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2005-0336-F

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FOIA MARKER

**This is not a textual record. This is used as an
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Record Group/Collection:	George H.W. Bush Presidential Records
Collection/Office of Origin:	Chief of Staff, White House Office of
Series:	Card, Andrew, Files
Subseries:	

OA/ID Number:	00329
Folder ID Number:	00329-001

Folder Title:
[Andrew Card] Candidates for OSTP [Office of Science and Technology] Position [1]

Stack:	Row:	Section:	Shelf:	Position:
G	8	1	1	1

032054
FL006-01

April 27, 1989

MEMORANDUM FOR THE RECORD

RE: FOLDER OF CANDIDATES FOR SCIENCE ADVISOR

Yesterday, Governor Sununu's office transferred to ORM one folder containing files relating to candidates for the position of Assistant to the President for Science and Technology.

Among the papers are resumes, memorandum and correspondence, most of which was acknowledged by Andrew Card.

Enclosures filed in
Oversize Attachments #

329

COPY

CANDIDATE: Dr. D. Allan Bramley

Address (city, state)

35 Tokeneke Drive, No. Haven, CT 06473

Phones

(203) - 432-3082(203) - 248-3588

Remarks

Special Notes: A B C D E F G
(circle all that apply)

Source

Recommenders

Employment/Agency

EOP

Position

Science Advisor to the President

8

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY



December 6, 1988

25 JAN 1989

Adm

Dear Mr. Untermeyer:

I enthusiastically recommend Dr. D. Allan Bromley to serve as Science Adviser to President Bush.

Dr. Bromley, Henry Ford II Professor of Physics at Yale University and founder and Director of the A.W. Wright Nuclear Structure Laboratory at Yale, has created a world-class center for graduate education in the nuclear sciences. In August 1987, Vice President Bush participated in the dedication ceremony of Dr. Bromley's latest accelerator at the Wright Laboratory at Yale.

During the 1988 Presidential campaign, Dr. Bromley was active in recruiting Scientists and Engineers for Bush. He also organized a public forum at Yale that brought together faculty and students to support Vice President Bush.

A nuclear physicist of international stature, Dr. Bromley is a leader in the national and international scientific communities. He is past president of the 132,000 member American Association for the Advancement of Science, the world's largest scientific society, as well as of the International Union of Pure and Applied Physics, the world coordinating body for physics research. He has been a member or chairman of national advisory committees to many federal agencies and has contributed to national and international panels and commissions.

Dr. Bromley has led four Presidential missions -- three to India and one to Brazil -- to negotiate equitable U.S. science and technology cooperation with those countries. The Indian missions followed the 1982 announcement by President Reagan and Prime Minister Indira Gandhi of a Science and Technology Initiative between the United States and India; Allan Bromley chaired a panel of eminent scientists and engineers charged with developing and implementing the initiative. More recently, I signed a three-year extension of the S&T Initiative on behalf of President Reagan last October in India following eight months of intense negotiations in which Dr. Bromley played a key role.

In 1986, when President Reagan and President Sarney of Brazil established a Presidential Science and Technology Initiative, Dr. Bromley served as the U.S. chairman of the U.S.-Brazil Presidential Panel on Science and Technology Cooperation, which developed jointly a very useful set of recommendations for bilateral cooperation in science.

As a member of the White House Science Council since its inception in 1982, Allan Bromley has helped shape the debate and articulate the science policies of this nation. With David Packard, he chaired the White House Science Council's 1986 Report on the Health of U.S. Colleges and Universities, which influenced the Administration's decision to sustain and strengthen our unparalleled commitment to support for basic research.

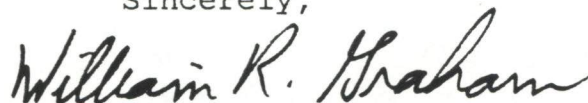
President Reagan awarded Dr. Bromley the National Medal of Science in 1988. The President has also nominated him to membership on the National Science Board, which governs the National Science Foundation.

In addition to being a distinguished scholar, Dr. Bromley serves on the board of directors of three major corporations and has a sound understanding of the relationship between science and technology on the one hand and U.S. economic strength and national security on the other. He would bring his formidable intellect, energy, prestige, and eloquence to the position of Science Adviser.

As President Reagan's Science Adviser, I have valued Allan Bromley's counsel, insight, and judgment. Scientist, scholar, teacher, diplomat, corporate director -- Allan Bromley is an indefatigable and highly valued contributor to the formulation and implementation of Administration science policy.

I recommend Allan Bromley to you with unreserved confidence and enthusiasm.

Sincerely,



William R. Graham
Science Adviser to the President
and Director,
Office of Science and Technology Policy

Enclosure

Resume and Biographical Data

Mr. Chase Untermeyer
Personnel Director
Office of the President-elect
1825 Connecticut Avenue, N.W.
Washington, D.C. 20270

cc: The Honorable John Sununu

D. Allan Bromley is the Henry Ford II Professor of Physics and Director of the A. W. Wright Nuclear Structure Laboratory at Yale University. Born in Westmeath, Ontario, Canada, he received his undergraduate education in the Faculty of Engineering at Queen's University, in Canada, receiving the B.Sc. degree with highest honors in 1948. He received the M.Sc. degree from Queen's University in 1950 and the Ph.D degree from the University of Rochester in 1952, both degrees in nuclear physics. He subsequently has been awarded 10 honorary doctorates from universities in Canada, France, Germany, Italy, South Africa, and the United States.

Remaining on the University of Rochester faculty from 1952-1955, he moved to the Chalk River Laboratories of Atomic Energy of Canada where he was Senior Scientific Officer and Section Head. In 1960 he was appointed to a professorship in physics at Yale; he served as chairman of Yale's physics department from 1970 to 1977, founded the Wright Laboratory in 1963, and has been its Director since that time, and was appointed to the Henry Ford II chair in 1972.

One of the world's leading nuclear physicists, he has carried out pioneering studies on both the structure and dynamics of nuclei and is considered the father of modern heavy ion science, one of the major areas of nuclear science. He has also played major roles in the development of accelerators, of detection systems, and in computer based data acquisition and analysis systems. An outstanding teacher, over the past two decades, his Laboratory at Yale has graduated more Ph.D's in experimental nuclear physics than any other institution, worldwide. He has published over 450 papers in science and technology and edited eighteen books.

Apart from his research and teaching at Yale, he has played an active role in both national and international science and science policy. As chairman of the National Academy's Physics Survey in the early 1970s, he contributed in a central way to charting the future of that science in the subsequent decade. As President of the American Association for the Advancement of Science—the world's largest scientific society—and of the International Union of Pure and Applied Physics—the world coordinating body for that science—he has been one of the leading spokesmen for US science and for international scientific cooperation.

In recent years he has served as chairman of the US side of both the Gandhi-Reagan Indo/US and the Sarney-Reagan Brazil/US Science and Technology Initiatives and is a member of the US/USSR Joint Coordinating Committee for Research on the Fundamental Properties of Matter and of the Council on Foreign Relations.

He is a charter member of the White House Science Council, the senior US advisory group in science and technology policy. In July of 1988 he was awarded the highest US scientific honor — the National Medal of Science — by President Reagan and was nominated for membership in the National Science Board.

He is married to the former Patricia J. Brasseur and they have two children, David John and Karen Lynn.

D. ALLAN BROMLEY

BIOGRAPHICAL DATA

BORN: May 4, 1926, Westmeath, Ontario, Canada

CITIZENSHIP: U.S.A. (naturalized April, 1970)

MARITAL STATUS: Married (Patricia Jane);
Two Children (David John - born 1953)
(Karen Lynn - born 1956)

UNDERGRADUATE EDUCATION:

B.Sc. (with highest honors) Faculty of Applied Science
(Engineering) 1948 Queen's University at Kingston,
Ontario

GRADUATE EDUCATION:

M.Sc. Physics, 1950
Queen's University at Kingston, Ontario

M.S. Physics, 1951
University of Rochester, Rochester, N.Y.

Ph.D. Physics, 1952
University of Rochester, Rochester, New York

M.A. (Honoris causa), 1961
Yale University, New Haven, Connecticut

Dr. Phil. Nat. (Honoris causa), 1978
University of Frankfurt, Frankfurt, Germany

Docteur [Physique] (Honoris causa), 1980
University of Strasbourg, Strasbourg, France

D.Sc. (Honoris causa), 1981
Queen's University, Kingston, Ontario

Litt. D. (Honoris causa), 1981
University of Bridgeport, Bridgeport, Connecticut

D.Sc. (Honoris causa), 1982
University of the Witwatersrand, Union of South Africa

Sc.D. (Honoris causa), 1982
Notre Dame University, Notre Dame, Indiana

Dottore [Fisica] (Honoris causa), 1984
University of Padua, Padua, Italy

D. H. L. (Honoris causa), 1987
University of New Haven, New Haven, Connecticut

D.Sc.

(Honoris causa), 1988
Trinity College, Hartford, Connecticut

EMPLOYMENT HISTORY:

1952-53	Instructor, Physics Department University of Rochester, Rochester, New York
1953-54	Assistant Professor, Physics Department University of Rochester, Rochester, New York
1955-57	Associate Research Officer Atomic Energy of Canada, Ltd., Chalk River, Ontario, Canada
1958-60	Senior Research Officer and Section Head Atomic Energy of Canada, Ltd., Chalk River, Ontario, Canada
1960-61	Associate Professor, Physics Department Yale University, New Haven, Connecticut
1960-63	Associate Director, Heavy Ion Accelerator Laboratory Yale University, New Haven, Connecticut
1961-present	Professor, Physics Department Yale University, New Haven, Connecticut
1963-present	Director, A.W. Wright Nuclear Structure Laboratory Yale University, New Haven, Connecticut
1970-77	Chairman, Physics Department Yale University, New Haven, Connecticut
1972-present	Henry Ford II Professor of Physics Yale University, New Haven, Connecticut

OFFICE:

Physics Department, WNSL
Yale University
New Haven, Connecticut 06511
203-432-3082 or
203-432-3083

HOME:

35 Tokeneke Drive
North Haven, Connecticut 06473
203-248-3588

PUBLICATION RECORD:

Please see attached listing.

HONORS:

- a) Governor General of Canada Medal - 1948
- b) Shell Oil Fellowship - 1949
- c) NRC (Canada) Predoctoral Fellowship - 1950
- d) NRC (USA) Postdoctoral Fellowship - 1952
- e) Fellowship, American Physical Society - 1962
- f) Fellowship, Connecticut Academy of Arts and Sciences - 1968
- g) Fellowship, American Academy of Arts and Sciences - 1972
- h) Fellowship, American Association for Advancement of Science - 1974
- i) Guggenheim Fellowship, 1977-78
- j) Humboldt Foundation Prize - 1978 and 1982
- k) Benjamin Franklin Fellowship, Royal Society of Arts (London)-1979
- l) Distinguished Alumnus Award - 1985
University of Rochester, Rochester, New York
- m) Fellowship, Brazilian Academy of Sciences, 1987-
- n) National Medal of Science, 1988

CLEARANCES:

- a) 1955-60, Top Secret Canadian Clearance
- b) 1969-present, USAEC/ERDA Q Clearance, No. WA131938
- c) 1972-present, Department of Defense, United Nuclear Corporation
- d) 1974-present, Department of Defense, Naval Studies Board, Top Secret
- e) 1981-present, White House, Top Secret and Specials

COMMITTEE AND PANEL ACTIVITIES:

American Physical Society

- a) Member of Council, 1967-71
- b) Member of Publication Committee, 1968-72

National Research Council

- a) Member of Panel on Nuclear Physics, 1965-66
- b) Member of Panel on Intermediate Energy Physics, 1965-66
- c) Chairman, Committee on Nuclear Science, 1965-74
- d) Member, Executive Committee, Division of Physical Science, 1967-74
- e) Member, Executive Committee, Assembly of Mathematical and Physical Sciences, 1974-78
- f) Chairman, Office of Physical Sciences, 1975-78
- g) Member, Naval Studies Board, 1974-78
- h) Chairman, U.S. National Committee, International Union of Pure and Applied Physics, 1973-1979
- i) Member, Board on International Organization and Programs, 1978-1981
- j) Member, Advisory Committee for the International Council of Scientific Unions, 1981-1987

National Academy of Sciences

- a) Chairman, Physics Survey Committee, 1969-73
- b) Member, US/USSR Working Group on Science Policy, 1974-present
- c) Head, U.S. Nuclear Science Delegation to the People's Republic of China, May-June, 1979
- d) Member, U.S. National Committee for ICSU, 1981
- e) Member, Advisory Board, Physics Survey Committee, 1984-1985

White House Science Council

- a) Member, 1981-present

Office of Science and Technology Policy

- a) Consultant on Nuclear Physics 1976-79
- b) Chairman, Presidential Panel on Indo-US Cooperation, 1982-present
- c) Vice Chairman, Panel on the Health of U.S. Colleges and Universities, 1984-1985
- d) Chairman, Presidential Panel on U.S. - Brazilian Cooperation in Science and Technology, 1986-present

U.S. Department of Energy (formerly ERDA)

- a) Member, High Energy Physics Advisory Panel (HEPAP), 1973-1977
- b) Member, US/USSR Working Group on Research on Fundamental Structure of Matter, 1974-present
- c) Member, Nuclear Science Advisory Committee (NSAC) 1981-1987
- d) Member, Basic Energy Sciences Evaluation Review Committee, 1981
- e) Member, Energy Research Advisory Board Panel on Interactions with Universities, 1982-1983
- f) Chairman, NSAC Panel on Electron Accelerator Facilities, 1982

National Science Foundation

- a) Member, US/USSR Working Group on Scientific Manpower and Education, 1972-73
- b) Chairman, Subcommittee to Review University Based Nuclear Science Laboratories, 1979
- c) Member, Alan T. Waterman Award, Selection Committee 1980-1983

U.S. Civil Service Commission

- a) Member, Presidential Award Selection Committee, 1981-1982

National Engineering and Science Research Council of Canada

- a) Member, Ad Hoc Committee on Nuclear and Particle Physics, 1979
- b) Member, Kaon Review Committee, 1986

Atomic Energy Control Board of Canada

- a) Member, TRIUMF Grants Committee, 1975-76

Premier's Council, Province of Ontario, Canada

- a) Member, Evaluation Panel for Centers of Excellence, 1987-1988

American Association for the Advancement of Science

- a) Chairman, Physics Section (B), 1978
- b) President-elect, 1980
- c) President, 1981
- d) Chairman of the Board, 1982

American Academy of Arts and Sciences

- a) Fellow, 1972-present
- b) Chairman, Membership Committee (Physical Sciences) 1987-present

International Union of Pure and Applied Physics

- a) Vice President, 1975-1981
- b) President-elect, 1981-1984
- c) President, 1984-1987

International Council of Scientific Unions

- a) Member U.S. Delegation 1976-1987
- b) Member Executive Board 1982-1983

Council on Foreign Relations (US)

- a) Member, 1982-present

Institute of Nuclear Power Operations

- a) Member, Advisory Council 1983-1987

Electric Power Research Institute

- a) Member, Advisory Board 1984-present

EDITORIAL ACTIVITIES:

- a) Member, Editorial Board, **American Scientist**, 1968-1981
- b) Member, Editorial Board, **Annals of Physics**, 1967-1979
- c) Member, Editorial Board, **Il Nuovo Cimento**, 1972-present
- d) Member, Editorial Board, **Nuclear Instruments and Methods**, 1975-present
- e) Member, Editorial Board, **Journal of Physics G-Nuclear Physics**, 1979-1984
- f) Member, Editorial Board, **Science, Technology and the Humanities**, 1978-1982
- g) Member, Editorial Board, **Nuclear Science Applications**, 1979-present
- h) Member, Editorial Board, **Technology in Society**, 1981-present
- i) Member, Editorial Board, **Atomic and Nuclear Data**, 1982-present
- j) Consulting Editor, **McGraw-Hill Encyclopedia of Science and Technology** (Atomic, Nuclear and Particle Physics), 1974-present
- k) Consulting Editor, **McGraw-Hill, Fundamentals of Physics Series**, 1967-present
- l) Editor, **Academic Press Series, Academic Paperbacks**, 1967-73
- m) Associate Editor, **Physical Review**, 1966-69

ACADEMIC VISITING COMMITTEES:

- a) Harvard (Physics Department), 1972-77
- b) M.I.T. (Physics Department), 1973-79 (Laboratory for Nuclear Science), 1968-73, 1988-1992
- c) University of Pennsylvania (Physics Department), 1974-75
- d) University of Rochester (Physics Department), 1974-75
- e) Cornell University (Physics Department), 1974-76
- f) State University of New York, Albany, 1972-74
- g) Brooklyn Polytechnic/NYU, 1973-74
- h) Queen's University, Canada (Faculty of Applied Science), 1973-75, 1982
- i) State University of New York, Stonybrook (Physics Dept) 1981
- j) McMaster University (Physics Dept) 1983
- k) Indiana University (Physics Dept) 1983-present

NATIONAL LABORATORY ACTIVITIES:

- a) Brookhaven National Laboratory
Consultant, 1961-present
Visiting Committee, Member, Physics Accelerator and Instrumentation Divisions, 1977-1983 Chairman, 1981
RHIC Policy Committee, Chairman 1984-present
- b) Oak Ridge National Laboratory
Consultant, 1962-present
Visiting Committee, Electronuclear Division, 1962-65
Visiting Committee, Physics Division, 1966-72
Advisory Committee, National Heavy Ion Laboratory, 1972-73
Policy Committee, Holifield Heavy Ion Laboratory, 1974-present
- c) Los Alamos Scientific Laboratory
Consultant, 1969-73
- d) Bates Linac Laboratory (M.I.T.)
Policy Committee, 1973-1981
- e) Argonne National Laboratory
Visiting Committee, 1975-78 (Chairman, 1978)
AUA Committee on Disciplinary and Laboratory Reviews (Chairman, 1979-1980)
University of Chicago Oversight Committee for the Argonne National Laboratory, 1987-present
- f) Lawrence Berkeley Laboratory
Visiting Committee, Nuclear Science Division, 1975-78, Chairman 1978
Visiting Committee, Accelerator Division, 1982-1987
Chairman 1985, 1986
- g) Lawrence Livermore National Laboratory
Consultant, 1959-1962; 1987-
- h) South Eastern Universities Research Association
Member, Board of Directors, 1985-present
Chairman, CEBAF Review Committee, 1986-present

INDUSTRIAL ACTIVITIES:

- a) UNC Incorporated, Director, 1967-present
Supplier of naval reactors, aircraft engine service, telecommunications, environmental services, precision manufacturing services, etc.
- b) United Illuminating Company, Director, 1973-present
Public Electrical Utility
- c) Union Trust Company, Director, 1975-present
Commercial Bank
- d) Northeast Bancorp, Inc., Director, 1975-present
Bank Holding Company
- e) Extrion Corporation, Founding Director, 1971-75
Manufacturer of ion implantation accelerators and devices (sold to Varian, July 1975)
- f) General Ionex Inc., Director, 1980-1984
Manufacturer of small accelerators and components
- g) Barnes Engineering Co., Director 1984-1986
Manufacturer of infrared detectors imaging systems and related devices.
(Sold to EDO Inc., 1986)
- h) Labcore, Incorporated, Founding Director, 1971-73
Supplier of architectural and conceptual design - hospital, academic, institutional areas
- i) Chronar Corporation, Director 1986-1987
Supplier of photovoltaic power sources and devices
- j) High Voltage Engineering, Technical Consultant, 1967-70
Manufacturer of particle accelerators and high voltage products
- k) International Business Machines Corporation
 - (i) Member, Laboratory Advisory Committee, 1970-72
 - (ii) Joint Study Program, Yale/IBM, 1967-73
Developed integrated computer based data acquisition system - hardware and software
 - (iii) Joint Study, Yale/IBM, 1975-1980
Profiling of hydrogenic contaminants in possible metals for containment vessels of breeder and fusion reactors
- l) General Telephone and Electronics, Founding Member, Technical Advisory Committee, GTE Laboratories, 1973-1982, Chairman 1973-1978
- m) Union Carbide Corporation, Management Advisory Council for Oak Ridge National Laboratory, 1973-1981
(Chairman, 1975, 1980, 1981)

NON PROFIT ORGANIZATION:

- a) Oak Ridge Associated Universities, Inc.
Director, 1977-1980
- b) University of Bridgeport
Trustee, 1981-1987
- c) Southeastern Universities Research Association
Director 1984-present
- d) David and Lucile Packard Foundation
Chairman—Junior Faculty Fellowship Committee 1988—

OTHER CONSULTING ACTIVITIES:

- a) Office of Science and Technology Policy, 1971-73; 1981-
- b) Brooklyn Polytechnic, Executive Technical Development Program, 1966-
- c) National Research Council of Canada, Ad Hoc Panel on Nuclear Science Planning, 1974-75
- d) Agency for International Development (Turkey), 1969
- e) New York State Board of Regents, 1973-74
- f) World Bank, 1976
- g) Ministry of Education, Federal Republic of Germany, 1982-1987
- h) Office of Technology Assessment, 1980-1985

LECTURESHIPS

Executive Seminar, CAP Lectures,	U.S. Foreign Service, 1968-1987 Queen's University, 1972 University of Toronto McMaster University McGill University
Lauritsen Lecture, Palmer Lectures, Wilson Lectures, Slack Lectures, Leon Lectures, Presidential Lecture	American Physical Society, 1974 Haverford University, 1975 University of Rochester, 1976 Vanderbilt University, 1980 University of Pennsylvania, 1980 American Association for the Advancement of Science, Washington, 1981
Keynote Lecture	International Conference on Nuclear Physics Munich, 1981
Newson Lectures, Damon Lectures, Fuqua Lectures, Director's Lecture, Centenary Lecture Keynote Lecture	Duke University, 1982 U.S. National Science Teachers, 1982 University of Florida, 1982 Argonne National Laboratory, 1982 University of the Witwatersrand, 1982 International Conference on Nuclear Physics Florence, 1983
Galileo Lecture Distinguished Invited Lecture Keynote Lecture	University of Padua, Padua, Italy, 1984 NATO Summer School Maratea, Italy, 1985
Director's Lecture, Rutherford Lecture, Presidential Lecture	Corporate Associates, American Institute of Physics, 1986 Annual Meeting Lawrence Livermore Laboratory, 1987 Daresbury Laboratory, Daresbury, England, 1987 International Union of Pure and Applied Physics Washington, 1987
Congressional Lecture Presidential Lecture	American Physical Society, 1987 Perkin-Elmer Corporation Norwalk, Connecticut, 1987
Miller Lecture	Burkett Center for Study of the Presidency University of Virginia, 1987
Davis Lecture	U.S. Naval Postgraduate School, 1988

OFFICE OF THE PRESIDENT-ELECT
WASHINGTON, D.C. 20270

10 January 1989

Dear Dr. Bromley:

On behalf of President-Elect Bush, thank you for your willingness to serve in his Administration.

The Presidential Personnel staff will review your letter closely and will be in contact with you directly.

With thanks and best wishes.

Sincerely,

A handwritten signature in dark ink, appearing to read "Chase Untermeyer", with a stylized flourish at the end.

CHASE UNTERMEYER
Director of Personnel

D. Allan Bromley, Ph.D.
Physics Department, WNSL
Yale University
New Haven, Connecticut 06511

cc: The Honorable William R. Graham
Executive Office of the President
Office of Science and Technology Policy
Washington, D.C. 20506

LETTER OF RECOMMENDATION TICKET

28847

Batch No: _____
 Accession No: _____
 Last Name: _____ F.I. _____

LETTER OF RECOMMENDATION

FILESTAT: 2
 BATCH NO: L 5 0 0
 LTR 1:

Enter from document,
 FNAME, LNAME, SEX, ADDRESS, CITY
 STATE, ZIP

RLTRCD: #11 #12 #14

 #15 #17 #18

RECFOR: _____

AGCY: WHS

INTERNAL ROUTING

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 Coding: _____
 Detailed Data Entry: _____
 Resume Storage: _____

Science & Technology
 Advisor

SCHMIDT, Dennis C.
 Pres. Gale

note
 reply

T 11-16

RECEIVED 12/22/88

DEC 22 1988



December 20, 1988

Dear President Schmidt,

I thoroughly enjoyed the opportunity to meet with you and some of your colleagues on December 5th. I am delighted that you promptly answered our request for suggestions by putting forward the name of Professor Allan Bromley for the position of Science and Technology Advisor to The President. I will forward Professor Bromley's name, along with your strong recommendation, to the appropriate people, and he will receive the highest consideration.

The President-Elect and I both hope to maintain a strong connection with the academic community in the future, demonstrating that the Bush Administration's commitment to education is more than just campaign rhetoric.

Thank you once again for meeting with the President-Elect and I last week and for your recommendation of Professor Bromley. Please accept my warmest wishes to you and your family during this holiday season and into the new year.

Sincerely,

Governor John H. Sununu

President Benno C. Schmidt
Yale University
New Haven, Connecticut 06520

*Yale Press
for your
Joh. n. n.*

1-1

Bernie C. Schmidt

356-0063

08 DEC 1960

YALE UNIVERSITY
NEW HAVEN CONNECTICUT

06520

207-432-2550

OFFICE OF THE PRESIDENT

Wednesday

Dear Governor Sumner:

Thank you for meeting with
me and my colleagues from other universities.
We appreciate very much the strength
of the Vice-President's commitment to
education, and we hope to be of help
to him in any way that we can.

You asked for suggestions about
the position of Science Advisor, or Assistant
to the President for Science and Technology
or whether the position will be titled.

I would like to recommend in the
most enthusiastic terms my Yale
colleague Allan Bromley, Henry Ford 2d
Professor of Physics and Director of
Yale's Wright Nuclear Structure Laboratory.
Professor Bromley has probably trained more
of America's nuclear scientists than
anyone in the nation. He is a great
figure in nuclear research, respected
around the world. He has been one of the
country's leading figures in science
policy, and co-chaired the White House
Science Council, with David Packard, which

YALE UNIVERSITY
NEW HAVEN CONNECTICUT

OFFICE OF THE PRESIDENT

produced an enormously influential report three years ago. He teaches a very effective seminar in national science policy. He is a superb scientist, a thoughtful policy analyst, a very effective administrator, and a person of great vision and practicality.

I recommend him without qualification.

Thank you again for seeing me.

Sincerely,
Benjamin Schmidt

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
01. Biography	Biography of Alvin W. Trivelpiece [personal information redacted] (1 pp.)	4/88	(b)(6)	

Collection:

Record Group: Bush Presidential Records

Office: Chief of Staff, Office of the

Series: Card, Andrew A., Files

Subseries:

WHORM Cat.:

File Location: [Andrew Card] Candidates for OSTP [Office of Science and Technology] Position [1]

Date Closed:	12/29/2009	OA/ID Number:	00329-001
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

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 advice 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]

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

PRM. Removed as a personal record misfile.

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

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

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Professor Herman:

Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,

A handwritten signature in dark ink, appearing to read "Andrew H. Card, Jr.", with a stylized flourish at the end.

Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Professor Robert Herman
Department of Civil Engineering
College of Engineering
University of Texas
Austin, Texas 78712-1076



COLLEGE OF ENGINEERING
THE UNIVERSITY OF TEXAS AT AUSTIN

Department of Civil Engineering • Austin, Texas 78712-1076 • (512) 471-4921

February 1, 1989

Mr. Andrew H. Card
Deputy Chief of Staff
The White House
Washington, D. C. 20500

Dear Mr. Card:

I was very interested to learn that **Dr. Ruth Reck** is being considered for the post of Presidential Science Advisor in the White House. I have known her for close to twenty five years as a colleague and as friend. It gives me great pleasure to recommend her to you since she is outstanding scientifically and technically and an outstanding person.

Dr. Reck is highly intelligent with an excellent scientific background. It is significant to indicate that she has done a fine body of scientific work herself and also in collaboration with others. She has excellent experience and strengths to bring to this important position.

She has a keen overview of environmental problems that comes from personal efforts over a period of more than twenty years. This view is exceptionally broad ranging from the technical aspects to international considerations. She has developed great skill in analyzing large-scale and multidimensional problems. As mentioned earlier, she can bring a hands-on know-how to the problems encountered in technology. May I emphasize that she is recognized for her analytical and problem solving abilities.

While I am certain that you must have her vita and know many of the details of her work, the following is worth mentioning. Her technical expertise is great, specifically in the area of modelling the earth's atmosphere, ozone layer problems, problems with particulates, long time temperature changes, etc. She also has expertise as a result of her many years at General Motors Research Laboratories in the impact of environmental problems on transportation and traffic. This latter is one of the most important problems in our time affecting the urban scene.

Dr. Reck has for many years consulted with the top management of General Motors on environmental science and technology. She is highly respected in the scientific community and has a very broad range of colleagues and acquaintances in many fields with whom she is in continual contact.

In addition, she has a creative capacity in the area of problem solving and policy development. She has a great deal of experience working with government officials and agencies and is therefore well recognized throughout the various scientific circles of

government as well as the National Academies. Moreover, she has maintained an unusual interest in military strategy and tactics. Her service on various boards and committees further stimulated her interest in this area.

Dr. Reck is an excellent manager, handles complex situations and people with insight and political sensitivity. She is an energetic person with great enthusiasm for her efforts. She works hard and is highly productive. Her scientific output and her contributions to various government, scientific society and Academy enterprises supports this. She is a person of great honesty and integrity and unusual in that she has an excellent overall view as well as the personal ability to do complex technical work herself. I recommend her to you most highly and without any reservation. I would be extremely comfortable knowing that she is in a position to work and advise on the deeply important and sensitive concerns of our country.

Please let me know if there is anything further that I might be in a position to assist with in this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Robert Herman".

Robert Herman
L.P. Gilvin Centennial Professor Emeritus
in Civil Engineering and
Sometime Professor of Physics

RH/sg

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Ms. Herzenberg:

Thank you for your recommendation on behalf of the Association for Women in Science of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Ms. Caroline L. Herzenberg, President
Association for Women in Science
Suite 303
2401 Virginia Avenue, N.W.
Washington, D.C. 20037

Association for Women In Science

Promoting Opportunities for Women To Enter The Sciences And Achieve Their Career Goals

February 22, 1989

Mr. Andrew H. Card
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Card:

I am president of the Association for Women in Science, a national organization that encourages women to pursue careers in the sciences and helps women achieve their career goals. We are pleased that President Bush has made a commitment to appointing more women to his administration and we would like to assist you in this process by recommending qualified women scientists.

The Association strongly recommends Dr. Ruth Reck for the position of Presidential Science & Technology Advisor. Dr. Reck received her B.A. in 1954 at Mankato State University and her Ph.D. in physical chemistry in 1964 at the University of Minnesota. Dr. Reck has worked with General Motors for over twenty years and this industrial background has enabled her to understand the important issues involved in technological competitiveness. Dr. Reck's extensive industrial, regulatory, and academic experience provides a good basis for the development of a consortium between the three. Dr. Reck has a broad knowledge of many areas of science and engineering, including transport properties, solid-state physics, quantum mechanics, and chemical kinetics.

Dr. Reck has hands-on knowledge of climate research and has been the independent technical counsel for General Motors on global environmental issues for many years. Her most recent research has been to study the impact of climate change on human health. Through adoption of this topic as a new initiative by SCOPE (Scientific Council on Problems of the Environment, an arm of UNEP), Dr. Reck will pilot a white paper on the subject for the World Health Organization.

Dr. Reck has served on 38 boards and committees and acted as chair for 12 of these boards. She has also been the recipient of a number of honors. In 1987, she was the first woman to receive the Gold Award in Engineering for outstanding contributions in chemical engineering. In 1987, she also received a Certificate of Special Tribute from the State of Michigan for her efforts to enhance the quality of life, and in 1988 Dr. Reck was awarded an Outstanding Achievement Award from the University of Minnesota's Institute of Technology.

If you would like further suggestions of women in science who we believe to be well qualified for consideration for the new administration, please contact us.

Sincerely,

Caroline L. Herzenberg

Caroline L. Herzenberg, President

cc: Dr. John Sununu

AWIS, Suite 303, 2401 Virginia Avenue, NW, Washington, DC 20037 (202) 833-1998

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Professor Hawthorne:

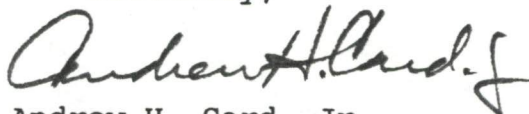
Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,

A handwritten signature in dark ink, appearing to read "Andrew H. Card, Jr.", with a stylized flourish at the end.

Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Professor M. F. Hawthorne
Department of Chemistry and Biochemistry
University of California
Los Angeles, California 90024

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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SANTA BARBARA • SANTA CRUZ

PROFESSOR M. FREDERICK HAWTHORNE

DEPARTMENT OF CHEMISTRY AND BIOCHEMISTRY
LOS ANGELES, CALIFORNIA 90024

February 7, 1989

Andrew H. Card, Deputy Chief of Staff
The White House
Washington, DC 20500

Dear Mr. Card:

I recently learned that Dr. Ruth A. Reck is being considered for Presidential Science Advisor in the White House and I want to write and express my support.

Dr. Reck first became known to me when I was chairman of a National Academy of Sciences Committee on Chemical and Biological Sensor Technologies. The subject of the committee was to review the preparedness of the U.S. Army for air-land battlefields which included nuclear, biological and chemical warfare or some mix thereof. Dr. Reck was asked to consider the role of environmental effects and the complications which meteorological conditions could impose.

The committee performed a very thorough review of both classified and unclassified information. We obtained hands-on knowledge of the topic including not only U.S. technology, but that used by both friendly and Warsaw Pact countries.

Dr. Reck's contributions to our committee work, and more recently to a corporate-wide systems analysis she performed for General Motors, attests to her ability to handle a wide range of scientific and technical topics. With Dr. Reck's background and ability she would be able to identify facts and present to the Administration simple and concise explanations of problems and possible solutions. The current national security, technological and global environmental issues are so far reaching that I believe it takes someone of the quality and dedication of Dr. Reck to tackle them.

Of equal importance to the topics above is the role of education. We must dedicate ourselves to improve the scientific knowledge of our future leaders and scientists and must strive to improve the understanding of the public as well. With Dr. Reck's background and contacts, I believe she could develop a much needed consortium between the government, industry and the scientific community. We dare not let the scientific and technological challenges of today go unmet. This requires a strong sense of science and technology in the White House and someone such as Dr. Reck to give sound advice.

Sincerely,

A handwritten signature in cursive script that reads "M. F. Hawthorne".

M. F. Hawthorne
Professor of Chemistry

CC: Dr. John Sununu, Chief of Staff

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Professor Ross:

Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Professor John Ross
Department of Chemistry
Stanford University
Stanford, California 94305

STANFORD UNIVERSITY, STANFORD, CALIFORNIA 94305

JOHN ROSS
CAMILLE AND HENRY DREYFUS PROFESSOR
OF CHEMISTRY

(415) 723-9203

February 9, 1989

Mr. Andrew H. Card
Deputy Chief of Staff
The White House
Washington, DC 20500

Dear Mr. Card:

I am writing on behalf of Dr. Ruth A. Reck who I understand is being considered for the position of Science Adviser to the President.

I have known Dr. Reck since she was a postdoctoral research associate at Brown University in 1964, and I have followed her career since then.

Dr. Reck is an excellent theoretical chemist with major research accomplishments in environmental and atmospheric chemistry. She has also worked in the field of polymers, traffic problems, stochastic processes, among others. Her work is marked by insight and high standards of performance. Her research contributions to the basic understanding of the chemistry of the atmosphere and its importance in environmental problems has deservedly earned her an international reputation.

