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WITHDRAWAL SHEET
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
1. Memo	From Deborah Wince-Smith to Bernadine Healy RE: intellectual property protection for the Human Genome Project (2 pp.)	10/31/91	P-5
Open on Expiration of PRA (Document Follows) By <u>MB</u> (NLGB) on <u>4/5/05</u>			
COLLECTION	Bush Presidential Records Science and Technology D. Allan Bromley Files		
FILE LOCATION	DO LS 1991 National Institutes of Health (NIH) [OA/ID 08716]		

RESTRICTION CODES

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

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

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

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

OCT 31 1991



UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Technology Policy
Washington, D.C. 20230

MEMORANDUM FOR: Bernadine Healy
Director, National Institutes of Health

FROM: Deborah Wince-Smith *[Signature]*
Assistant Secretary for Technology Policy

SUBJECT: Intellectual Property Protection for the
Human Genome Project

I wanted to let you know that I share your belief that it is imperative to establish appropriate intellectual property protection for the human genome project. It has been firmly established that such protection is absolutely essential to attract industrial sponsors for such projects. Without intellectual property protection there is little incentive for companies to invest in the extensive research and development costs that these large, complex projects entail.

It is also interesting that the Industrial Research Institute (representing many of the most research intensive U.S. companies) polled its members on the Administration's "mega-science" projects to determine which has the most commercial potential. The human genome project won hands down. It is not enough that we pursue basic science without regard to economic considerations. For projects like the human genome to reach their potential the private sector must be an integral partner. Without intellectual property rights being protected this partnership cannot succeed.

I am keenly aware of the controversy that has erupted over this project recently. It is unfortunate that this is generating more heat than light. There is no reason why intellectual property protection need interfere with scientific communication and research. This fear was expressed before passage of the Bayh-Dole Act (P.L. 96-517) and the Federal Technology Transfer Act (P.L. 99-502) which allowed universities and federal laboratories to perform proprietary joint R&D with the private sector. There has been no evidence that these laws inhibited scientific communication. Indeed, university publishing and patenting have both risen since 1980. What has changed though, is that the U.S. taxpayers are receiving an economic as well as scientific return on their investments. In the current economic climate this contribution cannot be ignored.

It is also unfortunate that some critics do not understand the patent system. The filing of a patent application does not imply that science is being "hidden", quite the opposite-- the patent system was designed to encourage public disclosure through the incentive of ownership.

There is also no implication that by filing patents exorbitant prices will be charged for the use of the discovery. Many Government patents are routinely made available non-exclusively with little, if any charge. Indeed, the Commerce Department is patenting the Digital Signature Standard system so that we can ensure that it is appropriately used--- not to "gouge the public." We intend to make this technology available royalty free!

You are to be commended for your leadership in this area. If my office can be of any assistance, please let me know.

cc: Dr. D. Allan Bromley
Dr. Robert White
Dr. James Mason
David McIntosh

THE WHITE HOUSE

WASHINGTON

June 5, 1991

SCHEDULE PROPOSAL

TO: Kathy Super
Deputy Assistant to the President for
Appointments and Scheduling

FROM: D. Allan Bromley, *dy* The Assistant to the
President for Science and Technology

REQUEST: For the President to participate in a swearing in ceremony
for Dr. Bernadine Healy, the Director of the National
Institutes of Health

PURPOSE: A visit to NIH by the President on this occasion will send
a message of his support for biomedical research and
enhance the Administration's visibility in an area that has
been perceived by some to have been neglected because of
the lack of a Director for the past 2 years. Dr. Healy is
also the first woman director of the NIH.

BACKGROUND: Dr. Healy was nominated by the President as Director of
the National Institutes of Health on January 9, 1991 and
was confirmed by the Senate on March 21, 1991. She has
been Vice Chair of the President's Council of Advisors on
Science and Technology.

**PREVIOUS
PARTICIPATION:** None

DATE AND TIME: 1st choice: July 2 or 3
2nd choice: Week of July 8

LOCATION: National Institutes of Health

PARTICIPANTS: D. Allan Bromley
Dr. Bernadine Healy
NIH Directors
Family & Guests

REMARKS REQUIRED: None.

MEDIA COVERAGE: Press pool.

RECOMMENDED BY: D. Allan Bromley

OPPOSED BY: No one.

THE WHITE HOUSE
WASHINGTON

February 1, 1991

MEMORANDUM FOR CHASE UNTERMEYER

FROM: D. ALLAN BROMLEY *EWB*
SUBJECT: ADMINISTRATOR FOR AGENCY FOR HEALTH CARE

Now that--I hope--we have Bernadine Healy's nomination as Director of NIH on track, I want to bring to your attention the important post of Administrator of the Agency for Health Care within HHS.

I know that action on nomination of a new administrator has been pending for quite some time.

In the meantime, the Acting Administrator, Dr. Jarrett Clinton's performance has been exemplary. I completely concur with the HHS recommendation that I believe Jim Mason has forwarded to you to the effect that Clinton be nominated as Administrator.

Further delay harms not only the Agency but also the reputation of the Bush Administration in the scientific community.

In case you have mislaid it, I enclose a copy of Dr. Clinton's curriculum vitae herewith. I consider him very well qualified and an appointment that would reflect credit on us all.

I would much appreciate your help in moving his nomination forward.

Enclosure

cc: Governor Sununu

CURRICULUM VITAE

J. JARRETT CLINTON, M.D., M.P.H.

EXPERIENCE

Present	Acting Administrator, Agency for Health Care Policy and Research Public Health Service Rockville, Maryland
1988 - 1989	Director, Bureau of Health Professions Health Resources and Services Administration Public Health Service Rockville, Maryland
1984 - 1988	Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance Office of the Assistant Secretary of Defense for Health Affairs Washington, D.C.
1983 - 1984	Associate Administrator for International Affairs, Alcohol, Drug Abuse, and Mental Health Administration Public Health Service Rockville, Maryland
1981 - 1982	Agency Director for Health and Population Agency for International Development Washington, D.C.
1978 - 1981	Senior Representative for South and East Asia The Population Council Bangkok, Thailand
1976 - 1977	Senior Consultant in International Health Family Health Care, Inc. Washington, D.C.
1969 - 1975	Population and Health Officer Agency for International Development USAID Mission to Indonesia Jakarta, Indonesia

