Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health

Division of Health Sciences Policy

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RESPONDING TO HEALTH NEEDS AND SCIENTIFIC OPPORTUNITY: THE ORGANIZATIONAL STRUCTURE OF THE NATIONAL INSTITUTES OF HEALTH

Report of a Study by a Committee of the
INSTITUTE OF MEDICINE
Division of Health Sciences Policy

October 1984
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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education.

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FREDERICK C. ROBBINS,
M.D.
PRESIDENT

October 16, 1984

The Honorable Margaret M. Heckler
Secretary
Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Madam Secretary:

This report, Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health, is submitted in fulfillment of the request to the Institute of Medicine, National Academy of Sciences, to review the organizational structure of the National Institutes of Health and to make recommendations of changes that might better equip the institution to deal with the future expansion of scientific and technologic knowledge. It also was requested that criteria be developed by which proposals for the creation of new institutes or other major structural changes could be evaluated.

The report was prepared by a distinguished study committee headed by one of the country's most eminent scientist-statesmen. The study committee and its excellent staff engaged in an intensive period of informing themselves in a variety of ways which are documented in the report. Their task was greatly assisted by the liaison committee created at the NIH and chaired by the Deputy Director, Dr. Thomas Malone. This committee was able to see that data were made available to the study committee and to check descriptive material for factual accuracy. However, although they were important in making the study possible, they played no part in the study committee's deliberations or in shaping its recommendations.

The study committee chose to present their findings and recommendations in a brief readable document. While this differs from the format of some other reports, I suspect that the average reader will applaud this approach. Much of the documentation on which the study committee based their analysis and conclusions is to be found in the appendices or in background materials available from the National Academy Press.

Some readers, particularly working scientists, may be disappointed that the report does not deal with some of the issues of special interest to them. These include concerns about peer review, relations between the intramural and extramural programs and various other managerial questions. As indicated in the report, the study committee was informed, in the course of their investigations, of some problems and concerns in those areas. However, it was not within their mandate to further investigate these issues, and the study committee itself felt that its attention was properly focused on the issues discussed in the report.

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Among the recommendations of the study committee is the proposed creation of a Health Science Board to advise the Secretary through the Assistant Secretary for Health on the desirability of any proposed change in the organizational structure of the health research programs of the Public Health Service. Reactions have ranged from strong support to equally strong opposition for the idea. The criticisms have centered around the possibility that the board might become politicized. The study committee was not unmindful of the issues that have been raised but came to the conclusion that on balance the board would meet an important need. The committee suggests ways to minimize the likelihood of its becoming unduly political. Furthermore, questions were raised about whether or not in this instance the study committee had exceeded its charge because it proposes that the board be concerned with research throughout the PHS and not only in the NIH. Because many of the most important organizational issues today involve the boundaries of the NIH mission, this recommendation is appropriate.

Although the study committee makes a number of suggestions for change, they also comment on some of the strengths of the organization and above all what a tremendous resource the NIH has become for our country and indeed the world. It is to be hoped that this report will be of assistance in preserving and strengthening this uniquely successful institution of our society as it faces a future of unparalled opportunity.

With kindest regards,

Sincerely,

Frederick C. Robbins,
M.D.

cc: James B. Wyngaarden, M.D.
Edward N. Brandt, Jr., M.D.

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Acknowledgements

The committee appreciates the contributions of many persons and organizations who provided information throughout the study, most of whom are listed in Appendix A. We are especially grateful to the staff of NIH and the Department of Health and Human Services, including members of the special liaison committee chaired by Dr. Thomas Malone, the project officer Kurt Habel, and many others who gave generously of their time.

Special thanks are due to the writers of case studies and other background papers used by the committee and panels, including Philip Cantelon, Philip Caper, Michael Duffy, Ruth Harris, Veronica Hill, Lorna Jaffe, Betty Lockett, Laural Radow, and Terri Schorzman. We are especially grateful to Dr. Enriqueta Bond, Director of the Institute of Medicine's Division of Health Sciences Policy at the time the committee's charge was being defined and while the committee was getting underway, not only for her essential contributions at that time, but also for valuable assistance at every stage of our work. Finally, the members of the committees and panels would like to express their appreciation to the capable and energetic project staff whose preparation and organization made the committee's work possible.

PREFACE

The idea of a study of the organizational structure of the National Institutes of Health (NIH) first arose while the Congress was considering the Health Research Act of 1982. Because of concern about the number of proposals to establish new institutes and make other organizational changes in NIH, a provision calling for a study by the Institute of Medicine was inserted in the bill. For unrelated reasons, however, the bill never became law.

NIH and the Assistant Secretary for Health of the Department of Health and Human Services realized the importance of such a study for focusing the debate about organizational changes, and in the spring of 1983, contracted with the Institute of Medicine to establish the Committee for a Study of the Organizational Structure of the National Institutes of Health. The committee has been asked to "make an independent objective study of the organizational structure of the NIH and considering scientific developments and economic conditions recommend the establishment of criteria (standards) to be met in determining the need for any substantial change in the organizational structure of the NIH," and (according to the contract) to perform the following three tasks:

1. Analysis of Organizational Evolution Conduct a thorough, systematic review of the agency's organizational evolution and development. This analysis shall include a review of the organization's development and an examination of the contributing factors involved in such development. The contractor shall also examine the present organizational structure and the underlying rationale for this structure.
2. Current Organization Analysis Examine the present approach for those issues which cut across organizational lines. The contractor shall examine the basis for the current methods of handling such issues and develop alternative approaches for consideration. The rationale for and implication within the current NIH structure of all approaches (current and alternatives developed) shall be analyzed.
3. Study Recommendations Considering scientific developments and economic conditions, the contractor shall develop rationale and criteria to be met to determine the need for change, in any substantial manner, in the organizational structure

of the NIH, and determine possible alternative organizational structures for the NIH.

The committee consisted of 15 individuals, appointed by the President of the Institute of Medicine (IOM) with the concurrence of the President of the National Academy of Sciences. The committee met six times in the course of 18 months to define its task, develop a study plan, analyze the issues, and make recommendations. A liaison committee of NIH and Department of Health and Human Services officials helped the IOM committee fully define its charge and gain access to the necessary information.

To gather information and develop preliminary recommendations, the committee established panels to explore: (1) the effect of past organizational changes on the flow of funds into, and the scope of research in, various disciplines and research areas, and on the management and coordination of health research; (2) the current organizational structure of the NIH, and the way that this structure deals with scientific and management issues that cut across institute lines; and (3) alternative means for goal setting, decision making, priority setting, and budgeting that might suggest directions for organizational change. A member of the main committee chaired each of these panels, and the panels also included, in total, 17 additional people. The complete membership is listed on the following pages. The reports of these panels have strongly influenced the deliberations of the main committee, and many elements have contributed to this report.

The committee and the panels relied upon a series of activities designed to gather information and opinions from a wide range of interested parties. The committee held three public meetings with representatives of professional societies, voluntary health associations, and other concerned individuals. More than 135 persons participated in these meetings in Washington, D.C., Woods Hole, Massachusetts, and Houston, Texas. In addition, the committee has received written comments from 145 organizations and individuals. Committee members and staff also interviewed some 185 people to obtain a broad perspective on health science policy issues; those interviewed include current and former NIH directors, institute directors, and other high officials of NIH; members of NIH advisory councils; secretaries, assistant secretaries and other officials of the Department of Health and Human Services (and of Health, Education, and Welfare); members of Congress and their staffs; and working scientists and representatives of the professional societies and voluntary health associations. A detailed list of meetings, commenters, and interviews appears in Appendix A.

These outreach activities have been extremely helpful in calling attention to critical organizational issues relevant to the committee's charge. They have also revealed a number of concerns about NIH, especially about the management of the peer review system and the intramural research program. The peer review system and the intramural program are both critical to ensuring NIH's continued success, and the concerns deserve the full attention of NIH and the research community. For the most part, the concerns that have been expressed relate to management and not organizational issues, so are beyond the committee's charge. The organizational structure of the peer review system and the intramural program, on the other hand, are critical elements of NIH's success, and are addressed in the report. For similar reasons, the committee has not made a detailed study of training programs. The committee reaffirms, however, the critical importance of research training to the mission of NIH now and in the future.

The panels also commissioned a series of case studies and background papers. These include seven case studies, reviewed by knowledgeable individuals, of new institutes and institutes that have experienced other major organizational changes; a statistical analysis of the relationship between organizational changes and research budgets; and papers about the historical evolution of NIH's organizational structure, relations between NIH and Congress, and the organizational structure of foreign research agencies. Some of these papers are available from the National Academy Press; see page xiv. In addition, committee member Thomas Morris conducted a baseline management analysis of the current organizational structures and practices at NIH. This analysis, which involved over 70 interviews and the review of many written documents, appears in Appendix B. Those readers who are not familiar with the current organizational structure of the NIH may find it helpful to read this appendix before they read the main report. In addition, the committee also reviewed many previous studies about NIH (for example the Wooldridge report and the President's Biomedical Research Panel; see page 29) and other science policy and management issues (for example, the reports of the Grace Commission and the White House Science Council's Federal Laboratory Review; see page 32).

Although the committee and panels have tried to be as thorough as possible in gathering objective information about the structure and functioning of NIH and alternatives to the current structure, and in documenting the causes and effects of previous organizational changes, much remains a matter of judgment. In the end, the findings and recommendations in this report are the product of a synthesis of objective analyses, the informed opinion of a wide range of respondents, the members' own extensive experience, and thorough committee discussions.

James D. Ebert
Chairman

PANELS Panel on Historical Issues

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MILDRED COHN, Ph.D., Senior Member, Institute for Cancer Research, Philadelphia, Pennsylvania

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ELMER STAATS, Ph.D., Washington, D.C.

STEPHEN P. STRICKLAND, Ph.D., Vice President, Aspen Institute for Humanistic Studies, Washington, D.C.

Panel on Current Organization

SAMUEL O. THIER, M.D., Chair, Sterling Professor and Chairman, Department of Internal Medicine, Yale University, New Haven, Connecticut

BARBARA C. HANSEN, Ph.D., Associate Vice President-Research, and Professor of Physiology and Psychology, Southern Illinois University, Carbondale,. Illinois

M. ALFRED HAYNES, M.D., M.P.H., President and Dean, Charles R. Drew Postgraduate Medical School, Los Angeles, California

DAVID MECHANIC, Ph.D., University Professor and Dean, Faculty of Arts and Sciences, Rutgers University, New Brunswick, New Jersey

THOMAS MORRIS, Washington, D.C.

JOSEPH G. PERPICH, M.D., J.D., Vice President, Planning and Development, Meloy Laboratories, Inc., Revlon Health Care Group, Springfield, Virginia

LEON E. ROSENBERG, M.D., Dean, Yale University School of Medicine, New Haven, Connecticut
STEWART WOLF, M.D., Director, Totts Gap Medical Research Laboratories, Inc., Bangor, Pennsylvania
Panel on Alternatives
STEVEN C. BEERING, M.D., Chair, President, Purdue University, West Lafayette, Indiana
THEODORE COOPER, M.D., Ph.D., Executive Vice President, The Upjohn Company, Kalamazoo, Michigan
ROBERT L. HILL, Ph.D., James B. Duke Professor and Chairman, Department of Biochemistry, Duke University Medical Center, Durham, North Carolina
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ARTHUR KORNBERG, Professor, Stanford University, Stanford, California

BACKGROUND PAPERS

1. A Brief History of the Development of the National Institutes of Health, by Stephen D. Nelson
2. A Summary of a Case Study of the National Cancer Institute, by Pamela J. Smith
3. A Summary of a Case Study of the National Eye Institute, by Pamela J. Smith
4. A Summary of a Case Study of the National Heart, Lung, and Blood Institute, by Stephen D. Nelson
5. A Summary of a Case Study of the National Institute on Aging, by Pamela J. Smith
6. A Summary of a Case Study of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, by Pamela J. Smith
7. A Summary of a Case Study of the National Institute of Environmental Health Sciences, by Pamela J. Smith
8. A Case Study of the National Institute of Mental Health, by Stephen D. Nelson

Each of these papers is available from the National Academy Press, Publication on Demand, 2101 Constitution Avenue N.W, Washington, D.C. 20418. (202) 334-3313.

SUMMARY

The National Institutes of Health (NIH) has earned a reputation for excellence in the support and conduct of research to improve the health of the American people. It has maintained its leadership position in the international scientific community even in the face of considerable changes in its political and social environment. But pressure continues to mount for change in the mission and organizational structure of NIH. The future success of NIH depends on it and the rest of the Public Health Service adopting a more unified and coordinated approach to meeting the nation's health research needs.

The mission of NIH demands that its leaders pursue two principal objectives: (1) to be responsive to health needs, achieving reductions in the burden of illness by capitalizing on scientific opportunities, and (2) to promote basic science and maintain standards of scientific excellence. Although it sometimes seems that these two objectives are contradictory rather than complementary, such is not the case. Both must be pursued with equal vigor, creative leadership, and hard work if the NIH is to continue its successful record.

The genius of the institution in shaping scientific excellence to health needs is found in the interplay of categorical research institutes and disciplinary study sections. The primarily disease-based institutes enable Congress to understand, appreciate, and support the research accomplishments and goals of the institutes, and also to express concerns and priorities about the need for further research. The study sections, on the other hand, cut across institute lines and ensure that appropriate scientific talent and ideas are brought to bear on the problems.

The committee feels that the NIH categorical structure is an effective tool for helping to shape scientific excellence to meet national needs. As society and its needs continue to evolve, however, NIH must evolve with it. This report suggests mechanisms, procedures, and institutional patterns to help NIH continue to meet its objectives, and criteria to guide the organization's future evolution.

ORGANIZATIONAL EVOLUTION

Since the 1930s NIH has seen the establishment of many new institutes and divisions. These entities grew out of existing

institutes, were transferred into NIH from elsewhere, or were built up from the start. In addition, existing institutes have changed their names and their research focus and have had their organizational status upgraded. Statistical studies have provided no evidence that such changes, in themselves, have led to an increased budget for NIH as a whole or that new institutes have tended to grow faster than the rest of NIH. On the other hand, case studies have shown that establishing a new institute has not hampered the scientific effort, and in some cases even seems to have helped it considerably. However, the same effects also have been achieved without creating a new institute. The establishment of the Lung Division in the Heart Institute, for instance, seems to have been scientifically and politically successful because of the active cooperation of institute leadership with those who were urging greater attention and resources for lung research. The critical elements of success seem to be scientific readiness for major advances and dynamic leadership from committed individuals with a vision for the field.

There are many ways for NIH to be responsive to health needs and scientific opportunities without changing its organizational structure. In the last decade, for instance, NIH's research management style has shifted from one driven primarily by scientific developments and individual researchers to one in which NIH staff cooperate with the research community through the planning process and, on this basis, take a more active role in setting research priorities and developing new research areas. Concomitantly, most of the institutes have switched from a research mechanism-oriented internal structure to a program-oriented one.

To respond to health needs without changing its organizational structure, NIH must improve its ability to:

- sense the emerging concerns of the public, the research community, and Congress;
- ensure through research planning that the emerging needs are addressed by NIH's research program;
- respond to the identified needs with activities matched to the magnitude and urgency of the demand (pp. 16-19).

The committee believes that NIH is now at a stage where there should be a presumption against additions at the institute level because such changes (1) fragment the scientific effort and diminish effective communication with key scientists in other institutes, (2) add to the burden and difficulty of effective program coordination by the NIH Director and his top staff, and (3) add to administrative costs without ensuring increased appropriations. There may, however, be circumstances in which organizational change is necessary, and it is important to recognize those circumstances.

The committee recommends that there should be a formal process to assess proposed major organizational changes in NIH and to interpret the need for change from a broad perspective (pp. 20-21). To focus the debate about the costs and benefits of new institutes, the committee recommends five criteria to be considered in evaluating proposals for organizational change:

1. The activity of a new institute or other organizational entity must be compatible with the research and research training mission of NIH. If a major emphasis of the proposed new entity is in regulation, in the delivery of services, or in other non-research activities, it is not appropriate for incorporation in NIH (p. 21);
2. It must be demonstrable that the research area of a new institute or other major organizational entity (defined either as a disease or health problem, or as a biomedical or behavioral process related to a health problem) is not already receiving adequate or appropriate attention (p. 22);
3. There must be reasonable prospects for scientific growth in a research area to justify the investment in a new institute or other major organizational entity (p. 22);
4. There must be reasonable prospects of sufficient funding for a new institute or other major organizational entity (p. 23);
5. A proposed change in the NIH organizational structure should, on balance, improve communication, management, priority setting, and accountability (p. 23).

NIH AND THE HEALTH POLICY ENVIRONMENT

Since NIH was formed, scientists have widened their view of the determinants of health. At the same time, the federal government's role in health care and related activities has expanded. Accordingly, health research that is broader than traditional biomedical research is increasingly regarded as crucial to the nation's well-being. Thus, the role of NIH and the functions in its mission have come under frequent examination. In recent years, for instance, there have been proposals to create in NIH new institutes for disease prevention and nursing research, and to transfer into NIH existing agencies concerned with research on occupational safety and health, health statistics, mental health, and the provision of health services. Such organizational changes would expand the boundaries of the NIH research mission, and perhaps involve NIH in the provision of health services and research in support of regulatory activities. Because of the complexity of the individual cases it was not possible for the committee to decide

whether the nation's needs would be best served by expanding NIH's mandate to include particular areas, by having these areas addressed by other agencies, or by devising improved methods of coordinating functions that inevitably cut across organizational lines. The committee believes that such boundary issues and the challenges of improved coordination and priority setting are crucial both for NIH and for the integrity of the federal health structure, and that there must be a mechanism to investigate these matters systematically and to propose workable solutions.

For many years Congress has been highly supportive of NIH and its mission, and also deeply involved in shaping its research priorities in broad terms. Over time, however, the nature of the relationship between NIH and Congress has changed. A once close working relationship that approached a unity of purpose has diffused to a state in which different parts of Congress, both subcommittees and individuals, exercise a multiplicity of often uncoordinated controls.

Additionally, in response to constituent pressures and sometimes because of a perception that NIH would not initiate action on its own, Congress often has proposed new institutes or other organizational changes to emphasize particular diseases or health problems. NIH has consistently opposed these changes and thus has acquired an image of being opposed to innovations proposed from outside the agency. Organizational changes should not be the only means, or even the primary means, of implementing changes in research priorities. Therefore, there should be an effective mechanism for judging the need for organizational changes as a means of addressing priorities, using the criteria suggested above, and for suggesting appropriate alternatives.

In order to accommodate changes in the policy environment of NIH the committee recommends that a Health Science Board be established within the Department of Health and Human Services to provide oversight for the health research organizations of the Public Health Service. This board would regularly review the missions of the respective units, study and advise the Secretary through the Assistant Secretary for Health on the desirability of any proposed change in organizational structure, and publish an annual report. To increase its prestige and sense of responsibility, to ensure the expertise of its members, and to promote consensus rather than representation of special constituencies, the board would consist of six distinguished scientists and laymen, appointed by the Secretary of Health and Human Services from a slate nominated by the Assistant Secretary in consultation with the National Academy of Sciences and the National Academy of Public Administration (pp. 26-29).

ENSURING A MANAGEABLE STRUCTURE FOR NIH

The NIH has evolved a complex, cross-cutting organizational structure that represents health needs through a system of categorical institutes and scientific priorities through disciplinary study

sections. This structure introduces a creative tension between external needs and scientific autonomy that eventually leads to more productive and useful research. However, there will always be some research areas, both basic and applied, that cross institute lines. Therefore, the activities of the individual institutes need to be coordinated to ensure coverage of all essential research areas and to oversee the organizational evolution of NIH as a whole.

The Office of the Director of NIH is the logical locus for a central coordination activity at NIH. To strengthen the Director's authority, and thereby increase the overall responsiveness of NIH to public concerns, the committee recommends:

The Secretary of Health and Human Services should delegate to the Director of NIH the authority, direction, and control over NIH that the position does not now possess, subject to the policy direction of the Assistant Secretary for Health and to existing statutory limitations, as recommended to be modified below (p. 31);

The Director of NIH should have greater budgetary authority and discretion in two regards: (1) a discretionary fund, not to exceed 1.0 percent of the NIH budget, with which to seed selected areas through existing institutes in accordance with a rigorous peer review process; and (2) limited authority to transfer up to 0.5 percent of the NIH budget across institute lines in response to a public health emergency (p. 32);

The current Director's Advisory Committee should be converted to a stronger and more independent NIH Policy and Planning Council to provide for the Director a continuous evaluation of the research mission and function of NIH, and to advise the Director in the formulation of long-term plans and in setting research priorities (full text on pp. 32-33);

Extramural research and intramural research (and the related support activities of each) should be grouped under two deputy NIH directors each of whom has line authority over support functions outside of individual institutes and staff responsibility for extramural and intramural research programs; and that the staff functions in the Director's office should be reorganized to improve span of control (p. 34).

Where appropriate, support functions of individual institutes and other components should be clustered to reduce unnecessary duplication and expense (pp. 34-35).

To facilitate public and scientific accountability, the committee recommends:

Each institute should provide its National Advisory Council members with full and easily understandable information on its entire portfolio of currently funded grants and grant proposals; institute directors should more uniformly involve their advisory councils in broad program and policy issues (pp. 35-36).

The NIH Director should assume overall responsibility for informing members of each institute's Board of Scientific Counselors of that institute's response to its recommendations about intramural research (p. 36).

The role and staffing of the Office of Communications should be strengthened (full text on p. 37).

To ensure the quality and independence of the scientific advice rendered to NIH, the committee recommends:

Quality should continue to be the overriding consideration in selecting all NIH advisory group members--scientific, clinical, and lay. The expertise of the advisory groups must be of the highest possible quality if they are effectively to fulfill their statutory responsibilities and to have credibility within the scientific community, with Congress, and with the public at large. Further, every effort should be made to reduce the levels of review and to expedite the selection process, so that advisory groups can always function at full strength. (p. 37)

Chapter 1

INTRODUCTION

The National Institutes of Health (NIH) has earned a reputation for excellence in the support and conduct of research to improve the health of the American people. It has maintained its leadership position in the international scientific community even in the face of considerable changes in its political and social environment. But pressure continues to mount for change in the mission and organizational structure of NIH. The future success of NIH depends on it and the rest of the Public Health Service adopting a more unified and coordinated approach to meeting the nation's health research needs.

THE MISSION OF NIH

Any study of the organizational structure of the National Institutes of Health must begin with its mission. The simplest and most complete statement of that mission can be found in one of its own publications:

> The mission of the National Institutes of Health (NIH) is to improve the health of the people of the United States by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease.
>
> NIH accomplishes this mission by:

- supporting research in universities, medical schools, hospitals, and research institutions in this country and abroad;
- conducting research in its own laboratories and clinics;
- supporting training for promising young researchers;
- helping to develop and maintain research resources;
- identifying research findings that can be applied to the care of patients, and helping to transfer such advances to the health care system;

- promoting effective ways to communicate biomedical information to scientists, health practitioners, and the public; and
- developing and recommending policies related to the conduct and support of biomedical research.[1]

Efforts by NIH to fulfill this mission have brought it recognition as an extraordinary national resource. In every recent session of Congress, however, bills have been introduced to change the organizational structure of NIH. Proponents of such changes see them as a way to enhance research in neglected areas. Opponents see them as administratively costly and scientifically ineffective. They fear that these changes, combined with funding limitations, could diminish the agency's flexibility to respond to emerging research opportunities.

