prolong and even improve respiratory function in ALS patients.

5) Regulated Gene Expression in Motor Neurons

Description:

Project A.L.S. has funded Thomas M. Jessell, Ph.D. (Howard Hughes Medical Institute, Columbia University) to apply contemporary methods of gene manipulation in mice to study the origins of ALS and the design of novel strategies to prevent the death of motor neurons that occurs in ALS and related neurodegenerative diseases. These mouse lines will be made freely available to other ALS researchers.

Potential:

Dr. Jessell's new mouse strains will provide new and improved mouse models for ALS researchers worldwide and tremendous insight into motor neuron pathologies.

Project A.L.S.

Neural Stem Cell Replacement in ALS

A Collaboration Between Scientists at Harvard University, Johns Hopkins University,
Columbia University and University of California, San Francisco
Funded by Project A.L.S.

Principal Investigator:

Evan Y. Snyder, M.D., Ph.D.
The Children's Hospital, Harvard Medical School

Co-Investigators:

Robert H. Brown, Jr., M.D., D.Phil.
Massachusetts General Hospital, Harvard Medical School

John D. Gearhart, Ph.D.
Johns Hopkins University

Thomas M. Jessell, Ph.D.
Howard Hughes Medical Institute, Columbia University

Jeffrey D. Rothstein, M.D., Ph.D.
Johns Hopkins University

Richard Sidman, M.D.
Harvard Medical School, New England Primate Research Center

Marc Tessier-Lavigne, Ph.D.
*Howard Hughes Medical Institute
University of California, San Francisco*

ALS (amyotrophic lateral sclerosis) is a fatal neurodegenerative disease that destroys motor neurons, which stimulate muscles involved in moving, speaking and breathing. Once damaged, motor neurons do not recover. But we may have found a way to replace them.

This historic collaboration, which has been formed and fully funded by Project A.L.S., may well demonstrate that neural stem cells effectively replace degenerated motor neurons in cell culture, animal models, and, ultimately, in people living with ALS. Neural stem cells may also represent a cure for a range of neurologic illness and injury, from Alzheimer's and Parkinson's to multiple sclerosis, epilepsy and spinal cord injury.

In March, 1999, Jay Lombard, M.D., a neurologist practicing in the Bronx, New York, told Project A.L.S. about Evan Snyder, a pediatric neuroscientist at Boston Children's Hospital, who was introducing his particular brew of neural stem cells--or progenitor cells--into the diseased spines and brains of animal models of devastating childhood neurological diseases like Tay-Sachs and various leukodystrophies (Lorenzo's Oil disease). Dr. Snyder was reportedly observing that the neural stem cells migrated to areas of injury in the animals, that the cells were "engrafting" or taking hold, and that they were actually transforming into the types of neurons and support cells that the given disease situation required. In some cases, Snyder was also observing the reversal of symptoms. For example, after having been treated with neural stem cells, Dr. Snyder's "shiverer mouse" stopped shivering.

Project A.L.S. visited Dr. Snyder's laboratory in March, was impressed with his data, so united him immediately with two of the world's leading neuroscientists with a concentration in ALS, Dr. Jeffrey D. Rothstein, M.D., Ph.D. (Johns Hopkins University) and Dr. Robert H. Brown, Jr., M.D., D. Phil. (Massachusetts General/Harvard Medical School). Doctors Rothstein and Brown were equally impressed with Dr. Snyder's data.

By the August, 1999, Project A.L.S. had launched Neural Stem Cell Replacement in ALS, with an eye toward speeding Dr. Snyder's basic science to human trial.

The laboratories of Snyder, Rothstein, Brown and Dr. Thomas M. Jessell, a molecular biologist specializing in the characterization of motor neurons, began full-throttle pilot experiments with Dr. Snyder's cells at the level of cell culture, in mice and in primate models of neurodegeneration.

Project A.L.S. further enhanced the team to include the eminent Richard Sidman, M.D., Ph.D. (New England Primate Research Center/Harvard University), a neuroanatomist who is advising on the animal work, world renowned stem cell biologist John D. Gearhart (Johns Hopkins University), who is developing additional neural cell lines, and Marc Tessier-Lavigne, Ph.D., who is advising on motor axons, or the reconnections between neurons and muscles.

Project A.L.S. and the neural stem cell team enjoy the support of the NINDS/National Institutes of Health, and are currently negotiating guidelines for the first human trials of Neural Stem Cell Replacement in ALS with the Food and Drug Administration. Pilot data presented at an informal meeting in New York, in January, 2000, were so promising that the team is designing the human trials, which will commence well in advance of original projections.

If you wish to receive further details on Project A.L.S./Neural Stem Cell Replacement in ALS, please contact Valerie Estess, at 212-627-2568.

###

Project A.L.S.

Mission Statement

PROJECT A.L.S., INC. is a non-profit organization that raises awareness and significant funds toward effective treatments and a cure for ALS (amyotrophic lateral sclerosis), also known as Lou Gehrig's disease.

PROJECT A.L.S. distributes funds raised through its charitable efforts to the most exciting ALS and related researchers worldwide.

In addition to fundraising, PROJECT A.L.S. will continue to increase public awareness for ALS, which has remained under-funded and poorly understood since it was first described in 1869. It is our goal that the public come to recognize ALS for what it really is: a fatal neuromuscular disease that is not rare (ALS is diagnosed with roughly the same frequency as multiple sclerosis), that does not discriminate on the basis of age, gender or ethnicity, and for which *there exists not one effective treatment.*

PROJECT A.L.S. intends to transform ALS -- which progressively robs people of the right to walk, speak, swallow and breathe -- into a matter of urgent national concern.

For more information about Project A.L.S., Inc. you can write to 511 Avenue of the Americas, PMB #341, New York, New York 10011 or call us at 1-800-603-0270 or 212-969-0329 email us: projectals@aol.com or visit us on the web: www.project-als.org

###

Medical Advisory Board

Robert H. Brown, MD, D. Phil.

Dr. Brown is an Associate Professor of Neurology, Harvard Medical School and Director of the Day Neuromuscular Laboratory and Muscular Dystrophy Clinic at Massachusetts General Hospital. He graduated from Harvard Medical School and completed his doctoral training in neurology at Oxford University. Dr. Brown trained in Neurology at Massachusetts General Hospital. The Day Neuromuscular Research Center was founded in 1984 by Dr. Brown to investigate neuromuscular diseases.

Over the years, the center has become an internationally recognized center for research and clinical care in neuromuscular diseases. Dr. Brown and his collaborators have made many important contributions to the understanding of the biology of important neuromuscular diseases. Perhaps Dr. Brown's most important contribution has been his ground-breaking work in amyotrophic lateral sclerosis (ALS), in which he identified mutations in the Cu/Zn superoxide dismutase gene in a subset of families with ALS. This observation has had a profound impact on current understanding and research in ALS and in other neurodegenerative diseases. His current work is focused on defining the consequences of the genetic finding in ALS, the role of oxidative damage, and the development of rational therapy based on this understanding.

Jeffrey D. Rothstein, MD, PhD

Dr. Rothstein's training in neuroscience began in the early 1970s when as an undergraduate at Colgate University in upstate New York he began to study the biological basis of brain functions when he majored in Neuroscience. He then began his graduate studies in neuroscience at the University of Chicago in 1977. He interrupted those studies in 1979 to begin medical school at the University of Illinois and in 1985 obtained a Masters from the University of Chicago, a PhD in neurochemistry from the University of Illinois and a medical degree from the University of Illinois. He moved to North Carolina to do a one year internship at the University of North Carolina at Chapel Hill, in part to spend time with his wife, who was completing her PhD in molecular immunology at the University of North Carolina at Chapel Hill. In 1986 he joined the staff at Johns Hopkins University, where he completed a neurology residency and a fellowship in neuromuscular diseases under the tutelage of Dr. Daniel Drachman.

He has remained at Johns Hopkins since 1986 and is currently an Associate Professor of Neurology, Neuroscience and the Program of Cellular and Molecular Medicine. In 1996, Johns Hopkins was designated as a Muscular Dystrophy Association/ALS clinic, and Dr. Rothstein co-directs the clinic along with Dr. Drachman. Since the late 1980s he has been actively engaged in research which examines a full range of basic neuroscience – studies aimed at understanding the biology of excitatory and synaptic transmission of the brain as well as extensive studies focused on the causes of ALS including the mechanisms for why motor neurons die in this disease, new experimental therapies designed to halt the disease, and more recently the development of biological markers for early diagnosis of the disease. He has actively pursued experimental therapeutics and has been the principal investigator for several national and international ALS trials.

