

FEDERAL POLICY
FOR
BIOMEDICAL
AND BEHAVIORAL
RESEARCH

AAMC ad hoc Committee on Federal Research Policy

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PREAMBLE

The federal government's commitment to improving the health and well-being of the American people incorporates a wide spectrum of programs and initiatives. An essential portion of this commitment is the system of biomedical and behavioral sciences research that has evolved as a result of the continued investment of federal funding. The success of this federal biomedical research enterprise in terms of scientific achievement and societal benefit is a testament to the policies that have guided this program over the last 40 years.

The recent pressure for deficit reduction on the Congress and the administration will force a reassessment of a number of these research policies. There is concern within the academic medical community that in their efforts to achieve a fiscally responsible budget, policy makers are concentrating on the short-term economic perspective rather than the longer-term programmatic consequences of reductions in research budgets.

An additional stimulus for reexamination of the Association's positions on federal research policy was provided by the House of Representatives Science Policy Task Force, chaired by Representative Don Fuqua (D-FL). This Task Force is conducting a 2 year study of all aspects of national science policy. The Association is concerned to assure that the Task Force receives thoughtful analysis of policy from all segments of the scientific community and that those elements of federal research policy that uniquely contribute to the preeminence of American biomedical and behavioral research be especially clearly articulated before a Task Force whose parent Committee on Science and Technology does not regularly deal with the Public Health Service research agencies.

As a result, the Association of American Medical Colleges appointed an *ad hoc* Committee on Federal Research Policy in June 1985. The Committee was given the general charge to conduct an overview of those broad policy issues related to the federal role in biomedical and behavioral sciences research as currently being debated by the Congress and the administration. The Committee was to develop new positions or reaffirm existing Association positions as the basis for its recommendations in six key areas related to biomedical and behavioral sciences research:

- goals of the federal research effort
- research manpower and training
- research infrastructure
- research awards system
- federal funding for research
- formulation of federal science policy

The following report contains the analysis and recommendations of the Committee. It is hoped that this report will facilitate the Association's participation in the public debate engendered by this crucial set of issues.

EXECUTIVE SUMMARY

Biomedical and behavioral sciences research in the United States is conducted predominantly within our nation's medical schools and academic medical centers, where the academic faculty seek to contribute new knowledge, educate the next generation of health professionals, and provide cutting edge patient care. The major source of support for biomedical and behavioral research comes from federal investment. In 1984, 58 percent of the National Institutes of Health (NIH) extramural budget was spent in academic medical centers and 67 percent of National Research Service Awards funds from NIH were awarded for research training in the health professions to academic medical centers or their trainees.

Thus, the Association of American Medical Colleges, which represents the nation's 127 medical schools, over 450 of its teaching hospitals, and over 80 academic faculty societies, is vitally concerned with the programs and policies that govern the federal investment in biomedical and behavioral sciences research. The Association's *ad hoc* Committee on Federal Research Policy has recently completed an analysis of present policy in key areas of the research effort and offers the following recommendations in response to the current pressures to reexamine the policy basis of the national research effort and establish funding priorities.

I. THE GOAL OF THE FEDERAL EFFORT IN BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCH

The goal of federally supported biomedical and behavioral sciences research should be to acquire an expanded base of scientific knowledge to improve the health of the American people. The federal commitment to this goal is reflected in the long-standing investment in biomedical research, which has resulted in the evolution of the world's preeminent bioscience enterprise.

Health research is conducted and supported by a number of federal departments and agencies; however, only the NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have the acquisition of basic biological and clinical knowledge as their primary mission. This mission must be protected and enhanced. Other vital and necessary components of national health policy, such as public education, demonstration projects, and health care delivery, should be entrusted to other agencies within the Public Health Service (PHS), other federal agencies, or, where appropriate, the private sector. In addition, the obligations of the NIH and ADAMHA need not be extended

to include full responsibility for the translation of basic biological and clinical knowledge to patient care. Finally, the goal of biomedical research must be realized through pursuit of excellence in research. The limited resources available for fundamental research must not be deployed to achieve non-scientific objectives. The benefit to all aspects of the economy derived from research should be a consequence, not a goal of the research effort.

II. THE SCALE AND SCOPE OF THE FEDERAL INVESTMENT IN BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCH

The federal contribution to biomedical research through the NIH and ADAMHA is unique because it emphasizes basic biological and clinical investigations, many of which would go unfunded without federal support. In fact, the overall biomedical research enterprise that has evolved as a result of this federal investment is of such a scale that only continued federal support can sustain it.

Biomedical research is a long-term endeavor; the nation's medical schools and academic medical centers took years to develop the talent and resources necessary to achieve the current level of productivity. Reductions in federal support for biomedical research have a far greater impact than merely the immediate cuts suffered by individual programs. These cuts have a lasting effect on the productivity of the nation's biomedical research effort that may take years to correct.

The federal objective of health improvement will not be fully realized by merely maintaining the *status quo*; federal funding for biomedical and behavioral sciences research should be increased. There are two reasons why more funding is needed. First, it costs more each year to maintain the same level of effort. In addition, as we penetrate more deeply to a true understanding of biologic processes, the research required to solve the next generation of scientific problems is increasingly more complex and expensive. An increase of 10 percent per year in annual appropriations for the NIH and ADAMHA is necessary to maintain the present scale of effort. Second, there needs to be real growth in federal biomedical research funding to take full advantage of currently available but unmet scientific opportunities. Such growth has been precluded in recent years by rising research costs. An additional 5 percent to 10 percent yearly increase in NIH and ADAMHA appropriations for the next 5 years would allow the system to expand to meet these challenges. Thus, the budgets for the NIH and ADAMHA should be increased by 15

percent to 20 percent annually for the next 5 years to restore the federal biomedical research effort to its traditional level of productivity and to more rapidly improve the nation's health.

III. PRIORITIES OF THE FEDERAL BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCH EFFORT

The present reexamination of federal research policy by the Congress and the administration must look beyond short-term, budget-driven decisions to the scientific, economic, and societal implications of these actions. Federal policy must recognize and preserve the unique strengths that have contributed to the system's overwhelming success. In addition to its focus on fundamental biological and clinical research, the system should continue to maintain diverse programs of research support that emphasize the vital role of investigator-initiated research. All research selected for funding should undergo rigorous technical review for scientific merit.

The system should continue to be predominantly extramural and academically-based to take advantage of the enormous national pool of creative scientific talent and resources, and to maintain the unique bond that exists between education and research. The intramural NIH and ADAMHA research programs should be maintained as a unique research resource. A diversity of institutions provides great flexibility to respond to scientific opportunities of varying degrees of scale and complexity.

An indispensable component of the federal biomedical research system is a strong program of research training. This should include the broad-based disciplinary and interdisciplinary training that is essential to produce scientists capable of working at the constantly changing frontiers of research. A key part of federal programs for research training is the institutional support provided to create an optimal training milieu. The heterogeneity of current federal research training programs should be maintained, with a continued emphasis on support for postdoctoral programs, which largely rely on federal funding.

The basic components of a sound federal program for the support of research training are in place. There are two areas of research manpower, however, that cause concern. First is the declining interest in careers in the biomedical sciences. Fewer young people are interested in and preparing for careers in biomedical research. The National Academy of Sciences (NAS) should undertake studies to identify reversible causes for this trend, and efforts should be made to address these causes.

There continues to be concern over the lack of well-qualified physician investigators. The declining ability

of M.D. investigators to successfully compete for research grants has been attributed to inadequate preparation for research careers. Programs such as the NIH Medical Scientist Training Program and the Physician Scientist Awards seek to provide the highest quality training in basic science for physicians and should be models for the design of M.D. research training.

Often overlooked in the debate surrounding the scale of the federal investment in biomedical research are the research resources beyond the direct cost portion of the grant that are needed to sustain the fragile environment in which research is performed. For example, research equipment, which is becoming increasingly important as research becomes more complex, often is not recognized as an integral part of the ongoing program of federal biomedical research. State-of-the-art equipment should be provided to federally funded investigators. Maintenance of research facilities is another area in which increased federal investment is needed to maintain the research effort. Facilities needs in the biomedical sciences should be determined so that rational resource allocation can proceed. Programs for shared resources, such as the NIH General Clinical Research Centers and the Animal Resources Program, should be enhanced to increase the efficiency and productivity of the federal biomedical research investment. Flexible support funds for institutions, such as those available through the NIH Biomedical Research Support Grants, should also be increased. These funds are used to meet the unique and changing needs of individual institutions, enhance the research environment, and sustain their federal research programs.

Federal support for biomedical research also includes reimbursement to institutions for the costs associated with research that cannot be attributed directly to individual grants or contracts. Indirect costs policies are an area of disagreement among investigators, university administrators, and the federal government. All segments of the research community need to work toward agreement that those costs included in indirect reimbursement are true and necessary costs of research. At the same time, the government must make efforts to streamline and reduce the bureaucratic requirements that add unnecessary institutional administrative burdens and indirect costs. Methods must be found to provide a reasonable level of accountability in a cost efficient manner and to reduce excessive documentation.