J. Jarrett Clinton, M.D.

Page 2

1968 - 1969	Graduate Student, Department of International Health, Johns Hopkins School of Hygiene and Public Health
1966 - 1968	Deputy Director and Regional Medical Officer Office of Medical Programs Peace Corps Washington, D.C.
1965 - 1966	Peace Corps Physician Pakistan and India

EMPLOYMENT STATUS

Assistant Surgeon General, O-8
United States Public Health Service

EDUCATION

1983	Senior Fellows Program JFK School of Government Harvard University Cambridge, Massachusetts
1968 - 1969	MPH - Johns Hopkins University Baltimore, Maryland
1960 - 1964	MD - Kansas University Lawrence, Kansas
1956 - 1960	BA - Baker University Baldwin, Kansas

CERTIFICATION

Medical License, Virginia

Diplomate, American Board of Preventive Medicine
(Public Health), 1973

J. Jarrett Clinton, M.D.

Page 3

MEMBERSHIP

American Public Health Association
Commissioned Officers Association
Association of Military Surgeons of the United States

AWARDS

1968	Foreign Duty Award, Public Health Service
1968	Isolated Hardship Award, Public Health Service
1975	William Jump Memorial Award for Public Administration
1982	Carl S. Schultz Award of the Population and Family Planning Section, American Public Health Association
1988	Secretary of Defense Award for Outstanding Public Service
1988	Meritorious Service Medal, Public Health Service
1988	Outstanding Service Medal, Public Health Service
1989	Citation, Public Health Service
1989	Commendation Medal, Public Health Service
1989	Surgeon General's Exemplary Service Medal, Public Health Service
1989	National Emergency Preparedness Service Medal, Public Health Service

THE WHITE HOUSE
WASHINGTON

July 9, 1991

Dear Deeda:

I very much regretted that I was unable to join you for the dinner in honor of Bernadine Healy on June 26th, but as my office told you, I had been committed to giving the keynote talk at the inauguration of my old friend, Don Langenberg, as Chancellor of the University of Maryland earlier that day, and again, speaking at a major banquet in honor of the event that evening.

I was delighted with the formal inauguration that we were able to arrange for Monday, June 24, when the President and Mrs. Bush joined Secretary Sullivan in formally swearing Bernadine in as the new NIH Director. I was particularly impressed by Bernadine's brief remarks on that occasion.

I regret that I am so belated in replying to your gracious note following our luncheon at the White House but, as I think you know, I have been travelling rather extensively. During the past year while my wife was ill, I did practically none at all and the number of international commitments had accumulated.

Unfortunately, I had misunderstood when you asked me about Ralph H. Henderson and had confused him with my new Associate Director for the Life Sciences, Dr. D. A. Henderson, formerly Dean of the School of Public Health at Johns Hopkins and the individual generally credited with having removed the scourge of smallpox from the planet. Unfortunately, I do not know Ralph Henderson at all and therefore would not be in a position to write in support of what I am sure is a very excellent nomination on his behalf.

Let me also assure you that you must never worry about letting me know when there is something you think I might be able to do that would be helpful to the life sciences or to NIH. I shall, in fact, count on you to keep me alerted to such opportunities if you would be willing to do so.

Our trip to the Soviet Union was indeed a fascinating one. I have been travelling to the USSR usually twice a year since 1972 when I first became one of the U.S. members of the Joint Coordinating Committee on Fundamental Research that was established by Nixon and Brezhnev. The changes have been rather remarkable and it is a little frightening to see the entire structure of a country as large and as powerful as is the Soviet Union falling apart before one's very eyes.

We were treated royally on this trip and had an opportunity to meet with many of the most senior officials, both of the national government and of several of the republics. This was the first occasion that I took the four and one half hour flight from Moscow to Novosibirsk, the Soviet science city in Central Siberia and, although it was a grueling trip it was very much worth while in terms of what I was able to learn about the relationships between the Siberian Academy and the National one and about the state of science in what is the Soviet Union's foremost scientific center.

Although it would have been relatively simple to fly directly from Novosibirsk to Baikonar for the space launch, bureaucratic difficulties made it necessary for us to fly back to Moscow and then take another four hours to fly to Baikonar where we watched the launch, which included the female English journalist. The launch was itself flawless, but the difference in the way in which the Soviets approach a launch and the way we do it at Cape Canaveral was somewhat mind boggling. Sometime when we have an opportunity I would be happy to tell you a few of the more amusing incidents involved.

Now that Florence Mahoney is back from Arizona, I would like to follow up on our discussion and get you and Florence together with Bernadine. Perhaps you could answer a specific question: namely, is Florence's health such that she could easily manage the stairs (there are about 5 steps) that are required to gain entrance to the Executive Dining Room in the White House. If you think she can make it, I would look forward to arranging a luncheon for the four of us at the first convenient time we can find. If you feel that this would be too difficult for her, then I can come up with other alternatives.

I realize also that Bernadine may already have met Florence at your dinner party and if so, please tell me.

I very much appreciate your sending me the copy of Sir John Wilson's keynote address at Harvard. He obviously is one of the world's great citizens and I much enjoyed reading what he had to say.

I am enclosing herewith a copy of the brochure that we prepared to mark the opening of the Decade of the Brain, an initiative that was developed with strong support from Representative Silvio Conte, who is unhappily no longer with us. This document was released on the occasion of the annual meeting of the Academy of Neurology in Boston where I had the pleasure of giving an after dinner speech.

It was thoughtful of you to send me Sir John's manuscript and I welcome material of this sort because my education in the life sciences, as I am sure you suspect, can stand substantial strengthening and broadening.

I look forward to seeing you in the not too distant future and, in the meantime, hope that you have a very happy and rewarding summer.

With all best wishes,

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mrs. William McCormick Blair, Jr.
2510 Foxhall Road
Washington, D.C. 20007

Enclosure

"CORRESPONDENCE TRACKING"

TYPE: INFORMATION

DOCUMENT NUMBER: 9121724

ORIGINATOR: 02

STATUS C

DIRECTORATE STATUS

FROM: BLAIR, Mrs. William McCormick

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 06/08/91

SUBJECT: A COPY OF SIR JOHN WILSON'S KEYNOTE SPEECH AT THE
PRESIDENT'S WEEKEND AT THE HARVARD SCHOOL OF PUBLIC
HEALTH ON THE ISSUES OF GLOBAL PUBLIC HEALTH.