Lewis P. Rowland, MD

Dr. Rowland was Professor and Chairman, Department of Neurology, Columbia University College of Physicians and Surgeons, and Director of the Neurology Service, Presbyterian Hospital from 1973-1998. He is Co-Director of the H. Houston Merritt Clinical Research Center for Muscular Dystrophy and Related Diseases at Columbia-Presbyterian Medical Center, and Co-Director of the Eleanor and Lou Gehrig MDA/ALS Center. Previously, he was Professor and Chairman, Department of Neurology, Univ. Of Pennsylvania School of Medicine.

Dr. Rowland received both his B.S. and his M.D. from Yale University where he graduated cum laude and was elected to Alpha Omega Alpha. He was trained in biochemistry and is especially known for research in neuromuscular diseases and age-related neurodegenerative diseases. He is currently a member of the Editorial Boards of the *New England Journal of Medicine*, *Medical Letter* and the *Journal of Neurological Sciences*. He was the Editor-in-Chief of *Neurology*, 1977-1987 and is the author of many papers and editor of several books, including *Merritt's Textbook of Neurology*. He was President of the American Neurological Association (1980-81) and President of the American Academy of Neurology (1989-91); currently heads the Academy Education and Research Foundation and is President of the Parkinson's Disease Foundation.

About Project A.L.S.

Project A.L.S. is a not-for-profit 501(C)(3) organization that raises awareness for ALS (amyotrophic lateral sclerosis, commonly known as Lou Gehrig's disease) and funds the most promising ALS research worldwide. Founded in 1998 by Jenifer Estess, a theater and film producer, Project A.L.S. has already funded investigations into neural stem cell replacement, high throughput drug screening, functional genomics, and accelerated animal trials --approaches that may well alter the lifestyle of those living with the disease.

When she was diagnosed with ALS at the age of thirty-five -- upon learning that there were no drugs or treatments to prolong or improve her life -- Ms. Estess, her sisters and friends formed Project A.L.S. Drawing upon her experience and expertise, Estess united the corporate and entertainment communities in the interest of raising significant research funds.

In June, 1998, Project A.L.S. held its inaugural benefit at New York's fabled Roseland Ballroom. The event raised over \$500,000 and enjoyed the support and participation of First Lady Hillary Rodham Clinton, Sarah The Duchess of York, Jane Alexander, Fiona Apple, William Baldwin and Ben Stiller.

In February, 1999, Project A.L.S. hit Los Angeles for a gala that raised over \$750,000. Sponsored by Saks Fifth Avenue and MovieFone, hosted by Ben Stiller and Kristen Johnston, and co-chaired by Jamie Tarses, President, ABC Entertainment, and Laura Ziskin, President, Fox 2000, the evening featured performances by Melissa Etheridge and Randy Newman, and appearances by Helen Hunt, Greg Kinnear, Camryn Manheim, Julianna Margulies, Penelope Ann Miller, Brooke Shields, Julie Moran, Marisa Tomei, Rob Morrow and Gina Gershon.

In September, 1999, Project A.L.S. held its second New York City fundraiser at the Hammerstein Ballroom. Sponsored by American Airlines, AOL MovieFone, Bloomberg LP, Citigroup and Vogue, the event was a tremendous success, netting over \$1.3 million. Co-chairs for the evening were Michael Bloomberg, CEO and Founder of Bloomberg LP, Steven Fisher, CEO, Plaza Construction, Andrew Jarecki, CEO and Founder, AOL MovieFone, and Frederic Seegal, President, Wasserstein Perella. With the outstanding support and participation of the Wall Street community, along with the talents and participation of the entertainment community, Project A.L.S. was able to reach historic levels of fundraising for ALS research, left in the shadows for nearly two centuries. The event was hosted by Ben Stiller, Kristen Johnston, Janeane Garofalo and Jon Stewart, and included Kevin Spacey, Nathan Lane, Edie Falco, Jesse L. Martin, Scott Wolf and many others.

In May, 1999, Saks Fifth Avenue launched the David Yurman Project A.L.S. Angel Pin, which is being sold in Saks Fifth Avenue stores nationwide for one year. Mr. Yurman and Saks Fifth Avenue have designated that 100% of every sale of the pin go to Project A.L.S. To purchase an Angel Pin by phone call 1-800-347-9177.

In addition to its fundraising efforts, Project A.L.S. is creating a public service campaign for print and television, and an original television movie for CBS.

Along with leading scientists, Project A.L.S. believes that if we solve the mystery of ALS, we will learn more about its sister diseases Parkinson's, Alzheimer's and Huntington's, which affect millions. Says Estess, "If you think of those numbers, ALS becomes a major player. It's our job to pull this disease out of the shadows now."

The Federal ID number for Project A.L.S. is: 13-4019464

For more information or to contact Project A.L.S. call: #1-800-603-0270 email: projectals@aol.com
write: 511 Avenue of the Americas PMB #341 New York City 10011 or visit us on the web: www.project-als.org

THE WHITE HOUSE
WASHINGTON

June 23, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: HEATHER HOWARD
CC: MELANNE VERVEER
ANN O'LEARY
SUBJECT: STEM CELL RESEARCH

As you know, stem cell research holds tremendous promise for advancements in medical science. Embryonic stem cells, which are derived from fertilized eggs created by in vitro fertilization, can regenerate many types of human cells and may be able to replace tissue that has been damaged by disease or injury, offering hope of new treatments for many diseases. Per your request, following is an update on the status of stem cell research:

Since 1995, federal law has banned the use of federal funding for human embryo research. However, in January 1999, the U.S. Department of Health and Human Services issued a legal memorandum which concluded that the ban against funding for the scientific use of embryos does not extend to stem cell research, as long as federal funding is not used to destroy embryos in order to derive the stem cells. That is so, HHS reasoned, because stem cells, unlike the embryos from which they are derived, lack the potential to grow into a human being.

In September 1999, the President's National Bioethics Advisory Commission (NBAC) delivered its report entitled "Ethical Issues in Human Stem Cell Research." The Commission recommended that public funding of stem cell research be permitted. It also recommended a process that would allow researchers to derive the cells from unused embryos donated by couples who seek in vitro fertilization – embryos that otherwise would be discarded. A copy of the report is attached.

In December 1999, HHS issued proposed guidelines for stem cell research funded by NIH. The proposed guidelines would require that for research involving stem cells derived from human embryos, NIH funds could be used only if the cells were from "surplus" embryos created for infertility treatment. Until the guidelines are finalized, no federally-funded stem cell research will be conducted, but of course the private sector does not operate under any restrictions. The proposed guidelines are in comment period now.

The debate in Congress this year is likely to focus on whether the current human embryo research ban covers stem cell research. Last year, Sen. Specter intended to clarify that stem cell research was not covered by the ban, but in exchange for dropping the matter, Sen. Specter secured a promise from Sen. Lott to have a vote this year. Sen. Specter, along with Sen. Harkin,

introduced legislation that would permit funding for research on human embryos for the limited purpose of generating embryonic stem cells, and would codify HHS's decision to allow federally-funded stem cell research. It is unclear whether Sen. Lott will allow a vote on Sen. Specter's bill (or why he would do so, since it would probably pass). There may be amendments on the issue, or on fetal tissue research, in the Senate during consideration of Labor-HHS appropriations next week. You should know that federally-funded fetal tissue research is allowed, although federal law prohibits the sale of fetal tissue for profit, and a woman's abortion decision must be made before she consents to donating the fetal tissue.

THE WHITE HOUSE
WASHINGTON

June 23, 2000

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CC: MELANNE VERVEER
ANN O'LEARY
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In September 1999, the President's National Bioethics Advisory Commission (NBAC) delivered its report entitled "Ethical Issues in Human Stem Cell Research." The Commission recommended that public funding of stem cell research be permitted. It also recommended a process that would allow researchers to derive the cells from unused embryos donated by couples who seek in vitro fertilization – embryos that otherwise would be discarded. A copy of the report is attached.

