

FROM BENCH TO BEDSIDE

Preserving the Research Mission of Academic Health Centers

Findings and Recommendations of
The Commonwealth Fund Task Force on Academic Health Centers

April 1999

Support for this research was provided by The Commonwealth Fund. The views presented here are those of the Task Force on Academic Health Centers and should not be attributed to the Fund or its directors, officers, or staff.

**THE COMMONWEALTH FUND
TASK FORCE ON ACADEMIC HEALTH CENTERS**

CHAIR

Samuel O. Thier, M.D., *President and
Chief Executive Officer*
Partners HealthCare System, Inc.

Lawrence S. Lewin, M.B.A., *Chairman and
Chief Executive Officer*
The Lewin Group

VICE CHAIR

Bill Gradison, *Senior Public Policy Counselor*
Patton Boggs & Blow

Charles B. Mullins, M.D., *Executive Vice
Chancellor for Health Affairs*
University of Texas System

MEMBERS

Edward N. Brandt, Jr., M.D., Ph.D.,
Regents Professor
University of Oklahoma Health Sciences Center

Richard M. Rosenberg, *Chairman and CEO
(Retired)*
BankAmerica

EXECUTIVE DIRECTOR

Gail Cassell, Ph.D., *Vice President,
Epidemiology*
Eli Lilly & Company

David Blumenthal, M.D., M.P.P., *Director*
Institute for Health Policy
Massachusetts General Hospital/Partners
HealthCare System, Inc.

Janice Douglas, M.D., *Professor*
Department of Medicine
Case Western Reserve University

TASK FORCE STAFF

Alain Enthoven, Ph.D., *Professor*
Graduate School of Business
Stanford University

James A. Reuter, Sc.D., *Director*
Institute for Health Care Research and Policy
Georgetown University Medical Center

Paul F. Griner, M.D., *Vice President
and Director*
Center for the Assessment and Management of
Change in Academic Medicine
Association of American Medical Colleges

Joel S. Weissman, Ph.D., *Senior Scientist*
Institute for Health Policy
Massachusetts General Hospital/Partners
HealthCare System, Inc.

Michael M.E. Johns, M.D., *Executive Vice
President for Health Affairs*
*Director of the Robert W. Woodruff Health
Sciences Center*
Emory University

Eric G. Campbell, Ph.D., *Research Associate*
Institute for Health Policy
Massachusetts General Hospital/Partners
HealthCare System, Inc.

COMMONWEALTH FUND STAFF

William B. Kerr, *Executive Vice President and
Chief Operating Officer*
University of California, San Francisco Stanford
Health Care

Brian Biles, M.D., *Senior Vice President*
Melinda Abrams, M.S., *Program Associate*

CONTENTS

FIGURES AND TABLES	vi
PROLOGUE	vii
EXECUTIVE SUMMARY	ix
INTRODUCTION	1
The Objectives of the Task Force.....	1
Growth in the National Institutes of Health Budget	3
Direct Support for Academic Health Center Missions	4
1. BIOMEDICAL RESEARCH IN ACADEMIC HEALTH CENTERS.....	5
The Importance of Biomedical Research.....	5
Government Support for Health-Related Research	6
The Value of Research at Academic Health Centers.....	7
2. FINDINGS ON THE CURRENT STATUS OF BIOMEDICAL RESEARCH IN ACADEMIC HEALTH CENTERS	9
Specific Findings.....	9
Summary and Conclusions.....	38
3. RECOMMENDATIONS.....	41
Management of Research at Academic Health Centers.....	41
Policies of the National Institutes of Health.....	46
Federal Support for Health Services Research.....	52
REFERENCES	55
APPENDIX. 1996 NIH APPROPRIATIONS TO AHCs.....	59

FIGURES AND TABLES

FIGURES

Figure 1.	National Trends in Health-Related R&D Expenditures, FY 1984–97	9
Figure 2.	AHCs’ Contribution to the National Research Effort, FY 1997.....	10
Figure 3.	Sources of Research Funding in AHCs, FY 1997	11
Figure 4.	Distribution of NIH Awards to AHCs, FY 1996	12
Figure 5.	Indirect Costs as a Percentage of Total Cost of NIH Research Grants, by Type of Institution, FY 1985–94.....	16
Figure 6.	Trends in Institutional Support of Research by Ownership Status for Selected Years, FY 1973–93	19
Figure 7.	Trends in Medical School Expenditures for Renovation and Construction of Research Facilities, FY 1990–96.....	20
Figure 8.	Average Faculty Practice Plan Margin by Managed Care Intensity, FY 1989–95.....	21
Figure 9.	Average Margin (Transferable Dollars) per Faculty Practice Plan, FY 1989–95.....	22
Figure 10.	NIH Awards to Medical Schools in Different Managed Care Markets, by Dollar Amount, 1986–95	23
Figure 11.	Relative Share of HMO Discharges Compared with Other Privately Insured Discharges, by Type of Hospital, FY 1994.....	24
Figure 12.	Number of Applications to NIH for Competing Research Project Grants, by Degree of Investigator, FY 1986–95.....	29
Figure 13.	Percentage Change in First-Time Applications for NIH Funding, by Degree of Investigator, FY 1994–96.....	29
Figure 14.	Percentage of NIH Research Project Grant Awards, by Degree of Investigator, FY 1986–95.....	30
Figure 15.	Affiliation of Clinical Trials Investigators, 1993	31
Figure 16.	Trends in Medical School Graduates Participating in Research Activities, Selected Years, FY 1985–95	35
Figure 17.	Success Rates for Investigator-Initiated Grant Applications, FY 1997	38

TABLES

Table 1.	Trends in Expenditures by the National Institutes of Health, FY 1977–97	14
Table 2.	Funding for Clinical and Other Research by the NIH, FY 1996	28
Table 3.	Trends in Federal Appropriations to the National Institutes of Health and the Agency for Health Care Policy and Research, FY 1977–97	37

PROLOGUE

Accelerating change in all aspects of the health care system is forcing academic health centers (AHCs) to undertake dramatic reforms to sustain and promote their social missions. These missions consist of teaching, research, the provision of rare and highly specialized services, and continuous innovation in patient care services.

The first report of The Commonwealth Fund Task Force on Academic Health Centers, *Leveling the Playing Field*, noted that increased competition in health care markets could compromise the complex web of clinical, organizational, and financial relationships on which AHCs have relied to fulfill these missions. In this second report, the Task Force examines the status of AHCs' research mission—the accomplishments, problems, and unexploited opportunities. The nation's AHCs, as the following pages make clear, play a pivotal role in advancing knowledge of health and disease, thereby improving health and welfare not only in America, but internationally as well. To continue playing that role, AHCs and public policymakers must cope with enormous upheaval in both the health care system and in the nature of the scientific enterprise. These developments challenge the traditional ways that AHCs have performed biomedical research. Unless private managers and governmental leaders address these issues effectively, AHCs will not take full advantage of the generous funding that the federal government provides them to conduct health care research. Nor will the full benefits of new knowledge produced by AHCs translate quickly into new methods of patient care.

In the view of the Task Force, assuring the future of research in the nation's AHCs and promoting higher-quality and more cost-effective health care demands changes in the way these institutions manage their research enterprises. These changes also require the reform of federal policies that govern the National Institutes of Health and other federal agencies. Our hope is that this report will inform policymakers and contribute to the dialogue already taking place concerning these matters.

We are grateful to The Commonwealth Fund for its support of this project, as well as to the Pew Charitable Trusts, which supported important primary data-gathering that informed our work. We are also grateful to Brian Biles, M.D., senior vice president of the Fund, for his leadership and insight, and to the members of the Task Force and its staff for their wisdom and hard work. In the future, we hope that the Task Force will contribute to further understanding of how the nation can promote the effectiveness and efficiency with which it conducts the social missions of AHCs.

David Blumenthal, M.D., M.P.P.

Samuel O. Thier, M.D.

Executive Director

Chair

EXECUTIVE SUMMARY

The nation's 125 academic health centers (AHCs)—consisting of medical schools and their closely affiliated clinical facilities and faculty group practices—are a cornerstone of the health-related research enterprise in the United States and throughout the world. Yet recent changes in the health care market and public policies may hamper the ability of AHCs to conduct their research activities as effectively as they have in the past. These changes could also reduce the volume of certain types of biomedical research—including clinical research—that are vital to achieving the goals of public investment in biomedical research generally. Policymakers, health care leaders, AHC managers and faculty, and American voters must decide how to respond to looming uncertainty about the ability of AHCs to sustain past levels of productivity in biomedical research.

This report of The Commonwealth Fund Task Force on Academic Health Centers is intended to provide a resource for future policy development and management related to the research mission of AHCs. It addresses two major questions: (1) What is the current status of the research enterprise in AHCs: its strengths, weaknesses, unmet needs, and imminent challenges? and (2) What responses by the public and private sectors could help preserve and enhance the capabilities of AHCs to contribute to the production of new knowledge in the biomedical and related sciences?

FINDINGS

Over the last year, the Task Force has examined the role of AHCs in conducting biomedical research and the impact of managed care on the future of the AHC research mission. New information is documenting the pressures that AHCs are facing, the impact of those pressures, and how individual institutions are responding to change.

The key findings are:

- The United States spends an estimated \$42 billion annually on health-related research and development.
- Academic health centers perform approximately 28 percent of all health-related research and development in the United States.
- The federal government is the dominant source of support for research in academic health centers.
- The policies of the National Institutes of Health do not provide for adequate support to

academic health centers for the direct costs of research.

- The policies of the National Institutes of Health do not provide for adequate support to academic health centers for the indirect costs of their research mission.
- Academic health centers have historically cross-subsidized research with clinical revenues and other internal resources.
- In areas with high managed care enrollments, cross-subsidies for research are decreasing, threatening the future of the academic health center research mission.
- Support for biomedical research at academic health centers is being reduced by the growth of managed care.
- The Balanced Budget Act of 1997 will reduce Medicare payments to academic health centers, a change that may adversely affect their research mission.
- Academic health center responses to managed care may have adverse consequences for research.
- Clinical research in academic health centers may be undersupported at the current time.
- The clinical research mission of academic health centers faces competition from non-academic research organizations.
- Academic health centers could improve the management of both clinical and non-clinical research activities.
- Academic health centers provide substantial amounts of research training.
- Health services research is undersupported by the federal government at the present time.

Collectively, these findings generate four conclusions, or summary findings, about the immediate challenges faced by AHCs:

- Changes in clinical markets may reduce the ability of academic health centers to subsidize research and enroll patients in clinical investigations.

- Increased competition from clinical research organizations, most of them privately owned, is creating new challenges for academic health centers.
- The federal government's reliance on academic health centers to share the direct and indirect costs of performing health-related research demands reexamination.
- After several decades of extraordinary progress in basic investigation, the potential for translating accumulated new knowledge depends on increased national investment in clinical investigation.

RECOMMENDATIONS

The Task Force recommendations address issues in three areas: (1) the manner in which academic health centers currently manage their own research enterprises; (2) the allocation and management of extramural biomedical research expenditures by the National Institutes of Health (NIH); and, (3) the allocation of federal health care research funds in general. Several recommendations call for increased support for certain types of research functions or activities at AHCs. The Task Force believes that the necessary funds should be provided within the NIH budget, a change that should be possible as a result of the recent increase in NIH funding.

The Task Force offers five recommendations regarding the management of the research enterprise at academic health centers:

- Academic health centers should improve the management of their clinical research enterprise.
- Academic health centers should take steps to ensure the academic standing and prestige of clinical and health services researchers.
- Academic health centers should strengthen the management and organization of their basic research enterprise, including investment in and reliance on cross-disciplinary research programs.
- Academic health centers should promote and invest in applied research and development to increase the dissemination of new and emerging cost-reducing technologies and improve the delivery of health care services.
- Academic health centers should adopt measures to assure the status and viability of research within academic health care systems being challenged by the growth of

managed care.

Concerning the policies and expenditures of the National Institutes of Health, the Task Force makes five recommendations:

- The National Institutes of Health should provide appropriate funding for construction and renovation of research facilities, through explicit capital support and the restoration of the Biomedical Research Support Grant.
- The National Institutes of Health should increase the percentage of requested funds actually provided for projects and raise the maximum salaries of investigators to appropriate market levels.
- The contribution of the National Institutes of Health toward indirect cost rates should be sustained at no less than current levels to support the real costs of conducting research and maintaining laboratories and offices for investigators.
- The National Institutes of Health and other institutions should recognize the growing importance of clinical research by increasing support for clinical research at academic health centers.
- The National Institutes of Health should increase support for training clinical researchers at academic health centers.

The Task Force also makes a final recommendation concerning federal support for health services research.

- Federal support for health services research should be increased overall.