DIRECTORATE
ASSIGNED:

STAFF
ASSIGNED:

ACTION
REQUIRED:

STAFF
ACTION:

SENDER'S DUE DATE:

OSTP DUE DATE:
DATE COMPLETED:

STAFF DUE DATE
DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley
LIFE SCIENCES

WHITE HOUSE TRACKING #:

CONTACT PERSON:

REMARKS:

PHONE:

EXT:

OSTP RECEIVED: 06/12/91
DEPT RECEIVED:

FILE: LIFE SCIENCES

2510 FOXHALL ROAD
WASHINGTON, D. C. 20007

RECEIVED

91 JUN 12 12:41

June 8, 1991

OFFICE OF THE
DIRECTOR

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
17th and Pennsylvania Avenue
Washington, D.C. 20500

Dear Allan,

In early May we had The President's Weekend at The Harvard School of Public Health and we were able to get Sir John Wilson to be the keynote speaker. Without exception he is the most dazzling and brilliant speaker on issues of global public health. Sir John is blind and has dedicated his life to combating (very effectively) blindness in Africa and India as well as other devastating problems in developing countries. I thought you might enjoy seeing a copy of what was a breath taking talk.

I am sorry you won't be with us for the dinner to honor Bernadine on June 26th. Unfortunately this was the best date available, but we will try again. I hope your trip to the Soviet Union was wonderful.

All the best,

W. McCormick Blair, Jr.

Mrs. William McCormick Blair, Jr.



Population and Public Health

Keynote speech by Sir John Wilson at a symposium
at the Harvard School of Public Health, Boston, May 10, 1991

One of the things that I most admire in the United States is the optimism of your scientific community, the conviction that the movement of history is still forward, that there is no intellectual barrier which may not be crossed by the spirit of enquiry. More than your power or your money, it is that optimism which justifies your claim to leadership of the science of the modern world.

Nowhere is that optimism more evident or more justified than in your great centres of excellence like Harvard where, in a multidisciplinary framework, research at the limit of scientific imagination walks alongside a vigorous discipline of practical delivery.

I have had the privilege of meeting your students in many countries. They work at the centre of health and development programmes and, even more impressively, at the essential point of delivery in slums, villages, deserts and the wildernesses of the world. That vigour, that optimism, has never been more necessary than today in relation particularly to the theme of this symposium, "Population Control and the Role of Public Health."

We all know the statistics. Just about now the five billionth inhabitant of the world approaches a fourth birthday. By the time of the fortieth birthday, he, or more likely she, will share the world and its resources with 8 billion inhabitants. In the developing countries, population has doubled over the past thirty years and the urban population has quadrupled.

At a United Nations meeting recently, we were told that sometime during the next century there would be more people on the earth than in all previous generations put together. When that happens, apart from its other complexities, you might say that history will have become a minority subject.

Already, a billion people live in absolute poverty, 800 million go hungry every day, 100 million are permanently homeless and 450 million are disabled.



RECEIVED

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Dear Allan

SI MAY 8 P 4:36

Even so many thank yous
you were so nice to organize
such a delightful luncheon

I so much enjoyed meeting
Bernadine. It was a joy
to talk to her. She is
going to be so wonderful for
NIH. Better to wait those
long months and end up
with a great star. One has
an instant impression of
intelligence - judgement -
breadth - sensitivity - perception
And to combine so many
skills with enthusiasm
and grace is going to be
unbeatable

It occurred to me when
we touched on the subject



Dr Jordan Guttenman, Director
Albert-Lasker Medical Research Awards
Dept of Immunology and Biological Therapy
M.D. Anderson Cancer Center
1515 Holcombe Blvd
Houston, Texas 77030

- Again best wishes on the Academy
- that was super great
 - Have a wonderful trip to the Soviet Union
 - When Florence Mahoney's back from Arizona - and you're back from Russia let's try to get Bernadine and come for dinner

Again many thanks
Deeda

Healy Turns In Engaging Performance In Debut Before House Appropriations

NIH Director Bernadine Healy gave an engaging performance in her first appearance before the House Labor, HHS, Education Appropriations Subcommittee this month.

Healy, enjoying a honeymoon during which she cannot be blamed for any of the difficulties facing NIH, spent more than five hours expounding on NIH past, present, and future, and outlined some of her priorities for the months and years ahead.

More than anything, Healy expressed a sense of excitement in and confidence about NIH that has been missing recently. Her closing sentence in her formal statement to the subcommittee was one example:

"With the model of scientific pursuit exemplified by the National Institutes of Health, the American biomedical research enterprise has become an unrivaled success, the envy of the world, and a source of hope for every American who has ever been touched directly or through loved ones by the starkness and pain of illness--and that is virtually every one of us."

But Healy promises to be more than NIH's head cheerleader. Both in her prepared statement and in her answers to the subcommittee's questions, she showed a fluency with some of the toughest problems facing NIH and her willingness to tackle them from day one.

"I assume the directorship of NIH with a tempered

sense of optimism that this is a job enormously worth doing, and one that can be done," Healy said. "But a lot needs to be done, and no one woman, or one man for that matter, will be able to do it right without a lot of support--support from Congress, the White House, the Secretary who has a major commitment of NIH; support from the research institutions, from the working scientists, from the talented and dedicated members of the NIH community, and from the public."

"The first and foremost priority for a successful NIH is its human talent base," Healy said. "We must attract gifted individuals of all types."

NIH must have "strong support systems," such as peer review. "We must be sure that peer review is above reproach, without conflict of interest, always objective and fair, and also sufficiently wise so that unconventional ideas are given appropriate consideration."

Though Healy said she supports the NIH financial management plan developed in response to Congress last year, she said additional steps are needed.

"As a matter of top priority, I plan to formulate specific proposals in consideration of a range of strategies to make NIH's funding mechanisms more effective," Healy said. "Furthermore, I feel that a second phase of cost management is in order, in which longer term issues such as indirect costs, long term planning, unexpected crises, mathematical modeling of grant award fluctuations, approaches to training and infrastructure are addressed."

She noted that 95 percent of biomedical researchers work in nonfederal employment in universities, research institutions, and industry.

"The health of these institutions ultimately determines the professional health of the scientists, the quality of their work and the generation of future talent. Virtually all federal policies that affect the biomedical research enterprise have an impact on the institutions conducting research and teaching. These institutions must be partners in the policy setting dialogue."