In addition to her scientific work, Dr. Reck has contributed extensively in the area of public service with high skill, common sense, balance, and devotion. I served with her, for a number years, on a major committee of environmental protection agency and she showed good judgement and thorough understanding of complex issues involving science, technology, and public policy.

Dr. Reck has lived in the academic world, with the major part of her career in industry. She has executive experience, knows how to listen and knows how to make decisions. I recommend her to you highly.

Sincerely yours,

A handwritten signature in blue ink that reads "John Ross". The signature is written in a cursive style with a large, looping "J" and a stylized "R".

John Ross

JR:dmb

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Professor Drost-Hansen:

Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Professor W. Drost-Hansen
Department of Chemistry
University of Miami
Post Office Box 249118
Coral Gables, Florida 33124



February 2, 1989

W. Drost-Hansen
Professor of Chemistry
(305) 284-5842

Mr. Andrew H. Card
Deputy Chief of Staff
The White House
Washington, D.C. 20050

Dear Mr. Card:

Never before in our Nation's history has the President been confronted with so many crucial issues the solutions to which will depend on our scientific insight and skills. Thus it is imperative that the President be afforded access to the best possible advice in all science-related matters.

For the position of Presidential Science Advisor I warmly recommend Dr. Ruth A. Reck as one of the most qualified persons in the scientific community.

The success of our technology-based industry is the foundation of our nations competitive edge; however, technology is merely the large-scale exploitation of scientific principles. Thus, to maintain our lead, to secure our continued financial success, and to assure our military pre-eminence, we must judiciously promote and advance our national efforts in scientific research.

To appreciate the characteristics needed in a Presidential Science Advisor it is worthwhile enumerating some of the vastly different problem areas facing the Administration and requiring scientific efforts to solve. Our national security will depend on our success in quantum optics (such as lasers), computer and communications technology (including "radiation hardened" installations), space research, global climate changes and defense against terrorists and possible chemical and bacteriological warfare. Our nations economic future will depend on the growth of our high-technology industry based on scientific breakthroughs in areas as diverse as superconductivity, supercomputers, fusion research, and other efforts in the area of alternate energy resources. The health of our Nation will require immense efforts in biology, medicine and biotechnology. The success of our efforts to compete intellectually in the world will depend on our efforts to educate our young people so they may not only be able to

College of Arts & Sciences
Department of Chemistry
P.O. Box 249118
Coral Gables, Florida 33124
(305) 284-2174

function responsibly in a technological society, but also provide the necessary intellects for staffing our research institutions. Our national standing as an intellectual giant will also require that we support the most fundamental types of research from the supercollider and radioastronomy to human genome sequencing and cell physiology.

No single person can be an expert on all subjects. However, one of the most useful backgrounds with which to tackle such a bewildering array of subjects as those enumerated above is no doubt physical chemistry. More than any other discipline physical chemistry touches upon, and integrates over, all aspects of physical matter and is quite readily extended to biological systems. Thus, one of Dr. Recks foremost assets is her very impressive background in physical chemistry.

Dr. Reck is an outstanding intellect, highly respected in the scientific community. She has demonstrated an uncanny ability to deal with the analysis of large-scale and multidimensional problems (she is an expert on global climate studies) and is widely recognized for her analytical and problem-solving capacity.

Dr. Reck has established an enviable reputation as a scientist, capable of, and interested in, working with researchers in academia, industry and the Federal Government. In this sense, she has a significant opportunity to provide the best imaginable integration of all scientific efforts from the widest spectrum of society. Because of her personality and background she is able to work effectively with people representing a very broad distribution of disciplines. It is also worth noting that Dr. Reck has represented the United States at many International Symposia, Meetings and Workshops in Canada, Europe and the Soviet Union.

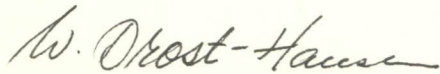
Obviously no one has reached her status of achievement without the ability to work hard, effectively and with cheerful enthusiasm. Dr. Reck is a good manager, able to handle complex situations and people with political savvy.

Dr. Reck has maintained a strong (and unusual) interest in military strategy and tactics. She has served on several boards and committees which have further stimulated her interest in this area. More traditional scientists generally have far less interest and insight into military matters than Dr. Reck.

Finally, as the result of her long association with General Motors and her extensive work on various committees of Federal Agencies (including the National Academy of Sciences) she has a strong sense of the politically and economically feasible (a trait which may perhaps be somewhat lacking in some academic colleagues.)

In summary: I strongly recommend Dr. Reck for the position of Presidential Science Advisor. The President, our Nation, and Science will be well served by Dr. Reck in this position.

Yours sincerely,

A handwritten signature in cursive script, reading "W. Drost-Hansen".

W. Drost-Hansen
WDH:th

cc: Dr. John Sununu, Governor

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Dr. Cowgill:

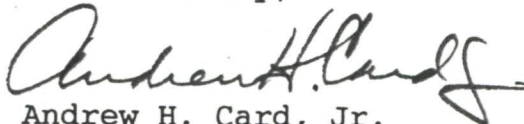
Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Dr. U. M. Cowgill
Associate Environmental Consultant
Environmental Toxicology Research Laboratory
1702 Building
The Dow Chemical Company
Midland, Michigan 48674



THE DOW CHEMICAL COMPANY

February 3, 1989

MIDLAND, MICHIGAN 48674

Mr. Andrew Card
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Card,

This is in reference to Dr. Ruth Reck who is being considered for the position of Scientific Advisor to President Bush. Dr. Reck is quite well known in the scientific community. She has been a member of or a consultant to various advisory councils of the scientific advisory board of the U.S. Environmental Protection Agency for the past decade. She was chairman of the climate research group of the International Joint Commission for several years. She has been a member of a number of National Academy of Sciences' environmental committees. Recently, she has been part of the Chemical Warfare Committee (Chemical and Biological Sensors Technology - Department of Defense). I think that her greatest asset is that she has extensive training in both the hard sciences, physics, math and chemistry, as well as the so called soft sciences, namely the environmental sciences. I, therefore, recommend her for your consideration for the position of Science Advisor to the President without any reservation.

Sincerely yours,

U.M. Cowgill, Ph.D.
Associate Environmental Consultant
Environmental Toxicology Research Laboratory
1702 Building
(517) 636-1735

tjz

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Mr. Penner:

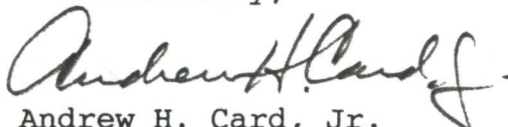
Thank you for your recommendation of Dr. Ruth Reck for the position of Assistant to the President for Science and Technology.

Please know that Dr. Reck was considered, along with many others, for this important position. While her background is certainly impressive and many strong letters of recommendation were written on her behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,

A handwritten signature in dark ink, appearing to read "Andrew H. Card, Jr.", with a stylized flourish at the end.

Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Mr. Stanford S. Penner
Department of Applied Mechanics and
Engineering Sciences
Mail Code B-010
University of California
La Jolla, California 92093-0310

UNIVERSITY OF CALIFORNIA, SAN DIEGO

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DEPARTMENT OF APPLIED MECHANICS AND
ENGINEERING SCIENCES, MAIL CODE B-010

LA JOLLA, CALIFORNIA 92093-0310

January 31, 1989

Mr. Andrew H. Card
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Card:

I understand that Dr. Ruth Reck is a possible candidate for the position of Science Advisor to the President. The purpose of this letter is to support her candidacy for this position enthusiastically.

Dr. Reck and her work have been known to me for many years, including a period of about 20 years during which I served as a consultant to the Physics Division at the General Motors Research Laboratory.

Among Dr. Reck's qualifications, I would especially emphasize her excellent background in pure and applied science, her pioneering work relating to the use of global circulation models in order to elucidate the greenhouse effect, and her general preoccupation with research on environmental and energy issues. I believe that she will do an outstanding job in attracting to her office the best scientists and engineers, including the younger people who have been notably absent from the scene in recent years. In terms of breadth, understanding and sound judgement, she can be counted upon to perform her job competently and in accord with the best interests of our country.

As someone who has long been involved in all aspects of the U.S. energy-supply and utilization issues, I am especially concerned that judgements on the greenhouse effect will reflect deep, balanced and conservative assessments of the issues. Ruth Reck can be depended upon to comprehend and handle this issue and the linked energy problems with the needed perception and effectiveness.

Please do not hesitate to call me if you require additional information.

Sincerely yours,

Stanford S. Penner
Professor of Engineering Physics and
Director, Center for Energy and
Combustion Research

SSP:sl

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Ms. Raines:

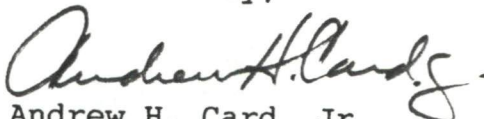
Thank you for your recommendation of Dr. George Rathmann for the position of Assistant to the President for Science and Technology.

Please know that Dr. Rathmann was considered, along with many others, for this important position. While his background is certainly impressive and many strong letters of recommendation were written on his behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate the time you took to share your views with the Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Ms. Lisa Raines
Director of Government Relations
Industrial Biotechnology Association
1625 K Street, N.W.
Suite 1100
Washington, D.C. 20006



**Industrial
Biotechnology
Association**

1625 K Street, N.W.
Suite 1100
Washington, D.C. 20006
(202) 857-0244
FAX: (202) 857-0237

Lisa J. Raines
Director of
Government Relations

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Ralph W.F. Hardy
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David A. Jackson
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Charles C. Leighton
Merck, Sharp & Dohme
Research Laboratories

Roger H. Salquist
Calgene, Inc.

Gabriel Schmergel
Genetics Institute, Inc.

Hubert J.P. Schoemaker
Centocor, Inc.

James L. Vincent
Biogen Inc.

Robert H. Williams
Eli Lilly and Company

BY MESSENGER

February 13, 1989

Mr. Andy Card
Assistant to the President and
Deputy Chief of Staff
1st Floor, West Wing
The White House
Washington, D.C. 20500

Dear Mr. Card:

Enclosed please find a letter sent to the Office of Presidential Personnel urging the nomination of Dr. George B. Rathmann for the position of Assistant to the President for Science and Technology. It has been suggested to me that you might appreciate a copy of these materials.

Dr. Rathmann's credentials make him superbly qualified for this post, as the enclosed materials amply demonstrate. You might also be interested to know that, while Dr. Rathmann is a long time Republican party supporter, he enjoys broad bipartisan support in Washington, as exemplified in letters of support from such politically diverse supporters as Frank Fahrenkopf and Ted Kennedy. I am confident that Rathmann's nomination would lead to speedy Senate confirmation and will contribute substantially to the stature of the Office of Science and Technology Policy.

I urge you to give Dr. Rathmann every consideration for this important position. Please let me know if I can provide additional information.

Very truly yours,

LJR:lmw

Enclosures



**Industrial
Biotechnology
Association**

1625 K Street, N.W.
Suite 1100
Washington, D.C. 20006
(202) 857-0244
FAX: (202) 857-0237

Richard D. Godown
President

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Amgen

Vice Chairman
Hugh A. D'Andrade
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American Cyanamid Co.

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Ralph E. Christoffersen
The Upjohn Company

Nicholas M. Frey
Pioneer Hi-Bred
International, Inc.

Ralph W. F. Hardy
BioTechnica International, Inc.

David A. Jackson
E.I. du Pont de Nemours & Co.

John R. Norell
Phillips Petroleum Company

Roger Salquist
Calgene, Inc.

Hubert J. P. Schoemaker
Centocor

Mark B. Skaletsky
Biogen Inc.

Robert A. Swanson
Genentech, Inc.

January 30, 1989

Mr. Chase Untermeyer
Director
Office of Presidential Personnel
Room 131
The Old Executive Office Building
Washington, D.C. 20500

Dear Mr. Untermeyer:

I am writing on behalf of the Industrial Biotechnology Association and its eighty-seven member companies to nominate George B. Rathmann, Ph.D. for the position of Assistant to the President for Science and Technology. I am pleased to report that Dr. Rathmann's admirers have prevailed upon him to agree to being considered for this important position.

I believe that Dr. Rathmann possesses extraordinary intelligence and insight into the mechanisms and goals of federal science and technology policy, particularly with regard to how federal investment in scientific research can be translated into national economic growth by the private sector. Dr. Rathmann's boundless energy and vision, combined with thirty-four years of corporate research management experience, will enable him to revitalize our nation's commitment to science and technology leadership. I believe that Dr. Rathmann is uniquely qualified to develop a workable framework for a public-private partnership that will lead to U.S. scientific and technological excellence in all areas of research much as he has contributed so substantially to American leadership in biotechnology.

Dr. Rathmann's distinguished career as a scientist and research executive spans many technologies and corporate environments. After managing research and development in such major companies as 3M, Litton Industries, and Abbott Laboratories, Dr. Rathmann started a new company, Amgen, in October 1980 which has since grown to more than 450 employees, making it the third largest biotechnology firm in the United States and a member of the BusinessWeek 1000. Since its inception and under Dr. Rathmann's leadership, Amgen has pursued an aggressive program of new product discovery and development. The company has distinguished itself as one of the most successful in the biotechnology industry at bringing products through research and development and into clinical testing, and currently leads the industry with nine of its pharmaceutical products in human clinical testing.

Mr. Untermeyer

Page 2

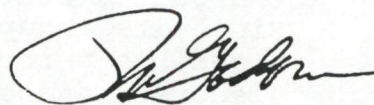
Through judicious management of its technical and financial assets, the company has maintained a successful balance of resource allocation which has enabled it to assume a leadership position in terms of both its scientific and financial performance. Dr. Rathmann's successful entrepreneurship is demonstrated by Amgen's 1988 revenues of \$53.3 million dollars representing a 54% increase over the company's 1987 results, and the company posted its third consecutive year of increasing profits with an increase of 52% over 1987 results. The federal research program could certainly benefit from similar stewardship.

In addition to Dr. Rathmann's substantial business experience, he is a long time Republican party supporter, and during the 1988 election cycle provided substantial support to state and federal Republican campaigns. He was a strong supporter of President Reagan's programs and feels deep personal loyalty and philosophical compatibility with President Bush's Science and Technology Program, as articulated in speeches and fact sheets produced during the campaign.

Dr. Rathmann has, throughout his career, demonstrated consistently superior judgement and integrity, and has earned the tremendous respect, admiration, and affection of his colleagues in the scientific and business communities. His colleagues in the biotechnology industry elected him to IBA's Board of Directors repeatedly since the Association's inception and he recently completed service as Chairman of our Board of Directors. Perhaps even more revealing of the tremendous admiration earned by Dr. Rathmann is the fact that he has been selected to be the Biotechnology Executive of the Year for the past two consecutive years by the Wall Street securities analysts who follow our industry. (He was among the top three during the preceding two years.) I might add that Dr. Rathmann has considerable personal charisma and inspires loyalty in his staff.

In conclusion, I believe that Dr. Rathmann would make an outstanding Assistant to the President for Science and Technology and I urge his nomination.

Very truly yours,



RDG:lmw

Enclosures

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
02. Resume	Resume of George B. Rathman [personal information redacted] (1 pp.)	1/30/89	(b)(6)	

Collection:

Record Group: Bush Presidential Records

Office: Chief of Staff, Office of the

Series: Card, Andrew A., Files

Subseries:

WHORM Cat.:

File Location: [Andrew Card] Candidates for OSTP [Office of Science and Technology] Position [1]

Date Closed:	12/29/2009	OA/ID Number:	00329-001
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

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 advice 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]

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

PRM. Removed as a personal record misfile.

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

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

Science & Technology

BIO TECHNOLOGY

THE HORMONE THAT'S MAKING AMGEN GROW

EPO builds red blood cells. And it could build Amgen into a major drugmaker

Beer-and-popcorn bashes with the boss are a monthly affair at Amgen, a biotechnology company with a young staff that likes to hang loose. But the Thousand Oaks (Calif.) company's 250 employees were in an especially festive mood at their most recent party. In mid-January a major medical journal published promising results of clinical tests on Amgen's most promising potential product, a hormone called erythropoietin (EPO). And Wall Street has joined the party. Since September, Amgen's stock price has more than doubled, outpacing most of its biotechnology competitors. By the end of February it closed at 38 1/4, an all-time high.

The latest excitement was caused by an article in the *New England Journal of Medicine*. It reported that Amgen's gene-spliced EPO had corrected anemia and eliminated the need for blood transfusions in all 25 kidney-dialysis patients who tested the substance. And it seemed to do so without significant side effects. That hormone, which is normally produced by healthy kidneys, combats anemia because it induces cells in the bone marrow to produce red blood cells.

MARKETING MAGIC. Analysts believe EPO can be a very big drug indeed. While the total worldwide market for patients with kidney failure is \$350 million annually, anemia affects a great many others. In the U.S. alone, some 750,000 rheumatoid arthritis and about 1 million cancer patients undergoing chemotherapy suffer from anemia, as do the AIDS victims being treated with a new drug called AZT. EPO may even help surgery patients avoid risky transfusions by building up their blood supplies beforehand. Stuart Weisbrod, an analyst with Prudential-Bache Securities Inc., predicts that "EPO will be the second blockbuster product using gene-splicing techniques after tissue plasminogen activator," a drug produced by Gen-

tech Inc. for dissolving blood clots.

EPO, in fact, could thrust Amgen into the biotech big leagues. Founded in 1980, the company has kept a low profile. After five years of losses, it finally showed a modest profit of \$548,000 on revenues of \$23 million last year. But fully 96% of those revenues came from

could approve EPO by early 1989 if the drug passes muster in large-scale clinical tests now under way. And Amgen has a sizable lead over some nine other biotech companies that are also exploring the drug. Of those, only Genetics Institute Inc. in Cambridge, Mass., has begun clinical tests—and only in Europe.

Amgen is "obviously the leader in clinical trials," admits Genetics Institute Senior Vice-President Robert I. Kamen. And being first could give the company a hammerlock on the substance. Last year the FDA granted EPO "orphan-drug" status because fewer than 200,000 U.S. kidney-dialysis patients would require it. "The company that gets to the finish line first gets exclusive marketing rights for seven years," explains Dr. Stephen B. Fredd, former head of the FDA's Office of Orphan Products Development.

Amgen is confident it will stay ahead. In early March, the company announced that it was raising \$75 million to fund clinical tests of EPO and other drugs through an R&D limited partnership. And it is counting on marketing deals with large drug companies to help it push EPO into the pharmacy. In 1985 the company gave Johnson & Johnson the right to market EPO for general anemia in the U.S. and for all uses in Europe. A year earlier, Amgen formed a joint venture, capitalized at \$24 million, with Japan's Kirin Brewery Co. Under that agreement, Kirin gained the right to manufacture and market EPO in Japan.

OTHER BASKETS. But Amgen has avoided one pitfall common to biotech companies: trading potential profits and technology for cash to develop promising drugs. The company figures it will reap at least 25% of J&J's pretax profits on EPO, instead of the 10% that is typical in such deals. In addition, it will retain the right to manufacture and sell the drug to dialysis patients in the U.S.—a manageable market for a small compa-



CEO RATHBURN AND STAFF EXPECT FOR APPROVAL BY 1989

research partnerships with major drugmakers and from interest income, not products. Now its research seems ready to pay off. And analysts are ranking it with industry stars Genentech and Cetus Corp. "Amgen is clearly emerging from the pack of second-tier biotech companies," says Peter F. Drake, an analyst at Kidder, Peabody & Co. in New York.

The Food & Drug Administration

ly. Amgen, says James D. McCamant, editor of the *Medical Technology Stock Letter*, "is a pioneer in making attractive deals with big companies."

The company is already gearing up for its market debut by building a \$15 million, 20,000-sq.-ft. manufacturing facility for EPO near its headquarters. And George B. Rathmann, Amgen's chief executive officer, says he hopes to have a 40-person sales and marketing staff by early 1989.

Rathmann, an amiable 59-year-old who was vice-president for research and development at Abbott Laboratories' diagnostics division before he came to Amgen in 1980, does not have all his eggs in one basket. Along with EPO, the company has a variety of other drugs in various stages of clinical testing, including a vaccine against hepatitis-B and three products that stimulate the body's disease-fighting system—interleukin 2 (IL-2) and two kinds of interferon. "No one product is good enough to build a company around," he says.

COMPING WITH CANCER. None of these drugs, however, has the lead time or patent position that EPO has. IL-2 is a case in point. Last August, Amgen asked the courts to determine whether its IL-2 products infringed the four patents that Cetus holds on gene-spliced versions of the substance. Cetus promptly countersued, claiming infringement. The case is pending.

Amgen, however, has already set its sights on another new drug that may dominate its field. In 1985, Amgen became the first company to engineer genetically a substance called granulocyte colony-stimulating factor (G-CSF). It belongs to a family of substances that induce cells in the bone marrow to produce disease-fighting white blood cells. Researchers hope it will prove helpful in fighting bacterial infections or certain types of cancer, such as leukemia. It may also help cancer patients cope with the ravaging effects of radiation and chemotherapy.

Already, G-CSF is being tested on cancer patients undergoing chemotherapy at Memorial Sloan-Kettering Cancer Center in New York City. And it could win FDA approval by 1990. Analysts say it could command an annual U.S. market of \$200 million by 1992.

So Rathmann will soon have to prove that he can turn a research operation into a manufacturing company. If he pulls it off, his tiny company could be sitting on billion-dollar markets in just a few years. That would be enough to satisfy the largest drugmaker, let alone a biotech upstart that is charging into the big leagues.

By Julie Flynn in Thousand Oaks

Breaking Out of the Biotech Pack

With approval expected for EPO, its kidney drug, Amgen is ready to become a major drug company.

By LAWRENCE M. FISHER

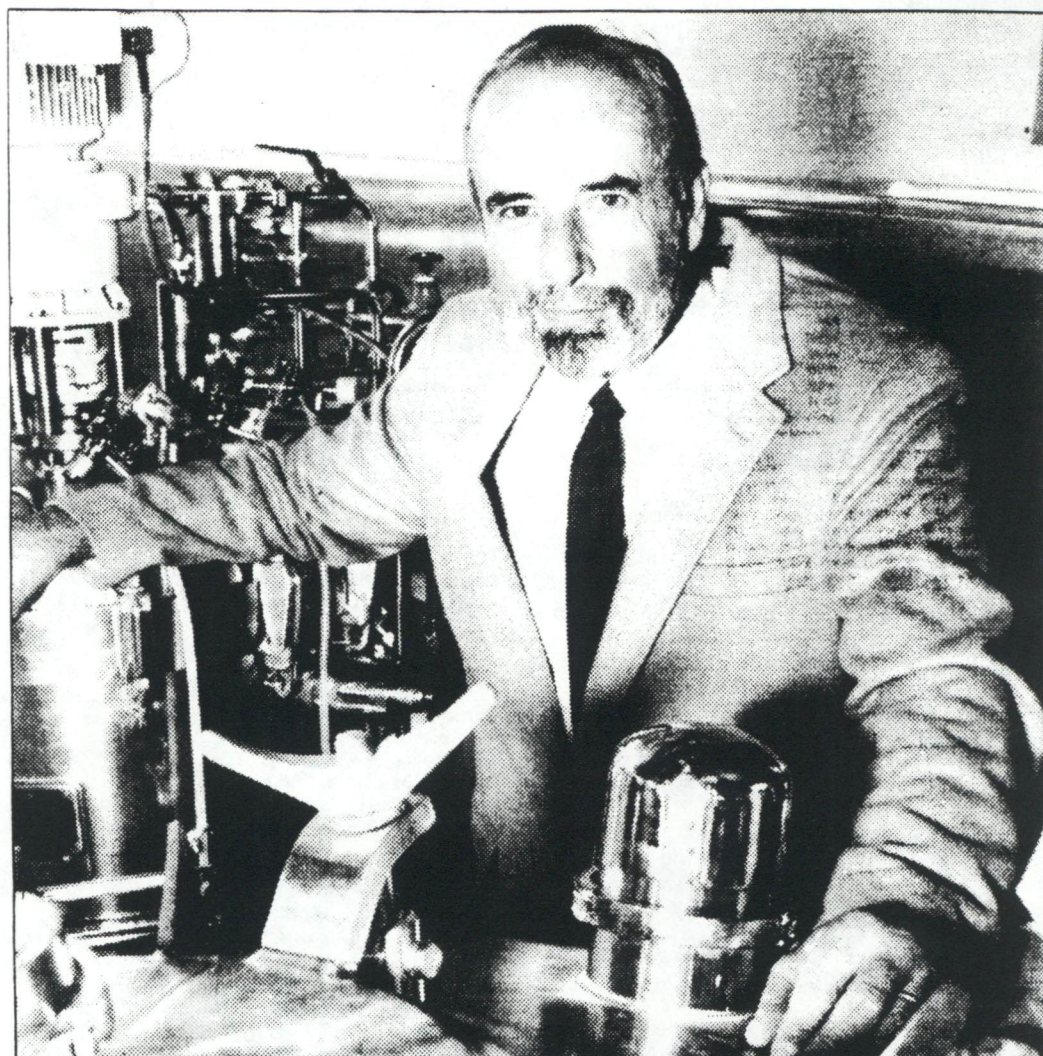
WHEN kidney dialysis patients taking part in the clinical trials of Amgen Inc.'s erythropoietin talk about the drug's impact on their lives, they tend to use words like "wonderful" and "dramatic," with all the restraint of a carnival barker hawking snake oil.

But erythropoietin, or EPO, is no hoax. Kidney specialists say the genetically engineered product successfully alleviates the chronic anemia that saps late-stage kidney disease sufferers of their energy. Amgen's EPO has been approved for sale in Switzerland and France and is expected to receive United States Food and Drug Administration approval by the end of this year.

When that happens, Amgen will become the second biotechnology company (Genentech Inc. was the first) to make the transition from a research and development organization to an integrated pharmaceuticals company. Many analysts now view Amgen — with six other drugs in clinical trials, partners like Johnson & Johnson and Abbott Laboratories and a war chest of cash — as the leading biotech company after Genentech, ahead of such concerns as the Cetus Corporation and the Chiron Corporation.

But this is the biotech business, where everything is even more complicated than it seems. Genentech has seen its stock price drop sharply since its first drug, Activase, was approved for marketing, in part because sales have been less than expected. And biotech companies often spend as much time in court contesting patents as they do in the lab perfecting gene-splicing techniques.

For more than a year, Amgen has been locked in bitter patent-infringement litigation over EPO with Genetics Institute Inc. of Cambridge, Mass., and Genetics' manufacturing partner, Chugai Pharmaceuticals of Tokyo. A promising follow-up drug, Granulocyte Colony Stimulating Factor, G-CSF, which could come to market about two years after EPO, may also lead to a patent dispute with Chugai.



The New York Times/Bart Bartholome

George B. Rathmann, Amgen's chairman, in a lab where Epogen is made.

Even so, the mood at Amgen's headquarters northwest of Los Angeles is almost relentlessly upbeat these days. In an industry where press releases have seemed to substitute for products, Amgen has always been conspicuously quiet, letting articles in medical journals chronicle its accomplishments. Now the company is letting a bit of the testimonial into its language.

"A concern of ours from the earliest day is that we have been trying to make a dream happen, and a dream that doesn't come true is called hype," said George B. Rathmann, Amgen's chairman, president and chief executive officer. But now, when anemic kidney disease patients are "brought back to normal life, when they all are corrected by the use of EPO, you know you've got a miracle," he said.

From the outset, Amgen differed from many of its rivals. It settled in southern California, while many biotech companies are based near San Francisco, because Winston Salzer, one of the founding scientists, insisted on being within driving distance of the University at California at Los Angeles, where he is a professor of microbiology. And in an industry that typically runs on red ink, Amgen has reported a profit in its last three fiscal years.

To be sure, the earnings are small — derived mostly from research and development contracts, and the proceeds from a limited partnership. But they represent more than accounting finesse, said Lowell Sears, Amgen's treasurer. "We felt it was a management discipline to maintain that profitabil-

ity," he said, adding that Amgen has achieved its profitability in part by running lean: "By any type of statistical measure — products, revenues, market capitalization — we have the fewest number of people" of any biotech company.

Amgen owes its lean corporate culture to M. Rathmann. The venture capitalists and scientists who founded Amgen in 1980 sought someone with experience as both a manager and a scientist. M. Rathmann, a physical chemist who was then vice president for research and development at Abbott Laboratories, was Amgen's first employee.

"He's one of the few scientists who also turned out to be a good businessman," said David Webber, editor of Biotech Investor. "He has a combination of abilities some of the professional managers brought in to run other biotech companies don't have."

NORMALLY produced in the kidney, erythropoietin is a hormone that circulates in the bloodstream to the bone marrow, where it stimulates immature stem cells to grow, multiply and mature into red blood cells. Patients with kidney disease often have an impaired ability to make EPO and in turn to make red blood cells, leading to a condition of chronic anemia. Patients with chronic anemia lack the energy to lead a normal active life.

Through recombinant DNA technology, Amgen is able to produce in mammalian cells a very pure EPO that closely resembles the hormone produced

in human kidneys. Patients who receive EPO say their energy returns, their skin color loses its pallor and they no longer feel cold all the time. "As soon as it started working I had so much energy I didn't know what to do with it," said Barbara Karlin, a 45-year-old Los Angeles writer and reviewer of children's books.

There have been few side-effects from EPO. Some patients taking EPO have developed high blood pressure, and some experienced seizures. But there have been no cases of patients developing antibodies to the drug, an indication that it very closely mimics the natural substance.

Among kidney specialists, known as nephrologists, "the vast majority just can't wait for this to come out," said Allen R. Nissenson, a professor of medicine and director of the dialysis program at the University of California at Los Angeles. "We've been waiting for it for years."

That wait will probably end soon. Johnson & Johnson's Ortho Pharmaceuticals subsidiary is introducing EPO in Europe under license from Amgen, with approvals from Switzerland, France and the new pan-European regulatory body already in hand. Analysts expect F.D.A. approval by the end of the year, or by mid-1989 at the latest.

INITIAL approval will be for treatment of severe anemia in dialysis patients, for which the Biotech Investor estimates the total United States market to be between \$150 million and \$200 million annually. Treatment of other anemias is likely to follow once the drug's safety record is established, although Johnson & Johnson will realize the most of the revenues from these applications, as well as from European dialysis-related EPO sales, with Amgen receiving a 10 percent royalty. Some analysts say the ultimate market for the drug could reach \$1 billion a year, with Amgen receiving as much as half of that.

But this sunny forecast is clouded by several concerns: First and foremost are the competing patent claims by Genetics Institute, which, if successful, could limit Amgen's EPO revenues. There is also some question whether Medicare will reimburse the \$6,000 or more annual cost of EPO for dialysis patients. And some analysts, citing the disappointing level of use for Activase, Genentech's recombinant blood clot-dissolving drug, worry that nephrologists may be slow to adopt EPO.

The patent issue is especially cloudy because Genetics Institute, to the surprise of most biotech experts, actually received a patent for EPO in June 1987. But Genetics Institute's patent only covered the pure EPO itself, not the means of producing it. In October 1987, Amgen was granted a patent for its recombinant process, which is the only commercially viable means of making EPO. It immediately filed suit for patent infringement against Genetics Institute and Chugai. A counter-suit followed.

Since one patent was not useful without the other, analysts predicted that the companies would reach a cross-licensing agreement; Genetics Institute and Chugai have indicated that they would favor one. But Amgen has been adamant that it will ultimately prove the Genetics Institute patent invalid, establish exclusive rights to recombinant EPO and receive damages.

"Because we were first with the cloning of the gene, and expeditiously filed our patent application, we feel that the system is supposed to give us exclusive rights," said Robert D. Weist, Amgen's senior vice president and general counsel. "We feel our position is strong enough that we shouldn't give away half," he said.

In addition to pursuing its case in the courts, Amgen has asked the International Trade Commission to block Chugai from importing EPO, which the Japanese company is currently doing for its own clinical trials in the United States.

Bruce Eisen, Genetics Institute's vice president and chief patent counsel, said the company believes its patent will ultimately prevail. While a settlement is still in both companies' best interests, he said, Genetics Institute's terms have gone up since a Federal District Court judge ruled in February that Amgen's EPO infringes Genetics Institute's patent. "We believe the tide is in our favor," he said.

AMGEN AT A GLANCE

All dollar amounts in thousands, except per share data.

Three months ended		
June 30	1988	1987
Revenues	\$19,447	\$12,581
Net income	305	494
Earnings per share	\$0.02	\$0.03
Year ended		
March 31	1988	1987
Revenues	\$53,325	\$34,722
Net income	1,725	1,137
Earnings per share	\$1.0	\$0.08

Total assets, March 31, 1988	\$192,835
Current assets	118,961
Current liabilities	12,788
Long-term debt	16,503
Book value per share, March 31, 1988	\$9.80
Stock price, Sept. 8, 1988	
NASDAQ close	31 1/4
Stock price, 52-week range	37 1/2-16
Employees, Sept. 8, 1988	420
Headquarters	Thousands Oaks, Calif.

There is some skepticism in the industry about Amgen's all-or-nothing approach. "If Amgen is unable to block imports by Chugai, it is really in a much more vulnerable situation than most people think," said Mr. Webber of Biotech Investor.

Pricing remains another big unknown. In Switzerland, where Johnson & Johnson set the price, the annual cost of EPO, based on about 150 treatments, came in at between \$7,500 and \$9,000. In the United States, where Amgen is still in talks with the Health Care Financing Administration, the price is expected to be considerably lower. Kidney dialysis is already the single costliest health care program provided by Medicare, which spent \$2.3 billion in 1986 on the nation's 91,000 patients.

Amgen officials decline to talk about pricing, but Mr. Rathmann said he is confident that Medicare will support EPO. "Dialysis was intended to rehabilitate people and they haven't been; they've just survived," he said. "Now we have a product that will rehabilitate them."

ANOTHER question for Amgen will be the extent to which doctors embrace EPO. "Nephrologists do seem unusually united, but we have run into quite a few who really have no experience with EPO at all," said Viren Mehta, an analyst with S.G. Warburg and Company.

Spreading the word about EPO will be up to Amgen's sales and marketing staff, which is only now being assembled. Openly adopting a General Tech strategy, Amgen is tapping established professionals from large drug companies. It hired Paul Dawson to run the operation, which will have about 50 employees by the time EPO is approved. Mr. Dawson was vice president for sales and marketing at G.D. Searle & Company and had held a similar position at Merck & Company.

Kathleen M. Wiltsey, Amgen's marketing manager, said most nephrologists know about EPO, the challenge now is to attach Amgen's name to the drug, and in recent literature the company always refers to it by the proprietary name Epogen. She said that the effort is simplified because both EPO and G-CSF, the next drug in Amgen's future, have one specific function: to modify blood chemistry. Other biotech drugs, like the interferons and interleukins, have a broad range of possible uses and side effects.

Despite all the attention now focused on EPO, Amgen anticipates that its second drug, G-CSF, will actually provide greater long-term revenue. Amgen has moved G-CSF rapidly through development and clinical trials, and expects FDA approval by 1990. Its primary competitor is likely to again be Chugai, although Chugai has so far only conducted clinical trials in Japan. Both companies have filed for patents on G-CSF, but none has been issued. With no patent, there is no dispute, but with a \$500 million projected market for G-CSF in the mid-1990's, "it is reasonable to expect the could be a conflict," Mr. Weist said.