The mission of NIH demands that its leaders pursue two principal objectives: (1) to be responsive to health needs, achieving reductions in the burden of illness by capitalizing on scientific opportunities, and (2) to promote basic science and maintain standards of scientific excellence. Although it sometimes seems that these two objectives are contradictory rather than complementary, such is not the case. Both must be pursued with equal vigor, creative leadership, and hard work if the NIH is to continue its successful record.

The task of this committee, as we see it, is to provide guidance for the pursuit of these two objectives. This report examines procedures and institutional patterns to meet these objectives and recommends criteria to guide the organization's further evolution.

THE ORGANIZATIONAL STRUCTURE OF NIH

The genius of the institution in shaping scientific excellence to health needs is found in the interplay between the categorical research institutes and the disciplinary study sections. A complete description and analysis of this structure appear in Appendix B. None of the research organizations that we have investigated in the United States or abroad has a more effective structure for mobilizing scientific research against disease.

“Categorical” refers to the fact that most of the research institutes at NIH are focused on a category of disease or health problem and have both clinical and basic research components. Because of their association with diseases, the institutes provide for two-way communication with Congress and the public. They enable Congress to appreciate the accomplishments of the institutes and to understand and support their further goals. At the same time, the structure enables Congress to express public concerns and priorities about the need for research on current health problems. One important exception to this categorical organizational plan is the National Institute of General Medical Sciences, which has the vital

responsibility for supporting basic biomedical sciences, such as molecular biology and genetics, that do not fit fully into any of the categorical institutes.

The other part of the organizational plan is a set of disciplinary study sections, independent from the institutes, that review research grant applications for scientific merit, as described in Appendix B. The peer review study sections ensure that the best available scientific talent and ideas are brought to bear on the problems identified through the categorical institutes, and that the source of future scientific results--basic research--is continually replenished. In many ways, the study sections are the glue that holds the categorical system together.

In addition, NIH has a strong intramural research program that is managed by the categorical institutes with effective NIH-wide coordination and scientific communication. This program complements the categorical/disciplinary extramural program of the institutes and provides attractive opportunities for scientists in basic and applied research, thus enabling NIH to recruit and retain the best scientists and scientific managers. NIH also relies on advice from highly qualified external scientists, especially those on the study sections and other advisory committees. These scientists and managers transform a structure that would appear unwieldy to a management analyst into an effective means for simultaneously furthering scientific excellence and being responsive to the needs of society.

This gamut of research notwithstanding, NIH is repeatedly confronted by those who seek more research results that will have practical applications. In the past four years alone, there have been proposals for at least eleven new institutes at NIH, with three of these proposals introduced as legislation.[2] There also have been at least four legislative proposals to transfer existing agencies into NIH.[3] And Congress continues to consider modifications of the legislative basis of the NIH mission and authority.

RECOMMENDATIONS

In order to preserve and enhance an effective and appropriate organizational structure the committee makes recommendations in three areas. Chapter 2 analyses the effect of major organizational changes in the past and recommends both a process and a set of criteria to guide future changes. Chapter 3 explores the NIH relationship with the rest of the Department of Health and Human Services and with Congress and the public, and describes a mechanism to ensure that NIH and the other agencies of the Public Health Service are making adequate contributions to the nation's health research effort. Finally, Chapter 4 analyzes the internal organization of NIH, including structures for dealing with issues that cross institute lines, and suggests a series of measures to ensure a manageable structure for NIH and its overall responsiveness to health needs and scientific opportunities.

Chapter 2

ORGANIZATIONAL EVOLUTION

GROWTH AND ORGANIZATIONAL CHANGE

NIH has experienced phenomenal growth in the past four decades. Its budget has grown from $1.3 million in 1943 to almost $4.5 billion in 1984,[4] and the number of its employees has grown from slightly over 1,000 to over 16,000 during the same period.[5] The number of extramural research grants made by NIH went from 79 in 1946 (the first full year in which NIH had authority to make external grants for research) to about 20,000 in the 1983 fiscal year.[6] Few, if any, other federal agencies have enjoyed such a rapid and sustained rate of growth.

Growth necessarily brings increasing organizational differentiation into institutes, divisions, and so forth. At NIH such change has generally taken the form of categorical institutes, organized around a particular health problem or issue. Beyond the concept of categorical institutes, NIH has never had a systematic design for its organizational development. As the nation's concern for health research grew in the years after World War II, Congress and the Executive Branch created new institutes to cover major areas of human disease.[7] As a result, NIH now has four bureaus, eleven research institutes (three of which are counted among the bureaus), and six other research and support divisions.[8] Appendix B describes the relationship among these entities more fully. The foci of the research institutes are anything but uniform: some are diseaseoriented (Cancer; Neurological and Communicative Disorders and Stroke; Arthritis, Diabetes, and Digestive and Kidney Diseases; Allergy and Infectious Diseases), others are anatomical (Heart, Lung and Blood; Dental; Eye), others relate to stages in human development (Child Health and Human Development; Aging) and still others have broad themes (Environmental Health Sciences; General Medical Sciences). This mixture does, however, allow NIH to cover all important research areas and simultaneously accommodate public interest in particular health issues.

In this categorical system, the public, acting through Congress, can indicate broad priorities among health problems for which they want research answers. NIH and the scientific community then determine how to address these public desires scientifically. In addition, the scientific community, operating on the basis of perceived opportunities, also influences the direction of research programs. The committee believes that the interplay of categorical

institutes and disciplinary study sections introduces a creative tension between national needs and scientific autonomy that leads to productive and useful research. This balance between apparently opposing factors has had a great deal to do with NIH's well-deserved reputation for excellence, as well as with the countless contributions to the public's health that can be traced to the efforts of NIH. However, if the tension between these forces is too great it can impede rather than stimulate; if it is unrelenting it becomes wearing rather than inspiring. The balance is a delicate one, and attempts to shift it markedly in one direction or the other are likely to yield less, not more, valuable results.

One consequence of a categorical system is that demands for increased emphasis in particular areas often turn into proposals for changes in the NIH organizational structure. Between 1943 and 1968, the total appropriations for NIH grew from $1.3 million to $1.1 billion.[9] This is nearly a thousand-fold increase, and constitutes an average growth rate of 27 percent per year. (Even with an adjustment for inflation, the average growth rate during this period was 24 percent.[10]) Since then growth has slowed, but compared with other federal research agencies, NIH continues to receive close attention and strong financial support from Congress. Its 1984 appropriation was $4.5 billion, contributing to an average annual growth rate of 9 percent (2 percent after adjustment for inflation) between 1968 and 1984.[11] As the overall rate of growth slowed, pressure increased for more activity in particular areas. In response to public interest, members of Congress and others continue to propose new institutes or other organizational changes. Since 1970, there have been at least 23 new institutes proposed for NIH, 13 through the legislative process and 10 by other means.[12]

Although many institutes were proposed, only three new ones have been added to NIH since 1968. NIH has thus acquired an image of being opposed to innovations proposed from outside. However, many of the proposals have led to major alternative organizational changes: three institutes changed their title and mission (twice each), and three institutes were granted bureau status.[13]

The committee believes that the current structure is sufficiently flexible to respond to most needs. However, the time has come to articulate an attitude about responsiveness to national health needs and to define a process and a set of criteria for future organizational growth and change. Before doing so, it is important to understand as fully as possible the effect of organizational change on research budgets and research programs.

Overall NIH Appropriations

Since the 1930s, NIH has seen the establishment of many new institutes and divisions. These entities grew out of existing institutes, were transferred into NIH from elsewhere, or were built up from the start. In addition, existing institutes have changed their

names, their research focus, and have had their organizational status upgraded. Figure 1a shows the total NIH appropriation in the years 1940 through 1982. It also shows when new institutes were added and other organizational changes (new divisions, name changes, elevation to bureau status) took place. Figure 1b shows the same data, but on a logarithmic scale. On this scale, exponential growth appears as a straight line, and the details of NIH's early budgetary history are easier to see.

Because the effects of organizational and budgetary changes are difficult to isolate in a single year, it is best to analyze longer periods of growth and organizational change. The figures indicate that there have been three phases in the growth of NIH. During the late 1940s many new institutes appeared and the budget grew dramatically. Between 1955 and 1965 there were few organizational changes but the budget again grew dramatically. Since then there have been many more organizational changes but less growth. Thus, there is no evidence that the addition of new institutes and other organizational changes, in themselves, have led to increased budgetary growth for NIH as a whole.

There may seem to be one exception to this conclusion. Between 1971 and 1973, the NIH budget grew by more than 40 percent in constant dollars. This growth was concentrated almost exclusively in the appropriations for the National Cancer Institute (NCI) and the National Heart and Lung Institute (NHLI), and coincided with the National Cancer Act of 1971 and the National Heart, Blood Vessel, Lung, and Blood Act of 1972. It is important to note that this legislation did not create new institutes but rather raised the status of existing institutes to bureaus, gave them expanded responsibilities, and made them subject to periodic reauthorization.

Appropriations for the Affected Institutes

The committee has examined whether there is a cause and effect relationship between creation of new institutes or elevation to bureau status and funding patterns. While we could not find conclusive evidence of such a relationship, we report the following observations.[14]

The longest period of sustained relative growth for a new institute occurred for the National Institute on Aging (NIA), which has grown faster than the remainder of NIH in every year since its first appropriation in 1976. NIA's growth did taper off, however, from an average annual differential (between it and the rest of NIH) of 22 percentage points between 1976 and 1980, to 6 percentage points between 1980 and 1984. Between 1976 and 1980, the National Eye Institute (NEI) and the National Institute of Environmental Health Sciences (NIEHS) also grew at a rate substantially above the remainder of NIH. Although these three are the most recently established institutes, NIEHS and NEI were, respectively, eight and nine years old in 1977. Thus, the relative increase in the NIEHS and NEI budgets,

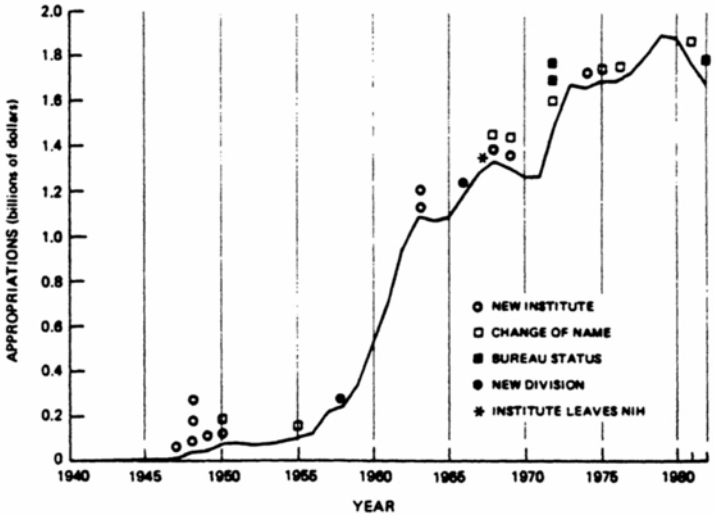

FIGURE 1a. Total congressional appropriations for NIH (excluding all programs that were eventually transferred out of NIH), in 1972 dollars, from 1940 to 1982. The occurrence and nature of major organizational changes are also indicated. The two new divisions noted are those that later became institutes.

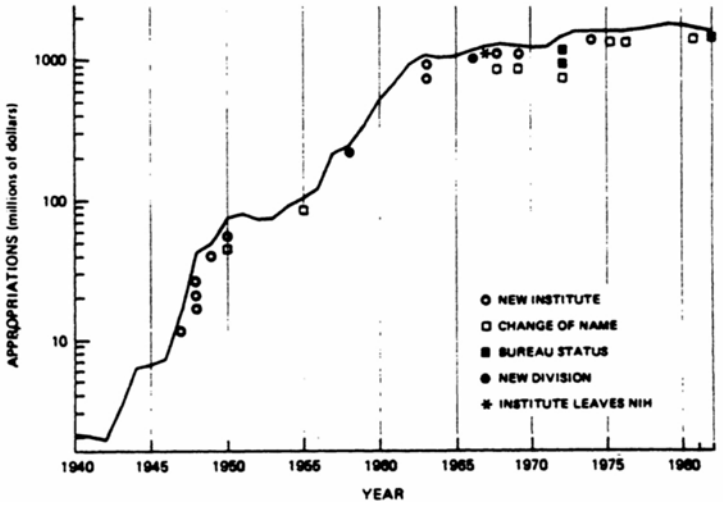

FIGURE 1b. The same data represented on a logarithmic scale.
SOURCE: Calculated from data in the 1983 NIH Almanac.

and perhaps the NIA budget as well, probably reflected increased Congressional interest, but was not necessarily related to their "newness."

Because reliable figures are not available for comparable research expenditures in the area of a new institute before it was established, it is impossible to measure the full effect of establishing a new institute on the funding of research in the affected field. However, the effect of establishing a new institute out of a previously existing one can be portrayed. Figure 2 shows that NEI, which was split off from the National Institute of Neurological Diseases and Blindness in 1968 (but did not have its own budget until 1970), grew faster than the rest of NIH for only one year. The "remainder" institute, which is now called the National Institute of Neurological and Communicative Disorders and Stroke, grew more slowly than the rest of NIH for four years. The total of the two grew more slowly than the rest of NIH for six years. In the case of NIA, Figure 3 shows that the new institute grew faster than the rest of NIH, but the remainder institute, the National Institute of Child Health and Human Development (NICHD), grew at about the same rate as NIH during the same period. The total of the two grew faster than the rest of NIH.

NCI provides one example of an organizational change--elevation to bureau status--that was associated with a major redistribution of funds within NIH. In the years before and after the National Cancer Act, NCI grew relative to the rest of NIH. Since 1976, however, it has been shrinking relative to the rest of NIH. This can be seen in Figure 2 and Figure 3 as a general tendency for the other institutes to exhibit negative relative growth in the early 1970s and positive relative growth in later years.

In summary, although there have been substantial changes in the distribution of funds within NIH, the committee finds no evidence of a consistent, sustained causal effect of organizational changes on the distribution of the budget.

The Effect on Science and Management

The remaining question is the extent to which different organizational forms facilitate the NIH objectives of maintaining scientific excellence and being responsive to the needs of society.

It is extremely difficult to assemble objective data on the impact of new institutes or other organizational changes on the scientific productivity and the generation of health research in these fields. The health research enterprise is extraordinarily complex, with extensive interaction between different fields and interdependence of developments in basic science that emerge from laboratories of all disciplines. As a result, even a thorough analysis of the research output of an institute could not give an unequivocal picture of its precise contribution to the research advances. The difficulties may be insurmountable in trying to achieve cause-and-effect conclusions.

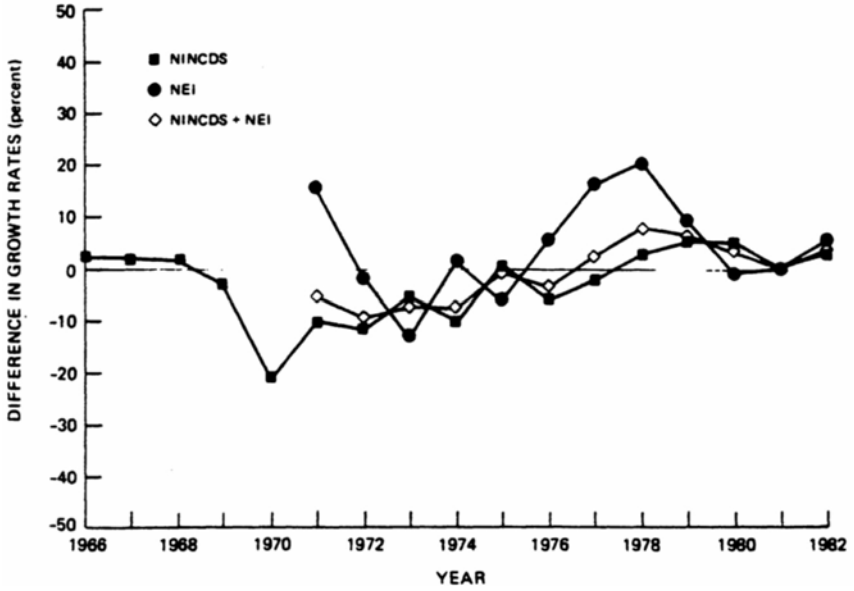

FIGURE 2: Differential growth rates of congressional appropriations for the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and its predecessors, the National Eye Institute (NEI), and the total of the two, 1955-1982, in 1972 dollars. The figures represent the annual growth rate of the given institute minus that of the rest of the NIH.

SOURCE: Calculated from data in the 1983 NIH Almanac.

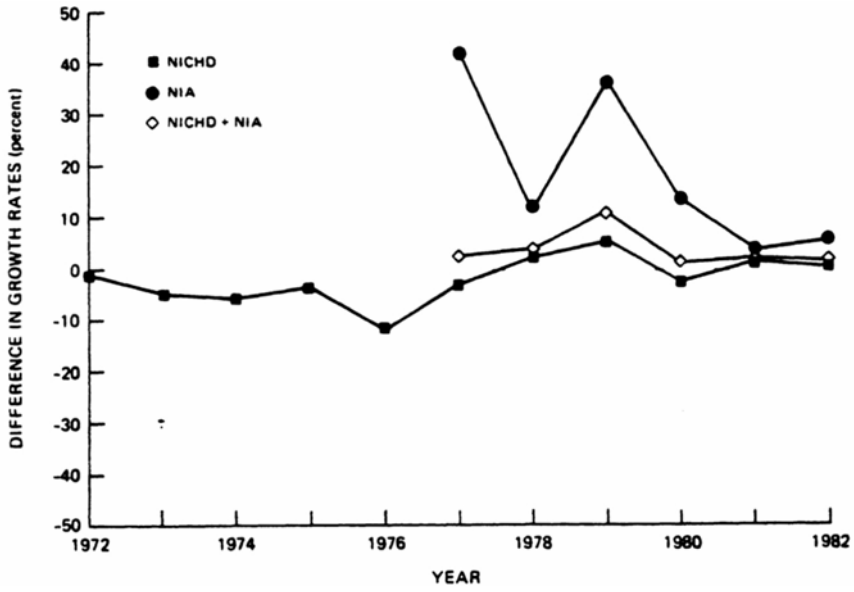

FIGURE 3: Differential growth rates of congressional appropriations for the National Institute of Child Health and Human Development (NICHD), the National Institute on Aging (NIA), and the total of the two, 1965-1982, in 1972 dollars. The figures represent the annual growth rate of the given institute minus that of the rest of the NIH.

SOURCE: Calculated from data in the 1983 NIH Almanac.

Based upon the best evidence available, however, the committee concludes that establishing a new institute at least has not hampered the scientific effort, and may have helped it considerably.

The National Eye Institute appears to be an example where the creation of a new institute had major qualitative effects on the research field. For example, by expanding the intramural vision research program and developing workshops and programs emphasizing an interdisciplinary approach to visual disorders, the NEI has significantly expanded the scope of vision research to encompass developments in such areas as immunology and molecular biology. And by attracting eminent epidemiologists and statisticians, the NEI was able to expand epidemiological vision research efforts which led to advances in the evaluation and demonstration of effective treatments for diabetic retinopathy and macular degeneration, two of the leading causes of blindness in the United States.[15]

On the other hand the establishment of the Lung Division and the addition of "Lung" to the title of the National Heart Institute led to similar effects without establishing a new institute. Through a series of actions taken to increase the visibility of and resources for this area, lung research was transformed from a relatively undeveloped area into a thriving one that underwent a scientific revolution in the 1970s.[16] Frommer characterizes this as a shift from "studying the lung simply as a bellows and gas exchange organ to studying it as a complex physiological organ involved in numerous other processes and to studying it at the cellular and subcellular levels and also by biochemical, immunological, and other techniques."[17] In the case of the Lung Division, a major reason for the successful outcome was the active cooperation of institute leadership with the forces urging greater attention and resources for lung research.

What both of these cases had in common was a scientific readiness for major advances and dynamic leadership from committed individuals with a vision for the field. These elements, together with increased resources and visibility, may be more critical to scientific progress than institute status itself.

RESPONDING TO NEEDS AND OPPORTUNITIES

In the last decade the research management style of NIH has shifted from one driven primarily by scientific developments and individual researchers to one in which NIH staff cooperate with outside scientists in a planning process and, on this basis, take a more active role in setting research priorities and developing new research areas.[18] Although the planning process varies from institute to institute, as described in Appendix B, it generally involves interactions with the larger research community to determine promising research possibilities.[19] The institutes then stimulate activity in those areas through requests for grant applications, contract proposals, and other means. The goal is to plan the research environment, not specific research projects. All applications and proposals are

reviewed by scientific peers. Close interactions both with the public and the scientific community have enabled NIH to structure scientifically appropriate and effective research programs that expand basic research and attack specific health problems.

Two examples suffice to illustrate this point. In genetics research, the early efforts of NIH were driven almost exclusively by scientific opportunities and were oriented toward grants for basic research. But as the promise of this field grew in the minds of clinical researchers and the public, the program staff developed a portfolio of activities linking basic scientists and clinicians. The main focus remained on investigator-initiated research grants, but the staff, with advice from external advisors, became more active in stimulating proposals in needed areas and in developing a short-term research contract program to complement the grant program.[20] The Sudden Infant Death Syndrome research program, which was established because of public concern about "crib death," illustrates a similar approach to a more applied problem. In this case, NIH program staff worked with the scientific community to develop a research agenda and draw more scientists into the field, and worked with the public to develop educational programs and to develop support for basic research in the field.[21]

Simultaneously, most of the institutes have switched from an internal structure organized around research mechanisms to one organized around research programs.[22] Before the 1970s most institutes had divisions or offices of intramural research, research grants, research contracts, and so on. But partly as the result of an internal study completed in 1973, most institutes have since adopted a program-oriented structure.[23] The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, for instance, now has divisions corresponding to each of the disease groups in the title, and under them nine branches in rheumatic diseases, musculoskeletal diseases, skin diseases, diabetes, endocrine and metabolic diseases, digestive diseases, nutrition, kidney and urologic diseases, and blood diseases. This program orientation enables coordinated efforts in identified research areas, committed and accountable program leadership, and organizational responses below the institute level.

As is argued below, NIH now is at a stage in which the addition of new institutes tends to be a costly and inappropriate way to implement changes in research priorities. As discussed above, however, a shift in organizational emphasis now enables NIH to respond to health needs and scientific opportunities without resorting to major organizational changes. The committee believes that all of the components of NIH, and especially the Director's office, must adopt an active approach and a visible mechanism for assessing and responding to needs and opportunities when they first arise. Such an approach, suggested in the following set of recommendations, should reduce sharply the need for new institutes and perhaps the pressure for them.

Sensing the Need for Action

The committee recommends:

The Director of NIH should establish an NIH-wide mechanism to (1) keep abreast of the views, concerns, and proposals of the NIH scientific and public constituencies; (2) assess their potential implications for NIH and its functioning; and (3) plan responses.

