

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	Perry Cohen to Office of Chris Jennings re: Attendee at Meeting with Jennings Social Security number redacted (1 page)	6/8/98	P6/b(6)

COLLECTION:

Clinton Presidential Records
 Domestic Policy Staff
 Chris Jennings (Subject File)
 OA/Box Number: 23753 Box 13

FOLDER TITLE:

Increase in nIH Funding for Biomedical Research [2]

gf29

RESTRICTION CODES

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

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

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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

- b(1) National security classified information [(b)(1) of the FOIA]
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NIH INVESTMENT IN RESEARCH AND RESEARCH TRAINING
PROGRAMS RELATED TO MINORITIES

File

Minority

Health

The NIH investment in research and research training programs related to the minority populations in the U.S. is about \$1.5 billion. Of this, about \$115 million supports research training in the preparation of minorities for careers in biomedical research. Examples are: 1) the Minority Access to Research Careers Program for undergraduate student training in research and minority and predoctoral faculty fellowships; 2) the Bridges to the Future Program for students to make the transition from two-year to four-year colleges and from Master's degree granting to doctoral degree granting programs; 3) support for minority high school, college, graduate and postdoctoral students by supplemental funds to regular research grants; and 4) a program within NIH for loan repayment scholarship funds for undergraduate, graduate and medical students, as well as postdoctoral trainees studying AIDS.

Support for research activities performed by minority investigators and their students totals about \$136 million. Under the Minority Biomedical Research Program, research is performed by faculty and students at academic institutions having a significant number of minority students [Historically Black Colleges and Universities (HBCUs); Hispanic Serving Institutions (HSIs) having an enrollment of at least 25% Hispanic students; and institutions in inner cities and some other geographic areas in which a large number of minority students are enrolled].

Support for Research Centers at Minority Institutions is about \$32 million and includes special funds for construction at these institutions. The total funds provided to HBCUs will be about \$86 million and to HSIs about \$69 million in FY1998.

Funds for research related to diseases or conditions that inordinately affect the minority populations of this country are provided by the Institutes and Centers and total over \$2 billion. These funds are particularly directed to studies of breast, prostate and lung cancer, cardiovascular disease, hypertension, diabetes, stroke, sickle cell disease, sudden infant death syndrome and infant mortality.

The Office of Research on Minority Health serves as a focus of coordination of the activities of all the NIH Institutes and Centers and is described in the attached Fact Sheet. The Office is responsible for the Minority Health Initiative, which provides about \$70 million a year for projects supported by the Institutes and Centers. These include perinatal studies and interventions to improve infant mortality rates, the effects of alcohol on the fetus, adolescent alcohol use, lead poisoning in children, research on HIV infection in adolescents, studies of asthma in minority children, auditory and visual impairments in minority children, and many others.

The NIH is committed to ensuring that all Americans have equal access to good health and that all scientists have the opportunities to compete fairly for research funds.

PHOTOCOPY
PRESERVATION

April 1998

Background

The President has been invited to participate in the ground breaking ceremony for the new Clinical Research Center (CRC) (state-of-the-art research hospital) on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland. This new building, by an act of Congress, is to be called the Mark O. Hatfield Clinical Research Center, in honor of Senator Hatfield, who served for 30 years in the Senate and as Chairman of the Committee on Appropriations for 8 years.

The Messages

This is an opportunity for the President to:

- Take credit for initiating construction of this building, which symbolizes the Clinton Administration's investment in the future and its commitment to improving the health of the Nation.
- Underline the Administration's promise to provide quality health care for all Americans. Medical research involving patients, conducted in this building, will pave the way for treatments and cures for patients everywhere.
- Cite an activity of the Federal government-- investment in medical research-- that has bipartisan, enthusiastic support in the Congress and is overwhelmingly popular with the American public (as shown by regional and National surveys).
- Point out that while government is downsizing, this new building is symbolic of what the public wants from government and the Clinton Administration is providing--a means of developing treatments and cures for devastating diseases.
- Remind the public that the long-term support of NIH (including by this Administration) has brought advance after advance in the laboratory that are ready to be translated--in this new building--into better diagnosis, treatment and even cures for difficult and dreaded diseases. The new building will speed translation of discoveries from the laboratory to the patient.
- Make the point that medical research has progressed at an unprecedented rate in the past decade. We are now on the brink of applying these advances to treat and cure a host of diseases from arthritis to childhood cancer and heart disease to diabetes.

The Photo Opportunity

At the ceremony, the President could meet patients with Alzheimer's disease, genetic disorders, AIDS, cancer, and other diseases who are participating in NIH studies. These patients (as described in the attached Washingtonian magazine) come from all across the country to seek help and participate in research (thereby helping countless others).

The agenda will include a former patient who will talk about how NIH (and its clinical research) brings hope to individuals who volunteer to participate in the research and to sick people everywhere.

The first two rows of the audience for the event will include patients--especially children and young adults--from around the country.

- Stem Cell File

THE WHITE HOUSE

WASHINGTON

November 14, 1998

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

Dear Dr. Shapiro:

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

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

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

Sincerely,

Bill Clinton

OSTEOPOROSIS

Prohides FH

- **Twenty-five million Americans have osteoporosis -- 80% are women.**
- **One out of two women over the age of 50 will have an osteoporosis-related fracture during her lifetime.**
- **Osteoporosis is frequently called the "silent killer" because many women do not know they have it until they have a broken bone.**
- **In fact, sixty percent of women over the age of 45 are not familiar with a disease called osteoporosis.**
- *1.5 million fractures per year*

DIABETES

- **16 million Americans have diabetes. More than one-third have not been diagnosed. There are 800,000 new cases of diabetes diagnosed every year.**
- **Nearly 20 percent of Americans over the age of 65 have diabetes. (6.3 million). (6.3 million and over 3 million have been diagnosed).**
- **People with diabetes are more likely to suffer from heart disease, high blood pressure, and strokes. People with diabetes are 2 to 4 times more likely to suffer from cardiovascular disease, and 2 to 4 times more at risk for a stroke. High blood pressure affects nearly two-thirds of people with diabetes.**
- **Diabetes is the leading cause of end-stage renal disease (ERSD), non-traumatic amputations, and blindness. Diabetes accounts for 36 percent of new ERSD cases (kidney disease) -- about 20,000 cases each year. In addition, 54,000 amputations are performed on diabetics each year, and up to 24,000 adults are blinded each year from diabetes.**

- **It is estimated that we spend \$92 billion per year on diabetes care.** Of the total, costs directly attributable to diabetes total \$45 billion, while indirect medical costs, such as work loss, disability, and premature death total \$47 billion.
- **Medicare pays for ERSD for the non-elderly population as well.** About 20,000 Americans develop this disease through diabetes each year, and Medicare expenditures on kidney dialysis for each of these people averages nearly \$40,000 annually.

List of Speakers

Gandy
Usman
Nathaniel

Fuse
Breath

Sandy Puczynski

Her daughter, Michelle, is 13 and has diabetes. Michelle has been faced with many hardships due to the disease, including numerous injections and fingerstick blood tests, a structured meal plan, and constant fear of persistent high blood sugar levels which could lead to death. She is thankful for the commitment by the President towards a research initiative that would hopefully find a cure for diabetes.

Mrs. Mary Delaney

She is an elderly, African-American woman that has a history of diabetes in her family and suffers from the disease. She cannot afford many of the treatments and medicine she needs in order to combat diabetes. She thanks the President for the Medicare benefit that will help older Americans get the health care they need to manage diabetes.

Chief Joyce Dugan

She is the Chief of the Eastern Band of Cherokee Indians. She is concerned with the way diabetes has become an epidemic in Native American communities recently. She is thankful for the education and prevention initiatives, in the form of a Dialysis Center and Wellness Center for her community, and for the establishment of a special diabetes program for Native Americans.

Other VIPS Meeting with POTUS

Domino

Robert

Woody Johnson

Braz

Stephen J. Satalino, Chair of the American Diabetics Association

Mary Tyler Moore, the Juvenile Diabetes Foundation International's International Chairman

Other Validators

Dr. Richard Kahn, Medical Director of the American Diabetic Association
703-299-2065

Dr. Philip Gordon, Head of the National Institute of Diabetes and Digestive and Kidney Diseases
301-496-5877

Eric Schutt, Juvenile Diabetes Foundation
202-371-9746

Tim Overby - Goldman Sachs

MILLER & CHEVALIER

CHARTERED

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CLARENCE T. KIPPS, JR.
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September 19, 1997

HAND DELIVERED

Mr. Christopher C. Jennings
Special Assistant to the President for Health Policy
Office of Policy Development
212 R Old Executive Office Building
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Re: Increased Funding for Parkinson's Research in the Senate Labor,
HHS, and Education Appropriation

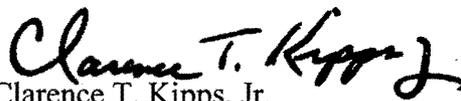
Dear Mr. Jennings:

Pursuant to our March meeting with Dr. James Bennett, Jr., Dr. Curt Freed, Ms. Joan Samuelson, and Mr. Paul Smedberg, I promised to update you on our progress towards seeking increased funding for Parkinson's research. Due in large part to the valiant efforts of the dedicated Parkinson's grassroots organizations, the Senate Labor, HHS, and Education Appropriation (as passed on September 11, 1997) contains a \$100 million appropriation for increased funding for Parkinson's research.

With the approaching passage of the House's version of the HHS Appropriation, the Parkinson's community is seeking the President's support for retention of the Senate funding provision in conference. I have attached a copy of the Senate Appropriation language for your review. If there is any additional information that I can provide you, please do not hesitate to give me a call. My number is 202-626-5840.

Pursuant to your earlier advice, I am simultaneously sending a letter to OMB's Acting Associate Director for Health Care, Joshua Gotbaum. On behalf of the nearly one million Americans that suffer from this disorder, I would like to express their gratitude for your time and your concern.

Sincerely,


Clarence T. Kipps, Jr.

Attachments

Mr. Christopher C. Jennings
September 19, 1997
Page 2

cc: Mr. Daniel C. Tate, Jr.
Dr. Dr. James Bennett, Jr.
Dr. Curt Freed
Ms. Joan Samuelson
Mr. Paul Smedburg
Ms. Angela Barbee Styles

AMENDMENT NO. _____ Calendar No. _____

Purpose: To provide for the establishment of a program for research and training with respect to Parkinson's disease.

IN THE SENATE OF THE UNITED STATES—105th Cong., 1st Sess.

S. 1061

Making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. WELLSTONE (for himself and Mr. MCCAIN)

Bryan Hatch

Viz:

d. Borns, Durbin, Ford, D'Amato, Breaux, Mosley-Brown, Santorum, Johnson

- 1 At the appropriate place, insert the following:
- 2 SEC. ____ PARKINSON'S DISEASE RESEARCH.
- 3 (a) SHORT TITLE.—This section may be cited as the
- 4 "Morris K. Udall Parkinson's Research Act of 1997".
- 5 (b) FINDING AND PURPOSE.—
- 6 (1) FINDING.—Congress finds that to take full
- 7 advantage of the tremendous potential for finding a
- 8 cure or effective treatment, the Federal investment
- 9 in Parkinson's must be expanded, as well as the co-

1 ordination strengthened among the National Insti-
2 tutes of Health research institutes.

3 (2) PURPOSE.—It is the purpose of this section
4 to provide for the expansion and coordination of re-
5 search regarding Parkinson's, and to improve care
6 and assistance for afflicted individuals and their
7 family caregivers.

8 (c) PARKINSON'S RESEARCH.—Part B of title IV of
9 the Public Health Service Act (42 U.S.C. 284 et seq.) is
10 amended by adding at the end the following:

11 "PARKINSON'S DISEASE

12 "SEC. 409B. (a) IN GENERAL.—The Director of
13 NIH shall establish a program for the conduct and sup-
14 port of research and training with respect to Parkinson's
15 disease (subject to the extent of amounts appropriated
16 under subsection (e)).

17 "(b) INTER-INSTITUTE COORDINATION.—

18 "(1) IN GENERAL.—The Director of NIH shall
19 provide for the coordination of the program estab-
20 lished under subsection (a) among all of the national
21 research institutes conducting Parkinson's research.

22 "(2) CONFERENCE.—Coordination under para-
23 graph (1) shall include the convening of a research
24 planning conference not less frequently than once
25 every 2 years. Each such conference shall prepare
26 and submit to the Committee on Appropriations and

1 the Committee on Labor and Human Resources of
2 the Senate and the Committee on Appropriations
3 and the Committee on Commerce of the House of
4 Representatives a report concerning the conference.

5 “(c) MORRIS K. UDALL RESEARCH CENTERS.—

6 “(1) IN GENERAL.—The Director of NIH shall
7 award Core Center Grants to encourage the develop-
8 ment of innovative multidisciplinary research and
9 provide training concerning Parkinson’s. The Direc-
10 tor shall award not more than 10 Core Center
11 Grants and designate each center funded under such
12 grants as a Morris K. Udall Center for Research on
13 Parkinson’s Disease.

14 “(2) REQUIREMENTS.—

15 “(A) IN GENERAL.—With respect to Par-
16 kinson’s, each center assisted under this sub-
17 section shall—

18 “(i) use the facilities of a single insti-
19 tution or a consortium of cooperating insti-
20 tutions, and meet such qualifications as
21 may be prescribed by the Director of the
22 NIH; and

23 “(ii) conduct basic and clinical re-
24 search.

1 “(B) DISCRETIONARY REQUIREMENTS.—

2 With respect to Parkinson’s, each center as-
3 sisted under this subsection may—

4 “(i) conduct training programs for
5 scientists and health professionals;

6 “(ii) conduct programs to provide in-
7 formation and continuing education to
8 health professionals;

9 “(iii) conduct programs for the dis-
10 semination of information to the public;

11 “(iv) separately or in collaboration
12 with other centers, establish a nationwide
13 data system derived from patient popu-
14 lations with Parkinson’s, and where pos-
15 sible, comparing relevant data involving
16 general populations;

17 “(v) separately or in collaboration
18 with other centers, establish a Parkinson’s
19 Disease Information Clearinghouse to fa-
20 cilitate and enhance knowledge and under-
21 standing of Parkinson’s disease; and

22 “(vi) separately or in collaboration
23 with other centers, establish a national
24 education program that fosters a national

1 focus on Parkinson's and the care of those
2 with Parkinson's.

3 "(3) STIPENDS REGARDING TRAINING PRO-
4 GRAMS.—A center may use funds provided under
5 paragraph (1) to provide stipends for scientists and
6 health professionals enrolled in training programs
7 under paragraph (2)(B).