RIVALS UNITE TO FIGHT CRIME

IN the race to bring erythropoietin, or EPO, to market, Amgen's only real competition has been Genetics Institute and Genetics' manufacturing partner, Chugai Pharmaceuticals. The three companies are locked in a tangled patent infringement litigation with suits piled upon countersuits.

But when a letter signed only "Pimpernel" arrived at Genetics' Cambridge, Mass., offices in June, containing secret Amgen information and promising more in return for \$150,000, or 10,000 shares of stock, Genetics immediately turned the letter over to Amgen. Genetics also supplied F.B.I. agents with a company letterhead used to respond to the letter, setting up what became the first biotech "sting" operation.

The undercover agents took a quick course in biotech talk from Amgen's chief executive, George Rathmann, so they could act as officials of Genetics Institute with some credibility. Still, they had trouble pronouncing erythropoietin (a-RITH-ro-PO-etin), and avoided using the term during negotiations with the mysterious Pimpernel.

Their seven-week investigation culminated on Aug. 11, when they arrested John Ste-

phen Wilson at a Ventura County restaurant. Mr. Wilson, a 33-year-old researcher who had left Amgen voluntarily in July, was charged with one count of interstate transportation of stolen property, and if convicted could be sentenced to as much as 10 years in prison and fined up to \$250,000. He pleaded not guilty.

Amgen said the briefcase the F.B.I. recovered contained more than 500 pages of photocopied documents, a virtual blueprint of the company's process for producing EPO. The company estimated the documents' value at about \$50 million.

The documents would probably have been of little value to Genetics Institute. According to Amgen's patent infringement suit, Genetics and Chugai are already producing EPO by the same recombinant method Amgen uses.

But the same cannot be said for other potential competitors who might have been offered the secret information. "If the material had fallen into the hands of someone not advanced in the art, it could have been of substantial value to them," said Lowell Sears, Amgen's treasurer.

THE CEO 1000



AMERICAN TELEPHONE & TELEGRAPH

James E. Olson

New York, N. Y. (212) 605-5500

Sales: \$34.1 bil. Profits: \$228 mil.

Market value: \$35.38 bil.

► Born 12/03/25, Devils Lake, N. D.; BSC, U. of N. D. 1950. Career path—operations, marketing, administration; tenure—43 years, CEO 1 year. Compensation: 1986 salary & bonus, \$1,108,000; ownership, 24,000 shares. ► Started as a manhole digger and splicer's helper. Post-divestiture drive to cut costs just starting to pay off. That and invincible long-distance business helped improve earnings in first two quarters. Biggest challenge: reversing 1986's \$1.5 billion hit in computers, office-phone switches, electronic components.



AMERICAN WATER WORKS

James V. LaFrankie

Voorhees, N. J. (609) 547-3211

Sales: \$466 mil. Profits: \$55 mil.

Market value: \$602 mil.

► Born 3/26/27, Elizabeth, Pa.; BS (business management), Georgetown 1964. Career path—operations; tenure—39 years, CEO 5 years. Compensation: 1986 salary & bonus, \$260,000; ownership, 5,000 shares. ► Heads largest, fastest-growing water utility in U. S. Stock has sprinted from 3 to 17 in six years, thanks mainly to heavy reinvestment of earnings, strong customer service. Knows business inside out—and is said to know hundreds of employees by name. Has his hands in everything, and admirers say he could motivate a brick wall.



AMERITECH

William L. Weiss

Chicago, Ill. (312) 750-5000

Sales: \$9.4 bil. Profits: \$1.1 bil.

Market value: \$13.20 bil.

► Born 5/21/29, Big Run, Pa.; BS (industrial eng.), Penn. State 1951. Career path—operations; tenure—5 years, CEO 5 years. Compensation: 1986 salary & bonus, \$930,000; ownership, 2,000 shares. ► Runs Baby Bell that serves Midwest. Sees telecommunications, computer-information converging fast. Hopes someday to integrate communications, hardware, software—if he can persuade federal courts to go along. Recent prohibitions on expansion into information services mean he'll have to keep preaching.



AMERITRUST

Jerry V. Jarrett

Cleveland, Ohio (216) 687-5000

Sales: \$828 mil. Profits: \$88 mil.

Market value: \$916 mil.

► Born 10/31/31, Abilene, Tex.; BBA, U. of Okla. 1957; MBA, Harvard 1963. Career path—banking; tenure—13 years, CEO 4 years. Compensation: 1986 salary & bonus, \$536,000; ownership, 6,000 shares. ► Ameritrust reigned as the leading Ohio bank, but management saw the competition pass it by in the 1970s. Trying to expand company's turf and services, but foray into Denver banking ill-timed. Profits are up, but two local businessmen attempted takeover and were bought out at a premium. He is building defenses against others.



AMES DEPARTMENT STORES

Herbert Gilman

Rocky Hill, Conn. (203) 563-8500

Sales: \$1.8 bil. Profits: \$27 mil.

Market value: \$700 mil.

► Born 12/25/24, Hartford, Conn.; BS, Conn. 1949; Yale. Career path—merchandising; tenure—28 years, CEO 7 years. Compensation: 1986 salary & bonus, \$597,000; ownership, 342,000 shares. ► Stepped aside November, 1986, cause of illness. Back briefly—and fully recovered. But now taking top job to Peter Hollis, current COO. Built a major for discounting by turning around ailing retailers. Expanded 14 more states, snatched G. C. Murphy Co. from raider Irwin Jacobs in 1985. But now dogged by big merchandising losses.



AMETEK

John H. Lux

Paoli, Pa. (215) 647-2121

Sales: \$568 mil. Profits: \$37 mil.

Market value: \$786 mil.

► Born 2/03/18, Logansport, Ind.; BS, Purdue 1939; PhD (chem. eng.), Purdue 1942. Career path—engineering; tenure—20 years, CEO 20 years. Compensation: 1986 salary & bonus, \$548,000; ownership, 72,000 shares. ► Moved diversified technology company from mechanics to solid-state electronics, chemical engineering. Company visionary committed to U. S. manufacturing, automation, prods managers to risks. Leaves day-to-day to President Robert Noland. Now glib on very-high-speed computers for oil exploration.



AMFAC

Ronald R. Sloan

San Francisco, Calif. (415) 772-3400

Sales: \$2.0 bil. Loss: \$15 mil.

Market value: \$534 mil.

► Born 9/29/34, Eugene, Ore.; BS, Ore. State 1959. Career path—administration, operations, engineering; tenure—26 years, CEO 1 year. Compensation: 1986 salary & bonus, \$325,000; ownership, 5,000 shares. ► He's said aloha to several unprofitable holdings, including discount clothier and chemist. But Amfac, one of Hawaii's legendary Big Five, is still a goliath, with some 50,000 acres of land, lots of resorts, and various industrial divisions. The job ahead is rough. But away from work he relaxes by tending his large flower garden.



AMGEN

George Blatz Rathmann

Thousand Oaks, Calif. (805) 499-5725

Sales: \$30 mil. Profits: \$1 mil.

Market value: \$531 mil.

► Born 12/25/27, Milwaukee, Wis.; BS, Northwestern 1948; PhD, Princeton 1952. Career path—engineering/technical; tenure—7 years, CEO 7 years. Compensation: 1986 salary & bonus, \$346,000; ownership, 544,000 shares. ► An able bear of a man, he's steered clear of biotech's pitfall: trading potential profits, technology for cash to develop promising drugs. After five loss years, company has turned a profit, now leads the biotech pack with six drugs in clinical trials. Will the company be biotech's next superstar?

• THE CORPORATE ELITE •



AMERITRUST

Jerry V. Jarrett

Cleveland, Ohio 216-687-5000

Sales: \$934 mil. Loss: \$10 mil.

Market value: \$814 mil.

► Born 10/31/31, Abilene, Tex.; BA (business admin.), U. of Okla., 1956; MBA, Harvard, 1963. Career path—finance/accounting; tenure—15 years, CEO 6 years. Compensation: 1987 salary & bonus, \$400,000; ownership, 13,000 direct, 14,000 indirect shares. ► Selling 87% stake in Denver bank company, ending three-year heartbreak that lost more than \$50 million. Closed offices in Dallas, Tampa, Chicago, and cut corporate staff by 13%. In 1987 bought back 9.6% stake from Cleveland's Alfred Lerner. Will repurchase up to 2 million shares, issued poison pill.



AMES DEPARTMENT STORES

Peter B. Hollis

Rocky Hill, Conn. 203-563-8234

Sales: \$2.0 bil. Profits: \$33 mil.

Market value: \$698 mil.

► Born 4/9/43, Newton, Mass.; BS (marketing), U. of Vt., 1965. Career path—merchandising/marketing; tenure—3 years, CEO 1 year. Compensation: 1987 salary & bonus, \$594,000; ownership, 22,000 shares. ► Career discount store took reins of family-dominated, low-end retailer in 1987 just as it was socked with weak sales, shoplifting losses, and falling profits. Diversifying into craft shops, office-supply discounting. Turn-around taking shape as he plunges into an even bigger challenge: The \$800 million purchase of troubled Zayre discount stores.



AMETEK

John H. Lux

Paoli, Pa. 215-647-2121

Sales: \$620 mil. Profits: \$41 mil.

Market value: \$621 mil.

► Born 2/3/18, Logansport, Ind.; BS (chem. eng.), 1939; PhD (chem. eng.), 1942, Purdue. Career path—engineering/technical; tenure—23 years, CEO 19 years. Compensation: 1987 salary & bonus, \$600,000; ownership, 111,000 shares. ► This diversified technology company has startup problems in computers plus spiraling materials costs. That has resulted in flat profits and a disappointing stock price. So he'll spin off a batch of high-risk, high-tech divisions into Ketema (spell it backward), leaving a "cleaner" company that Wall Street might like better.



AMFAC

Richard L. Griffith

San Francisco, Calif. 415-772-3506

Sales: \$2.3 bil. Profits: \$15 mil.

Market value: \$761 mil.

► Born 5/4/81, Blue Hill, Nebr.; LLB, U. of Colo. Law, 1953; JD, Georgetown Law, 1958. Career path—legal; tenure—4 years, CEO 10 months. Compensation: 1987 salary & bonus, \$257,000; ownership, 2,000 shares. ► He was put in last December to make sense of this Hawaiian Big Five company's grab-bag of businesses. Instead, he put his company into play by launching an LBO. After the dust cleared, the winner and soon-to-be-owner was JMB, the big Chicago real-estate syndicator and developer. He may stay on for a while.



AMGEN

George Blatz Rathmann

Thousand Oaks, Calif. 805-499-5725

Sales: \$44 mil. Profits: \$2 mil.

Market value: \$514 mil.

► Born 12/25/27, Milwaukee, Wis.; BS (physical chem.), Northwestern, 1948; PhD (physical chem.), Princeton, 1952. Career path—engineering/technical; tenure—8 years, CEO 8 years. Compensation: 1987 salary & bonus, \$398,000; ownership, 335,000 shares. ► Amiable researcher who is ushering his company into the biotech big time at last. An expert in shepherding drugs smoothly through the FDA approval maze—his new anemia drug is likely to make it to market without a hitch. Another formula still down the pike may rack up \$200 million a year by 1992.



AMOCO

Richard M. Morrow

Chicago, Ill. 312-856-6111

Sales: \$20.2 bil. Profits: \$1.4 bil.

Market value: \$19.42 bil.

► Born 2/27/26, Wheeling, W. Va.; BS (mining & petro. eng.), Ohio State, 1948. Career path—engineering/technical, production/manufacturing; tenure—41 years, CEO 5 years. Compensation: 1987 salary & bonus, \$1,000,000; ownership, 43,000 shares. ► Oil explorer and Amoco lifer might seem an unlikely man to break with this conservative outfit's traditions. But his \$4.2 billion deal for Dome Petroleum is a bet that natural gas will be key to the company's future. Buy makes Amoco North American the leader in gas reserves and production.



AMP

Walter F. Raab

Harrisburg, Pa. 717-564-0100

Sales: \$2.3 bil. Profits: \$250 mil.

Market value: \$4.57 bil.

► Born 11/25/24, Philadelphia, Pa.; BS (econ.), Wharton, 1945. Career path—finance/accounting; tenure—36 years, CEO 6 years. Compensation: 1987 salary & bonus, \$541,000; ownership, 40,000 shares. ► Stabilizing returns at world's leading electronic connector maker. Technology slid in mid-80's and earnings bumped around. Closed dozens of plants, consolidated into larger, newer ones. Acquired Matrix Science Corp., maker of aerospace/military connectors, for \$110 million. Spending all-time high of \$225 million on technology this year.



AMR

Robert L. Crandall

Fort Worth, Tex. 817-963-1234

Sales: \$7.2 bil. Profits: \$198 mil.

Market value: \$2.54 bil.

► Born 12/6/35, Westerly, R. I.; BS (business), U. of R. I., 1957; MBA, Wharton, 1960. Career path—merchandising/marketing, finance/accounting; tenure—16 years, CEO 4 years. Compensation: 1987 salary & bonus, \$954,000; ownership, 46,000 shares. ► Flying high as head of American Airlines' holding company. Pioneered frequent-flyer programs and sophisticated discounting plans, which have hurt industry upstarts. To stay ahead, he must keep American lean and mean. Jogs five miles—and smokes two packs of cigarettes—every day.

Biotechnology

Implications for Public Policy

Papers by ALBERT GORE, JR.

JOSHUA LEDERBERG

JOHN D. DINGELL

LEWIS THOMAS

JAMES J. FLORIO

GEORGE B. RATHMANN

SIMON A. LEVIN & MARK A. HARWELL

BERNAIDINE HEALY BULKLEY

*presented at a conference at the Brookings Institution,
on January 15-16, 1985*

Edited by SANDRA PANEM

THE BROOKINGS INSTITUTION
Washington, D.C.

Research, Commercialization, and the Future

GEORGE B. RATHMANN



IN THE PAST, much about biotechnology was overstated. There was substantial disagreement about what biotechnology promised. There was not much question of the conviction that biotechnology would have enormous impact on society. Different surveys projected a range of sales as a result of the applications of this technology. Some projected \$64 billion in sales by the year 2000; others claimed \$3 billion, \$9 billion, \$10 billion, or \$13 billion.

There was also significant variability in the projected timing of appearance and size of markets. For example, in the energy area, it was believed that an impact would not occur until well into the twenty-first century. No milestones have been met in the last few years. Although biotechnology may have an impact on dependency upon fossil fuels, the impact is off in the future.

The promise surrounding chemical products was broad and included industrial enzymes, fibers and plastics, specialty chemicals, animal husbandry chemicals, food processing agents, albumen and enzymes and blood expanders, and so on. Many of these chemicals are no longer of high priority, and others have displaced some of the early candidates. What of this promise was delivered?

In January 1980, there was the announcement of the tour de force that led to the cloning of interferon. In 1980, monoclonal antibodies, a product of advanced biotechnology, represented less than 2 percent of the diagnostic products being produced at that time. Today, monoclonal antibodies are a dominant factor in the diagnostic business, providing better, more specific, more sensitive, diagnostic ability.

The use of DNA molecules as hybridization probes has defined a new sensitivity range—the attomolar range—which provides detection of molecules at the concentration of 1 in 10^{-18} molar. This makes possible the detection of the equivalent of a cube of sugar in a lake several square miles in area. It also has a great potential for monitoring the environment and detecting ecological changes.

*Faci-
pract
probl*

Biotechnology's elucidation of oncogenes has provided important insights into the process involved in the development of cancer and the potential for new quantitative diagnostics. In animal health care, agents for the prophylaxis of a number of serious diseases are already being sold. For example, interferon could affect shipping fever, a disease which takes a heavy toll when cattle are moved around. Milk production is now safely improved by products not yet on the market, through the use of bovine growth hormone.

Finally, there are vaccines in development for major viral diseases. Some of these would offer safety advantages over classic vaccines because live viruses would not be introduced into the food chain; rather, protection is provided by developing antibodies to viral peptides.

There has been progress in introducing new genes into plants and controlling their expression. For example, soybean plants have been inoculated with a genetically altered rhizobium, resulting in greatly increased efficiency of nitrogen fixation. The plant's need for fertilizer is reduced, with an ecological benefit that could expand food production.

Finally, magic bullets, which carry toxins and other chemical agents directly to specific sites of disease, are already in human clinical trials. An example is the genetic engineering of erythropoietin. Erythropoietin was first defined in 1905, yet it took advanced biotechnology to produce it. Erythropoietin causes the production of red blood cells in a mouse to increase 50 percent in about two weeks. By analogy, in man, one milligram of human erythropoietin would be the equivalent of providing a patient with two units of blood for transfusion. It would be perfectly matched blood, without the introduction of any foreign proteins or the risk of infection. This very exciting opportunity is made possible entirely through genetic engineering.

Facing the practical problems

Are there practical problems in implementing biotechnology? Can sufficient quantities of these materials be made? With gamma interferon, 225,000 doses of the drug can be made in one production run by using a 300-liter fermenter. That suggests a production feasibility that perhaps many people have not realized is now at hand. Although the purification process is tedious, it is relatively straightforward. It is possible to produce the mentioned pharmaceuticals in the quantities necessary to meet world demand. I believe there is clear evidence on the scientific side that the promise of biotechnology has been met.

What is forecast for the 1985 to 1990 period? As before, there are different estimates. There is the high probability that biotechnology will have an impact on cardiovascular disease, renal carcinomas, anemias, hemophilias, and viral diseases.

Commercially, there is a very interesting phenomenon. Many relationships have developed between Japanese companies and non-Japanese biotechnology firms. This is recognition that the United States not only has produced and met the goals of the promise of biotechnology, but has been acknowledged as the world leader.

This U.S. lead, in my opinion, is a result of the support of biological research by the National Institutes of Health. Between 1978 and 1983, the NIH awarded a total of 4,700 grants. Prior to this period, the U.S. government laid the foundation for this science; government grants for biomedical research attracted people of quality to work in this field and enabled the manpower pool to develop effectively. This is one of the most significant contributions to the current U.S. lead.

Another contribution is the National Institutes of Health Recombinant DNA Advisory Committee (RAC). The RAC developed and administered the guidelines of the National Institutes of Health for conducting research with recombinant DNA in an enlightened and conscientious way. Other contributions are the venture capital system, which generated billions of dollars, and a strong, effective partnership between academic, industrial, and government scientists and administration. In addition, society has been the beneficiary of a highly motivated, brilliant group of scientists who at present are mostly in the United States.

U.S. leadership

Biotechnology research is continuing, with or without a leadership position by the United States. What are the critical factors necessary to maintain this leadership and to move ahead? Although I do not think there is any way to quantify it, it would appear that the Japanese commitment far exceeds anything going on in the United States. Yet the U.S. commitment is certainly a very big commitment. For example, in 1983, Paine-Webber estimates R&D expenditures in the United States of the biotechnology industry as a whole, of about \$236 million. They further estimate a market capitalization of about \$1.6 billion. In fact the total expenditure in this country for biotechnology in just the pharmaceutical industry accounts for 10 percent of R&D.

*Fulfilling
biotechnology's
promise*

What is needed to maintain momentum in a field? One needs financing, talent, and opportunity. It appears that the talent, the opportunity, and the finances are present in the United States. How can the odds of maintaining U.S. leadership be increased? Several options are evident. Support research and support development. It is not clear whether development should be government supported or left up to private capital, as it has been in the past. Develop R&D tax incentives. Tax breaks should be sustained or appropriately expanded. These options are targeted to support and stimulate the biotechnology industry.

Other courses of action would reduce the barriers that the biotechnology industry perceives to exist and that introduce additional time and cost into the process of doing business. For example, evaluate the patent process. When patent issues remain in doubt, it is hard to make the commitments to move products into the marketplace. Export barriers should be reduced. There are products that apply overseas very effectively, but at the present time there are major barriers to exporting such products. As a result, biotechnology firms are induced to work with overseas partners so that they can manufacture the materials and are not forced to export from this country. Finally, there should be an expeditious regulatory process. There is always the implication and possibility that industry wants to shortcut safety considerations. But nobody wants to shortcut safety considerations; it is a very poor strategy for the long term.

Other options are not typical of the way the United States has operated in the past, for example, the use of national targets. Most members of the Industrial Biotechnology Association would not feel it was useful to have a national goal. On this point, I think there is uniform agreement.

The United States could maintain leadership in biotechnology, but, should it? To answer that question one asks, what are the best alternatives to biotechnology for confronting the world's problems in disease, nutrition, congenital defects, environment, aging, energy, and others? Most people have not come up with very good alternatives to biotechnology. Biotechnology could still slow down in the hopes that other alternatives present themselves. However, I think society would have to address how to deal with those individuals whose only hope today is the potential impact of biotechnology on their specific problems.

The United States can develop a process to move ahead safely and rapidly, simply by maintaining the momentum of the past and not introducing new constraints that could have a negative

impact. Such a process would have the full support of all the participants in the biotechnology industry. It would be a great step toward proving the reality of the futuristic promises of biotechnology.

Comments by Jack Doyle

THERE ARE SOME very significant choices to make regarding the potential of biotechnology in agriculture. First, there is a major opportunity to reduce the use of chemical pesticides in the environment. There have been promises of genes being engineered into crops to make them insect and disease resistant. There have also been promises of manmade "good bugs" fighting bad bugs such as Monsanto's new microbial pesticide. If these products can be brought to market safely, they will help reduce the load of toxic chemicals in the environment. And today, especially in the shadow of the recent disaster in Bhopal, such promises need to be considered with a new fervor. Bhopal exemplifies the extensive nature of the chemical system, from factory production on the one hand and worker exposures, to the application of the products in the field and broader public exposures on the other.

Although there is a dramatic opportunity to apply some of the new genetic technologies in a constructive way to reduce pesticide toxicity in the environment, I urge extreme caution with biotechnology in the microbial realm. It is very, very important for the Environmental Protection Agency and other agencies to have a predictive ecology in place before genetically engineered microbial products are released into the environment. It is also very important that a neutral, public-sector science capability be in hand as the new era of commercial biotechnology is entered.

The public sector must play a leadership role in evaluating and pointing the way toward constructive products in biotechnology. There has already been a massive movement of scientific talent from the public sector to the commercial sphere in the field of molecular biology. Traditionally, society has relied on the university to produce a neutral base of evaluation for new products, and that neutrality is no less important now.

With those two caveats in mind—the need to proceed with caution in the microbial realm and the importance of public sector science—let us explore how biotechnology can help reduce and eliminate the pesticide system that we have lived with now for forty years. As already mentioned, one possibility is to develop crops that have been genetically engineered for disease and insect

resistance. Society can look forward to the use of such crops because they will reduce the need for pesticides and will help lower the farmer's cost of production.

Another area of promise is viral insecticides. These viruses are biodegradable. They can be used in small quantities, have a long shelf life, and can be used with existing pesticide equipment. Yet to date there has been little commercial activity in viral insecticides, primarily because they serve a very tiny market. In addition, before the Supreme Court Chakrabarty decision in 1980, there was no patent protection on viruses, then regarded as a product of nature.

Another promising area where biotechnology may help is the development of allelopathic chemicals. These chemicals, which have herbicidal effects, are produced naturally by some plants. Certain cover crops, which produce these natural herbicides, may be used in conjunction with cash crops to reduce the need for synthetic herbicides.

These are only a few of the products that might be advanced by biotechnology. What is actually being done commercially in these areas? Monsanto recently advanced a new microbial product, a genetically engineered soil bacteria that emits a toxin to kill black cutworms, which are presently a pest of corn in the Midwest. Monsanto's scientist, Bob Kaufman, mentioned at the announcement of their proposed microbial pesticide for fighting black cutworms, that with such products, it is possible that insecticides could be phased out in twenty-five years.

That comment is interesting for a couple of reasons. First, he said insecticides *could* be phased out; that does not mean they will be. Second, some might suggest that twenty-five years is too long. With this technology at hand, it might be possible to do it sooner than twenty-five years. Another important point: although the use of insecticides is now declining, the use of herbicides in the environment is rapidly increasing.

While the opportunity to reduce the chemical load on the environment with biotechnology exists, I am not optimistic that with its application the pesticide era will rapidly close. For example, at least seventeen companies are now using biotechnology in herbicide resistance work. The point of this research is to give herbicide-sensitive crops the genetic capability of resisting herbicides that are sometimes lethal to them and damaging to crop yields. I am very concerned with this application of biotechnology because it may increase the load of herbicides in the environment as well as expand the range of their use.

Some people suggest that herbicides are safer than table salt, and indeed maybe some of them are. But the fact is, not much is known about herbicide toxicity. Complete "environmental fate" data are available for only a handful of the herbicides now in use. Generally, not much is known about pesticides. Sixty to 70 percent have not been tested for their ability to cause birth defects; 90 percent have not been tested for their potential to cause genetic mutations.

Recent revelations about herbicides such as atrazine, paraquat, and alachlor in groundwater should give one pause for the kind of genetic research that we now see with making crops herbicide resistant. I think the Environmental Protection Agency should look at some of the herbicides that are now being pursued for herbicide resistance. They should take a close look at the potential toxicity of these herbicides before society is faced with products that may have to be recalled under difficult circumstances.

On a related front, a major seed company has recently asked a major chemical company for samples of its new herbicide, chlor-sulfuron. Seed company scientists are screening their new hybrid corn lines with that chemical to see if the corn lines will be resistant to the herbicide. I hope that this screening of genetic material to fit a chemical product does not become a customary practice. If such practices become the rule in the crop genetics industry, a whole new set of questions will have to be addressed, including how biotechnology may be facilitating a process that is selecting out certain other genetic traits as well. For example, might genetic traits be screened out that may be valuable for disease resistance, or for other purposes, when corn lines are screened for herbicide resistance?

In sum, although some of the research investments now occurring in biotechnology hold great promise for the environment, the work we now see going on in herbicide resistance suggests that the pesticide era in agriculture is far from over and will likely be present for at least another generation of patented products.

On that point, however, I hope to be proven wrong. I hope that the pesticide era will end sooner with the constructive and safe application of biotechnology rather than later. Yet one of the biggest obstacles to that happening is a vested interest in using the existing pesticide capital and factories to produce more pesticide products. That is why it will take twenty-five years to phase out insecticides. But there will be a change in chemistry here. Lower toxicity? Maybe. There will certainly be a more sophisticated agricultural chemistry.

The elimination of chemical toxicity in agriculture? I am not sure. This conference has focused on the questions of regulation. Yet the kind of progressive product development we are hoping to see in the future is something that cannot be regulated into existence. There may be only one "window of opportunity" to pursue some of the benign agricultural products now made possible with biotechnology. But if substantial capital investments are made in one direction, that window may be missed. I hope not.

Comments by Zsolt Harsanyi

I WOULD like to clarify what the responsible promise of biotechnology was originally. The promise was that biotechnology was going to allow us to make things in a new way—a new method of production. This can be underscored with a quote from the Office of Technology Assessment report, "The Impacts of Applied Genetics." During the study, many asked about the economic potential of the technology. The report stated, "The difficulty in predicting the economic impact is exemplified by interferon. If it is found to be broadly effective against both viral diseases and cancers, sales would be in the tens of billions of dollars annually. . . . If these potential effects were not found to hold true, the impacts would be significantly less."

The conclusion by the Office of Technology Assessment was that biotechnology offered great potential. How much of this potential can actually come to pass? Wall Street has been rather impatient. Stock prices have fallen to 50 percent of their peak level for biotechnology. Some are actually traded well below their initial public offering prices. The problem is that many people expected instant solutions, but solutions are not instantaneous.

Concerning the actual successes of biotechnology, well over 400 genes have been cloned. About 10 percent of these are human genes. Today, approximately two dozen products are in the preclinical or clinical stage of testing. Monoclonal antibodies are being tested clinically in such areas as bone marrow transplantation and in drug delivery in cancer therapy. In the area of diagnostics of infectious disease, we can now rapidly identify previously unidentifiable diseases.

The key question about government regulatory apparatus concerns what would constitute undue delay. In the early stages of all recombinant DNA and biotechnology developments, the tendency has been that because it is a new technology, it deserves undue scrutiny or exceptional scrutiny. It is my bias that this is indeed undue.

Today many are coming to the conclusion that yes, indeed, the scrutiny has been overdone, and perhaps regulation can be relaxed. Biotechnology is not a single technology, but a variety of technologies under the same rubric. These various processes have various kinds of impacts, whether environmental, health, economic, or otherwise, and each one really should be looked at very carefully. Some could be just placed in the category of being really no different from the technologies that were looked at in the past.

What should some of the guidelines for regulation be? The most important distinction would be the distinction of whether a released product is a living organism or not. To look at everything that is a product of fermentation, that is a product of an enzyme reaction of a biological process, as coming under the heading of biotechnology is to go too far. It is important to recognize what the unique characteristics are that cause us to look at something carefully. I believe that the only characteristic that is strong enough to merit special consideration is whether the organism is living or not.

Comments by Lee Miller

IN DECEMBER 1984, twelve leading biotechnology companies in the European Economic Community (EEC) met to petition the EEC on ways in which they could improve their competitiveness in biotechnology. Three things were requested.

First, the community was requested to modify its approach to regulation so that there would be a single regulatory authority for the entire European Economic Community. Second, the companies asked that the EEC improve the property rights situation. This would ensure that companies that develop new biotechnology expertise would have an opportunity to profit and to sustain the R&D needed for success. Third, companies asked that the EEC provide raw materials at world competitive prices. This would provide access to raw materials beyond the tariff barriers that have built up over the years.

These three requests are also necessary for U.S. industry to ask of the U.S. government. Yet there are additional considerations. The first one is the U.S. government support of R&D. In the very beginning, government provided a fertile seed bed for the offensive thrust that we have seen. The second is the proposal that regulation of biotechnology be managed by the existing regulatory agencies. We in Monsanto believe that the Environmental Protection Agency, the Food and Drug Administration,

and the other appropriate regulatory agencies are well equipped to provide the first-class management of regulatory affairs that is needed. Third, the United States has the free enterprise system, which is going to be very hard to replicate in the EEC.

How can the overall U.S. biotechnology development be accelerated? The current ban on export of animal and human health drugs that are not approved for sale in the United States will have an increasingly negative impact on this industry. Although this ban sounds relatively innocuous, it forces the company to place the initial plant outside the United States. A company simply cannot build a major capital factory in the United States while recognizing that it cannot export or sell in the United States until that regulatory clearance is achieved. This necessity puts a company at risk of being held hostage on a no-production basis in this country. Therefore the company's decision is to build the plant outside of the United States, thereby transferring that portion of the U.S. leadership to foreign shores. I hope this is something Congress can address. I know it is something that the biotechnology industry can respond to in a very positive, responsible fashion.

Another critical area that cannot be overemphasized is the need for property rights. These are needed in order to sustain and justify the kind of research that industry is involved in.

Application of Biotechnology

Environmental and Policy Issues

Edited by John R. Fowle III



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9. An Industry View of the Public Policy Issues in the Development of Biotechnology

INTRODUCTION

In light of the other chapters in this volume, it seems appropriate to remind ourselves about some of the rewards of biotechnology. This chapter will present an industry view of public policy issues in the development of biotechnology, and will also examine how we can verify that biotechnology has met its promise.

The key issues for domestic policies, which are outlined in Chapter 10, are to maintain U.S. leadership in biotechnology, to minimize ecological and ethical risks, and to maximize the benefits of biotechnology. Because some of those benefits have been overdramatized, people may wonder whether they actually will be realized. As a matter of fact, there are strong assurances that there will be important contributions from biotechnology. One issue, perhaps not adequately highlighted, is that policy should address the successful applications of biotechnology, which are very likely today, rather than focusing exclusively on the assessment of low-probability risks. This is particularly true if addressing those risks will cause major time delays before some of the benefits can be realized by society.

BIOTECHNOLOGY: PROMISE AND PERFORMANCE

What were the promises of biotechnology? In the early 1980s, it was suggested that recombinant DNA (rDNA) would be used to produce various types of fuels, such as ethanol and hydrogen. The change in the economics of petroleum has

caused a shift of emphasis, and some of the longer time horizons place fuel development using rDNA well into the future. However, there still is great potential in the area of energy after the year 2000.

The advent of biotechnology suggested that rDNA would also produce chemical, agricultural, and pharmaceutical products. Potentially, the spectrum of chemicals includes secondary metabolites, simple organic chemicals, complexed organic chemicals, enzymes, sugars, glycols, fibers, plastics, mineral-concentrating organisms, chemical-degrading organisms (for waste disposal), oils, and lubricants. Future agricultural benefits may include lower nitrate utilization, high salt tolerance, and pathogen and insect resistance in plants; improvements in food processing; and improved health and economics in animal husbandry through vaccines and growth hormones. Potential pharmaceutical products include blood expanders, hormones, antibiotics, and vaccines. Many of these products may be available for the very first time because of biotechnology. The volume of business projections for these areas by the year 2000 has generally exceeded \$2 billion (OTA 1984).

What has been delivered in the period 1980-1987? In the area of agriculture, genes that carry heritable traits which can be passed from generation to generation and exhibit controlled expression have been introduced into plants. For example, some of these gene products allow plants to achieve full nutrition with reduced fertilizer; others increase resistance to herbicides, viruses, and insects. These are remarkable achievements, and all have been accomplished within the last several years.

In animal health care, prophylaxes for a number of diseases among cattle (such as colibacillosis) have been marketed. Bovine growth hormone has improved milk production. While it is true that the United States produces an excess of milk, for the rest of the world (and even for the United States), improving the economics of milk production is a very important contribution. Interferon (an antiviral protein) and a number of recently announced natural stimulants of white blood cell production may reduce the incidence of shipping fever. A number of other potential vaccines for major diseases have been developed. In almost every case, substances being introduced into the food chain for human beings are safer than anything previously used. The safety of the process, as well as the benefit to society, is being realized.

In the area of diagnosis, monoclonal antibodies are highly specific and are rapidly changing the nature of med-

ical practice. Hybridization probes (which use cloned nucleic acid copies of the gene itself as a marker to detect the gene in other cells or organisms) provide sensitivities down to 10^{-18} molar. With this type of sensitivity, DNA the size of a lump of sugar can be detected with ease in a volume of water of one cubic mile. The ability to measure to this minute degree is progressing very rapidly. If these techniques are used to look for the ecological consequences of the release of genetically engineered organisms into the environment, detectable alterations from the normal state may be so small that we will have to determine exactly how significant what we see really is.

Studies of oncogenes (genes whose altered expression result in tumor formation) provide insights into the biology and etiology of cancer and new diagnostic possibilities. When the structure of DNA was first elucidated in the 50s, Watson and Crick promised insight into all life processes. That promise is being realized very rapidly in cancer research because of what is now being learned about oncogenes.

In human therapeutics, many of the major human proteins targeted for study have been cloned, levels of production of these proteins by the organisms into which they are cloned approach theoretical limits, and there are major advances toward the use of rDNA techniques to develop safe vaccines. The recombinant products are proceeding through the regulatory process, and various types of "magic bullets" with antibody carriers are already being examined in human clinical studies. Tissue plasminogen activator has proven extraordinarily effective in the rapid dissolution of blood clots associated with cardiac infarcts in both animals and humans. After administration of this substance, blood flow in occluded arteries is increased in minutes.