"But as we deal with the scientific talent base and complexities of the research enterprise we must be fully aware that whatever we do in science is ultimately in the context of society; whatever we do in biomedical research must be in the interest of the public."

Healy suggested some "public interest principles":

►Long term planning. "As a mature agency, NIH needs a long term plan that lives beyond immediate interests. A long term plan imparts a needed stability and predictability to the enterprise."

►NIH as a leader in areas of public trust. "We must

be aggressive in promoting good scientific conduct and in dealing with problems of scientific misconduct. NIH must also vigorously lead in setting research priorities in the interest of the public. For the most part, NIH has done this very well, often with some healthy nudging from Congress. One salient area of where NIH needs to be better is in the area of research on women's health."

►Technology transfer. "If we are ever to realize the mission of NIH, technology transfer must work. The discoveries of the laboratory must be carried to the bedside. The federal government has developed a strong legislative portfolio over the past decade to foster that transfer in partnership with industry."

►Something Healy called "the interface of science and social policy." According to Healy, "The success of science in this country is due in large measure to the fact that it has largely been nonpolitical and nonpartisan, and that it has been allowed to thrive by the objective pursuit of truth. That must continue. But there are circumstances that arise where the moral or ethical concerns of our society may appear to collide with the pursuit of science. The NIH experience has shown us that most often science proceeds within a certain framework defined by public interest. This is the history of guidelines or regulations for recombinant DNA research, and of research involving human subjects or animals. As we move ahead, these approaches should serve as models for assuring the public that science indeed does not live by and unto itself, but in the service of man and womankind."

Indirect costs came up several times in the hearing. "I don't really understand the indirect cost problem and don't know what ought to be done," said Rep. David Obey (D-WI). "But I've had some experience dealing with unpleasant institutional problems [Congressional ethics] and you sometimes have an institutional overreaction. My concern is that unless the scientific community is leading the reform effort, you're going to be run over by outside 'help.' What do you think we can expect from NIH?"

"First I think the indirect cost issue was an accident waiting to happen," Healy said. "There are inherent problems in this method of accounting. But the focus has to be on how we can improve the system. HHS has to be a lead player in this."

Healy said plans to meet with the HHS Inspector General and the Office of Management & Budget to "discuss strategy and try to commit our staffs to look at the OMB circular [which sets forth the indirect cost rules] and come up with some options."

Other issues Healy addressed:

►New animal welfare regulations--Healy worked on

these six years ago. The Cleveland Clinic, where Healy worked before coming to NIH, spent "a lot of money" to bring its facilities up to standards, but Healy said she supported the new rules. "There are cost burdens, but in my experience, I never came across a cost I disagreed with."

►US leadership in biomedical research--"Where we are now is superb, but I'm concerned about the future. Science needs a lot of lead time," Healy said. When resources are tight, "only safe research might be funded." Asked how to interest young people in science, Healy said, "Let them see exciting science. What's going on in medicine today is as exciting as Sputnik. [Young people] should see medicine as thrilling and exciting, and an opportunity to serve others."

►Grants funding. Rep. William Natcher (D-KY) asked Healy whether she would favor fewer, larger grants rather than cutting grants. "We would not be serving the system well by having fewer grants," Healy said. Natcher noted that "each institute seems to be designing its own cost management plan" in response to budget pressures. "We need to take a stronger role centrally," Healy said. "The science should be decentralized but cost management should be centralized." She called for uniform accounting, but said, "one institute might be treated in a less uniform way, based on scientific opportunities." Later, she said cuts will still have to be made, first through peer review recommendations, then NIH scientific staff, though no across the board cuts will be taken.

►Research training. Trainees need higher stipends, "but I don't write the check," Healy said. The current stipend "is what NIH can pay at this time. A career in biomedical research is a personal sacrifice. It's the price for pursuing an incredibly exciting career."

►Research centers. "I happen to be a fan of centers. I worked in two [Hopkins and Cleveland]. Their advantage is in bringing basic science together with clinical research. I'm very supportive of them; they are really a continuation of the R01 grant."

Subcommittee Chairman Natcher said when he was first elected to Congress, the NIH budget was \$73 million. "Now, it's nearly \$9 billion, and if I had my way, it would be \$10 billion." He primed Healy for her appearance at next year's hearing: "One of the ablest directors was [former NCI director] Vincent DeVita," Natcher said. "Every year Dr. DeVita would come before this committee and I would ask him, 'Dr. DeVita, what can you tell me this year that you couldn't tell me last year?'"

William Raub has returned to his former post as NIH deputy director.

Albert Lasker Medical Research Awards

1991

NOMINATION BLANK

☐ ~~BASIC MEDICAL RESEARCH AWARD~~

(Please check)

☐ ~~CLINICAL MEDICAL RESEARCH AWARD~~

(Please check)

THE SPECIFIC SCIENTIFIC CATEGORY FOR THIS BASIC OR CLINICAL RESEARCH NOMINATION MUST BE INDICATED BELOW.

THE PUBLIC SERVICE AWARD

(Scientific Category)

NOMINATOR

NAME: SIR JOHN WILSON CBE

TITLE: Senior Consultant
United Nations Development Programme
IMPACT

ORGANIZATION NAME & ADDRESS:

22 The Cliff, Roedean,
Brighton, East Sussex, BN2 5RE
England

TELEPHONE:

(0273) 607667

NOMINEE

NAME: DR. RALPH H. HENDERSON

TITLE: Assistant Director General,
World Health Organisation
(formerly Director EPI)

ORGANIZATION NAME & ADDRESS:

World Health Organisation
1211 Geneva 27
Switzerland

TELEPHONE:

(022) 791 2111

SUMMARY OF NOMINEE'S SCIENTIFIC CONTRIBUTIONS

Dr. Ralph H. Henderson is nominated for the Albert Lasker Public Service Award for his leadership in directing the Expanded Programme on Immunisation (EPI). Conceived as a sequel to the smallpox eradication programme, the EPI is already rivaling the success of its predecessor. It has raised immunisation coverage of children reaching their first year of life in developing countries from negligible levels in the mid-1970s, when the programme was established, to levels approaching 70% today. As a consequence deaths of some two million children are being prevented each year from measles, whooping cough and neonatal tetanus. In prospect is the reduction of measles by 90% and the elimination of neonatal tetanus by 1995 and the global eradication of poliomyelitis by the year 2000.