8 "(4) DURATION OF SUPPORT.—Support of a
9 center under this subsection may be for a period not
10 exceeding five years. Such period may be extended
11 by the Director of NIH for one or more additional
12 periods of not more than five years if the operations
13 of such center have been reviewed by an appropriate
14 technical and scientific peer review group established
15 by the Director and if such group has recommended
16 to the Director that such period should be extended.

17 "(d) MORRIS K. UDALL AWARDS FOR EXCELLENCE
18 IN PARKINSON'S DISEASE RESEARCH.—The Director of
19 NIH shall establish a grant program to support investiga-
20 tors with a proven record of excellence and innovation in
21 Parkinson's research and who demonstrate potential for
22 significant future breakthroughs in the understanding of
23 the pathogenesis, diagnosis, and treatment of Parkinson's.
24 Grants under this subsection shall be available for a period
25 of not to exceed 5 years.

and section 301 and
title IV of The Public
Health Service Act with
respect to direct
Parkinson's disease research

O:\BAI\BAI97.743

6

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated \$100,000,000 for fiscal year 1998, and
4 such sums as may be necessary for each of the fiscal years
5 1999 and 2000.

a total of

Morris K. Udall Parkinson's Research & Education Act of 1997

Senate Bill Number: S. 535
Principal Senate Sponsor: Senator John McCain
Senate Co-Sponsors: 65

Facts: The Udall Parkinson's bill was attached by amendment to the Senate Labor, HHS & Education Appropriation (S. 1062). The Amendment (#1074) was passed by a recorded vote of 95 to 3. The Appropriation bill passed by a vote of 92 to 8.

House Bill Number: H.R. 1260
Principal House Sponsor: Congressman Fred Upton
House Co-Sponsors: 251

Facts: Although majority of the members of the House of Representatives, a majority of the members of the House Commerce Committee (30 of 51), a majority of the members of the House Commerce Subcommittee on Health (20 of 29) and a majority of the members of the House Appropriations Committee (30 of 60) have cosponsored this bill, the bill has not passed the House, nor will the bill be called up as an amendment to the House Labor, HHS & Education Appropriation.

Parkinson's Research Funding Facts

- ◆ 1 out of every 263 Americans are *known* to have Parkinson's
- ◆ 70% of the people afflicted with Parkinson's are over the age of 50
- ◆ The Federal Government spends only \$26 per patient for direct Parkinson's research
 - * The Federal Government spends \$1,069 per HIV/AIDS patient for research
 - * The Federal Government spends \$295 per Cancer patient for research
- ◆ The National Institutes of Health have a annual budget of more than \$11 billion, but can't find the money to fund Parkinson's research
 - * The scant \$26 per Parkinson's patient has been spread between four different National Institutes of Health

With Adequate Funding a Cure Could Be Found Within FIVE YEARS

- ◆ Leading Scientists have predicted that with adequate funding, a cure is within reach in FIVE YEARS
- ◆ There is no other neurological disease about which we have so much information and no other area in neuroscience that is as fertile.
- ◆ Leading Scientists agree that funding should be focused on diseases that are the THRESHOLD of a CURE, but NIH has refused to divert money away from basic research and has vigorously opposed efforts in Congress to earmark money for Parkinson's.
- ◆ With Adequate funding substantial new treatments could be available within TWO to THREE YEARS.

Finding a Cure Could Save An Estimated \$26 billion per year

- ◆ According to Dr. Ole Isacson of Harvard, Parkinson's is estimated to cost America \$26 billion per year.
- ◆ According to Dr. Kurlan of the University of Rochester, even a 10% slowing of the progression of Parkinson's will save \$327 million per year.
- ◆ The costs of treating Parkinson's have significant effects on the overall costs of MEDICARE and MEDICAID.

■ WHAT IS PARKINSON'S????

- Parkinson's results from degeneration of cells in the brain that produce dopamine that controls motor function of the body.
- Parkinson's starts with tremors and falling, progresses to freezing of muscles and uncontrollable body movements, loss of memory, confusion and depression, and degenerates into total incapacity, including loss of speech.
- 1 out of every 263 Americans are known to have Parkinson's. Widely known victims include Rev. Billy Graham, Mo Udall, Muhammad Ali and Janet Reno.

MILLER & CHEVALIER

CHARTERED

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CLARENCE T. KIPPS, JR.
(202) 626-5840
CKIPPS@MILCHEV.COM

September 19, 1997

HAND DELIVERED

Mr. Joshua Gotbaum
Acting Associate Director for Health Care and Personnel
Old Executive Office Building, Room 254
725 Seventeenth Street, N.W.
Washington, D.C. 20503

Re: Increased Funding for Parkinson's Research in the Senate Labor,
HHS, and Education Appropriation

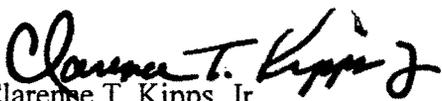
Dear Mr. Gotbaum:

In March of this year, Chris Jennings met with me and two leading Parkinson's disease research doctors and several active members of the Parkinson's disease support community to discuss the promising future for breakthroughs in Parkinson's research. At that meeting, Mr. Jennings recommended that I work with your office to ensure that White House stays abreast of funding issues that effect the Parkinson's community.

Due in large part to the valiant efforts of the dedicated Parkinson's grassroots organizations, the Senate Labor, HHS, and Education Appropriation (as passed on September 11, 1997) contains a \$100 million appropriation for increased funding for Parkinson's research. With the approaching passage of the House's version of the HHS Appropriation, the Parkinson's community is seeking the President's support for retention of the Senate funding provision in conference. I have attached a copy of the Senate Appropriation language for your review. Attached also are brief background statements on Parkinsons disease and the relevant legislation.

If there is any additional information that I can provide you, please do not hesitate to give me a call at 202-626-5840. I am a partner at the Washington, D.C. law firm Miller & Chevalier and am actively involved (on a pro bono basis) in the efforts of the Parkinson's community to increase funding for Parkinson's research.

Sincerely,


Clarence T. Kipps, Jr.

Enclosures

Mr. Joshua Gotbaum
September 19, 1997
Page 2

cc: Mr. Christopher C. Jennings
Mr. Daniel C. Tate, Jr.
Dr. Dr. James Bennett, Jr.
Dr. Curt Freed
Ms. Joan Samuelson
Mr. Paul Smedburg
Ms. Angela Barbee Styles

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OA/Box Number: 23753 Box 13

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Increase in NIH Funding for Biomedical Research [2]

gf29

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Parkinson's Care Networks

Perry D. Cohen, Ph.D.

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Washington DC 20015
202-686-9430 (voice/fax)
pdcohen@alum.mit.edu**

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FACSIMILE COVER PAGE

Date: 6/8/98
Time: 17:34:22
Page: 1

To: Donna, c/o Chris Jennings Office
Company: The White House
Fax #: 456-5557

From: Perry Cohen
Address: 3914 Harrison St. NW
Washington, DC 20015
USA
Fax #: 202-686-9430
Voice #: 202-686-9430

Message:

In addition to Mr. Hoffheimer and myself Mr. Paul Smedberg of APDA will attend this Wednesday's, 2 pm meeting with Mr. Jennings. Mr. Smedberg is a US citizen.

Paul C. Smedberg

DOB P6/b(6)

Thank you and we look forward to seeing you then.

Perry Cohen



National Parkinson Foundation, Inc.

Lawrence S. Hoffheimer
Washington Counsel

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PCN

Parkinson's Care Networks

Perry D. Cohen, Ph.D.

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Date: 6/8/98
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To: Donna, c/o Chris Jennings Office
Company: The White House
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Telephone: (202) 467-8313
Toll Free: (888) 331-4NPF
Fax: (202) 466-0585

Lawrence S. Hoffheimer
Washington Counsel

Message:

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Paul C. Smedberg

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Thank you and we look forward to seeing you then.

Perry Cohen

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PHOTOCOPY



National Parkinson Foundation, Inc.

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- U.S. Senator Paul D. Wellstone

Lawrence S. Hoffheimer, Esq.
Washington Counsel

Reasons for Funding the Morris K Udall Parkinson's disease Research and Education Act

Parkinson's disease is a debilitating neurological disorder that effects more than one million Americans today.

- **It's already the law.** The Udall bill, (S.535), passed the Senate last year by a vote of 95 to 3! H.R. 1260 enjoyed the cosponsorship of more than 255 members of the House of Representatives. The same authorizing language was signed into law by President Clinton on November 13, 1997.
- **A CURE is close.** (some say within 5 years). Neurologists and neuroscientists agree that we know more about Parkinson's than any other neurological disorder. Also, learning more about what causes Parkinson's will provide unique insight into the causes of other neurological disorders like Alzheimer's, ALS and stroke.
- **It's cost effective.** Spending \$100 million/year for 3 years to save \$25 BILLION* in annual costs to society, is an incredible return on investment. *(Societal cost as determined by Dr. Ole Isacson, Harvard University, 1995).
- **The "Baby Boomers" are coming.** As our nation's population continues to age, and more and more people approach the average age of diagnosis, 57, the burden on our economic and family structure will be staggering. If extraordinary steps are not taken now to find a more effective treatment and/or cure for Parkinson's, not to mention other age-related disorders, there will be absolutely nothing we can do to control health care costs.
- **Parkinson's is consistently under-funded.** Despite a new level of demonstrated commitment from both Congress and the Clinton Administration to significantly increase the federal investment in biomedical research through NIH, "direct" Parkinson's disease research continues to receive relatively conservative rates of increase that are disproportionate to total rates of increase for NIH as a whole. In fact, in terms of annual per-patient funding for the different disease groups, Parkinson's disease ranks at the bottom consistently.

For America's more than one million Parkinsonians, time is running out. Scientific momentum un-funded is scientific momentum lost.



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Norma Udall

U.S. Congressman Henry Waxman

U.S. Senator Paul D. Wellstone

Udall Act Background

Lawrence S. Hoffheimer, Esq.
Washington Counsel

On November 13, 1997, President Clinton and Vice President Gore held a signing ceremony in the East Room of the White House to sign into law the Labor, Health and Human Services, Education and Related Agencies Appropriations Act for FY 1998. Included as an amendment to that bill was the Morris K. Udall Parkinson's Research and Education Act of 1997. The Udall bill authorized Congress to direct "up to \$100 million for research focussed on Parkinson's disease," through the National Institutes of Health. However, although the bill has been passed and is now law, the additional funding authorized has yet to be appropriated.

In attendance at the signing ceremony was Mrs. Norma Udall, wife of the former congressman, a delegation of executives from the National Parkinson Foundation, and other leading Parkinson advocates, all of who had worked for years to garner the bipartisan support necessary to pass the bill. In their remarks, both the President and the Vice President recognized Mrs. Udall and presented her with one of the ceremonial pens. At that time the urgency to find a cure for Parkinson's disease was stressed. The abundance of attention that the Udall Act received at that ceremony was seen by the Parkinson's community as both a testament to their years of grassroots activism, and a sign of commitment from the Administration and Congress that Parkinson's disease research would not continue to go under-funded.

President Clinton also mentioned Parkinson's disease specifically in his State of the Union Address earlier this year. He used the recent discovery of a gene that actually caused Parkinson's in a large Italian family to highlight recent medical breakthroughs and to stress the importance of significant increased federal investment in biomedical research. Once again the Parkinson's community rejoiced. Surely this was a sign that a specific line item to seek funding for the Udall Act would appear in the President's FY '99 Budget Request. This was unfortunately not the case.

There is a certain level of accomplishment in getting so many in Washington to even pay lip service to increasing funding for Parkinson's research. The true victory, however would be realized if the authorized funding levels outlined in the Udall Act were requested as a priority of the Administration to appear in this year's FY '99 Appropriations measure from Congress. NIH calculates that it spends \$35 million per year on "direct" Parkinson research, while the Udall Act authorizes up to \$100 million be spent in this area.



As referenced earlier, the Udall bill enjoyed widespread bipartisan support in both houses of Congress. Last year, the bill (H.R. 1260) was cosponsored in the House by more than 255 Members, and passed the Senate by a vote of 95-3 (S.535).

This is a pivotal time. As the House and Senate Labor HHS Appropriations Subcommittees are considering what funding to include in their respective bills, an indication of priority from the Administration could be the final push that finally secures funding for this legislation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 21, 1998

The Honorable John McCain
United States Senate
Washington, D.C. 20510

Dear Senator McCain:

Enclosed is the information you requested on the actual and projected direct funding of Parkinson's disease research, as well as information on funds expended on related research by the National Institutes of Health (NIH) through the period including fiscal years 1994 through 1999.

We are very pleased with the direction that research on Parkinson's disease is going, both in understanding the basis of the disorder and of the mechanisms by which the neurodegenerative process occurs. A number of new initiatives have begun or are planned; among the most promising are establishment of Parkinson's Disease Research Centers of Excellence that will begin their collaborative, interdisciplinary studies this year. We believe that, in the near term, these studies will result in successful interventions for those suffering from its debilitating effects.

Thank you for your interest in the NIH and our efforts to understand and find a cure for Parkinson's disease.

Sincerely,

Harold Varmus, M.D.
Director

Enclosure

PARKINSON'S DISEASE

BACKGROUND. Parkinson's disease (PD) is a progressive, neurodegenerative disorders marked by the loss of the dopamine-producing cells of the substantia nigra. Dopamine is a neurotransmitter—one of several chemicals that serve as communication signals between nerve cells—critical to many processes in the brain, including purposeful control of movement. When the level of dopamine-producing cells in the substantia nigra falls below a critical threshold of about 20 percent, symptoms of the disease appear. These include tremor, the gradual loss of voluntary movement, rigidity, postural instability, and gait abnormalities. These symptoms are progressive, ultimately leading to total disability and death. While there is no cure for Parkinson's disease, and the cause(s) of the disease remain unknown, recently the genetic origins of a familial form of Parkinson's has been discovered. Genetics, environment, aging, and several pathogenic processes all may contribute to the development of Parkinson's disease. Parkinson-like symptoms may also occur as a result of cerebral infection, repeated cerebral trauma (e.g., boxing), and as a complication of medications and illicit drugs.

At present, most people with Parkinson's disease receive drugs designed to replace or mimic dopamine in the brain. Standard therapy for Parkinson's disease consists primarily of administering the drug levodopa, a substance converted to dopamine by the brain, that often is combined with other agents to enhance its effect. None of the currently available drugs stops the underlying degeneration associated with Parkinson's, the effects of drug therapy often wear off over time, and they often have unpleasant side effects. Researchers are now experimenting with a number of advanced surgical and non-surgical approaches to treating Parkinson's, and hope that these new therapies will help patients who do not benefit from current drugs, perhaps even slowing the course of the disease.