Vaccine production is another area in which biotechnology has made important contributions to human health. For example, infected blood is the source of the vaccine called Hepatitis B, produced by Merck from antigens from hepatitis B-infected patients. Because of the source of this material, there is a great risk that the blood from which it is derived may carry other diseases (for example, non-A, non-B hepatitis, and possibly even AIDS). As a result, its use has been limited. The vaccine is also very costly. Recombinant DNA technology, in contrast, has produced an alternative hepatitis vaccine that reduces the cost to a potential of five dollars per vaccination. At

this price, the entire United States population could be vaccinated every five years if necessary. The rDNA vaccine eliminates the risk of causing disease through the use of infected blood. It is an attractive product today, both for the United States and for other countries. In fact, the Centers for Disease Control has recommended an eradication program for hepatitis similar to the program launched for smallpox some years ago. However, there are 200 million people with type B viral hepatitis around the world, with a significant portion in Third World countries. Even the potentially low cost of five dollars is a very high price for these countries, whose citizens may not realize the benefits of an rDNA vaccine unless ways are found to cover the costs of inoculation programs.

Erythropoietin is a hormone produced in the kidney that causes the blood-forming stem cells to differentiate into erythrocytes (red blood cells). Because kidney disease inhibits production of the active hormone, persons suffering from kidney disease, such as patients on dialysis, often suffer from anemia. Treatment of anemia for dialysis patients now costs more than \$100 million a year. There are 75,000 patients who undergo dialysis in the United States, most of whom would benefit from this product. Recombinant DNA techniques have enabled production of this hormone for the first time, and the rDNA product has proved effective in extensive human trials in the U.S. and several other countries. Erythropoietin treatment will change the lifestyles of those people who are presently on dialysis and must return home to bed between treatments due to severe anemia. It should also ameliorate many other forms of anemia.

Recombinant DNA technologies have proved successful for the identification and isolation of genes of interest, but what about the ability to use these technologies to produce biological products? Isn't that the barrier? In fact, the bacterium *Escherichia coli* can produce high levels of foreign proteins, and the feasibility of using this organism for producing the quantities of biologicals necessary for most therapeutic purposes has been demonstrated. For example, one 300-liter fermentation batch of *E. coli* can produce 225,000 doses of a protein such as interferon in a few days. Thus, the production of millions of doses per week is carried out routinely for many biologicals. Because *E. coli* can be grown inexpensively and has been selected for its nonpathogenicity, such production can take place without enormous investment or significant risk.

For all these products, which do not require intentional releases of genetically altered material into the environment, there is still a concern about accidental releases (see Chapter 10). It is true that incidental to the manufacturing process, there are bacteria that are producing biologically active proteins, such as interferon and interleukin 2, among others. If deliberate release is the primary focus of regulation, there certainly will be concerns about non deliberate release. If the concern that earthquakes or other such low-risk scenarios might result in accidental releases leads to major changes in regulation, it will be a long time before some of these products can produce benefits for those whom they are intended to serve.

Table 9.1 shows the statuses of eleven biologicals as of May 1987. In general the products are reaching the market as projected by Paine Webber, Inc. in 1985. As of May 1987 there are four recombinant DNA products available in standard medical practice: recombinant human insulin, currently being used to treat thousands of patients; human growth hormone, which was approved by the Food and Drug Administration in 1985 and is used to treat the 10,000 to 15,000 children in the United States who suffer from hypopituitary dwarfism; alpha interferon, approved for treatment of hairy cell leukemia, a deadly form of cancer; and a recombinant-derived hepatitis B vaccine. Five years from now, millions of patients will be treated by recombinant-derived products.

We in the United States are pleased to say that we think we are the world leaders in this field. Start-up biotechnology companies are responsible for ninety-five percent of these developments. For example, through December 1987, start-up biotechnology companies accounted for virtually all of the major new biologicals undergoing clinical studies. One demonstration of the U.S. leadership position in biotechnology in the world today is Japanese alliances with biotechnology companies; ninety-five percent of these alliances are with American biotechnology firms. This is a clear testimonial to the contention that today the United States is the global leader in biotechnology.

MAINTAINING THE MOMENTUM OF BIOTECHNOLOGY

What are the critical factors necessary to maintain the momentum of biotechnology, which in my mind represents

TABLE 9.1 Status of Selected Biotechnology Products, May 1987

Product	U.S. Regulatory Status	Company/Collaborators	Indication
Alpha interferon	Marketed 1986	Genentech, Hoffman-LaRoche, Biogen, Schering Plough	Hairy cell leukemia
Beta interferon	Human clinical testing	Cetus, Shell Oil	Anticancer, anti-infective
Consensus interferon	Human clinical testing	Amgen	Anticancer, anti-infective
Erythropoietin	Human clinical testing	Amgen, Kirin, Johnson and Johnson	Chronic anemia
Gamma interferon	Human clinical testing	Biogen, Shionogi, Genentech, Boehringer Ingelheim, Daiichi-Selkyu, Toray Industries, Amgen, Schering Plough-Suntoray	Anticancer, anti-infective, anti-arthritis
Human growth hormone	Marketed 1985 Marketed 1986	Genentech, Kabi Vitrum Eli Lilly	Growth hormone deficiency
Interleukin 2	Human clinical testing	Cetus, Biogen, Takeda, Amgen	Anticancer
Tissue plasminogen activator	Market approval pending	Genentech, Boehringer Ingelheim, Mitsubishi Chemical, Kyowa Hakko	Thrombolytic agent
Tumor necrosis factor	Human clinical testing	Genentech, Cetus, Asahi	Anti-tumor agent
Hepatitis B vaccine	Marketed 1986	Chiron, Merck	Immune prophylaxis
Human insulin	Marketed 1982	Genentech, Eli Lilly	Diabetes

Source: Linda Miller, Paine Webber, Inc.

a responsibility for the United States at this time? The consulting firm of Arthur D. Little, Inc. (ADL) investigated this question. They looked at issues associated with commercialization, risks, legislation, the long-term impact of biotechnology, and basic research. According to ADL, university-industry relationships are probably of most concern, followed by commercialization of biotechnology, risks in biotechnology, regulation, and long-term impact, in that order. I'm not sure that there are many in the industry-scientists or business people who would agree that university-industry relationships, and for that matter, university-industry-government relationships present any problem. Most feel that the effectiveness of these relationships has probably been responsible for the U.S. leadership position. The university-industry relationship has been an extraordinary example of collaboration, and as far as I have seen, has caused little change in the academic freedom and the academic responsibilities of those who have contributed to the transfer of technology to industry.

It is important to note that ADL pointed out that there were a number of federal agencies active in biotechnology issues, and raised concerns about the wisdom of giving additional agencies authority to control and influence other aspects of biotechnology. This issue could be pivotal to future U.S. leadership.

How should the United States maintain its leadership position in biotechnology? We should recognize that our current position was attained partly because of the risk capital system and partly because of government support of research through the National Institutes of Health (NIH) and the National Science Foundation. The support of research should not be diminished even when the federal budget is tight. The government, through NIH and other agencies, has supported basic research for a long time. This support has increased over the years to the point where the annual budget is in excess of \$500 million. This support certainly must be viewed as the foundation of modern biotechnology in the United States; it should not be curtailed.

Letting the government do the job is not always the best way. However, most of the biotechnology innovations have been made by small companies that live from hand to mouth; they have perhaps one or two years of financing and must move very quickly to prove that they can produce something viable in order to be financed beyond that time. It would be inappropriate for these companies to be funding basic, long-range research. There is a formula that the

government has found to be useful, which ought to be sustained. A significant percentage of the NIH budget should be going to basic biological research, without deciding in too much detail what is good and what is bad. For example, support was provided for the scientists who performed the microbial genetic studies that laid the foundation for genetic engineering. If we look back fifteen years, their studies did not seem appropriate for the good of humankind.

Support for applied research is somewhat more questionable. Perhaps industry can take care of that. The suggestion has been made that the United States needs to develop goals such as those adopted by other countries for the development of their biotechnology industries. This has not seemed to be a particularly worthwhile approach for the United States, and it certainly has not been relevant to the success experienced to date by American biotechnology companies.

FUTURE EXPANSION

Are there real barriers to continuing the expansion of biotechnology at its current rate? Recognizing first of all that biotechnology has progressed effectively and safely over the past ten years, it seems as though expansion should continue if possible. A number of events have highlighted potential concerns of the public about the rapid development of biotechnology. In Germany, the Social Democratic Party and an environmentalist party have expressed strong objections to some biotechnology programs. In the United States, a number of experiments involving controlled release of organisms and genetically engineered viral vaccines have become issues of increasing public concern. The public was clearly surprised by some of these developments, although the Industrial Biotechnology Association and most of the companies active in biotechnology have made serious efforts to inform the public of their activities and about the technology in general.

It is evident that such concerns must be addressed promptly and openly. Equally important will be far more extensive, realistic, and informative communications to the public on a continuing basis, and possibly formal programs to provide clarification of the issues involved and a greater understanding of benefits and risks. Companies must recognize that it is extremely shortsighted to shortcut any regulations or guidelines or to initiate experiments that do not adhere to accepted practices. Only if these

issues are carefully addressed will the following suggestions for safely expanding biotechnology be useful.

Recommendations

Expediting patent actions certainly would accelerate progress. Foreign counterparts to U.S. patent applications are published and made available around the world. These complete disclosures are made in exchange for a period of exclusivity. Delays in granting U.S. patents mean that these disclosures are made without commensurate protection.

Export barriers should be reduced. In 1985, many products could not be exported. It was very difficult for an American firm to contemplate developing a product involving malaria or foot-and-mouth disease without export opportunities. Export of a product without government approval for that product in the United States was considered marketing a banned product. In these cases, many biotechnology companies decided to export the technology rather than the product, thus eroding the U.S. leadership position. Taking note of this situation, the 99th Congress took action in 1986 to remove export impediments. Biotechnology companies may now export their products without restriction.

The regulatory process should be expedited. No one wants to introduce shortcuts into safety considerations about major risks of biotechnology. If something untoward happens, the public and the industry will suffer, both immediately and in the long term. Those that are in the industry are well aware of that. At the same time, the regulatory process today is extremely burdensome, as can be seen from the number of federal agencies involved in biotechnology activities. I don't think laissez-faire in biotechnology is acceptable. Risk assessment is appropriate. Alertness and discussion are important. However, we should be examining real risks, not imaginary ones. It's a question of what brakes are applied while risk assessment is being done. Such assessment should be performed with equal concern for the potential benefits as for the possible risks.

Capital is the other element that is necessary to maintain momentum. The risk capital system has provided the resources; the motivation is profit making. March 1987

estimates put annual expenditures by the biotechnology industry in excess of \$1 billion, with a market capitalization of about \$8 billion (Industrial Biotechnology Association 1987). It appears that in the United States, the capital is available to pursue biotechnology.

Why U.S. Leadership Should Be Maintained

Perhaps underlying the question "How should the United States maintain its leadership?" is another question, "Should we maintain our leadership in biotechnology?" To answer that, let's look at the prospective benefits. In medicine, there is important progress in many areas: cancer, cardiovascular disorders, anemias, dwarfism, congenital defects, diabetes, autoimmune diseases, and pulmonary disorders. If we acknowledge this progress and consider some of the fundamental problems facing the world, what are the best alternatives other than biotechnology for addressing these problems? The scientists with whom I have talked do not see any major alternative with the same time horizon as biotechnology. Policy, then, should address the issues surrounding successful applications of biotechnology, rather than focusing exclusively on the low-probability risks.

If biomass alternatives for the production of energy and chemicals begin to function effectively, they will affect the entire petroleum balance around the world. The ecological impact of biomass expansion could be very important. Shifting sources of natural products could mean that a developing country which is just emerging with some new natural material that it can produce can have its whole economy scuttled by RNA sources for the very same material. This would be much like the production of indigo from petrochemicals about one hundred years ago.

In the field of agriculture, there will be dissemination of a new technology, and a shifting of world food sources. The United States will be exporting some of its foodstuffs, with their nutritional characteristics, both good and bad. There will be some long-range effects as the Third World receives those imports.

Finally, in the area of human health, there will certainly be population increases, shifting age distributions, and an increase in inherited diseases as we can supply improved treatments for diseases which otherwise would fail to be propagated to future generations.

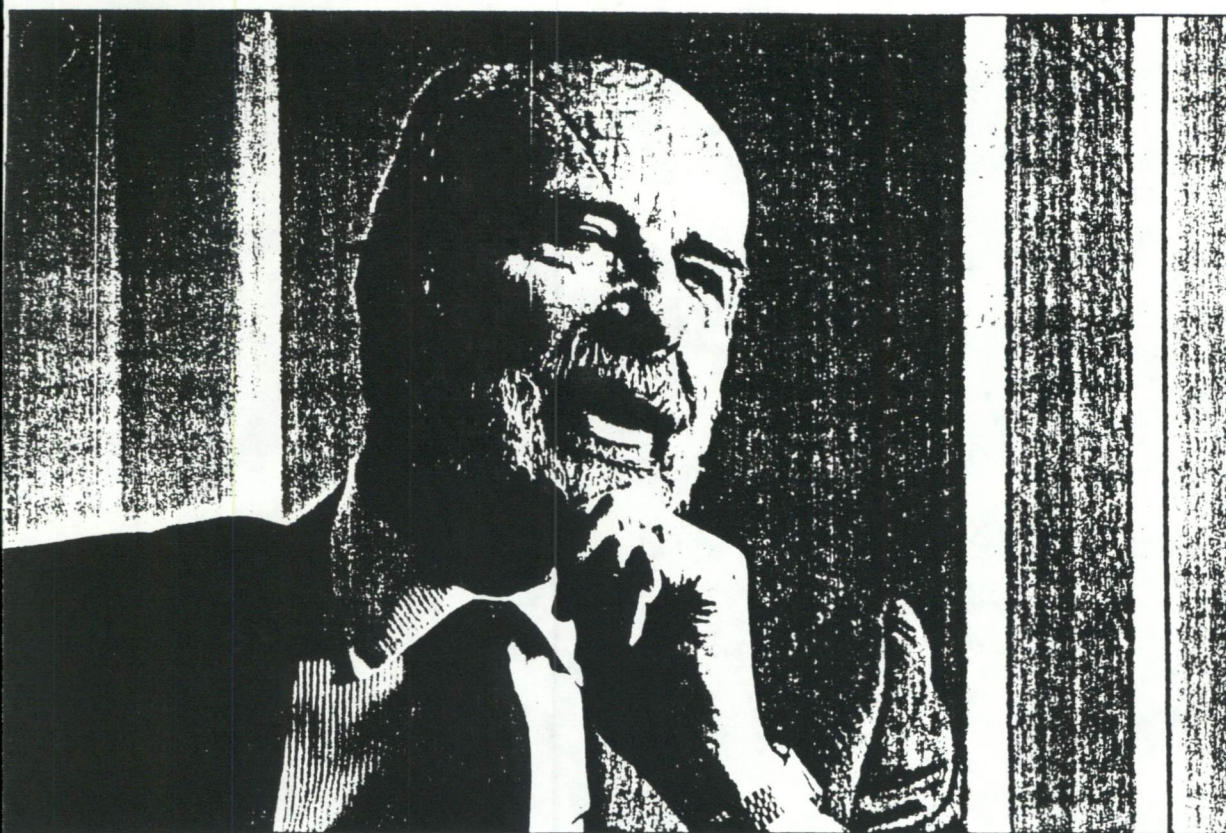
The potential to eradicate, cure, arrest, or ameliorate diseases prevalent in the Third World is a very serious issue. We have in our armamentarium today the ability to address these diseases as never before. The risk of failing to do that job would increase the disparity in health care delivery between the United States and other developed countries and the rest of the world.

I think that issues concerning the successful application of biotechnology are important. If we think that the United States still might have reason not to proceed, then be assured that this field will be pursued. Japanese firms are engaging in biotechnology with a great deal of conviction, as anyone who visits Japanese companies would know. There is momentum in the engineering area, in the energy and textile area, in the chemical sector, in the agriculture and food processing sector, and in the diagnostics, pharmaceutical, and health care sectors. The United States is the leader today. I think we can move ahead, minimizing the risks, maximizing the benefits, and maintaining leadership. We should ensure that our society and the rest of the world are comfortable with the way this is being done -- in a responsible and safe manner. We should be dedicated to realizing the spectacular future that has sometimes been described for biotechnology.

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INSIDER INTERVIEW



George Rathmann

President and CEO, Amgen Inc.

HEALTHWEEK: What happened to Genentech? About 11 months ago, they got TPA approved, sales took off and everything seemed to be going right. What went wrong?

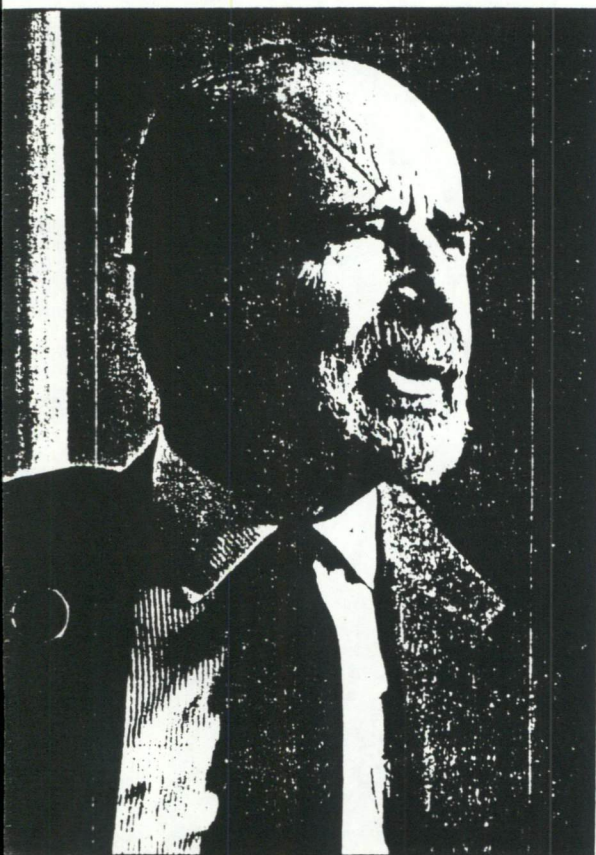
RATHMANN: I have a little trouble second-guessing Genentech. We have learned from them time and time again the right thing to do. It's a fairly arrogant attitude to say they did all these things right but in our assessment they did these things wrong. I would just as soon climb in with them and try to help solve the problems.

It's tough breaking ice. The guy out there first is a hero when he does it right. When he stumbles, it's easy to say, "You've done something stupid." Genentech's vulnerability was the extraordinary perceived value of the company, although far be it for me to say there was anything wrong with that.

As part of their strategy, they have concentrated on a relatively small number of products. So their vulnerability is a direct consequence of a successful strategy. You have to concentrate, you have to focus. But there are risks.

HW: Amgen is probably the next biotechnology company that will be out there in the public eye. What will you do to avoid Genentech's problems?

RATHMANN: Amgen has a responsibility to live up to expectations. But we cannot hope to live up to whatever expectations



As biotechnology leader Genentech Inc. struggles with disappointing earnings and eroding sales, the mantle of heir apparent and spokesman for the industry has fallen on George Rathmann, 60, president and chief executive officer of Amgen Inc. The Thousand Oaks, Calif., company has emerged as a clear second to Genentech on the crucial yardstick of marketable products.

Amgen is expected to receive approval from the Food and Drug Administration in the next few months to sell its genetically engineered erythropoietin, or EPO. EPO—an acronym that may soon be as well known as Genentech's heart drug TPA—is a hormone made by the kidneys that stimulates production of red blood cells. It will first be used for kidney dialysis patients in place of blood transfusions.

With the launch of EPO, Amgen will become the second earnings-driven biotech company, subject to the same sort of inflated expectations that have proven to be Genentech's downfall.

Rathmann, also chairman of the Industrial Biotechnology Association, a Washington, D.C.-based trade group, is familiar with the promise—and perils—of breaking new ground. He has led Amgen since 1980 and before that spent 25 years in scientific and management positions with such research-oriented companies as Abbott Laboratories and 3M Co.

HealthWeek Senior Editor Karen Southwick interviewed Rathmann one day after Genentech stunned the investment community late last month with its disclosure of slumping TPA sales and flat earnings.

INTERVIEW

anybody wants to suggest. We have the assignment—and we're going to do it with the media—to keep our expectations in proportion to what we can deliver. It's difficult to do, but there is great risk [to the industry] if an Amgen fails to live up to expectations. We'll temper the expectations when we see that they're going beyond a reasonable probability.

We don't intend to be a fair-weather friend—to disassociate ourselves from the Genentech model. We're all in this together. We all have a great mission and the same kinds of goals. We will benefit from what has happened to Genentech. It will be easier for Amgen to control expectations because of Genentech.

HW: What about Amgen's lead product, EPO [erythropoietin]. Most industry analysts are predicting Food and Drug Administration approval for use in kidney dialysis patients by the end of the year. Does Amgen have any indication of an approval date? Are you geared up to manufacture EPO in commercial bulk?

RATHMANN: We certainly aren't making predictions ourselves. We have no reason to disagree with any of the analysts. We would be prepared to get EPO in the first quarter of 1989.

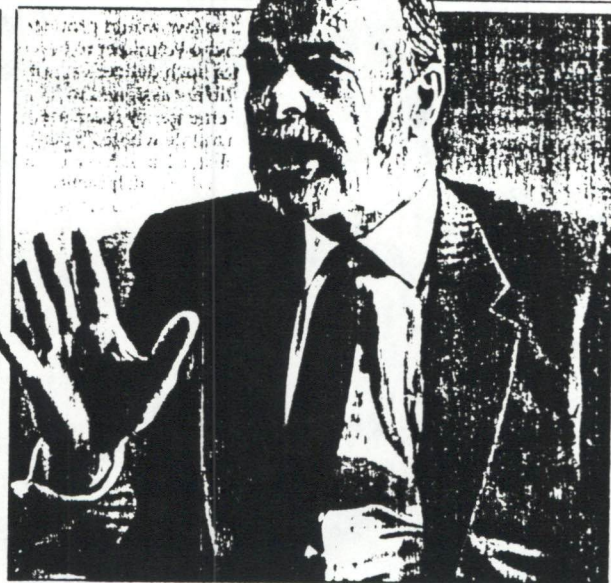
HW: There also has been considerable speculation about the price of EPO. Johnson & Johnson, your European partner, has priced it there in the \$7,500 to \$8,500 range annually. How do you anticipate pricing in the U.S. market? Will it be similar to J&J's price or will you be more conservative?

RATHMANN: It's hard to tell what the annual costs will be. They will vary by an extreme amount between the sickest patients and those that require less blood transfusions. It's like the average American family having 2½ kids—you don't see many families with 2½ kids running around. There's a similar problem here [with EPO].

I think J&J's price is a benchmark for some part of the population, but we're not obligated to match their pricing. Our initial dose is generally higher than their initial dose. This will be an independent decision as to how to price in the United States.

[Compared with blood transfusions], it's certainly obvious we're offering a tremendous number of advantages. We've eliminated any risk of giving the patient blood or contaminated blood. The price [of the competing product—blood transfusions—] is a rock-bottom price.

HW: Since Medicare covers virtually all of dialysis in this country, the Health Care Financing Administration will decide how much of the cost to



The single most important use [for EPO after dialysis] will be as an adjunct to AZT [the AIDS drug that can cause severe anemia] ... A number of AIDS patients have to be taken off AZT because of anemia. EPO would be a clear therapeutic gain.

reimburse. Are you negotiating with HCFA, and are you hopeful that agency will look at EPO as a separate, fully covered cost similar to blood transfusions?

RATHMANN: I don't anticipate negotiating in the usual sense. We're making comparisons and giving them [HCFA] information. EPO is superior to blood transfusions.

HW: As we learned from Genentech's experience with TPA, biotechnology companies walk a fine line in pricing their products. On one hand, shareholders and investors want the highest possible return. On the other, the health care industry—your customers—is justifiably worried about the high cost of new technology and what it does to medical inflation. How do you balance the needs of both these groups?

RATHMANN: That's addressing a difficult problem. EPO is the first of a new generation of biopharmaceuticals. With the other four biotechnology products, there were competing products already out there. In the case of EPO, you can't get it any other way.

The health care community should be interested in new products that are going to improve health care. What we want is the best health care in the world and still make it affordable. The [health care community] thinking tends to go in one direction—price, the lower the better. That's not going to lead to quality health care.

Profits are what it takes to fund the next breakthrough. There's a need for incredible investment. The health care com-

munity should emphasize quality controls and new products. They should worry about who's going to fund the developments you and I need over the next few years. You have to consider all these aspects.

We would like to educate a lot of groups [about the needs of investors]. We don't want to kill the goose that's laying those golden eggs. Retired people in this country have been indoctrinated with the fact that they want lower Medicare rates. Health care costs are all they care about, when we haven't solved Alzheimer's or Parkinson's ... It's not a matter of pinching the costs back. These companies have to be financed.

EPO is one of the best products to be introduced in the past five years. Our dialysis bill is \$2.3 billion a year and many [patients] are merely surviving. The role of EPO is to provide a quality of life. I've talked to people [kidney dialysis patients] who haven't sweated in three years. When they take EPO, they sweat. For them it's a wonderful thing.

HW: After dialysis, what do you see as the next major market for EPO—areas such as autologous transfusions or sickle-cell anemia?

RATHMANN: The single most important use [after dialysis] will be as an adjunct to AZT [the AIDS drug that can cause severe anemia]. That is Ortho's indication. [Ortho Pharmaceuticals is a division of Johnson & Johnson.] They're developing the program. A number of AIDS patients have to be taken off AZT because of anemia.

EPO would be a clear therapeutic gain.

As for sickle-cell anemia, the data is not extensive enough. EPO turns on the production of red blood cells; it may turn on the production of more sickle-cell genes, too. We don't know yet.

Autologous transfusion is a wonderful concept—to reduce dependency on other people's blood except in extensive trauma. Using EPO with autologous transfusions probably will come to pass. But then you're giving it to healthy people and you have to know whether there's any downside.

HW: Some analysts think these uses combined will be a larger market than dialysis, yet you licensed all other EPO uses to Johnson & Johnson's Ortho. What was the trade-off for Amgen here? Do you feel in hindsight that you gave up too much?

RATHMANN: We talked about any alternative that seemed to be feasible. We found that the best combination of Amgen's strengths with another company was with Johnson & Johnson. We had already established a lot of precedents by carrying our products into the clinic [the human stage of testing] on our own. We possibly would have been better off had we carried EPO on our own for a few more years. The risk was that if the [stock] market had been very unkind, we wouldn't have had the money to fund our research. The best choice was to pick a very strong partner.

HW: What about the patent situation? You've challenged Genetics Institute and its partner Chugai Pharmaceuticals of Japan in patent court and before the International Trade Commission. Some analysts have called your position overly aggressive and suggested that to avoid the court costs you settle for cross-licensing with Genetics Institute. Is that a possibility?

RATHMANN: We would not like to compromise our position very much. There may be something that would be appropriate. As you go through the ITC and court cases, you find out the substance and timing behind each other's patent action. Hopefully, you both reach the same conclusions. Then there may be a basis for discussion. That has not happened yet.

HW: Your second major product appears to be G-CSF [granulocyte-colony stimulating factor], which stimulates production of white blood cells. Can you fill us in on the uses for G-CSF?

RATHMANN: G-CSF acts specifically on neutrophils [one type of white blood cells]. The first direct application is in

replacement of neutrophils that have been depressed by some disease state or by medical intervention such as chemotherapy. Often the patient's neutrophil count gets so low they take him off the treatment. We can pump the neutrophils back up again with G-CSF.

HW: Analysts are anticipating that Amgen will file for market approval of G-CSF early next year. Is that realistic, and who are your corporate partners with this product?

RATHMANN: We'll probably file sometime in the first half of 1989. To our knowledge we're the only company that has reported clinical data. We have a relationship with Kirin-Amgen [a Japanese joint venture] giving them rights to G-CSF in Japan, and we're sharing the rights in the rest of the world except Europe. We have all the rights in the U.S.

HW: One of the biggest problems for pharmaceutical companies is a lack of new products. Will biotech companies like Amgen face the same problem? If you did, would you consider a merger?

RATHMANN: With all the [biotech] products coming down the road, there's not going to be the same dry spell as those that the large pharmaceutical companies have. It takes them 9½ years to get something approved, so they have a pipeline that's dry for many years. EPO got through in three years, so we're only looking at a dry spell of a few years if we've got a product in [human trials]. We're not looking at a sterile pipeline for seven or eight years.

I would consider a merger for filling my [product] pipeline but not so much because of any perceived drought. I think biotech companies need marketing muscle, and it's useful to have a single marketing effort for a flood of those products. You might be able to market jointly, or that by itself might be enough synergy to justify a merger. But it would be very difficult to do.

HW: As chairman of the Industrial Biotechnology Association, as well as being head of one of the major biotech companies, what do you see as the industry's biggest challenge today?

RATHMANN: There are at least a couple of areas. Those include the protection of intellectual property around the world and the pressures on the health care system in terms of cost. It would be unfortunate if the system became disenchanted with biotech because people decide it doesn't justify the cost. In a free-enterprise system like ours, people should say that this has such therapeutic value that we should be able to tolerate a lot of cost. □



Amgen Inc.
(Thousand Oaks, California)



George B.
Rathmann, Ph.D.
Chairman,
President, and Chief
Executive Officer

Widely regarded as one of the outstanding biotech companies with a therapeutic focus, Amgen is well along in bringing to market one of the flagship products of the industry. Dr. Rathmann tells a story of well-managed progress—and of the intrinsic risks and challenges of making biotechnology work on a commercial basis.

Editors' Note:
Dr. Rathmann, President and Chief Executive Officer of Amgen since October 1980, is one of the industry's accredited pioneers. Under his guidance, Amgen was among the first biotechnology companies to make a public equity offering, and it has gone on to develop an impressive portfolio of products at various stages of clinical testing. Most in the public eye at this point, erythropoietin (EPO) has been shown in clinical trials to correct the anemias of dialysis patients. It promises to be a major early product of the industry, with diverse potential applications.

At fiscal year end, March 31, 1987, Amgen had total revenues of \$34.7 million and a net income of \$1.1 million. Its total assets were \$96.8 million, and its staff numbered 260.

As the current chairman of the Industrial Biotechnology Association (IBA), George Rathmann has been entrusted by his peers with the responsibility of speaking for the industry as a whole. The logic of that choice is clear when one meets the man.

AY: Did you first recognize a market need for EPO, or did you have "on hand" a molecule searching for an application?

Dr. Rathmann: I wasn't actually involved in the initial selection of erythropoietin as an Amgen project. It was targeted at an early stage of the company's existence by our scientific board, a group of very prominent scientists asked to consider what kinds of projects Amgen could and should undertake. Their meetings occurred before I was recruited as CEO, although I subsequently sifted their suggestions and liked the EPO proposal. We specifically mentioned it in the prospectus for our Initial Public Offering and earlier in a private placement memorandum of October 1980.

I had to make a decision about the texture of that particular project versus many others. I weighted very heavily that erythropoietin had already been recognized as a biologically active molecule present in every body which seemed to be essential for producing red blood cells. It was thought to be—and now we understand that it is—the dominant molecule causing red cells. There was also evidence that it is produced in the kidney, and many dialysis patients suffer serious anemia. So the trial linkage could be made: Dialysis patients are anemic because their disabled kidneys do not produce enough erythropoietin.

Today that theory is so well-substantiated that it seems as if there could be no alternatives, but there were many alternatives and uncertainties at the time. To say that EPO was a perfectly defined commercial target would be something of an exaggeration. On the other hand, there was interesting work by a research team at the University of Chicago, under Dr. Eugene Goldwasser, indicating that EPO was a potential focus for development.

Reprinted from Biotech 88: Into the Marketplace:

A Survey of an Industry in Evolution,
Including Interviews with Key Industry
Leaders

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They had prepared erythropoietin by separation from the urine of aplastic anemic patients. Aplastic anemia is another cause of deficient red blood cell production, and the body doesn't appreciate that. It responds by putting out large amounts of erythropoietin, which spills over from the kidney into the bladder and urine—thus providing a source but still not in substantial quantity. Dr. Goldwasser's group had evidence that they had prepared pure erythropoietin, but he had no way of determining whether it really worked.

So there was a technical feasibility of sorts and commercial potential of sorts. Relative to other opportunities, EPO looked good because it had some of both, whereas in other cases you might make a molecule but you weren't sure of its importance. As we

The technical uncertainties were so great that nominally accurate market forecasting would have been overkill.

went on with our examination, the commercial implications became clearer. Here was a critical-care population—which creates an attractive commercial dimension—and we would be setting out to replace the deficiency of a substance that seemed more than likely to be essential to good health. We wouldn't be simply enhancing the quantity of, let's say, interferon in the blood stream, in the hope that this would do something beneficial.

We moved along. Once EPO was selected, we had to examine the commercial and technical feasibilities in adequate detail. In both respects we made good progress over the next two years, due in large part to the dedicated, persistent, and innovative efforts of Dr. Fu-Kuen Lin and the rest of the team at Amgen.

AY: On the commercial side, what sort of team did you build in those first years to make sensible evaluations?

Dr. Rathmann: We had very intelligent people on the scientific advisory board, but in the first two years I suppose I was the only person strongly backgrounded in the commercial area. In 1982 we brought in a Director of Strategic Planning to look at the commercial dimensions. But at most there were two or three of us, certainly not a massive contingent on the commercial side.

AY: Did you engage in formal market research?

Dr. Rathmann: We never attempted either to buy market analysis or to conduct extensive research. The technical uncertainties were so great that nominally accurate market forecasting would in fact have been overkill. We were dependent on our technical assumptions, for the most part. It was not hard to recognize that under a best-case scenario we had a big market, and under a worst-case scenario probably no market at all. If we made the assumption that an inhibitor prevents red blood cell formation, we could forget erythropoietin. If we made the assumption that it is not made in the kidney, we could forget erythropoietin—with dialysis patients, at least. If we made the assumption that when it stops being made in the kidney, it is augmented by other tissue, we had no business. If we made the assumption that for some reason or other

when we tried to administer the material we would run into problems—again, no market. In light of the technical challenges, refining our market research was not all that critical.

AY: This is real entrepreneurship—something of a seat-of-the-pants operation, but for the best of reasons.

Dr. Rathmann: Yes and no. "Seat of the pants" implies that were you to take the time and do the analysis, you would predict the right result. My assessment is that only people who think about these things but don't actually do them would take that view. Afterwards we're asked, "But couldn't you figure out this and this and this? Couldn't you develop the correct scenario beforehand?" Yes, we might have—but if we had given proper weighting to equally probable scenarios, we would have had hundreds of them.

The real entrepreneurial approach in selecting programs is to say: I believe in this field, and I believe it's going to lead to exciting new products. Now which of the potential products is in the best condition to be worked on, which has the best probability of technical and commercial feasibility? And once the best has been picked, don't bother reassessing whether it has a feasibility probability of 99 percent or 96 percent or 38 percent—as long as it's better than the alternatives, the absolute value doesn't matter.

Some people may consider this approach a cop-out; they would argue that the better companies are the ones that do the better analysis. But it is fastidious enough—and all that can substantively be done—to rank your programs: This one is more probable than that one.

AY: Once the EPO program was decided, you needed people to develop the science and technology, and you had a financing question. Can we look next at human and financial resources?

Dr. Rathmann: We had a scientific advisory board of great credibility, and its members were willing to share the task of interviewing the early candidates for scientific positions. The selection process, with their participation, not only gave us a shot at the best people, but it gave those people an intense interest in Amgen because they knew the members of our scientific advisory board either personally or by reputation.

None of them knew me. I was not a *prima facie* attraction for the young scientists. They may have been intrigued by my views on how to develop a biotech company, but they wouldn't have come here without the knowledge that an outstanding scientific advisory board took Amgen seriously.