IV. FORMULATION OF SCIENCE POLICY

There is concern about the quantity and quality of scientific advice available to Congress and the administration for the purposes of policy formulation. Efforts must be made to ensure that the Congress and the President receive impartial, realistic, and timely advice

from the scientific community related to the goals of biomedical research and the means to achieve these goals. The advisory councils to the individual institutes at the NIH and ADAMHA should be more involved in the debate and make timely recommendations related to research policies and priorities to the Director of NIH and the Administrator of ADAMHA. Each agency should provide consensus advice to the Office of the Assistant Secretary for Health. The President's Office of Science and Technology Policy should include strong representation from the biomedical and behavioral science community so that the unique interests of the

medical and life sciences are integrated into overall national science policy.

The NAS Institute of Medicine, which has served admirably in undertaking long term studies on key policy issues, should also undertake the task of providing immediate and impartial advice to the legislative and executive branches in such areas as budget and resource allocation in the federal program for biomedical and behavioral research. Such advice should represent a consensus of the scientific view responsive to public concerns.

I. THE GOAL OF THE FEDERAL EFFORT IN BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCH

The ultimate goal of the biomedical and behavioral sciences research conducted and supported by the federal government is to improve the health of the American people through the acquisition of scientific knowledge. This goal has a high priority for both the general public and the federal government. People today want and expect to have longer, healthier lives, free from the crippling disabilities caused by disease and aging. At the same time, the federal government has a basic responsibility, articulated in the Preamble of the Constitution, to promote the "general Welfare" of the people. One way is to work toward health improvement.

The federal role in health has evolved as the science of medicine has grown. Early efforts were devoted to sanitation, quarantine, and other hygienic measures. One of the earliest legislative initiatives was the passage of "an Act for the relief of sick and disabled seamen," which established the Marine Hospital Service—the predecessor of the Public Health Service (PHS)—in July 1798. As precise knowledge of the causes and treatments of human disease became the dominant influence in improving health, federal participation in acquiring this knowledge grew commensurately. Recognition of the role to be played by biomedical research in the battle against disease dates from the creation in 1879 of the National Board of Health, the first attempt at an organized, comprehensive, national medical research effort supported by the federal government. In 1887, the Laboratory of Hygiene, which served as the genesis for the National Institutes of Health (NIH), was founded.

The essential dependence of improvements in the nation's health upon fundamental biological and clinical research was reflected in the creation of the PHS. Since 1944, section 301 of the PHS Act [42 U.S.Code 241] has stated that the agency:

...shall conduct and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man....

Clearly, the acquisition of new knowledge through biomedical research is only one component of the federal government's agenda to improve the health of its citizens. Better health for the American people can only be realized through determined efforts to expand the knowledge base through research and to apply this

information through social and health care delivery programs. A broad-based approach, acknowledging the importance of an entire spectrum of federal responsibilities and initiatives, has enabled this nation to make great strides towards its identified health goals. The vast panoply of federal programs that contribute to the health of our citizens, ranging from toxic waste disposal to school lunches to Medicare, is administered by almost every federal agency and department. However, without the insight supplied by advances in fundamental scientific knowledge, federal efforts to improve health would be seriously limited. Research must continue to be protected and fostered as a critical component of the overall federal health policy.

Federally sponsored biomedical and behavioral sciences research is the foundation for the government's programs to improve the health of the American people.

Health research is conducted and supported by a number of federal departments and agencies. PHS agencies, including the Centers for Disease Control, the Food and Drug Administration, and the Health Resources and Services Administration, as well as the National Center for Health Statistics and the National Center for Health Services Research within the Office of the Assistant Secretary for Health, pursue various components of health research with a focus on clinical science, public education, health regulation, or health care delivery.

Agencies and departments outside the Department of Health and Human Services, such as Defense, Energy, and Agriculture, the Veterans Administration (VA), the National Aeronautics and Space Administration, and the National Science Foundation (NSF), also perform biological, biomedical, and health-related research. However, with the exception of the small VA and NSF programs, these departments and agencies focus primarily on targeted rather than basic research and emphasize the application rather than the development of novel scientific information. The NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have as their primary mission the acquisition of fundamental knowledge through biologic and clinical research. Together they represent 75 percent of the federal investment in health research and development.

Over the past 40 years, advances in public health and health care have grown steadily more dependent on this expanding base of fundamental scientific knowledge, which provides the scientific opportunities that

ultimately and often unpredictably lead to the solution of specific health problems. The unique focus of the NIH and ADAMHA in supporting and conducting fundamental biomedical and behavioral sciences research has fostered the development of the world's greatest scientific enterprise. This emphasis must continue.

Increasing pressures to extend the missions of the NIH and ADAMHA to include health care delivery, public education, regulation, and other goals of national health policy must be resisted, and these non-research objectives undertaken by other components of the PHS, by industry, or by medical educators and practitioners as appropriate. Along a continuum from basic discoveries to the full application of such discoveries to patient care, the efforts of the NIH and ADAMHA should continue to be devoted to the acquisition of new knowledge and to the clinical research necessary to translate this knowledge into effective therapies. Demonstration projects, educational programs directed at professionals and the public, and patient care represent valuable and necessary efforts to achieve the national goal of improved health, but they should not compete for the limited financial and personnel resources available to sustain and expand the knowledge base.

The research mission of the NIH and ADAMHA must be preserved. Non-research components of the federal health agenda such as public education and health care delivery should be entrusted to other federal agencies or, when appropriate, to the private sector.

On another front, the limited federal resources available for biomedical research are being threatened by the very success of the system these resources have created. Recent research advances, such as those in

molecular genetics that spawned an entire biotechnology industry and contributed to national prestige and economic development, have generated pressures to divert federal research resources to achieve non-scientific goals. Examples of such broader societal concerns include using scientific investment as a mechanism for regional economic development, maintaining the competitiveness of American industry in the world marketplace, promoting geographic diversity of research centers, and enhancing the participation of all segments of the population in a society based on science and technology.

However laudable such goals may be, a reordering of research priorities specifically for the purpose of accomplishing these non-scientific objectives will only serve to divert scarce resources from the primary mission of acquiring knowledge to improve health. Furthermore, on the basis of 40 years of past experience, one can reasonably expect that many of these societal benefits — including economic development, world prestige, and equity of access to new therapies and to careers in science — will continue to be achieved as a consequence of the fulfillment of the primary goal of federal biomedical research. In fact, because most of these other societal goals can be achieved only as a result of success in generating a base of fundamental knowledge, a diversion of resources away from such research would eventually undermine the success of the entire federal biomedical and behavioral sciences research effort, and thereby be self-defeating.

The reordering of research priorities to achieve non-scientific objectives diverts limited resources from the principal goal of acquiring new knowledge to improve health and serves to weaken the overall federal biomedical research effort.

II. THE SCALE AND SCOPE OF THE FEDERAL INVESTMENT IN BIOMEDICAL AND BIOBEHAVIORAL RESEARCH

The long-standing federal commitment to investment in biomedical and behavioral sciences research as a way to improve the health of the American people has been tremendously successful in terms of scientific achievement and societal gain. This support has led to the discovery of biological and clinical knowledge that has extended the length and improved the quality of life for millions of people, thus benefiting the nation by increasing the well-being and productivity of its citizens. In addition, these advances have provided substantial gain for the national economy. It is estimated that the rate of return on every \$1 invested in biomedical research is \$13. For example, the introduction of lithium treatment for manic-depressive disorders has saved an estimated \$6.5 billion, far exceeding the total federal investment in the National Institute of Mental Health since its inception.

The federal contribution to biomedical research remains a unique one because of the continued emphasis on basic biological and clinical investigations. Much of

this research would be unfunded and therefore would not be done if not for federal resources. The system of biomedical research that has evolved with the benefit of federal support is so extensive that it must rely primarily on continued federal investment to sustain the present effort.

Historically, the federal government has followed a pattern of continued growth in the annual budget for biomedical research. In the early years these increases provided exceptional real growth, whereas more recently, large annual increases have been necessary just to achieve stable purchasing power (Figure 1). Each year it costs more for the system to support the same level of research, i.e., the same number of research projects, because of increases in equipment and personnel costs. The Biomedical Research and Development Price Index (BRDPI) provides some measure of the cost growth characteristics for research in the medical sciences. This index has increased by an average of 7.4 percent per year between 1975 and 1984 (Table 1).