EPIDEMIOLOGY & ECONOMIC COSTS. Approximately 500,000 Americans, or about 1 percent of the population over 50, suffer from PD. Parkinson's disease affects both sexes and occurs all over the world. Because the disease most commonly affects people in later life, the number of people with Parkinson's disease and the associated costs will grow as the average age of the American population increases. The total annual direct and indirect cost of Parkinson's disease was estimated to be \$6 billion in 1992. (*Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support*, November 1995)

[NOTE: The reports of prevalence rate for Parkinson's disease have in the past varied widely as a result of community-based studies over the years, reflecting population differences and variations in study methods. Review of these sources, however, consistently identified that the most widely cited reputable sources (Kurtzke, 1983 and the Office of Science and Technology Policy, 1991) reported the prevalence at 500,000. Most recently, a newly published, case-control study by Drs. Caroline Tanner and Samuel Goldman, utilizing recognized standard epidemiological techniques has confirmed the level at approximately 500,000. (*Neurology Clinics* 14 (2) May 1996, pp. 317 - 336)]

RECENT ADVANCES

One conclusion of an NIH-sponsored international Parkinson's Disease Planning Workshop in August, 1995 was that genes might play more of a role in PD than previously recognized, and that finding the genes that cause inherited forms of PD could provide crucial clues toward understanding what triggers all forms of the disease. A collaboration sponsored by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Human Genome Research Institute (NHGRI) for the first time showed that a single gene alteration on chromosome 4 could cause PD. A team of scientists, including NIH intramural investigators and extramural grantees then discovered the precise defect in a specific gene that causes some cases of inherited PD. The gene carries the blueprint for a protein called alpha-synuclein. Synuclein earlier had been identified as one of the components of "amyloid plaques," the abnormal clumps of proteins in the brains of Alzheimer's patients. Under NINDS and NHGRI sponsorship, scientists are now trying to discover the role of synuclein in PD and to find other defective genes that may contribute to PD in other families. A major study to map the gene(s) that predispose to the common form of PD is also beginning.

In one encouraging follow up study, scientists demonstrated that synuclein is found in *Lewy bodies* of the most common, non-inherited form of PD. *Lewy bodies* are abnormal clumps of material in certain parts of the brain that are a hallmark of PD and are also found in certain other diseases. This finding supports the idea that inherited PD may provide insights about the more common forms of the disease. The finding also complements a growing body of evidence that abnormal aggregations of proteins, such as those found in PD, Alzheimer's disease, and Huntington's disease are actively damaging the brain. Stopping or slowing the formation of these aggregations may present an entirely new approach to preventing the death of brain cells in neurodegenerative diseases. NINDS and NIA are actively supporting research in this area.

NINDS-supported scientists and their collaborators have shown that a growth factor derived from glial (supporting) cells of the nervous system (GDNF) supports and protects dopamine neurons. They have also demonstrated that recombinant GDNF has similar effects. This growth factor preserves cells from destructive effects and repairs cells after damage. NINDS will support further studies of GDNF and similar compounds in rodent models of neurodegenerative disorders and in grafted tissue to determine the mechanism of action.

OVERVIEW OF RESEARCH PROGRAM

To capitalize on the recent research success in Parkinson's disease, three areas are being pursued: First, the search for new genes is continuing. While some families with inherited forms of Parkinson's disease are now known to have an abnormal gene on chromosome 4, it is clear that in other families with forms of Parkinson's disease, other genes will be involved. In 1997 NINDS announced a Program Announcement (PA) on the genetics of Parkinson's disease. The response to this PA has begun and this research will continue through 1999.

A second major approach focuses on the study of cell biology. To capitalize on the genetic gains, whole new areas of research techniques are being used by NINDS grantees, including making transgenic mice that often mimic the clinical disease, using yeast two-hybrid systems to

identify interacting proteins, and investigation of pathological functions or related proteins in simple organisms. Further work to clarify the role of alpha-synuclein and other proteins and to determine their relation to the disease is beginning.

Third, trials of surgery (pallidotomy), deep brain electrical stimulation, and other clinical studies are being pursued. Pallidotomy is a procedure that attempts to re-balance the brain circuitry disrupted by disease. Although surgery was tried in the past with mixed results, now surgeons can use the behavior of individual brain cells, recorded with microelectrodes, to find precise locations in the brain for surgical intervention. The positive results from these improved surgical therapies have led to a systematic clinical trial. Attempts to replace dopamine cells by transplantation of fetal tissue are also ongoing; this procedure has provided benefits to at least some patients. Transplants of cultured cell lines and stem cells should eventually replace fetal tissue with further study. Because of the time involved in bringing a new treatment to successful clinical trial, NINDS encourages animal testing and pilot studies in humans of both existing ideas for treatment (e.g. new anti-oxidants; cell transplants) and those that we hope will develop from the recent genetic findings.

NINDS is encouraging investigators seeking to carry out pilot studies of clinical research in preparation for a clinical trial in Parkinson's disease to make use of the "NINDS Pilot Clinical Trial Grant For Neurologic Disease" as described in a PA issued August 29, 1997. Close collaboration and integration between research Center activities and clinical trials is encouraged.

NINDS has also recruited a new staff person with primary responsibility for neurodegenerative disorders which include Parkinson's, Huntington's, dystonia, and similar disorders.

Intramural-- NINDS scientists are isolating the individual brain receptors for dopamine using molecular genetic techniques. The ability to produce these receptors on cells grown in culture will allow more efficient screening of experimental drugs for Parkinson's disease, resulting in more effective treatments with fewer side effects. NINDS intramural scientists are studying several dopamine agonists to develop a drug that would mimic the actions of dopamine, targeting the specific dopamine receptors involved in PD, but avoiding the receptors involved in the negative side effects now experienced by nearly half of the patients receiving levodopa. The NINDS Intramural Division is now conducting several clinical studies on Parkinson's disease. The NINDS Experimental Therapeutics Branch is conducting a two-year clinical trial to investigate the effect of a new drug, OPC-14117, which may retard the death of nerve cells.

PROGRAM ACTIONS

WORKSHOPS AND COLLABORATIONS

- Recently, the NINDS and NHGRI sponsored a second workshop on the genetics of Parkinson's disease in December, 1997 at Cold Spring Harbor that has continued to spark research interest. Additional work will focus on understanding the products and processes that are affected by the genes involved in familial, and perhaps other, forms of Parkinson's disease.

- In 1997, NINDS sponsored a panel of experts to critically examine the many clinical and pathological elements involved in diagnosing Parkinson's disease. The result of their deliberations will be published in a report, "Diagnosis of Parkinson's Disease," expected in 1998.
- In all the NIH research program on Parkinson's disease represents the work of eight NIH Institutes and Centers. Those most active in Parkinson's research have formed a staff committee to monitor research directions and to identify opportunities for co-funding and joint initiatives.
- NINDS is forming a collaboration with the Department of Veterans Affairs to identify families with Parkinson's and Parkinson's-related diseases to help develop epidemiological studies. This effort would allow more accurate estimates of prevalence, and allow investigation of genetic and environmental risk factors. Because the idea of a genetic component for Parkinson's disease is new, the collection of families has been sporadic and poorly coordinated.

SOLICITATIONS

The 1995 international Workshop in August 1995 spawned several initiatives, including two new Program Announcements. These call for applications in the areas of "Genetics of Parkinson's Disease" and the "Mechanisms of Cell Death and Injury in Neuro-degenerative Disorders," the latter also sponsored by the National Institute on Aging, the National Institute of Environmental Health Sciences, and the National Institute of Mental Health.

Parkinson's Disease Research Centers of Excellence. In November 1997, the NINDS issued a Request for Applications inviting grant applications in FY 1998 for Parkinson's Disease Research Centers of Excellence. This program is intended to foster multidisciplinary research in Parkinson's disease and related neurodegenerative disorders. It is anticipated that each Center will include both basic and clinical research in proportions that are appropriate for research objectives designed to achieve cross-fertilization and collaboration. In FY 1998 the NINDS will allocate up to \$5 million to support up to three Research Centers for up to five years of support. For applications received from groups with high potential but are not fully developed as Centers, a developmental center grant for up to \$350,000 in direct costs per year may be awarded.

PLANNED INITIATIVES

NINDS plans to issue an announcement calling for work on the cell biology of neurodegenerative disease. This initiative will complement a PA issued last year on the Mechanisms of Cell Death and Injury in Neurodegenerative Disease that is continuing to stimulate applications.

Epidemiology and Genetics Consortium. The NINDS plans to establish a small consortium of investigators and clinicians to develop and implement use of a database for Parkinson's and Parkinson's-related diseases, both sporadic and familial. This would provide a standardized format for ascertainment of families and collection of materials. Under the appropriate privacy protections, the data and materials would be made available to the entire research community.

Special Parkinson's Disease Research Activities by Fiscal Year:

FY 1997	FY1998	FY 1999
	o RFA— Research Centers of Excellence to be Funded	o Research Centers of Excellence (ongoing)
o PA—Clinical Trials	o Clinical Trials (ongoing)	o Clinical Trials (ongoing)
o PA—Genetics of Parkinson's Disease	o Lewy body/ Protein Aggregate Studies	o Genetics and Cell Biology Studies
o Collaborative Genetic Studies and Discovery	o Cold Spring Harbor Workshop	o Epidemology and Genetics Consortium
o PA—Mechanisms of Cell Death in Neurodegenerative Disorders	o Multiple System Atrophy Workshop	
	o PA—Cell Biology of Neurodegenerative Disorders (Perhaps with NIA, NIMH, NIEHS, NICHD, and NINR)	

FY1998 Congressional Appropriations Report Language.

Conference Report. "The conference agreement includes in modified form (section 603) language contained in the Senate bill authorizing funding for Parkinson's disease research at the National Institutes of Health (NIH). The agreement drops Senate language directing NIH to support particular research mechanisms and authorizes up to \$100,000,000 in fiscal year 1998 and such sums thereafter for these research activities. The House bill contained no similar provision. The conferees acknowledge the importance of Parkinson's disease research, but are concerned that inclusion of this language may set an unfortunate precedent for using the appropriations bill as a vehicle whenever the authorizing committees fail to act. While currently there is no cure for Parkinson's disease, the conferees are encouraged by recent scientific advances. Scientists have for the first time identified a gene abnormality that causes some cases of Parkinson's disease and which suggests an important new link between Parkinson's and Alzheimer's. Due to these promising research discoveries and the threat of more individuals being diagnosed with Parkinson's disease in future years, the conferees urge NIH to place stronger emphasis on research in this area."

House. "The Committee recognizes the personal and economic costs resulting from Parkinson's disease, amounting to nearly \$25 billion a year, and also notes the promising research in this field. The Committee was pleased to receive very moving and compelling testimony from Muhammad and Lonnie Ali about the need for more funding for Parkinson's research. Accordingly, the Committee urges the Institute to intensify its efforts to identify the factors contributing to the development of Parkinson's disease, to develop new methods of treating, delaying, or preventing this devastating illness, and to strengthen its research portfolio on Parkinson's. The Committee recommends that NINDS utilize all available mechanisms, as appropriate, including centers, requests for applications, program announcements, and extended funding of selected investigators now working in the field. The Committee also encourages the Institute to explore areas of promising research identified in the 1995 international workshop, to assist in developing new ideas in Parkinson's research, and to stimulate investigators in different, but related, fields to focus on this disease."

Senate. "The Committee continues to seek intensified and expanded efforts by the Institute to understand the pathophysiology of Parkinson's disease and develop effective therapies for this devastating disorder. The Committee was pleased to learn of important advances in the genetics of Parkinson's disease, resulting from collaborations developed after the international workshop sponsored by the NINDS in collaboration with the NIA, the NIEHS, and the NIMH. Other Institute initiatives, including two recent program announcements, have stimulated additional research that will provide important insights into this devastating disorder. However, much remains to be done to improve the outlook for patients and their families. The Committee recommendation includes sufficient funds for the Institute to expand funding for research in Parkinson's disease. This will allow a balanced program of basic and clinical research, including centers, clinical trials, and further work in the genetics and cell biology of neurodegenerative disease. The Committee notes that the Institute has made use of exploratory center grants and is developing a similar mechanism to encourage the design of high quality clinical trials. The Institute is encouraged to use these and other innovative mechanisms to stimulate the field, such as a consortium of investigators focusing on the genetics and epidemiology of Parkinson's

disease and the center without walls approach that proved successful for Huntington's disease research. The Committee looks forward to hearing about the progress of these efforts at the fiscal year 1999 hearing. The Committee also encourages the Institute to consider the creation of a position for a senior program officer with specific responsibility for the coordination of the NIH-wide Parkinson's research program."

The "Udall Bill" authorization provisions in Section 603 of P.L. 105-78 do not provide any additional funds for Parkinson's research. The Section authorizes appropriation of funds for Parkinson's research activities, but funding authority was already provided in basic NIH statutes. In the NINDS section of the explanatory Conference Report Language accompanying the resulting Appropriations Act (H.R. 2264; P.L. 105-78), the conferees state that they understood that "sufficient funds are available within the amounts provided for the Institute" (in the appropriations) to expand research on Parkinson's disease. In fact, with NINDS and other initiatives, the NIH total budget estimates for Parkinson's disease research are near to the \$100 million mark for FY 1998 (\$98.4 M) and well above it for FY 1999 (\$106.8M). While the "Udall" legislation would specify the funding level for "direct" costs only, the NIH is not in a position to exclude from its funding estimates research characterized as "related" to Parkinson's disease, since knowledge of the basic, fundamental neurological science underlying the mechanisms of the disease is vitally important to finally finding a prevention or cure.

Background on Parkinson's Disease

Parkinson's disease is a degenerative disease that impacts approximately 500,000 Americans, mostly over the age of 50. The National Institutes of Health estimates that the total annual direct and indirect effect of Parkinson's disease in 1992 was \$6 billion. The symptoms of this disease are tremor, gradual loss of movement, and rigidity. These symptoms are progressive and ultimately lead to disability and death.

While there is no known cure for Parkinson's, researchers have made encouraging strides on this disease. Last year, scientists made unprecedented progress in understanding the genetics of Parkinson's disease. Researchers are also focusing efforts on the biology of this disease, as well as possible surgical procedures, including brain stimulation, that might prove to be more effective than current drug therapies.