A1: Looking again at EPO, we were fascinated by a recently published diagram that lays out the various financial arrangements you have entered into to develop and market the product (*see diagram*). It's spectacularly complex, at least on paper.

Dr. Rathmann: It is an accurate representation but only a snapshot in time—the present time. For insight into why it took that shape and how it really works, we would have to look at the time dimension over the past 4 years, starting with Amgen as it was in January 1984—particularly our needs then, and how we met them.

Should reagent sales be in or out?
How are we going to handle manufacturing? How do we determine cost? There were stepwise additions.

The first step was the formation of Kirin-Amgen, our joint venture with the well-known Japanese firm, Kirin Brewery Co.

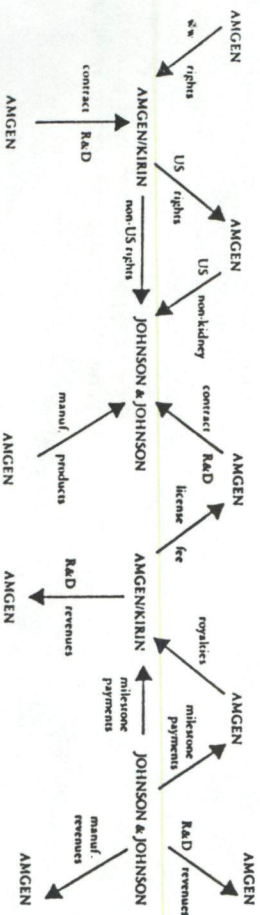
Ltd., to develop and commercialize EPO. That step alone led to the ramifications of nearly half of the chart because once a joint venture is formed, you need understandings as to who's funding what, who gets paid what, who has rights to what, how will it work in the States, how will it work in Japan, how will it work in the rest of the world. All of that is laid out in the diagram. Agreements evolve as you go along that need to be put down in black and white. Should reagent sales be in or out? How are we going to handle manufacturing in various respects? What do we do in terms of pricing manufactured product as it moves downstream to various markets? Do we charge cost? How do you determine cost? So there were stepwise additions as our relationship with Kirin progressed.

At the same time, we recognized from the beginning that the joint venture needed the option to select partners in markets around the world. We had the option to select one partner, many partners, or no partners. That was all in the original deal. We did assume that there would be one or more partners, in addition to Kirin and Amgen, involved in marketing the product.

Schematic of transfer of rights and revenues for Amgen's Erythropoietin

(Transfer of Rights)

(Transfer of Capital)



Source: Management Securities, by permission

A1: Was this because Kirin is not experienced in pharmaceutical marketing or...

Dr. Rathmann: Kirin currently has no pharmaceutical market. You might then ask why we formed a joint venture with Kirin if it has no pharmaceutical market. We ourselves wanted control of the U.S. market—that was the most important thing. We also wanted sufficient financial support so that we wouldn't bankrupt ourselves while aggressively pursuing our EPO program. Those were our prerequisites at the time, and Kirin saw its way to joining us in the venture on terms that we found congenial.

But the initial arrangement didn't give us real marketing clout—we begged that question. We figured that we could create a marketing force in the United States if necessary, and that we could probably find a way to market directly in Europe or with a partner. Kirin was committed to helping us on those issues, and that was encouraging. That first stage, then—the snapshot of early 1984 through mid-1983—clearly led on to our subsequent joint development agreement with Johnson & Johnson, which bears on marketing.

Negotiations with Johnson & Johnson became complicated because it wanted some degree of participation in the U.S. market. Had it not, we would have been quite content with a much less complicated

relationship. Licensing off any part of U.S. marketing rights was not in our original thinking. The agreement to cede certain U.S. market rights to J & J created extra pathways in the diagram that would not otherwise be there.

A1: Einstein said that Nature is as simple as it can be—would you say that this deal is as simple as it can be?

Dr. Rathmann: Obviously, you can conceive of simpler deals, but if nobody's interested in them, they don't do you any good. This deal is as simple as it could be to meet the requirements of the various partners.

You can conceive of simpler deals, but if nobody's interested they don't do you any good.

It was only part of the financing of EPO, you understand. When a company is able to sell stock, a lot of the financing still comes about from cash raised in the capital market. What we were adjusting here were relationships that could support our program—without undermining future profits so much that the market for our stock would dry up.

A1: Thank you for explaining. There are further key issues we would like to go into. It's clear that biotech companies need very experienced people running the clinical trials process and the relationship with regulatory agencies. Did you find those people at Johnson & Johnson?

Dr. Rathmann: No, we have them here. People can attribute to the larger pharmaceutical companies what they will, and some of their accomplishments are outstanding, but I'm not going to be a spokesman for that. Amgen set up its clinicals indepen-

dently, and we monitored them independently. Yes, it's now Johnson & Johnson's responsibility to pursue those trials outside of the dialysis area. But we continue to manage them, we continue to work with FDA (*Food and Drug Administration—Eds.*), and we are independently seeking approval of EPO for use in the dialysis market where we have retained the marketing rights.

The big pharmaceutical firms like to say that they know how to conduct clinical trials—and that small companies don't.

This is a fairly delicate subject. The big pharmaceutical firms like to say that they know how to conduct clinical trials—and that small companies don't. The latest story on TPA proves the point, doesn't it, that biotech companies are going to be measured by the same standards as everybody else. Some of the big companies contend that biotech companies aren't sophisticated enough to meet those standards on a reliable basis.

I don't want a contest with the big companies. But I just as surely don't want to abdicate or disavow our ability to get products into the clinic and move them along well. Our relationship with FDA is superb,

it is not dependent upon anybody else, and it does involve expertise. We aren't johnny-come-lately's in this business. A number of us have had broad experience in working with FDA. There's no exclusive franchise vested in the large pharmaceutical companies enabling them to move something through the approval process. The smaller firms certainly know that we have much to gain by cooperation between biotech companies and pharmaceutical companies, but I don't think that cooperation requires prostration.

Biotech companies in general have a "can-do" philosophy, and I share it completely. However, if I were sitting in a pharmaceutical company I might feel exactly as they do. There is a natural conflict of viewpoints. When a fact emerges, such as the TPA situation, those different viewpoints automatically lead to different conclusions. The conclusion of the biotech company is "Wow, they got a bit of a surprise there, and chances are some mistakes were made. We're going to study those mistakes, and maybe we won't have to make them ourselves. It's not Genentech's fault—they're breaking new ground. What happened? How did it happen? This is a learning experience, and nobody is perfect. If we're lucky enough to do some of our learning vicariously, we'll save a lot of time and money."

What is the typical pharmaceutical company attitude? "Biotech showed that it can't do the job. You need us to work out your PLA (*Product License Application—Eds.*), otherwise you're never going to get it done."

The two very different points of view lead to opposite conclusions about many issues. Consider the question of where biotech fits into the scheme of things with respect to pharmaceutical products. We think that we are not just a means to an end—we think that we are achieving some wonderful ends.

EPO is a wonderful end-product, and there will be many more. But the pharmaceutical companies generally believe that in the broad context of health care many of our new products, both monoclonal antibodies and new proteins, are just stepping stones to drugs of the kind we've always had before. They construe our products as intermediates on the way toward really good drugs in the classic tradition of foreign chemicals that are poured into the body.

Their point of view has some merit, but another point of view is very much on our minds these days. What better molecule is there for correcting the anemia caused by

What better molecule is there for correcting erythropoietin deficiency than erythropoietin?

erythropoietin deficiency than erythropoietin itself? And if it's a million times more potent on a molecular basis than something you can synthesize from a petrochemical, isn't it likely to be the preferred molecule rather than a stepping stone to a foreign molecule?

We have very strong feelings about this—not from a financial standpoint but in terms of the real justification for this business. What is the frontier that we've reached, and where is it moving on from here? We think there are going to be extraordinarily important proteins, which will be important as precursors of synthetic molecules.

A1: Can we look now at the patent issue—in offensive and defensive terms? As the head of Amgen, you vigorously defend your company's current and future interests, and this has already led to patent disputes with other biotech companies. However, as the chairman of IBA, you surely need to work for unity in the biotech industry. How can you do both? Don't patent disputes leave scars?

Dr. Ralbmami: If my role as IBA chairman threatened to affect adversely my decisions as CEO of this company, I would have only one choice. I'm chairman of IBA because I'm chairman of this company, not vice versa. Since one of the two roles would have to go, it would of course be the chairmanship of IBA.

What reconciles the two roles? I believe that *how* you pursue justice determines their compatibility. Are you willing to use questionable methods that might just lead to success in a patent dispute? It might not solve all the problems, but it could solve a lot of them to adopt a strategy of red herrings, to provide information of questionable validity in support of a position.

However, irresponsible accusations and other tactics that might impress judges and juries would, I think, put you at grave risk. You would be rending apart the relationship between companies. The honest pursuit of your company's interests—for example, seeking an objective determination of whether there is a priority date in favor of company A or company B, or whether a patent has been misgranted to company A or B—is a necessary part of commerce and good business practice.

If those determinations are made earlier rather than later, all parties benefit. Those who have been ignorant of their risk will have an opportunity to measure that risk; those who have assumed a certain result may

discover that the assumption was erroneous—and possibly save themselves massive expenditures. To my mind, Amgen's interests are served by resolving these types of problems, even if they aren't resolved as our own counsel and our thinking and desires would suggest. If the parties to patent disputes behave in a respectable, business-like manner, we won't tear things apart.

AY: Should biotech patents be challenged by biotech companies?

Patents are a way of keeping the people out ahead who were ahead initially.

Dr. Rathmann: It's true that when you start challenging patents, you are likely to weaken the benefits of a leadership position for any and all biotech companies. Patents tend to support the initiators of actions and the discoverers of things. When you start to challenge them, you set the stage for people who are not at the leading edge to catch up. Patents are a way of keeping the people out ahead who were ahead initially.

So there's good reason to ask if it's appropriate for a biotech company to challenge another biotech company's patent. I have put that question forcefully in a number of cases where I believed it inappropriate. At the same time, Amgen strongly supports the patent structure in this country and around the world, and all companies in biotechnology share our view. The industry strongly supports the patent system—yet a number of companies have challenged patents. It is a dilemma of sorts, one that can only be resolved on a case-by-case basis. I may be wrong—I may be living in a fool's paradise—but I have not found that these kinds of controversies cause the key executives of biotech companies to behave other than objectively in their dealings in other areas. We may have certain sensitive areas with respect to patents, but when it comes to other issues, we have an excellent understanding with each other.

AY: When a biotech company brings suit against another on a patent matter, there are legal expenses and time is invested by senior scientists and executives. Are there other negative effects?

Dr. Rathmann: If you challenge a patent and it is found to be invalid, if you challenge the scope of a patent and it is made more narrow, or if you have challenged the unobviousness of a patent and it is found to be obvious, all of those things may be bad precedents in cases where the challenger becomes the challenged and wishes to have his own patent supported. This is the downside of a court ruling against the breadth or validity of a patent.

AY: What is your view of the recent product patent on EPO granted to Genetics Institute, one of Amgen's direct competitors?

Dr. Rathmann: I believe that the Genetics Institute patent will have no commercial impact on Amgen. Properly construed, that patent does not extend to recombinant EPO. In addition, the patent is of very questionable validity.

AY: As our concluding question, we would like to ask for your assessment of the industry's future.

Dr. Rathmann: This industry is headed toward delivering the commercial results that were projected a long time ago. There will be billions of dollars of sales. Whether those sales will be in agriculture or chemicals or diagnostics or pharmaceuticals is a question everybody will differ on. But without any question, biotechnology is changing the world, and it's going to have tremendous commercial impact.

I suspect that the combined sales of biotech companies in the health care market will, in time, just about equal the combined sales of pharmaceutical companies; and similarly in chemicals, agriculture, and so on. You can predict from first principles that where you have a technological revolution, you have opportunities for shifts in market share. There will be shifts in market share, and some of the gains will belong to independent biotechnology firms. They are earning those shares through the tremendous innovations they're bringing to the marketplace. But the bigger companies won't be hurt. Shifts in market share usually occur because the people that let it happen are also doing pretty well.



Dr. George B. Rathmann discusses the role of science and technology in advancing U.S. economic competitiveness before a congressional audience in July 1988.



To Our Stockholders

Amgen entered fiscal 1988 facing a series of challenges unprecedented in the Company's short operating history. We are pleased to report that fiscal 1988 has been highlighted by a series of accomplishments which will accelerate Amgen's transition into a fully integrated operating company. The progress which we have made in every aspect of our operation strategically positions Amgen to be a successful participant in the growth of the emerging biotechnology industry. The solid scientific foundation which has been established and developed since the Company began operations in 1981 will serve as the cornerstone for Amgen's commercial success as we prepare to introduce our products into the marketplace during the next phase of the Company's evolution and maturation.

Financial Performance

Fiscal 1988 marked Amgen's third consecutive year of profitability, a feat distinguishing it as one of a select group of companies within the biotechnology industry to have achieved and maintained such operating performance. The combination of product sales, corporate relationships and partnership funding has enabled Amgen to execute a strategy of operating at or near breakeven during the development phase of the Company's evolution. Such a strategy, combined with one of the strongest balance sheets within the industry, has enabled Amgen to optimize the management of its financial resources and ensure that it has the necessary capital available to bring its products through development to the marketplace.

Revenues for fiscal 1988 were \$53.3 million, an increase of 54% over the prior year's revenues of \$34.7 million. Over 80% of the Company's revenues were derived from operations, principally from relationships with corporate partners, and approximately \$2.1 million of product sales to the scientific research community. The Company posted its third consecutive year of increasing profits, with a net income of \$1,725,000, an increase of 52% over fiscal 1987 results.

The financial profile of the organization was substantially strengthened during this past fiscal year with the completion of two major financings. The first of these was the successful offering

of 2.3 million shares of common stock, which brought the Company approximately \$75 million in net proceeds. Proceeds from this offering will be used to meet the expected increase in capital expenditures and working capital requirements relating to the commercialization and further development of Epogen,TM erythropoietin (*Epogen*) and the Company's other products under development.

The second infusion of capital resulted from the completion of the offering of Amgen Clinical Partners, L.P., a research and development limited partnership, whose principal objectives are the clinical development and commercialization of granulocyte colony stimulating factor (G-CSF) and selected growth factors for wound healing. The \$75 million in net proceeds from the offering will further accelerate the clinical development of these important biotechnology products.

With this added capital, Amgen possesses one of the strongest financial positions of any company in the biotechnology field and is well positioned to meet the financial challenges of bringing its products to the marketplace.

Product Progress

Since its inception, Amgen has pursued an aggressive program of new product discovery and development. The Company has distinguished itself as one of the most successful in the biotechnology industry at bringing products through research and development and into clinical testing, and currently leads the industry with six of its pharmaceutical products in human clinical testing; however, new product development has not taken place at the expense of prudent fiscal policy as the Company continues to maintain a strong operating profile. Through judicious management of its technical and financial assets, the Company has maintained a successful balance of resource allocation which has enabled it to assume a leadership position in terms of both its scientific and financial performance.

The enthusiasm of Amgen's staff for developing innovative solutions to important health care problems continued to fuel the Company's clinical progress during fiscal 1988. The increased pace of development and the higher level of achievement are reflected in the progress the Company has made in advancing its major programs toward the market.

Erythropoietin

Amgen became only the second company in the biotechnology industry to author and file a Product License Application when it submitted its 19,500 pages of documentation to the United States Food and Drug Administration last October on *Epogen*, Amgen's designation for its proprietary human recombinant erythropoietin product. After review and approval of its application by the United States Food and Drug Administration, Amgen will introduce the product directly to the kidney dialysis market through its own dedicated sales force. *Epogen* will offer new hope to many of the 90,000 kidney dialysis patients throughout the United States who suffer from chronic anemia associated with renal failure.

Granulocyte Colony Stimulating Factor

During fiscal 1988, Amgen reported the first clinical response to human recombinant G-CSF in studies being conducted with cancer patients at New York's Memorial Sloan-Kettering Cancer Center. In these trials, investigators demonstrated that G-CSF can restore the level of a population of white blood cells known as neutrophils in patients undergoing chemotherapy. At the close of fiscal 1988, Phase III clinical testing of G-CSF had been initiated as part of our multicenter trial in patients suffering from small cell lung cancer who are undergoing chemotherapy. We expect that these pivotal trials will supply the necessary data to support Amgen's second PLA which we hope to file by the end of fiscal 1989.

Hepatitis B Vaccine

Phase III clinical testing of Amgen's recombinant hepatitis B vaccine continued during fiscal 1988 in conjunction with our marketing partner, Ortho Pharmaceutical Corporation, a subsidiary of Johnson & Johnson. When completed, the data collected from these trials will be used in support of an application to market this important prophylactic and help curb the threat of hepatitis B infection throughout the world.

Interferon

The Company continued to invest in research to better understand the diverse activities of the body's immune system and the potential therapeutic benefits of immune modulators such as the interferons. Both consensus interferon and gamma interferon advanced in Phase III and Phase II clinical trials, respectively, exploring applications as either anticancer or antiviral treatments. While more trials and studies are needed to better assess the role of these products in cancer therapy and in treating viral disorders, the Company remains optimistic regarding the use of these important immune modulators based on the results obtained to date in clinical trials.

Interleukin 2

IL-2 continued to advance in Phase II clinical trials being conducted in conjunction with Ortho Pharmaceutical Corporation. With researchers throughout the world investigating the role of this immune regulator, we remain hopeful that this product will ultimately play an important role in assisting cancer patients.

Planning For Success

In order to accommodate the demands on the organization which accompany the Company's successful product development, Amgen expanded both its staff and facilities in fiscal 1988. During this past fiscal year, the Company completed and occupied a new 59,000 sq. ft. research and development building, which provides space for 150 scientists when fully occupied as well as the 24,000 sq. ft. manufacturing facility which provides the Company with a dedicated mammalian cell culture production capability. The space added during this past fiscal year equals the total for the Company during its first five years, a concrete testimony to the success of our technical programs and the scientists who manage them.

The new R&D building allows us to consolidate the various molecular biology and basic research groups under one roof and provides a more conducive environment for scientific staff interaction. This facility also houses our product development group and library as well as provides for some staff expansions in the years to come. The \$13 million facility is the finest ever built at Amgen and highlights the progress we have made since commencing operations with 3,000 sq. ft. of research space in 1981.

The completion of the mammalian cell culture manufacturing facility is another milestone on Amgen's road to commercialization. The state of the art GMP facility was completed at the end of the fiscal year and is currently undergoing a series of qualification production runs to insure that it meets all of the FDA requirements for the production of human pharmaceutical products. We expect the plant to be producing product during the second half of fiscal 1989 in advance of the anticipated market introduction. The dedicated mammalian cell culture manufacturing facility will provide Amgen with sufficient capacity to meet the anticipated demand for *Epogen*.

Amgen's staff has grown to meet the changing requirements of the organization. As the Company's product portfolio has broadened and expanded beyond the discovery phase of product development, personnel additions have focused on the downstream support activities which are critical functions during the latter stages of product development. Staff additions in fermentation, process development, cell culture manufacturing, clinical and regulatory affairs and, most recently, marketing and sales, signal the maturation of the Company and emphasize its transition from a research and development organization to a fully integrated, independent health care company. The marketing and sales

organizations are now expanding in anticipation of the eventual approval of *Epogen* by the FDA in order to insure that all of the elements are in place for a successful product launch.

At the close of fiscal 1988, Amgen's staff had grown to 353, an increase of 33% over the previous year. We enthusiastically welcome our new staff members to the Amgen family and know that each will contribute to the growth and prosperity of the Company and help meet the challenges which are ahead. As stockholders in Amgen, most of our staff members have the opportunity to participate in the growth and success to which they have contributed.

Converting Expectations

To Results

The achievements of the past year have brought Amgen to the threshold of the commercial success which was envisioned when the Company commenced operations seven years ago. At that time, *Epogen*, G-CSF and other products were merely scientific challenges whose true value and clinical efficacy remained undiscovered. Today, through the efforts of Amgen's staff, those visions of the future are being transformed into important human therapeutics and commercial reality.

While some may gauge the long term value of the Company in terms of potential sales, products or profits, the truest measure of the character and worth of the Company today may be taken from the success of our staff. Amgen's progress testifies to a standard of excellence which has been achieved and which rises with each new success.

Through such efforts, the objective of building a biopharmaceutical company based on advanced molecular biology and recombinant DNA technology is becoming a reality. Many challenges still lie ahead, but we are better positioned today than at any time in our history to meet these challenges and fulfill the expectations of patients, physicians, stockholders and staff members.

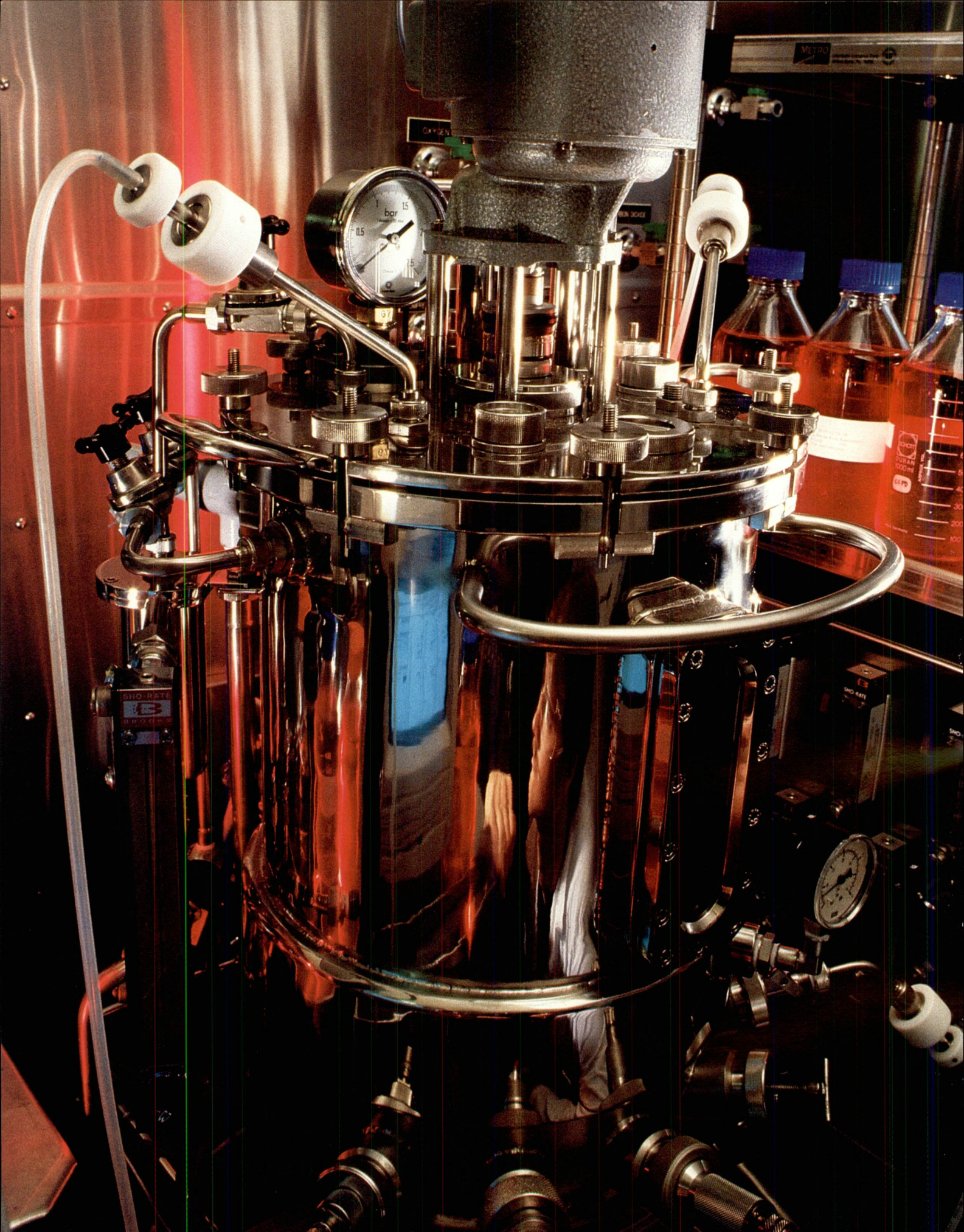
For those of you who have become Amgen stockholders during the past year, I would like to welcome you and thank you for the confidence you have displayed by your investment decision. I look forward to a long and mutually beneficial association. To those long term holders of Amgen shares, I thank you for your continued support and confidence. You have seen the Company grow and evolve to reach the most exciting period in the Company's history. We look forward to sharing our continued growth, progress and success with each of you during the coming years as we transform Amgen into a successful biopharmaceutical company. We renew our commitment to maintain Amgen's position as one of the leaders in the emerging biotechnology industry and a company with which we are all proud to be associated.

George B. Rathmann

George B. Rathmann
*Chairman of the Board,
President and
Chief Executive Officer*

May 29, 1988





**Pioneering Innovative
Solutions To Important
Medical Problems**

Erythropoietin

The development of recombinant DNA technology represents the dawn of a new scientific era. The molecular wizardry of the molecular biologist or genetic engineer is producing a new generation of therapeutic products in quantities and at a purity level suitable to solve major human health problems. With these developments a new age of therapeutic medicine will emerge, and Amgen intends to be a major contributor to this new generation of pharmaceutical products based on recombinant DNA technology. During fiscal 1988, Amgen continued to put in place the infrastructure and internal organization to insure a smooth transition from a research and development company to an independent commercial enter-

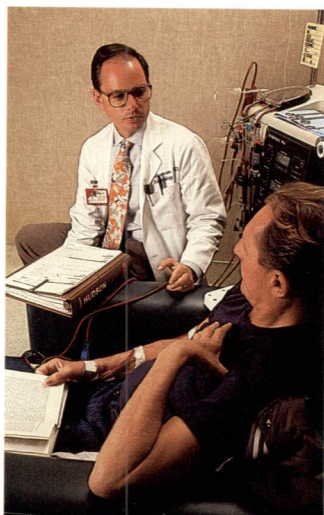
prise. The Company's first product, *Epogen*, holds the potential to revolutionize the treatment of severe anemia, especially that which is associated with chronic kidney disease.

Epogen is Amgen's designation for its proprietary form of human recombinant erythropoietin. Erythropoietin is a glycoprotein which normally is produced in the kidney, circulates in the bloodstream and is transported to the bone marrow where it stimulates the growth, multiplication and maturation of immature stem cells into mature red blood cells. In patients who develop kidney disease, there is often an impaired ability to make erythropoietin and, in turn, an impaired ability to make red blood cells, a condition defined as anemia. In the extreme situation where a person's kidneys fail, the patient is unable to produce sufficient red blood cells, and often has a red

cell level, or hematocrit, of one-third to one-half of normal. As a result of this chronic anemia, patients often suffer from severe fatigue and exhaustion and lack the energy to live a fully active life.

Prior to the development of *Epogen*, the only therapeutic alternative for treating such chronic anemia was repeated red cell or whole blood transfusions, which carried with them the risk of exposing a patient to infectious agents carried in the blood. In clinical trials being conducted throughout the world by Amgen and in conjunction with its commercial partners, *Epogen* has been shown to increase the level of red blood cells in kidney dialysis patients, thus reducing their dependence on blood transfusions and improving the quality of their lives.

*Allen Nissenson,
M.D., Director of Medical Nephrology at
UCLA and an Amgen
clinical investigator,
chats with dialysis
patient, Bob Hudson,
one of the participants
in Amgen's Phase III
clinical trial.*



*Research into deep
tank fermentation pro-
cedures is aimed at
improving the output
and efficiency of the
manufacturing pro-
cess for Epogen.*

Highlighting the clinical progress on *Epogen* were the Company's presentations of its Phase III multicenter trial at both the American Society of Hematology and the American Society of Nephrology meetings, which were held in Washington, D.C. during December. Several clinical investigators and Amgen researchers reported on the various trials and studies with *Epogen*, and their presentations were considered by many to be the highlight of the meetings.

Amgen further reinforced its position as the worldwide leader in the clinical development of human recombinant erythropoietin when it filed its first Product License Application on *Epogen* at the end of October. This 19,500 page

submission summarized the clinical and technical progress which Amgen has achieved on this important therapeutic product during the past six years. The filing of this application was a major milestone in the maturation of the Company, distinguishing Amgen as one of only two companies in the biotechnology industry who have authored and filed such an application on one of their therapeutic proteins. This accomplishment further demonstrates the ability of biotechnology companies to progress beyond research and development and assume responsibilities to insure their long term commercial success. It is a source of great pride to our staff, which made such an achievement possible, as it is with great anticipation that we look forward to FDA approval and marketing of this important product.

Another major milestone reinforcing Amgen's position in the commercial development of *Epogen* took place on October 27, 1987 when Amgen was awarded the first United States Patent covering the production of recombinant human erythropoietin. The patent, U.S. 4,703,008, claims the DNA and gene sequences encoding erythropoietin, as well as the vectors and the host cells which manufacture and produce the product. We believe this patent demonstrates the strength and breadth of our position on this important therapeutic product, and reaffirms Amgen's role as the worldwide leader in its clinical development and commercialization.

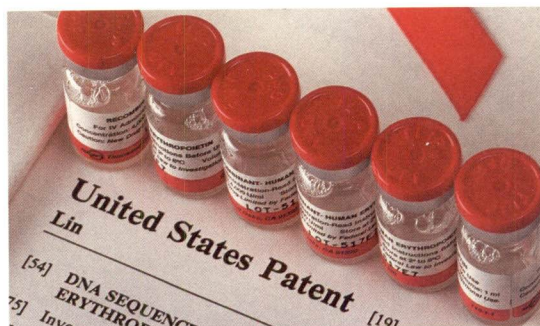
In an effort to enforce our rights under the patent, the Company has initiated two infringement

suits in the United States District Courts against competitors which we believe are infringing the claims of the patent. We have also initiated an action before the United States International Trade Commission against a licensee of one of our competitors seeking to prevent acts of unfair competition in their importation of recombinant human erythropoietin into the United States. While there can be no assurance as to the ultimate outcome of such actions, the Company is resolved to protect its technology and the interests of its stockholders.

During the early stages of the Company's evolution into an independent health care company, Amgen has developed a series of select commercial relationships in order to complement its internal skills and capabilities in bringing its products to the marketplace. As the Company

A substantial amount of support and documentation is required for the filing of a PLA. Amgen's Regulatory Affairs Manager, Larry Johnson, reviews a portion of the application which the Company submitted in support of *Epogen* last October.

Amgen has always sought to protect its technical leadership and proprietary technology through an aggressive patent strategy. On October 27, 1987, Amgen received the first patent granted by the U.S. Patent and Trademark office on recombinant human erythropoietin.



develops and introduces its own products into the marketplace directly, such relationships will have a much less material impact on Amgen's success. The Company's long term objective is to build an organization which both manufactures and markets the products which result from its research and development.

Epogen will be the first product which Amgen will introduce into the marketplace directly through its own dedicated sales organization. The Company is committed to achieving the same success and standard of excellence in the marketing of its products as it has achieved in the other sectors of its business operations. In anticipation of the approval of *Epogen*, Amgen is well along on the implementation of its plan to ensure that the marketing and sales

organizations are in place and prepared to introduce the product into the marketplace once FDA approval is received.

Amgen's sales force will market *Epogen* to nephrologists for use in kidney dialysis patients in both the hospitals and free standing dialysis centers. As additional Amgen products are developed, the sales organization will expand to meet the demands of calling on the hospital based physicians and specialty practitioners to whom the Company's products will be targeted.

Amgen believes that the excellence of the products it has developed should be reflected in the quality of the organization which markets them, and it is committed to duplicating the quality of its research efforts in the development of its sales and marketing organization.

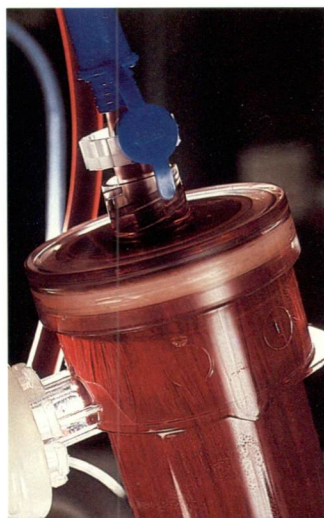
Amgen's GMP manufacturing facility was completed during the fourth quarter of fiscal 1988. The \$20 million, 24,000 square foot facility is currently undergoing a series of manufacturing qualification runs to insure that it meets all the regulatory requirements for the production of human pharmaceuticals. We expect that the facility will be fully operational during the second half of fiscal 1989, in advance of the approval of the product, and should provide the Company with the capability to meet the market demand for the foreseeable future.

Beyond the kidney dialysis application, recombinant human erythropoietin holds the potential to treat a broad spectrum of anemias and other clinical conditions, especially those where

blood transfusions may be required. Studies to assess more accurately the full range of potential applications for the product are currently underway in conjunction with our marketing partners. As additional trials are carried out, we will more fully appreciate the broader potential role of recombinant erythropoietin in clinical medicine beyond chronic kidney disease.

With the approval of our first product, Amgen will cross the threshold of commercialization and realize the goal it set for itself when it commenced operations in 1981.

Epogen will help restore the level of red blood cells in kidney dialysis patients who suffer from chronic anemia.

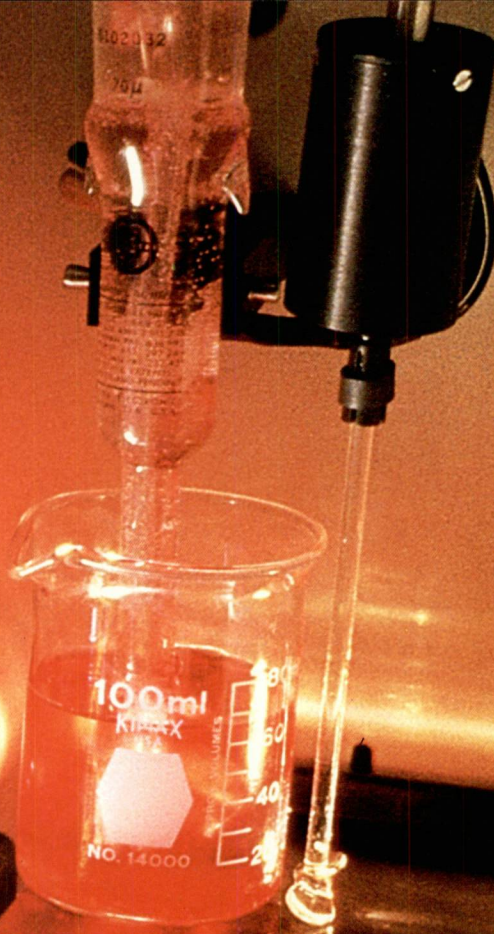


Amgen's dedicated mammalian cell culture facility will provide Amgen with sufficient capacity to meet the anticipated demand for Epogen.

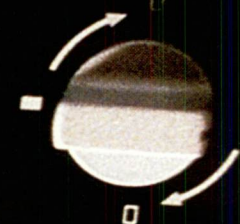


Dennis Tajiri, Amgen's Manager of Cell Culture Product Development, prepares an experiment aimed at studying the variables affecting cellular growth.