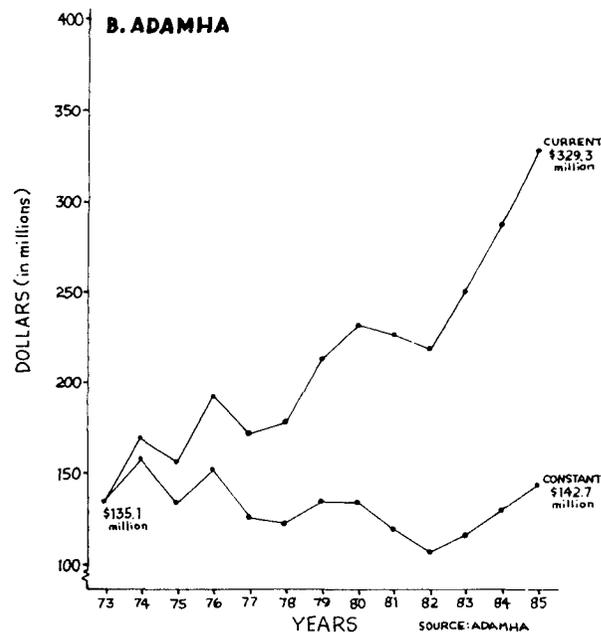
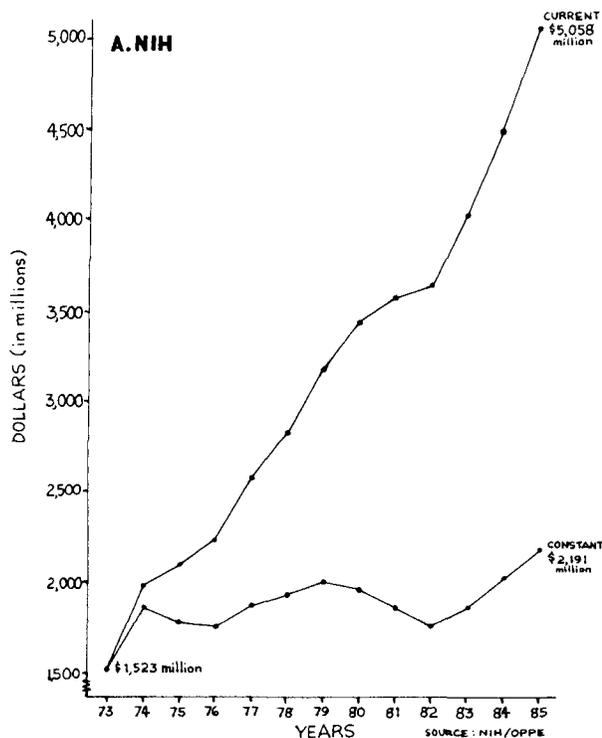


Figure 1. Research and research training in current and constant dollars, fiscal years 1973-1985. 1A. NIH funding; 1B. ADAMHA funding.

In addition, the information provided by current research often leads to more advanced and complex scientific inquiries. This next generation of research is more costly because of the need for more complex equipment and more highly trained, specialized technicians. The BRDPI probably underestimates the increased costs related to the increasing complexity of research. For example, the direct cost of individual research project grants increased an average of 8.2 percent between 1975 and 1984 (Table 2). This was in spite of mandated reductions of between 2 percent and 6 percent in direct costs in several of those years. These direct costs also did not provide needed equipment in many cases. As a result, the increasing direct cost of project grants only partially reflects the actual cost associated with increasingly complex research.

Increased funding for biomedical research is necessary to sustain the current effort because of the increasing complexity and cost of biomedical research. An increase of 10 percent per year in the annual appropriations for the NIH and ADAMHA is necessary to meet this need.

The situation with respect to funding for research and research training at ADAMHA is complicated by the fact that the agency experienced a one-third reduction in constant dollar purchasing power between 1974 and 1982. In spite of the significant funding increases that have been provided between 1982 and 1986, the ADAMHA funding base has not been completely restored to the 1974 level (Figure 1b). In 1985, this shortfall amounted to approximately 12 percent of the total ADAMHA budget for research and research training.

Table 1. BIOMEDICAL R&D PRICE INDEX

Year	BRDPI Index	Percent Increase
1975	100.0	—
1976	107.5	7.5
1977	116.0	7.9
1978	124.7	7.5
1979	134.9	8.2
1980	147.2	9.1
1981	162.3	10.3
1982	174.2	7.3
1983	182.8	4.9
1984	189.3	3.6

Source: NIH Data Book 1985

Funding for ADAMHA research and research training needs an additional one time increase of approximately 12 percent to compensate for the reduction in purchasing power that occurred between 1974 and 1982.

We must not only sustain the present effort; the national commitment to steadily improving the health of the American people demands real growth in the federal program for biomedical and behavioral sciences research. Why is continued growth in the biomedical research effort essential? And how much federal investment is necessary to ensure this growth? The answer to both questions is scientific opportunity. The federal biomedical research effort must grow to avail itself fully of the explosion of opportunities currently available in the biological sciences. There are indications that this may be the beginning of a "Golden Age" of discovery in biological and medical research. Former White House Science Advisor George A. Keyworth, testifying before the House Committee on Science and Technology in February 1985, said that the "biological sciences stand on the brink of understanding that I can only liken to the brink that Einstein saw for physics in 1905." A wise federal investment policy would be to ensure that the combination of federal and private resources devoted to fundamental research in the medical sciences is sufficient to take full advantage of the opportunities for significant discovery. Only this way can the research system be tuned to maximal productivity and fully reap the already significant federal investment in advancing knowledge.

Increased federal support for biomedical research is essential to take advantage of currently unmet scientific opportunities.

Table 2. AVERAGE DIRECT COST OF NIH TRADITIONAL RESEARCH PROJECTS (RO1) (current dollars in thousands)

Year	Average Direct Cost	Increase
1975	\$41.0	—
1976	43.7	6.6
1977	48.3	10.5
1978	52.3	8.3
1979	55.3	5.8
1980	59.0	6.7
1981	64.2	8.8
1982	69.1	7.6
1983	74.7	8.1
1984	83.3	11.5

Source: NIH, DRG, Statistics and Analysis Branch

Scientific opportunities far exceed the current federal investment. A rational approach to the question of the scale of growth — and the increase in federal funds necessary to achieve this growth — would be to base the federal investment on present or anticipated scientific opportunities. This might be accomplished in several ways. One would be to link the amount of funding to the availability of high quality scientific ideas, as measured by research proposals receiving excellent scores at scientific merit review. Technical merit is rated on a scale of 100 to 500, with 100 being the best. Since 1972, there has been a steady growth, averaging more than 10 percent per year, in the number of high quality (scores of 200 or less) research project applications (Figure 2).

High quality proposals not supported because of insufficient resources represent the capacity of the federal biomedical research enterprise to grow without compromising the quality of the science being funded. The increasing numbers of high quality research ideas that have gone unfunded in the last few years demonstrate both the existence of additional scientific opportunities and the need for continued growth to take full advantage of them. For example, there were approximately 1,100 NIH competing research project applications with very high technical merit ratings that were not funded in fiscal 1983. In fiscal 1984, this number rose to 1,500.

High quality merit-reviewed research project applications that cannot be funded are one measure of immediately available scientific opportunity.

Unfunded applications are one way to gauge unmet opportunity and determine the appropriate scale of the federal investment. Scientific opportunity also can be assessed by a process of periodic formal review. Such review might be conducted every five years by a panel of distinguished researchers drawn from different biomedical and behavioral science disciplines under the auspices of the National Academy of Sciences (NAS). This panel would review the progress being made in various research areas and attempt to identify fields of research that are expanding and would benefit from additional funding. This overview perspective also has the advantage of providing a basis for longer-range fiscal planning. For example, the panel might identify a particular area of research that has produced a significant number of first-rate research ideas and is clearly ripe for an increased investment. Another field of research might be seen as having great promise but few researchers, thus requiring a gradual increase in funding to sustain the field as it attracts more investigators. Recent examples of such blue-ribbon panel reports prepared under NAS guidance include the Pimentel report on *Opportunities in Chemistry*, the Institute of Medicine

report on *Research on Mental Illness and Addictive Disorders: Progress and Prospects*, and the current National Research Council Committee to identify Research Opportunities in Biology.

A panel of distinguished scientists, under the auspices of the National Academy of Sciences, should provide a periodic formal review of the fields of biomedical and behavioral research to identify scientific opportunity and the desirable level of investment.

The last 40 years have shown the wisdom of providing for continued growth in the federal biomedical research budget. Such growth has been essential to meet past scientific challenges and has provided the basis for the multiplicity of medical advances that have enriched human life. This growth also has proven to be a prudent investment in the future because it has afforded biomedical researchers new challenges and new opportunities. But this growth cannot be obtained merely by shifting funds from one budget mechanism to another. To take advantage of expanding scientific opportunities and to reach the full potential of this immensely productive national research program, an additional 5 percent to 10 percent yearly increase in NIH

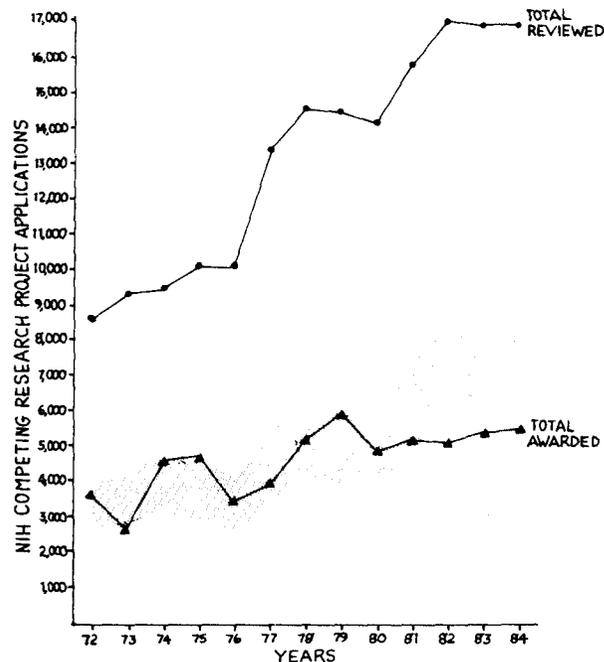


Figure 2. NIH competing research project grant applications; total applications reviewed and total grants awarded, fiscal years 1972-1984. Applications given priority scores of 200 to 250 in merit review are shown as a gray zone.

and ADAMHA appropriations for the next 5 years would be a wise and cost effective federal investment. This increase would be in addition to the 10 percent needed to sustain the current level of effort.

