

**BREAKING THE SCIENTIFIC BOTTLENECK**

**CLINICAL RESEARCH: A NATIONAL CALL TO ACTION**



**PARKINSON'S DISEASE  
AIDS  
DIABETES  
ALZHEIMER'S  
ARTHRITIS  
CANCER**

THERAPIES  
MEDICAL DEVICES  
PHARMACEUTICALS  
BIOTECH  
TREATMENTS  
PREVENTION  
DISEASE CONTROL  
CORES

The Clinical Research Summit project was convened by the Association of American Medical Colleges, The American Medical Association and Wake Forest University School of Medicine; chaired by Dr. William H. Danforth, Chancellor Emeritus, Washington University of St. Louis; and supported by the Burroughs Wellcome Fund, the Commonwealth Fund, the Robert Wood Johnson Foundation, the John. D. and Catherine T. MacArthur Foundation, the Merck Company Foundation, The Pew Charitable Trusts, and the Ethics and Leadership Fund at Wake forest University.

The conveners and supporters of the Summit wish to acknowledge and thank Dr. David Helms, President of the Alpha Center, for his expert contribution as facilitator of all of the focus groups and the consensus development conference.

---

To request additional copies of this publication, please contact:

Diana White

Association of American Medical Colleges

Division of Biomedical and Health Sciences Research

2450 N Street, NW

Washington, DC 20037-1127

Phone: (202) 828-0481

Fax: (202) 828-1125

E-mail: [dwhite@aame.org](mailto:dwhite@aame.org)

# Preface

## Our Commitment to America

The broad and ambitious agenda set forth by leaders drawn from across the clinical enterprise, and outlined on the subsequent pages, cannot be completed overnight. It will take the concerted effort of all Americans, working together, over time to achieve our mutually beneficial goals. The participants in the Clinical Research Summit project do not intend to issue this national call to action and then step aside expecting others to carry the load. We recognize that there is much that we as individuals, organizations, institutions, and industries can do to reform our own systems and processes and thereby contribute to the advancement of this agenda. You can expect to hear more from us, both individually and in some cases collectively, about the progress that we are making. In turn, we invite policymakers and the public to challenge us not only to do our part, but to do even more when more makes sense. The conveners and participants in the Clinical Research Summit project look forward to working with all Americans to improve the quality of health care for all people.

## Clinical Research: A National Call to Action

Medicine and science stand poised on the threshold of some of their greatest advances. At no time in human history has the potential been greater for translating biological knowledge and technological capability into powerful tools for preventing and treating disease and caring for our communities' health. Dramatic progress in the basic sciences has vastly increased our understanding of the causes of disease and opened up previously unimagined options for treatment and prevention. The burgeoning biotechnology industry has helped to revolutionize the development of new drugs. The mapping of the human genome is almost complete, and the fruits of genetic research alone promise to transform medical knowledge and practice beyond our wildest dreams. Before us lie virtually limitless possibilities for preventing and treating the major diseases of humankind and enhancing the health of our citizens and their communities.

At the same time, a new set of challenges threatens our ability to make the most of these scientific opportunities. Today's cost-conscious and competitive health care marketplace has had a major impact on funding streams that have long been available to support biomedical and health research and the training of scientists. The rapidly expanding capability of information technology, while a boon to many administrative and financial functions in the health care system, has not been sufficiently exploited for research purposes.

**Clinical research is the “neck of the scientific bottle,” through which all scientific developments in biomedicine must flow before they can be of real-world benefit to the public.** Landmark developments in genetics, bioengineering, neuroscience, and molecular and structural biology will mean little in practical terms if clinical researchers are unable to “translate” this science into new and effective medical and health practices. Nor will the practices be of maximum benefit to the public without the analysis of health services and epidemiological researchers. Without a robust national program of clinical research that enjoys the participation and harnesses the full strength of all components of the health sector, the impact of revolutionary advances in the biomedical and health sciences on the health of the public will be blunted.

The problem confronting all Americans is that the vitality of our country's clinical research enterprise is at risk. Many elements of the complex ecosystem that support clinical research are shifting or eroding, threatening the nation's ability to successfully translate research advances into effective, efficient treatments, cures, and strategies of disease prevention at the bedside, in the clinic, and in the community. The return on America's substantial and ongoing financial investment in medical research can only be realized if all stakeholders — from the public, to the professionals, to the policymakers — join together to promote a cohesive national agenda for clinical research.

## Unprecedented Unity of the Health Care Enterprise Regarding Clinical Research

Recognizing that what is at stake is the quality of health care in this country and the world, a broad cross-section of stakeholders in the health care enterprise banded together in unprecedented unity to develop an action agenda to address this burgeoning national problem. More than 175 representatives from government and the private sector, funders of clinical research, the pharmaceutical industry, corporate and government purchasers of health care, health plans and insurance companies, patient advocates and ethicists, diverse health care professionals, and academic health centers were enlisted by the Association of American Medical Colleges (AAMC), the American Medical Association (AMA) and Wake Forest University in a Clinical Research Summit project that was supported by seven foundations and took 18 months to complete.