In December 1999, HHS issued proposed guidelines for stem cell research funded by NIH. The proposed guidelines would require that for research involving stem cells derived from human embryos, NIH funds could be used only if the cells were from "surplus" embryos created for infertility treatment. Until the guidelines are finalized, no federally-funded stem cell research will be conducted, but of course the private sector does not operate under any restrictions. The proposed guidelines are in comment period now.

The debate in Congress this year is likely to focus on whether the current human embryo research ban covers stem cell research. Last year, Sen. Specter intended to clarify that stem cell research was not covered by the ban, but in exchange for dropping the matter, Sen. Specter secured a promise from Sen. Lott to have a vote this year. Sen. Specter, along with Sen. Harkin,

introduced legislation that would permit funding for research on human embryos for the limited purpose of generating embryonic stem cells, and would codify HHS's decision to allow federally-funded stem cell research. It is unclear whether Sen. Lott will allow a vote on Sen. Specter's bill (or why he would do so, since it would probably pass). There may be amendments on the issue, or on fetal tissue research, in the Senate during consideration of Labor-HHS appropriations next week. You should know that federally-funded fetal tissue research is allowed, although federal law prohibits the sale of fetal tissue for profit, and a woman's abortion decision must be made before she consents to donating the fetal tissue.



AHERWITT@naral.org

06/21/2000 06:54:20 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP

cc:

Subject: Re: stem cell research

(See attached file: Stem Cell Research 1-19-00.doc)

Heather -- Here's some quick background. We're also attached our fact sheet on stem-cell research (above).

Stem cells were first successfully isolated about 18 months ago. (As I'm sure you already know, they have fantastic potential for biomedical research because they can grow into different tissue types.) Shortly after, the HHS general counsel issued draft guidelines stating that federally funded research using stem cells did not fall under the human-embryo ban rider. (Anti-choice members, of course, disagree and have been very vocal.) Also, the National Bioethics Advisory Commission has recommended strongly to allow federal funding of stem-cell research, and has gone even one step further: that the human-embryo ban should be lifted.

But the debate in Congress, if and when one happens this year, is likely to focus on stem-cell research and whether the current human-embryo research ban does or doesn't cover stem-cell research.

Sen. Specter was intending to clarify this issue in last year's Labor-H bill, but in exchange for staying silent (in order to pass the approps bill without this issue, which could have tied it up), Lott agreed to give him a vote on the matter in a freestanding bill. Thus, Specter and Sen. Harkin have introduced S. 2015, which would permit federal funding for research on human embryos for the limited purpose of generating embryonic stem cells. Further, the bill would codify the Administration's HHS decision to allow federally funded stem cell research. However, S 2015 would make the heretofore year to year funding ban on research using human embryos permanent law. (making the human embryo ban permanent law is a problem for us)

Hope this is helpful. Let us know if you need anything else.

allison & donna

Allison Herwitt
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Heather_H.
_Howard@opd.eop.gov To: AHERWITT@naral.org
cc:
06/21/00 01:38 PM Subject: stem cell research

Allison -- can I get whatever you have on stem cell research? HRC met with some disease groups asked for an update on where things stand. You can email to this address or fax to 456-2878. Thanks.

P.S. -- are you around during the week of July 4th? I want to take you to the mess.



- Stem Cell Research 1-19-00.doc

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(See attached file: Stem Cell Research 1-19-00.doc)(See attached file: PIC31246.PCX)



- Stem Cell Research 1-19-00.doc



- PIC31246.PCX

THE WHITE HOUSE

Office of the Press Secretary
(Auckland, New Zealand)

For Immediate Release

September 13, 1999

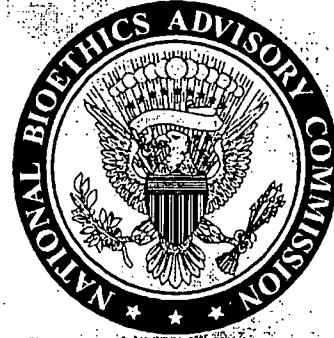
STATEMENT BY THE PRESIDENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on, "Ethical Issues in Human Stem Cell Research." Because of the enormous medical potential of such research, I asked the NBAC in November, 1998, to look at the ethical and medical issues surrounding human stem cell research. The scientific results that have emerged in just the past few months already strengthen the basis for my 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.

The issues addressed by the NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

###



ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH

EXECUTIVE SUMMARY

**Rockville, Maryland
September 1999**

The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975, signed by President Clinton on October 3, 1995. NBAC's functions are defined as follows:

- a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:
 - 1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and
 - 2) applications, including the clinical applications, of that research.
 - b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.
 - c) NBAC shall not be responsible for the review and approval of specific projects.
 - d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.
-

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*To avoid the appearance of a conflict of interest, Commissioner Charo recused herself from all Commission deliberations as of February 1, 1999. She neither dissents from nor endorses this report and its recommendations.

**To avoid the appearance of a conflict of interest, Commissioner Greider recused herself from Commission deliberations as of July 19, 1999.

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*Until May 1999

**Until July 1999

Executive Summary

Introduction

In November 1998, President Clinton charged the National Bioethics Advisory Commission with the task of conducting a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations. The President's request was made in response to three separate reports that brought to the fore the exciting scientific and clinical prospects of stem cell research while also raising a series of ethical controversies regarding federal sponsorship of scientific inquiry in this area. Scientific reports of the successful isolation and culture of these specialized cells have offered hope of new cures for debilitating and even fatal illness and at the same time have renewed an important national debate about the ethics of research involving human embryos and cadaveric fetal material.

Scientific and Medical Considerations

The stem cell is a unique and essential cell type found in animals. Many kinds of stem cells are found in the body, with some more differentiated, or committed, to a particular function than others. In other words, when stem cells divide, some of the progeny mature into cells of a specific type (e.g., heart, muscle, blood, or brain cells), while others remain stem cells, ready to repair some of the everyday wear and tear undergone by our bodies. These stem cells are capable of continually reproducing themselves and serve to renew tissue throughout an individual's life. For example, they constantly regenerate the lining of the gut, revitalize skin, and produce a whole range of blood cells. Although the term *stem cell* commonly is used to refer to the cells within the adult

organism that renew tissue (e.g., hematopoietic stem cells, a type of cell found in the blood), the most fundamental and extraordinary of the stem cells are found in the early stage embryo. These *embryonic stem (ES) cells*, unlike the more differentiated adult stem cells or other cell types, retain the special ability to develop into nearly any cell type. *Embryonic germ (EG) cells*, which originate from the primordial reproductive cells of the developing fetus, have properties similar to ES cells.

It is the potentially unique versatility of the ES and EG cells derived, respectively, from the early stage embryo and cadaveric fetal tissue that presents such unusual scientific and therapeutic promise. Indeed, scientists have long recognized the possibility of using such cells to generate more specialized cells or tissue, which could allow the generation of new cells to be used to treat injuries or diseases, such as Alzheimer's disease, Parkinson's disease, heart disease, and kidney failure. Likewise, scientists regard these cells as an important—perhaps essential—means for understanding the earliest stages of human development and as an important tool in the development of life-saving drugs and cell-replacement therapies to treat disorders caused by early cell death or impairment.

The techniques for deriving these cells have not been fully developed as standardized and readily available research tools, and the development of any therapeutic application remains some years away. Thus, ES and EG cells are still primarily a matter of intense research interest.

At this time, human stem cells can be derived from the following sources:

- human fetal tissue following elective abortion (EG cells),

- human embryos that are created by *in vitro* fertilization (IVF) and that are no longer needed by couples being treated for infertility (ES cells),
- human embryos that are created by IVF with gametes donated for the sole purpose of providing research material (ES cells), and
- potentially, human (or hybrid) embryos generated asexually by somatic cell nuclear transfer or similar cloning techniques in which the nucleus of an adult human cell is introduced into an enucleated human or animal ovum (ES cells).

In addition, although much promising research currently is being conducted with stem cells obtained from adult organisms, studies in animals suggest that this approach will be scientifically and technically limited, and in some cases the anatomic source of the cells might preclude easy or safe access. However, because there are no legal restrictions or new ethical considerations regarding research on adult stem cells (other than the usual concerns about consent and risks), important research can and should go forward in this area. Moreover, because important biological differences exist between embryonic and adult stem cells, this source of stem cells should not be considered an alternative to ES and EG cell research.