Through good management, Dr. Henderson has provided the EPI with a foundation of technical excellence and has catalyzed effective and innovative application of existing technologies to the benefit of primary health care in developing countries. Through outstanding personal leadership, he has been instrumental in transferring the 'ownership' of the EPI from WHO to the world at large, contributing to its success and helping to assure its sustainability.

PLEASE ANSWER PRECISELY THE FOLLOWING THREE QUESTIONS REGARDING THE NOMINEE'S SCIENTIFIC CONTRIBUTIONS, (please type):

1) WHY DOES THIS WORK REPRESENT A MAJOR ADVANCE IN EITHER THE BASIC OR CLINICAL FIELDS?

The Expanded Programme on Immunization (EPI) directed by Dr. Henderson represents a major contribution to public health, rivaling the significance of the WHO Smallpox Eradication Programme which was its predecessor.

In 1974, when the EPI was established, immunisation coverage levels for children in developing countries were less than 5%, and the vaccines used were frequently impotent due to poor conditions of transport and storage. Five million children were dying annually from vaccine preventable diseases. Now, in 1991, coverage levels for children reaching their first year of life in developing countries for a measles vaccine, a dose of BCG, a third dose of polio and a third dose of DPT vaccines are each at or over the 65% mark. As a result, the deaths of two million children from measles, neonatal tetanus and whooping cough are being prevented each year. This already represents a major public health triumph and, with the advent of new vaccines, could change the landmarks of public health.

Immunization coverage levels of over 80% are forecast for all the EPI vaccines by the early 1990s in all but a handful of developing countries. Programme goals for the coming decade include achieving levels of 90% coverage, in the context of comprehensive maternal and child health services, by the year 2000. The World Health Assembly has given the programme the mandate for eradicating poliomyelitis from the globe by the year 2000 and for reducing measles by 90% and eliminating neonatal tetanus by the year 1995. These goals were confirmed at the summit conference of heads of state, New York, September 1990.

The Smallpox Eradication Programme was, from the outset, a time limited effort. In contrast, the EPI is a permanent programme. The vaccine delivery infrastructure which is now being built will be needed for the foreseeable future. This will not only be increased by achieving higher levels of immunization coverage, but also by introducing an increasing array of vaccines. These vaccines are expected to become available in coming years, representing the fruits of past years of investments in research and development. But the benefits of these new vaccines cannot be realized by developing countries unless the delivery systems which have been developed through the EPI are in place and the development of this "highway to health" has been the outstanding emphasis in all Dr. Henderson's work.

The EPI stands as a remarkable success in the area of delivery of immunization services. It is also making a major contribution to the development of primary health care as a whole, as indicated by the following examples:

- EPI has markedly improved the safety of injections provided for immunization. It has developed syringes and needles which can only be used once as well as plastic reusable syringes and practical sterilization materials and methods for use at health centre level. These improvements are now in the process of being generalized throughout the health care system.
- The EPI has developed a "cold chain", which permits the safe storage and transport of vaccines from the place of manufacture to the place of use, which now functions effectively in all developing countries. This system will help assure the effective distribution of other items required for use at health centre level, including essential drugs which are temperature sensitive.
- EPI is working with the WHO Global Programme on AIDS using EPI knowledge regarding the safe storage and transport of vaccines to help in building effective blood-banking and transport systems in developing countries.

ALBERT LASKER MEDICAL RESEARCH AWARD - 1991 NOMINATION BLANK

2) WHY DOES THE NOMINEE DESERVE AN AWARD, ESPECIALLY WHEN COMPARED TO OTHER SCIENTISTS AND THEIR CONTRIBUTIONS IN HIS/HER FIELD?

The Expanded Programme on Immunization is now an obvious public health priority enjoying world-wide support. This was not always the case. For the programme had a slow start after it had been established in 1974. Between then and the time when Dr. Henderson was appointed Programme Manager in 1977, a number of EPI seminars had been given in the WHO regions, a draft of an EPI field manual had been prepared, operational research studies were being completed in Ghana, and national immunization programmes were being planned in fifteen and implemented in five countries.

Dr. Henderson was able to catalyze and stimulate rapid programme progress on his arrival. As cited in the EPI report to the WHO Executive Board in January 1982:

"Between 1977 and 1982, EPI has progressed from being a WHO-sponsored initiative to being an operational programme of Member States. By the end of 1981, most of the countries of the world had become active in EPI, and over 3000 national and international staff had participated in intensive two-week EPI management training courses... In 1981, development of regional EPI information systems permitted the first estimates to be made of immunization coverage by region and data to be provided on the quality of the vaccines in use."

Dr. Henderson's excellent programme management, combined with his leadership abilities and his conscious strategy to transfer EPI "ownership" from WHO to the world as a whole, have made the programme increasingly popular with bilateral development agencies, non-governmental organizations and developing countries themselves. Perhaps two of the most dramatic examples of that transfer are the involvement of UNICEF, which has become perhaps the most active promoter of the EPI on the international scene, and Rotary International, which has raised over US\$ 200 million for the EPI under its "PolioPlus" initiative. While UNICEF has always supported childhood immunization, it was not until the maturation of the EPI in the early 1980s that UNICEF was willing to accord to it the same degree of support which it had previously been providing to oral rehydration.

Dr. Henderson is being nominated for this award because of the excellence and significance of his work. There are really no other scientists to which to compare his accomplishments. An added consideration for this nomination is that he has, until recently, received little public recognition for it, with the outstanding exception that in May 1990, he received the Distinguished Service Medal from the United States Public Health Service, their highest honour. Many in the world know of UNICEF, which, in order to raise resources, publicizes its efforts widely and effectively. Few who are made aware of UNICEF's contributions in the field of immunization know that it is the technical expertise of who, mobilized under the leadership and managerial skills of Dr. Henderson, which has made the programme possible and which is continuing to guide its further developments. This Lasker Award would provide merited recognition both to Dr. Henderson and to the multitude of health workers in many countries who, under his leadership, have achieved one of this century's most notable advances in public health.

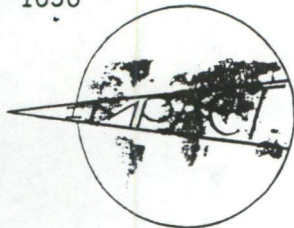
3) WHAT IS THE PRIORITY AND SPECIAL SIGNIFICANCE OF THE NOMINEE'S CONTRIBUTION AS COMPARED TO THE WORK IN THE FIELD AS A WHOLE?