Throughout the various stages of the project, participants put aside individual concerns to hammer out a broad and inclusive agenda. A fundamental part of this agenda is the recognition of nine core problems that confront the clinical research enterprise. These include:

- There is not an agreed-upon definition of clinical research and its components.
- Clinical research is not adequately understood or valued by the public.
- There is a lack of data on clinical research funding and productivity.
- There is insufficient funding for the conduct of some types of clinical research.
- There are insufficient numbers of clinical investigators.
- There is insufficient emphasis on incorporating research findings into clinical practice.
- There is inadequate coordination of clinical research among research entities and disciplines.
- The ability of academic health centers to conduct clinical research is at risk.
- There is a lack of a comprehensive, dynamic clinical research agenda.

To address these nine problems, Summit participants developed a set of goals, objectives and recommendations. These are briefly summarized on the following pages and fully described in the *Report of the Graylyn Consensus Development Conference*, a companion to *Clinical Research: A National Call to Action*.

In delivering this report to the American people, the conveners and participants of the Clinical Research Summit project affirm their desire to continue to work together to realize the scientific promise that will benefit all of humankind.

## A National Call to Action: 9 Core Problems and Recommendations

### **1 No Agreed-Upon Definition of Clinical Research**

Fundamental to an effective national call to action is an inclusive and comprehensive definition of clinical research. The definition unanimously agreed to by Clinical Research Summit participants addresses not only the complexity, but the interconnectedness of the separate categories of clinical research.

Clinical research is: a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health.

Clinical research embraces a continuum of studies involving interaction with patients, diagnostic clinical materials or data, or populations, in any of these categories: disease mechanisms; translational research; clinical knowledge, detection, diagnosis, and natural history of disease; therapeutic interventions including clinical trials; prevention and health promotion; behavioral research; health services research, including outcomes; epidemiology; community-based and managed care-based research.

### **2 Clinical Research Is Not Adequately Understood or Valued**

The public clearly understands and supports basic medical research such as that funded by the National Institutes of Health (NIH), seeing in it the promise of cures and prevention for debilitating diseases and better treatments for disability. Less recognized and appreciated is the nature of clinical research and the unique challenges it faces as a distinct component of medical and health research. Even various segments of the government and the health care community do not fully grasp and appreciate the crucial role of clinical research. This is reflected in inadequate funding and other support for some categories of clinical research. Many clinical research trials go begging for participants — for example, fewer than 4 percent of cancer patients participate in clinical trials. Segments of the public are wary of researchers' need for access to archived medical and health information databases, despite the tremendous importance of such data to improving health outcomes and enhancing the public health.

### The Summit recommends:

- The uniform definition of clinical research developed by Summit participants, deliberately inclusive of the broad scope and complexity of clinical research, should be universally endorsed by all parties in the clinical research enterprise. This definition should be used to help inform and educate the public about clinical research, as well as to monitor its financial support and workforce needs.
- The ethical foundations of clinical research must be reinforced. Federal protections (or their equivalent) for human research subjects should be applied irrespective of funding or venue. Training for health professionals in the ethical framework of clinical research should be expanded.
- Public understanding of clinical research and confidence in clinical research ethics must be strengthened through dialogue that promotes mutual understanding. The research community should develop separate and coordinated strategies to enhance public understanding of, support for, and participation in clinical research, with special efforts made to reach out to populations now underrepresented in clinical research. All entities involved in clinical research should seek out means to restore trust between the scientific community and populations that have been subject to questionable or unethical research practices.

## 3 Lack of Data on Clinical Research Funding and Productivity

The lack of systematic data on the funding of clinical research by industry, government, foundations, and health plans is a major problem. Better information is necessary in order to determine the appropriate levels of investment needed for the different categories of clinical research, in order to mobilize an effective national response to compelling scientific opportunity and pressing health needs.

### The Summit recommends:

- Mechanisms should be established to track and disseminate the aggregate levels of financial support for clinical research provided by public funders, industry, foundations, voluntary organizations, health plans and insurers, academic health centers, hospitals, and other health care providers. Data on the funding of and participation in clinical research should be reported regularly by all funding entities and made available to groups with an interest in the vitality of clinical research.
- A national strategy should be developed for a federal-private sector partnership to fund the creation of broad-based clinical information systems. A substantial investment is needed to meet the requirements of health services and population-based research and the advancement of evidence-based medicine.

## **4** Insufficient Funding for the Conduct of Some Types of Clinical Research

While funding for basic biomedical research has increased at unprecedented rates in recent years, Summit participants believe that certain categories of clinical research are underfunded. Particularly in need of increased funding are research on clinical knowledge, diagnosis, and the natural history of disease, and critically important bi-directional “translational” research, which draws upon the collaborative efforts of both basic and clinical scientists. Significant new funding is also needed for research on primary and secondary prevention and health promotion, health services research, epidemiology, and community-based health issues.

### **The Summit recommends:**

- In the current climate of public enthusiasm for expanding the funding of medical research, efforts should be made to strengthen support for clinical research at NIH, the Centers for Disease Control and Prevention, the Agency for Health Care Policy and Research, and the Department of Veterans Affairs. Funding for population-based research through these agencies should also be substantially increased by leveraging the multiple sources of funding in the public and private sectors.
- Funding for clinical research infrastructure, particularly information technology systems, should be increased so that information systems can be enhanced and made more responsive to the needs of the full spectrum of clinical research.