Ethical and Policy Considerations

The scientific reports of the successful isolation and culture of ES and EG cells have renewed a longstanding controversy about the ethics of research involving human embryos and cadaveric fetal material. This controversy arises from sharply differing moral views regarding elective abortion or the use of embryos for research. Indeed, an earnest national and international debate continues over the ethical, legal, and medical issues that arise in this arena. This debate represents both a challenge and an opportunity: a challenge because it concerns important and morally contested questions regarding the beginning of life, and an opportunity because it provides another occasion for serious public discussion about important ethical issues. We are hopeful that this dialogue will foster public understanding about the relationships between the opportunities that biomedical science offers to

improve human welfare and the limits set by important ethical obligations.

Although we believe most would agree that human embryos deserve respect as a form of human life, disagreements arise regarding both what form such respect should take and what level of protection is required at different stages of embryonic development. Therefore, embryo research that is not therapeutic to the embryo is bound to raise serious concerns and to heighten the tensions between two important ethical commitments: to cure disease and to protect human life. For those who believe that the embryo has the moral status of a person from the moment of conception, research (or any other activity) that would destroy the embryo is considered wrong and should not take place. For those who believe otherwise, arriving at an ethically acceptable policy in this arena involves a complex balancing of a number of important ethical concerns. Although many of the issues remain contested on moral grounds, they co-exist within a broad area of consensus upon which public policy can, at least in part, be constructed.

For most observers, the resolution of these ethical and scientific issues depends to some degree on the source of the stem cells. The use of cadaveric fetal tissue to derive EG cell lines—like other uses of tissues or organs from dead bodies—is generally the most accepted, provided that the research complies with the system of public safeguards and oversight already in place for such scientific inquiry. With respect to embryos and the ES cells from which they can be derived, some draw an ethical distinction between two types of embryos. One is referred to as the *research embryo*, an embryo created through IVF with gametes provided solely for research purposes. Many people, including the President, have expressed the view that the federal government should not fund research that involves creating such embryos. The second type of embryo is that which was created for infertility treatment, but is now intended to be discarded because it is unsuitable or no longer needed for such treatment. The use of these embryos raises fewer ethical questions because it does not alter their final disposition. Finally, the recent demonstration of cloning techniques (somatic cell nuclear transfer) in nonhuman animals suggests that transfer of a human somatic cell nucleus into an oocyte

might create an embryo that could be used as a source of ES cells. The creation of a human organism using this technique raises questions similar to those raised by the creation of research embryos through IVF, and at this time federal funds may not be used for such research. In addition, if the enucleated oocyte that was to be combined with a human somatic cell nucleus came from an animal other than a human being, other issues would arise about the nature of the embryo produced. Thus, each source of material raises ethical questions as well as scientific, medical, and legal ones.

Conscientious individuals have come to different conclusions regarding both public policy and private actions in the area of stem cell research. Their differing perspectives by their very nature cannot easily be bridged by any single public policy. But the development of public policy in a morally contested area is not a novel challenge for a pluralistic democracy such as that which exists in the United States. We are profoundly aware of the diverse and strongly held views on the subject of this report and have wrestled with the implications of these different views at each of our meetings devoted to this topic. Our aim throughout these deliberations has been to formulate a set of recommendations that fully reflects widely shared views and that, in our view, would serve the best interests of society.

Most states place no legal restrictions on any of the means of creating ES and EG cells that are described in this report. In addition, current Food and Drug Administration regulations do not apply to this type of early stage research. Therefore, because the public controversy surrounding such activities in the United States has revolved around whether it is appropriate for the federal government to sponsor such research, this report focuses on the question of whether the scientific merit and the substantial clinical promise of this research justify federal support, and, if so, with what restrictions and safeguards.

Conclusions and Recommendations

This report presents the conclusions that the Commission has reached and the recommendations that the Commission has made in the following areas: the

ethical acceptability of federal funding for research that either derives or uses ES or EG cells; the means of ensuring appropriate consent of women or couples who donate cadaveric fetal tissue or embryos remaining after infertility treatments; the need for restrictions on the sale of these materials and the designation of those who may benefit from their use; the need for ethical oversight and review of such research at the national and institutional level; and the appropriateness of voluntary compliance by the private sector with some of these recommendations.

The Ethical Acceptability of Federal Funding of ES and EG Cell Research by the Source of the Material

A principal ethical justification for public sponsorship of research with human ES or EG cells is that this research has the potential to produce health benefits for individuals who are suffering from serious and often fatal diseases. We recognize that it is possible that the various sources of human ES or EG cells eventually could be important to research and clinical application because of, for example, their differing proliferation potential, differing availability and accessibility, and differing ability to be manipulated, as well as possibly significant differences in their cell biology. At this time, therefore, the Commission believes that federal funding for the use and derivation of ES and EG cells should be limited to two sources of such material: cadaveric fetal tissue and embryos remaining after infertility treatments. Specific recommendations and their justifications are provided below.

Recommendation 1: EG Cells from Fetal Tissue

Research involving the derivation and use of human EG cells from cadaveric fetal tissue should continue to be eligible for federal funding. Relevant statutes and regulations should be amended to make clear that the ethical safeguards that exist for fetal tissue transplantation also apply to the derivation and use of human EG cells for research purposes.

Considerable agreement exists, both in the United States and throughout the world, that the use of fetal tissue in therapy for people with serious disorders, such

as Parkinson's disease, is acceptable. Research that uses tissue from aborted fetuses is analogous to the use of fetal tissue in transplantation. The rationales for conducting EG research are equally strong, and the arguments against it are not persuasive. The removal of fetal germ cells does not occasion the destruction of a live fetus, nor is fetal tissue intentionally or purposefully created for human stem cell research. Although abortion itself doubtless will remain a contentious issue in our society, the procedures that have been developed to prevent fetal tissue donation for therapeutic transplantation from influencing the abortion decision offer a model for creating such separation in research to derive human EG cells. Because the existing statutes are written in terms of tissue transplantation, which is not a current feature of EG cell research, changes are needed to make it explicit that the relevant safeguards will apply to research to derive EG cells from aborted fetuses. At present, no legal prohibitions exist that would inhibit the use of such tissue for EG cell research.

Recommendation 2: ES Cells from Embryos Remaining After Infertility Treatments

Research involving the derivation and use of human ES 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 ES cells from this source under appropriate regulations that include public oversight and review. (See Recommendations 5 through 9.)

The current ban on embryo research is in the form of a rider to the appropriations bill for the Department of Health and Human Services (DHHS), of which the National Institutes of Health (NIH) is a part. The rider prohibits use of the appropriated funds to support any research "in which a human embryo [is] destroyed, discarded; or knowingly subjected to risk of injury greater than that allowed for research on fetuses *in utero*" (Pub. L. No. 105-78, 513(a)). The term "human embryo" in the statute is defined as "any organism . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human

diploid cells." The ban is revisited each year when the language of the NIH appropriations bill is considered.

The ban, which concerns only federally sponsored research, reflects a moral point of view either that embryos deserve the full protection of society because of their moral status as persons or that there is sufficient public controversy to preclude the use of federal funds for this type of research. At the same time, however, some effects of the embryo research ban raise serious moral and public policy concerns for those who hold differing views regarding the ethics of embryo research. In our view, the ban conflicts with several of the ethical goals of medicine and related health disciplines, especially healing, prevention, and research. These goals are rightly characterized by the principles of beneficence and nonmaleficence, which jointly encourage pursuing social benefits and avoiding or ameliorating potential harm.

Although some may view the derivation and use of ES cells as ethically distinct activities, we do not believe that these differences are significant from the point of view of eligibility for federal funding. That is, we believe that it is ethically acceptable for the federal government to finance research that both derives cell lines from embryos remaining after infertility treatments and that uses those cell lines. Although one might argue that some important research could proceed in the absence of federal funding for research that derives stem cells from embryos remaining after infertility treatments (i.e., federally funded scientists merely using cells derived with private funds), we believe that it is important that federal funding be made available for protocols that also derive such cells. Relying on cell lines that might be derived exclusively by a subset of privately funded researchers who are interested in this area could severely limit scientific and clinical progress.