NIH has numerous points of contact with its constituencies, but no office at a high level whose primary job is to monitor the emerging concerns and demands for more focus, greater investment, or faster progress in particular areas of health research.

The individual or office charged with this surveillance function should keep track of scientific developments and public perceptions so as to alert the Director when strategies of response are required. This mechanism would allow NIH to seize the initiative in interacting with the external world, rather than simply reacting to its pressures.

Research Planning

The committee recommends:

NIH should strengthen its planning efforts, particularly at the institute level and in the coordination of NIH-wide activities.

Having sensed a need or an opportunity, NIH must ensure that it is addressed. Program planning provides a means for doing so.

Overall NIH planning involves the Director, his planning staff, and the individual institute directors. In addition, each institute has its own planning process, responsive both to its own needs and also to a common NIH process. However, the involvement of extramural scientists, Congress, and the public in the planning process is still uneven.

The planning process can be strengthened in a number of ways. Effective planning must obtain and rely on the views of the scientific community and the public, and be linked with budgeting. At the institute level, national advisory councils and boards of scientific counselors must be involved. By now, each of the institutes has developed its own unique planning process; each should examine and benefit from the successes of others. At the NIH level, there should be better planning and coordination of research activities that cross institute boundaries.

Range of Effective Responses

The committee recommends:

NIH should avail itself of a range of activities, short of establishing new institutes, to respond to health needs and opportunities.

NIH has at its disposal a continuum of possible responses to the needs and opportunities it identifies, matched to the magnitude and urgency of the demand. Proponents of new institutes often are not aware of these options, and should explore them carefully. Some examples of these responses are:

- publicizing what scientific research has accomplished, and the status and promise of current research in the area;
- disseminating the results of research widely to centers that can make immediate clinical use of them;
- accelerating research by such means as soliciting applications for grants, scheduling special peer review sessions, appointing special study sections, and utilizing "high relevance scores" for applications in the area concerned;
- holding major conferences of the leaders of the scientists and practitioners concerned to exchange ideas and discuss future actions, and in appropriate situations, creating such groups by action of the Secretary, or the White House, or by joint action with Congress;
- naming special panels or subcommittees of the national advisory councils, boards of scientific counselors, review committees, and study sections, as appropriate, to examine both extramural and intramural programs and opportunities;
- forming an NIH-wide or inter-agency committee, preferably led by an institute director, to coordinate and develop research in the area;
- providing higher visibility and stronger leadership over the area of concern by organizational upgrading; for example, elevating sections to branches, branches to programs, or programs to divisions.

THE BASIS FOR MAJOR ORGANIZATIONAL CHANGE

The evidence about the effect of organizational change and therefore about its desirability, as we have seen, is mixed. Many of the changes in the past have been successful. The committee believes, however, that NIH has reached a point at which there should be a presumption--to be overridden only in exceptional circumstances-against additions at the institute level, whether they are proposed to occur by fission or by transfer from outside NIH. Although a particular research area may benefit from the establishment of a new institute, the overall manageability of NIH suffers from the cumulative effect of such additions. This is because new institutes (1) fragment the scientific effort and diminish effective communication with key scientists in other institutes, (2) add to the burden and difficulty of effective program coordination by the NIH Director and his top staff, and (3) add to administrative costs without ensuring increased appropriations. Furthermore, as discussed above, there are effective alternatives to establishing new institutes. Organizational structure has implications for long-range institutional dynamics, so thought must be given before any research area is singled out for increased organizational attention.

On the other hand, there have been cases in the past in which organizational changes have brought new vitality to a scientific field, and there are likely to be such cases in the future. The committee is not opposed to major organizational changes, but believes that such measures should be taken sparingly. Of the many proposals for new institutes, only a small fraction are likely either to be necessary or appropriate. Therefore, the committee proposes the following process and set of criteria for assessing the need for major organizational changes.

A Process to Assess Proposed Organizational Changes

The committee recommends:

There should be a formal process to assess proposed major organizational changes in NIH.

This process must involve the entire range of interested parties. Proposals for institutional change always have emerged, and will continue to emerge, from a number of different sources. NIH should consider them all seriously. As part of any request for institute status there should be documentation that the appropriate alternative mechanisms for meeting perceived needs have been explored and were found to be inadequate. All proposals should be analyzed at a level of broader perspective than that of NIH to encourage and focus the debate along the lines of the criteria stated below, to evaluate the arguments presented by NIH and the various interested parties, and to analyze the pros and cons for decision makers in the Administration

and Congress. To serve this as well as other purposes, the next chapter recommends the establishment of a Health Science Board in the Department of Health and Human Services.

An entity outside of NIH would be especially important in considering proposed transfers into or out of NIH. These cases must be examined from three perspectives: that of NIH itself, that of the entity that is proposed to be moved, and that of the overall strategy of the Public Health Service for improving the nation's health. No single agency, or advisory board associated with a single agency, would have the broad perspective and the public credibility that are needed to address transfer issues.

Criteria to Assess Proposed Organizational Changes

The criteria described below identify a set of issues to be addressed in the discussion about the need for a new institute or other major organizational change in NIH. Only when most of these factors are positive are the benefits from the creation of a new institute likely to exceed the costs. Because the decision must reflect an assessment of the organizational costs and benefits of a proposed change, and because the particulars of every individual proposal are complex, it is not possible to develop simple formulas to determine the need for change. Instead, the criteria must be adapted to the situation and interpreted. The Health Science Board described in the next chapter can provide such judgment.

1. The activity of a new institute or other organizational entity must be compatible with the research and research training mission of NIH. If a major emphasis of the proposed new entity is in regulation, in the delivery of services, or in other non-research activities, it is not appropriate for incorporation in NIH.

These considerations would be most clearly applicable to the case of a proposed transfer into NIH of an existing function currently located elsewhere in the Public Health Service, or of a proposed new institute. In either event, the formal statement of mission would have to be consistent with the overall mission of NIH. One reason for this criterion is that activities do not flourish unless they exist in a supportive environment. Another is that the need to manage non-research activities necessarily distracts the attention of the NIH leadership from the primary mission of NIH, that of research. The National Institute of Occupational Safety and Health, which currently has significant direct and indirect responsibilities in support of regulatory activities, for example, does not match the NIH research mission. Similarly, the major service mission of the National Institute of Mental Health was a critical factor in its removal from NIH in 1967.[24]

2. It must be demonstrable that the research area of a new institute or other major organizational entity (defined either as a disease or health problem, or as a biomedical or behavioral process related to a health problem) is not already receiving adequate or appropriate attention.

As a case in point, calculations of the burden of illness associated with arthritis formed one of the main arguments used by proponents of the National Institute of Arthritis and Musculoskeletal Diseases. These calculations include the number of people affected by the disease and economic costs such as medical expenses, disability payments, and loss of earning power. In arguments for institutes focused on other diseases, mortality statistics (annual number of deaths attributable to the disease, years of life lost, and so on) are often cited.

The problem with such arguments is that, although they often sound convincing in particular cases, they are extremely difficult to construct on a consistent basis across all institutes and disease groups. First, the burden of illness includes mortality, morbidity, economic impact, and quality of life; diseases have differential impacts on each of these components. Furthermore, there are many ways to measure each of the components, and some are obviously more favorable to the argument than others. Second, even if there was a unique index of the burden of illness, resources probably should not be allocated strictly on this basis. According to economic theory, to maximize the overall benefit, resources ought to be allocated so as to equalize the marginal benefit of the last dollar spent on each of the alternatives. Such a calculation, if it could be made, would have to include the scientific potential of a field and the potential reduction in the burden of illness (not the total burden). Thus, comparative calculations are extremely difficult, and probably cannot be done for one institute at a time.

3. There must be reasonable prospects for scientific growth in a research area to justify the investment in a new institute or other major organizational entity.

Critical mass arguments cut both ways. In the case of vision research, proponents of a new eye institute claimed that the scientific personnel and research ideas already existed, but were not getting enough attention.[25] The National Institute on Aging, on the other hand, was established, in part, in order to develop a cadre of researchers on aging, and personnel development continues to be one of the institute's top priorities.[26]

The committee feels that the research area to be emphasized must have a potential for growth, both in terms of the underlying science and in the number of scientists whose efforts could profitably be directed toward the area. This does not mean that the research ideas have already been fully worked out or that there already exists a critical mass of scientists working in the area. It simply means that upgrading the organization is likely to promote such growth.

4. There must be reasonable prospects of sufficient funding for a new institute or other major organizational entity.

Organizational upgrading involves the creation of new functions and positions, and so must require additional funds for administration. Such additional funds must be regarded as the price to pay for the benefits of the new organizational structure, and thus should not come out of research budgets. Furthermore, although budgets are set on a yearly basis, there must be reasonable prospects for adequate long-range financial support, if scientists are to shift their research interests.

5. A proposed change in the NIH organizational structure should, on balance, improve communication, management, priority setting, and accountability.

Organizational changes that are intended to focus and enhance the effort of NIH in one area, especially those that divide existing institutes into component parts, necessarily interfere with communication and research management in other areas. Thus the need for visibility and focus must be balanced against the need for a broad-based approach that enhances scientific communication and allows research areas to cross-fertilize each other. Research on the lung, for instance, has much in common with research on the heart and blood, and thus there are substantial benefits from the continuing integration of these research areas in one institute.

Organizational structures define the trade-offs in the budget process, and thus have an important impact on priority setting. In this respect, an organizational change is an improvement if it leads to a more appropriate set of trade-offs, for instance, one in which the alternatives are different scientific approaches toward the same health goals. In addition, because institute appropriations are determined outside of NIH, narrowly defined institutes may lead to excessively detailed external control.

Similarly, organizational structures define the loci of authority and accountability. Creating a new institute involves establishing a potentially powerful new institute director who can be held accountable for progress in the new field. But at the same time, it dilutes the authority necessary for managing NIH's overall research program.

Prevention research provides an example of the importance of this final criterion. Because of a perceived need to strengthen prevention research, some have proposed the creation of a separate National Institute of Public Health in NIH. The problem with such a proposal is that prevention research is and should be an essential part of every institute's research mission. Establishing a new institute would disrupt critical lines of communication between population-based and laboratory-based researchers working on the same problems. It would create inappropriate budgetary trade-offs between budgets for “prevention” and “disease-specific” research rather than between population-based and laboratory-based approaches toward the same goals. And finally, it would tend to absolve the other institutes of responsibility for prevention research, a critical part of NIH's mission.

Chapter 3

NIH AND THE HEALTH POLICY ENVIRONMENT

THE NEED FOR COMMUNICATION AND COORDINATION

If NIH and its sister agencies in the Public Health Service are to be responsive to health needs and to promote scientific excellence, there must be clear channels of communication between them, the public, and Congress to make sure that policies are coordinated and well in tune with health research needs. Such communication has always taken place, but generally in a highly informal manner. It is now time, the committee believes, to formalize certain aspects of this process. In particular, the process must respond to changes in recent years concerning the scope of health research and governmental patterns and practices, which together have increased external pressures for organizational change within the Public Health Service.

The Scope of Health Research

Many of the most recent proposals for organizational change at NIH reflect interests in improving and strengthening research areas at the boundaries of NIH's current mission. In recent years, for instance, there have been legislative and other proposals for a National Institute of Nursing Research and a National Institute of Public Health. There also have been proposals for the transfer into NIH of the National Center for Health Services Research, the National Institute for Occupational Safety and Health, the National Center for Health Statistics, and the National Institute of Mental Health. And there have been calls for NIH to do more on technology assessment and transferring research results into practice.

These “boundary issues” share many common features. First, they are all examples of health research, broadly defined. As scientists' perceptions about the determinants of health widen, as the federal government's role in the provision of health care expands, and as the nation becomes more concerned about health care expenditures, health research that includes more than traditionally conceived biomedical research is increasingly recognized as necessary to the nation's well-being. Second, although the research mission of NIH does not totally include any of the research areas mentioned above, it also does not totally exclude them. Third, not all of these areas enjoy the same

prestige and visibility as does the biomedical research now carried out by NIH. Finally, some of the agencies proposed for transfer have regulatory or health service delivery missions that, while of great importance, are distinctly different from that of NIH.

Because of the complexity of the individual cases, it was not possible for the committee to decide whether the nation's needs would be best served by expanding the NIH mandate to include particular areas, by having them addressed by other agencies, or by devising improved methods of coordinating functions that inevitably cut across organizational lines. The committee believes that such boundary issues and the challenges of improved coordination and priority setting are crucial both for NIH and the integrity of the federal health structure, and that there must be a mechanism to assist the Assistant Secretary for Health to investigate these matters systematically and to propose workable solutions.

Governmental Patterns and Practices

For many years, Congress has been highly supportive of NIH and deeply involved in shaping its research priorities in broad terms. Over time, however, the nature of the relationship between NIH and Congress has changed.

In the 1950s and 1960s, the relationship between NIH and the public was focused in Congress by close working relationships among Senator Lister Hill, chairman of the authorization committee and the appropriations subcommittee in the Senate with authority over the budget of the NIH; Representative John Fogarty, chairman of the appropriations subcommittee in the House of Representatives; and James Shannon, the Director of NIH.[27] Public interest, to a large extent, was exerted through the long-term involvement and commitment of Mary Lasker and her associates.[28] The result was unified and organized public and congressional interest in NIH. This strong central focus depended partly on the personalities involved, but also on the way that congressional affairs were conducted in those years.

Since then, these relationships have changed. First, the members and committees of Congress now have staff numbering about 17,000, more than five times as many as in 1947.[29] This has led to increased involvement in day-to-day Executive Branch activities, and the knowledge, ability, and incentive to write very specific directives into law or legislative reports. Second, partly because of legislation enacted in the past decade, authorization committees as well as appropriations committees now have substantial impact on NIH activities. Some of the institutes, for instance, must now be periodically reauthorized by Congress. The result of these and other changes in governmental operations is that NIH management has gradually become more fragmented and less coordinated.

In response to constituent pressures and sometimes because of a perception that NIH would not initiate action on its own, Congress often has proposed new institutes or other organizational changes to emphasize particular diseases or health problems. NIH has consistently opposed these changes, and thus has acquired an image of being opposed to innovations proposed from outside the agency. Organizational changes should not be the only means, or even the primary means, of implementing changes in research priorities. Therefore, there should be an effective mechanism for judging the need for organizational changes as a means of addressing priorities, using the criteria suggested above, and for suggesting appropriate alternatives.

THE HEALTH SCIENCE BOARD

To address these changes in the NIH policy environment, and to deal with the increased pressures for organizational change documented in the previous chapter, the committee recommends:

1. A Health Science Board should be established in the Department of Health and Human Services to oversee the health research organization, missions, priorities, and institutional management of the several elements of the Public Health Service: the National Institutes of Health; the Centers for Disease Control; the Food and Drug Administration; the Alcohol, Drug Abuse, and Mental Health Administration; the Health Resources and Services Administration; the National Center for Health Statistics; and the National Center for Health Services Research.
2. On the basis of periodic reviews, the Health Science Board should advise the Secretary of Health and Human Services through the Assistant Secretary for Health on any change proposed in the organizational structure or function of these elements, such as the initiation or termination of institutes of the National Institutes of Health and of other units of the Public Health Service, or the reassignment of responsibilities among institutes and units.
3. The Health Science Board should be composed of six members appointed by the Secretary of Health and Human Services from a slate nominated by the Assistant Secretary for Health after consultation with the National Academy of Sciences and the National Academy of Public Administration.
4. Appointments should be made for a term of six years, with one-third of the board's membership replaced every two years, and the reappointment of members limited to one additional term.

5. Members of the Health Science Board should be selected on the basis of a judicious combination of scientific experience, capacity for sound judgment, and knowledge of health policy issues and the principles of public management.
6. The Health Science Board should elect its own chair, meet at least four times a year and additionally whenever requested by the Assistant Secretary for Health, be assigned its own staff and have a defined budget, and have the authority and resources to establish study groups or panels to assist it in its mission.
7. The Health Science Board should report annually to the Secretary of Health and Human Services through the Assistant Secretary for Health.

The Health Sciences Board is intended to communicate public perceptions of health research needs to the scientific establishment and to assure the public that these needs are being adequately and appropriately addressed. In particular, the board would be concerned with the boundaries of the research missions of NIH and the rest of the agencies of the Public Health Service, and with proposals for major organizational changes in those agencies.

The board's role is, in many respects, like that of the trustees or regents of a public institution. The National Science Foundation's National Science Board, the Smithsonian Institution's Board of Regents, and the regents of many state universities, for instance, are extremely effective in guiding and protecting these institutions. But unlike trustees or regents, the Health Science Board would not have the ultimate responsibility for the agencies under its aegis; this responsibility belongs to Congress and the Secretary of Health and Human Services.

The board would, however, prepare an annual report that would be carefully read by Congress and various scientific and public interest groups as well as the Executive Branch agencies. The publication of a report would make the board's views widely known, and its broad public exposure would ensure that the board members take their responsibility seriously. Six-year terms and frequent regular meetings would make them fully aware of the important health and health science issues under discussion.

Because of the proposed board's role in communicating with the public and serving as an independent review group, it is essential that its members be widely respected persons, both scientists and non-scientists. The committee feels that appointment by the Secretary of Health and Human Services is necessary to enhance the prestige and sense of responsibility of the board and its members. The members must have individual expertise as scientists and administrators, and knowledge and interest in health policy issues. Partisan political considerations should have no place in the choice of members for the

board. In order to guarantee excellence in appointments to the board, the committee recommends that the National Academy of Sciences and the National Academy of Public Administration (both of which have congressional charters and responsibilities to advise the federal government on matters within their expertise) be involved in the nomination process.

The members of the board should be capable of considering the national interest in health research in the broad sense. They should not be chosen to represent any particular group or constituency. In order to promote the development of consensus and to emphasize the fact that the members are not representatives, the committee recommends that the board have only six members.

Successful institutions tend to cling to their past successes and resist change. Periodic review by an independent outside group can help counter this tendency. In this respect, the Health Science Board could be a potent force for organizational renewal and vitality for NIH and the other agencies of the Public Health Service. The committee recommends that, to preserve its independence, the board elect a chair from among its members, and have its own budget and sufficient staff to prepare agenda and compile background materials. Many of the issues that would come before the board, such as proposals for new institutes, terminations, or transfers, require more intense and thorough attention than the board alone could provide. In such cases, the board must have the authority and resources to establish appropriate study groups or panels.

To deal with the full range of health research, the Health Science Board must be located in the Public Health Service of the Department of Health and Human Services. Many agencies and departments of the federal government have a health research mission, but much of this research--almost 80 percent in 1982--is concentrated in the Public Health Service.[30] As the list of the Public Health Service units indicates, the range of issues covered and approaches used is quite broad. And unlike other governmental departments, the Public Health Service has the improvement of health as its central mission.

For these reasons, the Public Health Service is the key locus of coordination and control of health research in the United States. But because many of the organizational issues described above concern the boundaries of the research missions of the NIH and the rest of the agencies of the Public Health Service, the committee feels that more effective coordination of their missions is necessary. The Health Science Board proposed here is intended to provide such coordination.

Organizational issues are prominent among those that involve the total mission of the Public Health Service. These include the creation of new institutes at NIH and the transfer of units or functions among the elements of the Public Health Service. Because of its broad perspective, the board would be able to provide useful and unbiased advice on such matters, and to interpret the criteria suggested in the previous chapter.

The Secretary of Health and Human Services, through the Assistant Secretary for Health, has the responsibility for managing and setting long-term policies for the Public Health Service research agencies. The board should not become involved in day-to-day management of the research agencies, but rather would advise the Secretary through the Assistant Secretary on issues that involve the spectrum of agencies of the Public Health Service on the full range of their research missions.

The Health Science Board would advise on issues that cross agency boundaries as now defined. Prevention research is one example. Research on health promotion and disease prevention necessarily includes a spectrum of approaches ranging from basic to applied, drawing on the biomedical, behavioral, and social sciences. Most of the Public Health Service agencies, including NIH, have expertise and explicit responsibilities for prevention research as part of their basic missions. Thus a single institute or agency cannot coordinate this research. But coordination is necessary, and the Health Science Board could help to ensure that the government's total approach is complete, coordinated, and appropriate.

The board is not intended to replace the current Advisory Committee to the Director of NIH, or other advisory committees in NIH or other Public Health Service agencies. These have important roles to play in overseeing the research programs of individual agencies. Instead, the board would ensure that the individual agencies are making adequate contributions to the total effort.

The committee knows of no alternative that would be more effective in serving these purposes than a board at the level of the Assistant Secretary for Health. No advisory board or other entity in any of the Public Health Service agencies would have the necessary perspective or the credibility to deal with such issues. At a level higher than the Assistant Secretary, health research is only one of many important issues, and the board's advice would not get full attention. And because of its permanence, the board would be more effective than many past ad hoc efforts to review the structure, research mission, or priorities of NIH and its sister agencies. These include many congressional investigations, the Bayne-Jones committee in 1956, the Wooldridge committee in 1965, the President's Biomedical Research Panel in 1976, the National Conference on Health Research Principles in 1978 and 1979, and the committee writing this report.

There have been proposals for similar oversight mechanisms in the past. The closest example is the President's Council for the Health Sciences, proposed by Senator Edward Kennedy in 1979. This council would have prepared for Congress and the President a five-year plan for funding health sciences research. The committee feels that the preparation of budgets is the responsibility of the officials of the Department of Health and Human Services, the Office of Management and Budget, and Congress. The Health Science Board, however, would be able to provide advice on these matters, especially on the determination of priorities among the various agencies and broad areas of health science,

Chapter 4

ENSURING A MANAGEABLE STRUCTURE FOR NIH

OVERALL COORDINATION AND ACCOUNTABILITY

The complex organizational structure of NIH--with categorical institutes and disciplinary study sections--reflects both its mission and its environment. In any institution, however, organizational arrangements designed to enhance communication along certain dimensions tend to diminish it along other dimensions. There will always be research areas, both basic and applied, that cross institute lines.

As Appendix B describes, NIH has been successful in introducing a number of coordinating mechanisms to alleviate the problem of communication across organizational boundaries.[31] The disciplinary study sections, because they cut across the categorical institutes, contribute some degree of integration and safeguard scientific quality. Other means of coordination include the program planning and budgetary processes; trans-NIH and other coordinating committees; weekly, biweekly, or monthly meetings of officers from the bureaus, institutes, divisions, and the Director's office with common interests and responsibilities (intramural research, extramural research, planning and evaluation, and so on); and various in-house publications. In addition, the abilities both of the NIH staff and its external advisors have helped to counter the communication difficulties inherent in a growing, increasingly elaborate organization.

Authority in NIH has become increasingly decentralized over the years for a variety of reasons. The institutes have become more autonomous, with their own congressional appropriations and their own specific constituencies. The symbiotic relationship that evolved in the late 1940s between NIH, the congressional committees overseeing it, and outside interest groups has tended to break up into a number of smaller alliances, organized around more restricted areas of research.[32] In addition, since the late 1960s, the Department of Health, Education, and Welfare (and now, Health and Human Services) and the Executive Office of the President have asserted greater actual as well as nominal authority over NIH. A striking example is the independent President's Cancer Panel, which was established in a time of perceived emergency. This anomaly, the committee believes, should at some point be reconsidered.