INTRODUCTION

The nation's 125 academic health centers (AHCs)—consisting of medical schools and their closely affiliated clinical facilities and faculty group practices—are a cornerstone of the health-related research enterprise in the United States and throughout the world. Indeed, as this report documents, AHCs conduct nearly 30 percent of the health-related research in the United States and train a substantial portion of the nation's health care researchers. Yet recent changes in the health care market and public policies may affect the ability of AHCs to conduct their research activities as effectively as they have in the past.

AHCs conduct nearly 30 percent of the health-related research in the United States and train a substantial portion of the nation's health care researchers.

THE OBJECTIVES OF THE TASK FORCE

The Commonwealth Fund Task Force on Academic Health Centers was established in 1995 to gather and analyze information about the traditional missions of AHCs—including education, research, specialty care, and indigent care—and support the development of public policy to sustain those missions in a changing health care system. The Task Force issued its first report, *Leveling the Playing Field: Financing the Missions of Academic Health Centers*, in 1997. Future reports will present information and recommendations on specialty care, the provision of indigent care, and the educational mission of AHCs.

Over the past year, the Task Force has concentrated on reviewing the status of the research mission at AHCs, especially in light of recent growth in managed care. Among the activities carried out by Task Force staff were analyses of large, quantitative databases, close examination of AHC budgets and the research funding they receive from the National Institutes of Health (NIH) and other sources, a comparison of the status of AHCs in areas with high and low managed care enrollments, and site visits to numerous AHCs. These studies, along with the expert advice of Task Force members, have produced the findings and recommendations presented in this report. The report is intended as a resource for future policy development and management.

The findings and recommendations of the Task Force address two major questions about the research enterprise of AHCs: (1) What is the current status of the research enterprise in AHCs: its strengths, weaknesses, unmet needs, and imminent challenges? and (2) What responses by the public and private sectors could help preserve and enhance the capabilities of AHCs to contribute to the production of new knowledge in the biomedical and related sciences?

Any description of the state of research in academic health centers must start by

acknowledging the extraordinary commitment of the American people toward health care research in the United States and in AHCs in particular. Through war, recession, budget crises, and changes in administration, a bipartisan consensus at the federal level has provided steadily increasing support for biomedical research. Academic health centers have competed effectively for those funds, and the result has been the creation of a national research enterprise that is both enormously successful and heavily dependent on AHCs. That enterprise is large and resilient. As long as support for the National Institutes of Health continues at current levels, the potential problems identified in this document are unlikely to produce drastic reductions in the rate of progress in biomedical research or the productivity of research within academic health centers.

Changes in markets and public policy could, however, affect the ability of AHCs to use federal funds to maximum advantage and could also reduce the volume of certain types of biomedical research—including clinical research—that are vital to achieving the goals of public investment in biomedical research in general. In addition, recent developments could have other effects with important potential long-term consequences. These include discouraging young investigators from entering vulnerable fields and changing the internal culture of academic health centers in ways that reduce their institutional commitment to biomedical research.

In preparing this report, the Task Force has pursued three objectives. First, the report is intended to document and make explicit the challenges facing AHCs. Second, the report seeks to alert academic health centers and the American people to the potential consequences of recent changes in the health care system. Finally, the report incorporates recommendations by the Task Force for managing those consequences.

The American people have benefited from an extraordinarily productive research alliance between public and private institutions in the health care sector. Policymakers, health care leaders, AHC managers and faculty, and American voters must decide how to respond to looming uncertainty about the ability of academic health centers to sustain past levels of productivity in biomedical research.

Before proceeding to the findings and recommendations of the Task Force, two issues must be addressed. The first concerns the implications for AHC research missions of the recent substantial increase in the budget of the National Institutes of Health. The second concerns previous recommendations of the Task Force, especially that proposing the creation of an Academic Health Services Trust Fund, and their potential effects on the research missions of AHCs.

GROWTH IN THE NATIONAL INSTITUTES OF HEALTH BUDGET

In recent years, members of the U.S. Congress and the executive branch have indicated support for significant growth in federal spending on biomedical research. At least seven bills were

introduced during the 105th Congress to increase the NIH budget substantially over the next five to seven years, and similar proposals appeared in budgets put forward by the Clinton Administration.¹ The final omnibus appropriations bill passed by the 105th Congress and signed by the President increased the budget of the NIH by \$2.0 billion, representing a 15 percent increase over 1998 appropriations.²

This increase in the budget of the NIH will almost certainly lead to improved understanding of the biomedical basis of health and disease, and eventually to health and economic benefits for humanity. In addition, the new funding will help address a number of issues related to the research mission of AHCs. Faculty members, for example, may find it easier to get grant applications funded without numerous resubmissions. Young investigators (including physician applicants) may have a greater chance of getting their first grant applications approved and establishing track records essential to launching their careers. Clinical researchers, whose proposals have historically fared less well than those of non-clinical researchers in the NIH peer-review process, may also find fewer hurdles to cross in pursuing their research.

Important as these potential benefits are, however, the current optimism should not divert attention from the many complex reforms required to assure that AHCs are capable of putting increased federal support to the best possible use. Indeed, the growth in NIH funding could exacerbate some problems, calling into question the ability of AHCs to absorb and use added monies effectively. Within AHCs, for example, higher grant revenues could produce greater demand for

Current optimism should not divert attention from the many complex reforms required to assure that AHCs are capable of putting increased federal support to the best possible use.

capital expenditures and other forms of infrastructure support, yet it is not clear that payments for indirect research costs received on a grant-by-grant basis will be adequate to meet that demand. AHCs have historically relied heavily on loans from commercial sources to support the capital needs of their research infrastructure. Pressures on the clinical revenues of AHCs could reduce the availability or increase the cost of borrowed funds in the future. In addition, growth in the NIH budget will not necessarily address concerns about the underfunding of certain types of important health care research, including clinical and health services research.

Increased federal funding for biomedical research has intrinsic merits above and beyond its potential effects on AHCs. However, increasing the NIH budget should not be viewed as a cure-all for the problems facing the research missions of AHCs. The need for proactive interventions will remain.

DIRECT SUPPORT FOR ACADEMIC HEALTH CENTER MISSIONS

The Task Force has previously recommended the creation of a source of direct support for AHCs, for the purpose of leveling the playing field in health care markets between AHCs and competing health care providers.³ The goal of the proposed Academic Health Services Trust Fund would be to protect the social missions of AHCs in competitive clinical markets by providing an alternative to clinical revenues to subsidize those missions. The conduct of health care research is one of those social missions.

Although direct support with sufficient funding could go a long way toward preserving the ability of AHCs to participate effectively in the nation's health care research enterprise, the prospect for establishing a mechanism to deliver such support is uncertain. Furthermore, some of the problems facing AHCs, such as competition from industry and reduced access to managed care patients, would not be addressed by direct support. It is therefore prudent to consider other measures to help preserve the research missions of AHCs.

This report on the present and future of the research mission of AHCs is organized in three sections. Section 1 presents the policy rationale for providing support to biomedical and health care research, both in general and in AHCs in particular. Section 2 presents the findings of the Task Force concerning the current status of the research missions of AHCs and summarizes those findings in four general conclusions. Section 3 presents recommendations for change in public policy and private management.

1. BIOMEDICAL RESEARCH IN ACADEMIC HEALTH CENTERS

After fifty years of federal support for biomedical and health-related research, we rarely pause to ask certain basic questions about why the American people are in this business to begin with. Yet at a time of great flux in our health care system, when fundamental assumptions are cast aside daily in health care markets, it is worth reflecting for a moment on the policy rationale for supporting research in general, and in academic health centers in particular.

THE IMPORTANCE OF BIOMEDICAL RESEARCH

The health care research enterprise in the United States has many concrete benefits. Most fundamentally, it is an expression of the hope and generosity of the American people: hope that the application of human intelligence can conquer suffering and disease, extend life, and improve its quality; and generosity toward one another and the other peoples on the globe, since whatever our scientists find will ultimately benefit all humankind. From this perspective, the American public's fifty-year investment in biomedical and health-related research can be seen not just as a wise investment of capital, which it has been, but as a manifestation of spirit, faith, and optimism. Health care research is one way that Americans have chosen to share their economic good fortune at this point in history and to advance the welfare of the human race for all time.

The American people have also been well rewarded in concrete terms for their support of biomedical research. Biomedical research has generated undeniable progress in the form of new ways to prevent, diagnose, and treat illness. Discoveries made during this century, such as the prevention and treatment of cardiovascular disease, the development of new antibiotics, and the treatment of premature newborns, have extended the lives and reduced the suffering of millions of people. Yet it is the future potential of recent and ongoing research—its still unrealized benefits—that is in many ways most exciting. By all accounts, the pace of discovery in America's biomedical laboratories is accelerating continuously. New understanding of the interactions of drugs and cell receptors, the human immune system, and genetic diagnosis and therapy hold enormous promise.

Biomedical research has generated undeniable progress in the form of new ways to prevent, diagnose, and treat illness.

Aside from the direct health effects of health-related research, there are also indirect economic benefits. A number of sources document the economic returns that flow from publicly funded research. Some of this information pertains directly to returns from the research conducted in the nation's AHCs, which is the primary concern of this document. For example, one study estimated that 27 percent of the new products and 29 percent of the new

processes commercialized by drug companies could not have been developed (without substantial delay) in the absence of recent academic research.⁴ A recent analysis of citations on U.S. industry patents found that 50 percent of papers cited on patents for drugs and medicines in 1993–94 were authored by researchers at academic institutions.⁵

The research mission of AHCs has been shown to have a positive impact on local economies.

- Academic researchers have played a central role in influencing the organization and innovative character of nearby companies.⁶ Examples include the extensive biotechnology industry in California’s Bay Area and Boston, the biomedical device industry in Minneapolis, and activities of the research triangle in North Carolina.
- AHC research contributes to local and regional economies by producing high-paying, skilled jobs and enabling local economies to be exporters of knowledge-based products and services.^{7–9}
- AHCs help to establish national research profiles. Economists have found that, within a given nation, private companies tend to specialize in the same scientific fields as its universities, indicating a transfer of technology from the public and nonprofit sectors to the private sector.¹⁰

Economic theory on the benefits of public funding of research seems to be buttressed by public opinion. Recent polls suggest that the public strongly values health-related research. Sixty-five percent of those surveyed opposed any cuts in the financing of medical research, and 73 percent said they would pay higher taxes to support research.¹¹

GOVERNMENT SUPPORT FOR HEALTH-RELATED RESEARCH

The fact that biomedical and health-related research has value does not address other questions: Why should government be involved in the support of such investigation? Why can’t the private sector do the job on its own? The answers have to do with the nature of biomedical research as an economic good. It is widely agreed that competitive markets fail to allocate resources to research and development activities in an optimal manner.

Research, especially in its more fundamental stages, has many attributes of a public good.¹² Once new knowledge is produced from basic research, it becomes difficult for its funders to appropriate the full value of that knowledge, which may have protean and unpredictable applications. Also, because the value of new information is not diminished with use, it is inefficient from a societal perspective to restrict its availability for proprietary reasons.

Other research and development activities are also subject to market failure, but less so. Research activities that result in saleable products or services (such as drugs and medical devices) allow investors to capture only about 50 percent of the benefit from their internal investment, meaning that about half the benefit of private investment in applied research and development spills over to other businesses or to consumers.¹³ Because health-related research and development often produces larger societal than private returns, there is a strong rationale for the public, acting through government, to participate in funding it.

THE VALUE OF RESEARCH AT ACADEMIC HEALTH CENTERS

Academic health centers, comprising medical schools and their closely affiliated teaching hospitals and faculty group practices, perform a considerable portion of the biomedical and health-related research that occurs in the United States. Many of the world's leading basic and clinical researchers are faculty members of American medical schools and see patients at their affiliated clinical facilities.

This situation has not evolved by chance. Academic health centers have acquired their prominence in research by competing for projects in the peer-review process that governs allocation of research at the National

Institutes of Health, the National Science Foundation, and other supporters of health-related investigation. AHCs compete effectively on the merits of their proposals because they have succeeded in attracting

AHCs compete effectively on the merits of their proposals because they have succeeded in attracting and retaining excellent investigators.

and retaining excellent investigators. The attractiveness of AHCs to premier researchers stems from several factors, but one of the most important is the natural advantages that AHCs enjoy as locations in which to perform basic and applied health care research. Nowhere else in our health care system is it so easy for basic and clinical researchers to interact, and to do so in the presence of patients whose clinical problems motivate and direct the process of discovery. At AHCs, physicians who spend most of their time in laboratories can also provide patient care on a part-time basis; clinicians can attend a lunchtime seminar on the basic mechanisms of disease, then return to their clinics and rounds for the afternoon. The passage of knowledge from bench to bedside and back again happens automatically and effortlessly in this environment.

Some research that has traditionally been performed at AHCs could arguably be performed effectively elsewhere. Examples include some large clinical trials of drugs and devices that are undergoing advanced testing for regulatory approval and certain basic research. Yet translating knowledge

Translating knowledge effectively from bench to bedside requires close contact with clinical settings.

effectively from bench to bedside requires close contact with clinical settings. As previous work by the Task Force has established, research and teaching in any clinical setting add to the costs of providing patient care.³ These costs would occur no matter where the research took place, whether at an AHC hospital or a community hospital that decided to become more involved in research.