Trying to separate research in which human ES cells are used from the process of deriving those cells presents an ethical problem, because doing so diminishes the scientific value of the activities receiving federal support. This separation—under which neither biomedical researchers at NIH nor scientists at universities and other research institutions that rely on federal support could participate in some aspects of this research—rests on the

mistaken notion that the two areas of research are so distinct that participating in one need not mean participating in the other. We believe that this is a misrepresentation of the new field of human stem cell research, and this misrepresentation could adversely affect scientific progress for several reasons.

First, researchers using human ES cell lines will derive substantial scientific benefits from a detailed understanding of the process of ES cell derivation, because the properties of ES cells and the methods for sustaining the cell lines may differ depending on the conditions and methods that were used to derive them. Thus, scientists who conduct basic research and are interested in fundamental cellular processes are likely to make elemental discoveries about the nature of ES cells as they derive them in the laboratory. Second, significant basic research needs to be conducted regarding the process of ES cell derivation before cell-based therapies can be realized, and this work must be pursued in a wide variety of settings, including those exclusively devoted to basic academic research. Third, ES cells are not indefinitely stable in culture. As these cells are grown, irreversible changes occur in their genetic makeup. Thus, especially in the first few years of human ES cell research, it is important to be able to repeatedly derive ES cells in order to ensure that the properties of the cells that are being studied have not changed.

Thus, anyone who believes that federal support of this important new field of research should maximize its scientific and clinical value within a system of appropriate ethical oversight should be dissatisfied with a position that allows federal agencies to fund research using human ES cells but not research through which the cells are derived from embryos. Instead, recognizing the close connection in practical and ethical terms between derivation and use of the cells, it would be preferable to enact provisions applicable to funding by all federal agencies, provisions that would carve out a narrow exception for funding of research to use or to derive human ES cells from embryos that are being discarded by infertility treatment programs.

Recommendation 3: ES Cells from Embryos Made Solely for Research Purposes Using IVF

Federal agencies should not fund research involving the derivation or use of human ES cells from embryos made solely for research purposes using IVF.

ES cells can be obtained from human research embryos created from donor gametes through IVF for the sole purpose of deriving such cells for research. The primary objection to creating embryos specifically for research is that there is a morally relevant difference between generating an embryo for the sole purpose of creating a child and producing an embryo with no such goal. Those who object to creating embryos for research often appeal to arguments about respecting human dignity by avoiding instrumental use of human embryos (i.e., using embryos merely as a means to some other goal does not treat them with appropriate respect or concern as a form of human life).

In 1994, the NIH Human Embryo Research Panel argued in support of federal funding of the creation of embryos for research purposes in exceptional cases, such as the need to create banks of cell lines with different genetic make-ups that encoded various transplantation antigens—the better to respond, for example, to the transplant needs of groups with different genetic profiles. This would require the recruitment of embryos from genetically diverse donors.

In determining how to deal with this issue, a number of points are worth considering. First, it is possible that the creation of research embryos will provide the only way in which to conduct certain kinds of research, such as research into the process of human fertilization. Second, as IVF techniques improve, it is possible that the supply of embryos for research from this source will dwindle. Nevertheless, we have concluded that, either from a scientific or a clinical perspective, there is no compelling reason at this time to provide federal funds for the creation of embryos for research. At the current time, cadaveric fetal tissue and embryos remaining after infertility treatment provide an adequate supply of research resources for federal research projects.

Recommendation 4: ES Cells from Embryos Made Using Somatic Cell Nuclear Transfer into Oocytes

Federal agencies should not fund research involving the derivation or use of human ES cells from embryos made using somatic cell nuclear transfer into oocytes.

Somatic cell nuclear transfer of the nucleus of an adult somatic cell into an enucleated human egg likely

has the potential of creating a human embryo. To date, although little is known about these embryos as potential sources of human ES cells, there is significant reason to believe that their use may have therapeutic potential. For example, the potential use of matched tissue for autologous cell replacement therapy from ES cells may require the use of somatic cell nuclear transfer. The use of this technique to create an embryo arguably is different from all the other cases we considered—due to the asexual origin of the source of the ES cells—although oocyte donation is necessarily involved. The Commission concludes that, at this time, federal funding should not be provided to derive ES cells from this source. Nevertheless, scientific progress and the medical utility of this line of research should be monitored closely.

Requirements for the Donation of Cadaveric Fetal Tissue and Embryos for Research

Potential donors of embryos for ES cell research must be able to make voluntary and informed choices about whether and how to dispose of their embryos. Because of concerns about coercion and exploitation of potential donors, as well as societal controversy about the moral status of embryos, it is important, whenever possible, to separate donors' decisions to dispose of their embryos from their decisions to donate them for research. Potential donors should be asked to provide embryos for research only if they have decided to have those embryos discarded instead of donating them to another couple or storing them. If the decision to discard the embryos precedes the decision to donate them for research purposes, then the research determines only how their destruction occurs, not whether it occurs.

Recommendation 5: Requirements for Donation to Stem Cell Research of Embryos That Would Otherwise Be Discarded After Infertility Treatment

Prospective donors of embryos remaining after infertility treatments should receive timely, relevant, and appropriate information to make informed and voluntary choices regarding disposition of the embryos. Prior to considering the potential research use of the embryos, a prospective donor should have been presented with the option of storing the embryos, donating them to another woman, or discarding them. If a prospective donor chooses to discard embryos remaining after

infertility treatment, the option of donating to research may then be presented. (At any point, the prospective donors' questions—including inquiries about possible research use of any embryos remaining after infertility treatment—should be answered truthfully, with all information that is relevant to the questions presented.)

During the presentation about potential research use of embryos that would otherwise be discarded, the person seeking the donation should

- a) disclose that the ES cell research is not intended to provide medical benefit to embryo donors,
- b) make clear that consenting or refusing to donate embryos to research will not affect the quality of any future care provided to prospective donors,
- c) describe the general area of the research to be carried out with the embryos and the specific research protocol, if known,
- d) disclose the source of funding and expected commercial benefits of the research with the embryos, if known,
- e) make clear that embryos used in research will not be transferred to any woman's uterus, and
- f) make clear that the research will involve the destruction of the embryos.

To assure that inappropriate incentives do not enter into a woman's decision to have an abortion, we recommend that directed donation of cadaveric fetal tissue for EG cell derivation be prohibited. Although the ethical considerations supporting a prohibition of the directed donation of human fetal tissue are less acute for EG cell research than for transplantation, certain concerns remain. Potential donors of cadaveric fetal tissue for EG cell derivation would not receive a direct therapeutic incentive to create or abort tissue for research purposes in the same way that such personal interest might arise in a transplant context. However, we agree that the prohibition remains a prudent and appropriate way of assuring that inappropriate incentives, regardless of how remote they may be, are not introduced into a woman's decision to have an abortion. Any suggestion of personal benefit to the donor or to an individual known to the donor would be untenable and possibly coercive.

Recommendation 6: No Promises to Embryo Donors That Stem Cells Will Be Provided to Particular Patient-Subjects

In federally funded research involving embryos remaining after infertility treatments, researchers may not promise donors that ES cells derived from their embryos will be used to treat patient-subjects specified by the donors.

Existing rules prohibit the practice of designated donation, the provision of monetary inducements to women undergoing abortion, and the purchase or sale of fetal tissue. We concur in these restrictions and in the earlier recommendation of the 1988 Human Fetal Tissue Transplantation Research Panel that the sale of fetal tissue for research purposes should not be permitted under any circumstances. The potential for coercive pressure is greatest when financial incentives are present, and the treatment of the developing human embryo or fetus as an entity deserving of respect may be greatly undermined by the introduction of any commercial motive into the donation or solicitation of fetal or embryonic tissue for research purposes.

Recommendation 7: Commerce in Embryos and Cadaveric Fetal Tissue

Embryos and cadaveric fetal tissue should not be bought or sold.

If and when sufficient scientific evidence and societal agreement exist that the creation of embryos specifically for research or therapeutic purposes is justified (specifically through somatic cell nuclear transfer), prohibitions on directed donation should be revisited. For obvious reasons, the use of somatic cell nuclear transfer to develop ES cells for autologous transplantation might require that the recipient be specified.