Since the President took office, there has been a nearly 50 percent increase in funding for Parkinson's at the NIH (\$71 million in FY 1993 and \$106 million in FY1999). NIH recently sponsored a new workshop to collaborate on genetic research in this area, and the Institute is currently collaborating with the Department of Veteran Affairs to identify families with Parkinson's and Parkinson's-related diseases to develop epidemiological studies.

Udall Authorization Bill

Despite increases in research at the NIH, the advocates (one of the most vocal disease advocates) do not believe there has been enough research in this area and have been long pressing hard for large budget increases. Last year, they were successful in attaching the Udall legislation (which they have been pushing for several years) onto the Labor-HHS Appropriations bill. This Udall bill authorized that at least \$100 million be spent on Parkinson's disease. Senator Wellstone is considered one of the main advocates for this bill, although it received broad bipartisan support in the Congress.

The NIH was not supportive of this legislation, because they oppose earmarking for research for any particular diseases. They have been quite effective at discouraging their appropriators from earmarking "disease by disease" and ensuring that the science determines funding for particular diseases.

The problem with this legislation is that it was passed as an authorization for more funds; it did not appropriate any additional funds for Parkinson's research. There is currently a difference of opinion as to whether the Udall bill provided for \$100 million additional in funding for Parkinson's disease on top of what NIH already spends or whether there just has to be \$100 million in research spent in this area.

NIH argues that since this legislation was an authorization rather than an appropriation, they only are required to fund \$100 million in total. They have been through similar cases and believe that the legal interpretation in this area clearly backs their position. However, NIH says they are sympathetic and extremely supportive of research on this disease. They did a thorough examination of promising research on Parkinson's disease for the President's FY1999 budget and allocated an \$8 million or about an 8 percent increase in funding in this area. The advocates are no doubt frustrated with the outcome, as they expected a much larger infusion of dollars from the legislation.

While we would recommend that you would, of course, convey great empathy for Mrs. Udall and her priorities, we believe that it would probably be advisable not to make a commitment on this legislation. Doing so would set a precedence for many other similar disease advocates, many of whom also can make strong arguments for the urgency of their cause. We have noted an increase in these requests following the diabetes research set-aside that was included in the Balanced Budget Act last year.

We can commit to pushing NIH to be more sensitive and responsive to the great potentials of research in this area. Chris Jennings has been receiving calls on this issue as well and is meeting with some Parkinson's advocates next week. You may want to see if Mrs. Udall would want to attend or send representatives to this meeting.

Christopher Reeve Files

Date: 2/18/99

FAX



Health Division



Office of Management and Budget
Executive Office of the President
Washington, D.C. 20503

To:

~~XXXXXXXXXX~~ / Chris

Fax:

65557

Phone:

From:

MARC GARVERI

Number of Pages (not including cover): 5

Subject: PER OUR CONVERSATION, ATTACHED IS SOME
BACKGROUND ON SPINAL CORD RESEARCH AND THE
PRESIDENT'S COMMITMENT TO C. REEVE.
CHRIS CAN CALL ME IF HE NEEDS MORE INFORMATION.

Please call if there are any problems with this transmission:

Health Division (Front Office)	202/395-4922
Health & Human Services Unit	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7840

5-6377



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

August 23, 1996

MEMORANDUM FOR THE CHIEF OF STAFF
HAROLD ICKES

FROM:

Jacob J. Lew
Acting Director

A handwritten signature in dark ink, appearing to be "J. Lew", written over the typed name and title.

SUBJECT:

Update on NIH's Plans for Achieving the President's Commitment to Increase FY 1996 Funding for Spinal Cord Research

On May 15, 1996, Christopher Reeve met with the President to express concern that NIH funding for spinal cord research was insufficient. We understand that at the meeting the President committed to increase NIH funding for spinal cord research by *up to* \$10 million in FY 1996. Christopher Reeve announced to the press that the President had promised to work with NIH "to find \$10 million that will go to spinal cord research." NIH's initial FY 1996 plan included \$49 million for spinal cord research.

Given the sensitivity of this issue, we asked HHS to provide a NIH spinal cord research plan for achieving the President's request. The NIH plan appears to be consistent with the President's commitment. The three elements of the plan are:

- NIH indicates that between now and September it will fund 12 grants and four awards to young investigators that would not have been supported otherwise. Thus, this means NIH will be spending an additional \$5 million over the \$49 million it originally intended to spend on spinal cord research in FY 1996. This increase appears to achieve the President's commitment to spend *up to* an additional \$10 million on spinal cord research this fiscal year.
- In addition, NIH intends to increase its planned FY 1997 funding for spinal cord research by \$10 million, which will raise FY 1997 NIH spinal cord research funding by 20%, from \$50 million to \$60 million.
- To foster high-quality spinal cord research grant applications and encourage researchers to enter the field of spinal cord injury research, NIH plans to hold a conference on spinal cord research at the end of September.

If you have any additional questions or concerns about NIH spinal cord research, or if we should supply this information to anyone else, please let me know.

NATIONAL INSTITUTES OF HEALTH

Spinal Cord Injury Research

QUESTION:

Following the President's visit with Christopher Reeve and his pledge to increase spending for spinal cord regenerative research, what has been done?

ANSWER:

- ▶ The NIH, under Dr. Varmus' leadership, is currently accessing the expansion of potential projects which are focused on regenerative research.
- ▶ NIH had projected spending \$49.4 million in FY 1996 on this field of research. With the President's pledge, NIH is at work developing additional projects. The President promised that we would spend up to \$10 million more than was in our previous plan for FY 1996.

NIH Spinal Cord Injury Research

(Dollars in millions)

<u>1995</u>	<u>1996</u>	<u>1997 P.B.</u>	<u>Change</u>	<u>% Chg.</u>
\$47.0	\$49.4*	\$50.4	+\$1.0	+2.0%

* Following President Clinton's meeting with Christopher Reeve, the NIH will be spending up to an additional \$10 million on spinal cord injury research.

ADDITIONAL INFORMATION:

- ▶ Funding: NIH expects to spend about \$50 million in 1997 on research on spinal cord injury. Within NIH, this research is supported primarily by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Child Health and Human Development (NICHD).
- [ALERT: Advocates of spinal cord injury research, led by actor Christopher Reeve, are waging a public campaign to seek an additional \$40 million in NIH for this purpose. Both Senators Specter and Harkin, following the President's visit with Christopher Reeve, pledged to find the necessary additional funding.]
- ▶ NINDS Research: NINDS supports several large, multiproject centers devoted to clinical and basic research on spinal cord injury. The projects range from fundamental studies of cellular responses to injury to clinical studies of movement

in chronic spinal cord injury. Specific examples include:

- Multicentered Animal Spinal Cord Injury Study supports a consortium of laboratories testing promising pharmacological agents in a standardized model of spinal cord injury in order to make more drugs available for clinical testing.
- Neural Prostheses are being developed to restore nervous system functions, such as sensation or movement. Already this program has yielded:
 - A hand-grip prosthesis that enables paralyzed people to pick up objects or to grasp a cup and drink without assistance;
 - Tiny electrodes, measuring about one-third the width of a human hair, that can be implanted inside the body and used to stimulate muscle or nerve cells;
 - New understanding of the nervous system and its pathways that will help scientists place future prostheses in the most effective location; and
 - Artificial sensors that may help paralyzed patients to better control movement.
- DNA Damage and Repair: Because DNA damage is present in central nervous system (CNS) injury and defects in repair mechanisms are also associated with neurodegenerative disease, NINDS supported a workshop, "DNA Damage and Repair," in September 1995, to bring together scientists and clinicians with expertise in DNA injury and repair with investigators in CNS trauma to foster research in this new area of science.
- Implanted Progenitor Cells: In March 1996, NINDS issued a Request for Proposals to investigate the use of implanted progenitor cells to treat central nervous system trauma. Recent discovery of the presence of progenitor cells within the adult nervous system has suggested another potential source of replacement tissue for the injured CNS.
- ▶ NICHD Research: The National Center for Medical Rehabilitation Research (NCMRR, a component of NICHD) is emphasizing the support of research to promote the independence, productivity, and health of people with spinal cord injury. Included in that research are studies seeking:
 - Better ways of preventing urinary tract infections and skin problems to which people with spinal cord injury are prone;
 - Improvements in uses of computer-controlled electrical stimulation to make walking possible; and
 - More effective means of dealing with the chronic pain that many of these people experience.
- ▶ About 200,000 Americans are now permanently confined to wheelchairs because of spinal cord injury.

- ▶ Each year, about 10,000 more people are injured, suffering paralysis and loss of sensation. About two-thirds of these people are under the age of 30.
- ▶ Specialized care for people with spinal cord injury costs our Nation as much as \$10 billion each year.

**NATIONAL INSTITUTES OF HEALTH
Spinal Cord Injury**

(Dollars in thousands)

ICD	1997 Actual	1998 Estimate	1999		
			Pres. B.	vs. 98	% Chg
NINDS....	\$46,541	\$49,471	\$53,481	+\$4,010	+8.1%
NICHD....	4,648	5,500	5,800	+300	+5.5%
NEI.....	6,825	7,321	7,910	+589	+8.0%
NIMH.....	997	1,035	1,117	+82	+7.9%
NIDA.....	464	500	550	+50	+10.0%
NINR.....	0	0	0	+0	+0.0%
NCRR....	1,088	1,188	1,386	+198	+16.7%
Total.....	\$60,563	\$65,015	\$70,244	+\$5,229	+8.0%

TELEFAX TRANSMITTAL

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Director, National Institutes of Health
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DATE: November 30, 1998

TO: Chris Jennings
Deputy Assistant to the President
for Health Policy Development

FAX NUMBER: 202-456-5557

PHONE NUMBER: 202-456-5560

NUMBER OF PAGES (INCLUDING COVER PAGE): 8

[] PLEASE CALL TO CONFIRM RECEIPT. THANK YOU.

REMARKS: Per telephone conversation.

Questions and Answers for 12/2 hearing

November 30, 1998

- **What are human embryonic stem cells and are they related to human embryo research?**

Because the term "embryonic stem cell" can be so easily confused with the embryo itself, it is preferable to refer to these cells as "pluripotent stem cells." ~~The term "embryonic stem cell" was borrowed from mouse research, which derived stem cells from mouse embryos.~~ Human pluripotent stem cells are cells of an organism which have an unlimited capacity to divide, and the ability to turn into many of the cells or tissues in the body. They are related to human embryo research in that one of the ways pluripotent stem cells can be derived is from the human embryo. These stem cells are not themselves embryos and would not develop into a fetus or result in a live birth if implanted into a woman's uterus. Pluripotent stem cells can also be derived from human fetal tissue. It is believed that pluripotent stem cells can also be derived from cells created by somatic cell nuclear transfer.

- **What is human embryo research?**

Human embryo research involves studies of human fertilization (entry of sperm into a mature egg) and the subsequent several cell divisions that occur in a laboratory dish. This research is also called human in vitro fertilization research. The research is only conducted at these very early stages of development. At these stages, the embryo is also referred to as a preimplantation embryo because it is not yet to the point at which it would have finished implanting into the wall of the uterus. Human embryo research does not involve human embryos (or fetuses) developing in the uterus. It does not involve abortion or aborted human fetal tissue.

Unfortunately, the widely used term "embryo research" has caused a misperception about the nature of this work. In fact, the research is conducted with the one-cell product of fertilization and the subsequent few cell divisions that follow fertilization.

- **What are pluripotent stem cells?**

Pluripotent stem cells are cells from an organism that have an unlimited capacity to divide and the ability to turn into many different types of cells or tissues in the body. These stem cells are not themselves embryos and would not develop into a fetus or result in a live birth if implanted into a woman's uterus. They can be derived from embryos,

from fetal tissue germ cell tissue, and possibly by using somatic cell nuclear transfer technology.

- **Are pluripotent stem cells embryos? Do they have the potential to become embryos?**

Pluripotent stem cells are not embryos because they do not have the capacity to develop into a fetus if implanted into a woman's uterus. On their own, pluripotent stem cells do not have the potential to become embryos.

- **Do the regulations that govern human subjects research cover embryo research? Do they cover fetal tissue research? Would they cover embryonic stem cell research?**

Human embryo research is covered by DHHS regulations, 45 CFR 46 Subpart B entitled, "Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization." The regulations require that, before being initiated, research involving human in vitro fertilization must be reviewed and approved by an institutional review board. In addition, research involving human embryos or fetuses developing in the uterus is regulated by 45 CFR 46.201-46.211. Human embryos, however, are not considered human subjects under the HHS human subjects regulations. Although NIH is currently prohibited from supporting IVF and preimplantation embryo research due to a Presidential directive and Congressional ban, this research would be permitted under the human subject regulations. The 1994 Presidential directive prohibits the use of Federal resources to support the creation of human embryos for research purposes. In addition, in FY 1996 appropriations law (P.L. 104-99), DHHS was prohibited, for the first time, from conducting or supporting human embryo research. This annual prohibition in appropriations law has been repeated in every subsequent year since. The current appropriations law is P.L. 105-277. The language prohibits DHHS from supporting research in which a human embryo or embryos—organisms derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells—are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

These regulations would not cover research on the pluripotent stem cells derived from either embryos or fetal tissue, since the stem cells themselves are not embryos.

Human fetal tissue research—the study of tissues and cells from *nonliving* fetuses—is also addressed in Subpart B of the HHS human subject regulations (45 CFR 46.210), requiring that such research be conducted only in accordance with any applicable State or local

laws regarding such activities. Furthermore, the regulations require that individuals engaged in research involving fetuses, pregnant women, and human IVF will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy (45 CFR 46.206(a)(3)(I)). Nonliving fetuses are not considered human subjects under the regulations. In addition to these regulations governing human fetal tissue research, section 498A of the Public Health Service Act (42 U.S.C. 289g-1) permits HHS to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes, but such tissue may be used for research only if a number of statutory requirements are met.

- **Has NIH ever funded human embryo research? Has NIH ever considered funding human embryo research?**

The NIH has never funded human embryo research. From 1980 to 1993, Federal funding of human embryo research was subject to a de facto administrative moratorium. In 1993, Congress passed legislation (P.L. 103-43) that effectively nullified this moratorium, making it possible for NIH to consider funding human embryo research. The NIH did not proceed, however, without first broadly considering the moral and ethical questions raised by such research and developing guidelines for its review and conduct.