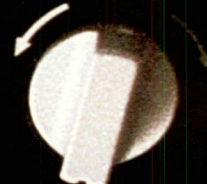




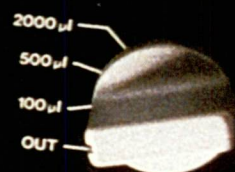
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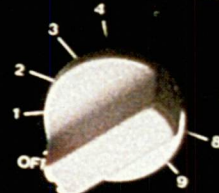
FOCUS



MANOMETER SELECT



STIRRER CONTROL



SAMPLING
STAND II

**Innovative Products
To Improve The Success
Of Cancer Therapy**

**Granulocyte Colony
Stimulating Factor**

Like its counterpart erythropoietin, which controls red blood cell production, G-CSF is the molecule which is responsible for the regulation and control of a population of white blood cells known as neutrophils. Neutrophils are important because they represent one of the body's primary means of defense against bacterial infection. In certain patient populations such as those undergoing chemotherapy and radiation, there is often an impaired ability to mount an effective immune response. The indiscriminate

nature of such anticancer therapies results in the destruction of cells crucial to the immune response, such as neutrophils, in addition to the malignant cells against which the therapy is directed.

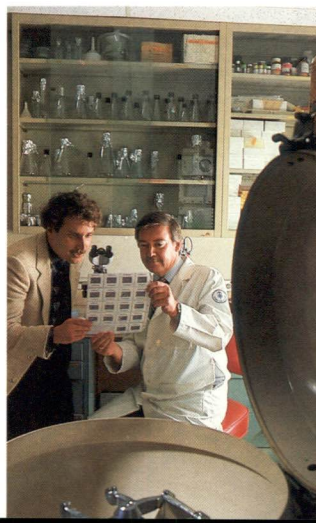
Amgen became the first and today remains the only United States company evaluating G-CSF in human clinical testing. The trials, which began at New York's Memorial Sloan-Kettering Cancer Center, have now been expanded to include twelve centers throughout the United States. In addition, Phase I/II testing of G-CSF is also underway at sites in Europe, Japan and Australia. Early clinical results on the potential of G-CSF as an adjunct to chemotherapy have demonstrated the dramatic effect of this

compound in increasing neutrophil levels. Additional Phase I/II clinical trials to investigate other indications also began in fiscal 1988, broadening Amgen's program to define the potential applications for this innovative therapeutic.

The Company has reported the results of its clinical trials at the International Society for Experimental Hematology in Tokyo and the American Society of Hematology in Washington, D.C., and recent results of European and Australian investigators have been published in *The British Journal of Cancer* and *Lancet*, respectively.

Collaborative efforts between Amgen and Memorial Sloan-Kettering Cancer Center helped accelerate the clinical development of G-CSF. Amgen's Lawrence Souza, Director of Exploratory Programs, confers with Malcolm Moore, M.D. of MSKCC on some preliminary results from the G-CSF studies.

Amgen's early success with G-CSF has closely paralleled its initial success with Epogen. At the close of Fiscal 1988, Amgen had initiated Phase III multicenter trials at twelve medical centers throughout the United States.



At the close of fiscal 1988, Amgen initiated a multicenter Phase III clinical trial of G-CSF at several medical centers in the United States exploring the role of G-CSF as an adjunct to chemotherapy in small cell lung cancer patients. The results of this pivotal study will provide Amgen with the data for its PLA submission on G-CSF, which it anticipates filing by the end of fiscal 1989.

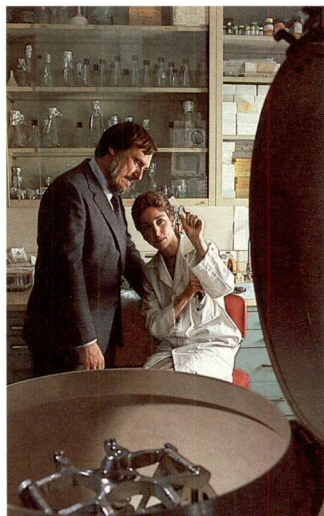
With the success of G-CSF adjunctive therapy, biotechnology offers the potential of increasing the efficiency and effectiveness of

conventional cancer therapies. Such treatments may allow more frequent and greater doses of chemotherapeutic agents without the subsequent depression in white cell counts which have limited the current chemotherapy regimens. By restoring the immune competence of such patients and raising their neutrophil levels, we hope to reduce the risk of infection and the dependence on antibiotic therapy employed in such treatments.

Amgen continues to explore other applications for G-CSF beyond the role it may play in chemotherapy. Funded by the resources of Amgen Clinical Partners, L.P., a research and development limited

partnership which was sold in fiscal 1988, the Company is currently conducting trials on patients undergoing bone marrow transplantation and is exploring applications in the area of severe burns and systemic infection. By better understanding how to control and regulate the immune response, medical science may be better able to develop innovative approaches to improve the success of cancer treatments.

Kirby Alton, Amgen's Director of Therapeutic Product Development, confers with Janice Gabrilove, M.D., the principal investigator overseeing the clinical trial of G-CSF being conducted at MSKCC.



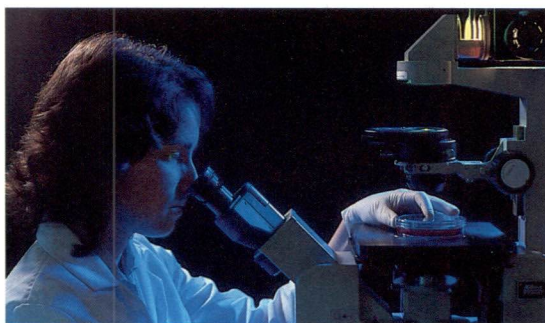
Growth Factors

Amgen commits a substantial portion of its research budget to the discovery and development of new product candidates. The Company has long recognized that its ultimate success depends on its ability to discover successful product candidates which will allow it to build upon the foundation of its first generation products such as *Epogen* and G-CSF. One area of research which has appeared most promising is the area of growth factors for tissue regeneration and wound healing. Funded by the resources of Amgen Clinical Partners, L.P.,

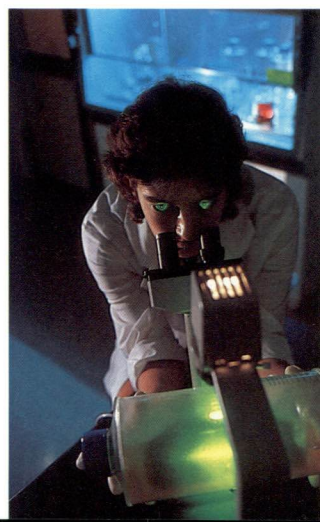
Amgen has been able to accelerate its development programs in this area during the past year. Amgen has one of the most comprehensive programs in wound healing of any company competing in the biotechnology field, and during the past year, the Company has moved four of its product candidates into advanced stages of preclinical testing using a variety of model systems. We are investigating the potential of platelet derived growth factor (PDGF) and epidermal growth factor (EGF) in accelerating the healing process and in treating surgical or soft tissue damage. Insulin-like growth factor (IGF-I) holds promise in accelerating both soft and hard tissue or bone

repair and might play a role in orthopedic surgery applications. Fibroblast growth factor (FGF) is currently undergoing investigation not only for its ability to accelerate the healing of surface wounds, but also to explore its ability to promote the growth of new blood vessels. Each of these product candidates offers exciting market opportunities for Amgen. While each will not necessarily result in a new product, we will select the most promising candidates for human clinical testing during fiscal 1989.

Amgen has one of the most comprehensive programs in wound healing of any company in the biotechnology field. Researcher Susan Schiffer checks a culture of cells producing PDGF, a growth factor which is being studied for its potential role in wound repair.



Amgen continues to study and evaluate alternative cell lines for the production of its biopharmaceutical products. Researcher Katie Fuller uses fluorescent microscopy to examine the morphology of a new cell line.



Beyond our efforts with growth factors, additional exploratory programs on lymphokines and hematopoietic growth factors, immunomodulators, vitamins, enzymes, growth promotants, pigments and specialty chemicals, strategically position Amgen for success in several segments of the emerging biotechnology industry. The Company believes that the successful selection and development of these programs will help to achieve a well filled product pipeline in the future.

Amgen Biologicals

Amgen's success at marketing its recombinant DNA products to the scientific research community has enabled Amgen Biologicals to set the industry standard for purity and product performance of such reagents. With demand increasing for existing products and the expansion of the product line to include several newly cloned proteins, sales have again shown steady growth. With approximately \$2 million in sales in fiscal 1988, the Company achieved another year of record performance and raised the standard for product quality in the industry. The enthusiastic response from university and corporate researchers worldwide provides further evidence of the success of the Company's early marketing efforts.

Animal Health Care

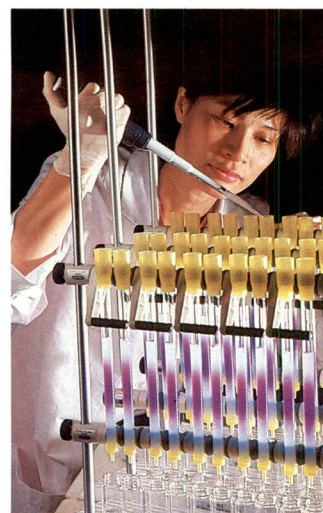
Building on the core technology which was developed in conjunction with the Company's pharmaceutical programs, Amgen's animal health programs covering natural growth promotants continued to advance through field testing during fiscal 1988.

Field trials on Amgen's porcine somatotropin continued on plan with partner SmithKline Beckman during fiscal 1988. Data from several of the trials continue to support the potential of this natu-

ral molecule for reducing the fat content of pork, in addition to increasing feed efficiency in pigs, thus representing a significant economic opportunity for hog farmers throughout the world.

Testing of Amgen's bovine somatotropin in conjunction with our corporate partner continued to demonstrate the utility of the product in increasing milk yield in dairy cattle by between 15% and 20%. Upon completion of the field testing program, this product should improve the production and economics of dairy farming operations.

Amgen has successfully extended its recombinant DNA technology to several applications in the field of animal health care. Researcher Rou-Yin Hsu assays samples to detect a gene sequence inserted into a cell as part of the Company's efforts on animal growth promotants.



Exploratory work with Arbor Acres Farm, Inc. to assess the application of Amgen's gene mapping and other genetic selection techniques to the poultry business continued as part of our 50-50 partnership in GT Systems.

Amgen's activity in the field of animal health care presents it with an opportunity to leverage its basic science into new markets beyond human pharmaceuticals. The application of such technology to animal health care is clearly established, and it provides us with new product candidates as we develop new solutions to the challenges facing today's farmer.

Specialty Chemicals

The application of genetic engineering techniques to the production of specialty chemicals has posed a series of unique challenges to molecular biologists within the biotechnology industry. The manipulation of families of genes to produce large quantities of compounds under rigid economic constraints has proven to be a serious challenge to all companies in the field.

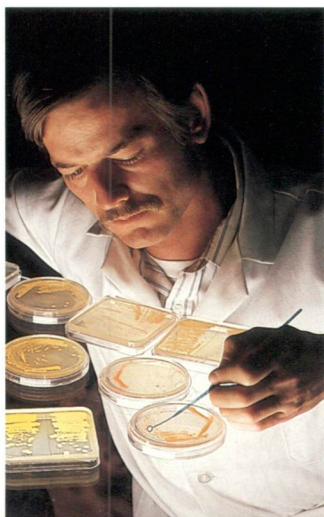
Since its inception, Amgen has pioneered the successful application of its multigene or gene

cluster cloning technology for the production of various dyes, pigments, vitamins, flavors, fragrances and other specialty chemicals. This capability dramatically expands the universe of potential target molecules whose synthesis is now possible through advances in recombinant DNA technology.

During the past year the Company expanded its portfolio of exploratory programs while continuing on plan with its corporate relationships. The Company's long term goal is to build a successful business unit in the area of specialty chemicals based on the application of its gene cluster technology and recombinant DNA techniques. Today, Amgen scien-

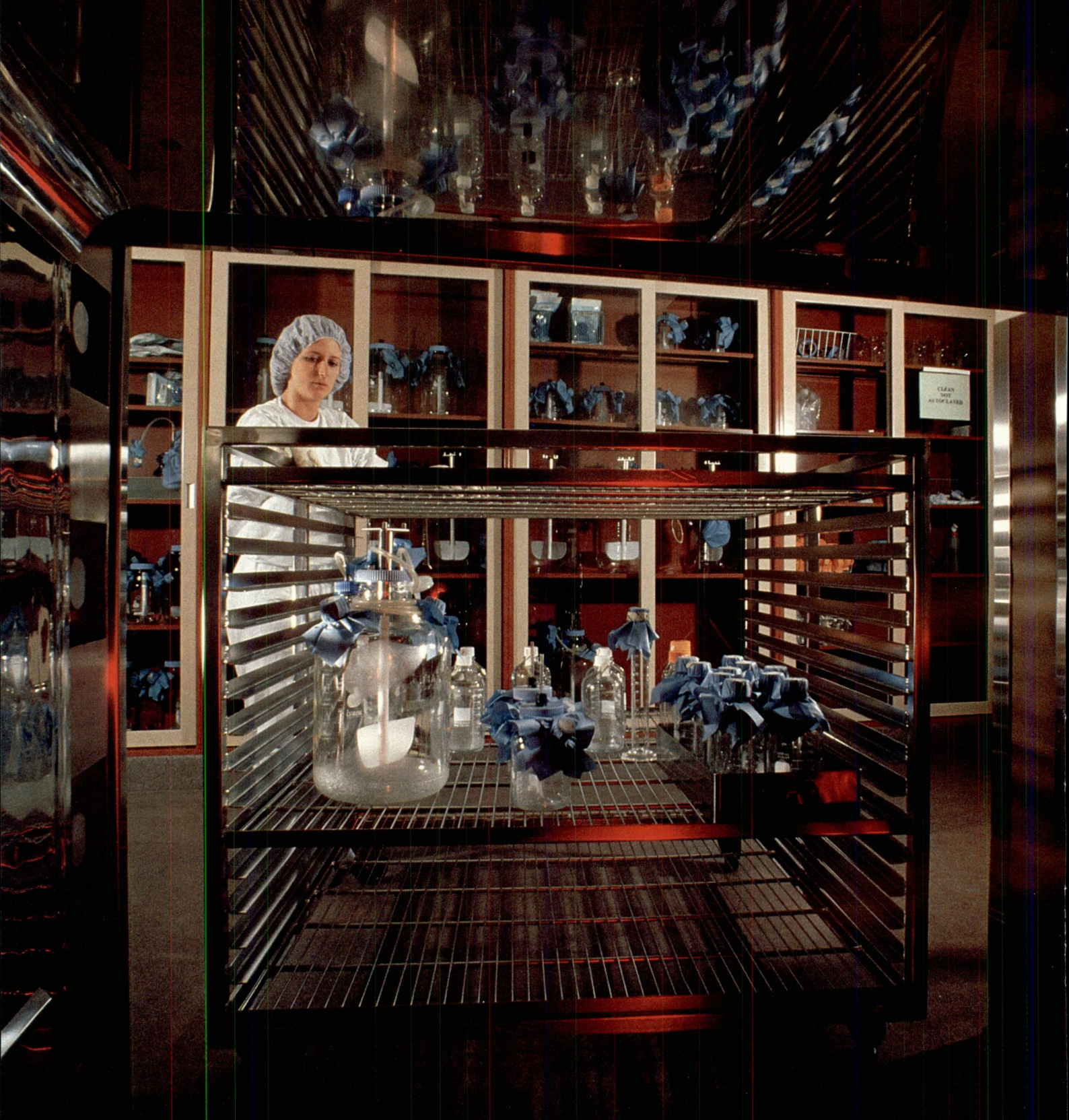
tists are applying their skills to a variety of projects ranging from pharmaceuticals and nutrition to industrial enzymes and fine chemicals.

Research scientist Eric Fisher explores the application of Amgen's gene cluster technology in an effort to develop new production techniques for dyes and pigments.



Researcher Barbara Karan-Tamir burns away the alcohol used to sterilize a wand prior to spreading bacterial colonies on an agar plate to evaluate genetically engineered organisms producing improved detergent enzymes.





Waiting For *Epogen*— The Road To The Marketplace

The development of new and improved pharmaceutical products is often an expensive and time consuming process, requiring sophisticated scientific and technical skills. Until recently, the search for new medicines has focused on synthetic compounds whose mode of action was to mimic the activity of those molecules which occurred naturally in the body. The advances in molecular biology and recombinant DNA technology heralded the start of the biotechnology revolution and opened new avenues for the development and commercialization of novel and innovative pharmaceuticals which could not be produced by conventional technology.

One such compound is *Epogen*, Amgen's proprietary form of human recombinant erythropoietin, which only a few years ago was no more than a research curiosity. Today, as we seek

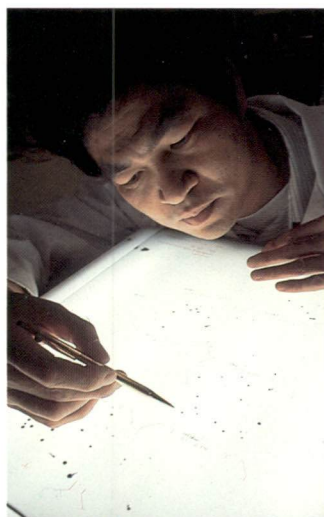
approval from the FDA, *Epogen* stands at the threshold of commercialization, offering renewed hope to those patients suffering from the anemia associated with chronic kidney disease.

Erythropoietin was first identified in 1906 as the molecule responsible for the regulation and control of red blood cell production. Over the next seventy-five years, attempts by researchers to purify and characterize the molecule met with limited success. Although erythropoietin occurs naturally in the blood stream, it is present at extremely low concentrations which makes its purification from blood or urine impractical as a source of material for therapeutic use. As a result, studies using erythropoietin derived from natural sources have been severely limited in scope and number. This shortcoming was first overcome in 1983 with Amgen's production of human recombinant erythropoietin.

Amgen scientists were the first to successfully apply genetic engineering technology to clone and express the gene for human erythropoietin thereby setting the stage for the production of this important molecule in quantities and at a purity level sufficient for human therapeutic use. With the assurance of greatly increased supplies of pure human erythropoietin, the comprehensive investigation of its clinical and therapeutic application was possible for the very first time.

Amgen initiated clinical testing of human recombinant erythropoietin in December 1985, when it entered Phase I/II testing of its *Epogen* product at Seattle's Northwest Kidney Center. The patients who participated in this trial were the first in the world to benefit from this important therapeutic compound. The

Fu-Kuen Lin led the team of Amgen scientists whose efforts resulted in the successful cloning and expression of the gene encoding erythropoietin.



John Adamson, M.D., along with colleague Joseph Eschbach, M.D., was one of the first physicians in the world to clinically evaluate Epogen as part of the studies which were initiated in December 1985 at Seattle's Northwest Kidney Center.



Joseph Eschbach, M.D., along with co-author John Adamson, published the results of the first United States trial on Epogen in the prestigious New England Journal of Medicine. Their early findings have now been validated at several clinical sites throughout the world.



Amgen's mammalian cell culture facility was completed at the close of fiscal 1988 and is currently being qualified to insure that it meets all GMP requirements for the production of human pharmaceuticals.

results of this investigation were published in the *New England Journal of Medicine*, and set the stage for a new era of therapy in the field of nephrology. After its initial clinical success, Amgen moved to more advanced Phase III testing at several clinical centers throughout the United States. A summary of these data was presented at both the American Society of Hematology and the American Society of Nephrology meetings in Washington, D.C. last December.

In October 1987, Amgen filed its PLA on *Epogen*, achieving another major milestone on the way to the marketplace. Today this product is undergoing FDA review.

As we await the FDA approval of *Epogen*, each of us has an opportunity to reflect on the signifi-

cance of the product. For Amgen, it signifies the culmination of a research effort which began with the Company's founding. It symbolizes the coming of age of erythropoietin as an important medical treatment as well as a commercial opportunity.

For Linda Bell, who lost her kidneys to polycystic kidney disease, and who has suffered from the fatigue and anemia which accompanied her condition, it meant a return to near normalcy, a chance to renew her daily activities and keep pace with her family once more.

For Jennifer Pelly, a Seattle mother of two teenagers, it has meant a chance to regain control over her life, which she had surrendered to the effects of her

chronic anemia. It has meant a chance to ski, bicycle or play tennis again—things that she had not done since her kidney function was lost.

For Barbara Karlin, an author and journalist, it has meant a chance to spend an active and enjoyable day shopping and walking in Westwood with her daughter. It also meant a return to work and a level of productivity which she had not enjoyed since the onset of her illness.

For Don Colter, M.D., a Seattle surgeon, it has meant a return to a full patient schedule and the resumption of the active surgical practice which he had to suspend due to the complications of his chronic anemia.

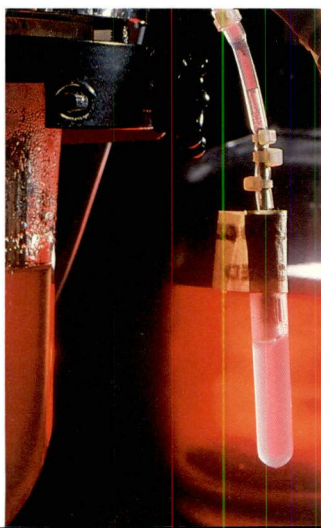
For Ron Labyorteaux, it has meant a chance to pursue a variety of recreational and physical activities he had not enjoyed since the onset of his illness.

For Christopher Blagg, M.D., head of Seattle's Northwest Kidney Center, *Epogen* marks the most significant advance in nephrology since dialysis and transplantation became a reality. For his colleagues John Adamson, M.D. and Joseph Eschbach, M.D., *Epogen* marks the dawn of a new era in treating the severe anemia of patients suffering from chronic kidney disease.

For each and every kidney disease patient who suffers from chronic anemia, *Epogen* signifies renewed hope: hope of alleviating the debilitating effects of their chronic anemia and hope for regaining control over their lives and lifestyle.

Through the application of genetic engineering technology, mammalian cells are converted to mini factories for the production of innovative biopharmaceuticals such as *Epogen*.

Christopher Blagg, M.D., head of the Northwest Kidney Center in Seattle, has hailed Epogen as the most important advance in the treatment of chronic renal failure since the advent of kidney dialysis.





Linda Bell



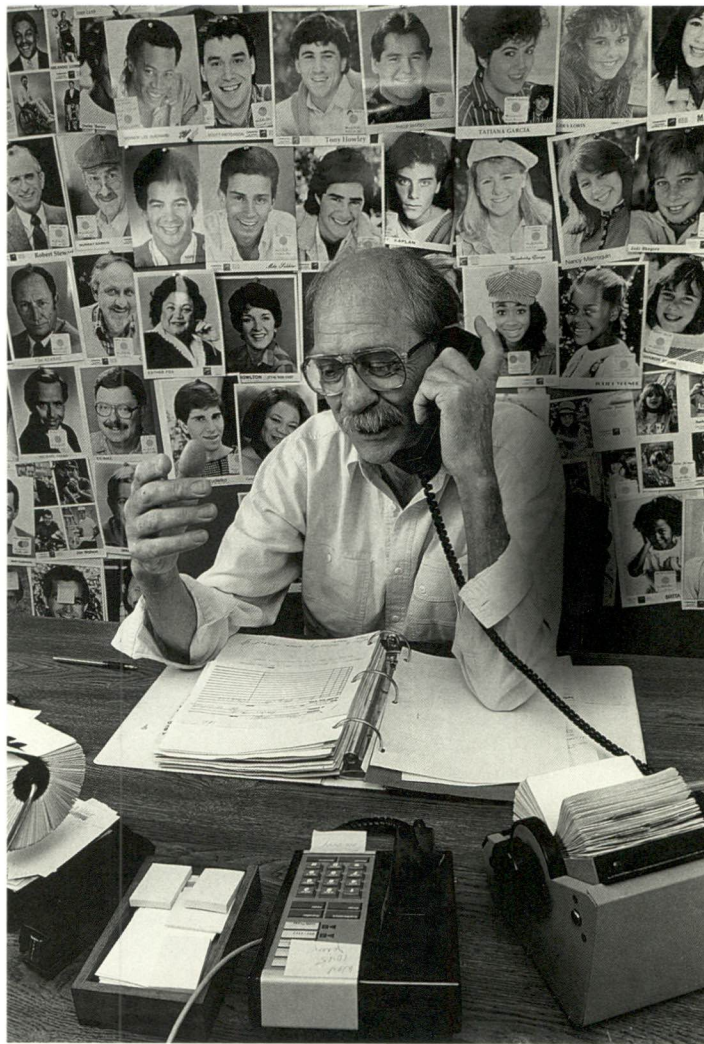
Jennibee Pelly



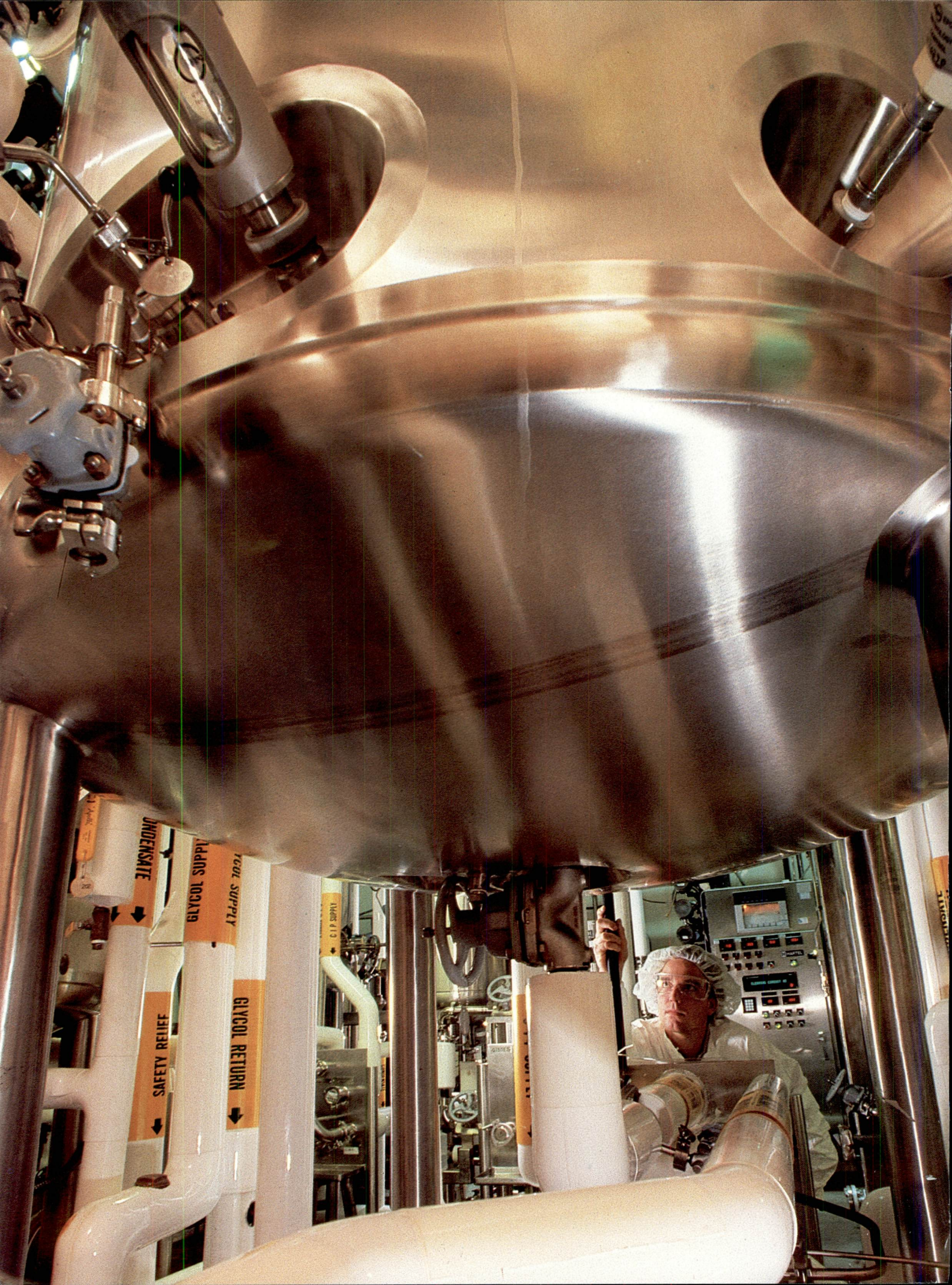
Barbara Karlin



Donald Colter mrl



R.C. Laboyortian



CONDENSATE

GLYCOL SUPPLY

GLYCOL RETURN

SAFETY RELIEF

GLYCOL RETURN

GLYCOL SUPPLY

GLYCOL SUPPLY

Results of Operations

Operations for the fiscal years ended March 31, 1988 and 1987 have been characterized by increasing revenues of \$53,325,000 and \$34,722,000, respectively, predominately derived from corporate partners, including payments for achieving technological milestones, and interest income. Such increases have been accompanied by increasing expenses, predominately for research and development. Research and development expenses for the fiscal years 1988 and 1987 were \$39,631,000 and \$24,450,000, respectively. General and administrative expenses have increased at approximately the same percentage rate as research and development expenses.

1988-1987 Total revenues increased by \$18,603,000 for the fiscal year ended March 31, 1988, as compared with the prior year, predominantly as a result of interest income, milestone and other corporate partner payments from Amgen Clinical Partners. Interest income increased for the same period as a result of higher levels of invested funds.

1987-1986 Total revenues increased by \$11,363,000 for the fiscal year ended March 31, 1987, as compared with the prior year, predominately as a result of interest income, milestone and other corporate partner payments from Johnson & Johnson, Kirin, Kirin-Amgen and Kodak. Interest income increased for the same period as a result of higher levels of invested funds.

In fiscal 1988, 1987, and 1986, the Company had two principal sources of revenue: revenues from its corporate partners and interest on short-term investments. Payments from Amgen Clinical Partners, Abbott, Johnson & Johnson, Kirin and Kirin-Amgen accounted for 69%, 70%, and 83% of total revenues for the 1988, 1987 and 1986 fiscal years, respectively. See Note 3 of Notes to Amgen's Consolidated Financial Statements. In addition to these sources, the Company has generated increasing revenues from sales of genetically engineered reagents for research purposes. Until revenues from product sales are substantial, the Company anticipates that corporate partner revenues and interest income will continue to be the Company's principal sources of revenue.

Equity in loss of affiliated companies, in the amounts of \$1,049,000, \$1,895,000 and \$648,000 in fiscal 1988, 1987, and 1986 respectively, reflects, principally, the Company's share of the losses of Kirin-Amgen that resulted from research and development payments by Kirin-Amgen to Amgen and Kirin.

Scale-up and production capability are essential elements of Amgen's long-term strategy for success. Cell culture production supervisor, David Bengston, checks the preparation of sterile media prior to the start of an Epogen production run.

Financial Condition

The Company's cash requirements have been satisfied from several major sources: proceeds from sales of equity securities, interest income and revenues from corporate partners. In addition, during fiscal 1988 the Company entered into various sale-leaseback transactions for the acquisition of certain equipment with an aggregate cost of \$11,269,000. The Company continues to maintain a strong financial position with cash, cash equivalents and marketable securities of \$105,565,000 at March 31, 1988.

In May 1987, the Company completed a public offering of 2,300,000 shares of Common Stock, resulting in net proceeds to Amgen of approximately \$75,000,000. The Company anticipates that the net proceeds, including interest thereon will be used for the expected increase in capital expenditures (including expansion of manufacturing capabilities) and expanded working capital requirements relating to the further development of *Epogen*, G-CSF and the Company's other products under development. Uncertainty as to the receipt and timing of regulatory approvals for products makes it difficult to estimate the amounts allocated to each use. Prior to significant sales of human therapeutic products, the Company will need to develop a marketing and sales organization, and a portion of proceeds may be used for this purpose.

In June 1987, the Company completed private placement of limited partnership interests, resulting in net proceeds of approximately \$75,000,000. The resulting limited partnership will fund the development of G-CSF and certain recombinant growth factors under a development agreement with the Company.

The Company expects its existing funds and cash payments under existing corporate partner agreements to be adequate to finance planned capital expenditures and operations for the next several years.

Amgen Inc. Consolidated Balance Sheets

March 31, 1988 and 1987

		1988	1987
Assets	Current assets:		
	Cash and cash equivalents	\$ 106,000	\$ 921,000
	Marketable securities, at cost which approximates market	105,459,000	56,723,000
	Receivables:		
	Corporate partners:		
	Related parties	7,023,000	3,379,000
	Others	1,052,000	1,493,000
	Interest	3,443,000	1,654,000
	Other	406,000	237,000
	Inventories	1,040,000	—
	Prepaid expenses	432,000	673,000
	Total current assets	118,961,000	65,080,000
	Property, plant and equipment, at cost—net	54,766,000	23,330,000
	Note receivable from affiliated company	9,600,000	—
	Funds held by Trustee for construction	5,955,000	5,611,000
	Investments in affiliated companies	672,000	872,000
	Other assets	2,881,000	1,916,000
		\$192,835,000	\$ 96,809,000
Liabilities and Stockholders' Equity	Current liabilities:		
	Accounts payable	\$ 6,617,000	\$ 3,018,000
	Employee compensation and benefits	1,953,000	1,136,000
	Other accrued liabilities	1,267,000	620,000
	Accrued clinical costs	793,000	73,000
	Unearned corporate partner revenue—related parties	150,000	453,000
	Current portion of long-term debt and lease obligations	2,008,000	450,000
	Total current liabilities	12,788,000	5,750,000
	Long-term debt and lease obligations	16,503,000	7,100,000
	Commitments (Note 5)		
	Stockholders' equity:		
	Common stock, \$.0001 par value; 50,000,000 shares authorized; outstanding—16,691,163 shares in 1988 and 14,262,301 shares in 1987	2,000	1,000
	Additional paid-in capital	181,619,000	103,760,000
	Deficit	(18,077,000)	(19,802,000)
	Total stockholders' equity	163,544,000	83,959,000
		\$192,835,000	\$ 96,809,000

See accompanying notes.

Amgen Inc. Consolidated Statements of Operations*Years ended March 31, 1988, 1987 and 1986*

	1988	1987	1986
Revenues and other income:			
From corporate partners:			
Related parties	\$34,927,000	\$14,611,000	\$11,389,000
Others	7,223,000	13,650,000	8,851,000
Product sales	2,130,000	1,580,000	856,000
Interest income	9,045,000	4,881,000	2,263,000
Total revenues and other income	53,325,000	34,722,000	23,359,000
Expenses:			
Research and development	39,631,000	24,450,000	17,424,000
General and administrative	10,284,000	6,782,000	4,600,000
Equity in loss of affiliated companies	1,049,000	1,895,000	648,000
Interest expense, net	287,000	—	15,000
Total expenses	51,251,000	33,127,000	22,687,000
Income before income taxes	2,074,000	1,595,000	672,000
Provision for income taxes	349,000	458,000	124,000
Net income	\$ 1,725,000	\$ 1,137,000	\$ 548,000
Earnings per share	\$.10	\$.08	\$.05
Shares used in calculation of earnings per share	17,334,000	14,933,000	11,644,000

Amgen Inc. Consolidated Statements of Stockholders' Equity*Years ended March 31, 1988, 1987 and 1986*

	<i>Common stock</i>	<i>Additional paid-in capital</i>	<i>Deficit</i>
Balance at March 31, 1985	\$1,000	\$ 59,191,000	\$(21,487,000)
Proceeds from issuance of 313,356 shares of common stock in a private placement	—	5,000,000	—
Net proceeds from issuance of 2,638,000 shares of common stock in a public offering	—	37,028,000	—
Issuance of 158,649 shares of common stock upon the exercise of stock options	—	299,000	—
Net income	—	—	548,000
Balance at March 31, 1986	1,000	101,518,000	(20,939,000)
Net proceeds from registration of common stock	—	714,000	—
Issuance of 286,515 shares of common stock upon the exercise of stock options	—	1,528,000	—
Net income	—	—	1,137,000
Balance at March 31, 1987	1,000	103,760,000	(19,802,000)
Net proceeds from issuance of 2,300,000 shares of common stock in a public offering	1,000	74,613,000	—
Net proceeds from issuance of warrants in connection with the Limited Partnership-1988 portion	—	2,191,000	—
Issuance of 128,862 shares of common stock upon the exercise of stock options	—	1,055,000	—
Net income	—	—	1,725,000
Balance at March 31, 1988	\$2,000	\$181,619,000	\$(18,077,000)

See accompanying notes.