The Need for National Oversight and Review

The need for national as well as local oversight and review of human stem cell research is crucial. No such system currently exists in the United States. A national mechanism to review protocols for deriving human ES and EG cells and to monitor research using such cells would ensure strict adherence to guidelines and standards across the country. Thus, federal oversight can provide the public with the assurance that research involving

stem cells is being undertaken appropriately. Given the ethical issues involved in human stem cell research—an area in which heightened sensitivity about the very research itself led the President to request that the Commission study the issue—the public and the Congress must be assured that oversight can be accomplished efficiently, constructively, and in a timely fashion, with sufficient attention to the relevant ethical considerations.

Recommendation 8: Creation and Duties of an Oversight and Review Panel

DHHS should establish a National Stem Cell Oversight and Review Panel to ensure that all federally funded research involving the derivation and/or use of human ES or EG cells is conducted in conformance with the ethical principles and recommendations contained in this report. The panel should have a broad, multidisciplinary membership, including members of the general public, and should

- a) review protocols for the derivation of ES and EG cells and approve those that meet the requirements described in this report,
- b) certify ES and EG cells lines that result from approved protocols,
- c) maintain a public registry of approved protocols and certified ES and EG cell lines,
- d) establish a database—linked to the public registry—consisting of information submitted by federal research sponsors (and, on a voluntary basis, by private sponsors, whose proprietary information shall be appropriately protected) that includes all protocols that derive or use ES or EG cells (including any available data on research outcomes, including published papers),
- e) use the database and other appropriate sources to track the history and ultimate use of certified cell lines as an aid to policy assessment and formulation,
- f) establish 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 ES or EG cells, and

- g) report at least annually to the DHHS Secretary with an assessment of the current state of the science for both the derivation and use of human ES and EG cells, a review of recent developments in the broad category of stem cell research, a summary of any emerging ethical or social concerns associated with this research, and an analysis of the adequacy and continued appropriateness of the recommendations contained in this report.

The Need for Local Review of Derivation Protocols

For more than two decades, prospective review by an Institutional Review Board (IRB) has been the principal method for assuring that federally sponsored research involving human subjects will be conducted in compliance with guidelines, policies, and regulations designed to protect human beings from harm. This system of local review has been subject to criticism, and, indeed, in previous analyses we have identified a number of concerns regarding this system. In the course of preparing this report, we considered a number of proposals that would allow for the local review of research protocols involving human stem cell research, bearing in mind that a decision by the Commission to recommend a role for IRBs might be incorrectly interpreted as endorsing the view that human ES or EG cells or human embryos are human subjects and therefore would be under the purview of the Common Rule.

We adopted the principle, reflected in these recommendations, that for research to derive human ES and EG cells, a system of national oversight and review supplemented by local review would be necessary to ensure that important research could proceed—but only under specific conditions. We recognized that for research proposals involving the derivation of human ES or EG cells, many of the ethical issues associated with these protocols could be considered at the local level, that is, at the institutions at which the research would be taking place. For protocols using but not deriving ES cells (i.e., generating the cells elsewhere), a separate set of ethical deliberations would have occurred. In general, the IRB is an appropriate body to review protocols that aim to derive ES or EG cells. Although few review bodies (including IRBs) have

extensive experience in reviewing protocols of this kind, they remain the most visible and expert entities available. It is for this reason, for example, that we make a number of recommendations (8, 9, 10, 11, and 12) that discuss the importance of developing additional guidance for the review of such protocols.

For proposals involving the derivation of human ES or EG cells, particular sensitivities require attention through a national review process. This process should, however, begin at the local level, because institutions that intend to conduct research involving the derivation of human ES cells or EG cells should continue to take responsibility for assuring the ethical conduct of that research. More importantly, however, IRBs can play an important role, particularly by reviewing consent documents and by assuring that collaborative research undertaken by investigators at foreign institutions has satisfied any regulatory requirements for sharing research materials.

Recommendation 9: Institutional Review of Protocols to Derive Stem Cells

Protocols involving the *derivation* of human ES and EG cells should be reviewed and approved by an IRB or by another appropriately constituted and convened institutional review body prior to consideration by the National Stem Cell Oversight and Review Panel. (See Recommendation 8.) This review should ensure compliance with any requirements established by the panel, including confirming that individuals or organizations (in the United States or abroad) that supply embryos or cadaveric fetal tissue have obtained them in accordance with the requirements established by the panel.

Responsibilities of Federal Research Agencies

Federal research agencies have in place a comprehensive system for the submission, review, and approval of research proposals. This system includes the use of a peer review group—sometimes called a study section or initial review group—that is established to assess the scientific merit of the proposals. In addition, in some agencies, such as NIH, staff members review protocols prior to their transmittal to a national advisory council for final approval. These levels of review provide an opportunity to consider ethical issues that arise in the proposals.

When research proposals involve human subjects, federal agencies rely on local IRBs to review and approve the research in order to assure that it is ethically acceptable. (See Recommendation 9.) A grant application should not be funded until ethical issues that are associated with research involving human subjects have been resolved fully. Therefore, at every point in this continuum—from the first discussions that a prospective applicant may have with program staff within a particular institution to the final decision by the relevant national advisory council—ethical and scientific issues can be addressed by the sponsoring agency.

Recommendation 10: Sponsoring Agency Review of Research Use of Stem Cells

All federal agencies should ensure that their review processes for protocols using human ES or EG cells comply with any requirements established by the National Stem Cell Oversight and Review Panel (see Recommendation 8), paying particular attention to the adequacy of the justification for using such cell lines.

Research involving human ES and EG cells raises critical ethical issues, particularly when the proposals involve the derivation of ES cells from embryos remaining after infertility treatments. We recognize that these research proposals may not follow the paradigm usually associated with human subjects research. Nevertheless, research proposals being considered for funding by federal agencies must, in our view, meet the highest standards of scientific merit and ethical acceptability. To that end, the recommendations made in this report, including a proposed set of *Points to Consider in Evaluating Basic Research Involving Human ES Cells and EG Cells*, constitute a set of ethical and policy considerations that should be reflected in the respective policies of federal agencies conducting or sponsoring human ES or EG cell research.

Attention to Issues for the Private Sector

Although this report primarily addresses the ethical issues associated with the use of federal funds for research to derive and use ES and EG cells, we recognize that considerable work in both of these areas will be conducted under private sponsorship. Thus, our recommendations may have implications for those working in the

private sector. First, for cell lines to be eligible for use in federally funded research, they must be certified by the National Stem Cell Oversight and Review Panel described in Recommendation 8. Therefore, if a private company aims to make its cell lines available to publicly funded researchers, it must submit its derivation protocol(s) to the same oversight and review process recommended for the public sector, i.e., local review (see Recommendation 9) and for certification that the cells have been derived from embryos remaining after infertility treatments or from cadaveric fetal tissue.

Second, we hope that nonproprietary aspects of protocols developed under private sponsorship will be made available in the public registry, as described in Recommendation 8. The greater the participation of the private sector in providing information on stem cell research, the more comprehensive the development of the science and related public policies in this area.

Third, and perhaps most relevant, in an ethically sensitive area of emerging biomedical research it is important that all members of the research community, whether in the public or private sectors, conduct the research in a manner that is open to appropriate public scrutiny. The last two decades have witnessed an unprecedented level of cooperation between the public and private sectors in biomedical research, which has resulted in the international leadership position of the United States in this arena. Public bodies and other authorities, such as the Recombinant DNA Advisory Committee, have played a crucial role in enabling important medical advances in fields such as gene therapy by providing oversight of both publicly and privately funded research efforts. We believe that voluntary participation by the private sector in the review and certification procedures of the proposed national panel, as well as in its deliberations, can contribute equally to the socially responsible development of ES and EG cell technologies and accelerate their translation into biomedically important therapies that will benefit patients.

Recommendation 11: Voluntary Actions by Private Sponsors of Research That Would Be Eligible for Federal Funding

For privately funded research projects that involve ES or EG cells that would be eligible for federal funding, private sponsors and researchers are

encouraged to adopt voluntarily the applicable recommendations of this report. This includes submitting protocols for the derivation of ES or EG cells to the National Stem Cell Oversight and Review Panel for review and cell line certification. (See Recommendations 8 and 9.)

In this report, we recommend that federally funded research to derive ES cells be limited to those efforts that use embryos remaining after infertility treatment. Some of the recommendations made in this context—such as the requirement for separating the decision by a woman to cease such treatment when embryos still remain and her decision to donate those embryos to research—simply do not apply to efforts to derive ES cells from embryos created (whether by IVF or somatic cell nuclear transfer) solely for research purposes, activities that might be pursued in the private sector. Nevertheless, other ethical standards and safeguards embodied in the recommendations, such as provisions to prevent the coercion of women and the commodification of human reproduction, remain vitally important, even when embryos are created solely for research purposes.