Indeed, it can be argued convincingly that if research now conducted in AHCs were transferred to community-based settings, those institutions would have to acquire many of the attributes of AHCs in order to succeed. They would need to attract the nation's best and most innovative clinicians—doctors who are always asking questions, challenging conventional care, pushing the envelope of traditional practice, and innovating in their daily work. And they would also need bench researchers with an interest in clinical practice: scientists who understand what is happening in basic research departments of major universities and drug companies around the world, but who are driven to apply that work to the diseases of human beings. In other words, if AHCs did not exist, something like them would have to be created to take maximum advantage of the federal investment in biomedical and health-related research.

The Task Force believes that policy in this area should be guided by the goal of assuring that the health care research enterprise realizes the greatest possible benefits for the American people, rather than by efforts to protect AHCs as institutions. Nevertheless, health care research in the United States has become so heavily dependent on AHCs that their institutional capacities cannot be ignored in developing national policy in this area.

2. FINDINGS ON THE CURRENT STATUS OF BIOMEDICAL RESEARCH IN ACADEMIC HEALTH CENTERS

The information gathered by the Task Force confirms that academic health centers play a vital role in performing the full spectrum of health care research—from basic to clinical to health services research—and this research is paying large dividends for the health of the public and U.S. economy. Supporting this research is appropriate for the public sector and enjoys broad public approval.

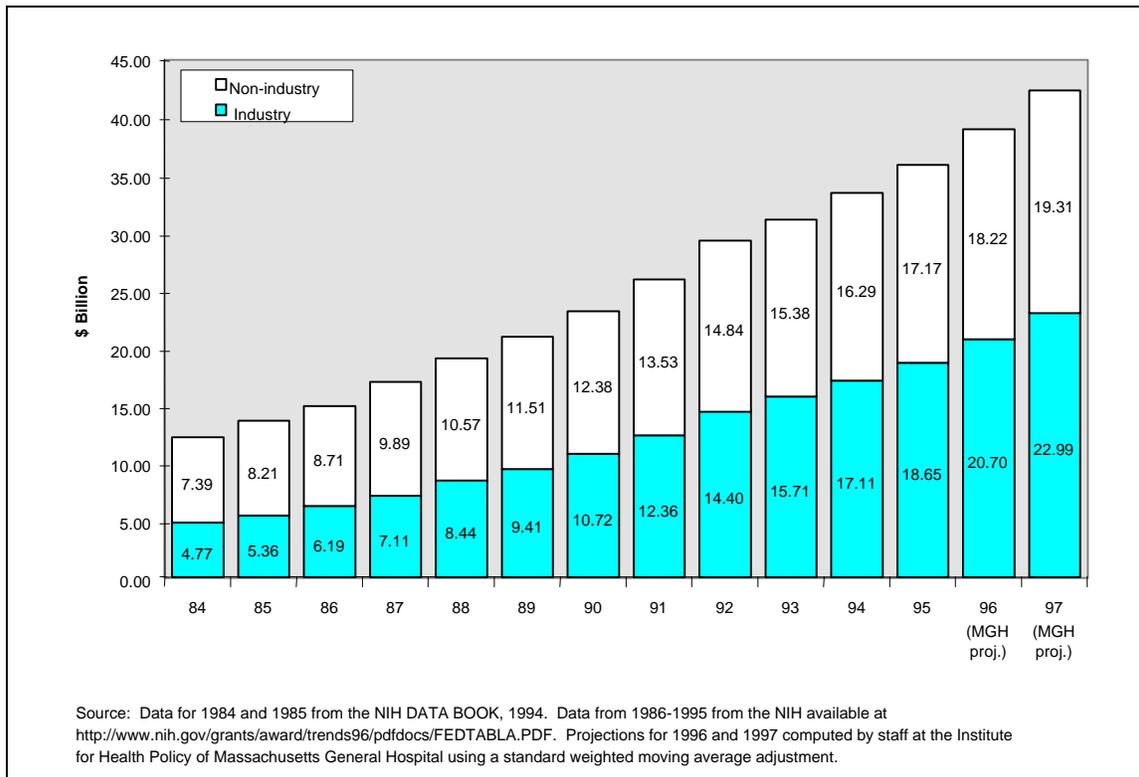
Overall, the research enterprise of AHCs is strong and thriving. At the same time, the research activities of AHCs face several challenges, stemming from changes in the markets for clinical care and clinical research and from shifting trends in public policy and science.

SPECIFIC FINDINGS

Finding 1. The United States spends an estimated \$42 billion annually on health-related research and development.

The total national investment in health-related research and development tripled from \$12 billion in 1984 to \$36 billion in 1995.¹⁴ National expenditures are estimated to have totaled approximately \$42 billion in 1997 (figure 1).

Figure 1. National Trends in Health-Related R&D Expenditures, FY 1984–97



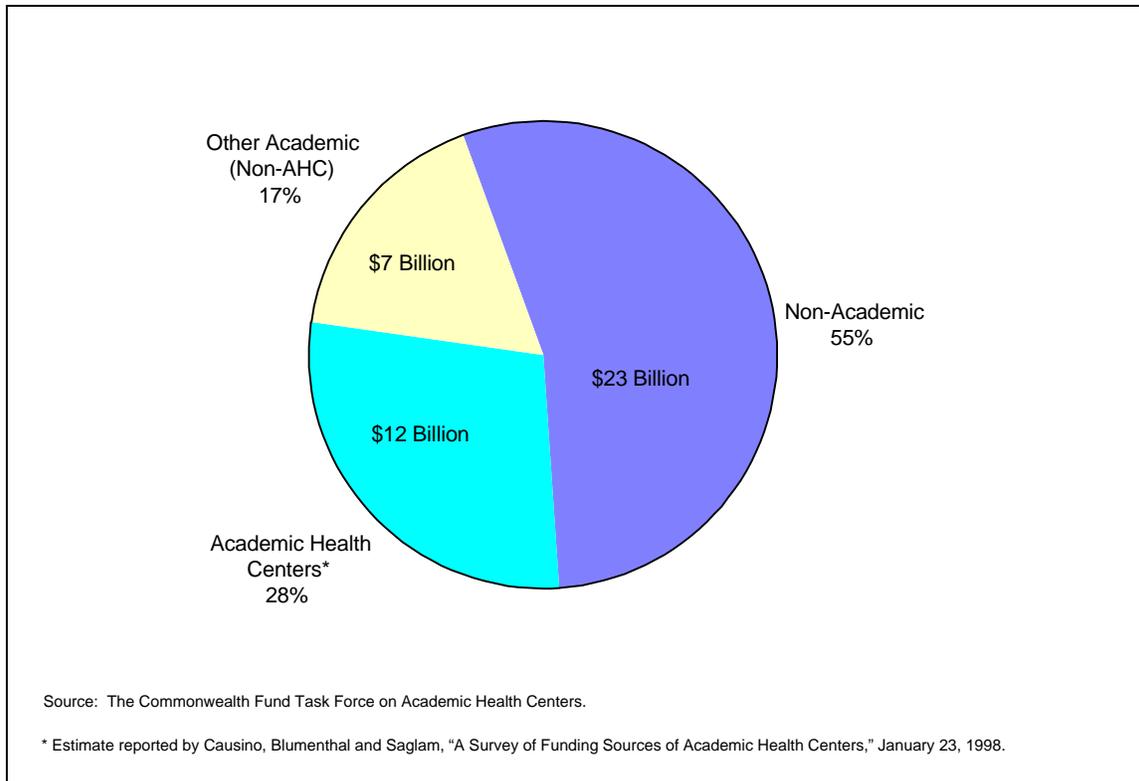
Much of the growth in research expenditures is attributable to the research activities of

private industry, mainly pharmaceutical companies and medical device producers. From 1985 to 1997, health-related research and development expenditures increased by 382 percent for industry, compared with 161 percent for non-industrial organizations.¹⁵

Finding 2. Academic health centers perform approximately 28 percent of all health-related research and development in the United States.

Academic institutions received 45 percent (\$19 billion) of national research and development funding in 1997. Of that, AHCs collectively received \$12 billion dollars, representing approximately 28 percent of national health-related research and development funding (figure 2).¹⁶

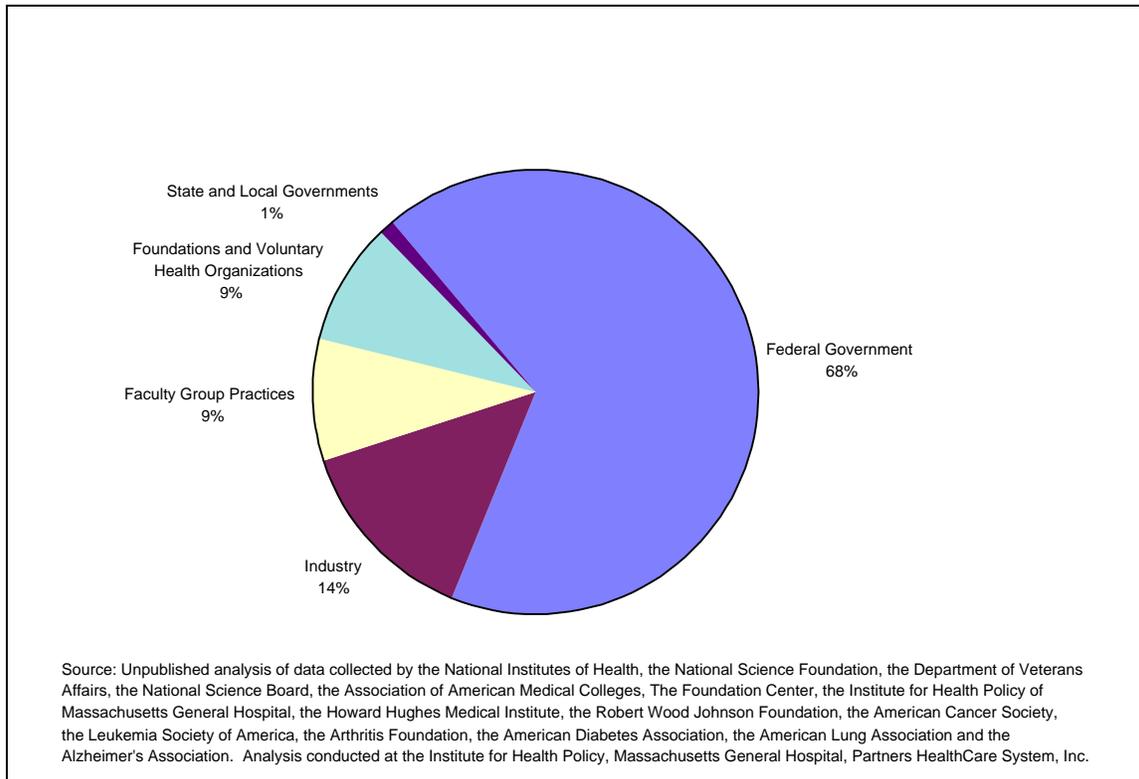
Figure 2. AHCs' Contribution to the National Research Effort, FY 1997



Finding 3. The federal government is the dominant source of support for research in academic health centers.

In 1997, the federal government provided 68 percent (\$8.1 billion) of all research funding for AHCs, while industry provided 14 percent (\$1.6 billion); faculty group practices, 9 percent (\$1.1 billion); foundations and voluntary health organizations, 9 percent (\$1 billion); and state and local governments, 1 percent (\$113 million) (figure 3).