Given the current budgetary constraints and increasing congressional and public demands upon the agency, decentralization puts additional pressure on the NIH Director. When budgetary growth barely keeps pace

with inflation, and when Presidential budget proposals often call for extremely small increases because Congress has historically voted large increases, the task of determining overall priorities in a highly decentralized organizational structure--and making those decisions stick--becomes extraordinarily difficult.

Thus, there are now strong incentives both for professional societies and the voluntary health associations to seek to enhance the power and position of "their" institute. There are no analogous special constituencies for the NIH Director, who has overall responsibility for the health of the entire NIH system. In order to balance the appropriate, but potentially destabilizing, centrifugal forces associated with the categorical institutes, there should be a strong central force to ensure coordination of cross-cutting research activities, to oversee orderly long-range evolution, and to maintain public accountability for NIH's overall program. The Office of the Director is the logical locus for these functions.

THE AUTHORITY OF THE NIH DIRECTOR

The following series of recommendations is aimed at providing the Director with adequate authority and resources to effectively lead NIH in an increasingly complex environment.

Delegation of Authority to the Director

The committee recommends:

The Secretary of Health and Human Services should delegate to the Director of NIH the authority, direction, and control over NIH that the position does not now possess, subject to the policy direction of the Assistant Secretary for Health and to existing statutory limitations, as recommended to be modified below.

The Director of NIH is nominated by the Secretary of Health and Human Services and appointed by the President, subject to confirmation by the Senate. The authority of the Director, however, is not clearly defined. There is a sizable collection of very specific authorities delegated to the Director by the Secretary, but these are largely housekeeping duties and do not get to the core of the Director's institutional responsibilities. There is no official delegation to the Director of the overall authority, direction, and control of NIH. Such a delegation would give the Director the means for ensuring the coordination of cross-cutting research activities and for overseeing the long-range evolution of NIH. It would also make it clear that the Director has the responsibility for keeping the whole of NIH's research program responsive to national health needs.

Enhanced Budgetary Authority

The committee recommends:

The Director of NIH should have greater budgetary authority and discretion in two regards; (1) a discretionary fund, not to exceed 1.0 percent of the NIH budget, with which to seed selected areas through existing institutes in accordance with a rigorous peer review process; and (2) limited authority to transfer up to 0.5 percent of the NIH budget across institute lines in response to a public health emergency.

Once Congress passes an appropriation and the President signs it into law, the Director of NIH has no authority to adjust the NIH research agenda, either with discretionary funds or by reallocation across appropriations categories. The Director can make adjustments among institutes in the budget formulation stage, but only at the margin and subject to action by the Department of Health and Human Services, the Office of Management and Budget, and Congress.

Any work supported by the proposed discretionary fund should be subject to peer review, and there should be no permanent commitment that would imbed the new effort in the budget before it got an appropriate trial. The discretionary fund should be an add-on, not a tax on existing activities. It would be used to promote emerging and cross-cutting research areas, especially those that are not obviously categorical. The White House Science Council has made a similar proposal for all federal research laboratories,[33] and the National Academy of Public Administration for all government agencies.[34]

The idea for emergency transfer authority is not new, but the AIDS (Acquired Immune Deficiency Syndrome) episode provides an example of how it could be valuable. Although some scientists found the response of NIH to the crisis appropriate, others did not. In any case, there seems to have been a failure adequately to inform the public of the steps that were taken. There was a considerable period of time during which the institutes, the NIH leadership, the Public Health Service, and the Congress debated the appropriate financial response to the AIDS threat.[35] Although some scientists began research almost immediately on already existing grants, and others sent in new applications on their own, NIH was slow in formally responding with requests for applications.[36] Episodes like this may be rare, but emergency transfer authority would be helpful in avoiding confusion and ensuring a prompt and appropriate response.

NIH Policy and Planning Council

The committee recommends:

1. The current Director's Advisory Committee should be converted to a stronger and more independent NIH Policy and Planning Council.

2. The council should provide for the Director a continuous evaluation of the research mission and function of NIH and of its component institutes, with special emphasis on issues that affect NIH as a whole or the interrelationship among the institutes. It should advise the Director in the formulation of long-term plans and in setting research priorities.
3. The council should function both as a sensing mechanism and major consensus-builder for the Director.
4. The council should be composed of twelve members appointed by the Secretary of Health and Human Services from a list prepared by the Director of NIH.
5. Appointments should be made for a single term of six years, with one-third of the council's membership replaced every two years.
6. Members of the council should be selected on the basis of scientific and professional competence and distinction.
7. The council should elect its own chair, prepare its own agenda, meet at least four times a year and whenever requested by the Director of NIH, be assigned its own staff and have a defined budget, and report annually to the Director of NIH.

The present 16-member Director's Advisory Committee, appointed by the Secretary of Health and Human Services and chaired by the Director, responds to specific requests from the Director, who also sets its agenda. It has no independent staff or budget.

The proposed name change is intended to underscore this study committee's intention that there be a qualitative change in the council's nature and functions. Increasing its independence and responsibility, the committee believes, will help make it more effective in support of the Director's essential role of coordinating and overseeing cross-cutting research areas. On the other hand, giving the Director full authority to nominate the members should result in a council with whom the Director could work more effectively. The council would advise the Director on NIH-wide policy issues, such as research training, the management of the peer review system, and the personnel and salary structure for intramural scientists. It would also consider long-range research priorities among the institutes, and the effectiveness of mechanisms to coordinate cross-cutting research areas.

The committee intends that the council and the Health Science Board complement each other. The council would concern itself exclusively with the NIH and its components; the board would concern itself with the NIH only in the context of the spectrum of Public Health Service agencies and the full range of their health research.

Structure of the Director's Office

The committee recommends:

Extramural research and intramural research (and the related support activities of each) should be grouped under two deputy NIH directors each of whom has line authority over support functions outside of individual institutes and staff responsibility for extramural and intramural research programs; the staff functions in the Director's office should be reorganized to improve span of control.

As Appendix B shows, there currently are 25 separate activities that report to the Director of NIH. These include the 18 bureaus, institutes, and divisions, and 7 functions in the Office of the Director itself. The NIH Director has a team of three staff officer deputies: one is a generalist, one deals with extramural and training programs, and one deals with intramural programs.

None of the current deputy directors has line authority. The committee proposes that the deputies for extramural research and intramural research be given line authority over the support activities related to their responsibilities, and that they continue to have staff authority to advise the Director on the coordination and direction of the research programs within the institutes. Such a reorganization could improve the Director's capacity to manage, and free his time and attention from the day-to-day exigencies of bureaucratic life. It could also reduce the Director's span of control to more manageable proportions. One possible reorganization plan appears in Appendix B.

The organization of the Director's office should continue to emphasize the centrality of the planning and budgeting functions. They need to work together closely, and have direct access to the Director in connection with resource planning and allocation decisions. The same should be true at the institute level as well.

Clustering of Institutes

The committee recommends:

Where appropriate, support functions of individual institutes and other components should be clustered to reduce unnecessary duplication and expense.

At present, each institute at NIH has both a program staff (the director and his immediate office, program officers, planning officers, and so on) and a support staff (personnel management, grants and contracts management, budgeting, public information, and so on). The current system is designed to maximize the effectiveness of the individual institutes in carrying out their own research programs, but can lead to unnecessary duplication.

In some cases it may be possible for institutes to share support staffs. One way is to create a cluster of institutes with common

interests and approaches. Each institute's director would retain responsibility for its scientific program, and have direct access to the NIH Director. The cluster would provide support services, and even scientific coordination if there were significantly overlapping research interests. If a new institute is necessary, it might share the support services of an existing institute but have an independent scientific program and direct access to the NIH Director. Such an arrangement could serve as an incubator for emerging research areas.

For instance, rather than establishing an independent National Institute on Aging in 1974, this institute could have been clustered with the National Institute on Child Health and Human Development. Although the new institute would have had its own scientific program, budget, and director, a cluster could have facilitated cooperation on common scientific interests, such as basic research on human development and social science approaches, as well as reduced administrative costs.

Clustering is a useful intermediate between complete centralization of support services and their full replication in all institutes. It has two benefits. First, it would help improve the NIH Director's span of control by reducing the number of decisions that have to be made at the NIH level. Second, it would reduce administrative costs. Together, these mean that clustering could increase ability of NIH to respond to emerging needs and opportunities by reducing the administrative and financial costs of establishing new institutes.

PUBLIC AND SCIENTIFIC ACCOUNTABILITY

The foregoing recommendations have dealt with improving the efficiency and effectiveness of NIH. The following recommendations are intended to facilitate accountability, both to the scientific community and to the larger public, as well as to ensure a manageable structure for NIH.

National Advisory Councils

The committee recommends:

Each institute should provide its National Advisory Council members with full and easily understandable information on its entire portfolio of currently funded grants and grant proposals; institute directors should more uniformly involve their advisory councils in broad program and policy issues.

An institute's National Advisory Council has two major roles. One stems from its statutory authority and responsibility to approve research grants made by the institute it advises. In this capacity the councils serve as a second level of review, approving grants initially recommended by study sections. In most instances, the councils endorse study section actions. Only rarely (1 to 2 percent of all grants for most institutes) do councils modify study section recommendations,

either by assigning high priority status to grants deemed to have high-relevance to the institute's program or, less often, by assigning low-priority status to grants with low program relevance.[37] The councils spend a large percentage of their time and energy on the review of research grant proposals, and the committee believes the reviews are carried out fairly and thoroughly.

If the councils are to act accountably, their members must receive sufficient information about their institutes' entire portfolio of currently funded and competing grants. This information is particularly important if council members are to evaluate those applications that fall at the border.

The second role of the councils is to provide the institutes with broad program or policy advice. Our interviews with past and present council members, however, indicate that this function is carried out unevenly. Some institutes have developed a variety of ways to obtain advice from council members (special sessions, ad hoc committees, public meetings, workshops, etc.), but other institutes make little use of their councils in this regard. In fact, some council members are barely aware that they have this second responsibility. This heterogeneity of understanding is accentuated because the advisory role of councils is not spelled out in detail in NIH documents, and because there is no parent group (like the Division of Research Grants for study sections) that focuses on their activities. To facilitate the councils' involvement in this second role, the NIH Director's Office, through the deputy director for extramural research, should provide all council members, at the time of their appointment, with a clearly written statement informing them of their advisory role and the various means used by NIH councils to facilitate that role.

Boards of Scientific Counselors

The committee recommends:

The NIH Director should assume overall responsibility for informing members of each institute's Board of Scientific Counselors of that institute's response to its recommendations about intramural research.

The Boards of Scientific Counselors review and evaluate the intramural research programs for their respective institutes. Based on discussions with past and present counselors, the committee believes that the intramural programs usually are reviewed in a timely and rigorous fashion by the boards. The board members expressed considerable concern, however, about the lack of feedback to them on the institutes' implementation of their recommendations. NIH has and occasionally employs procedures for phasing out or reducing support for intramural laboratories that fail to satisfy counselors of their productivity. This is true even for tenured scientists. This practice is essential for maintaining the high quality of the intramural research program. Counselors usually are not informed of such actions, but should be.

Communication

The committee recommends:

The role and staffing of the Office of Communications should be strengthened. The Director of NIH should establish an Advisory Panel on Public Information, to assist the office in improving the breadth of distribution of current publications, and in employing additional media.

NIH needs to make the public more aware of its work. The committee was impressed by NIH's present communications program, with its array of publications and other communications services. The committee has seen no evidence, however, that this information is reaching wider audiences in a timely and regular fashion.

QUALITY OF SCIENTIFIC ADVICE

Lastly, the committee turns to the issue of the quality and independence of scientific advice rendered to NIH.

The committee recommends:

Quality should continue to be the overriding consideration in selecting all NIH advisory group members--scientific, clinical, and lay. The expertise of the advisory groups must be of the highest possible quality if they are effectively to fulfill their statutory responsibilities and to have credibility within the scientific community, with Congress, and with the public at large. Further, every effort should be made to reduce the levels of review and to expedite the selection process, so that advisory groups can always function at full strength.

The quality of NIH's performance depends upon many factors, but one of the most important is the ability and integrity of the members of the many advisory bodies that are an essential part of NIH.

The committee has received information, however, that the advisory bodies are sometimes not able to operate at full strength because vacancies are not filled in a timely manner. This delay is usually the result of multilevel reviews of nominations put forward by NIH. Further, the committee has found a widespread perception in the scientific community that members of advisory groups are often selected, at levels above NIH in the federal hierarchy, for reasons other than quality, expertise, or eminence. The perception by many, including members of Congress, that the scientific capacity of the advisory groups is being eroded points to a continuing problem for NIH and the Department of Health and Human Services. If the facts behind this perception are accurate, the situation is unacceptable. Even the existence of the perception is a matter of grave concern.

NOTES

Chapter 1

1. U.S. Department of Health and Human Services, National Institutes of Health, Orientation Handbook for Members of Scientific Review Groups, August 1982, p. 1.

2. A Brief Review of Proposals to Change the NIH Organizational Structure, Staff paper, Office of Associate Director for Program Planning and Evaluation, National Institutes of Health, May 1984, Attachment 1, p. 2. Legislative proposals have been made for a National Institute of Arthritis and Musculoskeletal Diseases; a National Institute of Diabetes, Endocrinology and Metabolic Disorders; and a National Institute of Nursing Research. Among institutes proposed through other channels have been a Communications Institute; Institute for Pharmaceutical Sciences; Institute for Radiological Sciences; Institute for Technology Research; National Ear, Nose and Throat Institute; National Institute of Public Health; National Trauma Institute; and Population Institute.

3. Ibid., p. 3. Organizations proposed for transfer were the National Center for Health Services Research, National Center for Health Statistics, National Institute of Mental Health, and National Institute for Occupational Safety and Health.

Chapter 2

4. Appropriations data from the 1983 NIH Almanac, p. 121; and from the NIH Division of Financial Management.

5. 1983 NIH Almanac, p. 139; and the TAPS Monthly Employment Report Summary, July 1983.

6. U.S. Department of Health and Human Services, National Institutes of Health, 1983 NIH Data Book, p. 21; and U.S. Congress, House of Representatives, Subcommittee of the Committee on Appropriations, National Institutes of Health, 1985 Appropriations Hearings, p. 133.

7. Stephen D. Nelson, A Brief History of the Development of the National Institutes of Health, Institute of Medicine, 1984.

8. See Appendix B.

9. U.S. Department of Health and Human Services, National Institutes of Health, 1983 NIH Almanac, pp. 122-123. Appropriations figures adjusted to exclude any program later eliminated or transferred out of NIH.

10. Inflation rates calculated from the 1983 NIH Almanac, pp. 128-129.

11. Appropriations data from the 1983 NIH Almanac, p. 123; and the NIH Division of Financial Management. Inflation rate for FY 1984 calculated from the Congressional Budget Office, Research and Development Funding in the Proposed Fiscal Year 1985 Budget, March 1984, p. 6.

12. A Brief Review of Proposals to Change the NIH Organizational Structure, op. cit., pp. 1-2.

13. See Nelson, A Brief History of the Development of the National Institutes of Health, op. cit., pp. 14 ff. The National Institute of Neurological Disease and Blindness became the National Institute of Neurological Diseases and Stroke in 1968, and the National Institute of Neurological and Communicative Diseases and Stroke in 1975; the National Heart Institute became the National Heart and Lung Institute in 1969, and the National Heart, Lung, and Blood Institute in 1976; the National Institute of Arthritis and Metabolic Diseases became the National Institute of Arthritis, Metabolism, and Digestive Diseases in 1972, and the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases in 1981. The three institutes that became bureaus were the National Cancer Institute (1972), the National Heart and Lung Institute (1972), and the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (1982).

14. Appropriations figures from the 1983 NIH Almanac, pp. 122-123, excluding programs later eliminated or transferred, and adjusted for inflation.

15. Pamela Smith, A Summary of a Case Study of the National Eye Institute, Institute of Medicine, 1984.

16. Stephen D. Nelson, A Summary of a Case Study of the National Heart, Lung, and Blood Institute, Institute of Medicine, 1984.

17. Ibid.

18. Nelson, A Brief History of the Development of the National Institutes of Health, op. cit., pp. 19-22.

19. See Appendix B.

20. Henry W. Lane, Rodney G. Beddows, and Paul R. Lawrence, Managing Large Research and Development Programs, Albany: State University of New York Press, 1981, Chapter 5.

21. Ibid.

22. Nelson, A Brief History of the Development of the National Institutes of Health, op. cit., p. 18.

23. U.S. Department of Health, Education, and Welfare, National Institutes of Health, Report of the NIH Program Mechanisms Committee, February 14, 1973.

24. Stephen D. Nelson, A Case Study of the National Institute of Mental Health, Institute of Medicine, 1984.

25. Smith, A Summary of a Case Study of the National Eye Institute, op. cit.

26. Franklin T. Williams, Director, National Institute on Aging, NIH. Interview with Michael A. Stoto.

Chapter 3

27. Stephen P. Strickland, Politics, Science, and Dread Disease, Cambridge: Harvard University Press, 1972, Chapter V. See also Nelson, A Brief History of the Development of the National Institutes of Health, op. cit.

28. Strickland, op. cit., Chapter III.

29. President's Private Sector Survey on Cost Control, Task Force Report on Research and Development, December 1983, p. 46.; House Finance Office, July 1984; and Senate Disbursing Office, July 1984.

30. U.S. Department of Health and Human Services, National Institutes of Health, NIH Data Book, 1983. Calculated from data on p. 5.

Chapter 4

31. See Appendix B.

32. Nelson, A Brief History of the Development of the National Institutes of Health, op. cit.

33. Office of Science and Technology Policy, Report of the White House Science Council, Federal Laboratory Review Panel, Washington D.C., May 1983.

34 Revitalizing Federal Management: Managers and their Overburdened Systems, National Academy of Public Administration, Washington, D.C., November 1983.

35. Stephen Budiansky, AIDS research: Big enough spending? Nature, August 11, 1983, p. 478.

36. U.S. Congress, House of Representatives, Twenty-ninth Report of the Committee on Government Operations, The Federal Response to AIDS, November 30, 1983, pp. 22-27.

37. Data provided by the NIH Division of Research Grants.

APPENDIX A

Study of the Organizational Structure of the National Institutes of Health

Committee for the Study of the Organizational Structure of the National Institutes of Health
June 28-29, 1983, Washington, D.C.
August 31, 1983, Washington, D.C.
December 15-16, 1983, Washington, D.C.
February 28-29, 1984, Washington, D.C.
May 18-19, 1984, Washington, D.C.
July 20-21, 1984, Woods Hole, Massachusetts
Panel 1 - Historical Issues
October 12, 1983, Washington, D.C.
January 19, 1983, Washington, D.C.
March 12, 1984, Washington, D.C.
Panel 2 - Current Organization
October 17, 1983, Washington, D.C.
November 28-29, 1983, Washington, D.C.
February 10, 1984, New York, New York
Panel 3 - Alternatives
October 31, 1983, Washington, D.C.
January 18, 1984, Washington, D.C.
Other Meetings
August 17, 1983, Woods Hole, Massachusetts
September 26-27, 1983, Washington, D.C.--Public meeting
March 14, 1984, Houston, Texas

PEOPLE INTERVIEWED BY COMMITTEE OR STAFF OR PROVIDING WRITTEN MATERIAL

Adrian, Marlene, Director, Biomechanics Research Laboratory, University of Illinois at Urbana-Champaign
Alford, Charles A., Jr., Professor of Pediatrics, School of Medicine, University of Alabama, Birmingham
Amdur, Mary O., Associate Professor of Toxicology, Department of Nutrition and Food Science, Massachusetts Institute of Technology
Andreoli, Kathleen G., Executive Director of Academic Services, University of Texas Health Science Center at Houston
Austein, Cheryl, Office of Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services
Bagley, Shirley L., Acting Deputy Director, National Institute on Aging, NIH
Baldwin, Calvin B., Jr., Associate Director for Administration, NIH
Baldwin, Wendy, Chief, Social and Behavioral Sciences Branch, Center for Population Research, National Institute of Child Health and Human Development, NIH
Bardin, Clyde W., Vice President and Director, Center for Biomedical Research, Population Council, Rockefeller University
Barkley, W. Emmett, Director, Division of Safety, Office of Research Services, NIH
Beaubien, Mark S., Acting Director, Fogarty International Center; Acting Associate Director for International Research, NIH
Becker, Edwin D., Director, Office of Research Services; Associate Director for Research Services, NIH
Bennett, J. Claude, Chairman, Department of Medicine, University of Alabama at Birmingham
Berne, Robert M., Chairman, Department of Physiology, University of Virginia School of Medicine
Beveridge, Betty J., Committee Management Officer, NIH
Biles, Brian, Staff Member, Office of U.S. Representative Henry Waxman
Blagg, Christopher, Director, Northwest Kidney Center; Professor, University of Washington
Blum, Alan, Editor, New York State Journal of Medicine
Blumenthal, David, Executive Director, Center for Health Policy and Management, J.F. Kennedy School of Government, Harvard University
Bowery, Thomas G., Chief, Biomedical Research Support Program Branch, Division of Research Resources, NIH
Boyer, Paul D., Professor of Biochemistry, Molecular Biology Institute, University of California Los Angeles
Brandt, Edward N., Jr., Assistant Secretary for Health, Department of Health and Human Services
Breslow, Lester, Director for Cancer Control Research, University of California Los Angeles

Bridge, Peter, Scientific Director, Office for Planning, Policy Analysis, and Legislation; Alcohol, Drug Abuse, and Mental Health Administration
Brodie, H. Keith H., Chancellor, Duke University
Brooks, Frank P., Professor, School of Medicine, University of Pennsylvania
Brooks, Harvey, Professor, J.F. Kennedy School of Government, Harvard University
Brown, Carolyn P., Chief, Library Branch, Division of Research Services, NIH
Buchwald, Jennifer S., Professor, Department of Physiology, School of Medicine, University of California Los Angeles
Bulkley, Bernadine, Deputy Director, Office of Science and Technology Policy
Burger, Max, President, National Medical and Biology Research Council, Swiss National Science Foundation, Basel
Butcher, R.W., Professor of Biochemistry, University of Texas Health Science Center at Houston
Butler, Robert N., Chairman, Department of Geriatrics and Adult Development, Mount Sinai Medical Center, New York (Former Director, National Institute on Aging, NIH)
Califano, Joseph A.; Califano, Ross and Heineman, Washington, DC (Former Secretary, U.S. Department of Health, Education, and Welfare)
Carlos, James P., Associate Director, National Caries Program, National Institute of Dental Research, NIH
Carrese, Louis M., Director, Office of Program Planning and Analysis, National Cancer Institute; Associate Director for Program Planning and Analysis, NCI, NIH
Cavarocchi, Nicholas, Attorney, Washington, DC
Chalk, Rosemary, Program Head, Committee on Scientific Freedom and Responsibility, American Association for the Advancement of Science
Chalmers, Thomas, Visiting Professor, Department of Health Policy and Management, School of Public Health, Harvard University
Chicchirichi, David L., Executive Officer, National Institute on Aging, NIH
Clark, Wesley, Staff Member, Office of U.S. Senator Edward M. Kennedy
Clemente, Carmine D., Director, Brain Research Institute, School of Medicine, University of California Los Angeles
Cohen, Lois K., Planning Officer, National Institute of Dental Research, NIH
Cohen, Stanley N., Associate Professor, Department of Psychiatry, University of Oregon
Collier, Betty J., Medical Arts and Photography Branch, Division of Research Services, NIH
Condliffe, Peter G., Chief, Scholars-in-Residence Branch, Fogarty International Center, NIH
Cooper, Franklin S., Associate Research Director, Haskins Laboratories, New Haven, CT
Cooper, William G., Associate Director for Planning, National Library of Medicine, NIH