Recommendation 12: Voluntary Actions by Private Sponsors of Research That Would Not Be Eligible for Federal Funding

For privately funded research projects that involve deriving ES cells from embryos created solely for research purposes and that are therefore not eligible for federal funding (see Recommendations 3 and 4)

- a) professional societies and trade associations should develop and promulgate ethical safeguards and standards consistent with the principles underlying this report, and
- b) private sponsors and researchers involved in such research should voluntarily comply with these safeguards and standards.

Professional societies and trade associations dedicated to reproductive medicine and technology play a central role in establishing policy and standards for clinical care, research, and education. We believe that these organizations can and should play a salutary role in ensuring that all stem cell and embryo research conducted in the United States, including that which is privately funded,

conforms to the ethical principles underlying this report. Many of these organizations already have developed policy statements, ethics guidelines, or other directives addressing issues in this report, and the Commission has benefited from a careful review of these materials. These organizations are encouraged to review their professional standards to ensure not only that they keep pace with the evolving science of human ES and EG cell research, but also that their members are knowledgeable about and in compliance with them. For those organizations that conduct research in this area but that lack statements or guidelines addressing the topics of this report, we recommend strongly that they develop such statements or guidelines. No single institution or organization, whether in the public or the private sector, can provide all the necessary protections and safeguards.

The Need for Ongoing Review and Assessment

No system of federal oversight and review of such a sensitive and important area of investigation should be established without simultaneously providing an evaluation of its effectiveness, value, and ongoing need. The pace of scientific development in human ES and EG cell research likely will increase. Although one cannot predict the direction of the science of human stem cell research, in order for the American public to realize the promise of this research and to be assured that it is being conducted responsibly, close attention to and monitoring of all the mechanisms established for oversight and review are required.

Recommendation 13: Sunset Provision for National Panel

The National Stem Cell Oversight and Review Panel described in Recommendation 8 should be chartered for a fixed period of time, not to exceed five years. Prior to the expiration of this period, DHHS should commission an independent evaluation of the panel's activities to determine whether it has adequately fulfilled its functions and whether it should be continued.

There are several reasons for allowing the national panel to function for a fixed period of time and for evaluating its activities before continuing. First, some of the hoped-for results will be available from research projects

that are using the two sources we consider to be ethically acceptable for federal funding. Five years is a reasonable period of time to allow some of this information to amass, offering the panel, researchers, members of Congress, and the public sufficient time to determine whether any of the knowledge or potential health benefits are being realized. The growing body of information in the public registry and database described above (particularly if privately funded researchers and sponsors voluntarily participate) will aid these considerations.

Second, within this period the panel may be able to determine whether additional sources of ES cells are necessary in order for important research to continue. Two arguments are evident for supporting research using embryos created specifically for research purposes: one is the concern that not enough embryos remain for this purpose from infertility treatments, and the other is the recognition that some research requires embryos that are generated particularly for research and/or medical purposes. The panel should assess whether additional sources of ES cells that we have judged to be ineligible for federal funding at this time (i.e., embryos created solely for research purposes) are needed.

Third, an opportunity to assess the relationship between local review of protocols using human ES and EG cells and the panel's review of protocols for the derivation of ES cells will be offered. It will, of course, take time for this national oversight and review mechanism to develop experience with the processes of review, certification, and approval described in this report. Fourth, we hope that the panel will contribute to the national dialogue on the ethical issues regarding research involving human embryos. A recurring theme of our deliberations, and in the testimony we heard, was the importance of encouraging this ongoing national conversation.

The criteria for determining whether the panel has adequately fulfilled its functions should be set forth by an independent body established by DHHS. However, it would be reasonable to expect that the evaluation would

rely generally on the seven functions described above in Recommendation 8 and that this evaluation would be conducted by a group with expertise in these areas. In addition, some of the following questions might be considered when conducting this evaluation: Is there reason to believe that the private sector is voluntarily submitting descriptions of protocols involving the derivation of human ES cells to the panel for review? Is the panel reviewing projects in a timely manner? Do researchers find that the review process is substantively helpful? Is the public being provided with the assurance that social and ethical issues are being considered?

Summary

Recent developments in human stem cell research have raised hopes that new therapies will become available that will serve to relieve human suffering. These developments also have served to remind society of the deep moral concerns that are related to research involving human embryos and cadaveric fetal tissue. Serious ethical discussion will (and should) continue on these issues. However, in light of public testimony, expert advice, and published writings, we have found substantial agreement among individuals with diverse perspectives that although the human embryo and fetus deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone. We were persuaded that carrying out human stem cell research under federal sponsorship is important, but only if it is conducted in an ethically responsible manner. And after extensive deliberation, the Commission believes that acceptable public policy can be forged, in part, on widely shared views. Through this report, we not only offer recommendations regarding federal funding and oversight of stem cell research, but also hope to further stimulate the important public debate about the profound ethical issues regarding this potentially beneficial research.

THE WHITE HOUSE

Office of the Press Secretary
(Auckland, New Zealand)

For Immediate Release

September 13, 1999

STATEMENT BY THE PRESIDENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on, "Ethical Issues in Human Stem Cell Research." Because of the enormous medical potential of such research, I asked the NBAC in November, 1998, to look at the ethical and medical issues surrounding human stem cell research. The scientific results that have emerged in just the past few months already strengthen the basis for my 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.

The issues addressed by the NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

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BANNING FUNDING FOR STEM CELL RESEARCH IS HOLDING AMERICA'S HEALTH HOSTAGE

Stem cell research may be one of the keys to unlocking our medical future. To ban federal funding is to ban research that may lead to treatment for diseases and disabilities such as Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis. The possibilities are endless -- unless anti-choice politics are allowed to hold science, and our health, hostage.

Human pluripotent stem cells are cells that can regenerate many types of human cells, but not all types of cells. In stem cell research, a cluster of cells is isolated, most often from leftover eggs fertilized in a dish under laboratory conditions during in vitro fertilization. The cells are allowed to "develop in a laboratory for a few days, to the so-called blastocyst stage, when the embryo is a hollow ball of cells." The stem cells are then extracted from the blastocyst. These cells then are allowed to regenerate, creating healthy new cells that may be able to replace tissue that has been damaged by disease or injury.

Scientists at well-respected medical and educational institutions, from the members of the National Bioethics Advisory Committee to the over 9,000 members of the American Society for Cell Biology, anticipate that stem cell research may lead to significant advances in medical science, including the following:

- Tissue transplantation, permitting replacement of damaged heart tissue.
- Generation of neurons to cure Parkinson's disease.
- Growth of cartilage-forming cells to alleviate arthritis.
- Research into curing diseases such as cancer, birth defects, and diabetes.

Stem cell research also may "dramatically change the way we develop drugs and test them for safety. For example, rather than evaluating the safety of a candidate drug in an animal model, these drugs could be tested against human cell lines." The National Institutes of Health (NIH) predict that pluripotent stem cells "are enormously important to science and hold great promise for advances in health care."

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Since 1995, federal law has banned the use of federal funding for human embryo research. However, in January 1999, the U.S. Department of Health and Human Services (HHS) ruled that the ban against funding for the scientific use of embryos does not extend to stem cell research as long as federal funding is not used to destroy embryos in order to derive the stem cells. This is so, HHS reasoned, because stem cells lack the potential to grow into a human being.

Indeed, in September 1999, the National Bioethics Advisory Committee issued its recommendation that public funding of stem cell research be permitted. It also recommended a process that would allow researchers to derive the cells from unused embryos donated by couples who seek in vitro fertilization -- embryos that otherwise would be discarded.

In December 1999, the HHS proposed guidelines for stem cell research funded by the NIH. The proposed guidelines would require that for research involving stem cells derived from human embryos, NIH funds could be used only if the cells were from "surplus" embryos created for infertility treatment.

A careful balance should be struck between the demands of science and the commands of medical ethics. In an effort to craft such a balance, even after the HHS ruling was issued, the NIH has refrained from funding stem cell research until ethical guidelines for such research are promulgated by medical experts. This sort of self-policing by research scientists ensures the ethical use of stem cells for appropriate medical purposes.