Amgen Inc. Consolidated Statements of Changes in Financial Position
Years ended March 31, 1988, 1987 and 1986

	1988	1987	1986
Cash, cash equivalents and marketable securities provided (used) by operations:			
Net income	\$ 1,725,000	\$ 1,137,000	\$ 548,000
Depreciation and amortization	4,120,000	2,646,000	2,538,000
Equity in loss of affiliated companies	1,049,000	1,895,000	648,000
Changes in:			
Receivables	(5,161,000)	(4,179,000)	(1,608,000)
Inventories	(1,040,000)	—	—
Prepaid expenses	241,000	(116,000)	(127,000)
Accounts payable	3,599,000	1,996,000	78,000
Accrued liabilities	2,184,000	556,000	693,000
Unearned corporate partner revenue	(303,000)	(1,523,000)	1,613,000
Cash, cash equivalents and marketable securities provided by operations	6,414,000	2,412,000	4,383,000
Investment activities:			
Purchases of property, plant and equipment	(35,556,000)	(11,787,000)	(4,749,000)
Loan to affiliated company	(9,600,000)	—	—
Investment in affiliated company	(849,000)	—	—
(Increase) decrease in funds held by Trustee	(344,000)	(300,000)	2,263,000
Increase in other assets	(965,000)	(294,000)	(415,000)
Cash, cash equivalents and marketable securities used by investment activities	(47,314,000)	(12,381,000)	(2,901,000)
Financing activities:			
Net proceeds from registration and/or issuances of common stock and warrants	77,860,000	2,242,000	42,327,000
Increase (decrease) in long-term debt and lease obligations	10,961,000	(1,274,000)	564,000
Cash, cash equivalents and marketable securities provided by financing activities	88,821,000	968,000	42,891,000
Increase (decrease) in cash, cash equivalents and marketable securities	\$ 47,921,000	\$ (9,001,000)	\$ 44,373,000

March 31, 1988

1. Summary of significant accounting policies

Business Amgen Inc. (the Company or Amgen) was founded to develop, manufacture and market products based on advanced biotechnology. To date, the principal activities have included research, development and manufacturing of products for preclinical and clinical testing and sale to the scientific research community.

Principles of consolidation The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Investments in affiliated companies which are 50 percent owned and/or for which the Company exercises significant influence over operations are accounted for on the equity method. All material intercompany transactions and balances have been eliminated in consolidation.

Cash equivalents and marketable securities Cash equivalents consist of money market funds. Marketable securities consist primarily of debt securities and certificates of deposits.

Inventories Inventories are stated at the lower of cost or market.

Depreciation and amortization Depreciation of buildings and equipment is provided over their estimated useful lives on a straight-line basis. Equipment under capital leases and leasehold improvements are amortized on a straight-line basis over the shorter of their useful lives or lease terms, including periods covered by options which are expected to be exercised.

Revenues from corporate partners Revenues from corporate partners are recognized based on the terms and conditions of the related agreements, as follows:

Revenues related to agreements which provide for predetermined levels of effort and fixed funding over the life of the agreement are recognized over specified performance periods on a percentage of completion basis.

Revenues related to agreements which do not provide for fixed funding over the life of the agreement are recognized based on the specific levels of effort employed during the period.

Revenues related to milestone payments, which the Company has the irrevocable right to receive and retain, are recognized when the related milestone events are achieved. Payments received which are related to future performance are deferred and taken into income as earned over specified future performance periods.

Research and development costs Research and development costs are expensed as incurred. Included in research and development costs for the years ended March 31, 1988, 1987 and 1986 are \$22,614,000, \$12,768,000 and \$7,916,000, respectively, related to revenues from corporate partners.

Interest cost Interest cost on construction in progress capitalized for the years ended March 31, 1988, 1987 and 1986 is \$407,000, \$486,000 and \$499,000, respectively.

Income taxes The Company has elected early adoption of Statement of Financial Accounting Standard No. 96 "Accounting for Income Taxes" and has chosen to retroactively restate its 1987 and 1986 consolidated financial statements to apply this new method of accounting under which, among other things, loss carryforward benefits are treated as a reduction of the provision for income taxes rather than as an extraordinary credit. Adoption of this accounting standard has had no effect on the Company's net income for the years ended March 31, 1988, 1987 and 1986 or on the Company's deficit as of March 31, 1985 (See Note 8).

Investment tax credits are recorded on the flow-through method.

1. Summary of significant accounting policies
(continued)

2. Investments in affiliated companies

Per share data Earnings per share are based on the weighted average number of common shares outstanding. Shares issuable upon the exercise of stock option grants and warrants are included in the per share computation unless their inclusion would be antidilutive.

In June 1987, Amgen Clinical Partners, L.P. (the Limited Partnership), a limited partnership in its development stage, completed a private placement of limited partnership interests, resulting in net proceeds of approximately \$75,000,000. In connection with its formation, the Limited Partnership has been granted an exclusive royalty-free license and right from Amgen to certain patents, know-how and materials related to the research and development, manufacture and sale of products developed from certain technologies for human pharmaceutical use in the United States. Amgen Development Corporation, a wholly-owned subsidiary of Amgen, serves as the general partner of the Limited Partnership and has a one percent interest in the Limited Partnership.

In June 1984, the Company contributed \$4,000,000 and assigned all of its right, title and interest in and granted a worldwide royalty-free, exclusive license to certain technology for use in human therapeutics in exchange for a 50 percent interest in Kirin-Amgen, Inc. (Kirin-Amgen). In May 1985, the Company assigned all of its right, title and interest in and granted a worldwide royalty-free, exclusive license to certain technology related to the breeding of chickens and turkeys in exchange for a 50 percent interest in G.T. Systems. Such entities were formed for the development, manufacture and marketing of certain products based on advanced biotechnology.

The Company accounted for its equity in the net losses of Kirin-Amgen based on the relationship of its cash contribution to the total contributed cash received by Kirin-Amgen. At March 31, 1988, the Company's investment in Kirin-Amgen had been reduced to zero. The Company has recorded its investment in G.T. Systems at zero and, accordingly, is not required to recognize its equity in the net losses of G.T. Systems. The differences between the carrying amounts of the Company's investments in Kirin-Amgen and G.T. Systems and its underlying equity in their net assets is primarily attributable to the Company recording no value in its investment account for the contributed technologies.

Summarized financial information on a combined basis for the Partnership, Kirin-Amgen and G.T. Systems is as follows:

Financial position	<i>March 31, 1988</i>	<i>March 31, 1987</i>
Current assets, principally cash, cash equivalents and marketable securities	\$ 1,436,000	\$ 9,279,000
Intangible assets, net	3,785,000	6,087,000
Total assets	\$ 5,221,000	\$ 15,366,000
Current liabilities, principally related parties	\$ 10,914,000	\$ 4,287,000
Long-term debt, payable to Amgen	9,600,000	—
Capital	36,536,000	30,000,000
Deficit	(51,829,000)	(18,921,000)
Total liabilities and capital (deficit)	\$ 5,221,000	\$ 15,366,000

2. Investments in affiliated companies
(continued)

Operating results	<i>Year ended March 31, 1988</i>	<i>Year ended March 31, 1987</i>	<i>Year ended March 31, 1986</i>
Revenues from corporate partners:			
Amgen	\$ 1,000,000	\$ 1,500,000	\$ —
Other	2,500,000	2,500,000	2,500,000
Product sales	117,000	25,000	—
Interest income	580,000	859,000	1,275,000
Total revenues and other income	4,197,000	4,884,000	3,775,000
Operating expenses, principally related to research and development performed by related parties	34,503,000	12,168,000	6,561,000
Amortization	2,602,000	2,796,000	2,584,000
Total expenses	37,105,000	14,964,000	9,145,000
Net loss	\$(32,908,000)	\$(10,080,000)	\$(5,370,000)

3. Corporate partners

Limited Partnership Pursuant to the terms of an agreement entered into with the Limited Partnership, Amgen has agreed to use its best efforts to perform certain research and development, including that necessary to receive Food and Drug Administration (FDA) approval for sale of certain products in the United States. Amgen is paid for such services at an amount equal to its actual costs, as defined, plus a management fee equal to a stated percentage of such costs. Amgen has also irrevocably received certain milestone payments totalling \$4,000,000 upon entering the agreement and achieving a significant milestone during the development process. The total amount Amgen will be paid under this agreement is limited to the capital contributions of the partners, as reduced by certain other expenditures or commitments. Included in revenues from corporate partners—related parties for the year ended March 31, 1988 is \$16,344,000 earned under this agreement.

In accordance with the agreement, Amgen is obligated to fund certain cost overruns associated with the research and development up to specified limits. In addition, Amgen is also obligated to fund the costs of certain clinical trials necessary to receive certain regulatory approvals for such products in major European countries and has agreed to pay stated royalties to the Limited Partnership on sales of related products for human pharmaceutical use in specified geographic areas of the world, including Europe.

If the research and development efforts are successful and the necessary FDA approvals are obtained, Amgen will be responsible for manufacturing and marketing the resulting products in the United States on behalf of the parties.

Amgen has been granted an option to purchase all of the limited partners' interests in the Limited Partnership, upon the occurrence of certain future events. If Amgen exercises such option each limited partner will receive, at Amgen's discretion, either an initial cash payment, a distribution of a specified number of shares of Amgen's common stock or a combination of each. In addition, each limited partner will receive stated royalties on future sales of the Limited Partnership's products in the United States and certain other geographic areas of the world through December 31, 2005.

In order to fund certain initial expenditures, primarily related to organizational expenses and syndication fees and expenses, the Limited Partnership and Amgen entered into a loan agreement whereby Amgen agreed to lend the Limited Partnership \$9,600,000. The loan is full recourse to the Limited Partnership and is secured by notes receivable, aggregating approximately \$68,000,000, received by the Limited Partnership in connection with the offering of limited partnership interests. Interest on the loan is equal to the prime rate of a major bank plus .25% (8.75% at March 31, 1988) and is payable annually in arrears. The principal balance of the loan is due in full on June 30, 1990.

Johnson & Johnson In September 1985, Amgen and Ortho Pharmaceutical Corporation, a subsidiary of Johnson & Johnson (Johnson & Johnson), entered into an agreement whereby Johnson & Johnson was given certain rights to technologies involving three human therapeutic products in specified geographic areas of the

3. Corporate partners (continued)

world. In June 1987, Amgen and Johnson & Johnson entered into an additional agreement whereby Johnson & Johnson was given certain rights to the manufacturing know-how related to one of the aforementioned technologies. In connection with these agreements, Amgen has irrevocably received and will irrevocably receive certain milestone payments upon signing the agreements and achieving certain significant milestones during its performance under the agreements. In addition, Amgen conducts certain research and development activities with respect to the technologies on behalf of Johnson & Johnson and is paid for such services at specified amounts which exceed its research and development costs. Included in revenues from corporate partners—for the years ended March 31, 1988, 1987 and 1986 are \$4,115,000, \$10,409,000 and \$8,498,000 earned under these agreements, including milestone payments of \$2,000,000, \$8,000,000 and \$7,000,000, respectively.

Johnson & Johnson was also granted an exclusive license to sell any resulting products developed from such technologies in the related areas of the world. In return for such license, Amgen will receive certain profit sharing payments and royalties based on future sales. As of March 31, 1988, the Company has earned no profit sharing payments or royalties under this agreement.

Kirin-Amgen entered into a similar agreement with Johnson & Johnson regarding an exclusive license for the development and marketing of a product. For each of the years ended March 31, 1988, 1987 and 1986, Kirin-Amgen earned revenues of \$2,500,000 related to the irrevocable receipt of milestone payments from such agreement.

Kirin-Amgen Pursuant to the terms of agreements entered into with Kirin-Amgen, the Company conducts certain research and development activities on behalf of Kirin-Amgen and is paid for such services at specified amounts not to exceed their actual costs, as defined, plus a stated percentage of such costs. Included in revenues from corporate partners—related parties for the years ended March 31, 1988, 1987 and 1986 are \$10,369,000, \$4,937,000 and \$3,096,000, respectively, related to these agreements.

In December 1986, the Company and Kirin-Amgen entered into an agreement whereby Amgen was granted an exclusive license to manufacture and sell a product developed in a specified geographic area of the world. In connection with this agreement, the Company has paid and will pay Kirin-Amgen certain milestone payments (aggregating \$6,000,000) upon signing the agreement and the achievement of certain significant milestones during the development and regulatory approval process. Included in research and development expense for the years ended March 31, 1988 and 1987 are \$1,000,000 and \$1,500,000, respectively, related to milestone payments earned by Kirin-Amgen under this agreement. In addition, the Company will pay Kirin-Amgen royalties based on future sales of such product. The worldwide rights to the technology under this agreement were contributed to Kirin-Amgen by Kirin Brewery Company, Limited and Amgen in July 1986 (see Kirin Brewery Company, Limited).

In connection with its various agreements with Kirin-Amgen, the Company has been granted sole and exclusive licenses for the manufacture and sale of certain products in specified geographic areas of the world. In return for such licenses, the Company has either paid Kirin-Amgen stated amounts upon the receipt of the licenses or will pay Kirin-Amgen royalties based on future sales. As of March 31, 1988, the Company has had only minimal sales of such products.

Kirin Brewery Company, Limited In January 1986 and March 1987, Kirin Brewery Company, Limited (Kirin), a Japanese corporation which owns the remaining 50% interest in Kirin-Amgen (Note 2), and Amgen entered into agreements to collaborate in the further development of certain technologies. Pursuant to the terms of the agreements, Kirin will pay Amgen up to specified amounts for the performance of certain research and development activities with respect to such technologies and the achievement of certain significant milestones during the development process. Included in revenues from corporate partners—related parties for the years ended March 31, 1988, 1987 and 1986 are \$1,743,000, \$4,989,000 and \$3,258,000 earned under these agreements, respectively, including milestone payments for the years ended March 31, 1988, 1987 and 1986 of \$900,000, \$3,300,000 and \$2,000,000, respectively.

3. Corporate partners
(continued)

Upon the achievement of certain significant milestones in the development of the technologies, all right, title and interest in such technologies would be transferred to Kirin-Amgen. During the year ended March 31, 1987, the technology related to the January 1986 agreement was transferred to Kirin-Amgen.

Abbott Laboratories In May 1983, Abbott Laboratories (Abbott), a stockholder owning 1,250,000 shares of the Company's common stock as of March 31, 1988, entered into a five-year research and development agreement with the Company calling for payments aggregating approximately \$19,000,000. Under this agreement, the Company will perform research and development activities with respect to several types of diagnostic products which, if developed, will be manufactured and sold by Abbott. The Company will receive a royalty on net sales to the year 2000 on products which use certain diagnostic technologies. Products in areas funded under the agreement cannot be sold by the Company either alone or with another corporate partner in most instances until the year 2000. Included in revenues from corporate partners-related parties for the years ended March 31, 1988, 1987 and 1986 are \$4,487,000, \$4,006,000, and \$3,815,000, respectively, related to this agreement. The agreement terminated in May 1988.

**4. Long-term debt
and lease obligations**

Long-term debt and lease obligations consist of the following:

	March 31, 1988	March 31, 1987
Capital lease obligations	\$10,708,000	\$ —
Industrial development bonds	7,100,000	7,550,000
Note payable to Limited Partnership	703,000	—
	18,511,000	7,550,000
Less current portion	(2,008,000)	(450,000)
	\$16,503,000	\$7,100,000

In connection with various sale-leaseback transactions, the Company is obligated under capital leases for certain equipment with an aggregate cost at March 31, 1988 of \$11,269,000. These obligations bear interest at fixed effective rates of approximately 8% and are due in quarterly installments through December 1994. The leases include options to purchase the equipment at fair market value at the expiration of the lease terms.

The industrial development bonds represent a December 1983 loan from the City of Chicago (the City). The unexpended funds (\$5,955,000 at March 31, 1988) are invested in short-term cash investments and are stated at cost which approximates market. Such funds are to be used for the construction of a manufacturing facility in Chicago. The bonds bear interest, payable semi-annually, at a floating rate (6.8% at March 31, 1988) which is equal to 80% of a major bank's prime rate, not to exceed 12% or be less than 6 $\frac{3}{8}$ %. The bonds are collateralized by the manufacturing facility. In addition, payment of the outstanding principal amount and up to \$500,000 of accrued interest on such bonds has been guaranteed by a nonaffiliated party through December 1988. In connection with the bonds and the related guarantee, the Company is required, until December 10, 1988, to maintain unencumbered cash, cash equivalents and marketable securities aggregating \$15,000,000 and is prohibited from paying cash dividends. At March 31, 1988, the bonds are payable in fifteen annual installments of \$450,000 and a final payment of \$350,000 due on December 1, 2003; however, on December 10, 1988, the holders of the bonds have the right to put such bonds for payment in whole or part. In the event such bonds are put, the Company has the option to attempt to resell such bonds or to use the unexpended funds held for construction to repay the related amounts. At March 31, 1988, the bonds are classified in accordance with their stated maturities and the unexpended funds held for construction are classified as noncurrent assets.

The note payable to the Limited Partnership is a non-interest-bearing obligation representing the balance of the purchase price for the Company's general partnership interest in the Limited Partnership.

The aggregate stated maturities of all long-term debt, including capital lease obligations, due subsequent to March 31, 1988 is as follows: \$2,008,000—1989; \$2,057,000—1990; \$2,214,000—1991; \$2,098,000—1992; \$2,235,000—1993 and \$7,899,000 thereafter.

5. Commitments

The Company leases land, on which its Chicago manufacturing facility is being constructed, office and laboratory facilities and equipment under noncancellable operating lease agreements which expire on various dates through 2008. Certain of the lease agreements require the Company to pay operating costs, including property taxes, insurance and maintenance costs and contain renewal options at amounts adjusted for changes in the consumer price index.

Future minimum lease payments under noncancellable capital and operating leases at March 31, 1988 are as follows:

<i>Year ending March 31,</i>	<i>Capital</i>	<i>Operating</i>
1989	\$ 2,121,000	\$ 1,419,000
1990	2,121,000	1,382,000
1991	2,121,000	1,352,000
1992	2,121,000	1,139,000
1993	2,121,000	857,000
Thereafter	3,273,000	3,945,000
Total minimum lease payments	13,878,000	<u>\$10,094,000</u>
Less amount representing interest	(3,170,000)	
Present value of minimum lease payments	<u>\$10,708,000</u>	

Rent expense for operating leases was approximately \$1,792,000, \$1,283,000 and \$710,000 for the years ended March 31, 1988, 1987 and 1986, respectively.

6. Capital stock

On July 29, 1987, the Company's stockholders approved an amendment to the Company's articles of incorporation increasing the number of shares of common stock authorized to be issued from 27,200,000 to 50,000,000.

In connection with the sale of limited partnership interests, Amgen issued warrants to the limited partners to purchase an aggregate of 3,025,440 shares of its common stock in exchange for the right to purchase the limited partners' interests in the Limited Partnership (Note 3). The warrants entitle the holders to purchase the Company's common stock at a price of approximately \$50 per share from July 1, 1988 through June 30, 1992 and approximately \$55 per share from July 1, 1992 through June 30, 1994. The warrants are not freely transferable until certain events occur.

In addition to common stock, the Company's authorized capital also includes 5,000,000 shares of preferred stock, \$.0001 par value. At March 31, 1988, no shares of preferred stock are issued and outstanding.

7. Stock option plans

The following is a summary of the Company's various stock options plans.

The Company's Nonqualified Stock Option Plan is a non-statutory stock option plan covering the issuance of options that will not qualify as "incentive stock options." The Plan provides for the grant of options to selected employees and members of the Scientific Advisory Board. At March 31, 1988, options on shares of common stock available for future grant under this Plan total 1,600. Options granted have a maximum term of ten years, must be issued at an exercise price of at least 85% of the fair market value of the shares on the date granted and may not be transferred other than upon death.

Under the Company's 1981 Incentive Stock Option Plan, as amended, options on shares of common stock may be granted to eligible employees or officers of the Company at an exercise price of not less than the fair market value of the stock on date of grant. The maximum term during which any option may be exercised shall be ten years from date of grant. To date, options have been granted with two to five-year vesting schedules. At March 31, 1988, options on shares of common stock available for future grant under this Plan total 10,224.

7. Stock option plans

(continued)

The Company's 1984 Stock Option Plan, as amended, provides for option grants designated as either non-qualified or incentive stock options. The terms and conditions of this Plan are generally the same as those of the Company's Nonqualified Stock Option Plan or 1981 Incentive Stock Option Plan depending on the designation of the option. At March 31, 1988, options on shares of common stock available for future grant under this Plan total 140,196.

The Company's 1987 Directors' Stock Option Plan is a non-qualified stock option plan covering the issuance of options that will not qualify as incentive stock options. The Plan provides for the annual grant of 2,000 options to each member of the Company's Board of Directors who is not an employee of the Company. Under this Plan, options covering up to 100,000 shares of the Company's common stock may be issued at an exercise price of at least 85% of the fair market value of the shares on the date of grant. At March 31, 1988, options on shares of common stock available for future grants under this Plan total 72,000.

The Company's 1988 Stock Option Plan, which is subject to stockholder approval, provides for the grant of options to purchase up to 3,000,000 shares of the Company's common stock. The terms and conditions of this plan are generally the same as the 1984 Stock Option Plan.

Stock option information with respect to the Company's stock option plans follows:

	<i>Incentive stock options</i>		<i>Nonqualified stock options</i>	
	<i>Shares</i>	<i>Price</i>	<i>Shares</i>	<i>Price</i>
Balance March 31, 1985 unexercised	748,702	\$.67-10.67	362,375	\$4.50-5.63
Granted	221,114	\$6.87-18.50	61,886	\$6.50
Exercised	(146,728)	\$.67-10.67	(15,175)	\$4.50
Cancelled	(13,800)	\$.67-10.67	(4,875)	\$4.50
Balance March 31, 1986 unexercised	809,288	\$.67-18.50	404,211	\$4.50-6.50
Granted	277,637	\$14.25-39.00	174,187	\$17.75-33.15
Exercised	(243,788)	\$.67-10.67	(48,006)	\$4.50-6.89
Cancelled	(28,752)	\$6.13-23.75	(22,234)	\$4.50-20.19
Balance March 31, 1987 unexercised	814,385	\$.67-39.00	508,158	\$4.50-33.15
Granted	506,262	\$22.25-41.00	626,978	\$20.00-40.00
Exercised	(109,268)	\$.67-23.75	(22,100)	\$4.50-6.88
Cancelled	(88,851)	\$6.88-40.00	(341,278)	\$4.50-38.25
Balance March 31, 1988 unexercised	1,122,528	\$4.40-41.00	771,758	\$4.50-31.45

At March 31, 1988, incentive stock options and nonqualified stock options to purchase 402,127 and 343,662 shares, respectively, were exercisable and options on 3,224,020 shares were available for future grants, including 3,000,000 options under the 1988 Stock Option Plan subject to stockholder approval. During the years ended March 31, 1988, 1987 and 1986, stock options to purchase 11,183; 24,365 and 37,000 shares of common stock were exercised by tendering 2,506; 5,279 and 3,254 previously owned shares of the Company's common stock, respectively.

8. Income taxes

The provision for income taxes includes the following:

	<i>Year ended March 31, 1988</i>	<i>Year ended March 31, 1987</i>	<i>Year ended March 31, 1986</i>
Federal income taxes	\$ 55,000	\$ —	\$ —
State income taxes	294,000	358,000	124,000
Foreign income taxes	—	100,000	—
	\$349,000	\$458,000	\$124,000

8. Income taxes

(continued)

The provision for income taxes varies from taxes based on the federal statutory rate of 37% in 1988 and 46% in 1987 and 1986 as follows:

	Year ended March 31, 1988	Year ended March 31, 1987	Year ended March 31, 1986
Statutory rate applied to income before income taxes	\$ 767,000	\$ 734,000	\$ 309,000
Tax effect of equity in loss of affiliated company, not deductible for income tax purposes	323,000	872,000	298,000
State income taxes, net of federal income tax benefit	185,000	193,000	67,000
Tax effect of other expenses not deductible for income tax purposes	42,000	55,000	—
Foreign income taxes, net of federal income tax benefit	—	54,000	—
Tax benefit from utilization of net operating loss carryforwards	(1,023,000)	(1,478,000)	(546,000)
Other	55,000	28,000	(4,000)
	\$ 349,000	\$ 458,000	\$ 124,000

At March 31, 1988, the Company has tax-basis net operating loss, research and experimental credit and investment tax credit carryforwards available to offset future federal income taxes payable which expire as follows:

	Net operating losses	Research and experimental credits	Investment tax credits
1997	\$ —	\$ 252,000	\$ 66,000
1998	—	560,000	60,000
1999	5,190,000	613,000	53,000
2000	7,289,000	767,000	68,000
2001	—	267,000	38,000
2002	—	177,000	—
2003	—	347,000	—
	\$12,479,000	\$2,983,000	\$285,000

For financial reporting purposes, the Company has available net operating loss carryforwards of approximately \$12,636,000. Net operating loss carryforwards are different for income tax and financial reporting purposes primarily due to differences in depreciation rates and accounting for stock options.

9. Property, plant and equipment

Property, plant and equipment consists of the following:

	March 31, 1988	March 31, 1987
Land	\$ 1,385,000	\$ 923,000
Buildings	5,990,000	—
Laboratory equipment	16,695,000	11,106,000
Furniture and office equipment	2,051,000	1,180,000
Leasehold improvements	15,578,000	6,152,000
Equipment under capital leases	11,269,000	—
Construction in progress	13,723,000	11,969,000
	66,691,000	31,330,000
Less accumulated depreciation and amortization	(11,925,000)	(8,000,000)
	\$ 54,766,000	\$23,330,000

Included in Buildings at March 31, 1988 is \$5,199,000 related to a manufacturing facility in Chicago. In light of the Company's facilities needs, it does not anticipate using such facility in its current operations and is attempting to sublease such facility on an interim basis.

**10. Quarterly financial
data (unaudited)**

In thousands except per share amounts

	1988 Quarter Ended			
	March 31	December 31	September 30	June 30
Total revenues and other income	\$14,573	\$13,553	\$12,618	\$12,581
Total operating expenses	14,005	13,161	12,174	11,911
Net income	487	351	393	494
Per share	.03	.02	.02	.03

	1987 Quarter Ended			
	March 31	December 31	September 30	June 30
Total revenues and other income	\$10,626	\$ 8,939	\$ 7,414	\$ 7,743
Total operating expenses	10,131	8,745	7,065	7,186
Net income	232	136	295	474
Per share	.02	.01	.02	.03

The Company has elected early adoption of Statement of Financial Accounting Standard No. 96 "Accounting for Income Taxes" and has chosen to retroactively restate the above quarterly consolidated financial results to apply this new method of accounting under which, among other things, loss carryforward benefits are treated as a reduction of the provision for income taxes rather than as an extraordinary credit. Adoption of this accounting standard has had no effect on the 1988 and 1987 quarterly consolidated net income. See discussion in Summary of Significant Accounting Policies (Note 1 and 8) to the consolidated financial statements.

Report of Certified Public Accountants

**The Board of Directors
and Stockholders
of Amgen Inc.**

We have examined the accompanying consolidated balance sheets of Amgen Inc. at March 31, 1988 and 1987, and the related consolidated statements of operations, stockholders' equity and changes in financial position for each of the three years in the period ended March 31, 1988. Our examinations were made in accordance with generally accepted auditing standards and, accordingly, included such tests of the accounting records and such other auditing procedures as we considered necessary in the circumstances.

In our opinion, the statements mentioned above present fairly the consolidated financial position of Amgen Inc. at March 31, 1988 and 1987, and the consolidated results of operations and changes in financial position for each of the three years in the period ended March 31, 1988, in conformity with generally accepted accounting principles applied on a consistent basis during the period after restatement of the consolidated financial statements for 1987 and 1986 to give retroactive effect to the change, with which we concur, in the method of accounting for income taxes as described in Note 1 to the consolidated financial statements.

Arthur Young & Company

Los Angeles, California
May 9, 1988

Corporate Headquarters 1900 Oak Terrace Lane, Thousand Oaks, California 91320, (805) 499-5725

SEC Form 10-K A copy of the Company's annual report to the Securities and Exchange Commission on Form 10-K is available without charge upon written request to: Corporate Secretary, Amgen Inc., 1900 Oak Terrace Lane, Thousand Oaks, California 91320.

Transfer Agent and Registrar American Stock Transfer
99 Wall Street, New York, New York 10005

Counsel Cooley Godward Castro Huddleson & Tatum
Palo Alto, California
San Francisco, California

Auditors Arthur Young & Company
Los Angeles, California

Annual Meeting **The Annual Meeting will be held on Tuesday, July 26, 1988 at 10:30 a.m. at the Biltmore Hotel, 506 South Grand Avenue, Los Angeles, California 90071.**

Price Range of Common Stock The Company's Common Stock is traded in the over-the-counter market on the NASDAQ National Market System under the symbol AMGN. As of April 30, 1988, there were approximately 3,133 holders of record of the Company's Common Stock. No dividends have been paid on the Common Stock to date, and the Company currently intends to retain any earnings for further development of the Company's business. In addition, the loan guarantee obtained in connection with the Company's industrial development bonds related to the construction of a facility in Chicago prohibits the Company from paying cash dividends through December 31, 1988 without prior approval of the guarantor.

The following table sets forth, for fiscal periods indicated, the range of high and low closing sale prices for the fiscal years 1988 and 1987:

1988	High	Low
Fourth Quarter	\$35¾	\$30
Third Quarter	37¼	16¼
Second Quarter	34¼	26¾
First Quarter	41½	34¼
1987		
Fourth Quarter	44½	23¾
Third Quarter	24	17¾
Second Quarter	25½	13⅞
First Quarter	28½	18¼

Board of Directors	George B. Rathmann, <i>Chairman of the Board, President and Chief Executive Officer, Amgen Inc.</i> Raymond F. Baddour, <i>Lammot duPont Professor, Chemical Engineering, Massachusetts Institute of Technology</i> William K. Bowes, Jr., <i>General Partner, U.S. Venture Partners</i> Duane L. Burnham, <i>Vice Chairman and Chief Financial Officer, Abbott Laboratories</i> Franklin P. Johnson, Jr., <i>General Partner, Asset Management Partners</i> Steven Lazarus, <i>President and Chief Executive Officer, Argonne National Laboratory/The University of Chicago Development Corporation</i> Gilbert S. Omenn, <i>Dean, School of Public Health and Community Medicine, University of Washington</i> Bernard H. Semler, <i>President, Semler Associates, Inc.</i>
Corporate Officers	George B. Rathmann, <i>Chairman of the Board, President and Chief Executive Officer</i> Gordon M. Binder, <i>Senior Vice President and Chief Financial Officer</i> Harry F. Hixson, Jr., <i>Senior Vice President, Business Operations</i> Robert D. Weist, <i>Senior Vice President, Administration, General Counsel and Secretary</i> Marvin H. Caruthers, <i>Vice President, Research—Boulder</i> Daniel Vapnek, <i>Vice President, Research</i>
Scientific Advisory Board	Daniel Vapnek, Ph.D., <i>Chairman, Scientific Advisory Board, Vice President, Research, Amgen Inc.</i> Arnold J. Berk, M.D., <i>Associate Professor of Microbiology, University of California at Los Angeles</i> John A. Carbon, Ph.D., <i>Professor of Biochemistry, University of California at Santa Barbara (Member, National Academy of Sciences)</i> Marvin H. Caruthers, Ph.D., <i>Vice President, Research—Boulder, Amgen Inc., Professor of Chemistry, University of Colorado at Boulder</i> Norman R. Davidson, Ph.D., <i>Norman Chandler Professor of Chemical Biology, California Institute of Technology (Member, National Academy of Sciences)</i> David T. Gibson, Ph.D., <i>Professor of Biocatalysis and Microbiology, Department of Microbiology, The University of Iowa at Iowa City</i> Leroy E. Hood, M.D., Ph.D., <i>Bowles Professor of Biology, Chairman of the Division of Biology, California Institute of Technology (Member, National Academy of Sciences)</i> Arno G. Motulsky, M.D., <i>Professor of Medicine and Genetics, University of Washington (Member, National Academy of Sciences)</i> Robert T. Schimke, M.D., <i>American Cancer Society, Research Professor of Biology, Stanford University (Member, National Academy of Sciences)</i>
Major Consultants	Eugene Goldwasser, Ph.D., <i>Professor of Biochemistry, University of Chicago</i> Irving L. Weissman, M.D., <i>Professor of Pathology, Stanford University</i>

THE WHITE HOUSE
WASHINGTON

April 25, 1989

Dear Dr. Reck:

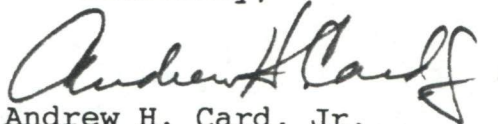
Thank you for your interest in the position of Assistant to the President for Science and Technology.

Please know that you were considered, along with many others, for this important position. While your background is certainly impressive and you many strong letters of recommendation were written on your behalf, a decision has been reached, and the candidate will be announced shortly.

Again, we appreciate your desire to be a part of the Bush Administration.

With best wishes,

Sincerely,



Andrew H. Card, Jr.
Assistant to the President
and Deputy to the Chief of Staff

Dr. Ruth A. Reck
7279 Westchester
West Bloomfield, Michigan 48322

7279 Westchester
West Bloomfield, MI 48322
31 Jan 1989

Andrew H. Card
Deputy Chief of Staff
The White House
Washington, D. C. 20500

Dear Mr. Card:

Thank you for returning my call this morning regarding my interest in the position of Presidential Science Advisor in the White House.

I am enclosing the items which we discussed on the phone. If I can provide any additional information that would assist you in your decision, please let me know.

Sincerely,

A handwritten signature in dark ink, reading "Ruth A. Reck". The signature is written in a cursive style with a large, stylized "R" and "A".

Dr. Ruth A. Reck

PRESIDENTIAL SCIENCE ADVISOR IN THE WHITE HOUSE

The situation defining the role of the presidential science advisor in the White House is:

- (1) National security is threatened by a change in the balance of power among nations.
- (2) Global environmental changes can lead to a change in the balance of power.
- (3) Decisions to deal with environmental change must be made by the administration in the face of limited economic resources.
- (4) A multinational protocol will likely be negotiated and will dictate necessary domestic responses to ameliorate climate change from the greenhouse gases.

The related concepts that the President will need to face are:

It is necessary to correctly identify the threats from environmental change: Over what spatial and temporal scale? How fast will crises occur? What will be the consequences for the U. S. and for its enemies? What is the likelihood of occurrence? Will proposed technologies be needed? Will they do what they promise to do? Are they worthwhile for the country to make investments in at this time?

Policy decisions relating to either (1) domestic means to deal with an environmental change or (2) military or economic ways to deal with a change in the balance of national security must be made in the face of very limited economic resources and limited information. Hence, costs must be carefully analyzed to identify appropriate policies.