Cowan, Maxwell, Professor and Vice President, Salk Institute for Biological Studies
Crane, Frederick L., Department of Biological Sciences, Purdue University
Crooks, Glenna M., Deputy Assistant Secretary for Health Planning and Evaluation, DHHS
Crout, J. Richard, Director, Office for Medical Applications of Research; Associate Director for Medical Applications of Research, NIH
Cummings, Martin M., Director, National Library of Medicine, NIH
Curl, Bonnie A., Office of Governmental Affairs, American Association of Colleges of Osteopathic Medicine
Danielsson, Henry, Secretary, Medical Research Council of Sweden
Darby, William J., Department of Biochemistry, School of Medicine, Vanderbilt University
Darnell, James E., Professor, Department of Molecular Cell Biology, Rockefeller University
De Cesare, William R., Chief, General Clinical Research Centers Program Branch, Division of Research Resources, NIH
de Tornyay, Rheba, Dean and Professor, School of Nursing, University of Washington
DeVita, Vincent T., Jr., Director, National Cancer Institute, NIH
Decker, John L., Director, Clinical Center; and Associate Director for Clinical Care, NIH
Demmerle, Alan, Chief, Computer Systems Laboratory, Division of Computer Research and Technology, NIH
Doak, William, Executive Officer, Fogarty International Center, NIH
Douglass, Carl D., Director, Division of Research Grants, NIH
Ducker, Otis, Director, Division of Administrative Services, Office of Research Services, NIH
Edelman, Isidore S., Professor, Department of Biochemistry, College of Physicians and Surgeons, Columbia University
Eden, Murray, Chief, Biomedical Engineering and Instrumentation Branch, Division of Research Services, NIH
Eichorn, Dorothy H., Associate Director, Institute of Human Development, University of California Berkeley
Eigler, Patricia A., Chief, Procurement Branch, Office of Research Services, NIH
Endicott, Kenneth, Federation of American Societies for Experimental Biology, Bethesda, MD (Former Director, National Cancer Institute, NIH)
Fanning, J.C., Professor of Chemistry, Clemson University
Farlee, Coralie, Assistant Director for Program Operations, Fogarty International Center, NIH
Feinlieb, Manning, Director, National Center for Health Statistics
Felix, Robert H., Former Director, National Institute of Mental Health
Fenderson, Douglas A., Director, National Institute of Handicapped Research, U.S. Department of Education
Fenninger, Leonard D., Consultant, American Medical Association, Chicago, IL
Field, James B., Professor of Medicine, St. Luke's Episcopal Hospital, Houston

Fishman, Alfred P., Director, Cardiovascular-Pulmonary Division, Department of Medicine, Hospital of the University of Pennsylvania

Fletcher, John, Chief, Laboratory of Applied Studies, Division of Computer Research and Technology, NIH

Foege, William, Director, Centers for Disease Control

Forbush, Wilford J., Deputy Assistant Secretary for Health Operations, DHHS

Fredrickson, Donald S., Vice President, Howard Hughes Medical Institute, Bethesda, MD (Former Director, NIH)

Freedman, Daniel X., Director, Division of Adult Psychiatry, Neuropsychiatric Institute, University of California Los Angeles

Fretts, Carl A., Director, Division of Contracts and Grants, NIH

Friedman, Kenneth, Associate Professor, Physiology, University of Medicine and Dentistry of New Jersey

Frommer, Peter L., Deputy Director, National Heart, Lung, and Blood Institute, NIH

Gay, William I., Chief, Animal Resources Program Branch, Division of Research Resources, NIH

Gazes, Peter C., Professor, College of Medicine, Medical University of South Carolina

Gee, Helen H., Chief, Program Evaluation Branch, Office of Program Planning and Evaluation, NIH

Gemmell, Michael K. Executive Director, Association of Schools of Public Health

George, Samuel W., Assistant Director for Finance, Division of Financial Management, NIH

Gibson, Don C., Associate Director for Planning and Extramural Affairs, National Institute on Aging, NIH

Glaudemans, John, Budget Examiner, U.S. Office of Management and Budget

Goggins, John F., Deputy Director, National Institute of Dental Research, NIH

Goldberg, Michael I., Director, Office of Program Planning and Evaluation; and Associate Director for Program Planning and Evaluation, NIH

Goldman, Le`oy G., Chief, Office of Planning and Analysis, National Institute of Neurological and Communicative Disorders and Stroke, NIH

Goldstein, Murray, Director, National Institute of Neurological and Communicative Disorders and Stroke, NIH

Goldstone, Donald, Associate Deputy Director for Medical and Scientific Affairs, National Center for Health Services Research

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Gordon, Robert S., Special Assistant to the Director, NIH

Gordon, Stephen L., Director, Musculoskeletal Diseases Program, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, NIH

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Greenlick, Merwyn R., Vice President for Research, Kaiser Foundation Hospitals; Director, Health Services Research Center, Portland

Greenwalt, Tibor J., Director, Hoxworth Blood Center, University of Cincinnati Medical Center
Habel, Kurt C., Chief, Program Planning Branch, Division of Program Analysis, Office of Program Planning and Evaluation, NIH
Hackerman, Norman, President, Rice University, Houston
Handler, Evelyn, President, Brandeis University
Hatch, Orrin G., Member, U.S. Senate
Hedley-Whyte, John, Professor of Anesthesia and Respiratory Therapy, Department of Anesthesia, Beth Israel Hospital, Boston
Hein, John W., Director, Forsyth Dental Center, Boston
Held, Joe R., Director, Division of Research Services, NIH
Hickey, Robert C., Executive Vice President and Professor of Surgery, The University of Texas System Cancer Center, Houston
Hirsch, Henry, Professor, College of Medicine, University of Kentucky
Holton, Gerald, Professor, Professor of Physics and History of Science, Harvard University
Hommes, Frits A., Professor, School of Medicine, Medical College of Georgia
Huang, Ru Chih C., Professor, Department of Biology, The Johns Hopkins University
Hughes, Phillip S., Under Secretary, Smithsonian Institution
Hupp, Robert P., Executive Director, Father Flanagan's Boys' Home, Boys Town, NE
Hyatt, Howard, Director, Division of Management Survey and Review, NIH
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Karle, Jerome, Naval Research Laboratory, Washington
Karnovsky, Manfred L., Professor of Biological Chemistry, Harvard Medical School
Kelso, John H., Deputy Administrator, Health Resources and Services Administration
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Kirschstein, Ruth L., Director, National Institute of General Medical Sciences, NIH
Klerman, Gerald L., Professor of Psychiatry, Massachusetts General Hospital (Former Administrator, ADAMHA)
Koprowski, Hilary, Director, The Wistar Institute, Philadelphia, PA
Korper, Samuel P., Director, Division of Legislative Affairs, NIH
Krause, Richard M., Director, National Institute of Allergy and Infectious Diseases, NIH
Kupfer, Carl, Director, National Eye Institute, NIH
LaVeck, Gerald D., Medical Consultant for Handicapped Children, Public Health Service (Former Director, National Institute of Child Health and Human Development)
Lamont-Havers, Ronald W., Director for Research Policy and Administration, Massachusetts General Hospital (Former Deputy Director, NIH)
Laosa, Luis M., Senior Research Scientist, Division of Educational Research and Evaluation, Educational Testing Service, Princeton, NJ
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Lawrence, Paul, Professor, Graduate School of Business Administration, Harvard University
Leder, Philip, Chairman, Department of Genetics, Harvard Medical School
Lederberg, Joshua, President, The Rockefeller University
Lenfant, Claude, Director, National Heart, Lung, and Blood Institute, NIH
Levinson, Rachel E., Office of Program Planning and Evaluation, NIH
Levy, Robert I., Vice President for Health Sciences, Columbia University (Former Director, National Heart and Lung Institute, NIH)
Lewandowski, Leon J., Director of Laboratory Medicine and Special Assistant for Medical Affairs, New York State Department of Health, Albany
Ling, Gilbert N., Director, Department of Molecular Biology, Pennsylvania Hospital, Philadelphia
Lipsett, Mortimer B., Director, National Institute of Child Health and Human Development, NIH
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Löe, Harald, Director, National Institute of Dental Research, NIH

Long, J. P., Professor, Department of Pharmacology, College of Medicine, University of Iowa
Loweth, Hugh, Energy and Science Division, U.S. Office of Management and Budget
Lynch, Edward J., Office of Program Planning and Evaluation, NIH
MacNichol, Edward F., Director, Laboratory of Sensory Physiology, Marine Biological Laboratory, Woods Hole, MA (Former Director, National Institute of Neurological Diseases and Stroke)
Maickel, Roger P., Professor of Pharmacology and Toxicology, Purdue University
Malone, Thomas E., Deputy Director, NIH
Mansfield, Norman D., Director, Division of Financial Management, NIH
Manson, Jeanne M., Assistant Professor, Department of Environmental Health, University of Cincinnati
Manuel, L. Lee, Executive Officer, Division of Computer Research and Technology, NIH
Margulies, Harold, Director, Office of Health Assessment Technology, National Center for Health Services Research
Marks, Paul A., President, Memorial Sloan-Kettering Cancer Center
Marshall, John E., Director, National Center for Health Services Research
Marston, Robert Q., President and Professor of Medicine, University of Florida (Former Director, NIH)
Masland, Richard L., Former Director, National Institute of Neurological Diseases and Blindness
Matsunaga, Spark M., Member, U.S. Senate
Maumenee, A. Edward, Professor of Ophthalmology, School of Medicine, The Johns Hopkins University
McCarthy, Charles R., Director, Office of Protection from Research Risks, NIH
McDuffie, Frederic C., Senior Vice President, Medical Affairs, Arthritis Foundation
McFee, Thomas, Assistant Secretary for Personnel, DHHS
McGinnis, Michael, Deputy Assistant Secretary for Disease Prevention and Health Promotion, DHHS
McManus, Edward H., Deputy Director, National Eye Institute, NIH
McNevin, Anthony J., American Association of Colleges of Osteopathic Medicine
Michelson, Robin P., Clinical Professor of Otolaryngology, University of California San Francisco
Millar, Donald, Director, National Institute of Occupational Safety and Health
Miller, Charles, Executive Officer, Institute of Medicine
Miller, Elizabeth C., Professor, McArdle Laboratory for Cancer Research, University of Wisconsin, Madison
Miller, Richard, Assistant Director for Budget, Division of Financial Management, NIH
Millstein, Richard A., Associate Administrator for Planning, Policy Analysis, and Legislation; Alcohol, Drug Abuse, and Mental Health Administration

Monier, Roger, Scientific Director for the Life Sciences, National Center for Scientific Research, Paris
Monroe, Edwin W., Associate Dean, School of Medicine, East Carolina University, Greenville, NC
Moore, Mark, Professor of Public Management, J.F. Kennedy School of Government, Harvard University
Morris, Julian, Chief, Office of Program Planning and Evaluation, National Eye Institute, NIH
Moskowitz, Jay, Director, Office of Program Planning and Evaluation, National Heart, Lung, and Blood Institute, NIH
Mosteller, Frederick, Chairman, Department of Health Policy and Management, School of Public Health, Harvard University
Naughton, Joseph D., Chief, Computer Center Branch, Division of Computer Research and Technology, NIH
Neale, Terrylin, Juvenile Diabetes Foundation
Nelson, Norton, Professor, Institute of Environmental Medicine, New York University Medical Center
Nicholas, Edward E., Jr., Director, Division of Personnel Management, NIH
Nickles, Don, Member, U.S. Senate
Nossal, Gustav, Walter and Eliza Hall Institute of Medical Research, Royal Melbourne Hospital, Australia
O'Donnell, James F., Deputy Director, Division of Research Resources, NIH
O'Hare, Michael, Lecturer in Public Policy, J.F. Kennedy School of Government, Harvard University
Oberhelman, Harry A., Department of Surgery, School of Medicine, Stanford University
Olson, Robert E., Professor, School of Medicine, University of Pittsburgh
Pardes, Herbert, Director, Office of Mental Health, New York State Psychiatric Institute (Former Director, National Institute of Mental Health)
Patton, Larry, Staff Member, Office of U.S. Senator William Proxmire
Peterson, Robert, U.S. General Accounting Office
Pickett, Betty H., Director, Division of Research Resources, NIH
Pincus, Harold, Special Assistant to the Director, National Institute of Mental Health
Pitot, Henry C., Director, McArdle Laboratory for Cancer Research, University of Wisconsin, Madison
Pratt, Arnold W., Director, Division of Computer Research and Technology, NIH
Quave, Robert, Acting Associate Director, Management, National Center for Health Statistics
Rall, David P., Director, National Institute of Environmental Health Sciences, NIH
Rall, Joseph E., Deputy Director for Intramural Research, NIH
Raub, William E., Deputy Director for Extramural Research and Training, NIH
Reinisch, Carol L., Chairman, Department of Comparative Medicine, School of Veterinary Medicine, Tufts University

Renault, Pierre F., Director, Program Planning and Analysis, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, NIH

Rice, Dorothy, Regent's Lecturer, Department of Social and Behavioral Sciences, School of Nursing, University of California San Francisco

Richmond, Julius, Professor and Director, Division of Health Policy Research and Education, Harvard University (Former Assistant Secretary for Health, DHHS)

Riecken, Henry, Professor of Behavioral Sciences, University of Pennsylvania School of Medicine

Riker, Ellen, Minority Staff Associate, Energy and Commerce Committee, U.S. House of Representatives

Robbins, Anthony, Majority Professional Staff Member, Energy and Commerce Committee, U.S. House of Representatives

Roberts, Eugene, Director, Division of Neurosciences, City of Hope Research Institute, Duarte, CA

Rogers, Paul G., Partner, Hogan & Hartson (Former Member, U.S. House of Representatives)

Rosenberg, Roger N., Professor and Chair, Department of Neurology, Southwestern Medical School, University of Texas Health Science Center, Dallas

Rosoff, Jeannie I., President, Alan Guttmacher Institute

Ross, John, Jr., Director, Cardiovascular Division, Department of Medicine, School of Medicine, University of California San Diego

Ross, Russell, Professor of Pathology, University of Washington

Russell, Elizabeth S., Senior Scientist Emeritus, The Jackson Laboratory

Russell, George F., Jr., Director, Division of Management Policy, NIH

Saha, Subrata, Associate Professor and Coordinator of Biomedical Engineering, Louisiana State University Medical Center, Shreveport

Salans, Lester B., Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, NIH

Saunders, J. Palmer, Dean, Graduate School of Biomedical Sciences, University of Texas, Galveston

Schachman, Howard K., Professor, Department of Molecular Biology, University of California Berkeley

Schmidt, Benno C., Managing Partner, J.H. Whitney and Company, New York, NY

Schoolman, Harold M., Deputy Director for Research and Education, National Library of Medicine, NIH

Schweiker, Richard S., President, American Council of Life Insurance (Former Secretary, U.S. Department of Health and Human Services)

Schweizer, Malvina, National Heart, Lung, and Blood Institute, NIH

Scribner, Belding H., Professor of Medicine, University of Washington

Seggel, Richard L., Director, Robert Wood Johnson Health Policy Fellowship Program, Institute of Medicine

Segre, Diego, Professor, College of Veterinary Medicine, University of Illinois at Urbana-Champaign

Shannon, James A., Former Director, NIH

Sherman, John F., Vice President, Association of American Medical Colleges

Shock, Nathan W., Gerontology Research Center, Baltimore City Hospitals (Scientist Emeritus, NIH)
Shoe, Thomas, Director of Contracts and Grants, Public Health Service
Silver, Larry B., Acting Director, National Institute of Mental Health; Alcohol, Drug Abuse, and Mental Health Administration
Skipper, Howard, President Emeritus, Southern Research Institute, Birmingham, AL
Smart, John O., Executive Officer, Division of Research Services, NIH
Smith, Kent A., Deputy Director, National Library of Medicine, NIH
Snow, James B., Jr., Chairman, Department of Otorhinolaryngology/Human Communication, School of Medicine, University of Pennsylvania
Sobel, Burton E., Professor, School of Medicine, Washington University
Sparber, Sheldon B., Professor, Department of Pharmacology, Medical School, University of Minnesota
Spellacy, William, N., Professor, Department of Obstetrics and Gynecology, College of Medicine, University of Illinois, Chicago
Starfield, Barbara, Professor, Health Care Policy, School of Hygiene and Public Health, The Johns Hopkins University
Stein, Bernard, National Science Foundation
Sterling, Theodor D., Professor, Department of Computing Science, Simon Fraser University
Stetten, DeWitt, Jr., Senior Scientific Advisor, Office of the Director, NIH
Stever, Guyford, Former Director, National Science Foundation; Former Science Advisor to President Ford
Stimler, Suzanne S., Chief, Biotechnology Resources Program Branch, Division of Research Resources, NIH
Stoiber, Susanne A., Executive Officer, Clinical Center, NIH
Stone, Robert S., Dean, College of Medicine, Texas A & M University (Former Director, NIH)
Sundwall, David N., Majority Professional Staff Member, Committee on Labor and Human Resources, U.S. Senate
Swartwout, Joseph R., Associate Dean for Institutional and Administrative Affairs, Mercer University, Macon, Georgia
Tan, Eng M., Head, W.M. Keck Foundation Autoimmune Disease Center, Scripps Clinic and Research Foundation
Terry, Robert J., Professor of Biological Sciences, Department of Biology, Texas Southern University
Thibodeau, Kenneth F., Division of Management Policy, NIH
Tosteson, Daniel C., Dean, Harvard Medical School
Tulcin, Doris F., President, Cystic Fibrosis Foundation
Upton, Arthur C., Professor and Chairman, Department of Environmental Medicine, New York University School of Medicine (Former Director, National Cancer Institute, NIH)
Vogt, Thomas M., Senior Investigator, Epidemiology, Kaiser Permanente Medical Care Program
Voorhess, Mary L., Professor, Department of Pediatrics, School of Medicine, State University of New York, Buffalo
Wallace, Craig K., Director, Fogarty International Center, NIH

Ward, J. Emmett, Chief, Data Management Branch, Division of Computer Research and Technology, NIH
Warriner, Thomas E., Assistant Attorney General of California
Watkins, Robert, American Society for Microbiology
Watson, William, Deputy Director, Centers for Disease Control
Weicker, Lowell P., Jr., Member, U.S. Senate
Weiss, George, Chief, Physical Sciences Laboratory, Division of Computer Research and Technology, NIH
Whaley, Storm, Associate Director for Communications, NIH
Whitney, Robert A., Chief, Veterinary Resources Branch, Division of Research Services, NIH
Williams, Lindsley, Director of Planning and Policy Analysis, National Institute of Mental Health
Williams, T. Franklin, Director, National Institute on Aging, NIH
Wilson, Marjorie P., Senior Associate Dean, School of Medicine, University of Maryland
Winsten, Jay A., Director of Office of Health Policy Information, School of Public Health, Harvard University
Wyngaarden, James, Director, National Institutes of Health
Yanofsky, Charles, Professor of Biology, Department of Biological Sciences, Stanford University
Yolles, Stanley F., Professor of Psychiatry, State University of New York at Stony Brook (Former Director, NIMH)
Yordy, Karl D., Director, Division of Health Care Services, Institute of Medicine
Young, John, Assistant Professor, Center for Technology and Administration, American University
Young, Leo, Director, Office of Research and Laboratory Management, U.S. Department of Defense
Zelen, Marvin, Chairman, Biostatistics Department, School of Public Health, Harvard University
Zobrist, Stephanie, Attache for Science and Technology, Embassy of Switzerland, Washington, DC
Zukel, William J., Associate Director for Scientific Programs, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, NIH

PARTIAL LIST OF PEOPLE ATTENDING MEETINGS OF THE COMMITTEE

* Alford, Bobby R., Professor and Chairman, Department of Otorhinolaryngology and Communicative Sciences, Baylor College of Medicine (Representing Association of Academic Departments of Otolaryngology)
Andreoli, Kathleen G., Executive Director of Academic Services, University of Texas Health Science Center at Houston
Austein, Cheryl, Office of Assistant Secretary for Planning and Evaluation, Department of Health and Human Services
Baime, David, Association of American Medical Colleges
Baldwin, Calvin B., Jr., Associate Director for Administration, NIH
* Berne, Robert, University of Virginia School of Medicine (Representing Association of American Medical Colleges)
Bishop, H. Eames, President, Amyotrophic Lateral Sclerosis Society of America
Borja, Audrey, U.S. Public Health Service
Bridge, Peter, Scientific Director, Office for Planning, Policy Analysis, and Legislation; Alcohol, Drug Abuse, and Mental Health Administration
* Bridgers, William F., Dean and Professor, School of Public Health, University of Alabama in Birmingham (Representing Association of Schools of Public Health)
Budiansky, Stephen, Nature
Bulkley, Bernadine H., President, American Federation for Clinical Research
Butcher, R.W., Dean, Graduate School of Biomedical Sciences, University of Texas Health Science Center at Houston
Butler, Barbara D., Member of Board of Directors, Lupus Foundation of America
Butler, William, President, Baylor College of Medicine
Carrese, Louis M., Director, Office of Program Planning and Analysis, National Cancer Institute; and Associate Director for Program Planning and Analysis, NCI, NIH
Crooks, Glenna M., Deputy Assistant Secretary for Health Planning and Evaluation, Department of Health and Human Services
Cuca, Janet M., Research Analysis and Evaluation Branch, Division of Research Grants, NIH
Culliton, Barbara J., Science
Dambach, Chic, Epilepsy Foundation of America
Davidson, Martha, Division of Financial Management, NIH
Dirks, Harley M., Association of Minority Health Professions Schools