## **5** Insufficient Numbers of Clinical Investigators

An infusion of dollars will mean little if there are insufficient appropriately trained clinical investigators. There has been a marked decline in the number of physician-investigators, a vital part of any successful clinical research system. Although NIH has been strengthening its institutional training programs, as well as its early and mid-career clinical research awards, workforce development requires more focus by federal funders, foundations, accrediting bodies, academic health centers, and the health industry as a whole.

### **The Summit recommends:**

- A process should be established to monitor and promote workforce career development across the health professions, in order to meet the needs and promote the different categories of clinical research and foster the development of a cadre of well-trained clinical investigators across all health disciplines, specialties and subspecialties.

- An ongoing high-profile forum should be initiated to discuss strategies that could include: recruiting more trainees from underrepresented communities, building upon promising training models developed at academic health centers and the NIH, evaluating new clinical research development awards at NIH, and examining investigator loan repayment and salary support programs.

## **6** Insufficient Emphasis on Incorporating Research Findings Into Clinical Practice

A broadened agenda of clinical research is needed, related more specifically to health outcomes and designed to assess the effectiveness of methods for incorporating evidence-based practice into clinical care. For example, the scientific community has failed to tap the potential for population-based clinical research offered by integrated health systems and practice-based networks. There is also particular need to establish a “real world” capacity to effectively assess surgical procedures and behavioral interventions with the same rigorous study design now being utilized for testing drugs.

### **The Summit recommends:**

- Support for efforts by industry and the NIH should be furnished to develop mixed academic/non-academic clinical trials sites. One attractive model is the “hub and spoke” organization pioneered by the National Cancer Institute.
- Incentives should be provided to managed care organizations and other providers to participate directly in clinical research. Grants from federal and private funders should also be structured to encourage collaboration among academia, industry, private health care providers, and managed care.
- Practice networks and managed care organizations should expand their clinical trials capabilities, as well as their health services, prevention, and epidemiological research. This will vastly expand the scope and venues for clinical research.

## **7** Inadequate Coordination of Clinical Research Among Research Entities and Disciplines

One barrier to a more efficient and effective clinical research enterprise has been the historical fragmentation of research in a culture built around separate “silos” of knowledge and expertise. Collaboration is crucial, but until now it has meant more talk than action.

### **The Summit recommends:**

- Federal agencies supporting clinical research should develop grants that foster coordination and collaboration among research disciplines and entities.

- The General Clinical Research Center (GCRC) program of the NIH should be expanded to become more comprehensive and to foster development of collaborative research networks and training programs across institutions. For example, affiliated sites might be funded as supplements to the GCRC, with the goal of developing multi-institutional collaborative networks.
- Health professions schools within academic medical centers should establish policies that foster cross-disciplinary collaboration.

## 8 Ability of Academic Health Centers to Conduct Clinical Research Is at Risk

During the period of the consensus conference, in 1998, there were scattered reports of financial difficulties at some academic health centers. Participants noted this with the comment that the ability of these institutions to conduct clinical research may be at risk. Since then, evidence of financial distress has become much more widespread and is affecting some of the most prestigious and traditionally strong research institutions in the country.

### The Summit recommends:

- The ability of medical schools, other health professions schools, and teaching hospitals to conduct clinical research and train investigators must be supported and strengthened.

## 9 Lack of Comprehensive, Dynamic, Clinical Research Agenda

In the absence of an ongoing, credible, independent, and broadly representative entity for monitoring and advocating for clinical research, it is unlikely that the multiple goals and objectives set forth by the Summit participants can be woven into a cohesive national action plan for clinical research. Broad representation means: academia; health care systems; organized medicine, nursing, public health, pharmacy and dentistry; managed care organizations and the health insurance industry; health-related foundations; patient advocacy groups; bioethicists; the pharmaceutical, biotechnology and medical devices industries; and the purchasers of health care.

*A successful clinical research agenda will require the commitment, participation, and support from all sectors of the health care enterprise.*

### The Summit recommends:

- A visible, credible, and broadly representative entity should be established to focus continuing national attention on the needs, priorities, and future progress of clinical research.

# The First Step

## National Clinical Research Roundtable: The First Step

An important first step toward the realization of this ambitious national agenda is the establishment of a Clinical Research Roundtable, to help inform and strengthen the processes necessary to nurture a robust, coherent clinical research enterprise. In response to the recommendations of the Clinical Research Summit project, the Institute of Medicine and the Commission on Life Sciences at the National Academies have agreed to convene such a Roundtable. This broadly representative group will help to focus national attention on the needs, priorities, and future progress of clinical research. The Roundtable will provide a forum for the parties interested in clinical research to identify and discuss the major barriers to the conduct of clinical research and develop strategies and approaches to overcoming them. It will be **representative**, continuing the inclusiveness of the Summit process; **credible**, as an autonomous and independent national body; **visible**, with a broad national focus; **responsive**—able to address both long-term and immediate issues; and capable of establishing an **accountable** process.