The conclusions that can be reached as a result of the above are:

The U. S. cannot afford to make false assumptions about the threat from climate change.

It cannot afford to make false assumptions relating technology to environmental change or to the change in security.

It is necessary to clearly identify problems, consequences, policy options and the value of proposed technology. We must seriously consider the domestic consequences of proposed options.

Good decisions require understanding between the academic community, industry and those in government who have the power to make decisions.

Preparedness requires future planning with progress appropriate for the cost.

(Note: equivalent statements can be written for any decisions which must be made by the administration which involve the use of science.)

The role of the Science Advisor:

- to inform and advise the administration about all matters pertaining to science and technology; to furnish leadership in dealing with the other branches of government in matters relating to these topics; to furnish a bridge between the government and both the academic community and industry to bring about good policies and good decision-making relating to all aspects of science, technology and the public welfare.

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
03. Resume	Resume of Ruth A. Reck [personal information redacted] (20 pp.)	1/31/89	(b)(6)	

Collection:

Record Group: Bush Presidential Records

Office: Chief of Staff, Office of the

Series: Card, Andrew A., Files

Subseries:

WHORM Cat.:

File Location: [Andrew Card] Candidates for OSTP [Office of Science and Technology] Position [1]

Date Closed:	12/29/2009	OA/ID Number:	00329-001
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

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 advice 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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- (b)(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- (b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- (b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- (b)(9) Release would disclose geological or geophysical information

Governor,

Mr. Bloch sent every annual report for the last 8 years. VERY BULKY. If you want to review them, I have them handy.

1c

NATIONAL SCIENCE FOUNDATION
WASHINGTON, D.C. 20550



OFFICE OF THE
DIRECTOR

March 13, 1989

Rec'd
MAR 13 1989

Honorable John H. Sununu
Chief of Staff
The White House
Washington, D.C. 20500

Dear Governor Sununu:

I appreciate having had the opportunity last week to talk to you and discuss NSF and its activities. Enclosed is the additional information you requested.

With regard to possible candidates for the President's Assistant for Science and Technology, the selection should focus on an individual who knows both the industrial and academic aspects of science, who has a good understanding of basic research, and who knows from experience how technology affects the marketplace and shapes the economic and security policies of the Nation.

Individuals who meet these criteria include:

Dr. Roland Schmitt, President, Rensselaer Polytechnic Institute, and former Senior Vice President for Research and Development, General Electric Co.

Dr. Solomon Buchsbaum, Vice President for Customer Services, AT&T.

Dr. Robert White, President, National Academy of Engineering.

Dr. Frank Rhodes, President, Cornell University.

John Young and Don Petersen, CEO of Hewlett-Packard and Ford respectively, should also be considered. They are, however, more likely candidates for the Position of Chairman of the Advisory Committee on Science and Technology mentioned in the President's message to Congress.

We agreed that additional information on NSF budgets and priorities would be useful to you:

Figure 1 tracks the President's budget request for NSF and the Congressional appropriation over the last ten years. Except for 1986, the year of the Gramm-Rudman reductions, the appropriations have followed the proposed increases for NSF, albeit at a reduced level. The reductions reflect attempts by Congress to spread the pain of the constrained budgetary situation between the disparate activities that are included in the HUD-Independent Agencies Appropriation, which includes non-science agencies like HUD and VA along with NSF and NASA.

We have established priorities in two areas of special importance (Figure 2). The first is research in groups and centers, which provide vehicles for economic competitiveness. The second is the education and human resources activities of the Foundation, including precollege education in science and mathematics, attracting women and minorities to science and engineering, and graduate fellowships.

The smallest percentage increase (Figure 3) over the last nine years is in disciplinary research and facilities. Within that area, however, (Figure 3a) the year-to-year increases in engineering have been significantly higher than the increases in the science areas. Other NSF initiatives that I mentioned in the areas that support technology, basic research in engineering, and the environmental and geosciences areas, are seen in Figure 3b.

NSF's center programs (Figure 4), including the Engineering Research Centers, Science and Technology Centers, and group research activities are the major vehicles for combining industry, academia, and the Federal Government in activities that have a long-term effect on the economic competitiveness of the country. The increases in that area of about 350 percent over the last eight years have been the foundation of our cooperation with industry, the States, and focusing universities on these new relationships.

The Education and Human Resources (Figure 5) efforts of the Foundation have been increased tenfold in the same period.

As can be seen from Figure 5a, the biggest increases in this support have been for students and precollege teachers and related programs.

As requested and for more detail, I have enclosed NSF's Annual Reports for the last decade.

Finally, I have discussed with Secretary Cavazos our joint activities in support of the President's initiative on education as well as the assessment issues that you mentioned last week. I am hopeful that we will be able to increase significantly our cooperation with the Department of Education.

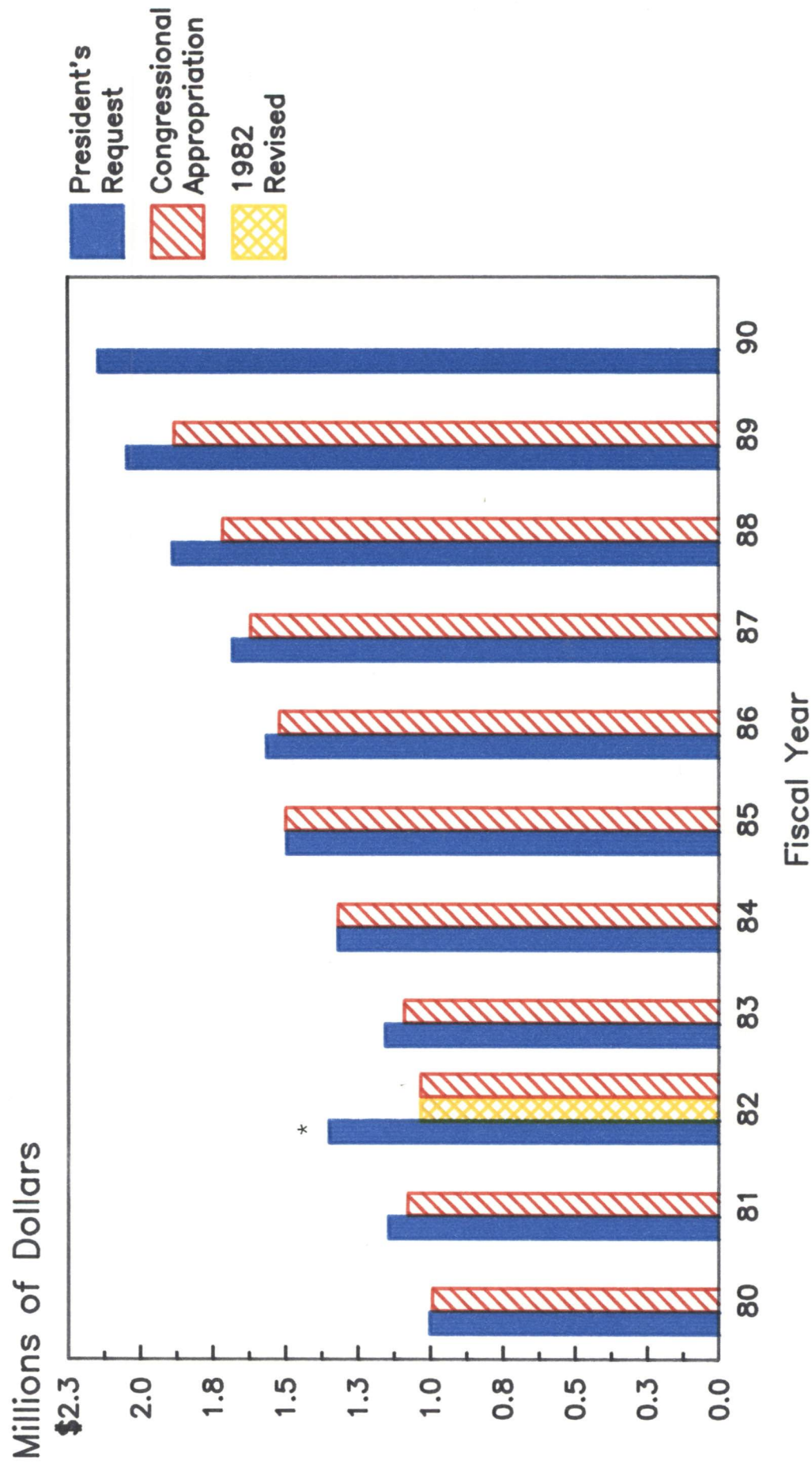
Sincerely,

A handwritten signature in blue ink, appearing to read 'E. Bloch', with a stylized flourish at the end.

Erich Bloch
Director

Enclosures: 1. NSF Annual Reports
2. Charts

NATIONAL SCIENCE FOUNDATION



* 1982 Request was revised downward as a result of the change in administration

Fig. 1

MAJOR THEMES COMPARISON

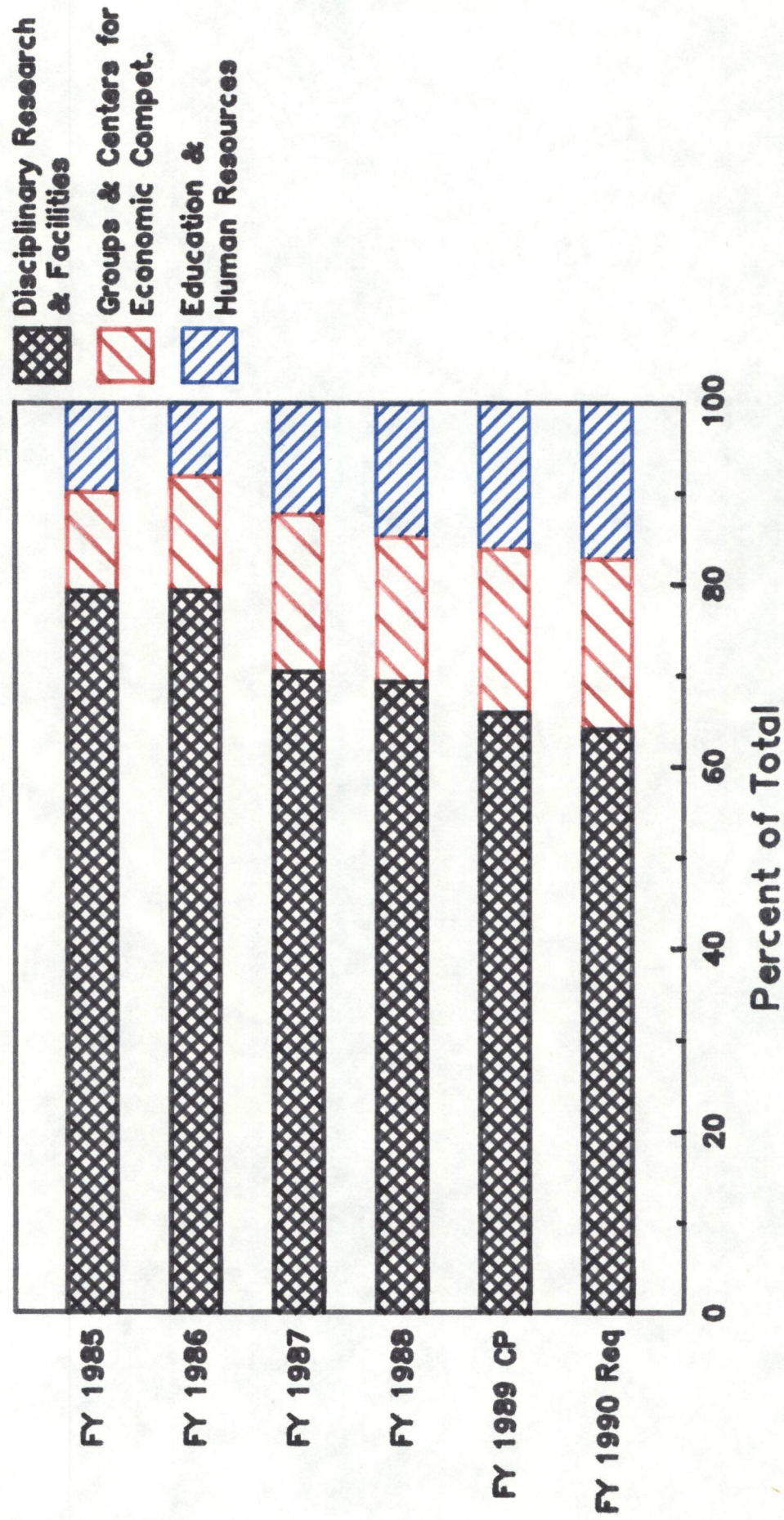


Fig. 2

DISCIPLINARY RESEARCH & FACILITIES

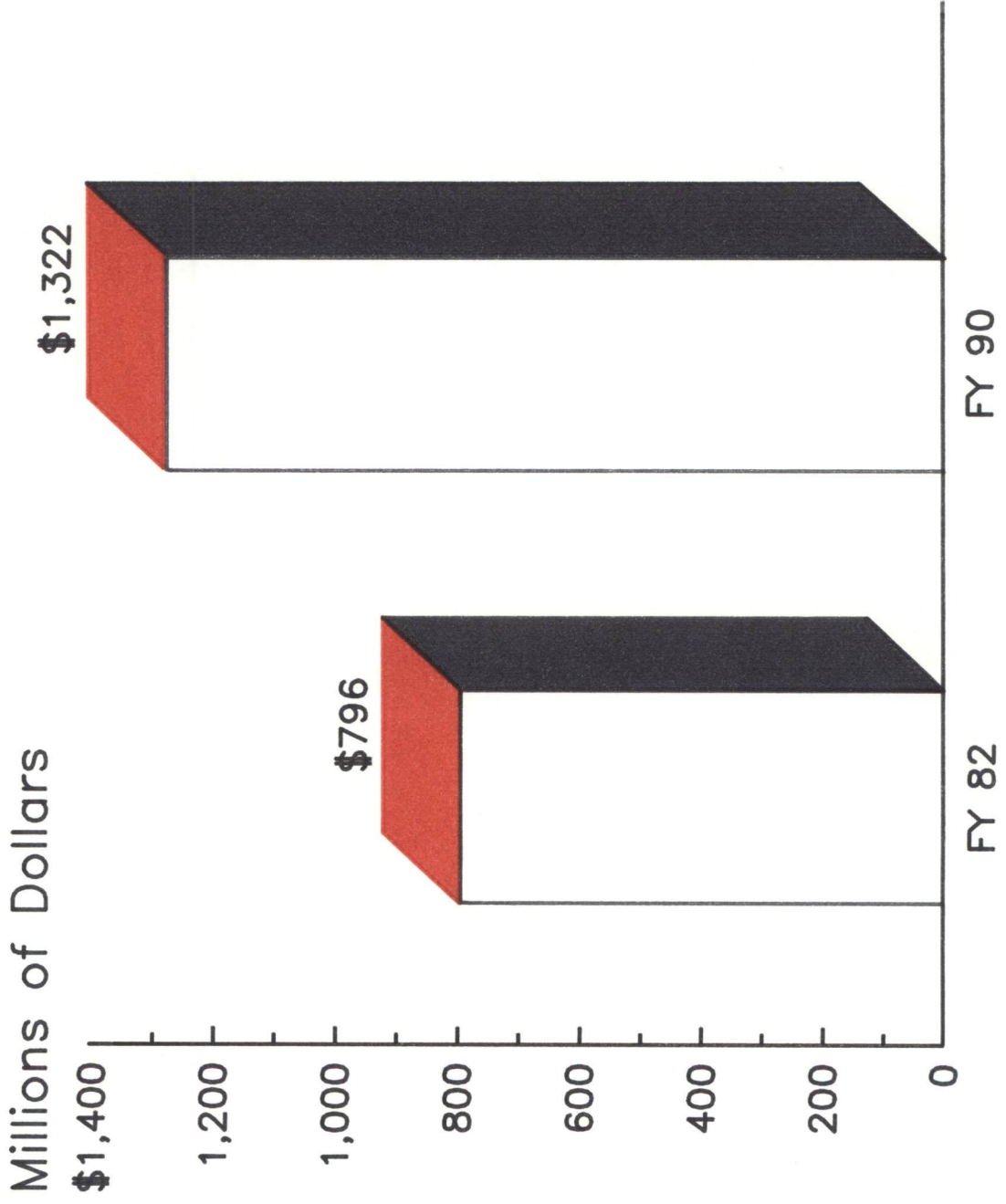


Fig. 3

SCIENCE & ENGINEERING COMPARISON **PERCENT INCREASE OVER PRIOR YEAR**

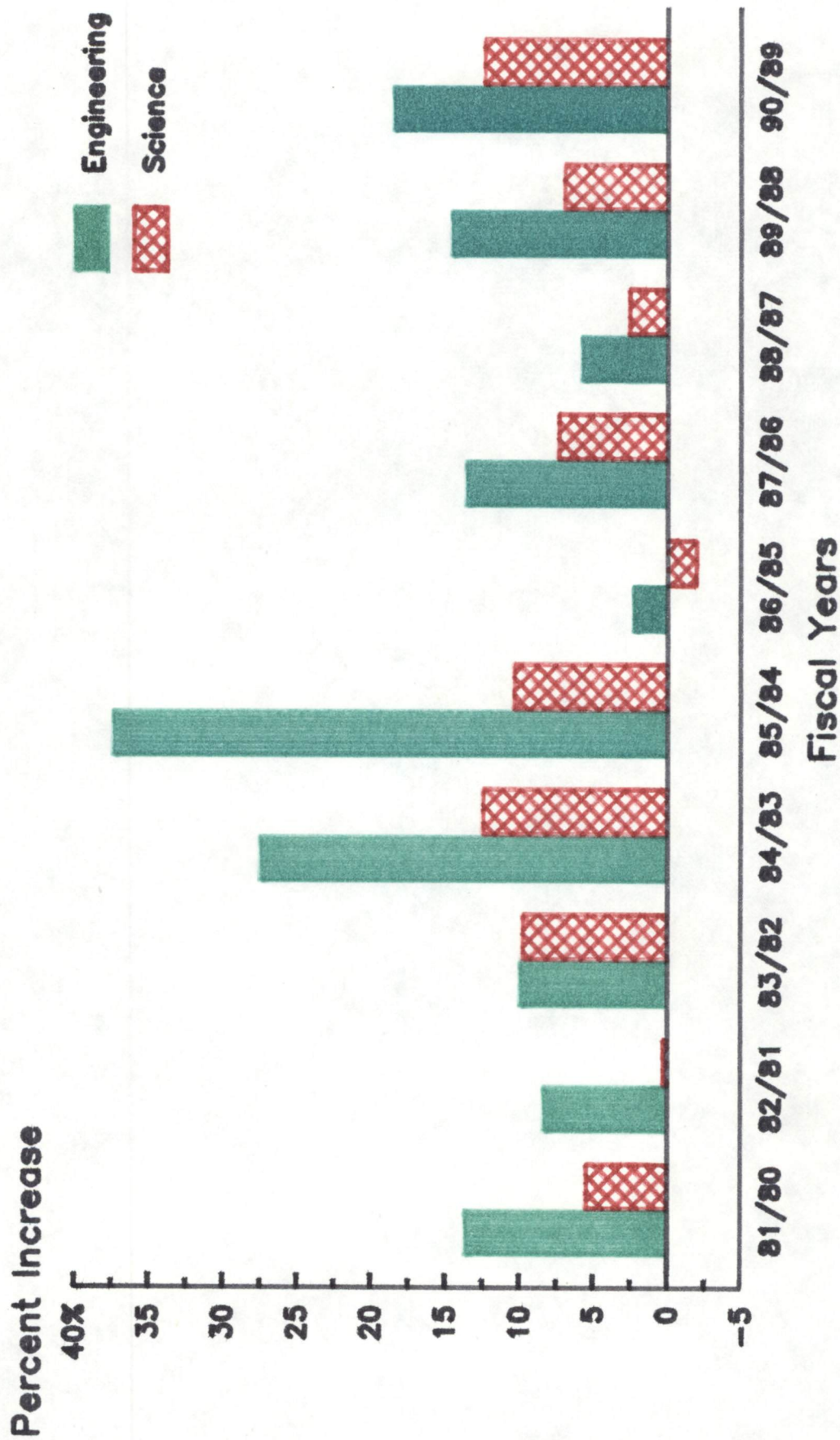
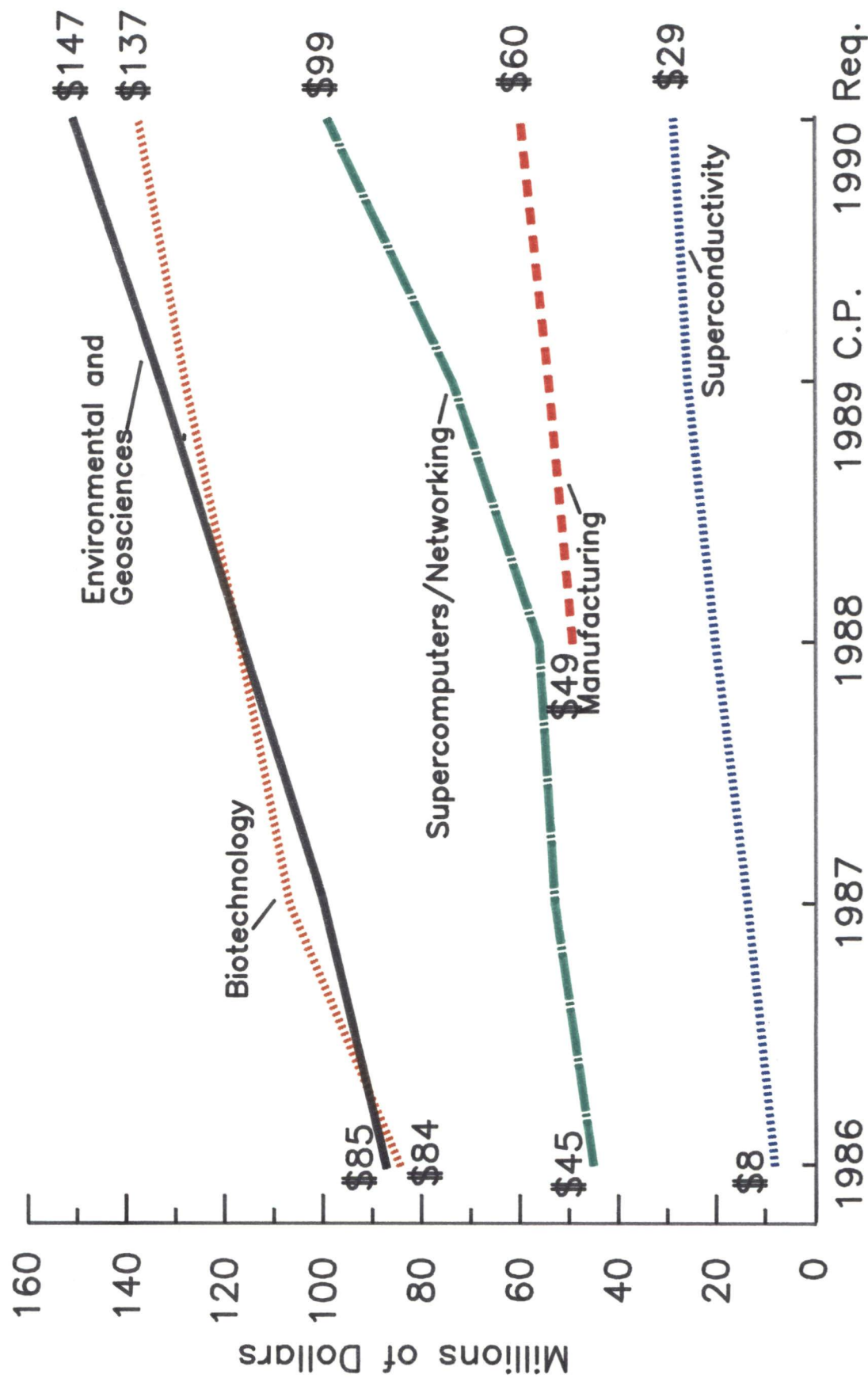


Fig. 3a

NSF Initiatives



Fiscal Year

Fig. 3b

ENGINEERING, SCIENCE AND TECHNOLOGY CENTERS AND GROUPS

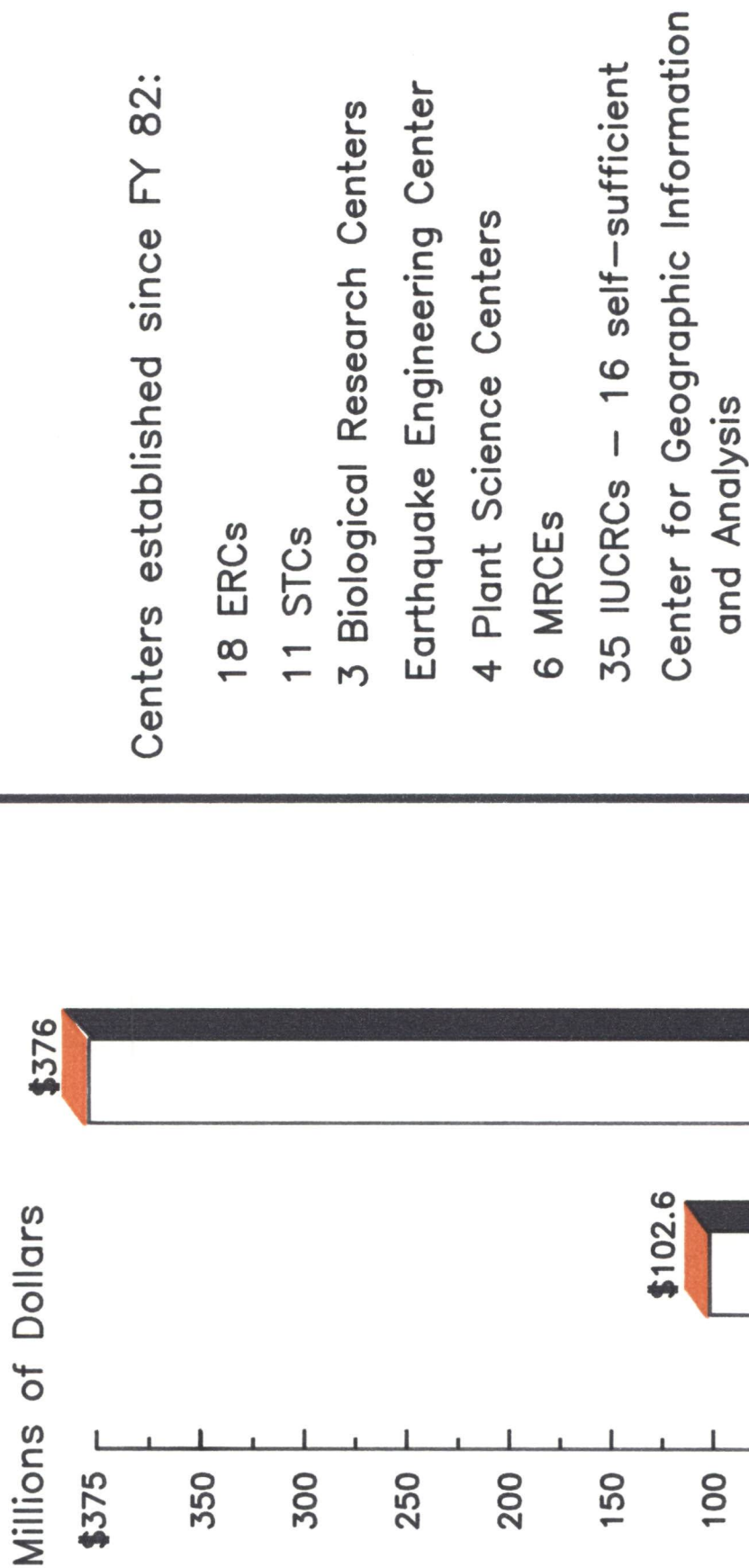


Fig. 4

EDUCATION & HUMAN RESOURCES

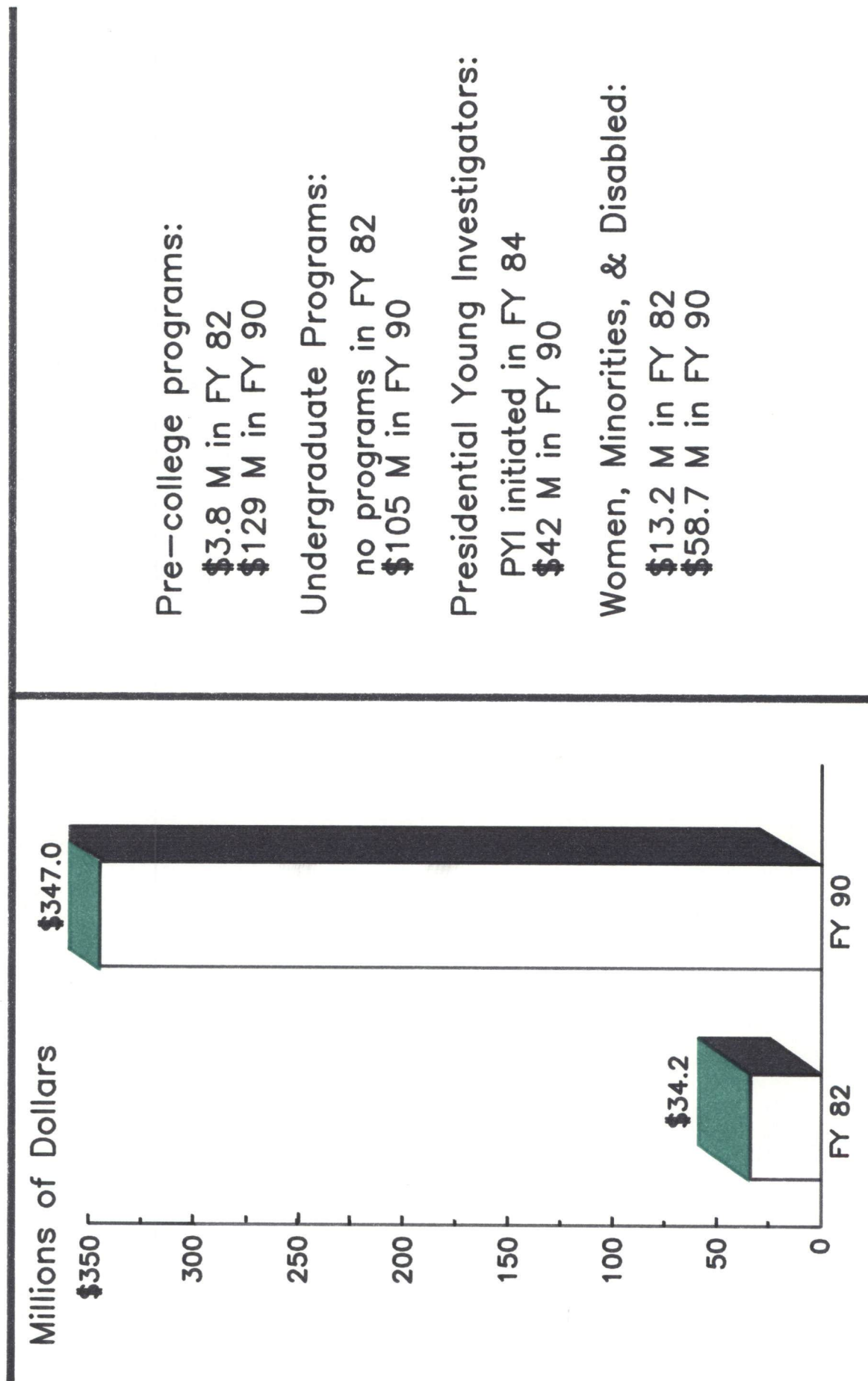


Fig. 5

NATIONAL SCIENCE FOUNDATION SUPPORT FOR HUMAN RESOURCES

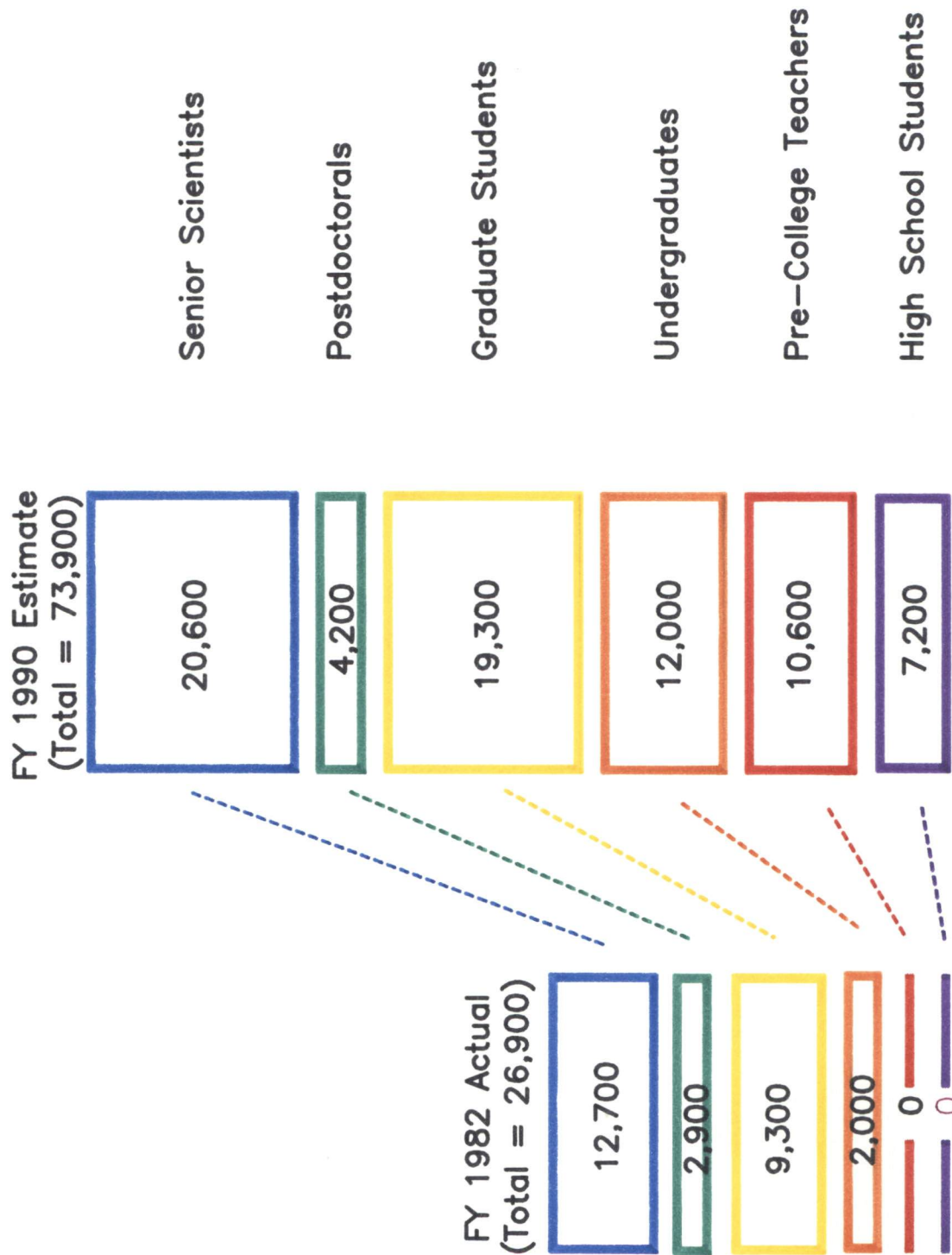


Fig. 5a