A total annual increase in appropriations for biomedical and behavioral research of from 15 percent to 20 percent for the next 5 years is needed both to sustain the present research effort and to take advantage of new opportunities.

The present political and fiscal pressures occasioned by the growing federal budget deficit are challenging this long-standing federal commitment to the biomedical research effort. Despite these pressures, any reevaluation of policy must acknowledge that reductions in research funding in attempts to reduce the deficit in the short-term will have serious repercussions for biomedical research — and thus the health and welfare of the American people — in the long term. Biomedical research is a long term endeavor; the nation's medical schools and academic medical centers took years to develop the talent and resources necessary to achieve the current level of productivity. Reductions

in federal support for biomedical research have a far greater impact than merely the immediate cuts suffered by individual programs. These cuts have a lasting effect on the productivity of the nation's biomedical research efforts that may take years to correct.

The current fiscal climate requires a careful husbanding of federal resources, but the potential of the federal biomedical research enterprise and the opportunities that are available argue that such husbanding includes *enhancing* the federal investment in biomedical research. Those who wish to reduce federal spending for health care research and at the same time cut the costs for providing the basic safety net of social service and medical care programs must realize that it is this very research that offers a significant prospect for eventually reducing expenditures for health care. An era of deficit reduction and decreasing federal budgets is, paradoxically, not the time to cut federal investment in research. Investment in basic research not only fuels the economy with jobs and funds, it also produces discoveries that improve the lives of our citizens and ensures our preeminence in world markets as well as domestic prosperity.

III. PRIORITIES OF THE FEDERAL BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCH EFFORT

The organizational structure for the conduct of biomedical and behavioral sciences research that has evolved as a result of the ongoing investment of federal funds has been highly successful in achieving its scientific goals of improving the quality of life for the American people. These triumphs were possible, in large part, because of several unique strengths of this system. It is imperative that federal policy recognize these strengths and preserve them in the face of increasingly stringent economic constraints by giving them the highest priority for the limited federal resources. These characteristics are:

- 1) emphasis on fundamental biological and clinical research;
- 2) emphasis on investigator-initiated research, selected through rigorous review for scientific merit;
- 3) support for predominantly extramural, academically-based research;
- 4) support for the research training system necessary to continue the flow of creative investigators; and
- 5) provision of the diverse resources necessary to sustain the extramural, investigator-centered research enterprise.

FUNDAMENTAL RESEARCH

The federal investment in biomedical research traditionally has placed a greater emphasis on basic or fundamental research than on targeted or applied research. Federal policy makers have acknowledged that the discovery of new scientific knowledge through basic biological research is the cornerstone in our understanding of human disease and its eventual prevention or treatment.

Such research includes as a key component clinical investigation to advance our knowledge of human biology and pathology. Clinical research is not only the crucial link where basic biological knowledge is both developed and utilized; it also serves to identify areas where further basic research is necessary.

In a time of fiscal constraint, this emphasis on fundamental research should be continued and strengthened. Federal funds should support heavily this portion of the spectrum of biomedical research, because other sources of support for it are not available. In some areas of applied research, such as large scale clinical trials where the general efficacy of already developed therapies is being tested, efforts should be made to identify other resources, such as patient care or phar-

maceutical industry funds, to share in the support of such research.

In general, the federal biomedical research effort should not extend into areas of applied or targeted research where the goal is the commercial development and production of diagnostics and therapeutics. The biomedical industry has both the resources and the expertise to carry out technology transfer for commercial development in a much faster and more efficient manner than the federal government could hope to accomplish; indeed, survival in today's competitive marketplace demands the ability to translate basic scientific discoveries into practical applications. A prime example of this is the growth of the bioengineering industry out of basic discoveries in molecular genetics.

The federal investment in biomedical research should continue to emphasize fundamental biological and clinical research. Such research is the source of the new knowledge needed to accomplish advances in health care.

INVESTIGATOR-INITIATED RESEARCH

Investigator-initiated research is the vital core of the federal biomedical research effort. Investigator-initiated grants have proven most productive for exploring and developing new scientific opportunities. This approach utilizes the unique talents of thousands of individual scientists to sustain a broad-based, flexible program of biomedical research. Investigators pursue their own ideas and use their scientific instincts and laboratory experience to develop new approaches to research problems and to follow up on unexpected findings. Investigator-initiated research may occur in multi-investigator and multi-disciplinary settings; its hallmark is that scientists formulate the proposed research whether through a program project, center, or other funding mechanism. The past has shown the value of a wide range of funding mechanisms to support biomedical research. The trend has been toward large numbers of relatively small projects, which provides NIH and ADAMHA with the flexibility to shift the emphasis in programs as scientists shift their research without disrupting large bureaucratic enterprises.

In a time of limited resources, however, the value of this far-ranging, broad-based fundamental research may not be immediately obvious to the public, which is understandably more concerned with short term applications of scientific knowledge to specific diseases. Yet

it is in such times of fiscal constraint that we should assign the highest funding priority to this most essential and creative component of the biomedical research effort.

The highest funding priority should be given to investigator-initiated research projects because these provide maximum creativity and flexibility in the research system.

EXTRAMURAL RESEARCH

The founding genius of our federal biomedical research effort was the decision to seek new knowledge in the biosciences predominantly through a system of awards to individuals in institutions all across the nation. This decision to fund the best and most promising scientific ideas regardless of where they originated sparked the development of the outstanding biomedical research enterprise the nation now enjoys. The research agencies have been able to tap the human, organizational, and physical resources of the entire country to create a truly national effort.

This extramural approach provides several distinct advantages. First, a vast national pool of creative scientific talent can be drawn from and the resources of many diverse institutions can be joined with those of the NIH and ADAMHA to further the federal biomedical research effort. This large and heterogeneous assortment of institutions has the capacity to undertake research projects of varying degrees of scale and complexity. Such a system encourages maximum creativity and flexibility from individual investigators or teams of researchers in responding to scientific opportunity.

Another advantage is that this research is conducted primarily in academic settings. In fiscal 1984, 75 percent of NIH extramural awards went to institutions of higher education, and 52 percent went to medical schools and their affiliated hospitals. The coupling of the research and educational efforts is a unique strength of the American university system. In most graduate programs, students are trained while they participate in research, thus yielding a dual dividend: talent and knowledge. The search for new knowledge and the dissemination of established learning make invaluable contributions to one another.

The diversity of institutions that participate in the extramural system also enables and encourages a cross-section of this nation's people to participate in the federal biomedical research effort, thereby benefiting both the institutions themselves and society as a whole.

The federal biomedical research enterprise should remain predominantly extramural and academically based.

INTRAMURAL RESEARCH

This emphasis on extramural research should not detract from the importance of the remarkably vigorous and productive intramural programs at the NIH and ADAMHA. The wealth of basic biological and clinical knowledge developed in these programs has contributed significantly to our current understanding of human disease. The recent achievements in research on the viral agent for acquired immune deficiency syndrome (AIDS) once again demonstrate the strength of the intellectual and creative resources of the intramural program. The Clinical Center at the NIH is the site of innovative clinical investigations into the mechanisms underlying human disease and should continue as a vital component of the intramural program. The presence of this active research effort at NIH also enhances the quality and sophistication of the administration of the extramural program.

In addition to the research itself, the NIH and ADAMHA programs make significant contributions to research training and serve as an important personnel resource for the extramural research community. A free flow of ideas and personnel between the intramural and extramural programs strengthens both and should be encouraged. The ability of the intramural program to recruit and retain well-qualified senior scientists and administrators should be enhanced. Such initiatives would ensure the continuation of the competent leadership provided by the senior staff at the NIH and ADAMHA, which is critical to the success of not only the intramural programs but also the entire extramural research effort.

The intramural research program at NIH and ADAMHA should be continued. Programs for research trainees and investigators to participate in intramural research should be strengthened and expanded. Initiatives should be undertaken to attract and retain exceptional senior scientists and administrators at the NIH and ADAMHA.

SCIENTIFIC MERIT REVIEW

The concept that the significance or merit of a scientific proposal is judged best by other scientists is not new; it has existed in various forms since the 17th century. Even so, the post World War II decision to allow scientists a primary role in determining the merit basis for the allocation of federal funds for scientific research was a rather bold one that did not command universal assent. The record of the past 40 years, however, has shown the wisdom and value of scientific merit review.

Recently the equity of the merit review system has been challenged both from outside and within the science community. As science and the federal investment

in it have grown in scale and impact, the desire to participate in and partake of this success has increased commensurately. The public, and their elected representatives, are increasingly interested in focusing these enormous talents and technical resources on the diseases that to them are most urgent. Judgment of the merit of research proposals on the criteria of scientific excellence and opportunity is increasingly at odds with congressional concern for equal distribution of scientific resources.

Many scientists also have joined the critics of the merit review system. These criticisms are probably more a consequence of the inordinate pressures brought to bear on the scientific review system because funds are not sufficient to keep pace with the burgeoning scientific opportunity in biomedical research. Scientists with good ideas that are not funded increasingly challenge the ability of the merit review system to make fine distinctions between the quality of ideas.