The Roundtable will be able, through workshops and other activities, to disseminate its findings and to propose formal studies that might be conducted by the National Academies.

- **Workshops:** The Roundtable will convene periodic workshops and other public events to explore approaches to the resolution of both short-term and long-term problems affecting clinical research. Workshops and published reports from the workshops will provide opportunities for those with an interest in clinical research, beyond the Roundtable's membership, to continue to participate in sustaining an environment for the conduct of high quality clinical research.
- **Membership:** Up to 25 members will be chosen for their professional and policy making perspective, as well as their scientific or public policy credentials. Members may include federal and private funders of clinical research, policymakers, health professionals, industry representatives, consumers, and active clinical researchers.
- **Meetings:** The Roundtable will meet up to four times a year. Two of the meetings will be held in conjunction with a Roundtable workshop.

## Convening Events:

---

July 17, 1997	“Preventing the Extinction of the Clinical Research Ecosystem,” written by James Thompson, M.D., and Jay Moskowitz, Ph.D., Wake Forest University, published in <i>JAMA</i>
October 9, 1997	AAMC, AMA, and WFU convene Executive Committee to respond to <i>JAMA</i> article
November 1, 1997	Executive Committee convenes first “Clinical Research Summit” planning meeting – Washington, D.C.
December 5, 1997	Executive Committee convenes second “Clinical Research Summit” planning meeting – Dallas, Texas
<b>Focus Groups:</b>	
March 13, 1998	Test focus group
April 24, 1998	Representatives of corporate and government purchasers of health care and selected health economists
May 29, 1998	Representatives of industry, government and foundations
June 4, 1998	Representatives of health plans and insurance companies
June 11, 1998	Trainees and recent fellowship graduates
June 12, 1998	Mid-level clinical investigators representing translational, clinical trials, and population-based research
June 25, 1998	Representatives of patients, consumers, advocacy organizations, and biomedical ethicists
July 1, 1998	Representatives from nursing, psychology, public health, dentistry, pharmacy, and genetic counseling
September 10, 1998	Representatives of AMA specialty and sub-specialty organizations
September 15, 1998	Representatives of leading basic science organizations
September 25, 1998	Leaders of medical schools and teaching hospitals
November 20-22, 1998	Clinical Research Summit Retreat at Graylyn International Conference Center, Winston-Salem, North Carolina
September 10, 1999	Clinical Research Summit event planning committee meeting
November 15, 1999	Clinical Research Summit concluding event

## Clinical Research Summit Executive Committee:

---

- Chair:** William H. Danforth, M.D.  
Chancellor Emeritus  
Washington University of St. Louis
- AAMC:** David Korn, M.D.  
Senior Vice President for  
Biomedical and Health Sciences Research
- Roger E. Meyer, M.D.  
Senior Consultant for Clinical Research
- AMA:** Reed V. Tuckson, M.D.  
Senior Vice President  
Professional Standards
- Myron Genel, M.D.  
Professor of Pediatrics  
Associate Dean  
Yale University School of Medicine  
Chairman, Council on Scientific Affairs
- Harry Jonas, M.D.  
Assistant Vice President  
Medical Education
- Wake Forest University:**  
James N. Thompson, M.D.  
Vice President and Dean
- Jay Moskowitz, Ph.D.  
Senior Associate Dean for Science and Technology
- Executive Committee staff:**  
Diana D. White  
Administrative Associate  
Association of American Medical Colleges
- Karen A. Goraleski  
Director  
Professional Standards Coordination  
American Medical Association
- M. Priscilla Short, M.D.  
Program Director  
Science, Research and Technology  
American Medical Association
- Michael P. Lischke, M.P.H.  
Senior Assistant to the Vice President and Dean  
Wake Forest University

## Clinical Research Summit Project Participants

Planning Groups • Focus Groups • Graylyn Retreat

### *Titles and affiliations as of date of participation*

Roy D. Altman, M.D.  
Professor of Medicine and Chief, Rheumatology  
and Immunology  
University of Miami School of Medicine  
(American Medical Association–Member,  
Council on Scientific Affairs)

Barbara Alving, M.D.  
Director, Hematology/Medical Oncology  
Washington Hospital Center  
(American College of Physicians)

Margaret Anderson  
Program Director  
Society for the Advancement of Women's Health  
Research

John Aquilino  
American Heart Association

David J. Baer, Ph.D.  
Research Physiologist  
USDA, ARS Beltsville Human Nutrition Research  
Center

Ralph Barocas, Ph.D.  
Professor, Department of Psychology  
George Mason University

Wayne B. Batchelor, M.D.  
Duke University

Robert Battjes, D.S.W.  
Department Director  
National Institute on Drug Abuse  
National Institutes of Health

Diana Beattie, Ph.D.  
Professor and Chair, Department of  
Biochemistry  
West Virginia University School of Medicine

Robert Berenson, M.D.  
Director of Health Plans and Providers  
Health Care Financing Administration

Ruth Berkelman, M.D.  
Senior Advisor to the Director  
Centers for Disease Control and Prevention

Merton Bernfield, M.D.  
Smith Professor of Pediatrics, Professor of Cell  
Biology  
Harvard Medical School

Ken Berns, M.D., Ph.D.  
Dean  
University of Florida College of Medicine

John Bertko  
COO and Senior Health Care Actuary  
PM-Squared, Inc.