* Discussion Leader

Dublinske, Stan, Director, American Speech-Language-Hearing Association
Elliott, Jerry M., National Cancer Institute, NIH
Fasano, Nancy, School of Nursing, University of Texas Health Science Center at Houston
Feazel, Sue, University of Texas Health Science Center at Houston
Fenninger, Leonard D., American Medical Association
Gemmell, Michael K., Executive Director, Association of Schools of Public Health
Gershenow, Rochelle, American Association of Colleges of Osteopathic Medicine
Goldberg, Michael I., Director, Office of Program Planning and Evaluation; and Associate Director for Program Planning and Evaluation, NIH
Goldman, Leroy G., Chief, Office of Planning and Analysis, National Institute of Neurological and Communicative Disorders and Stroke, NIH
Goldstein, J., American Academy of Otolaryngology
Goldwater, Collaborative Programs Policy Officer, Office of Extramural Research and Training, NIH
Gordon, Michelle, Association of American Universities
Gowans, Sir James L., Secretary, Medical Research Council, London
Gray, John A., American Association for Dental Research
Greathouse, Darlene M., Office of Program Planning and Evaluation, NIH
* Green, Gareth M., Chairman, Department of Environmental Health, School of Hygiene and Public Health, The Johns Hopkins University (Representing American Lung Association/American Thoracic Society)
Gumpert, Rick, National Reye's Syndrome Foundation
Habel, Kurt C., Chief, Program Planning Branch, Division of Program Analysis, Office of Program Planning and Evaluation, NIH
Haggerty, James F., American Red Cross Blood Services
Hatley, Cindy, American Association of Blood Banks
Haughton, James, Houston, TX
* Hirsch, Henry, Professor, College of Medicine, University of Kentucky
Hodges, Alton, Special Assistant to the President for Health Policy Development, University of Texas Health Science Center at Houston
Housewright, Riley D., Executive Director, American Society for Microbiology
Humphreys, Robert R., Humphreys and Mitchell, Washington, DC (Representing Arthritis Foundation)
Jackson, Portia M., Office of Assistant Secretary for Health, DHHS
* Jesse, Mary Jane, President, American Heart Association
* Jollie, William P., Professor and Chairman, Department of Anatomy, Medical College of Virginia (Representing American Association of Anatomists)
Kalser, Sarah C., Director, Liver and Biliary Diseases Program, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, NIH

* Discussion Leader

Kennedy, Thomas J., Director, Department of Planning and Policy, Association of American Medical Colleges
Kershner, Lorraine, Planning Office, U.S. Public Health Service
Kessler, Bonnie, Epilepsy Foundation of America
Kessler, John D., Vice President, Office of Public Affairs, American Heart Association
Kirschstein, Ruth L., Director, National I stitute of General Medical Sciences, NIH
Knobil, Ernst, Dean, Medical School, University of Texas Health Science Center at Houston
Kohut, Robert I., Bowman Gray School of Medicine, Otolaryngology, Winston-Salem, NC (Representing American Academy of Otolaryngology and Society of University Otolaryngologists)
Kusinitz, Marc, New York State Journal of Medicine
Lenfant, Claude, Director, National Heart, Lung, and Blood Institute, NIH
Levine, Laura, American Association of Colleges of Osteopathic Medicine
Lipsett, Mortimer B., Director, National Institute of Child Health and Human Development, NIH
Long, Janice, Chemical and Engineering News
Lynch, Edward J., Office of Program Planning and Evaluation, NIH
Malone, Thomas E., Deputy Director, NIH
McCurdy, Harry, Executive Vice President, American Academy of Otolaryngology
McCurdy, Paul, American Society of Hematology
* McDuffie, Frederick C., Senior Vice President, Medical Affairs, Arthritis Foundation
* McHugh, William D., Eastman Dental Center, Rochester, NY (Representing American Association for Dental Research, American Association for Dental Schools, American Dental Association)
McManus, Edward H., Deputy Director, National Eye Institute, NIH
* Minifie, Fred D., Department of Speech and Hearing Sciences, University of Washington, Seattle (Representing American Speech-Language-Hearing Association)
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Null, Cynthia H., Federation of Behavioral, Psychological, and Cognitive Sciences
O'Connor, Kevin, Federation of American Societies for Experimental Biology
Palmer, Craig, American Dental Association
Pearson, Greg, The Blue Sheet
* Preston, Samuel, Population Studies Center, University of Pennsylvania (Representing Population Association of America)

* Discussion Leader

Punch, Jerry, American Speech-Language-Hearing Association
Reiser, Stanley, University of Texas Health Science Center at Houston
Rich, Clayton, Provost, University of Oklahoma Health Science Center, Oklahoma City
* Rosenzweig, Robert M., President, Association of American Universities
Russell, Yvonne, Associate Dean for Community Affairs, University of Texas Medical Branch, Galveston
* Satcher, David, President, Meharry Medical College (Representing Association of Minority Health Professions Schools)
* Saunders, J. Palmer, Dean, Graduate School of Biomedical Sciences, University of Texas, Galveston
Scheman, Carol, Association of American Universities
Schuell, David, U.S. Department of Health and Human Services
Short, Elizabeth, Association of American Medical Colleges, American Federation for Clinical Research
Spahr, Frederick T., Executive Director, American Speech-Language-Hearing Association
Spencer, William A., President, Texas Institute of Rehabilitation and Research, Houston
Sprague, Charles C., President, University of Texas Health Science Center at Dallas
Stallones, Reuel, Dean, School of Public Health, University of Texas Health Science Center at Houston
Stein, Bernard, National Science Foundation
Stone, Robert S., Dean, College of Medicine, Texas A & M University
Swisher, Scott, Department of Medicine, Michigan State University (Representing American Red Cross)
Tate, Curtis D., Deputy Director, Division of Contracts and Grants, NIH
Theilheimer, Lucy, American Federation for Clinical Research
* Van Woert, Melvin A., Professor, Departments of Neurology and Pharmacology, Mount Sinai School of Medicine, New York (Representing National Organization for Rare Disorders)
Waters, Harold, Assistant Chief, Special Review Section, Scientific Review Branch, Division of Research Grants, NIH
Weymueller, Robert G., American Lung Association/American Thoracic Society
Willson, Peters D., Associate for Policy Development, Alan Guttmacher Institute

* Discussion Leader

ORGANIZATIONS THAT SUBMITTED MATERIAL TO THE COMMITTEE

Academy of Pharmaceutical Sciences
Ambulatory Pediatric Association
American Academy of Dermatology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology
American Academy of Pediatrics
American Association for Clinical Chemistry, Inc.
American Association for Dental Research
American Association for Respiratory Therapy
American Association for the Advancement of Science
American Association of Anatomists
American Association of Blood Banks
American Association of Colleges of Nursing
American Association of Colleges of Osteopathic Medicine
American Association of Colleges of Pharmacy
American Association of Colleges of Podiatric Medicine
American Association of Gynecologic Laparoscopists
American Association of Neuropathologists, Inc.
American Association of State Colleges and Universities
American Association on Mental Deficiency
American Board of Medical Specialties
American Board of Psychiatry and Neurology, Inc.
American College of Cardiology
American College of Epidemiology
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Preventive Medicine
American College of Radiology
American College of Surgeons
American Dental Association
American Dermatological Association
American Federation for Clinical Research
American Federation of Aging Research
American Fertility Society
American Gastroenterological Association
American Geriatrics Society
American Heart Association
American Institute of Biological Sciences
American Laryngological, Rhinological and Otological Society
American Liver Foundation
American Lung Association
American Medical Association
American Nurses' Association
American Pediatric Society

American Pharmaceutical Association
American Psychological Association
American Psychological Association/Division on Developmental Psychology
American Red Cross
American Society for Clinical Investigation
American Society for Clinical Nutrition
American Society for Clinical Pharmacology and Therapeutics
American Society for Microbiology
American Society for Neurochemistry
American Society of Andrology
American Society of Anesthesiologists
American Society of Animal Science
American Society of Clinical Pathologists
American Society of Hematology
American Society of Human Genetics
American Society of Nephrology
American Society of Transplant Surgeons
American Sociological Association
American Speech-Language-Hearing Association
American Thoracic Society
American Veterinary Medical Association
Amyotrophic, Lateral Sclerosis Society of America
Arthritis Foundation
Arthritis Health Professions Association
Association for Gerontology in Higher Education
Association of Academic Departments of Otolaryngology
Association of American Cancer Institutes
Association of American Medical Colleges
Association of American Universities
Association of Departments of Family Medicine
Association of Independent Research Institutes
Association of Medical School Microbiology Chairmen
Association of Minority Health Professions Schools
Association of Professors of Medicine
Association of Program Directors in Internal Medicine
Association of Schools of Public Health
Association of Teachers of Preventive Medicine
Association of University Anesthetists
Association of University Professors of Neurology
Breast Cancer Advisory Center
College of American Pathologists
Consortium of Social Science Associations
Cystic Fibrosis Foundation
Delegation for Basic Biomedical Research
Down's Syndrome Congress
Endocrine Society
Epilepsy Foundation of America
Federation of American Societies for Experimental Biology
Federation of Behavioral, Psychological, and Cognitive Sciences

The Alan Guttmacher Institute
International Cystic Fibrosis Association
Joslin Diabetes Foundation, Inc.
Liaison Committee for Obstetrics and Gynecology
Lupus Foundation of America, Inc.
Muscular Dystrophy Association, Inc.
National ALS Foundation, Inc.
National Association for Visually Handicapped
National Black Association for Speech, Language, and Hearing
National Council for International Health
National Easter Seal Society
National Foundation for Infectious Diseases
National Kidney Foundation
National Lupus Erythematosis Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Reye's Syndrome Foundation
National Society for Medical Research
National Tuberous Sclerosis Association, Inc.
Nutrition Foundation
Orthopaedic Research Society
Population Association of America
Renal Physicians Association
The Rockefeller Foundation
Society for Experimental Biology and Medicine
Society for Gynecologic Investigation
Society for Investigative Dermatology, Inc.
Society for Pediatric Research
Society for Research in Child Development
Society for the Study of Reproduction
Society of Chairmen of Academic Radiology Departments
Society of Investigative Dermatology
Society of Toxicology
Society of University Urologists
Spina Bifida Association of America
Tri-Council on Nursing
United Cerebral Palsy Association, Inc.
Washington Committee for Neurosurgery

APPENDIX B

THE CURRENT ORGANIZATIONAL STRUCTURE OF THE NATIONAL INSTITUTES OF HEALTH

Thomas D. Morris

CONTENTS

PART I

INTRODUCTION: PURPOSE AND METHOD

The objective of this paper is to provide the general reader with an overview of the internal organizational structure of the NIH as viewed by a management analyst, not from the perspective of either a scientist or a medical professional. It tries to portray observations on the dynamics of the organization--"what makes it tick"--and the motivations that appear to drive the organization, as well as its conventional management structure and processes. In Part III of this paper, suggestions are discussed which are aimed at preserving the great strengths of the current structure, while making it better able to cope with present and future demands on top management.

Fact Finding Performed in Preparing This Paper

The fact finding that underlies this paper consisted of four steps which are briefly described below:

Step 1. Interviews

By far the most significant work performed has been personal discussions with over 70 key officials. In summary, they consisted of the following:

	No. of Interviews
Office of the Director	16
Bureaus and Institutes	17 (plus associates)
Research and Central Services Divisions	28 (plus associates)
Agencies Proposed for Transfer to NIH	6
PHS/HHS Officials	¾(over 100 individuals)

The relatively large number of interviews in supporting organizations represents an effort to look closely at organizations many of whose costs are borne by levies on the Bureaus and Institutes, whose activities they support. It seemed prudent to understand these activities due both to their costs and to their importance in the overall operation of the NIH program from an organization structure viewpoint.

The responsiveness and clarity of those contacted were generally outstanding.

Step 2. Key Documents

In every interview we invited the submission of selected publications or reading materials to enhance our understanding. We were furnished with over 100 pieces, consisting of:

Basic Data: Budget Justification volumes (4), Organization Handbook, NIH Fact Book, NIH Public Advisory Groups, Scientific Directory, NIH Data Book, NIH Draft Research Plan FY 1985, NIH Evaluation Plan FY 1983.

Current News: The NIH Record published every two weeks for all employees; The Research Resources Reporter distributed to 22,000 readers on exciting developments in NIH supported research projects; The NIH Guide for Grants and Contracts, distributed monthly to 30,000 current and prospective grantees and contractors; the Search for Health (a weekly); and the News and Features from NIH (a monthly), distributed to the media.

Program Publications: One or more from every Institute and from most of the research support divisions, describing progress and plans as well as organization and operational matters. In several cases these are prepared by Councils or Boards as required by statute (as in the case of Arthritis, Diabetes, and Digestive Diseases).

These publications are skillfully written and illustrated to bring complex subjects within the grasp of the non-scientist. The documentation of the NIH story is superb and without question the best this observer has seen in the federal government. It would be a disservice to the nation to require curtailment of such high value educational materials. The list of available titles is in excess of 700 entries.

Step 3. Special Analyses of the Volume of Research Grant Applications by Institute

One of the most useful ways to view the interaction among Institutes and Study Sections is to examine the flow of grant applications. The excellent information system maintained by the Division of Research Grants makes this easy to do. Hence, we obtained computer printouts: by Study Section, showing the number of applications reviewed for each Institute in FY 1983; and by Institute, showing the number of secondary or dual interest referrals made to other Institutes. These data are useful for examining the application review and award processes, as well as the degree of overlapping interests among the Institutes.

Step 4. Public Hearings held by the Committee for the Study of the Organizational Structure of the National Institutes of Health, September 26-27, 1983

These excellent discussions provided a feel for the viewpoints of the various communities with which NIH and the Congress work on a continuous basis. The hearings also presented an opportunity to study their official views in a series of position papers.

In addition to the above, the committee staff has furnished a number of manuscripts dealing with past and current issues that are of high value.

PART II

FINDINGS IN RESPECT TO THE ORGANIZATIONAL STRUCTURE OF THE NIH AND CURRENT ISSUES

Figure 1 pictures an organizational structure in which 25 separate activities are reporting to the Director. By all rules of organization theory--the analyst would say--this is an unmanageable span of control.

Added to this apparently impossible managerial burden are many other complexities. The organizational basis for the scientific research activities does not follow a consistent logic as indicated below:

Some are by disease: cancer; arthritis, diabetes, digestive diseases, kidney diseases; neurological diseases; communicative disorders, stroke; allergies, infectious diseases.

Some are by organ: heart, lung, blood; eye; dental.

Some are by life stage: aging; child and human development.

Some are by field of science: general medical sciences; environmental health sciences.

Because all but one of the scientific research activities engage in a substantial in-house research program, requiring sophisticated laboratories and clinical facilities, there appears to the layman to be a proliferation of such organizational entities in the basic fields of science: biology, chemistry, genetics, pathology, etc.

Then, as one begins to inquire into operations, the highly decentralized nature of the National Institutes of Health comes into still sharper focus. There are fourteen entities outside of the Director's immediate office which receive direct congressional appropriations that are not subject to formal control by the NIH Director in the implementation stage.* Most of these entities were, in fact, established by Acts of Congress, and their activities are followed closely from year to year by both Authorizing and Appropriating Committees, as well as by the huge network of professional societies and associations that presses on many fronts for improvement in the nation's health care.

*It should be noted that the Institutes reimburse several of the central service and research support activities; and are assessed to maintain the “General Expense Fund” used by the Director to finance selected NIH-wide projects ($12.8 million in FY 1983).

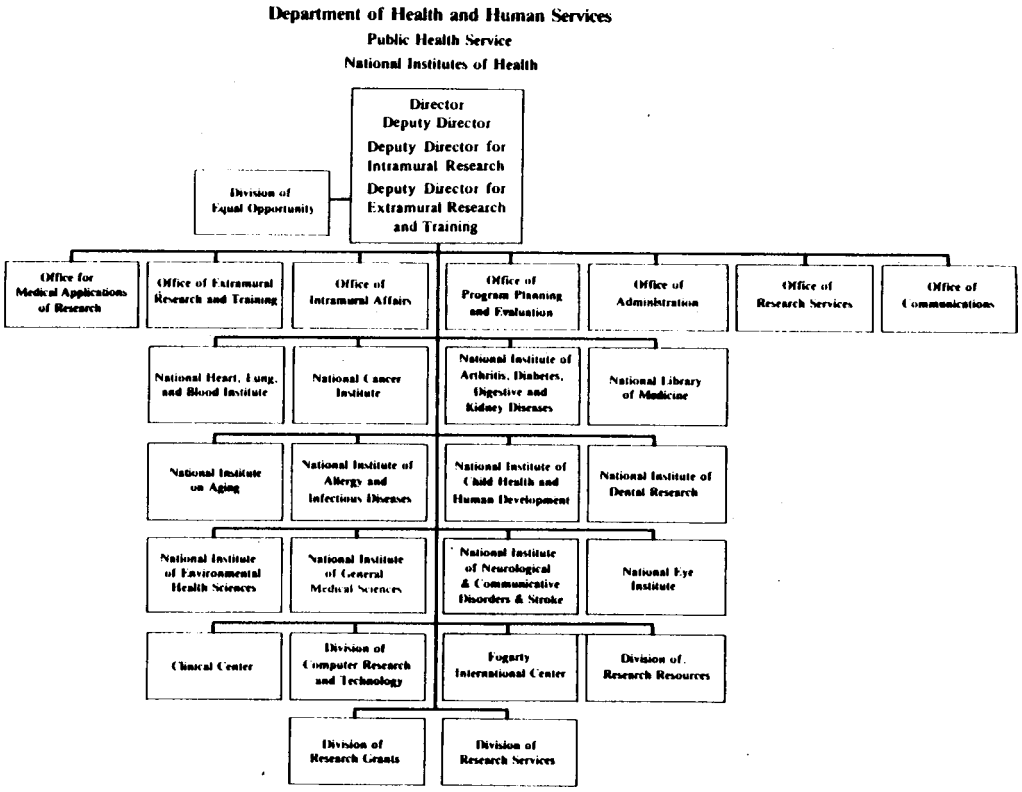


FIGURE 1 The organizational structure of NIH.
SOURCE: NIH Extramural Programs, 1983.

Are the above complexities, in fact, serious problems or hindrances to successful performance? The resounding answer is NO, not today. The directors of each Institute were asked how they assess today's structure. Except for widespread concern with current Congressional initiatives to create an Arthritis Institute, and move other PHS functions into NIH, general satisfaction was expressed:

"It is working."

" It is working well now."

"We have no problems."

"Today the Institutes work out their problems by bargaining in good faith."

"I am concerned by support costs."

"We are constantly working out joint interests with others. We welcome Congressional attention."

"No organization matters of concern."

"Present organization works because of the people, not the logic. It is working well today."

"Arthritis is inevitable. Support costs need tighter management."

"It is working well. . .planning with the community is the key."

"Our Institute makes sense because it meets a need."

"More overhead is not needed. NIH loses."

Based on fairly detailed interviews with its leaders, this paper examines how the present organizational structure achieves such satisfying results.

The Major Organizational Components of NIH

The three major components of NIH include: the Office of the Director; the Bureaus, Institutes and Divisions; and the NIH Research and Central Services Divisions. Figure 2 summarizes the size data for each of these components.

The Office of the Director is a tiny structure--largely staff in nature--whose role is leadership. The Bureaus and Institutes are the "producing/mission" entities and control most of the funds applied to research programs. The Research and Central Services Divisions exist primarily to support the programs generated or sponsored by the Bureaus and Institutes, but have some self-initiated projects, as discussed later. As illustrated, the formal structure today employs over 16,000 people, full and part-time, intermittent, permanent and temporary, including experts and consultants. Its budget for FY 1983 was $4.0 billion. Congress increased this amount to $4.5 billion in 1984.

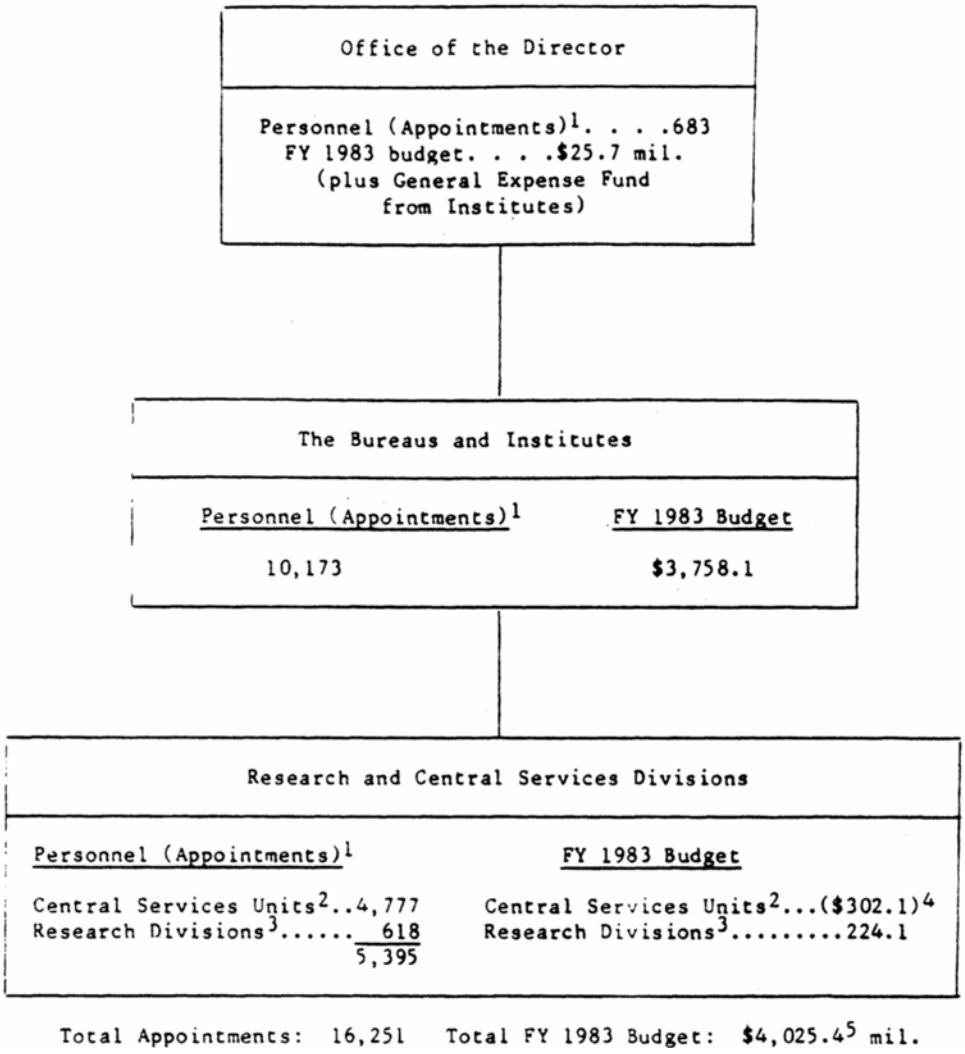


FIGURE 2 Overview of size data.

[1]Personnel Appointments data is total full and part-time including visiting program, staff fellows, experts and consultants. These figures represent both ceiling and non-ceiling employment.

[2]Includes Clinical Center, Division of Computer Research and Technology, Division of Research Services, and Office of Research Services.

[3]Includes Division of Research Grants, Division of Research Resources, and Fogarty International Center.

[4]The funds for the Central Services Units are included in the Bureaus/Institutes and Research Divisions budgets.

[5]Includes $17.5 million for the NIH Buildings and Facilities Account.

SOURCE: Based on data from the NIH Office of Administration; and TAPS Monthly Employment Report Summary, July 23, 1983.

Not displayed on the formal chart is the network of chartered advisory committees--some 149 in number and containing about 2,500 appointees, mostly non-government experts--which are a vital part of the NIH program:

The National Advisory Councils. An advisory council is located in each institute and the Division of Research Resources and is a source of advice on policy and planning issues. Their major purview is the extramural research program, and, by statute, they must approve each grant or cooperative agreement before it qualifies for funding. Some institutes also have chartered advisory committees or boards that deal with particular program areas within the institute. The Director's Advisory Committee provides advice to the Director on NIH-wide issues but has no statutory basis or authority.

The Boards of Scientific Counselors. Each institute with a major intramural research effort has a board of scientific counselors. The boards oversee the intramural program and periodically assess the work of each tenured scientist.