During 1994, therefore, the NIH organized a multi-disciplinary panel of experts—composed of 19 people from outside government with diverse background in science, ethics, law, sociology, theology, public health, and public policy—to study the ethical, scientific, medical, and public policy implications of Federal funding of this research. The work of this panel was carried out in open forums, involved substantial public input, and led to the formulation of recommendations for stringent guidelines that would govern the review and conduct of any future research that might be considered for funding by the NIH. The panel also recommended areas of research that were acceptable for Federal funding, were not acceptable for Federal funding, and areas that required further consideration.

- **Has NIH ever funded research on human pluripotent stem cells?**

The NIH has not funded research involving human pluripotent stem cells from either sources of these cells, human embryos or fetal tissue. However, NIH does fund research on human stem cells that are derived from sources such as adult blood cells. These stem cells can go on to differentiate into several different kinds of blood cells. Although they are also considered pluripotent, they have limited capacity to turn into other cells of the body.

- **If Federal funding of human embryo research were allowable, would NIH institute any limits to that funding and what standards would be applied to decide which research to fund?**

When this matter was initially under consideration in 1994, the NIH carefully considered the ethical, legal, scientific, and medical issues before moving forward and, with the help of a group of diverse outside experts, defined areas that should and should not be supported with Federal funding. The panel recommended that special guidelines be applied that would go beyond what is required of other areas of research and that an ad hoc review body be established at the Federal level to provide further oversight of the research. Had subsequent funding bans not been instituted, the NIH would likely have proceeded with the development of guidelines and the establishment of the review body.

- **If Federal funding of pluripotent stem cell research were allowed, would NIH institute any limits to that funding and what standards would be applied to decide which research to fund?**

Given the ethical and legal considerations as well as the need for clarification about Federal funding restrictions in closely related areas, the NIH would develop guidelines for the conduct of this research. As always, research proposals would be peer reviewed and funded on the basis of merit.

- **What are the arguments for the Federal investment in this research?**

Federal funding of this work would engage the attention of many more people and would bring more oversight to this area. For example, more investigators would likely enter the field and the pace of this critical work would be enhanced. In addition, Federal government involvement in this research area would also provide important scientific and ethical oversight. Federally supported research goes through rigorous ethical and scientific review, including detailed discussions at local institutional review boards (IRB) meetings, peer review groups and National Advisory Council meetings. This would encourage openness, ensure that researchers could use these important research tools, and assure public access to research information and to the practical medical benefits of this research. This would also increase the opportunities for collaboration in this research arena and sharing of data.

- **Is Federal funding of human fetal tissue research allowed?**

Federal funding of human fetal tissue research is allowed, and the NIH is funding studies that involve both basic and clinical investigations. Between 1988 and 1993, an administrative moratorium was in place that prohibited research involving clinical or therapeutic transplantation of human fetal tissue. Congress overturned the moratorium and added provisions to the Public Health Service Act that spelled out stringent rules that would have to be followed by Federally funded investigators. These rules include detailed informed consent procedures and a prohibition on commercialization of fetal tissue that would need to be followed if the research were to be Federally funded.

- **How does current law apply to research on the derivation of pluripotent stem cells?**

The stem cells isolated in Dr. Thomson's research were derived from spare embryos donated by couples who had undergone infertility treatment. Public Law 105-277 prohibits Federal funding of research in which an embryo is destroyed or harmed, therefore this work clearly falls within the Congressional ban on human embryo research.

Dr. Gearhart derived his pluripotent stem cells from fetal tissue. The Public Health Services Act includes a restriction on fetal tissue research. The Secretary, HHS, may conduct or support fetal tissue research and research on the transplantation of human fetal tissue for therapeutic purposes, but such tissue may be used in research only if a number of statutory requirements are met. Thus, as long as Dr. Gearhart followed these Federal statutes and regulations, NIH could support his recent work. This research was, however, supported from other non-Federal sources.

The work allegedly carried out by Dr. West's company involved fusion of a skin cell from an adult with an enucleated egg from a cow. It is not clear that the product of this fusion is an embryo, and if so, whether it is a human embryo. Therefore, how current law applies to this research is not clear.

- **Would current law prohibit NIH from funding research on pluripotent stem cells derived from human embryos or fetal tissue?**

The DHHS Office of General Counsel has advised that Federal funding of research that *utilizes* the cells and cell lines that resulted from Dr. Thomson's research is not prohibited. Pluripotent stem cells are not embryos since the cells that are necessary for implantation and embryo development have been lost in the derivation process. Because human pluripotent stem cells are not embryos, research on them is not research in which an embryo is created for research purposes, and it is not research in which embryos are

harmful, destroyed or discarded. This research, thus, would not violate the statutory prohibition. Using human fetal tissue, Dr. Gearhart derived human pluripotent stem cells that appear to be similar to Dr. Thomson's. The cell lines developed by Dr. Gearhart are from fetal tissue, not embryos. Further research on these cell lines would not violate the human embryo research ban for the same reasons stated above with regard to Dr. Thomson's cell line.

- **Were NIH funds used to support Dr. Thomson's research? Dr. Gearhart's? Dr. West's?**

NIH did not support the research of these investigators to derive pluripotent stem cells.

- **Has NIH ever supported the work of these investigators and, if so, what was the substance of that work?**

NIH supports the work of Dr. Gearhart on Down's syndrome using a mouse model and Dr. Thomson's work on non-human primate pluripotent stem cells.

- **Since Dr. Thomson's work is prohibited and Dr. Gearhart's is not, why not just encourage scientists to work with Dr. Gearhart's cell line?**

It is not known at this time whether or not the cells derived by these two investigators have identical capacities. Therefore, both lines of inquiry should be pursued.

- **Are there examples of research that have not been legally restricted but for which NIH has established special review and oversight procedures? How has NIH provided the oversight to ensure the research moves forward, while the ethical, legal, and social implications of the research are given full and public consideration?**

In the 1970s, when it was first possible to use molecular cloning in bacteria, there was a great deal of public apprehension about possible risks of the research. Fortunately, however, legislation was not enacted to ban the research. Instead, the scientific community established a voluntary moratorium until guidelines could be developed to govern the research. Guidelines were written by the NIH in a public process to provide oversight of the research. The Recombinant DNA Advisory Committee was also established to ensure public review of the research and ongoing policy development to keep pace with scientific progress. With the advent of human gene therapy, the NIH Guidelines were extended to address specific concerns associated with human trials. For

example, the NIH Guidelines state that protocols involving germline gene therapy will not be considered.

Xenotransplantation—which involves the transfer of living animal cells, tissues, and whole organs into humans—is another example. Xenotransplantation holds the promise of providing a means to treat a wide range of disorders, including diabetes, Parkinson's disease, and end-stage renal failure. However, it also presents a number of public health and ethical challenges, including the potential risk of transmission of infectious agents from animal donors to patients, their close contacts, and the general public; informed consent at individual and community levels; animal welfare issues; and social equity in access to novel biotechnologies. To this end, DHHS has issued draft Guidelines for the conduct of this research and is planning to establish a Secretarial Advisory Committee on Xenotransplantation. The Secretary's Advisory Committee on Xenotransplantation will provide an ongoing group to consider the full range of complex scientific, social, and ethical issues and the public concerns raised by xenotransplantation, including ongoing and proposed protocols, and makes recommendations to the Secretary on policy and procedures.

- **Are there any restrictions on this research in the private sector?**

With the exception of prohibitions on the commercialization of human fetal tissue, we are aware of no other restrictions in Federal statute affecting the conduct of this kind of research in the private sector.

- **If the government supports research on these cell lines, wouldn't it create an incentive to create embryos for research purposes or encourage abortions?**

Couples undergo infertility treatment and in vitro fertilization procedures for personal reasons that have little if anything to do with a desire to advance research. Likewise, the decision to terminate a pregnancy is also made for personal reasons, and there is no evidence that fetal tissue research has encouraged abortions.

Furthermore, steps can be taken to ensure that Federally funded research does not inadvertently create such incentives. For example, in part to address concerns that human fetal tissue research could encourage abortion, Federal law and regulations require a separation between fetal tissue research and decision-making regarding the termination of a pregnancy. Federal law prohibits the commercialization of fetal tissue.

~~SECRET~~
Stem cell research file

THE WHITE HOUSE
WASHINGTON
November 23, 1998

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: NEAL LANE *Neal*
BRUCE REED

SUBJECT: NBAC response concerning human cell/cow egg fusions

Dr. Harold Shapiro, Chair of your National Bioethics Advisory Commission (NBAC), sent you a letter on November 21 in response to your request that the Commission review the ethical, medical and legal concerns associated with fusing human cells to cow eggs. NBAC agrees with your view that this kind of research evokes serious concerns. The main points of the letter are:

- The ethical ramifications of these experiments depend heavily on whether or not the hybrid cell can become an embryo or support the development of a child.
- Because there is not yet enough scientific evidence to answer that question, NBAC discussed the ethical issues associated with three different possibilities:
 - NBAC agreed with you that any attempt to develop a **child** from these hybrid cells would raise the most profound ethical issues and should not be permitted.
 - If the hybrid cells have the capacity to develop into an **embryo**, the ethical issues that surround the creation of an embryo by any other means also apply here, and are complicated rather than simplified by the presence of non-human genetic material.
 - If the hybrid cell does not give rise to an embryo or support the development of a child, then its creation is no more controversial than other molecular engineering procedures.

Harold Varmus will be providing testimony at a Senate hearing on embryonic stem cell research, to be held on December 1 or 2. OSTP, DPC, and HHS are working together to plan a strategy for addressing this issue with Congress in the coming months.

Attachments

cc: Vice President
Chief of Staff



NATIONAL BIOETHICS ADVISORY COMMISSION

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20892-7508

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November 20, 1998

The President
The White House
Washington, DC 20500

Dear Mr. President:

I am responding to your letter of November 14, 1998 requesting that the National Bioethics Advisory Commission discuss at its meeting in Miami this week the ethical, medical, and legal concerns arising from the fusion of a human cell with a cow egg.

The Commission shares your view that this development raises important ethical and potentially controversial issues that need to be considered, including concerns about crossing species boundaries and exercising excessive control over nature, which need further careful discussion. This is especially the case if the product resulting from the fusion of a human cell and the egg from a non-human animal is transferred into a woman's uterus and, in a different manner, if the fusion products are embryos even if no attempt is made to bring them to term. In particular, we believe that any attempt to create a child through the fusion of a human cell and a non-human egg would raise profound ethical concerns and should not be permitted.

We devoted time at our meeting to discussing various aspects of this issue, benefiting not only from the expertise of the Commissioners, but from our consultation (via telephone) with Dr. Ralph Brinster, a recognized expert in the field of embryology, from the University of Pennsylvania. Also in attendance at our meeting was Dr. Michael West, of Advanced Cell Technology, who was given an opportunity to answer questions from Commission members. As you know, however, the design and results of this experiment are not yet publicly available, and as a consequence the Commission was unable to evaluate fully its implications.

As a framework for our initial discussion, we found it helpful to consider three questions:

1. ***Can the product of fusing a human cell with the egg of a non-human animal, if transferred into a woman's uterus, develop into a child?***

At this time, there is insufficient scientific evidence to answer this question. What little evidence exists, based on other fusions of non-human eggs with non-human cells from a different species, suggests that a pregnancy cannot be maintained. If it were possible, however, for a child to develop from these fused cells, then profound ethical issues would be raised. An attempt to develop a child from these fused cells should not be permitted.

Harold T. Shapiro, Ph.D.
Chair

Patricia Backlar

Arturo Brito, M.D.

Alexander M. Capron, LL.B.

Eric J. Cassell, M.D.

R. Alta Charo, J.D.

James F. Childress, Ph.D.

David R. Cox, M.D., Ph.D.

Rhetaugh G. Dumas, Ph.D., R.N.

Laurie M. Flynn

Carol W. Greider, Ph.D.

Steven H. Holtzman

Bette O. Kramer

Bernard Lo, M.D.

Lawrence H. Miike, M.D., J.D.

Thomas H. Murray, Ph.D.

Diane Scott-Jones, Ph.D.

Eric M. Meslin, Ph.D.
Executive Director

Henrietta Hyatt-Knorr, M.A.
Deputy Executive Director

This objection is consistent with our views expressed in *Cloning Human Beings*, in which we concluded that:

"...at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning."

2. ***Does the fusion of a human cell and an egg from a non-human animal result in a human embryo?***

The common understanding of a human embryo includes, at least, the concept of an organism at its earliest stage of development, which has the potential, if transferred to a uterus, to develop in the normal course of events into a living human being. At this time, however, there is insufficient scientific evidence to be able to say whether the combining of a human cell and the egg of a non-human animal results in an embryo in this sense. In our opinion, if this combination does result in an embryo, important ethical concerns arise, as is the case with all research involving human embryos. These concerns will be made more complex and controversial by the fact that these hybrid cells will contain both human and non-human biological material.

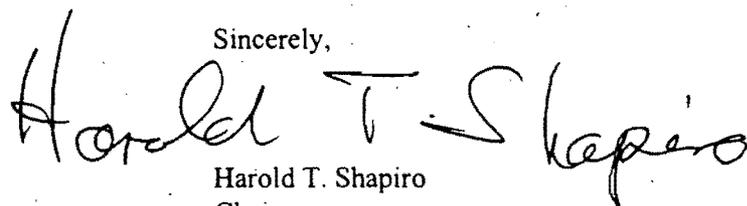
It is worth noting that these hybrid cells should not be confused with human embryonic stem cells. Human embryonic stem cells, while derived from embryos, are not themselves capable of developing into children. The use of human embryonic stem cells, for example to generate cells for transplantation, does not directly raise the same type of moral concerns.

3. ***If the fusion of a human cell and the egg of a non-human animal does not result in an embryo with the potential to develop into a child, what ethical issues remain?***

If this line of research does not give rise to human embryos, we do not believe that totally new ethical issues arise. We note that scientists routinely conduct non-controversial and highly beneficial research that involves combining material from human and other species. This research has led to such useful therapies as: blood clotting factor for hemophilia, insulin for diabetes, erythropoietin for anemia, and heart valves for transplants. Combining human cells with non-human eggs might possibly lead some day to methods to overcome transplant rejections without the need to create human embryos, or to subject women to invasive, risky medical procedures to obtain human eggs.

We recognize that some of the issues raised by this type of research may also be pertinent to stem cell research in general. We intend to address these and other issues in the report that you requested regarding human stem cell research.

Sincerely,

A handwritten signature in black ink that reads "Harold T. Shapiro". The signature is written in a cursive style with a large, prominent "H" and "S".