Brian Biles, M.D.  
Senior Vice President  
The Commonwealth Fund

J. Chris Bisgard, M.D.  
Director, Health Services  
Delta Airlines, Inc.

Henry R. Black, M.D.  
Chairman, Preventive Medicine  
Rush Presbyterian St. Luke's Medical Center

Ronald Bleday, M.D.  
Assistant Professor of Surgery  
Harvard Medical School  
(Association of Colon and Rectal Surgeons)

Abby Block  
Chief, Insurance and Policy Division  
U.S. Office of Personnel Management

David Blumenthal, M.D., M.P.H.  
Institute for Health Policy  
Massachusetts General Hospital

Philip R. Boulter, M.D.  
Senior Vice President and Chief Medical Officer  
Tufts Health Plan

Ralph A. Bradshaw, Ph.D.  
Professor, Department of Physiology and  
Biophysics  
University of California, Irvine

Thomas J. Brady, M.D.  
Chairman, Radiological Society of North  
America Research Development Committee  
Massachusetts General Hospital

Dennis Brimhall  
President, University Hospital  
University of Colorado

Zora Kramer Brown  
Founder and Chairperson  
Cancer Awareness Program Services

Roger J. Bulger, M.D.  
President  
Association of Academic Health Centers

Serdar E. Bulun, M.D.  
University of Texas Medical Center

Caroline Burnett, R.N., Sc.D.  
Associate Professor, Nursing Investigator in  
Cancer Control and Prevention  
Georgetown University

James Burris, M.D.  
Deputy Chief Research and Development Officer  
Department of Veterans Affairs

Kathleen Buto  
Deputy Director, Center for Health Plans and  
Providers  
Health Care Financing Administration

Robert M. Califf, M.D.  
Professor of Medicine and Director  
Duke Clinical Research Institute

Sally Canfield  
Senior Federal Legislative Representative  
Mutual of Omaha Insurance Company

J. Donald Capra, M.D.  
President  
Oklahoma Medical Research Foundation

Gail M. Cawkwell, M.D.  
All Children's Hospital

Jane Hart Chambers  
Vice President for Government Affairs  
College of American Pathologists

Hunter C. Champion  
Tulane University  
(American Medical Association–Student  
Representative, Council on Scientific Affairs)

Howard Chodash, M.D.  
Southern Illinois University

Paul Clayton, Ph.D.  
Chairman, Department of Medical Informatics  
Columbia University College of Physicians and  
Surgeons

Yank D. Coble, M.D.  
Jacksonville, Florida  
(American Medical Association – Board of  
Trustees)

Harvey J. Cohen, M.D., Ph.D.  
Chairman, Department of Pediatrics  
Stanford University School of Medicine

Judith A. Cooper, Ph.D.  
Deputy Director, Division of Human  
Communication  
National Institute on Deafness and Other  
Communication Disorders  
National Institutes of Health

Deborah Copeland  
Senior Director  
In Site Clinical Trials

Paulette Cournoyer, D.N.Sc., R.N., C.S.  
Program Director  
VA Headquarters Nursing Strategic Healthcare  
Group

Robert D. Coursey, Ph.D.  
Professor, Department of Psychology  
University of Maryland

Rex Cowdry, M.D., M.P.H.  
Senior Scientific Advisor  
American Association of Health Plans

Joseph Coyle, M.D.  
Chair, Department of Psychiatry  
Harvard Medical School

Glenn Crater, M.D.  
University of Florida

Larry Culpepper, M.D., M.P.H.  
Chief, Department of Family Medicine  
Boston Medical Center  
(American Academy of Family Physicians)

Larry H. Danziger, Pharm.D.  
Professor, College of Pharmacy  
University of Illinois - Chicago

Robert M. Daugherty, Jr., M.D., Ph.D.  
Dean  
University of Nevada School of Medicine  
(American Medical Association - Council on  
Scientific Affairs)

Gary Dennis, M.D.  
President-elect  
National Medical Association

Carla DiGirolama  
Allegheny University

Donna S. Dizon-Townson, M.D.  
University of Utah School of Medicine

Adrian Sandra Dobs, M.D., M.H.S.  
Associate Professor and Vice Chair,  
Clinical Research  
Johns Hopkins University School of Medicine  
(Endocrine Society)

Sir Collin Dollery  
Senior Consultant, Research and Development  
SmithKline Beecham Pharmaceuticals

Gregory Eastwood, M.D.  
President, Health Science Center of Syracuse  
State University of New York  
(American Gastroenterological Association)

Michael H. Ebert, M.D.  
Chair, Department of Psychiatry  
Vanderbilt University

Lynn Eckhart, M.D., Dr. P.H.  
Chair, Department of Family and Community  
Medicine  
University of Massachusetts

Gary B. Ellis, Ph.D.  
Director  
Office for Protection from Research Risks

John M. Eisenberg, M.D.  
Administrator  
Agency for Health Care Policy and Research