The concept of peer review is sound. The primary basis for allocation of federal funds for biomedical and behavioral sciences research must be the scientific quality of the research proposals submitted. Scientific quality is best judged by scientists who are familiar with the field of research in question and can, therefore, address issues such as scientific opportunity and technical merit. The record of the peer review system over the last 40 years speaks for itself. Through peer review for scientific merit and advisory council review for program priority, federal funds awarded to a remarkable array of institutions and scientists have led to world preeminence for American biomedical research and significant improvements in human health.

The allocation of federal funds for biomedical and behavioral research should continue to be based on the system of scientific merit review of proposals. This system is best able to identify scientific excellence and to insure the quality of the federal investment. Priorities for funding and long range planning to meet national goals should be determined by the institute advisory councils and funding decisions within these priority areas should be based on scientific merit.

Despite all of the concerns expressed by scientists and lay observers about the potential for abuse and conflict of interest inherent in any system that employs peer judgments, the peer review systems that have evolved at the NIH and ADAMHA remain the best and most objective method available to evaluate scientific merit. The scale of the review system, with over 1,000 scientists participating and one-quarter of the membership changing every year, does much to ensure that the majority of the research community, rather than a select few, eventually serve as evaluator as well as applicant.

The system works; it must be preserved and strengthened. There must be continued attention to maintaining a balanced representation on review groups and to insuring the quality of the peer review process in order to provide the best scientific review.

There should be a periodic, formal examination of the mechanisms for merit review of grant applications used by NIH and ADAMHA. Such review will insure that equitable peer review procedures are used to identify the best science.

RESEARCH TRAINING

This nation's remarkable achievements in biomedical research would not have been possible without strong federal support for the training of research manpower. A reservoir of highly trained biomedical scientists is indispensable to the national biomedical research system and must be replenished continually if we are to maintain our current research capabilities and take advantage of future opportunities. To ensure the continued availability of sufficient skilled scientists to meet these national research objectives, significant federal involvement in research training must continue.

The Current System

Federal biomedical and behavioral research training programs must provide a variety of training mechanisms and encourage the broad-based disciplinary and interdisciplinary training essential to produce scientists capable of productive careers within a profession with constantly evolving frontiers. This support ranges from formal research training programs funded under the authority of the National Research Service Awards (NRSA) to support of trainees as research assistants on individual project awards.

In research intensive universities, as many as 30 percent of Ph.D. candidates are supported as research assistants on federal research grants; nationally, almost half of all Ph.D. postdoctorals and 5 percent to 10 percent of M.D. postdoctorals are supported through research project funds. While these funds do not support the training environment per se, they are an appropriate source of support for trainees during those portions of training when they can and should function as integral members of individual research teams.

Currently, federal training programs provide approximately 15 percent of Ph.D. predoctoral support, but 34 percent of Ph.D. postdoctoral and 45 percent of M.D. postdoctoral research training support in the biomedical sciences. This federal emphasis on support for graduate, and even more for postgraduate, programs must continue. It is at the postgraduate level that those talented individuals who will make future

creative contributions to biomedical research are identified, and at this level that non-federal sources of support for such advanced training diminish, leaving a natural and essential role for federal programs.

A further important component of federal support for advanced trainees is the program of research career development awards through the NIH and ADAMHA. This varied portfolio of awards, designed to support the transition from research trainee to fully independent, funded investigator, is uniquely tailored to the needs of differing career stages and to addressing shortage areas such as physician investigators.

The heterogeneity of federal support mechanisms for biomedical and behavioral research training must be maintained. The mixture of support from different agencies and under the aegis of different programs, ranging from those specific for training to components of research or clinical programs, should be continued. Federal programs should continue to emphasize support of postdoctoral programs.

NRSA training programs include both institutional training grants and individual fellowship awards. At the recommendation of the National Academy of Sciences Committee on National Needs for Biomedical and Behavioral Research Personnel, 85 percent of NRSA grants are made to institutions. While the individual awards based upon competitively reviewed research proposals are an important mechanism for supporting advanced research fellows, the majority of funds should continue to be provided in the form of institutional training grants. Such grants enable institutions to amass sufficient trainees and the critical institutional resources to provide a proper and broad-based training milieu.

Federal programs should continue to emphasize and strongly support the institutional components of research training as well as trainee stipends to provide an optimal training milieu.

The exponential expansion of the "new biology" necessitates an average investment of ten years of training beyond the baccalaureate degree. The length of this training requires large scale programs involving extensive and long term commitments of personnel and laboratory resources in order to sustain sufficient numbers of trainees at each stage to eventually yield a small cadre of research scientists. The NAS estimates that nationally there are at any one time some 60,000 Ph.D. predoctoral candidates and 15,000 Ph.D. and M.D. postdoctorals in training in the biomedical and behavioral sciences. It is estimated that each year approximately 2,200 Ph.D.s, 1,200 M.D.s, and 150

M.D./Ph.D.s complete the entire training sequence and emerge from postdoctoral fellowship programs fully trained for careers as independent investigators.

These estimates emerge from the extensive manpower study conducted biennially by the NAS Personnel Needs Committee. This committee was chartered by the National Research Act of 1974 to develop projections of manpower needs and make recommendations regarding the appropriate scale and scope of federal training programs in the biomedical sciences. The data collected by this committee have proven useful in evaluating the current status of research manpower in the clinical, basic biomedical, and behavioral sciences as well as allied health sciences and nursing research.

The federal government, through the National Academy of Sciences, should continue to monitor all aspects of research training in the biomedical and behavioral sciences.

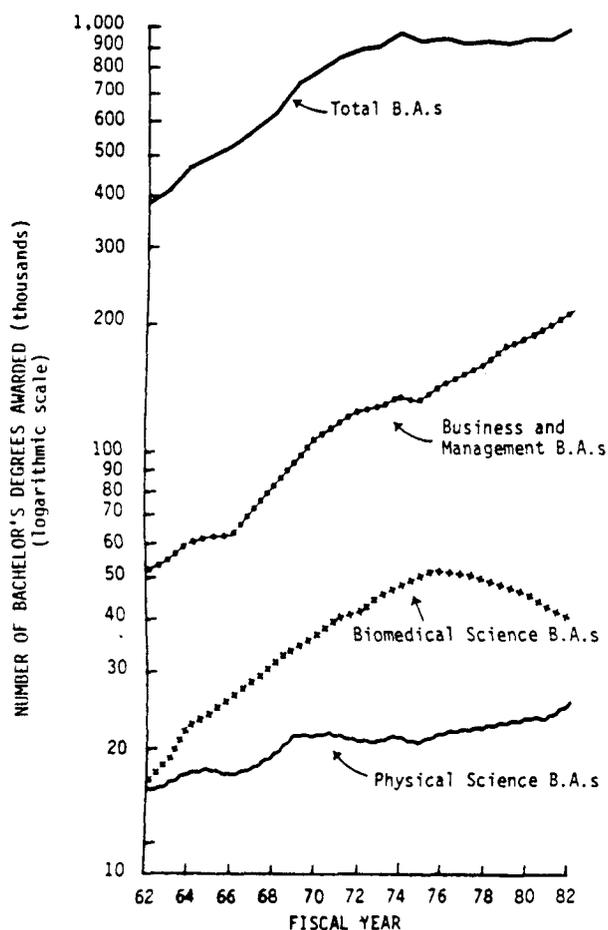


Figure 3. Bachelor degrees awarded in biomedical science fields compared to other fields, fiscal years 1962-1982. (Source: NAS Personnel Needs Committee, 1985 Report)

Unfortunately, while the present effort can be quantitated, projections of future manpower needs in rapidly evolving disciplines, based on unknown future scientific opportunity, cannot be made with a high degree of accuracy. The unpredictability of the rate of advance in various scientific fields and the long lag time between identification of the need for additional manpower and the production of more fully trained investigators argue for a system that makes only the most general estimates and tends to err on the side of overproduction. Elaborate efforts to quantify the unquantifiable should yield to ensuring an excess of broadly trained personnel in a system with sufficient flexibility, adaptability, and re-training capacity to provide a continual supply of new young researchers with the capability to pursue these dimly foreseen opportunities.

Future Concerns

The basic components of a sound federal program in support of research training in the biomedical sciences are in place. Continued attention to the appropriate scale of these programs to meet anticipated manpower needs and to the provision of adequate trainee support and institutional resources within each program are essential. In two areas, however, there is concern that research manpower needs are in jeopardy.

First, there is growing apprehension related to the declining interest in careers in the life sciences. The number of potential applicants for Ph.D. programs in biomedical research has declined over the past decade, and current indications are that this trend will continue. The number of people graduating with baccalaureate degrees in the life sciences has been decreasing since 1976 (Figure 3). Current estimates by the NAS are that the number of first year graduate enrollments in the biomedical sciences peaked in 1978, and has been declining ever since. The growing number of foreign nationals in Ph.D. programs should be assessed for its impact on future American scientific productivity. Medical school applications have fallen by 23 percent since 1974. In addition, training program directors in the biomedical sciences have noted deterioration in the quality of the predoctoral applicant pool, increased numbers of foreign nationals in these training programs, and an increased competition for qualified postdoctoral trainees. The trends are becoming apparent: fewer young people today are preparing for careers in the biomedical sciences.

These trends must be monitored closely, and studies undertaken to identify reversible causes for these declining enrollments. Anecdotal evidence suggests that careers in biomedical research appear less attractive to young people than they once did. The fierce competition to sustain grant support, increasing administrative and bureaucratic burdens, reduced freedom and flexibility to pursue independent research

ideas, and prolonged training are all cited. Efforts to document these or other causes and to reverse these trends should be undertaken. Specific federal programs to recruit and enhance the pool of qualified predoctoral candidates should be funded.