The Scientific (Peer) Review Groups. There are three major types of scientific review groups. The most common type, known as the Study Sections, works under the central coordination of the Division of Research Grants. Their function is the first level review and rating of individual applications for research grants. A second type, known as the Review Committees, is attached to the Institutes. They conduct the first level review of applications for Center grants, program grants, and training grants. Finally, Institutes often have Program Advisory Committees, which suggest types of contractual projects that should be undertaken, and review conceptual plans for contracts. Other types of scientific review groups are used for more specialized purposes.

In addition to the National Advisory Councils, some of the other committees are statutory, including the President's Cancer Panel, the the National Arthritis Advisory Board, the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the Board of Regents of the National Library of Medicine.

One final feature of the overall organizational profile is the budget and staffing profile, as outlined in Table 1 and Table 2.

The direct operations of NIH take place in the Bethesda enclave and at several leased locations in Bethesda (12,700 personnel including 2,600 in leased space); in Research Triangle Park, N.C. (the headquarters of NIEHS with 600 employees); and five other special sites: Poolesville, Md. (animal resources); Gerontology Laboratory, Baltimore, Md. (NIA); Frederick, Md. (primarily NCI); Rocky Mountain Laboratory, Montana (NIAID); Phoenix, Arizona Pima Indian Project (NIADDK).

TABLE 1. Budget profile for fiscal year 1983,

Item	Amount (Millions)	Percent	
Research Grants	$2,687.6		Covers some 23,000 grant and contracts of all type 10,600 research trainees 1,200 institutions.
Research Training Awards	164.7		
R&D Contracts	320.3		
Subtotal	$3,172.6	79	
Intramural	500.9	12	2,700 research projects.
Other Institute Costs Research Mgt. & Support	199.8		
NCI Disease Control & Construction	56.6	-	
Total Institutes & Research	3,929.9	98	Total of 16 appropriatio including Institutes, NL FIC, DRR, OD and Facilit
National Library Medicine	52.3		
Office of Director	25.7		
Buildings & Facilities	17.5	-	A significant feature of budget from year to year that over 80% of annual funds are "committed" in advance.
TOTAL	$4,025.4	100	

SOURCE: Data from the NIH Office of Administration.

TABLE 2. Staff profile as of July 23, 1983.

Full Time	Total Appointments
Civil Service	12,110
Commissioned Corps	837
Visiting Scientists	282
Staff Fellows	851
	14,080
Part-Time & Intermittent	
GS & Wage	1,573
Experts, consultants	598
	2,171
Total	16,251

SOURCE: Data from TAPS Monthly Employment Report Summary, July 13, 1983.

The Office of the Director

The Office of the Director is the "glue" that holds together the highly decentralized structure of the Institutes and Support Organizations (See Figure 3). Its major roles are, first, to provide such NIH-wide planning and administration as required in matters of program planning and evaluation, budget, personnel, contracting, public information--the normal functions of the front office of a major federal agency; and, second, to facilitate attention to the numerous crosscutting issues and initiatives that arise from emergencies, the interests of the Secretary, the concerns of Congress, and the proposals of innumerable outside groups. NIH has been blessed with the leadership of scientists with high sensitivity to the right degree of top management attention to these issues, and has avoided the micromanagement which tends to develop in most federal agencies.

The Director himself has a team of three Deputies to help him as partners in overall leadership: one is a generalist; one is in charge of intramural programs; and one is in charge of extramural research and training programs. Their key technique of management is through staff meetings. The most important is the weekly meeting of the Directors of the Bureaus, Institutes and Divisions (BIDs) with the NIH Director. Similar sessions are held at regular intervals among the Scientific Directors, the Extramural Program Officials, the Executive Officers, the Planning and Evaluation Officers, International Representatives, etc. The impression one gets is that these devices are highly respected and effectively used at NIH.

The immediate office of the Director and his Deputies contains a number of special assistants and small staff units, as well as Trans-NIH Committees which are set up, as needed, to attack high priority problems. Examples of the special staffs and special committees are as follows:

Special Staffs. These include the Office of Intramural Affairs, the Office of Extramural Research and Training, and the Division of Equal Opportunity. Other special staffs include the Office of Medical Applications of Research (OMAR) and the Office for Protection from Research Risks (OPRR). OMAR is seeking to improve the translation of biomedical research results into knowledge that can be applied in the practice of medicine and public health. OMAR holds eight to ten consensus conferences each year. OPRR develops and supervises HHS-wide policies governing the care and treatment of both human and animal subjects used in medical research.

Special Committees. These are communication and working groups covering a wide spectrum of cross-cutting subjects. Some special committees are required by statute such as the three groups for Arthritis, Diabetes, and Digestive Diseases. Special committees which are particularly active at present include: the

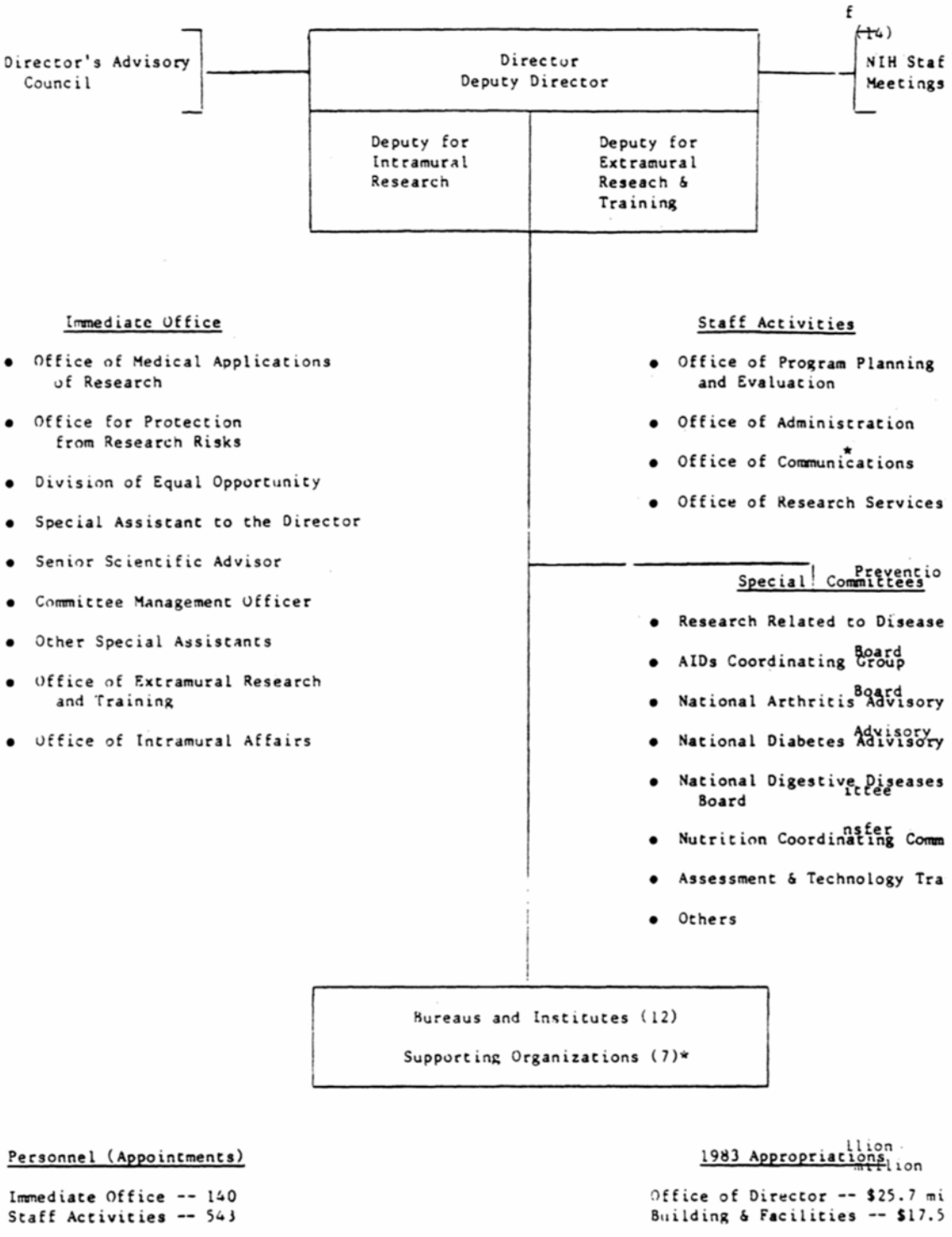


FIGURE 3 The Office of the Director.
SOURCE: Data from NIH Office of Administration.
*ORS is classified in our analysis as a "supporting organization" and is discussed as such in a later section. Its staff contains 1,636 total appointments.

special committee for Research Related to Disease Prevention; the AIDS Coordinating Group; and the Nutrition Coordinating Committee. More than a dozen others were mentioned in the various interviews including Alzheimer's Disease, Private Sector Coordination, Radiation, National Toxicology Program, Genetics Coordination, Recombinant DNA, and so on.

Three of the major staff activities in the Director's Office are the Office of Communications, the Office of Program Planning and Evaluation, and the Office of Administration. All three of these offices practice high decentralization to Institute counterparts, subject to NIH-wide policies and procedures. All three have professional staffs of the highest skill. The functions of these offices are outlined as follows:

The Office of Program Planning and Evaluation. This office advises the Director, NIH, and senior agency staff on health research and science policy issues, agency planning, evaluation, legislative, and program analysis responsibilities, and directs activities associated with the Director's Advisory Committee. These responsibilities encompass major policy analysis and development, management of the agency's central planning process, the development of legislative proposals and provision of legislative liaison, management of the agency's evaluation program and the development of cross-cutting evaluation studies, and the monitoring of the flow of funds supporting health research and development and production of research personnel in bioscience and relevant health-related fields. Key publications include the annual NIH Research Plan, NIH Evaluation Plan, Legislative Highlights and Issues, NIH Data Book, summaries of the Director's Advisory Committee meetings, and a wide variety of policy analysis papers.

The Office of Communications. This office is responsible for the overall coordination, planning and direction of NIH information activities. As mentioned earlier, the documentation of the NIH story is superb and much of the credit is due to the leadership of this office. Among its publications are the NIH Record for internal current news, and the Search for Health and News and Features which keep the media currently in tune with progress in medical research.

The Office of Administration. This office performs the tasks involved in overall coordination of the budget, personnel, contracting for R & D, and surveys of misconduct allegations. A vital role is the continuous budget planning cycle which begins two years in advance of the fiscal year. This cycle

involves: planning sessions by the NIH Director and each major organizational unit's Director (a responsibility of OPPE and a major linkage between the planning and budgeting functions); presentations to the Assistant Secretary and the Secretary and OMB; the final mark for the President's budget which the Director must allocate; the Congressional phase; and the implementation of the budget. The Director of Finance points out that there are over 400 “cells” in the NIH budget as it is displayed to Congress and through which it must be managed.

A continuing challenge appears to be achieving linkage between program planning and budget planning.

Summing up the Director's Office One is impressed most of all with the highly informal atmosphere and the obvious stress on excellence as the only standard acceptable to the Director. Second, one is impressed with the absence of the normal trappings of bureaucratic authority; hence the NIH Director manages largely on the basis of persuasion, consensus and knowledge. Third, one is impressed with the number, quality, and effectiveness of the special staffs, committees, and staff meeting mechanisms; without them the task of internal communications would be impossible.

The Key Questions Asked:

Can this Office, as now constituted, effectively support further growth, such as Congress might mandate?

Particularly, is closer management of the support actitivies needed, as suggested by some?

Is the Office able to respond with sufficient speed and effectiveness to emergency and cross-cutting issues?'

These and related questions will be examined further in Part III.

The Bureaus, Institutes, and Divisions

The scientific research program is carried out largely through the Bureaus and Institutes which were established in all cases save one by Congress since 1937. A recapitulation follows.

Bureau or Institute	Date of Establishment*	Personnel (Appointments) (as of 7/23/83)	FY 1983 Budget (millions)
Bureaus			
NCI	1937	2,860	$987.6
NHLBI	1948	1,075	624.2
NIADDK	1950	836	413.5
NLM	1956	659	52.3
Institutes			
NIA	1974	505	94.0
NIDR	1948	449	79.3
NIGMS	1963	190	369.8
NIEHS	1969 (Non-statutory)	939	164.9
NINCDS	1950	914	297.1
NIAID	1948	878	279.1
NICHD	1963	577	254.3
NEI	1968	291	141.9
Total		10,173	$3,758.0

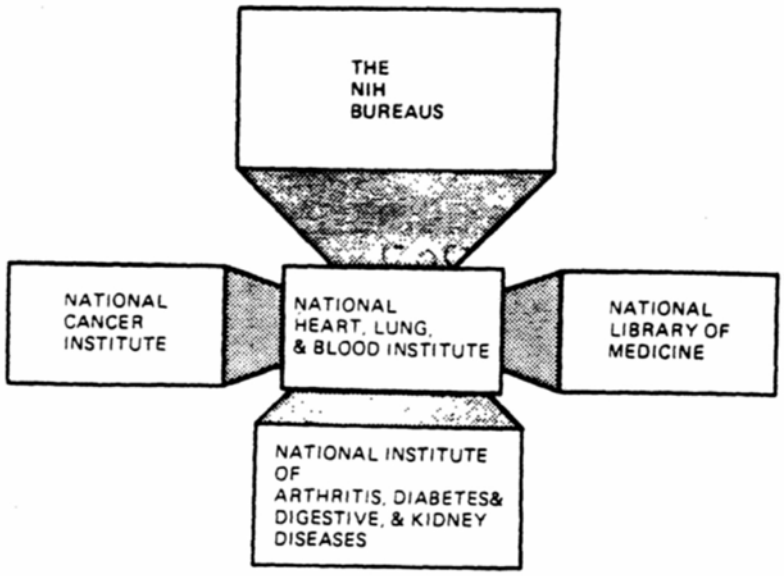
SOURCE: Data from the NIH Office of Administration; TAPS monthly Employment Report Summary, July 23, 1983; and 1983 NIH Almanac.

It should be noted that the only distinction between “Bureau” and “Institute” is one of hierarchical rank. Bureaus in the classical structure have Divisions as their components. Institutes, however, are themselves Divisional entities. In practice, the term “Institute” is the significant title. (See Figure 4.)

How Is An Institute Organized? A typical structure is shown in Figure 5. The Office of the Institute Director is small and a microcosm of the Office of the NIH Director, i.e., one finds here the Office of Administration, the Office of Program Planning & Evaluation, the Communications function and special assistants. At the Director's level are the National Advisory Councils covering the extramural program, and the Boards of Scientific Counselors covering the intramural.

The Intramural Program. With a FY 1983 budget of $500.9 million, the intramural program represents about 12% of the total NIH budget. The majority of the intramural program is located on campus in Bethesda and consists of a staff of over 5,000 laboratory and clinical workers, plus a substantial portion of the supporting staffs discussed later, as well as a substantial share of the overhead management staffs of the NIH and Institute Directors.

*Many were established under other names, some as divisions.



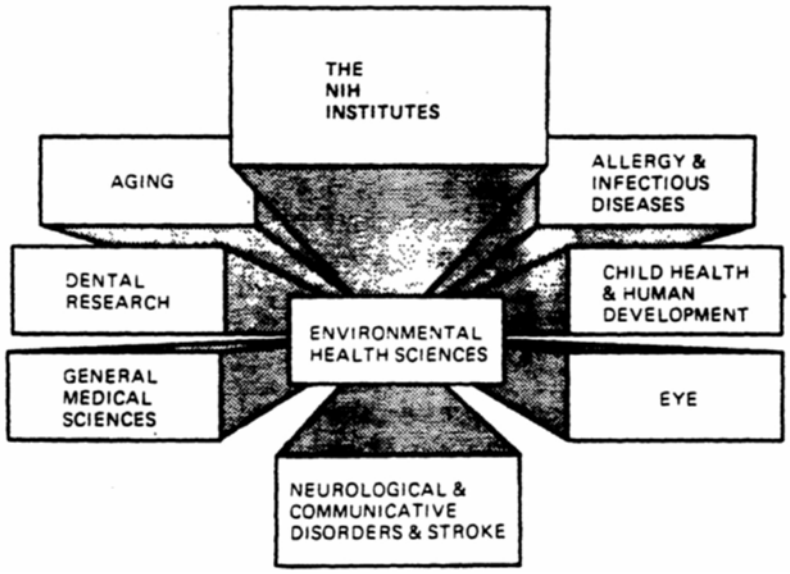


FIGURE 4 The NIH bureaus and institutes.
SOURCE: NIH Peer Review of Research Grant Applications, January, 1983,

The overseer of the Intramural Program within the institutes is designated the Scientific Director. This official enjoys wide latitude in the organization and work program of the Institute, with oversight from the Board of Scientific Counselors. The Scientific Directors meet regularly with their counterparts from other institutes under the chairmanship of the Deputy Director for Intramural Research. A second key official is entitled "Clinical Director" and these officials meet periodically with the Director of the Clinical Center and a designee of the Deputy Director for Intramural Research to set policies for the Clinical Center and patient care practices.

A key factor in the NIH intramural program is the stress on excellence. Selection and promotion of tenured appointees is controlled by the Scientific Directors. Only 5% of Staff Fellows can expect to reach tenure and that must occur within seven years. The NIH intramural program claims four Nobel Prize recipients within the last 15 years. A constant informal review of research in process is conducted and a formal review is made by the outside Board of Scientific Counselors. However, a virtue of the intramural program is the ability of its scientists to undertake initiatives which offer no immediate short-range payoff. Today there are approximately 2,700 separate projects in process, a catalog of which is published periodically. With limitations of both space and funds, the intramural program is projected to remain at its current level of effort.

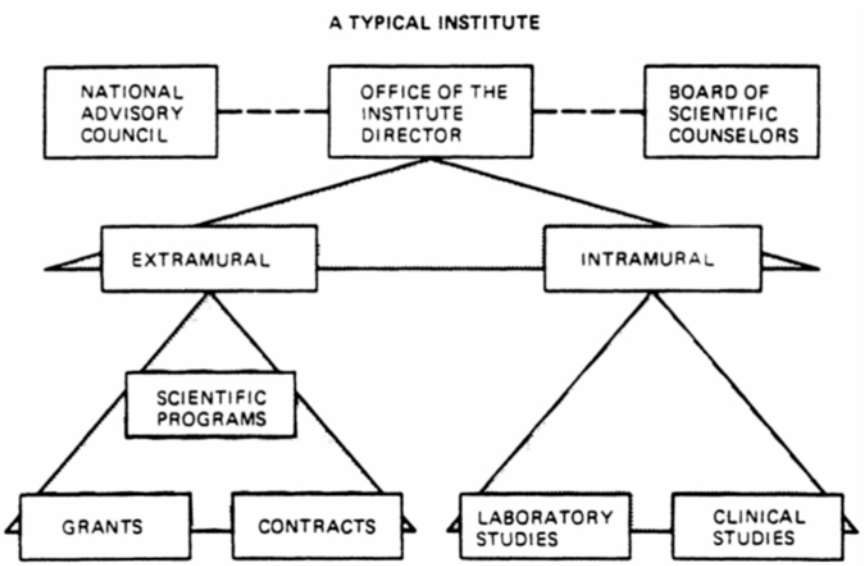


FIGURE 5 A typical institute. This figure, taken from an NIH publication, mixes mechanisms (bottom line) with structure. It should not be interpreted to mean that extramural programs are organized by mechanism (such as grants and contracts). Although the latter was typical 15 years ago, today program branches in the extramural programs have subject matter rather than mechanism titles. Also, a typical institute today has an epidemiology and biometry component, which is neither extramural nor intramural.
SOURCE: NIH Peer Review of Research Grant Applications, January 1983.

The Extramural Program. The extramural program involves the "research management and support" personnel in the Institutes plus the Division of Research Grants (DRG), the Division of Research Resources (DRR) and the Fogarty International Center (FIC). (Certain components of FIC also support the NIH intramural program.) The Institutes, DRR and FIC are the final award authorities and monitoring agencies for over 23,000 research and research training grants and contracts. The FY 1983 award projections (in millions of dollars) were:

Research Projects	$2,096.0
Research Centers	373.4
Other Research	218.2
Training Awards	164.7
R&D Contracts	320.3
	$3,172.6

How Are Grants Processed? In the opinion of a majority of the people that were interviewed, the NIH peer review process for grant awards is among its most "brilliant achievements." It is a two-level review as illustrated in Figure 6. Applications are received and recorded by the Division of Research Grants (DRG), a central operating organization which decides on the referral of the application for review and maintains the Study Sections which conduct the initial review of research project applications. DRG itself is manned by a group of 100 Ph.D.s and M.D.s who are experts in their particular subject matter. The Study Sections, of which there are currently 64, are structured to provide the highest level of scientific competence in their area of coverage. The Study Sections are primarily established along lines of scientific disciplines and with very few exceptions are not captives of the individual Institutes.

Applications are referred concurrently to the Institutes or Research Divisions, which have the final authority for awarding grants. The second level of review is performed by that unit's National Advisory Council, which must approve applications before they can be funded. For the most part, the institute or division selects applications for funding based on priority scores assigned to each application by the Study Sections. Project periods of competing

research project grants averaged 3.2 years in FY 1982 (67 percent of research grant awards were for three years, and 20 percent were for five years), and competing research training awards 5.0 years.

The one deviation from the above process occurs in connection with center grants, program project grants, and research training awards where the Institute establishes its own "Review Committee" of experts to conduct the first level of review. The rationale here is that multidiscipline committees are required and are better selected and maintained by the Institutes themselves. There are approximately 36 such committees active at the present time.