Harold T. Shapiro
Chair

THE WHITE HOUSE

WASHINGTON

November 14, 1998

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

Dear Dr. Shapiro:

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

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

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

Sincerely,

Bill Clinton

1/2

Researchers Claim Embryonic Cell Mix Of Human and Cow

AI
By NICHOLAS WADE

Venturing deep into uncharted realms of ethics and medicine, a small biotechnology company said yesterday that its scientists had for the first time made human cells revert to the primordial, embryonic state from which all other cells develop, by fusing them with cow eggs and creating a hybrid cell.

The research comes from biologists who are well known in their field but has yet to be confirmed or published in a scientific journal. Their company, Advanced Cell Technology of Worcester, Mass., said the method could eventually be used to grow replacement body tissues of any kind from a patient's cells, sidestepping the increasing scarcity of organs available for transplant and the problems of immune rejection.

The technique is likely to concern and perplex ethicists because it would involve the creation of an embryonic cell that is part human and part cow, consisting of a human cell's nucleus in a cow egg whose own nucleus had been removed. The company said the hybrid cell quickly became more humanlike as the human nucleus took control and displaced cow proteins with human proteins. Creation of the embryonic cells is an important component of a strategy that in principle offers high medical benefits if it can overcome the high barrier to public acceptance.

The technique would involve creating an embryo of uncertain moral status, and one that crosses the barrier between humans and other species. Even though a hybrid would be in the form of cells, not a whole organism, the concept of half-human creatures arouses deep-seated anxiety, as is evident from the unfriendly powers ascribed to werewolves, centaurs, mermaids, Minotaurs and other characters of myth and folklore.

"Many people are going to be horrified by this scenario, others will say 'So what?'" said Thomas Murray, director of the center for biomedical ethics at Case Western Reserve University in Cleveland and a member of the National Bioethics Advisory Commission. "This is the sort of thing that makes me very uncomfortable," Dr. Murray said. "I think we are likely to get a very powerful reaction to it, and I would like for all of us to have a breathing space here to articulate our moral concerns."

Another serious uncertainty is the preliminary nature of Advanced Cell Technology's work. No article has yet been submitted for peer review and publication in a scientific journal, an essential touchstone of credibility. Scientists asked about the company's work said they would require much more proof before believing that human embryonic stem-like cells had been created as the company contends, and some were skeptical that the technique would work.

Announcement Tests the Waters

The company said yesterday that it had performed the work with hybrid cells two years ago. Dr. Michael D. West, Advanced Cell Technology's chief executive, said that he was announcing the work to test its public acceptability. He said the company, which is privately held, was not planning to go public or raise money now but needed to decide whether to commit money to development of the technique.

Some scientists praised Dr. West's decision to make his work public but others were critical, saying he has invited a possibly fraught public debate on a slender basis of fact.

Dr. West is the founder of Geron, a biotechnology company in Menlo Park, Calif., that has had two spectacular successes this year in research on aging. In January it developed a method for "immortalizing" human cells grown in the laboratory by making them leap the supposedly immutable barrier at which cells usually lapse into senescence. Last week two university teams sponsored by Geron said they had isolated and cultivated human embryonic stem cells, the all-purpose cells from which the fetus develops. Dr. West laid the foundations for these developments by sponsoring leading scientists in the two fields.

Researcher Uses His Own Cells

Advanced Cell Technology, which Dr. West joined in October, has focused on cloning and genetically improving cows, a technology developed by James M. Robl and colleagues at the University of Massachusetts at Amherst. Dr. West said he hoped to use the technology to further the idea on which he founded Geron, that of delving into the mystery of human aging and sidestepping some of its processes.

The work with human cells was performed in 1996 by Jose Cibelli, a colleague of Dr. Robl's at the University of Massachusetts. Using 52 of his own cells, some of them white blood cells and others scraped from the inside of his cheek, Dr. Cibelli fused each one with a cow egg whose own nucleus and DNA had been removed. Most failed to thrive but one embryo grew and divided five times, generating cells resembling embryonic stem cells. Dr. Cibelli and Dr. West say the method could be made more efficient with present technology. They use cow eggs because these are far cheaper and more available than human eggs and raise no ethical problems.

Considering this work was sufficient to describe an invention, Dr. Robl and Dr. Cibelli filed a patent application and then set the research aside to focus on the more immediately practical field of cow cloning, they said. Only two others beside himself and Dr. Robl knew what had been done, Dr. Cibelli said. The patent has not yet been issued but Dr. West said he was confident of receiving "important intellectual prop-

erty" in the field. He said he is making the hybrid cell technique public now "because I want to be very open and level with everyone. We need to get the ethicists to talk about it so as to encourage a rational response to these new technologies."

Dr. Cibelli said he regarded any embryos obtained in this way as "not a separate individual, just a de-differentiated cell from a patient." Differentiation is the process whereby the all-purpose cells of the very early embryo, known as human embryonic stem cells, become committed to their roles as the various specialized tissues of the body. The process is irreversible in nature, but egg cells apparently have the ability to de-differentiate, or reset to default mode, the settings in a specialized cell's nucleus. This is presumably what happened in the experiment reported this July when mice were cloned by transferring the nucleus of an adult mouse cell into another mouse's egg cell.

Dr. Cibelli, who trained as a veterinarian in Argentina, said he and his colleagues "were the first to de-differentiate a human cell by nuclear transfer." Asked if he was concerned about destroying, in principle, potential twins of himself, he said: "I never thought about it, it's a good question. But if you use your own cells to treat a disease you may have, you are not taking cells from another person selfishly."

Dr. West and Dr. Cibelli said they had no intent of transferring the embryos to a uterus, a step considered unethical and unsafe: the embryos would be created solely for the purpose of tissue culture. "Any technology can be abused, but once the public understands how these cells can be used to treat any disease caused by loss or malfunction of cells, from Parkinson's to diabetes to heart disease, the concerns will be overshadowed," Dr. West said.

Lack of Evidence Raises Doubts

Whether Dr. West's prediction will be borne out depends on two major sets of factors, the scientific validity of the proposed method and the ethical and legal questions that related work has already raised.

From discussions with scientists, ethicists and lawyers in the past few days, these concerns have emerged.

Scientists are particularly critical of the lack of supporting evidence accompanying Advanced Cell Technology's announcement, saying in essence the claim could be true but there is no compelling reason to accept it. Even if the claim is valid, biologists note a serious uncertainty relating to an important component of the cells known as the mitochondria, which produce the energy the cell needs and are, in essence, its batteries. If the bovine mitochondria should prove incompatible with their humanized environment, the cells will not be viable.

Ethicists said the mixing of species was likely to trouble the public severely, at least at first. Lawyers who specialize in issues of human reproduction note that the moral and legal status of the human embryo is undecided in American law, a fact pointed up by the isolation of the human embryonic stem cells announced last week. The new entry adds further complexity.

If Advanced Cell Technology can produce viable hybrid cells, they would offer a new route to growing new tissues for transplant. This is the same goal held by the scientists who announced last week that they had grown human embryonic stem cells in the laboratory. It is widely accepted in principle that embryonic stem cells can be directed to develop into any desired tissue, with enormous potential for medicine, though this has yet to be achieved in practice.

Dr. West said the advantage of the Advanced Cell Technology method is that embryonic cells derived from the patient being treated would generate entirely compatible tissues. The two methods reported last week, by Dr. James A. Thomson of the University of Wisconsin and Dr. John

Gearhart of the Johns Hopkins University, derive stem cells from human embryos or fetuses. Tissues made from these cells would be incompatible with the patient, a problem that has not been resolved.

In support of its claim, Advanced Cell Technology supplied a patent application and a photograph taken of its embryonic cells under a microscope. The patent application describes how the cells are made but provides no proof that they possess the properties to be expected of human embryonic stem cells. Dr. Robi said his laboratory was not set up to perform the required tests at the time the hybrid cells were made.

Shown the photograph of the purported hybrid cells, Dr. John Gearhart of Johns Hopkins, author of one of the two methods reported last week, said that "they certainly could be embryonic stem cells" but that no scientific journal would publish the result without further proof. "It's not that I don't believe this biologically, I just think they could have given a little bit more assurance as to what was done here."

Dr. Roger Pedersen of the University of California, San Francisco, who also works on human embryonic stem cells, said he doubted any hybrid cells would last long enough to develop into useful tissue because of their cow-derived mitochondria. The mitochondria of chimpanzees and gorillas work well enough in human cells but those of primate species that diverged more than 10 million years ago from the human line, do not work.

Because cows and humans last shared an ancestor so long ago, cow mitochondria are very unlikely to work well with a human nucleus, in Dr. Pedersen's view, and as most of the mitochondria in the hybrid cells are contributed by the cow egg, the cells would probably not remain viable for long. "It's hard to say this is a total sham, but I smell a sham here," he said.

Citing the same data, Dr. Gearhart said the mitochondria in the hybrid cell had clearly carried it through its first few divisions but might not sustain it in further development, unless the few human mitochondria that were also present somehow took over.

Dr. Pedersen said Advanced Cell Technology should be held to a high standard of proof "because of what the implications are for upsetting people unnecessarily — if you cry fire in a crowded auditorium you may be liable if it's a false alarm."

New Frontiers For Medical Ethics

The human embryonic stem cells announced last week have already pushed against the frontiers of ethical acceptance. Experts in biomedical ethics say the public is likely to be alarmed by the new technique, particularly because of the mingling of species. Dr. Murray of Case Western Reserve University in Cleveland said that the hybrid embryo "escapes our usual categories." When biologists first learned to transfer genes from one species to another, "The idea of human-animal hybrids was often raised as the kind of monstrosity that no morally perceptive person would ever create," he said.

"Even if it's only to create tissue, the minute you start mixing species you raise all kinds of red flags in people's minds," said Bernie Steinboch, a moral philosopher at the State University of New York in Albany. But she noted that pig valves are now seen as acceptable replacements in human hearts.

Rebecca Dresser, a law professor at Washington University in St. Louis, noted, as did several biologists, that distinctions between humans and other animals are less clear in nature than they are in people's minds. "Biologically a lot of this research is showing us similarities and the upshot in a hundred years may be that the lines between humans and nonhumans will be viewed as a little bit grayer," Professor Dresser said.

A perplexing feature of the hybrid embryo would be that it would start mostly bovine, then become mostly yet not entirely human. But some legal experts have no doubt that any hybrid should be regarded from the start as a human embryo. "It doesn't matter that the mitochondria come from a cow, it also has human mitochondria and so has all the potentials of a human embryo," said Lori Andrews, a professor at the Chicago-Kent College of Law in Chicago.

"Once it's gone through that first division it has gone from being a somatic cell to a thing with potential life," Dr. Andrews said, referring by somatic to the ordinary specialized cells of the human body. If transferred to a woman's uterus the embryos might or might not come to term, "but under state laws it doesn't matter whether the fetus is going to be born or not — it doesn't make them less human."

The human body consists of 100 billion cells. Should embryos created from them by the cow egg method be regarded as having special status when they can be made so easily and plentifully? Dr. Andrews said that human embryos are not so hard to make the usual way, and the fact that an embryo is easily made, by whatever means, is irrelevant to arguments about its status.

The moral status of the human embryo "is not clearly established in U.S. law," Dr. Dresser said. The embryo can be regarded as mere property, as a person, or as something in between but deserving of special respect. Congress, in banning the use of Federal money for research on human embryos, has favored the view that they are in the category of people. But in custody battles over fertilized embryos, courts have favored the special respect status. Dr. Dresser said the hybrid cells could be seen as between the property and special respect status.

The company said the hybrid cells were made by Dr. Cibelli in Dr. Robi's laboratory in the University of Massachusetts at Amherst. Michael Weinberg, executive secretary of the university's human subjects committee, said the experiment was given administrative approval, without review by the committee or major discussion. Dr. Cibelli was using his own cells, not experimenting on other people, and self-experimentation does not require special consent. "If someone wants to inoculate themselves they can do that," Dr. Weinberg said.

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DAIMLERCHRYSLER

November 18, 1998

Human-Cow Hybrid Cells Are Topic of Ethics Panel

Forum

- [Join a Discussion on Beyond Dolly: The Future of Cloning](#)
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By NICHOLAS WADE

At the request of President Clinton, the ethical implications of creating hybrid human-cow cells were discussed by the National Bioethics Advisory Commission at its meeting Tuesday in Miami, but at least in the public portion of their discussion, none of the commissioners voiced concern about the creation of the hybrid cells.

Clinton requested the discussion last week in a letter to the commission's chairman, Dr. Harold Shapiro of Princeton University. Clinton said he was "deeply troubled" by news that Advanced Cell Technology, a small biotechnology company in Worcester, Mass., had created the hybrid cells. The company proposes to use the technique to take any body cell from a patient, return it to its embryonic form and use it to grow any of a variety of body tissues for possible transplant back into the patient.

One advantage of the technique is that the patient would receive tissues made from his own cells. Another is that no cells would be taken from human embryos or fetuses.

Noting that scientists had been fusing together cells of different origin for years, Dr. David R. Cox of Stanford University, a member of the commission, said, "We should tell the President there is nothing new in cells fused from different eggs."

The hybrid cow-human cells consist of the nucleus of a human cell inserted into a cow egg whose own nucleus has been removed. Factors in the cow egg are thought to make the human cell nucleus revert to its embryonic form. Because the proteins of a cell turn over rapidly, the cow proteins are expected to be rapidly replaced by human proteins. The mitochondria of the cell, however, are likely to remain cowlike, giving rise at least initially to cells that are not wholly

human.

An outside expert who spoke to the commission by telephone, Ralph Brinster, a physiologist at the University of Pennsylvania, said of the cow-human hybrid cell, "Most scientists would not regard it as a chimera." Chimeras are animals made from the cells of two different individuals by injecting the embryonic cells of one into the embryo of another.

Making human chimeras is widely regarded as unethical.

Dr. Michael West, the president of Advanced Cell Technology, attended the commission's meeting and was invited speak. In response to questions, he said he did not believe the cells formed in his procedure, called embryonic stem cells, were capable of forming a fetus if transferred to a uterus, something he said he had no intention of doing.

Asked how he would prevent the technique from being misused, such as in cloning a person, he suggested that the cloning of humans should be made a crime.

The commission members said they would draft a reply to Clinton.



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Ethics Panel Is Guarded About Hybrid Of Cow Cells

By NICHOLAS WADE

Struggling to respond to President Clinton's request for immediate advice on the hybrid cow-human cell announced earlier this month, the National Bioethics Advisory Commission has delivered a guarded and somewhat tentative reply, based on the few facts available to it.