The NAS should closely monitor worrisome trends toward diminishing interest in life science careers. Studies should be undertaken to identify reversible causes for this decline in the student groups from which future biomedical scientists are recruited.

Equally troubling is the continued lack of sufficient well-qualified physician investigators, first identified in the late 1970s. The percentage of physicians serving as principal investigators on NIH investigator-initiated research project grants (ROI awards) continues to decline (Figure 4) and the number of M.D. postdoctorals in the NRSA program remains below recommended levels (Figure 5). Clinical investigators make two vital and indispensable contributions to biomedical

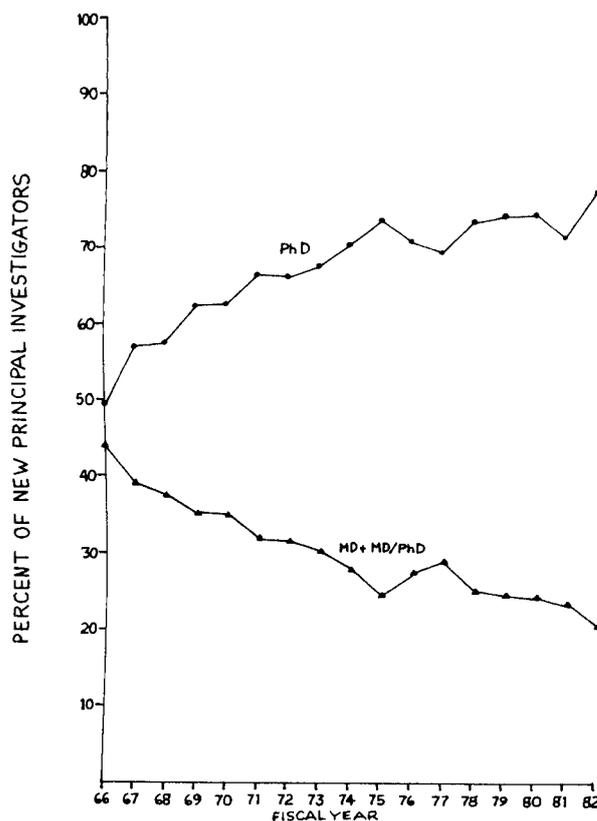


Figure 4. New NIH research project awards charted by type of earned degree of the principal investigator, fiscal years 1966-1982. (Source: NIH)

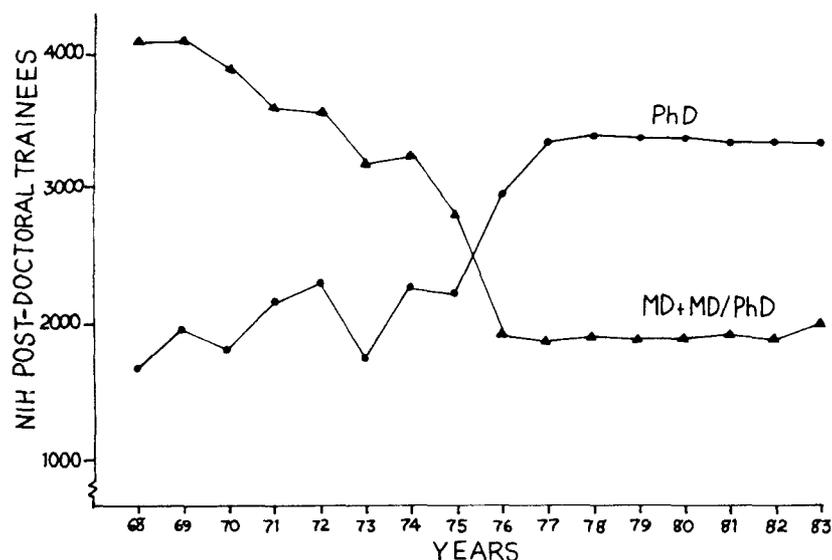


Figure 5. Postdoctoral traineeships and fellowships awarded by NIH to candidates with M.D. and M.D./Ph.D. degrees as compared with those with the Ph.D. degree only (full-time equivalent trainees and fellow), fiscal years 1968-1983. (Source: NIH)

research. First, there are certain types of research that are best done or can only be done by individuals with clinical training. Second, M.D. investigators uniquely employ their clinical knowledge and experience to identify important problems and needs for basic research. Physician investigators truly serve as vital bridges to achieve the necessary synthesis of new basic knowledge with its application to clinical situations and problems.

While the number of M.D. and M.D./Ph.D. applicants for research funding have remained relatively steady during the last 10 years, the percentage of grant applicants and recipients with clinical degrees has declined. This is because of the increasing numbers of Ph.D. applicants and the growth in the total number of grants funded. After a thorough examination of threats to this "endangered species," the NIH concluded that the declining ability of M.D. investigators to compete successfully for research grants and to successfully sustain full research careers can in large part be attributed to inadequate preparation to deal with the increasingly complex research required to make the next generation of advances in biological research. NIH has shown that the duration of research training correlates with later success in obtaining competitive research funding (Figure 6).

To remedy this problem, NIH has focused efforts since 1980 on developing programs to provide better research training opportunities for M.D.s. NIH has strongly recommended that M.D. trainees on institutional research training grants spend a *minimum* of 2 years and preferably longer in an advanced program of

research training. There have also been attempts, thus far unsuccessful, to increase the number of M.D.s on both institutional and individual training grants in the NRSA postdoctoral program. The distribution of career development awards has shifted to ensure that 50 percent of awardees will be young physician scientists. A special career development program — the Physician Scientist Award — was created to provide M.D.s with 5 years of training in both basic and clinical research. Renewed emphasis has been placed on generating interest in research careers among medical students by a short term research program and a joint venture with the Howard Hughes Medical Institute to support year-long research experiences for medical students at the NIH. Resources for the highly successful Medical Scientist Training Program (MSTP) have continued to increase. The MSTP program is an M.D.-Ph.D. program that provides participants with a firm grounding in basic biomedical research while supporting their training as physicians. Unfortunately, increased resources for this program have only kept pace with rising costs, and there has been no increase in the number of trainees or training sites since 1978.

There are many more qualified applicants and training sites than can be accommodated in the research intensive MSTP and Physician Scientist Award programs, and efforts should be made to increase the number of trainees in these programs as well as the number of M.D. trainees in rigorous institutional training grant programs. All of these initiatives are laudable and target identified causes for decreased physician participation in research. Physician investigators must have

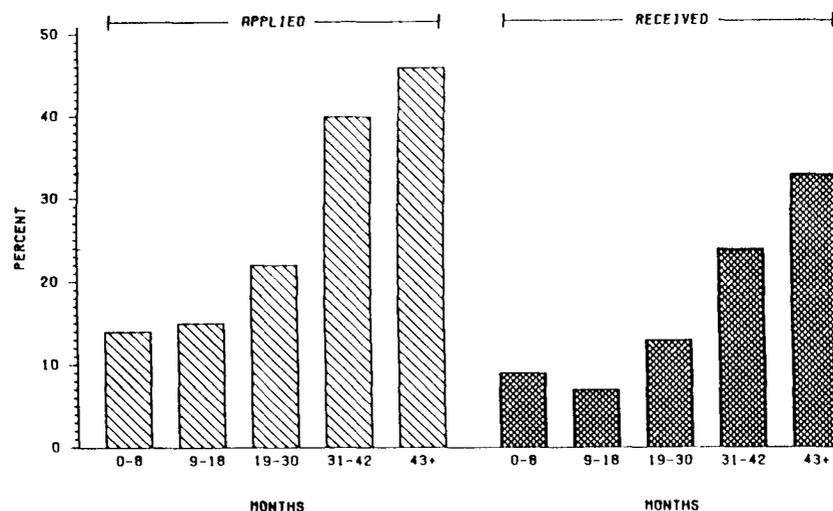


Figure 6. Percentage of M.D. postdoctoral trainees who applied for or received a research grant, by length of supported training, first year of training 1976-1980. (Source: NIH/OPPE/DPA)

basic and thorough research training comparable to that received by Ph.D.s. Such training is not an integral part of medical school or clinical residency programs and must be fully provided within the research portion of M.D. investigator training.

Recent federal emphasis on programs to train physician scientists should be continued and expanded to counter their declining participation in research. Efforts should focus on increasing the quality and duration of scientific training for M.D.s.

RESEARCH SUPPORT

Federal support for fundamental, investigator-initiated, extramural research necessarily involves more than just the direct cost portion of the grant. It includes all of the resources needed to ensure that the individual investigator or group of scientists can actually do the research. This is particularly true in fiscally austere times, when one possible policy option is to withhold certain elements of research support to sustain an arbitrarily determined number of grants with partial support. It should be a major goal of federal policy during periods of fiscal constraint to ensure that the scale of the effort does not exceed that which can be appropriately supported.

The number of extramural grants awarded each year should be maintained at the highest level at which adequate funds for full direct grant costs and research support resources can be provided.

Another factor to be considered is that even though the core of the federal biomedical research enterprise consists of ideas generated by individual investigators, the research support necessary for the realization of these ideas often extends far beyond that awarded to the individual scientists themselves. The federal investment in biomedical research must not only support the individual projects but also the entire system or environment in which the research takes place.