It is difficult to compare the priority and special significance of Dr. Henderson's work in the area of immunization with work in the field as a whole, as his contribution and that of the Expanded Programme on Immunization are unique. The International Task Force on Child Survival, leading on to last year's summit conference on the child, adopted the goal of bringing immunization services to all the children of the world but this involved the development of policies and technologies and an immense effort of social mobilisation and practical delivery in which the leadership came from Dr. Henderson and his staff. There is, for example, no other programme which is systematically moving to control measles on a world-wide scale, to eliminate neonatal tetanus or to eradicate poliomyelitis from the globe.

There are certainly a number of other good managers of ambitious public health programmes both in and outside the United Nations system. Dr. Henderson and the EPI stand apart, however, by their focus on and their success in making available rapidly throughout the developing world one of the most effective tools in our health armamentarium: Immunization.

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international meetings and for the Summit Conference on the Child
was written by Dr. Henderson



AN INTERNATIONAL INITIATIVE AGAINST AVOIDABLE DISABLEMENT

Promoted by the United Nations Development Programme, UNICEF and the World Health Organisation

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Dr. Jordan U. Gutterman
Director, Albert Lasker
Medical Research Awards Program
870 United Nations Plaza
New York, N.Y. 10017
USA

11th March 1991

Dear Dr. Gutterman,

ALBERT LASKER PUBLIC SERVICE AWARD - 1991
NOMINATION OF DR. RALPH H. HENDERSON

Last year, with the support of Dr. Halfdan Mahler (a copy of whose letter to Mrs. Mary Lasker I enclose), I had the privilege of putting forward, for the consideration of the Jury, the proposal that the Albert Lasker Public Service Award might be presented to Dr. Ralph H. Henderson.

When we learnt that the Awards were not made last year, Dr. Mahler and I resolved to renew this nomination for the 1991 Award. Accordingly, I enclose, on the nomination blank which you were good enough to send me, a description of Dr. Henderson's outstanding leadership of the Expanded Programme on Immunisation, together with his Curriculum Vitae.

Dr. Henderson's work at the centre of the Expanded Programme on Immunisation will, I am sure, already be well known to members of your Jury. I have had the privilege of being a close observer of this programme ever since its adoption by the World Health Assembly in 1974. It really did not begin to move on a global scale until Dr. Ralph Henderson was appointed Director in 1977. He guided this programme with skill and diplomacy, achieving a remarkable transfer of its "ownership" from WHO to the world at large, with the involvement of all related United Nations agencies, governments and the international nongovernmental organisations.

I have attended all the meetings of the International Task Force on Child Survival, leading on to the Summit Conference on the Child in New York in September 1990. It has been a remarkable story of translating a political aspiration into practical delivery, with Dr. Henderson always at the professional centre of

2.

that expansion. From minute beginnings, the programme has now achieved approximately 70% coverage of the world's children and, in the Americas, the success of the programme is apparent from the now rapidly approaching goal of hemisphere-wide poliomyelitis eradication.

Throughout these years, the programme has consistently reached or exceeded its targets and the mobilisation of funds, both from governmental and private resources, has far surpassed our early expectations. The plans for the decade to the year 2000 have been formulated; they include the control of measles on a worldwide scale, the elimination of neonatal tetanus and the eradication of polio from the globe. These specific objectives have always been seen in their context of the essential development of primary health services and national delivery systems and, like the smallpox eradication programme which preceded it, the programme has made, and is making, a decisive contribution to the development of primary health delivery systems in many countries and to the conceptual framework of public health.

It is surprising that the magnitude of accomplishment of the Expanded Programme on Immunisation, and with it the achievement of Dr. Henderson as its Director, has generally been little recognised. When the history of public health in the second half of this century comes to be written, I believe that the EPI programme will be seen as one of its most conspicuous achievements, lifting to a new level of practical action, one of the primary objectives of creating sustainable change in the field of global health.

In January 1990, Dr. Henderson became an Assistant Director General of the World Health Organisation, a position from which, though he will continue to oversee the global immunisation programme, he is now responsible for all communicable disease control programmes (with the exception of AIDS).

For all these reasons, I venture to commend this nomination to the Jury in the full confidence that Dr. Ralph Henderson not only merits this Award, but that he and his colleagues will be strengthened by it in carrying this remarkable programme to its conclusion.

Yours sincerely,



John Wilson
Senior Consultant IMPACT

Neale

Nov. 4, 1991

Dear Rudolph:

Ockarrah's memo to you dated Oct 31 concerning the quinine patenting issue seemed right on the mark.

Congratulations on your leadership as always.

It was good to see you at the library of medicinal bark and even better to hear you.

Warmest regards.

Sincerely

Alan

GEORGE BUSH LIBRARY

THIS FORM MARKS THE FILE LOCATION OF ITEM NUMBER /
LISTED IN THE WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER.

By Larry Thompson
Washington Post Staff Writer

The National Institutes of Health appears to be trying to corner the market on human genes.

Last summer, the federal government's bastion of biomedical research applied for patents on 347 human genes—the naturally occurring molecules that dictate the form and function of the human body. Next month, NIH says it expects to file a second application on 2,000 more human genes. Until now molecular biologists had patented only a few human genes, one at a time, as they were identified and used to make biotech products such as insulin and the blood-clot dissolver Tissue Plasminogen Activator (tPA).

The magnitude of NIH's action has ignited a firestorm of criticism. Biotech industry officials worry that government patents will stifle commercial development of gene-based products. Scientific leaders in Europe and Japan predict the filing will trigger an international race to nail down protective gene patents for their own countries.

Among the most vehement objectors has been James D. Watson, who shared a Nobel prize for discovering the gene's double-helix structure. "This offends our sense of justice," said Watson, who now directs NIH's human genome project, a massive program to identify all the estimated 50,000 to 100,000 genes in the human body. Watson's program has been pursuing a much more open approach to finding genes.

Craig Venter, leader of the relatively small, 15-person laboratory within NIH's National Institute of Neurological Disorders and Stroke that is identifying the genes, said he is amazed by the controversy. Using a strategy rejected by genome project leaders, he can "rapidly and inexpensively" find the most interesting genes—the specialized subset of genes that is active in a given type of cell. Critics charge he is skimming off the genetic cream.