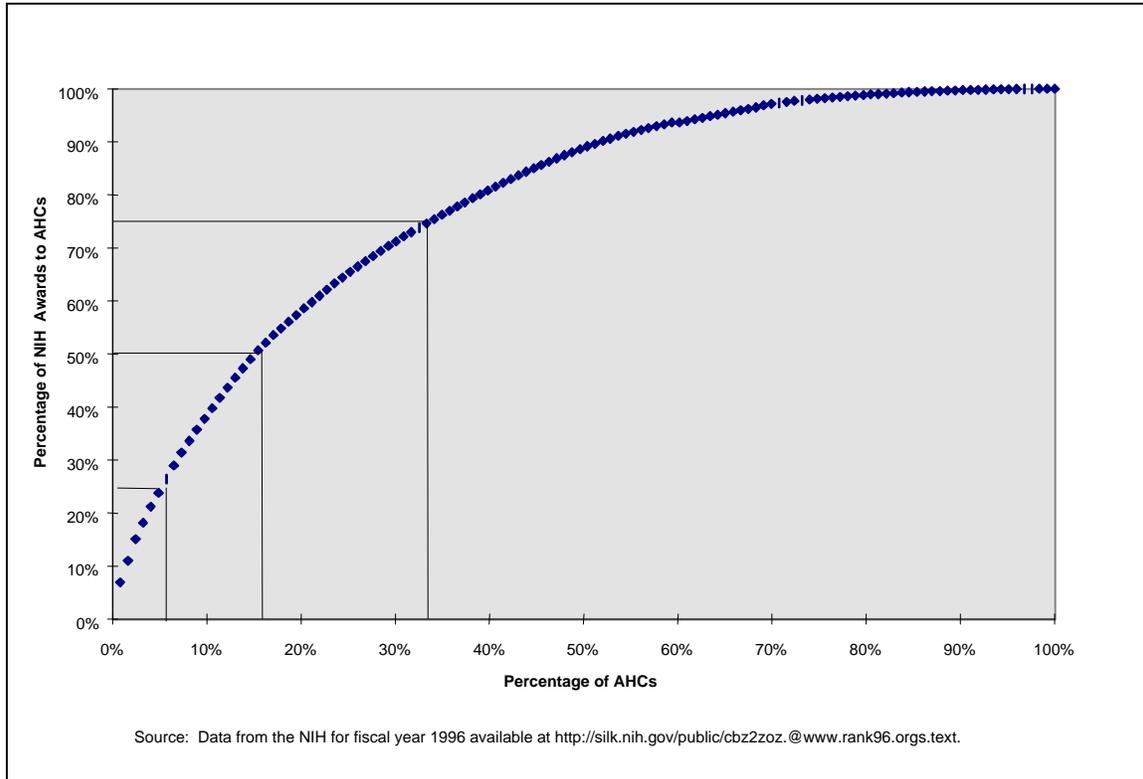
Figure 3. Sources of Research Funding in AHCs, FY 1997



The majority of federal funds can be traced to the National Institutes of Health, which provided \$7.4 billion to AHCs in 1997. The remaining \$700 million in federal monies originated in other agencies, including the Centers for Disease Control and Prevention (CDC), the Agency for Health Care Policy and Research (AHCPR), and the Department of Veterans Affairs (VA).¹⁶

Federal research funds are concentrated in a few institutions, a pattern that can be illustrated with data from the NIH. In 1996, 5 percent of AHCs received 25 percent of all NIH funds, and 15 percent of AHCs received 50 percent of all NIH funds (figure 4). (See the appendix for data on the share of NIH funding awarded to individual AHCs.)

Figure 4. Distribution of NIH Awards to AHCs, FY 1996



Proponents of the current distribution explain that, “leading [medical] schools have lower average and marginal costs of performing research than lesser institutions, and leading institutions have a comparative advantage at generating higher-quality, more highly cited research.”¹⁷ There are, however, potential drawbacks to such a disproportionate concentration of NIH research support. Overconcentration of federal research dollars in selected AHCs could make the national investment in research vulnerable to changes in research agendas and policies at just a few institutions. Further, it may deny medical students in less research-intensive institutions exposure to clinical research that might enhance their education. Ultimately, the increasing concentration of research dollars in a few AHCs may force others to discontinue or drastically curtail their research programs.

Another concern is that certain institutions—such as publicly owned AHCs serving many poor patients—may lack the clinical and other revenues necessary to support an infrastructure that will enable them to compete successfully for research funds. Such institutions may also be more likely to study problems that disproportionately affect the health of poor and minority patients, such as AIDS, tuberculosis, sexually transmitted diseases, violence, and illiteracy. The result could be a shortage of research on issues relevant to disadvantaged populations.

Finding 4. The policies of the National Institutes of Health do not provide for adequate support to academic health centers for the direct costs of research.

Research budgets, including investigators' salaries

NIH policy relies on AHCs to share a portion of the costs of health-related research. For a number of years, AHC leaders have claimed that NIH grants are covering a smaller and smaller percentage of overall project expenses, putting AHCs under increasing pressure to make up the difference. According to anecdotal reports, for example, it is common NIH practice to reduce the budget of an approved grant by an average of 20 percent below the amount requested by the investigator.

This trend may reflect the impact of specific policy changes, such as the congressional decision in the early 1990s to cap investigators' salaries on governmental research grants at \$125,000. In 1994, the average base compensation for a physician faculty member in the clinical sciences at the level of associate professor or higher was more than \$125,000 for every specialty except community health and preventive medicine.¹⁸ The net effect of the cap, therefore, is to require that AHCs either pay their physicians less than market rates (and thus risk losing talented investigators) or make up the difference from other sources, such as clinical revenues.¹⁹ No estimate of the total financial impact of this regulation is available.²⁰ In addition, the NIH as a matter of policy refuses to cover certain usual costs, such as the salary of an investigator's secretary.

Construction and renovation of research facilities

Over time the federal government has steadily reduced its direct support for construction and other infrastructure needs of AHCs as a percentage of total expenditures (table 1). This shift has placed AHCs under growing pressure to cross-subsidize research-related expenses. In 1991–92, the federal government also terminated the Biomedical Research Support Grant program, which provided untargeted, discretionary support for institutional costs associated with research.

Table 1. Trends in Expenditures by the National Institutes of Health, FY 1977–97

	Research Grants		R&D Contracts		Research Training		Construction		Total
	\$	%	\$	%	\$	%	\$	%	\$
	million		million		million		million		million
1977	\$1,435.7	71.3%	\$430.1	21.4%	\$131.6	6.5%	\$16.0	0.8%	\$2,013.4
1978	\$1,638.0	72.8%	\$451.6	20.1%	\$148.5	6.6%	\$12.0	0.5%	\$2,250.1
1979	\$1,951.7	75.4%	\$475.0	18.3%	\$149.3	5.8%	\$12.5	0.5%	\$2,588.5
1980	\$2,161.1	77.5%	\$432.4	15.5%	\$182.8	6.6%	\$10.8	0.4%	\$2,787.1
1981	\$2,331.4	80.9%	\$366.9	12.7%	\$181.7	6.3%	\$2.0	0.1%	\$2,882.0
1982	\$2,407.7	82.2%	\$358.7	12.2%	\$156.3	5.3%	\$6.2	0.2%	\$2,928.9
1983	\$2,702.3	83.3%	\$370.3	11.4%	\$171.1	5.3%	\$1.5	0.05%	\$3,245.2
1984	\$3,087.0	84.4%	\$394.7	10.8%	\$173.2	4.7%	\$1.0	0.03%	\$3,655.9
1985	\$3,591.3	84.6%	\$417.7	9.8%	\$224.0	5.3%	\$12.1	0.3%	\$4,245.1
1986	\$3,739.1	84.5%	\$462.6	10.5%	\$217.1	4.9%	\$5.0	0.1%	\$4,423.8
1987	\$4,735.1	84.9%	\$566.1	10.1%	\$263.8	4.7%	\$6.9	0.1%	\$5,574.9
1988	\$5,133.4	85.4%	\$600.6	10.0%	\$270.7	4.5%	\$0.0	0.00%	\$6,011.4
1989	\$5,619.0	84.6%	\$697.5	10.5%	\$288.3	4.3%	\$28.9	0.4%	\$6,640.9
1990	\$5,961.1	84.0%	\$777.4	10.9%	\$325.4	4.6%	\$25.8	0.4%	\$7,098.7
1991	\$6,541.5	84.6%	\$793.2	10.3%	\$351.0	4.5%	\$37.4	0.5%	\$7,732.7
1992	\$7,079.3	84.9%	\$866.9	10.4%	\$357.2	4.3%	\$23.9	0.3%	\$8,337.1
1993	\$7,257.0	85.3%	\$861.9	10.1%	\$359.7	4.2%	\$19.8	0.2%	\$8,508.0
1994	\$7,648.5	84.3%	\$1,001.8	11.0%	\$381.5	4.2%	\$27.2	0.3%	\$9,070.8
1995	\$7,928.1	84.6%	\$1,016.9	10.8%	\$391.4	4.2%	\$20.3	0.2%	\$9,371.9
1996	\$8,393.5	85.3%	\$994.3	10.1%	\$404.3	4.1%	\$25.1	0.3%	\$9,834.7
1997	\$9,046.5	86.5%	\$939.7	9.0%	\$422.5	4.0%	\$26.8	0.3%	\$10,456.0

Sources: 1977–86 data from the NIH Data Book, 1987; 1987–96 NIH data available at <http://www.nih.gov/grants/award/trends96/CONTENTS.HTM>; 1997 NIH data available at <http://silk.nih.gov/public/cbz2zoz.@www.trends97.allprog.hist8897.dsnc>; downloaded March 10, 1998.

Finding 5. The policies of the National Institutes of Health do not provide for adequate support to academic health centers for the indirect costs of their research mission.

Declining direct support of capital and infrastructure costs has led to greater reliance on indirect cost payments to support those needs. In governmental parlance, indirect payments support the facilities and administrative (F&A) costs related to research. These are defined as “costs that are incurred for common or joint objectives and, therefore, cannot be identified readily or specifically with a particular sponsored project, educational activity, or any other institutional activity.”²¹ F&A costs are incurred to construct, purchase, or maintain buildings and equipment and to provide operational support, including janitorial services, building maintenance, library operations, grants administration, and payroll services.

Over the years, federal agencies have been more forthcoming in paying for F&A costs than have other research sponsors. Research grants from foundations and voluntary health organizations frequently pay very little or nothing for indirect costs. Federal policies concerning F&A support have therefore become crucial to the health care research enterprise in AHCs.

Federal facilities and administrative rates are determined through a process of negotiation between the recipient institution and an agency of the federal government—usually the Department of Health and Human Services in the case of AHCs. Negotiations are based on a cost proposal prepared by the institution using actual budget data and reviewed by federal officials. When a medical school can demonstrate that their F&A costs vary substantially from those of its parent university, the medical school may negotiate a separate F&A rate. That rate is then applied to grants and contracts as a percentage of the modified total direct costs.

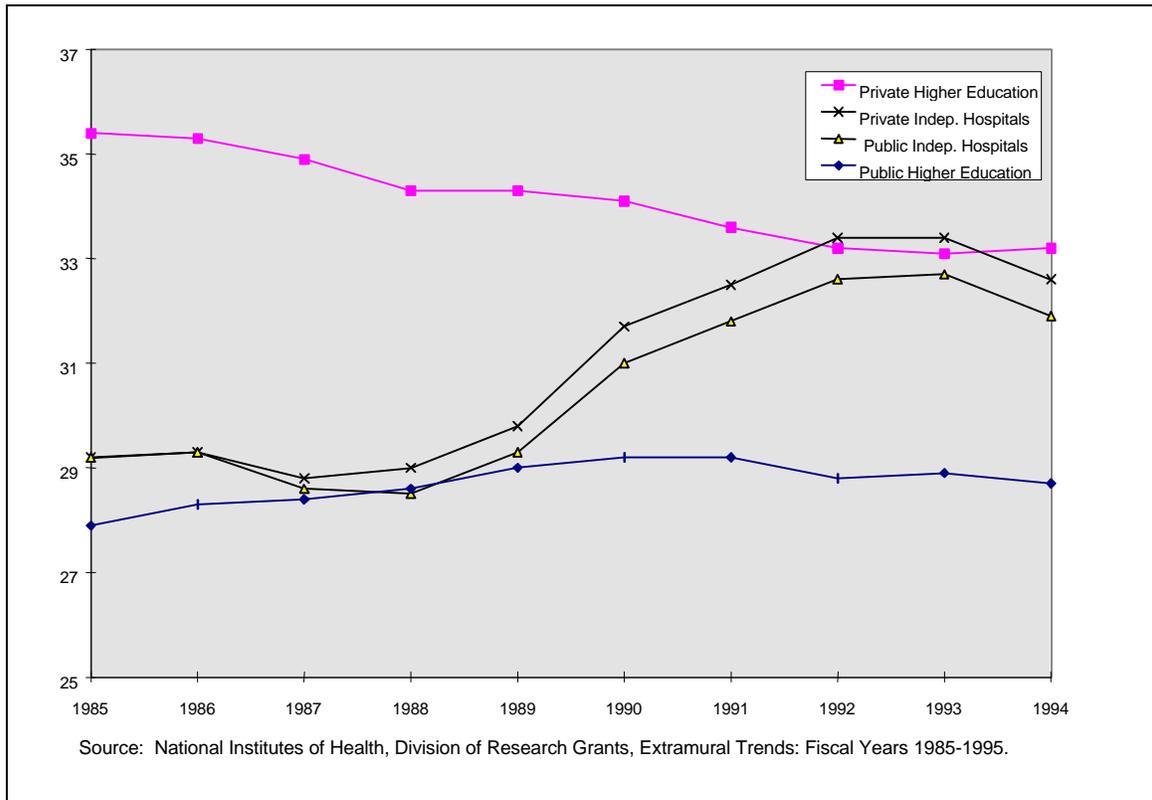
Since 1991, the federal government has placed an upper limit of 26 percent on the share of total research costs it will pay to cover the administrative portion of the indirect cost rate. The other major portion of indirect costs, facilities expenses, is not capped but has been relatively constant as a share of total research costs in recent years. In the past, federal officials have considered capping the facilities portion.