The chairman of the commission, Dr. Harold T. Shapiro, the president of Princeton University, said in a letter to Mr. Clinton that the news raised "concerns about crossing species boundaries and exercising excessive control over nature."

The proposed use of the hybrid cells to grow human tissues for transplant into a patient would or would not raise new ethical issues, depending on the nature of the cells, Dr. Shapiro said.

The cells are obtained by fusing a human skin or blood cell with a cow egg whose own nucleus has been removed. The cow egg is thought to make the nucleus of the human cell revert to the embryonic state. The human nucleus then takes over control of the cell, displacing most of the cow proteins with human proteins, and the cell divides into a cluster of embryonic stemlike cells, said Dr. Michael West, president of Advanced Cell Technology, who announced the technique earlier this month.

As embryonic stem cells have the potential to develop into any tissue of the body, Dr. West's company hopes to grow whatever replacement tissues a patient might need from his or her own cells.

Dr. Shapiro's letter pointed to the ambiguous nature of the cells apparently created in the technique. If the embryonic cells that result from the human cell-cow egg fusion are capable of developing into a fetus when transferred to a uterus, then they raise the same "important ethical concerns" as any other research on human embryos.

But if the embryonic cells are not capable of developing into an embryo, then "we do not believe that totally new ethical issues arise," Dr. Shapiro said.

issue raised in this case would be that of mingling human and animal cells, noting that this is routinely done for certain medical purposes.

The ability of the embryonic cells to grow into an infant cannot at present be determined. The original experiments were taken only to a very preliminary stage, and no scientific tests were performed on the cells that resulted.

Other experts said they would need more evidence to know if human embryonic, stemlike cells had indeed been produced, as the company asserted, although one expert, Dr. John Gearhart of Johns Hopkins University, said when shown a photograph of the cells that they could be embryonic stem cells.

Dr. West said previously that his company had no intention of transferring the embryonic cells created in this way to a person's womb and that it would be wrong to do so. Dr. Shapiro said the commission also held this view. Thus, it seems unlikely that the potential of the cells to become a person will be tested directly.

In his letter to the commission a week ago, Mr. Clinton said he was "deeply troubled" by news of the cow-human hybrid cells. In interviews, several commission members expressed a somewhat lesser level of alarm while saying they understood the reasons for the President's concerns.

Dr. Carol W. Greider, a biologist at Johns Hopkins, said that the thought that someone might transfer to a uterus the embryonic cells created by the hybrid technique was deeply troubling, but that she had fewer problems with the company's stated purpose of making transplantable tissues.

"I think there are some ethical issues there but they are much less worrisome," Dr. Greider said.

The commission plans in a later report to address a second issue that Mr. Clinton raised, the ethical problems and medical benefits of research on human embryonic stem cells derived from human tissue. Earlier this month two groups of university scientists isolated embryonic stem cells from embryos and from aborted fetuses, the first time that these primordial cells had cultured in the laboratory.

The company that sponsored the research, the Geron Corporation of Menlo Park, Calif., also plans to use the cells to grow transplantable tissues.

NYT

SATURDAY, NOVEMBER 21, 1998

Ethics and Embryos

THE PRESIDENT has asked the National Bioethics Advisory Panel to take a careful look at recent breakthroughs in embryo research. The request follows reports that two research labs have succeeded in producing human embryonic stem cells—the primitive “super cells” that can develop into any cell type or organ—and that a third lab, in experiments two years ago, had produced similar stem-like cells by merging human genetic material with the egg cell of a cow.

Discoveries such as these offer not just moral issues but a fair measure of goose bumps. The cow-human cell experiment ranks extremely high on the goose-bump index; the president, in his letter, stressed the dangers of techniques that could lead to the horrible scenario of fused human-animal creatures.

But set aside whether these cells actually would constitute a fusion of genetic material from two species. (The researchers involved say they do not, that the cow cell is merely a container for the human cell nucleus.) The notion that the cow cell experiments pose a more immediate moral danger than the better-

documented breakthroughs on embryonic stem cells may be a function less of scientific reality than of simple publicity spin.

News of the cow cell experiments was released two years late, in the wake of the stem cell announcements, without any indication that the cow cell experiments had been published or otherwise confirmed scientifically. Questions as to how they passed through ethics screening at that initial phase have yet to be answered. As more biotech labs, academic and entrepreneurial, begin to converge on this area, their jostling for position will become just one more factor to be weighed by the many official and unofficial bodies that will be considering the issues involved.

The government's ethics advisory panel needs to keep its eye on a few overriding questions. Which of the many apparent routes to the creation of embryonic stem cell material are morally defensible? Which ones seem actually in reach? Which of the many beckoning uses for that magical material can be deemed acceptable by the whole society?

Washington Post

Nov. 21, 1998



BIOTECHNOLOGY

Claim of Human-Cow Embryo Greeted With Skepticism

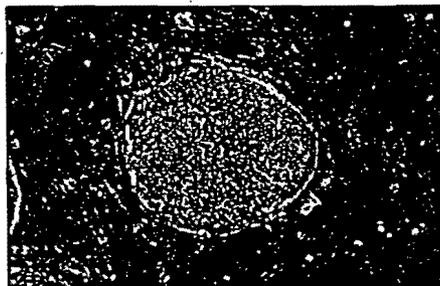
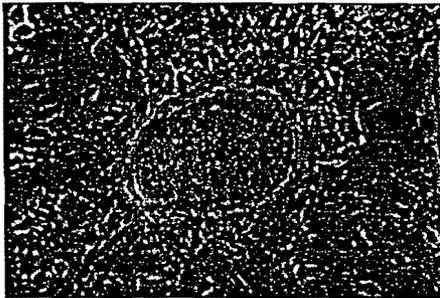
A small, privately held company in Worcester, Massachusetts—Advanced Cell Technology Inc.—startled the scientific world last week by announcing that it had fused human DNA with a cow's egg to create a new type of human cell. Company leaders say that a colony of these fused cells—created in 1996, kept alive for 2 weeks, and discarded—looked like a cluster of human embryo cells. On this basis, the company declared that it had “successfully developed a method for producing primitive human embryonic stem cells.”

The claim, announced in a front-page news story in *The New York Times* on 12 November, came just 6 days after two groups of researchers reported in *Science* and the *Proceedings of the National Academy of Sciences* that they had used traditional techniques to culture human embryonic stem cells—“undifferentiated” cells that have the potential to grow into any cell type (*Science*, 6 November, pp. 1014 and 1145). It added to the concerns already raised among ethicists and government officials. On 14 November, President Clinton sent a letter to Harold Shapiro, chair of the National Bioethics Advisory Commission (NBAC), saying he is “deeply troubled” by news of the “mingling of human and nonhuman species.” The president asked NBAC to give him “as soon as possible ... a thorough review” of the medical and ethical considerations of attempts to develop human stem cells. And a Senate committee may review the company's claim at a hearing on stem cell technology planned for 1 December.

Scientists, however, were startled for another reason: They were amazed that Advanced Cell Technology (ACT) broadcast its claim so widely with so little evidence to support it. Some were puzzled that the company had tried to fuse human DNA and cow eggs without first publishing data on the fu-

sion of DNA and eggs of experimental animals. Many doubted that ACT's scientists had created viable human embryonic stem cells. And most were left wondering why the company chose to go public now with this old experiment.

The company had inserted DNA from adult human cells into cow's eggs using a nuclear transfer technique similar to the one used to clone Dolly, the first mammal cloned from an adult cell. ACT's top researcher and co-founder—developmental biologist James Robl of the University of Massachusetts, Amherst—says an early version of the experiment was performed in his UMass lab “around 1990.” A student carrying out nuclear DNA transfer



Scant evidence. Experts question whether the cells in ACT's circular colony (top) are really human embryonic stem cells, like those from James Thomson's lab (bottom).

in rabbits had run out of donor cells, Robl recalls, and, almost as a lark, took cheek cells from a technician and transferred their DNA into rabbit oocytes. “I didn't even know about it,” Robl says. To everyone's surprise, the cells began to divide and look like embryos. “I got very nervous” on learning about it, Robl says, and shut down the experiment.

Robl and his former postdoc Jose Cibelli, now a staffer at ACT, returned to this line of experimentation in 1995 to '96, when

they were working with cow embryos on other projects. They remembered that the human DNA-animal oocyte combination worked before, and “we thought, ‘Maybe we can get a cell line’ ” this way. Cibelli transferred nuclear DNA from 34 of his own cheek cells and 18 lymphocyte cells into cow oocytes from which the nuclei had been removed. Six colonies grew through four divisions, according to Cibelli, but only one cheek cell colony grew beyond that stage—reaching 16 to 400 cells. Robl says they didn't follow up on the work because “we had about 15 other things we were doing,” and developing human stem cells was not at the top of the list. But the university did file for a patent on the technique, granting an exclusive license to ACT.

Robl concedes that the experiment did not yield publishable data. He says he classified the cells as human stem cells based on his experience of “look[ing] at hundreds and hundreds” of cell colonies. But Robl offered no other data to support this conclusion.

Other researchers agree that the cells may have had human qualities, because they continued to divide after the cow's nuclear DNA had been replaced with human DNA. But Robl and Cibelli didn't do any of the tests normally done to show that these cells were human or that they were stem cells, such as looking for expression of human proteins or growth of specialized tissues. James Thomson of the University of Wisconsin, Madison, lead author of the *Science* paper, says that ACT's cells “meet none of the criteria” for embryonic stem cells. And Gary Anderson of the University of California, Davis, who has isolated a line of embryonic pig cells, comments: “Just because someone says they're embryonic stem cells doesn't mean they are.”

A few researchers—including Robert Wall, a geneticist at the U.S. Department of Agriculture in Beltsville, Maryland—were willing to suspend their disbelief, however, if only because they respect Robl. He is “a top-notch, very solid scientist,” says Wall, who adds that anyone who has examined a large number of embryonic cells can distinguish real ones from impostors.

But others are less charitable. “This may be another Dr. Seed episode,” says Bridget Hogan, an embryologist at Vanderbilt University in Nashville, Tennessee, referring to Chicago physicist Richard Seed, who caused a furor early this year when he announced that he planned to clone humans. Although Seed didn't have the means to carry out his

CREDIT: (TOP) ACT; (BOTTOM) J. THOMSON ET AL.

Requiem for Mars life

Fiscal austerity creates a crisis for Brazilian science

Dressing up proteins in a polymer coat

project, Congress quickly drafted a criminal ban on many types of cloning research. Congress set that debate aside last spring but indicated it might take it up again later (*Science*, 16 January, p. 315 and 20 February, p. 1123). Hogan, a member of a 1994 National Institutes of Health (NIH) panel that proposed guidelines for human embryo research, agrees that "it's theoretically possible" to do what ACT claims to have done. But the company's announcement reminds her of the Seed case because "it smells to me of sensationalism" and seems "likely to inflame an uninformed debate."

Why did ACT publicize this experiment now? Some observers think the company wanted to ride the PR bandwagon created by the 6 November announcements by the labs that had isolated human embryonic stem cells using more traditional culture techniques. One group, led by developmental geneticist John Gearhart at The Johns Hopkins University, extracted primordial germ line cells from fetal tissue and kept them growing through 20 passages (transfers from one plate to another) for more than 9 months. The other group, led by Thomson at the University of Wisconsin, established a culture of stem cells derived from early human embryos. Thomson, whose cell line has survived 32 passages over 8 months, published molecular data suggesting that the cells may continue dividing "indefinitely."

Michael West, president and chief executive officer of ACT since October, says it is "pure coincidence" that ACT's news came out within a week of these announcements. West—noting that ACT won't benefit immediately, for it doesn't sell public stock—says that after becoming ACT's CEO last month, "I learned about the work that had been done in 1996 ... and I wanted to develop this technology." But he says he "didn't feel comfortable" moving ahead with nuclear DNA transfer experiments without getting a reading on how future U.S. laws and regulations might affect the field. "So I decided, 'Let's talk about the preliminary results,'" says West. "Let's get NBAC to help clear the air."

West notes that some information on ACT's mixing of human and cow cells was already public. In February, the World Intellectual Property Organization in Geneva had published Robl's application for a patent on "Embryonic or Stem-like Cell Lines Produced by Cross Species Nuclear Transplantation" (WO 98/07841). It describes the Robl-Cibelli experiment of 1996 and stakes

broad claims to stem cell technology based on transferring human or animal DNA into an animal oocyte. After being approached by the staff of CBS's news show *48 Hours*, West says, he arranged to discuss the research in exclusive but simultaneous releases to *The New York Times* and CBS. The CBS report aired on 12 November.

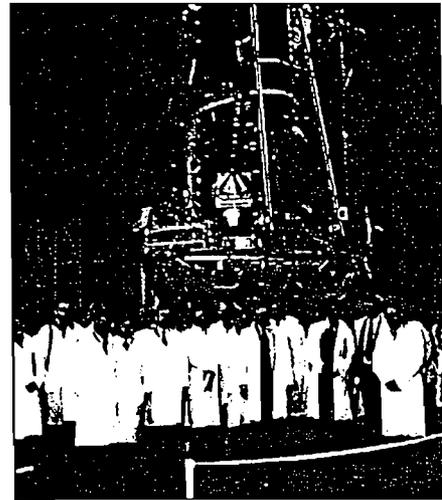
Robl confirms it was West, and not the scientific staff at ACT, who initiated the announcements. "I wouldn't have had the guts to do it," Robl says, although he agrees it is important to debate ethical concerns that might impede the technology.

These ethical concerns may get an airing next month. Senator Arlen Specter (R-PA), chair of the appropriations subcommittee that approves the budget for NIH, is planning a hearing on 1 December. There, NIH director Harold Varmus and developers of new human cell technologies are expected to testify about federal restrictions on the use of embryonic and fetal tissue and their impact on biomedical research. That discussion may now be expanded to include questions about ACT's single experiment. —ELIOT MARSHALL
With reporting by Elizabeth Pennisi.