The British journal *Nature* has warned that Venter's approach could launch a "patent gold rush" with every country's labs trying to stake out its own genes. If NIH gets

these patents, it will, in effect, control any dollar value that can be derived from their commercial use. While the potential wealth is unknown, the few biotech products already on the market—nearly all being manufactured with the aid of specific genes—have generated hundreds of millions of dollars in sales and will eventually reach billions annually.

"We don't look at patents as a fund-raising tool," said Reid G. Adler, who, as head of the NIH Office of Technology Transfer, filed the patent applications. Adler thought he was protecting the future of the American biotech industry. Once discoveries are described in scientific publications, Adler said, it is more difficult to win worldwide patents.

"I didn't want to miss the boat," he said. "Our primary goal is to get products developed. Having patent protection will enhance our ability to transfer this technology to companies. Without patent protection, companies won't spend the money to develop it."

Almost no one else sees it that way.

"This is a disincentive for small biotech companies," said Richard Godown, president of the Industrial Biotechnology Association. The patents could hamper small biotech companies trying to discover and market new gene-derived products. Companies might risk spending their limited venture capital to develop a product only to find that NIH already "owned" that gene.

Big Scale, Limited Evidence

How can anyone patent a human gene? After all, they are naturally occurring substances that have existed in humans, and their ancestors, for millions of years.

To receive a patent, according to patent office officials, an "invention" must be novel, "non-obvious" to someone in the relevant field, and it has to be useful. The problem of patenting naturally made chemicals first arose years ago in the pharmaceutical industry. Penicillin, for example, is a natural substance produced by fungi, yet it was granted a patent. Moreover, a few human genes have been patented—but in the specially prepared form used to manufacture gene-based drugs.

But no patents have ever been is-

NIH's Rush

to Patent

Human

Genes

Page 1 of 3



"This offends our sense of justice."

— James D. Watson,
NIH human genome project director

sued on the scale proposed by NIH. And seldom have scientists sought such broad patents for a gene and its gene products—the proteins that cells would manufacture under instruction from the gene—on such limited evidence. Venter's gene-analyzing factory, unlike the efforts of the genome project, analyzes gene bits, not the whole gene.

Instead of determining the entire sequence of subunits that make up the gene—the series of "letters" that spell the message—Venter's group analyzes just enough of these newly discovered genes to show that they exist and that the same code has not been reported before. They then leave it to others to finish the time- and money-consuming job of analyzing the entire gene and the protein it makes. But by then, he and NIH will hold the patent.

This approach has been strongly attacked by Watson and others.

"I mean it is brainless work," Watson said. "This is a perfect case of a brainless robot." Science magazine quoted Watson as saying that "virtually any monkey" could run these robot gene machines.

Initially stunned by these attacks, Venter and his staff now take the criticism with some humor: Last week, technicians purchased gorilla masks and posed for photographs in front of their sequencing machines.

Brainless or not, does it qualify for a patent? Opinions vary. Patent attorneys have raised doubts because Venter does not know the



"This is a bit of a tempest in a teapot."

— Bernadine P. Healy,
director of NIH

utility of his new genes. Scientists working in this field also argue that what he did is totally obvious.

While refusing to discuss the NIH application directly, Edward E. Kubasiewicz, director of the patent office's biotechnology group, said that to get a patent for the "DNA that represents the gene, the person has to identify that gene, isolate it, purify it, put it in a different form than it has in nature, and give it a different utility than it has in nature."

Even within the NIH, the debate has a sense of free-for-all. NIH Director Bernadine P. Healy said she has no intention of blocking the next patent filing even though Watson opposes it.

"One of Jim's strengths is that he is deliciously blunt and has strong opinions on things," Healy said. "My belief, at the present time, is that this is a bit of a tempest in a teapot. I think the discussion has become a little silly because it has been elevated to the level of some moral, science policy, [an] ethical issue."

Meanwhile, Healy said, "the patent office will look at it and see if there is anything here that is patentable."

As it happens, the patent office says it will be a year before it can get around to evaluating any applications. Until then, major genome projects in the United States, Europe and Japan may be forced to spend millions of dollars on a gene-finding race just in case Venter and NIH get their patents.

Page 2 of 3

THE WHITE HOUSE

Sept 15, 1991

Dear Bernadine:

Again my warmest Thanks
for your superb hospitality on
Thursday evening at The State
House!

Here with the data that I
mentioned from The FCCSET

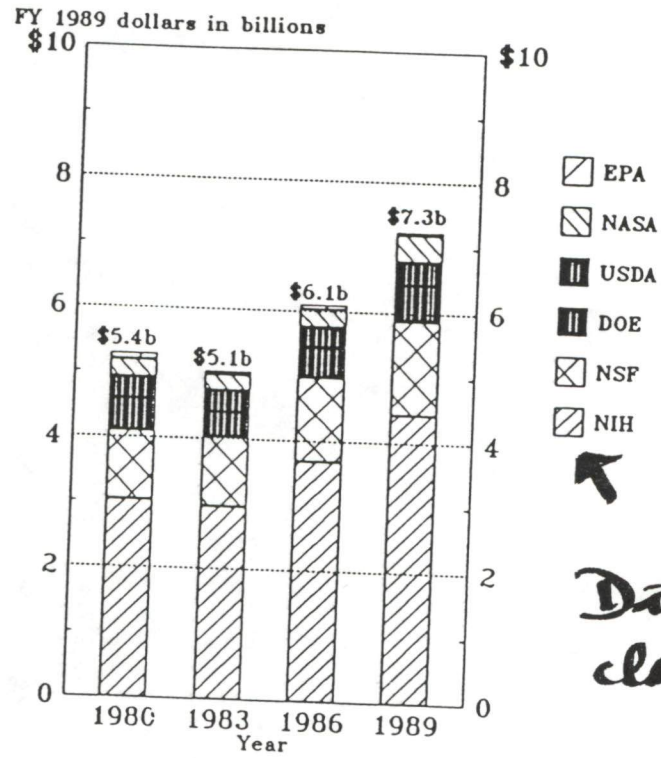
Working Group on the Structure &
The Support of U.S. Science.

I gather that while NIH
support of academic research
has gone up, intramural research
has grown at a much slower
rate. We need to discuss.