In 1994–95, medical schools received \$1.9 billion in F&A reimbursement, of which 63 percent (\$1.2 billion) went to private and 37 percent (\$700 million) to public medical schools.²² Public and private medical schools appear to be equally dependent on federal F&A reimbursements. In 1994–95, 81 percent of all F&A revenues for private medical schools came from federal research grants and contracts, compared with 83 percent for public schools.²²

Figure 5 shows trends in F&A costs as a percentage of the total amount of NIH research grants, comparing institutions of higher education (including medical schools and university-owned hospitals) with independent hospitals that received funding from the NIH.* As a share of total research expenditures, indirect costs have been declining or stable for most recipients of federal funds. The exception is independent hospitals, which conduct a comparatively small fraction of federally funded health care research.

* NIH Data Books report figures for all institutions of higher education. This category includes medical schools, non-medical school higher education components, research institutes, and university-owned hospitals. Thus, it is impossible to break out separate figures for university-owned hospitals.

Figure 5. Indirect Costs as a Percentage of Total Cost of NIH Research Grants, by Type of Institution, FY 1985–94



Variations in facilities and administrative costs

Significant differences exist in the F&A rates allowed by the federal government. A 1991 study found that three factors explained 67 percent of the variation at the 100 institutions receiving 90 percent of the dollars awarded to educational institutions: ownership status (public versus private), geographic location, and size of the institution’s research effort (measured as the amount of total direct costs awarded to an institution).²³ In general, the study found that private schools had higher indirect costs than public schools. Private schools may be more aggressive in recovering F&A costs, since public schools may be required to return surpluses to their states. Also, public schools receive some funding for capital expenses, one of the costs covered by F&A, from state governments, thus enabling public institutions to reduce their dependency on the federal government.

In terms of geographic location, institutions in the Northeast had the highest F&A rates while those in the Midwest and the South had the lowest. This may partly reflect climatic conditions that affect the cost of utilities and related operations and maintenance costs. For private institutions, the study found a positive relationship between institutional research intensity and F&A rates: rates increased by .17 percentage points for every million dollars of direct NIH funding awarded. A similar effect was not found for public institutions.

Indirect cost rates and capital for AHC infrastructures

Because direct federal support for research capital investment is comparatively small (table 1), the facilities' portion of indirect costs has come to play the primary role in supporting the capital infrastructure of AHCs. This system places the burden of raising funds to build research facilities on AHCs, which usually rely on commercial loans, state government funds (in some public institutions), philanthropy, and reserves from clinical revenues. AHCs depend in turn on their investigators to bring in sufficient federal grants to cover interest and depreciation on facilities. Strong AHCs have generally succeeded in this process, but institutions with less borrowing power and less robust research track records are likely disadvantaged in competing for the capital necessary to build their research infrastructures.

Furthermore, to the extent that clinical incomes are important to borrowing in commercial markets or funding capital expenditures directly, even strong AHCs may find problems in sustaining their capital

infrastructures as clinical markets become more competitive. Another concern about relying so heavily on federal indirect cost payments for capital is that they do not cover the full costs of research infrastructures.

Non-federal funding sources, which constitute 30 percent of research receipts,

generally pay much lower indirect cost rates, and the federal government is strict about not covering the indirect costs attributable to such work. Thus, many institutions report that they have indirect research costs that are not covered by any payer, and that these must be made up from other sources, including clinical revenues.

To the extent that clinical incomes are important to borrowing in commercial markets or funding capital expenditures directly, even strong AHCs may find problems in sustaining their capital infrastructures.

From their standpoint, federal officials raise questions about whether AHCs have been sufficiently accountable in their use of indirect costs for facilities. In the absence of limits on the facilities portion of F&A expenses, federal administrators seek evidence that AHCs and universities generally are building economically and appropriately for research functions. This concern has led to recent proposals for benchmarking standards for reasonable facilities costs that can be applied across institutions.

A general problem in judging the effectiveness of the system for funding the capital needs of AHCs is the absence of good data on the adequacy of the current research capital infrastructure of AHCs. Such data are essential to judging whether major reforms are needed. Also lacking are data on the costs of capital for which AHCs are not reimbursed because of low rates paid by non-federal funders of research. Better data on the capital needs of AHCs are essential to developing wise policy for sustaining the capacity of AHCs to use research funds

optimally.

Finding 6. Academic health centers have historically cross-subsidized research with clinical revenues and other internal resources.

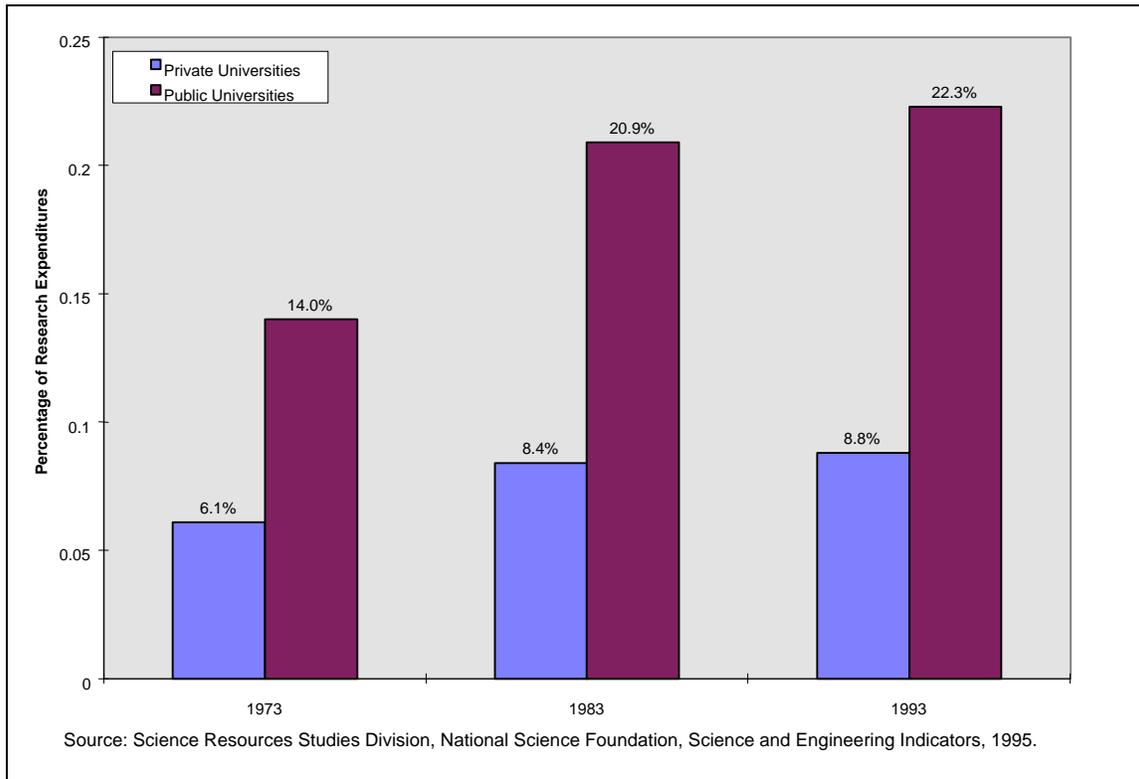
Substantial evidence indicates that AHCs cross-subsidize their social missions, including research, from clinical revenues. In case studies of more than 20 AHCs performed by Task Force staff, study informants typically referred to arrangements by which AHC hospitals and faculty practice plans transfer revenues to medical schools or provide direct staff support for research projects. A detailed analysis of the flow of funds within six AHCs found that, on average, clinical enterprises provide about \$50 million per year to a medical school for academic purposes. These funds do not include monies spent by faculty group practices to support research and other academic activities by members of those practices. A 1993 survey showed that faculty group practices provided an estimated \$816 million to support research.²⁵

Institutional funding

A recent survey of medical school faculty revealed that 43 percent receive some institutional funding from their universities for the direct costs of research, totaling approximately \$375 million in 1996–97.²⁴ Some institutional funding can be traced to cost-sharing requirements by the federal government. Furthermore, in the most competitive health care markets, institutional funding as a share of direct research costs is about half what it is in less competitive markets.²⁴ Thus, although institutional support is quite common, the amount received by faculty may depend on the competitiveness of the clinical market in which an AHC is located.

The demand on universities to increase their share of research-related expenses is suggested by the growth in overall institutional support for research between 1973 and 1993 (figure 6). At private universities, institutional funds accounted for 6.1 percent of total research and development expenditures in 1973 and 8.8 percent in 1993.²⁶ At public universities, institutional funds paid for 14 percent of total research and development expenditures in 1973 and 22.3 percent in 1993.

Figure 6. Trends in Institutional Support of Research by Ownership Status for Selected Years, FY 1973–93



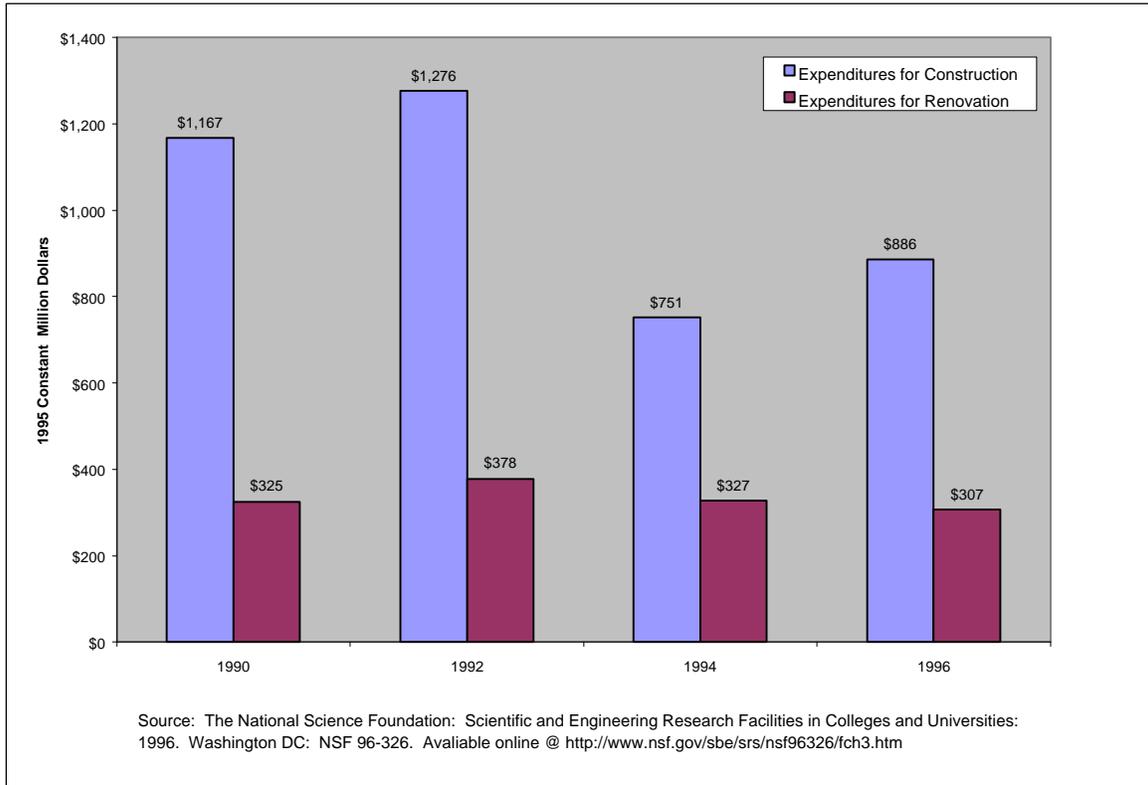
Unfunded research by AHC faculty

In addition to institutional funding, faculty at AHCs subsidize their own efforts by performing research that is not explicitly supported by either institutional or extramural funds. For example, a 1982 survey of internal medicine faculty found that 25 percent were not funded for their research.²⁷ In some specialties, such as pathology, unfunded research can account for 84 percent of publications.^{28, 29} A 1996 survey of medical school faculty revealed that 55 percent of faculty engage in unfunded research.²⁴ The 1996 survey also shed light on the characteristics of faculty most likely to report unfunded activities: clinical researchers (60 percent versus 51 percent for non-clinical, $p=.004$), principal investigators (PIs) (74 percent versus 27 percent for non-PIs, $p=.000$), and faculty with industry funding (60 percent versus 52 percent for those with none, $p=.014$).