Mary Jane England, M.D.  
President  
Washington Business Group on Health

Clyde Evans, Ph.D.  
Vice President  
Association of Academic Health Centers

Edd L. Evans, M.D., Ph.D.  
Mayo Foundation

Bernard G. Ewigman, M.D., M.S.P.H.  
Department of Family and Community Medicine  
Missouri University School of Medicine  
(American Academy of Family Physicians)

John R. Feussner, M.D.  
Chief Research and Development Officer,  
Veterans Health Administration  
Department of Veterans Affairs

Thomas M. Fitzpatrick, M.D., Ph.D.  
Chief, Critical Care Medicine  
Walter Reed Army Medical Center  
(American Thoracic Society)

Philip C. Fox, D.D.S.  
Clinical Director  
National Institute of Dental Research  
National Institutes of Health

Irwin M. Freedberg, M.D.  
Chairman, the Ronald O. Perleman Department  
of Dermatology  
New York University School of Medicine  
(Society for Investigative Dermatology)

Linda P. Fried, M.D., M.P.H.  
Deputy Director for Epidemiology and Health  
Services Research, Department of Medicine  
Johns Hopkins Medical Institutions  
(American Geriatric Society)

Lawrence Friedman, M.D.  
Director, Division of Epidemiology and Clinical  
Applications  
National Heart, Lung and Blood Institute  
National Institutes of Health

Michael Friedman, M.D.  
Acting Commissioner  
Food and Drug Administration

Steven G. Gabbe, M.D.  
Professor and Chair, Department of Obstetrics  
and Gynecology  
University of Washington Medical Center  
(American College of Obstetrics and Gynecology)

John I. Gallin, M.D.  
Director, Clinical Center  
National Institutes of Health

Robert S. Galvin  
Director, Corporate Health Care and Medical Programs  
General Electric Company

Deo Garlock  
Director, Business Integration  
Quintiles

Susan Gennaro, R.N., D.S.N.  
Professor  
University of Pennsylvania School of Nursing

Gregory G. Ginsberg, M.D.  
Assistant Professor of Medicine, Director of Endoscopic Services  
The Hospital of the University of Pennsylvania  
(American Society for Gastrointestinal Endoscopy)

Marshall D. Glesby, M.D., Ph.D.  
Community Research Initiative on AIDS

Robert M. Glickman, M.D.  
Dean, School of Medicine  
New York University

Margaret Grey, Dr. P.H.  
Independence Foundation Professor of Nursing,  
Associate Dean for Research Affairs  
Yale School of Nursing

Maureen Hannley, Ph.D.  
Associate Vice President and Director of Research  
(American Academy of Otolaryngology)

Sherrie Hans, Ph.D.  
The Pew Charitable Trusts

E. Nigel Harris, M.D.  
Dean and Senior Vice President for Academic Affairs  
Morehouse School of Medicine

Frederic Harwood, Ph.D.  
Executive Vice President  
Association of Clinical Research Professionals

Ziv Haskal, M.D.  
Associate Professor of Radiology  
The Hospital of the University of Pennsylvania

Michael D. Henderson, M.D.  
Chief Medical Officer  
CNA Insurance Companies

Chester J. Herman, M.D.  
Department of Pathology  
Grady Memorial Hospital  
(College of American Pathologists)

Roberta L. Hines, M.D.  
Professor and Chair, Department of Anesthesiology  
Yale University School of Medicine  
(American Society of Anesthesiologists)

Sam Ho, M.D.  
Vice President, Corporate Medical Director  
PacifiCare Health Systems

Beri Hull  
National Association of People with AIDS

Carl C. Hug, Jr., M.D., Ph.D.  
Department of Anesthesiology  
Emory University Hospital  
(American Society of Anesthesiologists)

Anna Huttenlocher, M.D.  
University of Illinois - Urbana

Barbara H. Iglewski, Ph.D.  
Professor and Chair, Microbiology and Immunology Department  
University of Rochester Medical Center

Steve Jenckes, M.D., M.P.H.  
Director of Priority Management for the Office of Clinical Standards and Quality  
Health Care Financing Administration

Andrea Kalfoglou  
Department of Health Policy and Management  
Johns Hopkins University

Audiey C. Kao, M.D., Ph.D.  
Research Director, Institute for Ethics  
American Medical Association

David G. Kaufman, M.D., Ph.D.  
Professor, Department of Pathology/Laboratory Medicine  
University of North Carolina at Chapel Hill  
Medical School

Ronald E. Keeney, M.D.  
Director, The Clinical Research Institute  
Wake Medical Center  
(American Academy of Pharmaceutical Physicians)

Jeffrey A. Kern, M.D.  
President  
American Federation for Medical Research

Mohamed K. Khan, M.D., Ph.D.  
Joint Center for Radiation Therapy  
(American Medical Association–Resident  
Member, Council on Scientific Affairs)

Darrel G. Kirsch, M.D.  
Dean  
Medical College of Georgia  
(American Medical Association - Chair-elect,  
Section on Medical Schools)

John La Montagne, Ph.D.  
Deputy Director  
National Institute of Allergy and Infectious  
Diseases  
National Institutes of Health

Sue Levi-Pearl  
Director, Medical and Scientific Programs  
Tourette Syndrome Association