Sincerely
Allan

A. Funding by Agency

Academic Research Funding by Six Civilian Federal Agencies:
FY 1980-FY 1989 (selected years)



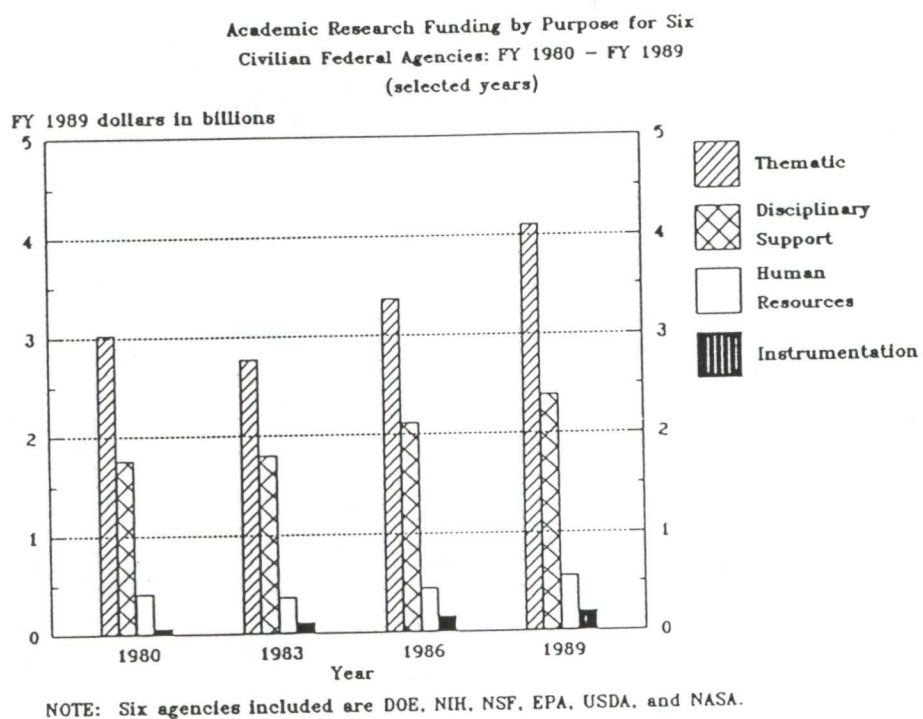
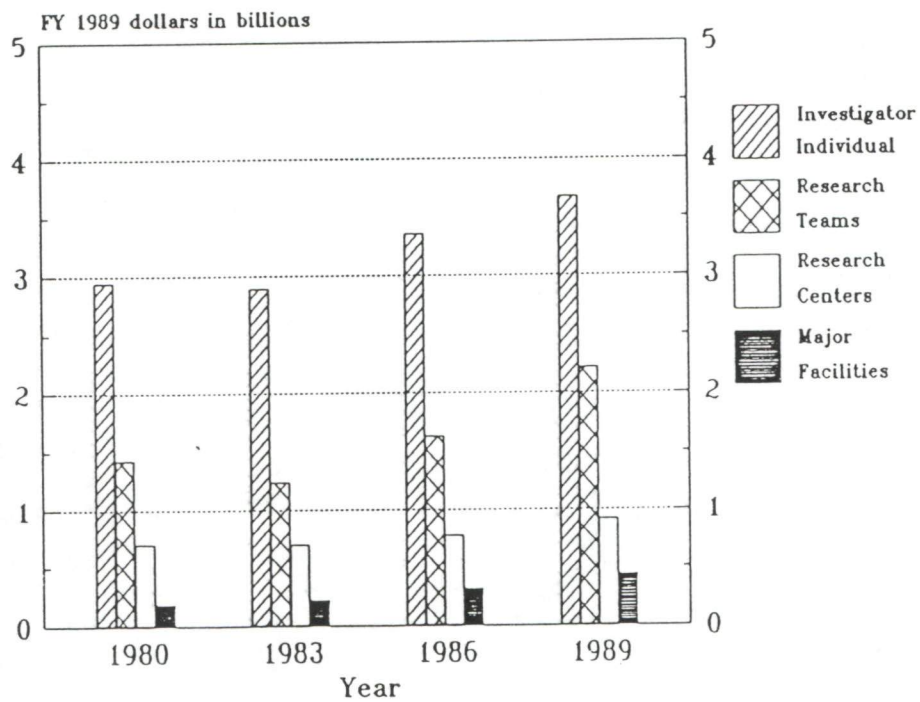
A. Amount

Figure 7

A. Amount

Academic Research Funding by Mode of Support for
Six Civilian Federal Agencies: FY 1980 - FY 1989
(selected years)



THE WHITE HOUSE

WASHINGTON

July 30, 1991

Dear Steve:

This is just a brief note to inquire about your daughter, Rachel, and to find out how her negotiations with Yale have proceeded. Specifically, if there is anything that I can do I would welcome the opportunity to make whatever arrangements might be in her interest.

In particular, she might want to spend a little time at Yale in one of the colleges getting a better feeling for the place once classes open in the fall.

I had hoped to see you when the President went to NIH to swear in Bernadine Healy but, as I might have expected, that degenerated into a total mob scene and the helicopter group was in and out so fast that we had time to see no one at all.

Peter keeps me up to date on the exciting developments in your laboratory and, once again, I must tell you how deeply indebted I am to you for all that you and your colleagues did for Pat over and beyond any possible professional call. I shall never forget it.

I had the pleasure of meeting your cousin who is taking over as President of the Academy of Neurology and only then realized that, together with Lee Rosenberg, the current Dean of the Medical School at Yale, I knew all three of the Rosenbergs in medicine--a most impressive collection!

Please do let me know if I can do anything to lend a hand with Rachel's application.

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Dr. Steven A. Rosenberg
Chief of Surgery
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

March 15, 1991

Dr. D. Allan Bromley
6716 Tulip Hill Terrace
Bethesda, Maryland 20816

Dear Allan:

This is just a short note to thank you for your kindness in contacting the Dean of Admissions at Yale to arrange an interview for my daughter, Rachel. The interview went well and she enjoyed her visit to Yale. Thank you for your help.

I hope that you are doing well. I often hear about you from Peter.

If there is anything that I can do to be of help to you, please do not hesitate to contact me.

Best wishes.

Sincerely,

A handwritten signature in cursive script, reading "Steve Rosenberg", with a long horizontal flourish extending to the right.

Steven A. Rosenberg, M.D., Ph.D.
Chief of Surgery
National Cancer Institute

SAR/mr