Institutional cross-subsidization for research appears to be declining. Since 1992, medical schools have spent considerably less for the construction of research facilities, decreasing by \$390 million over four years (figure 7). Yet the amount of research space in need of major renovation, repair, or replacement increased from 3.4 million square feet (15.5 percent of all research space) to 5.2 million square feet (17.9 percent) during the same time period.*

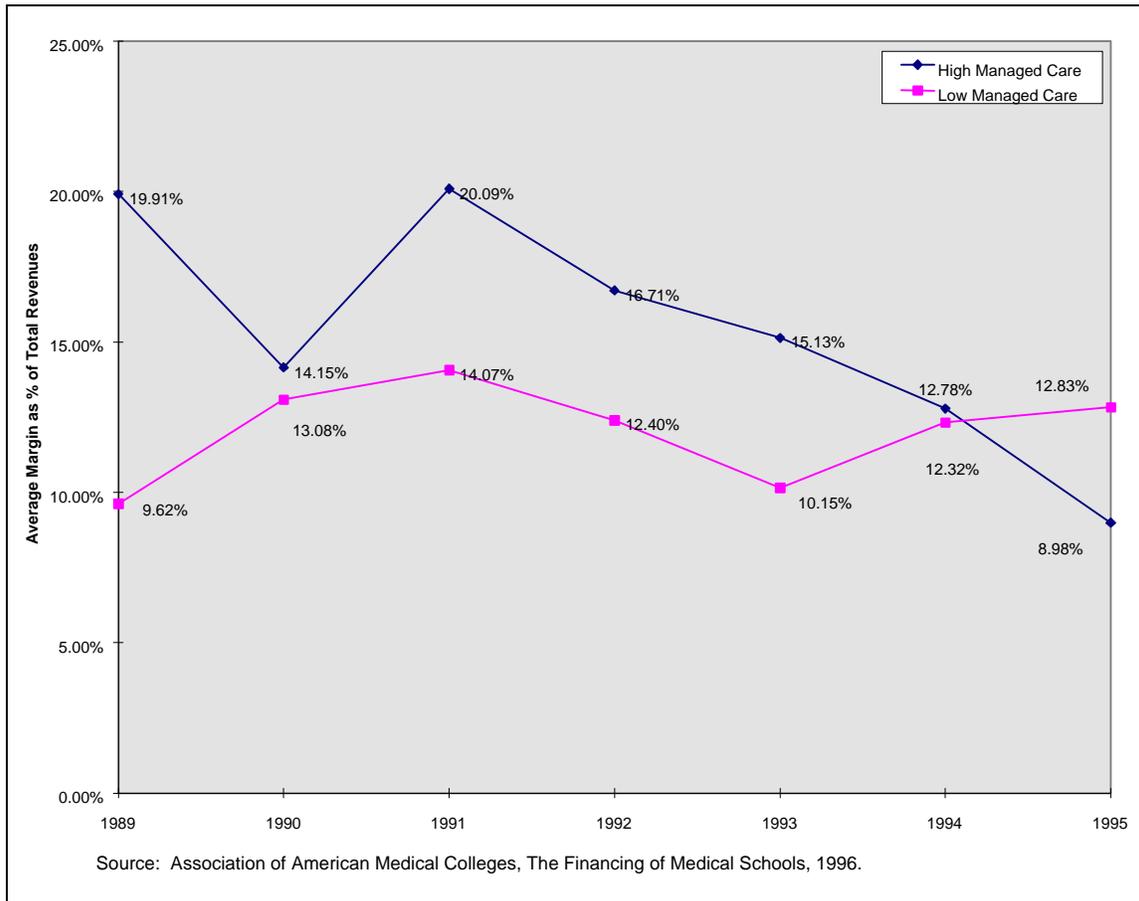
* National Science Foundation, Scientific and Engineering Research Facilities in Colleges and Universities: 1996, NSF 96-326.

Figure 7. Trends in Medical School Expenditures for Renovation and Construction of Research Facilities, FY 1990–96



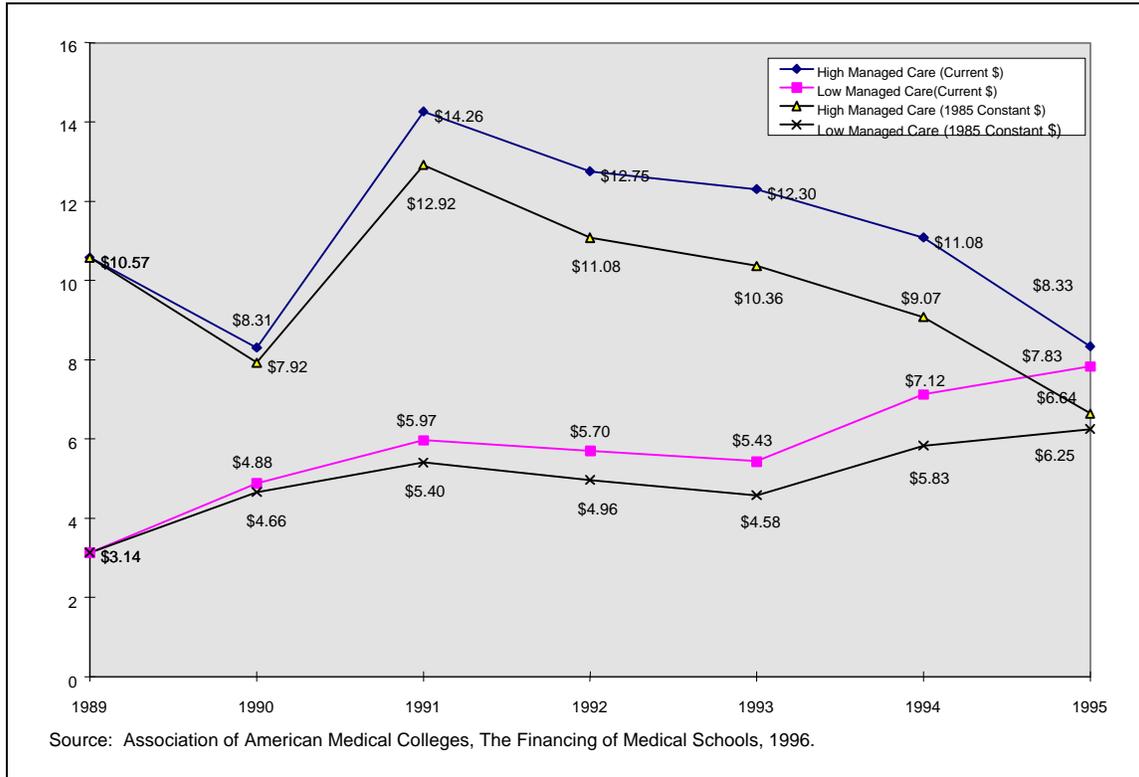
Finding 7. In areas with high managed care enrollments, cross-subsidies for research are decreasing, threatening the future of the academic health center research mission. Changes in clinical revenues are likely to affect research activities in AHCs. The Task Force compared average margins of 22 faculty practice plans located in areas with high and low levels of managed care enrollment. Margins were calculated by subtracting total plan expenses from total revenues before transfers. When expressed as a percentage of total revenues, the margins from plans in high managed care markets decreased from 20 percent in 1991 to 9 percent in 1995, while margins in markets with less managed care remained relatively constant or even increased slightly (figure 8).

Figure 8. Average Faculty Practice Plan Margin by Managed Care Intensity, FY 1989–95



Amounts of transferable dollars (or margins) are lower in areas with high managed care enrollment (figure 9). For faculty practice plans in high managed care markets, the average amount of transferable funds decreased by 42 percent, from \$14.3 million in 1991 to \$8.3 million in 1995. This represents a reduction of \$66 million for the 11 institutions in high managed care markets, or \$6 million per practice plan since 1991. Faculty practice plans in low managed care markets experienced a 135 percent increase in the average amount of transferable funds, from \$3.1 million in 1989 to \$7.8 million in 1995. Similar trends are observed when controlling for inflation.

Figure 9. Average Margin (Transferable Dollars) per Faculty Practice Plan, FY 1989–95



Finding 8. Support for biomedical research at academic health centers is being reduced by the growth of managed care.

Managed care is generating both internal and external pressures that affect the research mission of AHCs. External challenges arise from changes in health care markets and past and proposed changes in public policies. Internal problems arise, paradoxically, from the strategies AHCs may pursue to limit their vulnerability to these external threats.

Managed care and AHC research

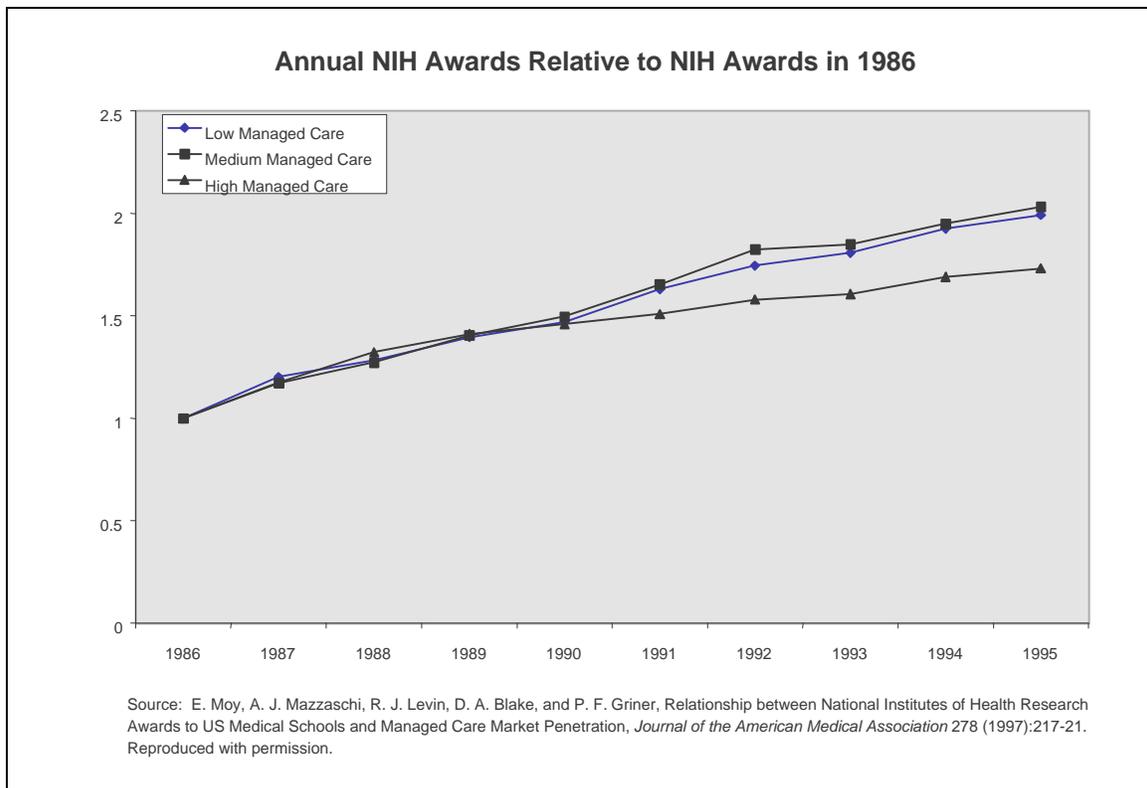
Over the last decade, the rise of managed care has reduced the payments AHCs receive for patient care services, a change that has limited the ability of AHCs to cross-subsidize their research mission from clinical revenues. This reduction in cross-subsidies is the rationale behind several proposals to establish more direct payments for clinical research activities.³

The challenge of building and managing clinical enterprises in a time of managed care is absorbing a great deal of AHC resources and management time. This is especially true of the most prominent AHCs, which have the capital and reputation to go head-to-head with clinical competitors. In this environment, senior leaders of AHCs—despite their best intentions—may find it increasingly difficult to devote as much time to managing and promoting their research mission as they have in the past. The growth of AHC-affiliated health care systems also raises

questions concerning governance, as the interests of community-based physicians and clinical providers become increasingly vital to the financial health of the AHC system as a whole. The question arises: will academic health systems place less priority on research and other academic missions than AHCs traditionally have?

Clinical investigation may be more vulnerable than fundamental research to changes in the health care market. A recent study showed that AHCs in areas with high managed care enrollment competed less successfully for NIH funds than sister institutions in less competitive areas (figure 10).³⁰ The effect was most marked in clinical departments.