Ed Linz  
American Heart Association and Transplant  
Recipients International Organization

Nicole Lurie, M.D., M.S.P.H.  
Principal Deputy Assistant Secretary for Health  
Department of Health and Human Services

H. Kim Lyerly, M.D.  
Professor of Surgery, Assistant Professor of  
Immunology and Pathology  
Duke University School of Medicine  
(American College of Surgeons)

Gailen D. Marshall, Jr., M.D.  
Assistant Professor and Director, Division of  
Allergy and Clinical Immunology  
University of Texas-Houston Medical School  
(American College of Allergy, Asthma and  
Immunology)

Jeffrey Martin, M.D.  
University of California at San Francisco

Thomas K. McInerney, M.D.  
Chief Medical Officer  
Rochester Community Individual Practice  
Association  
(American Academy of Pediatrics)

Barbara Medoff-Cooper, Ph.D.  
Director, Center for Nursing Research  
University of Pennsylvania School of Nursing

Ray Merenstein  
Vice President of Programs  
Research!America

Victoria Mock, D.N.Sc., R.N.  
Director of Oncology Nursing Research,  
Associate Professor, School of Nursing  
Associate Professor, Oncology, School of  
Medicine  
Johns Hopkins University

Andrew F. Morrison  
Vice President, Federal Affairs  
WellPoint Health Networks, Inc.

Monica Morrow, M.D.  
Professor of Surgery  
Director, Lynn Sage Comprehensive Breast  
Program  
Northwestern University Medical School  
(American College of Surgeons)

Sharon Moss, Ph.D.  
Director, Research Resources and Advocacy  
American Speech, Language and Hearing  
Association

Ralph W. Muller  
President  
University of Chicago Hospitals and Health System

David G. Nathan, M.D.  
President  
Dana Farber Cancer Institute

Fererrick Ognibene, M.D.  
Fellowship Program Director  
Department of Critical Care Medicine  
National Institutes of Health  
(Society of Critical Care Medicine)

Chris O'Flinn  
Manager, Global Benefits  
Mobil Corporation

Edward H. Oldfield, M.D.  
Chief, Surgical Neurology Branch  
National Institute of Neurological Disorders  
and Stroke  
National Institutes of Health  
(American Academy of Neurological Surgeons)

P. Pearl O'Rourke, M.D.  
Deputy Director, Office of Science Policy  
National Institutes of Health

Eugene P. Orringer, M.D.  
Professor of Medicine, Director, General Clinical  
Research Center  
University of North Carolina at Chapel Hill

Herbert Pardes, M.D.  
Dean of the Faculty of Medicine  
Columbia University

William A. Peck, M.D.  
Executive Vice Chancellor and President  
Washington University of St. Louis Medical  
Center

Edmund D. Pellegrino, M.D.  
Director, Center for Clinical Bioethics  
Georgetown University

Eileen H. Peterson  
Vice President  
United Health Care Corporation, Center for  
Health Care Policy and Evaluation

Diana Petitti, M.D.  
Director of Kaiser Permanente Southern  
California

Harold A. Pincus, M.D.  
Deputy Medical Director; Director,  
Office of Research  
American Psychiatric Association

Richard Platt, M.D.  
Director of Research  
Harvard Pilgrim Health Care

Peter J. Pronovost, M.D.  
Johns Hopkins Hospital

Chris Queram  
CEO  
Employers Health Care Alliance

Mitchell T. Rabkin, M.D.  
CEO  
CareGroup, Inc.

Robert E. Ratner, M.D.  
Medical Director  
Medlantic Clinical Research Center

Sandra C. Raymond  
Executive Director  
National Osteoporosis Foundation

Linda J. Rich  
Program Associate, Health and Human Services  
Program  
The Pew Charitable Trusts

Robert R. Rich, M.D.  
Executive Associate Dean  
Emory University School of Medicine

R. Lucia Riddle  
Vice President, Government Relations  
The Principal Financial Group

David Robertson, M.D.  
Director, Clinical Research Center, Professor of  
Medicine, Pharmacology and Neurology  
Vanderbilt University

Robert M. Rose, M.D.  
Director, Health Programs  
The John D. and Catherine T. MacArthur  
Foundation

Richard Rosenthal, M.D.  
American Academy of Allergy, Asthma and  
Immunology

Alan Roses  
Vice President, Worldwide Division of Genetics  
Glaxo Wellcome, Inc.