To the extent that these resources are beyond the scope of the direct costs on individual research awards, they must be available to ensure that maximal research productivity can be sustained. As funding for biomedical research has plateaued, these resources have become increasingly constrained. This frugal approach is perhaps understandable as a short-term strategy for coping with limited resources, but now it is becoming a *de facto* long term policy that is increasingly counterproductive as resources accumulated during years of expanding biomedical research investment become depleted in rapidly advancing fields.

Research support is particularly critical at a time when the academic medical center is threatened by resource constraints on all fronts. Pressures to reduce health care costs are reducing the institutional support derived from the education and clinical practice efforts of the faculty; medical school applications and enrollments are declining in response to a perceived physician surplus; and access to capital in the non-profit sector to restore or replace aging equipment and facilities is increasingly limited.

While responsible policy in the present era would support a cautious approach to investment in research resources and seek in all instances to maximize the

research return on these investments, this area of federal investment policy deserves concerted study. When "making do" hobbles research productivity, it is unsound public policy. It should be the responsibility of the federal government to monitor the resources of the extramural research community with a view to understanding what is needed to maintain the national research capacity.

The NIH and ADAMHA should analyze the research capability and anticipated needs for major equipment and facilities to maintain the biomedical and behavioral research capacity of the extramural community.

Direct Costs

During the past several years, the direct cost portion of biomedical research grants has risen dramatically. Much of this increase can be attributed to the increasing complexity of research in the biological sciences. This advance in science is reflected in proportional increases in all components of direct costs. However, personnel costs continue to account for over two-thirds of the direct cost of research grants. Salaries have increased because of the need to hire technicians with more advanced training to cope with advancing technology. Salaries for research personnel have also increased because of the need to make them more competitive with industry and other occupations to attract and keep well-trained personnel in academic laboratories. Efforts to limit or reduce direct costs below study section recommendations would have a chilling effect on biomedical research by making it difficult to hire and retain sufficient skilled laboratory personnel.

Direct costs for biomedical and behavioral sciences research grants should be provided at amounts determined to be adequate by scientific review.

Equipment

Equipment is a crucial component of a successful biomedical research effort; it has become increasingly vital over recent decades as research has become more complex. Between 1983 and 1985, the NIH examined the state of research instrumentation in the extramural research institutions through a study of the status of equipment, present expenditures, and projected needs. In the field of biomedical research the greatest need continues to be for equipment of a scale that can be provided through direct grant programs. The recent NIH/WESTAT study pinpointed a major need for equipment in the \$10,000 to \$50,000 range. To achieve optimal research productivity and remain at the forefront of science, appropriate equipment needs

should be met as an integral part of the ongoing federal biomedical research program.

Federal policies should encourage the provision of state-of-the-art equipment for biomedical research through direct award on individual grants or Shared Instrument Grant awards.

A recent interagency study[†] was also completed that explored ways of improving the purchase and management of research equipment to reduce waste and improve utilization. Federal policy in many areas impinges on the ability to obtain university research equipment. Tax policy can be constructed to encourage corporate donation of equipment; federal depreciation schedules can be accelerated in recognition of the rapid obsolescence of research equipment; novel arrangements can be tried to facilitate direct grant purchase of more expensive equipment by spreading the purchase cost over several years of the grant or among several grantees; and indirect costs policies can be reviewed with an eye toward encouraging economies of use and purchase for state-of-the-art equipment.

Federal policies that impinge on acquisition, maintenance, and use of research equipment should be reviewed to streamline procedures and encourage economies of use and purchase. State-of-the-art equipment must be appropriately available for use in federally funded research projects.

Shared Resources

As increasingly diverse scientific opportunities compete for limited resources, sound federal research policy must turn to ways in which needed resources can be used most efficiently and productively. One approach is through programs that provide research resources for shared use by entire institutions or even the entire research community. NIH provides such support programs through its Division of Research Resources. The General Clinical Research Centers (GCRC) Program supports 75 clinical research centers at our nation's academic medical centers. By providing centralized facilities and core laboratory and clinical personnel, these centers support the clinical research being performed on over 3500 project grants. These unique facilities with personnel trained in research procedures have been a remarkably efficient and productive resource, and full support of a vigorous GCRC grant program is warranted. The Animal Resources Program

[†]Financing and Managing University Research Equipment; Association of American Universities, National Association of State Universities and Land-Grant Colleges, and Council on Government Relations; Washington, D.C.: 1985.

also provides critical resources for research by supporting regional primate centers, laboratory animal sciences program grants, and a program to provide institutional animal resource improvements. In view of the well documented need for substantial investment to upgrade animal facilities at academic medical centers and research institutions, this program deserves increased funding to assist institutions in providing the facilities essential to maintain the high quality of research involving animals.

Creative federal grants programs to provide the shared research resources vital to realizing the full research potential of our nation's academic medical centers and universities should be continued and enhanced.

Flexible funds available for deployment at the discretion of individual institutions are awarded through the NIH program of Biomedical Research Support Grants. These funds are variously used for start-up and transition support for investigators, urgently needed equipment and other resources. They are carefully husbanded to meet the unique and changing needs of each institution and to maximize its ability to sustain the extramural federal research program.

Maximal research productivity and optimal institutional support for the federal research program are enhanced by the provision of some flexible research funds for deployment at the discretion of the institution. Programs such as the NIH Biomedical Research Support Grants should be continued.

Indirect Costs

There is no area of federal support for biomedical research that is more contentious than the reimbursements paid to universities for the costs they incur at a central or institutional level in support of federally funded research conducted at their facilities. The total cost of research at an institution can be divided into two categories — direct and indirect — depending on whether or not the costs can be attributed to individual research projects. Indirect costs are legitimate research expenses, documented by agreed upon accounting conventions and subject to audit. Their method of payment through a calculated average percentage of the direct costs across the entire university, however, creates a dissociation between these two equally real cost components of research and imparts an artificial quality to the indirect cost calculations. These indirect cost reimbursement policies evolved because it was not possible to assign all of their components to individual grants; yet, it is this lack of a concrete association between the direct project costs and these supporting costs at the

level of the individual grants that has engendered distrust and strained relations between individual faculty researchers and administrators. In biomedical research, this distrust is further fueled by a steady shift in the proportion of total research costs expended in the direct and indirect cost categories. Despite a number of policy reviews and examinations of this issue by universities and the federal government, the legitimacy of costs in the indirect category continues to be questioned.

Appropriately audited research costs assigned by convention or choice to the indirect costs category are a legitimate component of the total costs of research. Payment of these costs is as critical to extramural research productivity as payment of direct costs.

The division within the research community on this issue does not encourage thoughtful policy deliberation and invites outside intervention by budget cutters who seek to "control" research costs and decrease the federal investment rather than to optimize the productive allocation of research funds.

All segments of the research community should join together in a concerted effort to agree on the components and accounting of indirect costs so that these are better understood and accepted. All must agree that these are necessary costs of research for them to enjoy the confidence of the entire research community.

As the scale and complexity of the nation's biomedical research effort have increased, it has become increasingly cumbersome to administer. Numerous, individually well-intentioned procedures, directives, guidelines, regulations, and laws have been promulgated concerning the administrative and fiscal procedures that awardee institutions must follow to be eligible for and provide accountability for federal biomedical research funds. Little attention has been paid at the federal level to the degree to which this gradual bureaucratic accretion contains redundant, contradictory, counterproductive, or simply not cost effective requirements.

The cost to the institution of meeting these requirements reduces the total dollars available to fund the research itself. Ways must be found to achieve a level of accountability that is reasonable and agreeable to both the government and the research institutions, but which is cost efficient and does away with excessive documentation. Recent efforts by the NIH to increase the jurisdiction of the institutional prior approval system for grant rebudgeting and by the White House Science Council to recommend that investigators be permitted to use up to 10 percent of their grant support on a discretionary basis for research and educational

purposes and to carry forward unexpended funds from one fiscal year to the next are examples of laudable trends.

Concerted efforts should be made to streamline and reduce federal bureaucratic requirements that add unnecessary administrative burdens to research institutions and divert scarce research funds.

Facilities

Recent attention in the extramural research community has focused on the declining state of science facilities in all disciplines as a growing threat to the nation's research capabilities. The absence of significant federal investment in extramural facilities through competitive construction grants programs for over a decade is cited as a prime reason for this decline. This lack of support for facilities also is blamed for the growing trend toward individual universities seeking direct congressional appropriations for science buildings.

The inevitable deterioration of facilities built before 1970 and the limited resources to keep pace with the growth in scale and complexity of the research effort have taken their toll. However, at least in biomedical research, a thorough study of the nature and degree of these deficiencies in facilities has not been undertaken and is urgently needed to guide responsible policy decisions and program planning. Especially in the area of physical plant and fixed equipment, the needs of different disciplines are bound to vary, and decisions concerning the types of facilities and the means through which they should be funded should be field specific.

The federal government should assume responsibility for specific and ongoing studies to ascertain the state of the physical plant in the nation's universities and academic medical centers. Such studies are the necessary basis for policy decisions and program planning to assure that the capacity of the national effort in biomedical research is sustained.