In view of the differing bases of organization among the Institutes, there are frequent interfaces among them on individual applications. Similarly, the Study Sections typically review grant applications for several Institutes. In order to obtain insights into the extent of such interfaces, several preliminary studies were conducted, using data provided by the Division of Research Grants, which revealed:

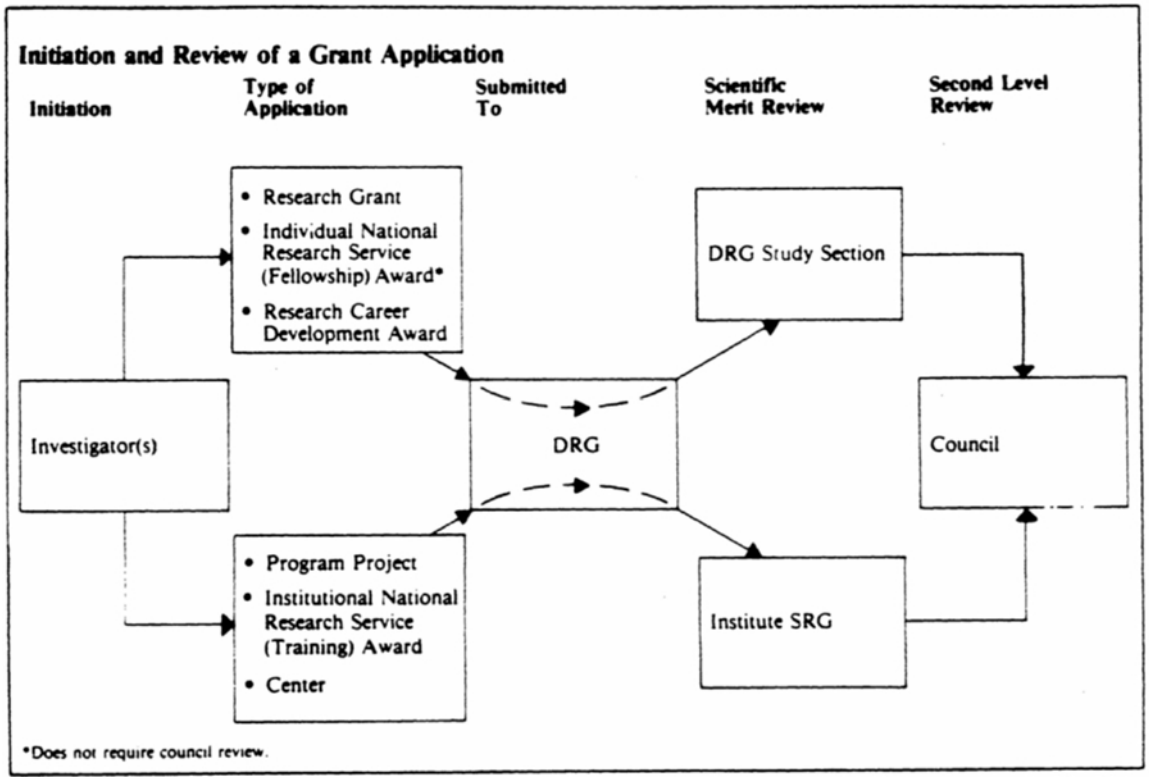


FIGURE 6 Initiation and review of a grant application.
SOURCE: Orientation Handbook for Members of Scientific Review Groups, August 1982.

1. Study Sections Typically Review Grant Applications for Several Institutes. In FY 1983 there were 33 Study Sections which reviewed 200 or more applications for RO1s (investigatorinitiated grants). The number of Institutes was:

No. of Institutes Primarily Served by Top 33 Study Sections*	Number of Study Sections	Study Sections Referring 5 or more Applications to an Institute
One Only	3	-Experimental Therapeutics -Radiation -Visual Sciences
Two Only	5	-Chemical Pathology -Experimental Immunology -Neurological Sciences -Pathology B -Reproductive Biology
Three Only	1	-Pathology A
Four Only	4	-Allergy and Immunology -Neurology A -Virology -Respiratory & Applied Physiology
Five Only	4	-Biomedical Endocrinology -Immunobiology -Physiology -Surgery, Anesthesiology & Trauma
Six or More	16	
TOTAL	33	

*Supported is defined as meaning that an institute received 5 or more applications from a study section in FY 1983.

2. Most Institutes Must Look to Several Study Sections to Review and Rate Their Applications The studies examined each Institute's relations with all Study Sections during FY 1983 and identified each case in which an Institute received 50 or more applications from a single Study Section:

Institute	Number of Study Sections Reviewing 50 or More Applications	Comment
NIA	1	Human Development and Aging Study Section. Also supports NICHD.
NIAID	9	Widely spread
NIADDK	15	Widely spread
NCI	17	Widely spread
NIEHS	1	Toxicology Study Section. Serves six.
NIGMS	18	Widely spread
NEI	3	Visual Sciences Study Sections
NHLBI	10	Widely spread
NINCDS	7	Widely spread
NIDR	2	Oral Biology and Medicine Study Sections
NICHD	6	Widely spread

The above would suggest that there are only four institutes with close attachments to a few study sections: Aging, Eye, Dental, and Environmental Health. But even here, many other Study Sections may review small numbers of applications.

3. About 19% of all Research Project Applications Interest Two Institutes. Another way of looking at the cross-cutting interactions of NIH Institutes is the number of research applications that are given both a primary and a secondary referral by the Division of Research Grants. In FY 1982-1983, there were 40,656 applications referred to NIH Institutes, 18.9% of which were of "dual interest." This indicates the degree to which Institutes have potential overlapping interests:

Institute	Total Primary Applications 1982-83	Total Primary Applications Also Referred to Another Institute 1982-83	Percent Referred
NIA	1,975	616	31.2%
NIAID	3,465	1,213	35.0
NIADDK	4,940	939	19.0
NCI	7,410	1,060	14.3
NIEHS	715	283	39.6
NIGMS	4,722	652	13.8
NEI	1,710	122	7.1
NHLBI	5,614	972	17.3
NINCDS	4,117	756	18.4
NIDR	1,091	114	10.4
NICHD	3,599	789	21.9
DRR	1,136	127	11.2
NLM	162	35	21.6
Total	40,656	7,678	18.9%

In addition to NIH Institutes, DRG processed applications for several PHS organizations, including the National Institute of Mental Health which had 2,897 applications, 313 of which were referred to other institutes including NIA, NICHD, and NINCDS.

4. Despite the High Incidence of Dual Referrals, There is Relatively Little Joint Funding of Grants by the Institutes. For fiscal years 1982-1983 (through August 15, 1983) there were approximately 300 jointly funded projects totaling $44.4 million. All Institutes were represented. Examples of such projects included:

Hypertension in the Elderly, six projects funded jointly by NIA and NHLBI.

Numerous workshops and conferences.

Numerous minority student training and biomedical research programs.

How is Program Planning Being Approached by the Institutes? Program planning and evaluation techniques have become actively used tools in the past decade, partly in response to congressional requirements (as in the case of NCI, NIADDK, NIA). Today an NIH-wide Research Plan and Evaluation Plan is prepared by the Office of Program Planning and Evaluation (OPPE) based on inputs from the Institutes, with whom OPPE is constantly working.

Some Institutes use special advisory groups to develop plans and make annual or periodic updates with budget forecasts. Institutes doing the most intensive planning involve the scientific community extensively. Most published plans are presented with high skill to attract wide readership. The National Eye Institute has one of the most vigorously applied planning programs, which covers five component five-year plans and sets out areas in the intramural and extramural programs to be held level and those to be expanded during the planning period. On the other hand, there are those who are skeptical as to the value of such comprehensive efforts other than to report on "where science is going." These officials stress that the course of research is driven by the individual investigator and that the keys to real progress are: (1) keeping only superior people in the intramural program; (2) attracting the best applications for grants and selecting only the best of these for award; (3) monitoring the research results carefully, and (4) acting promptly on findings. In a phrase: "Excellence is the watchword." The challenging question is the extent to which such planning tools can assist in setting priorities and guiding budget decisions.

The opportunity for Trans-NIH program planning, evaluation and coordination is illustrated by the large number of areas of crosscutting activity among the Institutes. Examples of some of the major cross-cutting areas are listed below:

Cross-Cutting Areas	Number of Institutes and Research Divisions	FY 1983 Actual (in millions)
AIDS	7	$ 21.7
Arthritis	11	75.5
Cystic Fibrosis	6	11.3
Diabetes	12	165.3
Immunology Research	12	406.9
Nutrition	12	164.3
Prevention	13	957.2
Smoking and Health	5	19.7

SOURCE: Data from NIH Office of Administration.

Summing up the Bureaus and Institutes The highly effective research programs of NIH are carried out by a system of autonomous Institutes whose structure has grown over the years in response to public and

congressional interests in specific diseases, organs, and other criteria including life stage and fields of science. To cope with the lack of perfect logic from a scientific and medical point of view, the Directors have developed successful techniques of communication to resolve cross-cutting interests. Furthermore, the 64 Study Sections, which are independent of the Institutes, constitute a powerful "organizational overlay" that brings the logic of science and medicine to the vital peer review process.

Today's Key Issues Regarding Organization:

Can this effective, decentralized mode of organization be preserved?

What would be the impact of statutory mandates to establish a separate Arthritis Institute or a Nursing Research Institute; and to transfer into NIH the National Center for Health Services Research (NCHSR), the National Center for Health Statistics (NCHS), and the National Institute for Occupational Safety and Health (NIOSH)?

Should relationships between the Intramural and Extramural Research Programs be reviewed?

Some observations on these questions will be offered in Part III of this paper.

The NIH Research and Central Services Divisions

The seven remaining components of NIH comprise those activities that not only engage in research programs themselves, in varying degrees, but also provide the professional facilities, tools, and resources needed by the Extramural community and the Intramural organizations to conduct scientific research. They are thus both unique and indispensable. Most are supported by reimbursements from the Institute budgets, but two have separate appropriations. These organizations include the divisions shown in Figure 7 plus the Office of Research Services (located in the NIH Director's Office). They have the following responsibilities:

The Clinical Center. The Center is staffed by 2,300 personnel and had a budget of $92.4 million in FY 1983. It is a 540-bed hospital and contains 40% of all the hospital beds in the U.S. devoted exclusively to clinical research. It also houses the new Ambulatory Care Research Facility and some Institute laboratories.

The Division of Computer Research and Technology. This Division is a unique scientific research support and computer service organization. With its staff of 345 personnel and a budget of $43.6 million in FY 1983, it serves 2,000 terminals and 200,000 databases. Its research staff engages in collaborative projects with the Intramural scientists, bringing expertise in the mathematical and physical sciences. The Computer Center serves all NIH activities, not just the Intramural, and the NIH Administrative management information system is considered to be in the forefront of management technology.

The Division of Research Services. With a staff of 496 and a FY 1983 budget of $28.0 million, this division provides scientific and technical support for Intramural research with animals, equipment, engineering and instrument fabrication, graphics, visual aids, and library services. High professionalism pervades all of these staffs. Biomedical engineers participate as collaborators with peer scientists in the laboratories and its members do some self-initiated projects. They also participate in training personnel from other countries. The Veterinary Resources Branch maintains a major facility for large animals and handles primates, livestock, and fox hounds. This branch also furnishes 700,000 rodents annually for research uses. There is international interest in the 250 strains of rodents produced.

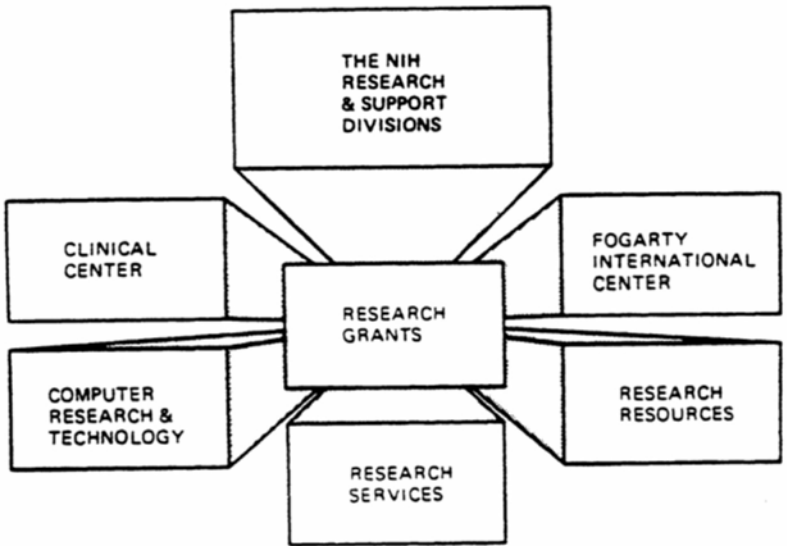


FIGURE 7 The NIH research and support division.
SOURCE: NIH Peer Review of Research Grant Applications, January, 1983.

The Office of Research Services. This office, officially part of the Office of the Director, NIH, and headed by a scientist administrator, supports the entire campus complex with safety programs, engineering and facilities services, and administrative services including purchases of supplies and equipment, transportation, and communications. The Division of Safety, headed by a Ph.D. engineer, is pushing the state of the art in areas such as environmental protection, chemical waste disposal, radiation safety and occupational safety in the research environment. The total staff number 1,636 with a FY 1983 budget of $114.0 million, which is reimbursed by the users.

The above four organizations provide campus and Intramural support as their primary mission, and are self-supporting through reimbursements. The remaining three organizations are predominantly Extramural:

Division of Research Grants. As previously described, the DRG handles the receipt and referral of all grant applications and operates the 64 Study Sections. Its FY 1983 budget $17.3 million. Its staff of 427 includes about 100 Ph.D.s and M.D.s to undertake the rigorous effort involved in substantive examination of 26,000 applications annually, and the preparation of the findings of the Study Sections. The peer review process is not just a “service” function, but an important part of the “quality control” management of the Extramural program, assuring objectivity and high competence in the examination and rating of applications.

Division of Research Resources (DRR). This division is a major grant-making organization, larger in fact than several of the Institutes. Its 1983 budget was $214 million, which Congress increased to $243 million in FY 1984. The staff is small at 127, but this is because the division has no Intramural program. The DRR's role to support recipient institutions of NIH grants and contracts with essential clinical facilities (74 now financed), animals (such as the 7 National Primate Centers currently being funded), development of advanced information processing and instrumentation technology (such as Nuclear Magnetic Resonance, Artificial Intelligence, and High Voltage Electron Microscopy). In addition, the grants program provides seed money to research institutions to finance pilot projects and provide financial flexibility. These supports are in the forefront of research support and indispensable to the scientific community. A special program for the support of minority biomedical research support is conducted in collaboration with the Institutes.

The Fogarty International Center (FIC). With a staff of 64 and a FY 1983 budget of $10 million, the FIC awards research fellowships and conference grants; has authority to award other grants and contracts; coordinates scientist exchanges, foreign visitors, and bilateral activities (with PHS-wide responsibility for some of these); manages the NIH International Visiting Scientists Program; and organizes and manages international scientific meetings. The FIC is also the funding channel for the Gorgas Memorial Laboratory in Panama.

These last two organizations, DRR and FIC, have autonomous research programs and direct congressional appropriations, and are known as research divisions. The majority of their budgets are devoted to extramural grants and contracts, for which DRR and FIC have final authority, and for most purposes they are treated as research institutes. Unlike the institutes, however, their missions primarily involve the support of research, through the development and support of research resources (DRR) and international research collaboration (FIC).

In total, the supporting organizations have a staff of 5,395 full and part-time personnel and annual expenditures of approximately $526 million, of which about $302 million is reimbursed by the Institutes. Interviews were conducted with Branch level supervisors in most of these organizations and one is impressed both with their technical competence and with their superior motivation to support the "biomedical revolution" of which they are an integral part. One is also impressed with the comprehensiveness and excellence of a major study which has recently been conducted for the Director of NIH, on the basis for charging the Institutes for these services, case by case, in the interest of cost control and equity. Some of the people that were interviewed raised the question as to whether tighter management of these supporting activities would be beneficial in the interest of cost management--but not to sacrifice in any way their excellent morale and high quality of performance. This question will also be considered in Part III.

In Part III of this paper, some of the questions posed in this section will be assessed and possible courses of action considered.

PART III

After considering the findings and observations resulting from this opportunity to view NIH through direct observation and discussion with its leaders, one is impressed with those features of its organization and culture which make it highly manageable today:

> The stress on performance, at every level, sweeps aside the bureaucratic struggles which usurp the time of supervisors in many organizations.
>
> The practice, almost subconsciously, of the best tenets of participative management is closely allied to the first attribute. It makes collaborators out of the entire workforce and encourages new levels of achievement in virtually every field.
>
> Tolerance for overlapping interests is perhaps the most remarkable attitudinal factor. The fact that the Institutes experience a high degree of dual interest in areas and applications, but yet are able to resolve such overlaps with a neutral party in the Division of Reseach Grants, is a brilliant achievement.
>
> Excellence of communications and documentation goes hand-in-hand with the above characteristics, and in many ways is both cause and effect.

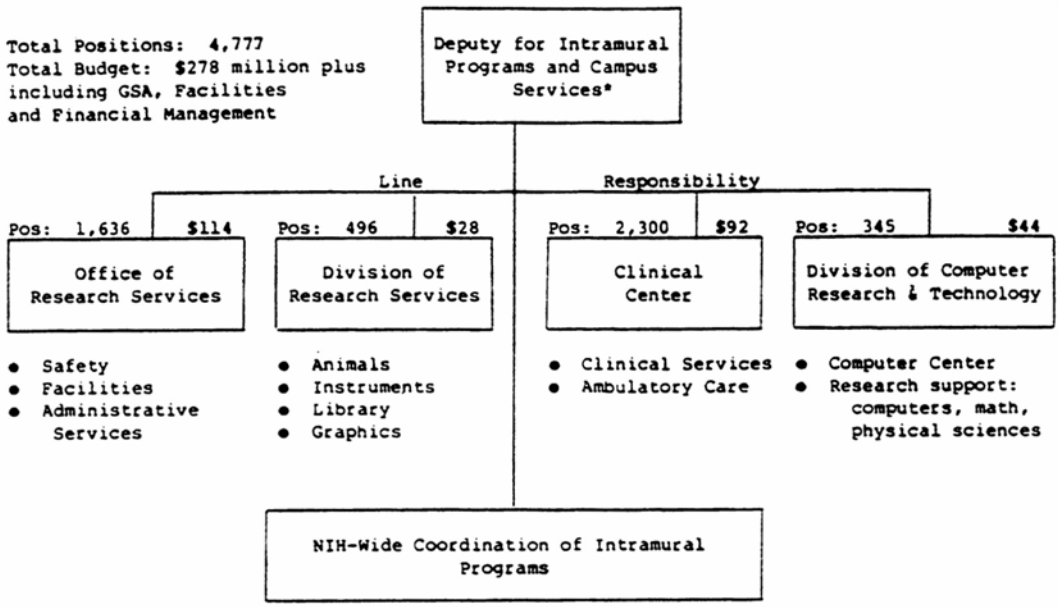
It is the purpose of this chapter to examine the proposition that without impairing these virtues, benefits might accrue from assuring greater attention to the day-to-day management and cost-effectiveness of the seven research and central services activities discussed in the preceding chapter. The chapter discusses one example of how this could be done.

To Accomplish This, Certain Responsibilities Could be More Sharply Defined Among the Deputy Directors of NIH

The concept suggests that the “front office” partnership employ two functional deputies with line authority over central service functions outside of individual institutes and staff responsibility for extramural and intramural research programs: one for Intramural Programs and Campus Services; one for Extramural Programs and Training.

Assign the Deputy for Intramural Programs and Campus Services Line Responsibility for the Major Supporting Activities

As envisioned, this would be the biggest "operating management" responsibility in NIH, and it would require a leader devoted first to the scientific research mission of NIH on campus and second to assuring that the supporting staffs, facilities, tools, and services are provided in a high-quality, cost-effective manner. The motto should be: "The dollar we save on support services can be invested in direct research." The methodology should be one of periodic cost-benefit analysis in collaboration with the Scientific and Clinical Directors. A possible organization is shown below:



It is believed that the most useful approach to managing this huge cluster would be to form task teams, over time, around a series of pre-planned projects. Examples of near-term issues which might be examined are:

Operation and utilization of the Clinical Center. Today beds are specifically assigned to and controlled by individual Institutes. Utilization ranges from 32% to 80% with an average of 62%. Should higher utilization rates be sought? Similarly, should consideration be given to utilization of surgical and related facilities on more than one shift?

*This expanded title seems appropriate. Budget data are FY 1983 actuals, as reimbursed by the Bureaus and Institutes.

The NIH-wide responsibility for library services is another area which might be assessed for cost-effectiveness. Should NLM be given this mission? Should individual DRS and Institute libraries (and/or journal subscription services) be coordinated to obtain desirable economies?

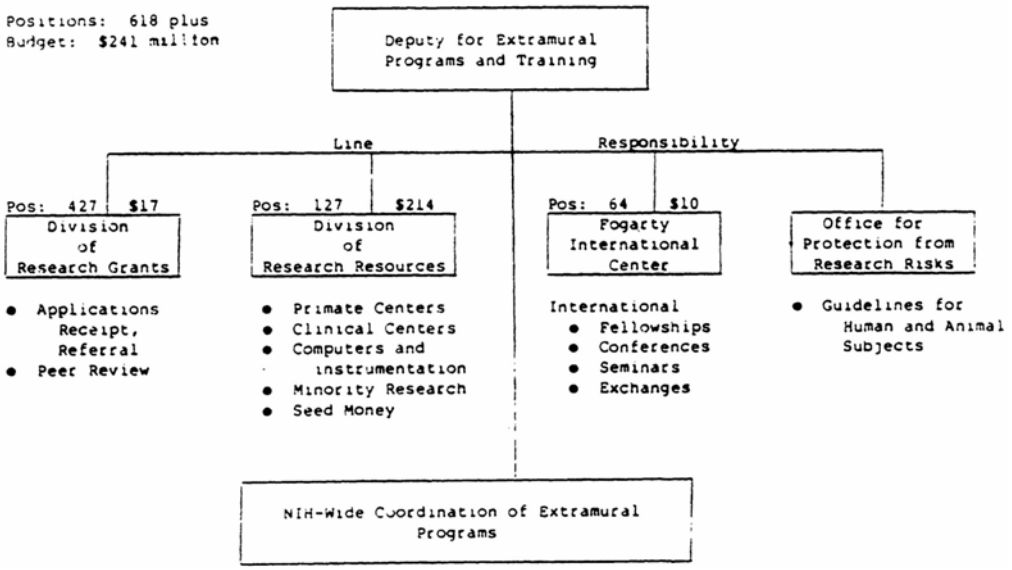
Organization for oversight of the Office of Research Services and the Division of Research Services: Should one management be established at an appropriate time?

Is there any value in closer coordination between the in-house support services and the Extramural programs? For example, does the DCRT computer capability and state of the art expertise offer value to the extramural community, and vice versa? It is recognized that issues of competition with private sector organizations must be carefully considered.

Some may challenge the wisdom of assigning such detailed management responsibilities to an executive whose main purview today is one of intramural research policy. This is a good question to consider, and a separate executive to specialize in support services management is certainly a proper alternative. The question may be whether a policy or a management orientation is most desired. On balance, the policy orientation has been chosen but with a strong and pressing mission to pay more attention to the managerial, cost-effectiveness aspects of these activities.

Assign to the Deputy for Extramural Programs and Training Line Responsibility for the Major Supporting Organizations

A possible cluster is shown on the following page:



This arrangement is less of a change in the present organization than the one proposed for Intramural Programs and Campus Services. But the principle is the same--namely, to assure a clear line responsibility for those support organizations which are clearly relevant to the Extramural Program; and to see that they relate in the most cost-effective manner to the Bureaus and Institutes. Among the questions encountered which would affect this cluster are:

Should the Grant Application Review process give more weight to program priorities, as in the case of the Eye Institute?

Should the Director of DRG have a coordinating role over all first level peer review groups, including the Review Committees, on behalf of the Deputy Director for Extramural Programs?*

Should Intramural projects be subjected to the same peer review mechanisms?

Should closer relations exist between the programs of the Institute for General Medical Sciences and the Division of Research Resources, particularly in the field of minority programs, and possibly computer/equipment development projects?

Should the DRR, whose programs are excellent and strongly supported by Congress, be retitled the "Institute for Research Resources?"

Should a more formalized program of research into research support be instituted to assure that these grants are meeting the most significant needs of investigators and institutions in the most cost-effective manner? Such an effort might be entitled Research Program on Research Support. Might it be linked also to the proposed evaluations to be carried out by the Deputy for Intramural Programs and Campus Services?

*It is noted that the Deputy Director has established an Extramural Programs Policy Staff which may accomplish this objective in part.