Figure 10. NIH Awards to Medical Schools in Different Managed Care Markets, by Dollar Amount, 1986–95



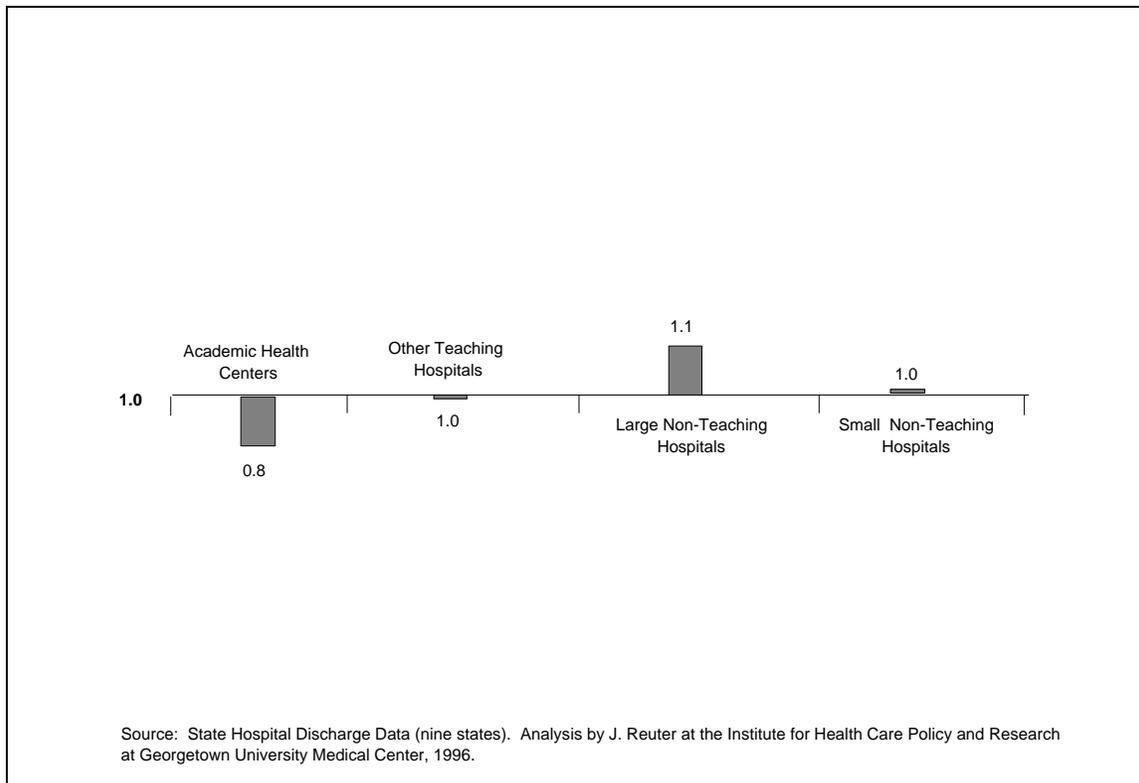
Further evidence of decreasing AHC research in high managed care markets was found in a 1993 survey of 2,100 life sciences faculty. Results show that clinical researchers in high managed care areas publish in peer-reviewed journals less often than those in low managed care markets, an indication that they may have less support for research and analysis. The mean number of publications in the previous three years was 17 percent higher for life sciences faculty in low managed care markets than for those in highly competitive markets.³¹ This effect was not found for basic researchers, suggesting that fundamental research—more likely to be funded by the NIH—may be comparatively protected in competitive environments.

Additionally, there seem to be greater pressures on young investigators to participate in clinical care in competitive markets, a finding consistent with the hypothesis that young clinical investigators are most vulnerable to market pressures.³¹

Faculty access to patients

The recent growth of managed care may also limit researchers' access to patients—an essential resource for conducting most forms of clinical research. Because of the comparatively high cost of services delivered in AHCs, managed care organizations may tend to direct patients to lower-cost, non-academic institutions. Figure 11 demonstrates that the 1994 market share for AHC patients insured by HMOs was only 80 percent of the expected share of the privately insured market generally, according to an analysis of discharge data for 24 metropolitan areas. This figure may decrease further for some AHCs as enrollment in HMOs climbs beyond its 1996 level of 64 million.*

Figure 11. Relative Share of HMO Discharges Compared with Other Privately Insured Discharges, by Type of Hospital, FY 1994



* The data for this analysis are based on discharge data for all payers in the study areas. Recent data restricted to a select group of major private employers suggests that AHCs' market share of managed care is more favorable, since they were able to obtain 27 percent of capitated admissions in their market areas, versus 22 percent of fee-for-service admissions.³² However, given the limited study sample and lack of information on geographic location, caution should be applied when interpreting these results.

In addition, anecdotal reports suggest that managed care organizations are unwilling to reimburse AHCs for the higher cost of the care patients receive as participants in clinical research. Although researchers' perceptions have not been confirmed by hard data, case studies of AHCs have found widespread concern about their ability to recruit patients.³³

Finding 9. The Balanced Budget Act of 1997 will reduce Medicare payments to academic health centers, a change that may adversely affect their research mission.

Changes in Medicare policy included in the Balanced Budget Act of 1997 (BBA) are likely to reduce Medicare payments to AHCs. Under the BBA, Medicare reimbursement for inpatient care will be reduced by \$44 billion over the next five years compared with previous projections. Reductions in the indirect medical education adjustment (IME) (from 7.7 percent to 5.5 percent over four years) and disproportionate share hospital payments (by 5 percent over five years) will also have major effects.³⁴

Reductions in Medicare payments may affect the research missions of AHCs by reducing their ability to cross-subsidize their research missions. Average margins at these facilities are on the order of 4 percent, while up to 40 percent of publicly owned teaching hospitals experienced negative operating margins in 1996.^{35,36}

Finding 10. Academic health center responses to managed care may have adverse consequences for research.

Just as potentially beneficial medical treatments may have unintended adverse side effects, so too may AHC strategies to cope with environmental pressures. Unanticipated negative consequences could be one result of AHCs' increased focus on generation of clinical revenues and reliance on industry funding for research support.

Actions to preserve clinical revenues

To protect or add to clinical income in the face of competitive markets, many AHCs are developing integrated health care systems that include networks of hospitals and physicians whose primary responsibility is to provide patient care services. The creation of these new integrated health systems is an enormous task, requiring large investments of AHC capital and managerial talent. One department chairman recently reported that, instead of devoting half his time to managing research and teaching as he did in the past, he now devotes barely 3 percent of his time to such tasks. The cost of building and sustaining clinical networks may be one reason why, in spite of recent healthy financial performance, some AHCs are losing their previous ability to cross-subsidize research missions.

Evidence suggests that, in competitive markets, conflict over the allocation of research resources is already growing. Faculty in the most competitive health care markets perceive

significantly more competition for research funding and lower levels of cooperation among colleagues.³¹

Further, pressure on faculty to devote more time to clinical activities seems to be on the rise, since AHCs must make more physicians available in order to compete for patients. In the past, many basic and clinical researchers practiced clinical medicine on a part-time basis, both to provide an extra source of income and to maintain exposure to clinical problems related to their research. However, because part-time clinician–researchers are less accessible to patients and may be less efficient, some institutions are requiring that clinicians choose between research and clinical careers. Managed care organizations often add to these pressures by requiring that clinicians spend more than a minimum number of hours—usually half-time—in practice.

These pressures may disproportionately affect young investigators, who may have difficulty sustaining full-time research careers without supplementary income from clinical practice. In areas with high managed care enrollment, there may be greater pressure on young investigators to provide clinical care, and thus young physician investigators may be the most vulnerable to market effects.³¹

Industry funding for AHCs

Fearful of declines in internal and external sources of research support and of competitive threats from contract research organizations (CROs), many AHCs are aggressively marketing their services to industrial research customers. In addition to its well-established benefits, however, industry funding of university research has a number of risks that suggest the need for caution. For example, faculty members receiving industry support are more likely than others to choose research topics according to the potential for commercial application and more likely to experience delays in publishing.³⁷ Life science

Faculty members receiving industry support are more likely than others to choose research topics according to the potential for commercial application and more likely to experience delays in publishing.

companies that sponsor research in academic institutions typically require investigators to keep their results secret six months or more to protect their commercial value. Faculty with industrial support are more likely to withhold results from colleagues and to report that trade secrets have resulted from their work.³⁷ These findings suggest that, unless carefully managed, the pursuit of industrial research support may have adverse consequences for academic norms in AHCs.

Finding 11. Clinical research in academic health centers may be undersupported at the current time.

Since the end of World War II, the federal government has invested heavily in fundamental science (table 1). Research grants, especially investigator-initiated R01 awards, have tended to fund basic types of investigation and have yielded huge dividends in terms of new knowledge with potential application to preventing and curing illness.

As the opportunity for applying new knowledge increases, greater support for clinical investigation is necessary to realize the potential benefits. Whether current public investments in clinical research are sufficient is difficult to assess definitively. It is fair to say, however, that available evidence does not suggest a trend toward increased overall federal support of clinical research. If anything, the opposite seems the case.

The role of AHCs in conducting clinical research

AHCs play a central role in the conduct of the nation's clinical research. Some basic biomedical research conducted at AHCs could probably be done just as well in universities without clinical connections. The same is not true, however, of clinical research, which requires both access to patients and involvement by trained physician investigators. Clinical research and its associated transfer of technology from bench to bedside are functions that AHCs are uniquely suited to perform. Thus, any attempt to increase the nation's overall commitment to clinical research will depend heavily on the ability of AHCs to use their research funds effectively.

Types of clinical research conducted at AHCs include translational studies and clinical trials. Translational clinical research is closest to fundamental investigation and involves the exploration of basic biological questions using human research subjects. Often a necessary step to moving basic insights into application, it may not lead directly to new medical technologies. Typical of translational investigation is the work of inpatient general clinical research centers (GCRCs) funded by the NIH. In 1997, the NIH provided \$157 million to 74 GCRCs at 64 institutions. These centers explore such questions as how sleep is regulated or how the calcium content of bone is hormonally controlled. Although some translational research is funded by the NIH, many observers believe that this type of work is particularly dependent on clinical cross-subsidies.

Clinical trials, a step closer to application, generally involve evaluating defined diagnostic or therapeutic technologies for safety or efficacy. The most applied forms are so-called phase III clinical trials, which are usually funded by drug companies or the NIH to provide data required for approval by the Food and Drug Administration (FDA).^{*} Clinical trials

^{*} Drug trials are usually classified into phases leading to approval by the FDA. Phase I tests safety and toxicity; phase II tests initial demonstration of efficacy and side effects; and phase III determines efficacy on larger populations and measures of dose-response. Phase IV refers to post-marketing analysis.

are regarded as much less dependent on internal AHC funding because of industry’s strong interest in supporting them. The exception may be studies of drugs and devices that are not protected through existing intellectual property statutes or are inherently unprofitable because their markets are small. Examples include studies of the costs and efficacy of off-patent medications and of surgical innovations that are not patentable.

Federal support for clinical research

Twenty-seven percent of all new NIH project awards and 38 percent (\$.91 billion) of all newly awarded amounts (for new, competing projects) supported clinical research in 1996 (table 2). Clinical research includes studies conducted with human subjects (or materials of human origin) in which the investigator directly interacts with the subject, as well as epidemiological and behavioral studies, outcomes research, and health services research.³⁸

Table 2. Funding for Clinical and Other Research by the NIH, FY 1996

	Projects	Amount
Total New Research Projects*	10,493	\$2.36 billion
	(100.0%)	(100.0%)
Percent of Research Projects that are:		
Non-Human Subjects Research	65.1%	41.10%
Human Subjects Research	34.9%	58.90%
Non-Clinical Research	8.3%	20.55%
Clinical Research**	27.0%	38.40%
Clinical Trials	4.9%	13.20%
Other Clinical	21.7%	25.08%

Note: Percentages may not add due to rounding.

*Source: National Institutes of Health, NIH Directors Panel on Clinical Research: Report to the Advisory Committee to the NIH Director, December 1997.

**Clinical research is a subset of studies that involve human subjects (or materials of human origin) in which the investigator directly interacts with the subject, epidemiological or behavioral studies, outcomes research, and health services research.

Federal support for physician investigators

Although 38 percent may be a reasonable level of NIH commitment to clinical research, some evidence regarding the numbers and success of physician investigators suggests that long-term trends are not favorable to the growth of clinical research investments. As figure 12 suggests, the overall ratio of Ph.D. to physician applicants for NIH funds has been relatively stable at 3:1 over the last decade. Among first-time applicants, however, the number of physicians is decreasing much more rapidly than the number of Ph.D.s.