RUSSIAN SPACE SCIENCE

Station Launch Hides Lingering Woes

MOSCOW—Valery Bogomolov welcomes the scheduled launch today of the first piece of the international space station as a sign of the world's commitment to space exploration. But the launch is also a bitter re-

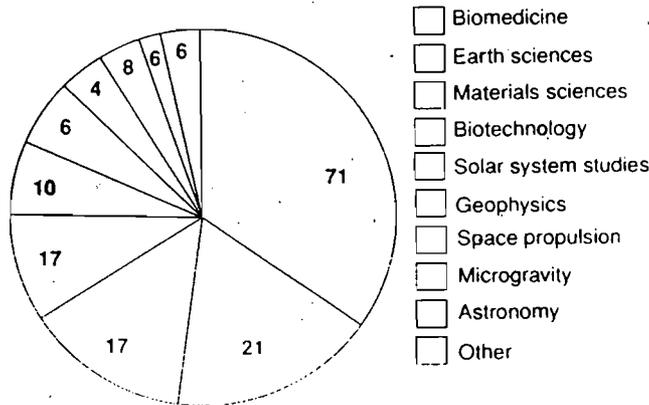


Still grounded. Managers hope to get the Spectrum-X-Gamma mission into orbit by 2001.

minder to Bogomolov, deputy director of Russia's premier space biology facility, the Institute for Biomedical Problems (IBMP), of his country's recent decision to sell NASA thousands of hours of station time earmarked for research by Russian cosmonauts for the \$60 million needed to complete a key station component (*Science*, 9 October, p. 206). "It was very sad for us, and for Russian science," says Bogomolov, whose institute is scrambling to plan experiments on the ground that were meant to be done in space. "We had no warning."

As the rest of the space community reads its payloads for the \$50 billion international space station, Bogomolov and his Russian colleagues must resign themselves to a limited role until at least 2003, when

they will vie for a share of research time aboard the completed station. And the lost opportunity is only one of several continuing crises for Russian space science. The launch of the Russian-backed Spectrum-X-Gamma spacecraft, a \$500 million international effort to study x-rays, is running almost a decade behind schedule. Even a last-ditch effort to postpone the dismantlement of the Mir space station, allowing some biology



Miraculous results. Biomedicine got the largest slice of Russia's \$20 million of research on Mir, both in dollars and number of projects (in blue).

CREDIT: (TOP) SPACE RESEARCH INSTITUTE, NAL; SOURCE: (BOTTOM) AMBER

A Cloning Claim's Controversies

Massachusetts Firm Says It Created Embryo Out of Human, Cow Cells

By RICK WEISS
Washington Post Staff Writer

Scientists, ethicists and federal regulators scrambled yesterday to sort out the many controversial issues raised by a small biotechnology company's announcement that it had used cloning techniques to create an embryo out of human and cow cells.

The work, conducted in 1995 and 1996 at Advanced Cell Technology of Worcester, Mass., but not made public until yesterday, was part of an effort to make medically useful tissues but also appears to be the closest that anyone has come to cloning a human being.

Among the many questions raised by the revelation was whether the research broke a ban on the use of federal funds for embryo research; whether it bypassed Food and Drug Administration rules on research; and how the work passed muster with the ethics review board at the University of Massachusetts in Amherst, where the company supported work was done.

Those and other uncertainties led several experts yesterday to call upon Congress and the White House to clarify the regulatory framework within which human embryo research and other high-tech human studies are conducted.

"We will be contacting the White House today to ask that the president leave the National Bioethics Advisory Commission examine these issues," said Carl Feldbaum, president of the Biotechnology Industry Association, who said he was excited by the findings but was concerned by the lack of regulatory clarity.

The Worcester company produced one cloned human embryo—perhaps the first ever made—and performed the unprecedented cross-species hybridization of a human cell and a cow egg.

Michael West, president of the company, said in an interview yesterday that although the technique was very similar to that used to clone Dolly the sheep, he had no intention of cloning adult humans. Rather, the project's goal was to grow replacement cells and tissues for transplantation into people with diseases.

West said he had recently reopened the files on the dormant experiment and concluded that it was largely successful. He was publicizing the findings, he said, because the company had the moral responsibility to get feedback from the public before going any further.

Several critics, however, said they suspected the company had made a business decision to ride a new wave of interest in cultured embryonic cells, spurred by recent promising reports published in scientific journals. In contrast to those recent studies, West's company has not submitted its findings for review and publication in a research journal. Instead it released its findings to the New York Times, which ran a report about it yesterday. That suggested to some that the company was primarily trying to position itself to make an intellectual property claim on cell transplant technology.

"What do they have? They've got no publication, they've got nothing," said George Annas, a professor of health law at Boston University. "All they have is the opportunity to tag along with the other stem cells in the news. They're saying, 'Let's cash in.'"

West said the company's team had fused a human skin cell to a cow's egg whose genes had been removed. The fluids that remained in the gutted cow egg caused the genes in the human cell to revert to their primordial state, as though they were back in a developing human embryo. The fused cell divided several times, and microscopic examination indicated that some of the resulting cells resembled stem cells, which scientists hope to harness for medical purposes and for which the company has submitted a patent claim.

Other scientists disputed West's conclusions, however, saying the Worcester team never did the basic tests used to see if cells are really stem cells. West confirmed those tests were never done.

Roger A. Pedersen, a stem cell researcher at the University of California, San Francisco, said the company's claim of having isolated stem cells shocked him. "One must be very circumspect about such a fanciful notion without good data to support it," he said.

Moreover, Pedersen and others said, experiments in other species have shown that hybrid embryos made from divergent species grow poorly and suffer many defects because of an incompatibility between the newly transferred genes (in this case human) and so-called mitochondrial genes that are left behind in the fluid of the gutted egg.

"There's a carefully choreographed dance between nuclear DNA and mitochondrial DNA," Pedersen said, saying he doubted the Massachusetts team's cells would have much medical value.

John Gearhart, who last week published a scientifically reviewed report showing he had isolated human embryonic stem cells from fetuses, agreed, saying the new report reminded him of the much ballyhooed and ultimately disproved claims of "cold fusion" earlier in this decade.

Experts also questioned the legal and ethical basis of the work. Congress has banned federal funding for human embryo research, and Gearhart, Pedersen and others work in labs from which federally purchased equipment has been scrupulously excluded.

West said the company's embryo work was done using only corporate funds, but officials at the University of Massachusetts said they were unaware that any of the labs in the building where the work was done had been specially cleared of all equipment purchased with federal grant money. "We don't have an NIH room and an NSF room and so on," said Michael Weinberg, special assistant to the vice chancellor for research. "Faculty members get funded and they go from room to room."

The role of the FDA also remained unclear yesterday. Acting FDA Commissioner Michael Friedman said that if the work was basic research then the company was under no obligation to get approval from the agency, but if it was done with the intention of developing a cellular therapy for use in humans then the company should have filed for an Investigational New Drug application. With only a newspaper report to describe what the team did, he said, it remained unclear to him which category the work belonged in.

Others questioned how the university's institutional review board could approve the species-mixing research. Weinberg, who heads that committee, said the group only considered whether it posed a risk to the researcher who donated his skin cells. But other experts said such committees are clearly required by federal law to consider the full range of scientific and ethical issues raised by proposed research. They said the committee's quick approval gives credence to a recent federal report that called for a major overhaul of the nation's local research review system.

"What this whole business shows is that we are in a regulatory nightmare," said Glenn McGee, a professor of bioethics at the University of Pennsylvania. "It's going to be impossible to state whether these things are really human, let alone how to protect them."

The Washington Post

FRIDAY, NOVEMBER 13, 1998

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Researchers Claim Embryonic Cell Mix Of Human and Cow Announcement Tests the Waters

By NICHOLAS WADE

Venturing deep into uncharted realms of ethics and medicine, a small biotechnology company said yesterday that its scientists had for the first time made human cells revert to the primordial, embryonic state from which all other cells develop, by fusing them with cow eggs and creating a hybrid cell.

The research comes from biologists who are well known in their field but has yet to be confirmed or published in a scientific journal. Their company, Advanced Cell Technology of Worcester, Mass., said the method could eventually be used to grow replacement body tissues of any kind from a patient's cells, sidestepping the increasing scarcity of organs available for transplant and the problems of immune rejection.

The technique is likely to concern and perplex ethicists because it would involve the creation of an embryonic cell that is part human and part cow, consisting of a human cell's nucleus in a cow egg whose own nucleus had been removed. The company said the hybrid cell quickly became more humanlike as the human nucleus took control and displaced cow proteins with human proteins.

Creation of the embryonic cells is an important component of a strategy that in principle offers high medical benefits if it can overcome the high barrier to public acceptance.

The technique would involve creating an embryo of uncertain moral status, and one that crosses the barrier between humans and other species. Even though a hybrid would be in the form of cells, not a whole organism, the concept of half-human creatures arouses deep-seated anxiety, as is evident from the unfriendly powers ascribed to werewolves, centaurs, mermaids, Minotaurs and other characters of myth and folklore.

"Many people are going to be horrified by this scenario, others will say 'So what?'" said Thomas Murray, director of the center for biomedical ethics at Case Western Reserve University in Cleveland and a member of the National Bioethics Advisory Commission. "This is the sort of thing that makes me very uncomfortable," Dr. Murray said. "I think we are likely to get a very powerful reaction to it, and I would like for all of us to have a breathing space here to articulate our moral concerns."

Another serious uncertainty is the preliminary nature of Advanced Cell Technology's work. No article has yet been submitted for peer review and publication in a scientific journal, an essential touchstone of credibility. Scientists asked about the company's work said they would require much more proof before believing that human embryonic stem-like cells had been created as the company contends, and some were skeptical that the technique would work.

The company said yesterday that it had performed the work with hybrid cells two years ago. Dr. Michael D. West, Advanced Cell Technology's chief executive, said that he was announcing the work to test its public acceptability. He said the company, which is privately held, was not planning to go public or raise money now but needed to decide whether to commit money to development of the technique.

Some scientists praised Dr. West's decision to make his work public but others were critical, saying he has invited a possibly fraught public debate on a slender basis of fact.

Dr. West is the founder of Geron, a biotechnology company in Menlo Park, Calif., that has had two spectacular successes this year in research on aging. In January it developed a method for "immortalizing" human cells grown in the laboratory by making them leap the supposedly immutable barrier at which cells usually lapse into senescence. Last week two university teams sponsored by Geron said they had isolated and cultivated human embryonic stem cells, the all-purpose cells from which the fetus develops. Dr. West laid the foundations for these developments by sponsoring leading scientists in the two fields.

Researcher Uses His Own Cells

Advanced Cell Technology, which Dr. West joined in October, has focused on cloning and genetically improving cows, a technology developed by James M. Robl and colleagues at the University of Massachusetts at Amherst. Dr. West said he hoped to use the technology to further the idea on which he founded Geron, that of delving into the mystery of human aging and sidestepping some of its processes.

The work with human cells was performed in 1996 by Jose Cibelli, a colleague of Dr. Robl's at the University of Massachusetts. Using 52 of his own cells, some of them white blood cells and others scraped from the inside of his cheek, Dr. Cibelli fused each one with a cow egg whose own nucleus and DNA had been removed. Most failed to thrive but one embryo grew and divided five times, generating cells resembling embryonic stem cells. Dr. Cibelli and Dr. West say the method could be made more efficient with present technology. They use cow eggs because these are far cheaper and more available than human eggs and raise no ethical problems.

Considering this work was sufficient to describe an invention, Dr. Robl and Dr. Cibelli filed a patent application and then set the research aside to focus on the more immediately practical field of cow cloning, they said. Only two others beside himself and Dr. Robl knew what had been done, Dr. Cibelli said. The patent has not yet been issued but Dr. West said he was confident of receiving "important intellectual prop-

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Clinton Asks Study of Bid to Form Part-Human, Part-Cow Cells

By NICHOLAS WADE

Saying that he is "deeply troubled" by the creation of part-human, part-cow embryonic stem cells, which was reported last week, President Clinton has directed the National Bioethics Advisory Commission to consider the implications of the research at its meeting on Tuesday and to report back to him "as soon as possible."

In a letter sent yesterday to the chairman of the commission, Harold Shapiro of Princeton University, Mr. Clinton also asked for a review of embryonic stem-cell research in general, including the all-human embryonic stem cells whose isolation was reported earlier this month. These cells — the primordial, all-purpose cells from which all tissues of the body develop — were derived from very early embryos or blastocysts and from tissues of aborted fetuses.

While the President signaled concern about the "mingling of human and nonhuman species," he was more positive about the all-human embryonic stem cell research, noting that it "may have real potential for treating such devastating illnesses as cancer, heart disease, diabetes and Parkinson's disease." Biologists hope to replace diseased tissue in all these diseases with new cells derived from the embryonic stem cells.

But he also stressed the ethical concerns raised by the research, telling the commission that he wanted a "thorough review, balancing all ethical and medical considerations."

The letter was sent after the President had consulted with the White House Domestic Policy Council and the President's science adviser, Dr. Neal Lane, "because he wanted the broadest views possible — the policy people, medical ethicists, as well as the scientists," an Administration official said.

stem cell research had not diminished since his statement of 1994 but that the benefits had become less hypothetical.

Dr. Lane said the implications of human embryonic stem-cell research had been under review but news of the human-cow hybrid cells, reported last week, "clearly raised urgent ethical, medical and legal issues that the President wants addressed and that's why he asked for the commission to give it immediate attention."

Human embryonic stem cells can develop into any of the body's 210

types of cells, a process that happens naturally during fetal development. Biologists at Geron, the company that supported the research, hope to grow the cells in the laboratory and guide them to develop into heart cells, blood cells and other tissues.

The cells would then be injected into the patient and integrate with his tissues under the control of local body signals.

In principle, the method could address a range of otherwise untreatable degenerative diseases, as well as relieving the severe shortage of organs available for conventional

transplants.

Many serious technical problems remain to be resolved, like how to guide the stem cells down desired paths of development and how to prevent immune rejection.

The ethical problems are also important because of the source of the embryonic stem cells. In one case the cells came from excess pre-implantation embryos created in infertility treatments, and in the other from aborted fetal tissue. Both sources were legal but research using the first would have been ineligible for Federal money.

The human-cow hybrid cell was also in compliance with all Federal, state and local laws, said Dr. Michael West, chief executive of Advanced Cell Technology of Worcester, Mass., the company that supported the research. In the hybrid cell, the cow cell's nucleus is first removed and the cow proteins are expected to be rapidly replaced with human proteins as the human nucleus takes over the cell.

Although the mingling of species raises many questions, scientists at Advanced Cell Technology regard the operation as one in which the cow egg is used simply to make the human cell's nucleus revert to its embryonic state. As the human cells can be provided by the patient himself,

from blood or skin, there is no problem of immune rejection when developed cells grown from his embryonic state cells are injected back into the body. The company favors cow eggs over human eggs because the former are cheap, available and uncontroversial.

Advanced Cell Technology performed its cow-human hybrid experiment only once, three years ago, and took the study only to a very preliminary stage. Other scientists say more evidence is needed to verify whether embryonic stem-like cells were created.

Dr. West said he was announcing the research now to test its public acceptability before making further investments in the technique.

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