In fact, "[f]ederal funding [would] provide oversight and direction that would be lacking if this research were the sole province of industry and academe." The federal government plays an important role in ensuring that stem cell research is conducted with due regard for ethical concerns. This role cannot be realized in the absence of federal financial involvement in this research.

A Congressional funding ban on stem cell research would hold the health -- indeed, the lives -- of millions of Americans hostage. Such a ban must not be enacted.

1/20/00

Notes

U.S. Department of Health and Human Services, National Institutes of Health (NIH), "Pluripotent Stem Cells: A Primer," Jan. 28, 1999 (fact sheet).

Rebekah Saul, "Federally Funded 'Stem Cell' Research: New Hope, Renewed Controversy," *Guttmacher Report*, vol. 2, no. 2 (Apr. 1999): 3.

Saul, "Federally Funded 'Stem Cell' Research," 3; National Bioethics Advisory Commission, "Ethical Issues in Human Stem Cell Research," Sept. 1999, 1; Testimony of Lawrence S. B. Goldstein, Ph.D., American Society for Cell Biology, before the Labor, Health and Human Services and Education Subcommittee of the Appropriations Committee, U.S. Senate (Jan. 12, 1999); Letter from over 60 medical and science organizations to Honorable Nita Lowey, U.S. House of Representatives (Feb. 19, 1999) (on file with NARAL); NIH, "Pluripotent Stem Cells."

NIH, "Pluripotent Stem Cells."

NIH, "Fact Sheet: Stem Cell Research," Jan. 28, 1999 (fact sheet).

Memorandum from Harriet S. Rabb, General Counsel, U.S. Department of Health and Human Services, to Harold Varmus, M.D., Director, National Institutes of Health (Jan. 15, 1999) (on file with NARAL).

National Bioethics Advisory Commission, "Ethical Issues in Human Stem Cell Research," 3-4.

64 Fed. Reg. 67576, 67577-78 (Dec. 2, 1999). Research involving stem cells derived from fetal tissue would be required to comply with any applicable state and local laws and with the federal prohibition against transferring fetal tissue for valuable consideration. 64 Fed. Reg. 67576, 67578 (Dec. 2, 1999) (citing 42 U.S.C. §§ 289g-1, 289g-2(a) and 45 C.F.R. § 46.210). Federal law permits research on fetal tissue derived from spontaneous or induced abortion or stillbirth. 42 U.S.C. § 289g-1(a)(2).

NIH, "Fact Sheet: Stem Cell Research."

NIH, "Fact Sheet: Stem Cell Research."



AHERWITT@naral.org

06/22/2000 04:06:20 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP

cc:

Subject: Re: stem cell research

we believe it will be allowed once HHS issues its final guidelines (you may recall that HHS published draft guidelines for comment last winter and were swamped by anti-choice form postcards and letters against the guidelines.)

but keep in mind that the private sector does not operate under any restriction in this area.

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_Howard@opd.eop.gov To: AHERWITT@naral.org
cc:
06/22/00 03:58 PM Subject: Re: stem cell research

so what is the current status of federal funding of stem cell research?
HHS thinks it's allowed but it's not being done?

(Embedded
image moved AHERWITT@naral.org
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To: Heather H. Howard/OPD/EOP

cc:

Subject: Re: stem cell research

(See attached file: Stem Cell Research 1-19-00.doc)

Heather -- Here's some quick background. We're also attached our fact sheet on stem-cell research (above).

Stem cells were first successfully isolated about 18 months ago. (As I'm sure you already know, they have fantastic potential for biomedical research because they can grow into different tissue types.) Shortly after, the HHS general counsel issued draft guidelines stating that federally funded research using stem cells did not fall under the human-embryo ban rider. (Anti-choice members, of course, disagree and have been very vocal.) Also, the National Bioethics Advisory Commission has recommended strongly to allow federal funding of stem-cell research, and has gone even one step further: that the human-embryo ban should be lifted. But the debate in Congress, if and when one happens this year, is likely to focus on stem-cell research and whether the current human-embryo research ban does or doesn't cover stem-cell research.

Sen. Specter was intending to clarify this issue in last year's Labor-H bill, but in exchange for staying silent (in order to pass the approps bill without this issue, which could have tied it up), Lott agreed to give him a vote on the matter in a freestanding bill. Thus, Specter and Sen. Harkin have introduced S. 2015, which would permit federal funding for research on human embryos for the limited purpose of generating embryonic stem cells. Further, the bill would codify the Administration's HHS decision to allow federally funded stem cell research. However, S 2015 would make the heretofore year to year funding ban on research using human embryos permanent law. (making the human embryo ban permanent law is a problem for us)

Hope this is helpful. Let us know if you need anything else.
allison & donna

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Stem Cell Research Funding Urged

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By THE ASSOCIATED PRESS

Filed at 3:54 p.m. ET

WASHINGTON (AP) -- Michael J. Fox and Mary Tyler Moore urged lawmakers Thursday to release federal funding for research involving embryonic stem cells, which the actors say could lead to cures for diseases such as Parkinson's, juvenile diabetes and Alzheimer's.

"The consistent and inescapable conclusion is that this research offers the potential to eliminate diseases, literally saving millions of lives," said Fox, who just won an Emmy for the ABC sitcom "Spin City." "I can't help but say, respectfully, enough! It's time to act on what we've learned. ... Further delay would come at a high price."

Fox left the show in May to devote more time to fighting Parkinson's, a progressive neurological disorder that he has contracted.

Senate Majority Leader Trent Lott, R-Miss., has promised a vote within the month on legislation allowing funding for research on stem cells from discarded human embryos, said Sen. Arlen Specter, R-Penn., chairman of the Appropriations Committee's Health and Human Services panel.

"I believe we have the votes," said Sen. Tom Harkin, D-Iowa, who co-sponsored Specter's legislation. "I hope we have the votes."

However, critics oppose the research, calling it illegal, immoral and unnecessary.

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“If a cure for diabetes and a host of other ailments require the production and destruction of human embryos, then I beg you to consider the possibility that some diseases are better than their cure,” said Russell Saltzman, pastor of Ruskin Heights Lutheran Church in Kansas City, Mo.

At issue are embryonic stem cells, the master cells that in very early embryos generate all the other tissues of the body. Scientists think those stem cells possibly could cure diseases like Alzheimer’s, diabetes, or Parkinson’s, or even repair broken spinal cords.

But the federal government has not funded any research into embryonic stem cells because of a congressional ban on any research that destroys human embryos. Taking stem cells from embryos does destroy them.

The National Institutes of Health has proposed allowing federal funding of research on stem cells that are removed from human embryos but forbidding research on the embryo itself.

Specter’s legislation would go further, letting women agree to donate to federally funded researchers their leftover embryos from in-vitro fertilization.

But Saltzman, who has diabetes, said just because the embryos were going to be discarded doesn’t mean it is right to use them for medical research. “We should not use human life for the benefit of human life,” he said.

Harkin noted that the embryos in question are no bigger than the period at the end of a sentence.

“The embryos that are being discussed, according to science, bear as much resemblance to a human being as a goldfish,” said Moore, star of “The Mary Tyler Moore Show” that aired from 1970 to 1977.

“We’re dealing with flesh and blood people now who feel and deal with real debilitation right now and our obligation is to those who are here,” said Moore, who suffers from juvenile diabetes and chairs the Juvenile Diabetes Foundation International.

Others disagreed.

“I’m not opposed to research,” said Ron Heagy, who is a quadriplegic, paralyzed from the neck down. “I’m not opposed to walking again. I’m just opposed to the process.”

Dr. Darwin Prockop, director of gene therapy at the Tulane University Medical Center, said researchers are getting close to major breakthroughs with adult stem cell research, with clinical

trials on patients with Parkinson's expected in two or three years.

But Prockop said embryonic cell research should proceed. "We are simply not ready for a moon-shot like strategy in which we place all our bets on adult stem cells," he said.

^-----

The bill number is S.2015.

On the Net:

NIH stem cell information:

<http://www.nih.gov/news/stemcell/index.htm>

Michael J. Fox Foundation for Parkinson's Research:

<http://www.michaeljfox.org>

Juvenile Diabetes Foundation: <http://www.jdf.org/>

Ron Heagy: <http://www.goron.com/>

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