M. Elizabeth Ross, M.D., Ph.D.  
Director, MSTP Combined MD/PhD Training  
Program, Department of Neurology  
University of Minnesota

Mark A. Rudberg, M.D., M.P.H.  
Associate Professor of Medicine  
The University of Chicago

Lewis G. Sandy, M.D.  
The Robert Wood Johnson Foundation

Fred Sanfilippo, M.D., Ph.D.  
Baxley Professor and Director of Pathology  
The Johns Hopkins Medical Institutions

Sandy Sanford, R.N., M.S.N.  
Manager, Education and Certification  
Association of Clinical Research Professionals

Nanette Santoro, M.D.  
Associate Professor and Director, Division of  
Endocrinology and Infertility  
Albert Einstein College of Medicine  
(American Society of Reproductive Medicine)

Alan N. Schechter, M.D.  
Chief, Laboratory of Chemical Biology  
National Institute of Diabetes and Digestive and  
Kidney Disease  
National Institutes of Health  
(American Society of Hematology)

Lowell E. Schnipper, M.D.  
Chief, Hematology/Oncology Division  
Beth Israel Deaconess Medical Center  
(American Society of Clinical Oncology–Public  
Issues Committee)

Amy Sehnert, M.D.  
University of California at San Francisco

Ruchir Sehra, M.D.  
Riley Children's Hospital

George F. Sheldon, M.D.  
Professor and Chairman, Dept. of Surgery  
University of North Carolina, Chapel Hill

Louis Sherwood, M.D.  
Senior Vice President for Medical and Scientific  
Affairs  
Merek and Company

Kenneth Shine, M.D.  
President  
Institute of Medicine

Lawrence E. Shulman, M.D., Ph.D.  
National Institutes of Health Emissary for  
Clinical Research to the Academic Community  
Past Director, National Institute of Arthritis and  
Musculoskeletal and Skin Disorders  
National Institutes of Health

Lana Skirboll, Ph.D.  
Associate Director for Science Policy  
National Institutes of Health

Richard J. Sohn, Ph.D.  
Associate Dean, Research Administration  
Director, Grants and Contracts  
Columbia University College of Physicians  
and Surgeons

Robert J. Sokol, M.D.  
Dean, School of Medicine  
Wayne State University

Patricia Spear, Ph.D.  
Professor and Chair, Department of  
Microbiology and Immunology  
Northwestern University

Ruth E.K. Stein, M.D.  
Professor and Vice Chairman, Director of Office  
of Academic Affairs, Department of Pediatrics  
Albert Einstein College of Medicine / Montefiore  
Medical Center  
(American Academy of Pediatrics)

Nancy Sung, Ph.D.  
The Burroughs Wellcome Fund

Bruce Taylor  
Director of Health Care Policy and Plans  
GTE Service Corporation

Clive R. Taylor, M.D., Ph.D.  
Senior Associate Dean of Academic Affairs  
University of Southern California School of  
Medicine

Palmer Taylor, Ph.D.  
Professor and Chair, Department of  
Pharmacology  
University of California, San Diego

Jeffrey Tice, M.D.  
University of California at San Francisco

Hugh H. Tilson, M.D., Dr. P.H.  
Senior Medical Advisor  
Glaxo Wellcome Company

Judith L. Vaitukaitis, M.D.  
Director  
National Center for Research Resources  
National Institutes of Health

Bruce C. Vladeck, Ph.D.  
Professor of Health Policy  
The Mount Sinai Medical Center

Peter Vlasses  
University Health System Consortium

William C. Waggoner, Ph.D.  
Chairman  
Essex Institutional Review Board

Brian E. Walden, Ph.D.  
Director of Research, Army Audiology and  
Speech Center, Department of Surgery  
Walter Reed Army Medical Center

August M. Watanabe, M.D.  
President, Lilly Research Laboratories  
Eli Lilly and Company

Myrl Weinberg, CAE  
President  
National Health Council

Michael Weinrich, M.D.  
Legislative Fellow  
Rep. Benjamin Cardin (D-MD)  
(American Academy of Neurology)

Samuel A. Wells, Jr., M.D.  
Director  
American College of Surgeons

John E. Wennberg, M.D., M.P.H.  
Director, Center for the Evaluative Clinical  
Sciences  
Dartmouth Medical School

Dan Wermeling, Pharm.D.  
Scientific Director  
Kentucky Center for Clinical Research and  
Investigator Services  
University of Kentucky

Elliot Wicks, Ph.D.  
Senior Fellow  
Economic and Social Research Institute

Huntington Willard, Ph.D.  
Director and Chairman, Center for Human  
Genetics, Department of Genetics  
Case Western Reserve University

Michael A. Williams, M.D.  
Neurosciences Critical Care Division  
Johns Hopkins Hospital  
(American Medical Association—Member,  
Council on Scientific Affairs)

Daniel H. Winship, M.D.  
Dean  
Loyola University of Chicago, Stritch School  
of Medicine  
(American Medical Association – Chair, Section  
on Medical Schools)

Savio L.C. Woo, Ph.D.  
Professor and Director, Institute of Gene  
Therapy and Molecular Medicine  
Mount Sinai School of Medicine

Mary Woolley  
President  
Research!America

Raymond L. Woosley, M.D., Ph.D.  
Chairman, Dept. of Pharmacology  
Georgetown University Medical Center

Donald A. Young, M.D.  
Senior Vice President for Policy and Clinical  
Services  
American Association of Health Plans

JoAnne M. Youngblut, R.N., Ph.D.  
Dean for Research and Professor, Frances Payne  
Bolton School of Nursing  
Case Western Reserve University  
(American Nurses Association)

Alan Zwerner, M.D., J.D.  
Sr. Vice President and Chief Medical Officer  
Health Net



## American Medical Association

Physicians dedicated to the health of America

515 North State Street  
Chicago, Illinois 60610