Based on results of such studies, policies should be developed to determine the yearly scale of the federal investment in maintaining and rejuvenating facilities for federally funded biomedical research. The methods by which these capital costs are met also should be carefully considered. Until 1969 the NIH had a Health Research Facilities Grants Program through which yearly appropriations for major construction and renovation

projects were channeled. The lapsing of authority for this program has undoubtedly contributed to the lack of major resources to revitalize the physical plant in the biomedical sciences. A direct facilities grants program would have the advantages that applications would be competitive and their relative scientific merit could be weighed. Funds would be provided to NIH and ADAMHA specifically for buildings in the fields of biomedical and behavioral sciences. The scale of the federal investment in capital costs for buildings would be reviewed yearly in competition with the federal appropriations for other research programs and based on a clear policy decision about resource allocation.

While an authorized program would permit capital costs to be provided through direct federal grant construction support, recovery of private capital investments is currently possible through federal reimbursement of use/depreciation charges and through indirect cost recovery of interest paid on buildings constructed through privately incurred debt. In 1985, NIH invested \$13.1 million in extramural research facilities through several specific categorical construction authorities and \$70 million through use allowance and depreciation costs. These reimbursement methods by which federal funds can be tapped to contribute to the financing of facilities at research institutions provide an important degree of flexibility for universities. They have the added virtue that they provide funding through mechanisms that intimately link federal funds for facilities with the continued ability of that university or academic medical center to be the venue for a large volume of merit-reviewed, competitive research grant funding. They have the disadvantage that federal investment in facilities is not subject to review of the scale of investment through the appropriations process, where it is weighed in competition with funding for other research programs when scarce funds are allocated, and that funds to pay for buildings in a given field of science through indirect cost reimbursement are partially provided from the budgets of agencies in other fields of science.

Federal policy should be developed to determine how documented need for research facilities should be met under conditions of fiscal constraint on research allocations. Programs of direct merit reviewed capital grants and opportunities for phased recovery of capital investments from non-federal sources should be provided. The scale of the federal investment from all sources should be monitored and weighed with other investment priorities.

IV. FORMULATION OF SCIENCE POLICY

Over the past 40 years, a complex system for federal policy-making in the biomedical and behavioral sciences has evolved. In theory, there are interrelated but separate roles assigned to each of the major participants; the Congress sets overall goals and allocates resources within very generic categories, and the executive branch, through its departments and agencies, establishes working priorities and determines the actual means to achieve these goals. In practice, the system is highly pluralistic. As the size and complexity of the federal biomedical research enterprise has grown, and as its successes and potential have become better known to the public, the number and variety of groups and persons seeking to influence federal health research policy has grown commensurately.

The formulation of federal biomedical research policy, because it involves the expenditure of public funds, rests with the President and the Congress. As fiscal constraints have become more dominant, resource allocation has become a major arena in which conflicts related to policy priorities are expressed. As a result, both the White House Office of Management and Budget (OMB) and the congressional appropriations committees have become major foci for research policy and priority decisions. Recent policy emanating from the OMB has caused particular concern because of the apparent priority given to the current fiscal exigencies over scientific considerations.

The priority of investment in science *vis a vis* other federal endeavors and the relative priority accorded different fields of science in the allocation of limited federal resources are rightly public decisions. Within any field of science, such as the biomedical and behavioral sciences basic to medicine, subsidiary goals must be chosen and priorities established to achieve the generic goal of advancing biologic knowledge and improving human health. While all segments of society should have a voice in setting overarching federal priorities and scientists should participate both as citizens and experts in these debates, it is increasingly critical that the best scientific advice be available to Congress and the executive branch as specific goals and priorities are established within a given scientific domain. Indeed, as the formulation of policy and decision-making about the allocation of resources move from general to more specific questions about the means to achieve a given goal, there must be a corresponding shift from the public and political arena to the professional administrators of the federal biomedical research enterprise working in concert with the scientists themselves.

The present system for obtaining advice about the allocation of resources within the domain of biomedical and behavioral research is pluralistic and decentralized.

This has the advantage that all shades of opinion are represented through both formal and informal channels, that laymen as well as scientists present their views, and that no aspect of the enterprise lacks adherents and advocates. It has the disadvantage that this chorus of opinion is cacophonous and often contradictory. The scientific community is concerned to ensure that Congress and the President receive impartial, realistic, and timely advice from scientists concerning goals, priorities, and means to achieve goals in the field of biomedical research so that federal decision-making may be as informed and effective as possible.

Formal mechanisms to achieve the best consensus of the scientific community on key policy issues and priorities for biomedical research would be a useful adjunct to the present process. Such mechanisms would focus debate and provide a forum for resolution to the extent that they were able to pursue practical policy questions in a realistic time frame as well as advise on long-range priority setting. While they would address issues of public concern, they would not be mechanisms for achieving agreement between scientists and the public but for presenting scientific advice. Potential forums for providing such scientific advice to the President and Congress currently exist in the institute advisory councils of the NIH and ADAMHA and the National Academy of Sciences/Institute of Medicine. To fulfill this role, these bodies must be charged with providing such consensus advice in a fashion more timely and germane to public policy debates than they provide in their current roles.

ADVICE TO THE EXECUTIVE BRANCH

The advisory councils of the individual institutes of the NIH and ADAMHA are duly constituted bodies chartered to provide policy advice and establish priorities within categorical disciplines as well as approve funding allocations within their respective institutes. These councils are charged to debate and develop recommendations on policies and priorities on broader issues germane to biomedical and behavioral research. Some of this is done in conjunction with the individual institute 5 year plans. To provide the consensus and broad view most useful to the public debate, it is important that the deliberations of the councils be sent directly to the Director of NIH or Administrator of ADAMHA to be integrated with the views of other councils and the senior agency staff so that the overall priorities that are recommended balance the views of differing disciplines. Such consensus should be achieved through the use of an integrating advisory mechanism that remains within the respective agency. The final recommendations of

each agency should be publicly available to assist in national policy debates.

To effectively serve as a scientific advisory body, each council requires an appropriate number of scientists drawn from the top ranks of the relevant academic disciplines. Such high quality active scientists broadly representative of the national cadre of working scientists in each discipline must continually be recruited to fill the ranks of the advisory councils to ensure that the most knowledgeable advice is obtained. The scientific expertise and calibre of these critical advisory bodies is essential to their current function and would be even more essential in an expanded role as policy advisors to NIH as a whole and ultimately the executive branch and the President.

Through these duly constituted standing panels of advisors, scientific advice with a disciplinary focus could be formally developed, integrated at the agency level, and presented through the Office of the Assistant Secretary for Health, who then provides overall biomedical and behavioral research advice to the Department of Health and Human Services and eventually to the President. While this administrative hierarchy is currently in place, the key changes that would cause it to function as a more useful biomedical research policy advisory mechanism would be to shift the focus of the advisory council towards providing such advice, thus making them the fulcrum for much of the debate that now occurs in a decentralized and fragmented way, and to require the formulation of timely recommendations on key issues from each of the research agencies.

The advisory councils of the individual institutes at NIH and ADAMHA are charged to advise on research policy and priorities and should submit their recommendations to the Director of NIH or Administrator of ADAMHA. The Directors in turn should develop and present consensus scientific advice on key issues in research policy to the administration via the Office of the Assistant Secretary for Health.

The executive branch also receives independent advice on science policy from the White House Office of Science and Technology Policy. This body was established to provide the President with advice that represents and integrates the major domains of science and examines issues of government-wide research policy. For this office to function optimally in providing such advice, it is important that it include strong representation from the life sciences, including a prominent senior scientist from the biomedical and behavioral research community who can provide expert advice on biomedical research policy and see that the unique interests of the medical and life sciences are integrated into the overall science enterprise.

The President's Office of Science and Technology Policy should include strong senior representation from the fields of biomedical and behavioral sciences.

ADVICE TO CONGRESS

While Congress has access to the views of the biomedical and behavioral research agencies through both oversight hearings and mandated reports, and is also besieged by many professional and public constituencies who speak for segments of the research community, it lacks a single formal mechanism for obtaining the highest level of advice in its efforts to formulate federal policy for support of biomedical and behavioral research. An independent advisory structure could provide an ongoing appraisal of the state of biomedical and behavioral sciences research, highlighting opportunities for current progress, areas of promise, and neglected disciplines or themes. Besides this ongoing function of evaluating the federal directions in biomedical and behavioral research, such an advisory body could provide timely counsel in formulating the health and life sciences research budgets and assist Congress in establishing short- and long-term funding priorities.

In theory, a new entity is not needed to fill this role. The National Academy of Sciences was chartered by President Lincoln in 1863 to serve as an official advisor to the federal government on any question of science or technology. It has fulfilled this role admirably in undertaking long-term studies on key policy issues and in providing a forum for debate and opportunities to seek consensus within the scientific community on many aspects of scientific policy and priority setting. These valuable functions should continue. The NAS could also organize itself through the Institute of Medicine to meet the need for timely advice and undertake the task of generating a consensus position on issues of immediate concern to Congress and the administration. Its membership of eminent scientists as well as other members of the science community could be tapped to deliberate such issues and charged to provide impartial and balanced scientific advice in areas of budget and resource allocation that is cognizant of the realistic pressures and choices faced by Congress and that presents a considered scientific judgment responsive to public aspirations and concerns.

The National Academy of Sciences through the Institute of Medicine should assume a strengthened role as an advisory body to Congress, the executive branch, and the public on issues of topical concern in the biomedical sciences and in areas where resource allocation and program priority decisions are being made under pressures of fiscal and time constraints.