Figure 13 shows that, from 1994 to 1996, first-time applications from physicians decreased by 30 percent, while first-time applications from Ph.D.s decreased by only 6 percent and from M.D./Ph.D.s by 16 percent.³⁸

Figure 12. Number of Applications to NIH for Competing Research Project Grants, by Degree of Investigator, FY 1986–95

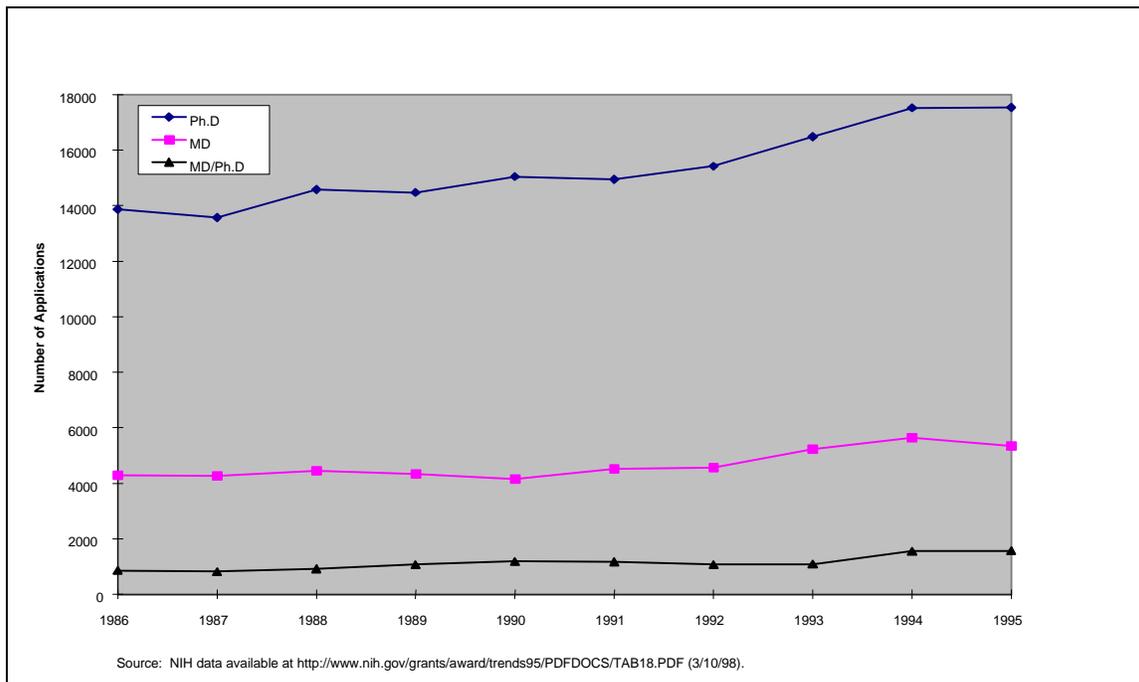
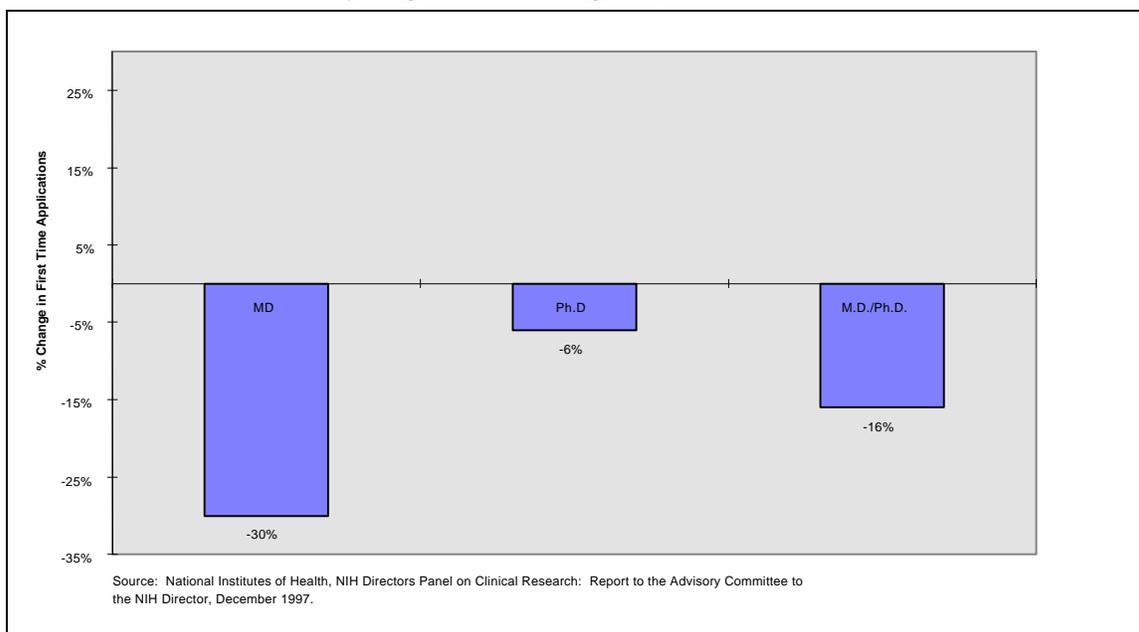


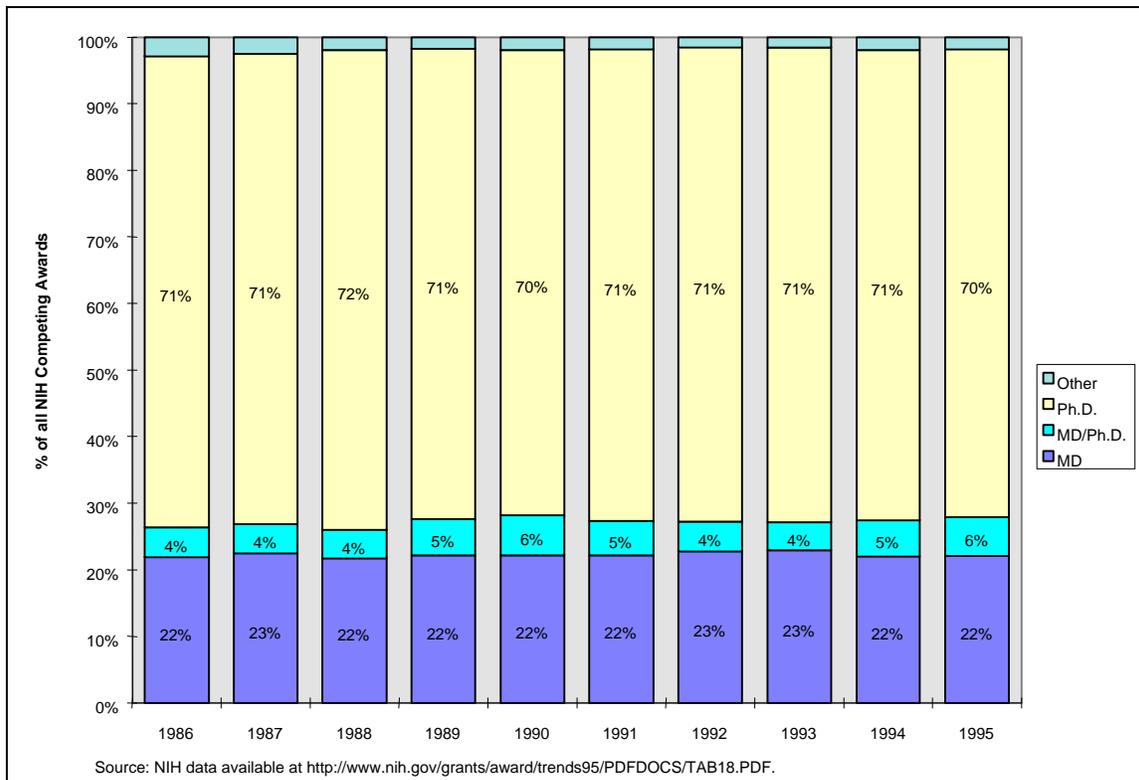
Figure 13. Percentage Change in First-Time Applications for NIH Funding, by Degree of Investigator, FY 1994–96



Further, the current level of physician participation in NIH research is less than it was 30 years ago. Much of this fall-off occurred in the 1970s, when the trend toward support of basic investigation seems to have accelerated. From 1970 to 1987, the percentage of all NIH awards made to physicians decreased from 36 percent to 26 percent, while the percentage of

awards to Ph.D. scientists increased from 51 percent to 64 percent.³⁹ This downward trend in awards to physicians may have stabilized in the last 10 years. Figure 14 shows that from 1986 to 1995, the percentage of NIH project grant awards to physicians remained almost constant at 23 percent.

Figure 14. Percentage of NIH Research Project Grant Awards, by Degree of Investigator, FY 1986–95



The status of clinical researchers at AHCs

A subtle but important barrier to clinical research in AHCs is the long-standing perception among clinical and health services researchers that their work is not valued by their institutions and faculty peers, and that they face unfair obstacles to academic promotion. Part of the problem may be traced to the competing demands of research, teaching, and patient care. A young investigator’s ability to succeed academically can be threatened by the need to build a referral base and contribute to faculty clinical income.³⁹ Added to this is the perception that laboratory-based research is somehow more scholarly. Although some institutions address this dilemma by placing their faculty on different tracks, promoting clinical faculty is hampered by the traditional reliance on the quantity and quality of peer-reviewed publications.⁴⁰ Although difficult to document objectively, this problem constitutes a major impediment to developing a revitalized clinical research enterprise and must be addressed by leaders of AHCs.

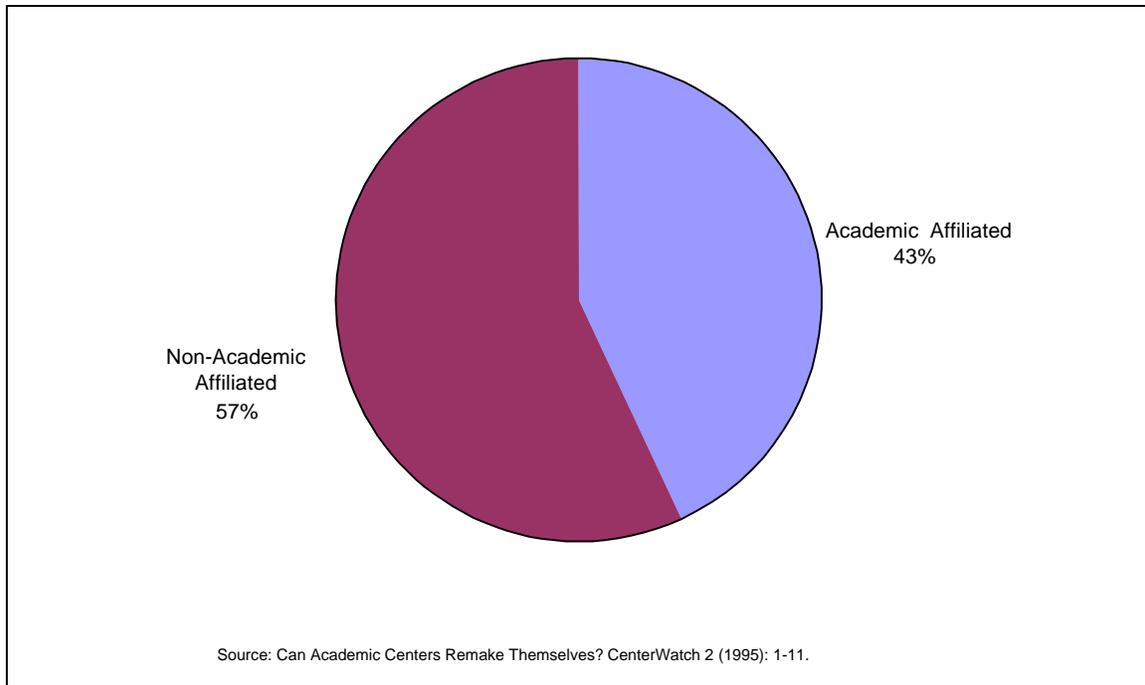
Finding 12. The clinical research mission of academic health centers faces competition from non-academic research organizations.

Contract research organizations (CROs) are private, for-profit firms that specialize in conducting clinical research, most often clinical trials for pharmaceutical and medical device manufacturers. CROs provide a wide range of clinical research services, including designing studies, managing drug supply activities, developing case report forms, selecting sites, managing budget negotiations, monitoring trials, recruiting patients, managing data, and preparing results for submission to the FDA. Many of these tasks were formerly performed by researchers in AHCs.

The last 20 years have seen significant growth in the number of CROs. In 1974, there were an estimated 200 such organizations—a figure that has since risen to about 1,300 in the United States alone.^{41, 42} One study found that, in 1993, 57 percent of all clinical trials were performed by investigators not affiliated with AHCs (figure 15).⁴³

The spread of CROs could affect AHCs, and the health of clinical research, in several ways. The phenomenon could reduce funding for clinical research at AHCs as industry sponsors turn elsewhere for services. The reduced volume of trials could affect the ability of AHCs to maintain a diverse clinical research enterprise. One adverse societal effect could be a decrease in the amount of innovation that occurs in clinical trials methodology, since innovation is widely thought to be the particular province of AHCs. A decline in clinical trials at AHCs could also affect other aspects of research, since relatively large, lucrative industry trials may subsidize less marketable work in translational investigation.

Figure 15. Affiliation of Clinical Trials Investigators, 1993



Finding 13. Academic health centers could improve the management of both clinical and non-clinical research activities.

Needed improvements in clinical research

AHCs face strong competition from for-profit contract research organizations and community-based physicians for clinical trials funded by pharmaceutical companies. The success of these competitors in attracting industry support for clinical research has highlighted several problems of AHCs in managing large-scale clinical research effectively:

- Delays in receiving institutional review board (IRB) approval. In explaining their move away from AHCs, pharmaceutical companies often cite the delays associated with receiving IRB approval for clinical research projects. A 1994 study by Pharmco LTD of 50 of their clinical research projects found that the average time from IRB submission to contract approval was 60–150 days for university hospitals, 30–60 days for private hospitals, and 7–28 days for private practices.⁴³
- Delays in negotiating agreements. Anecdotes from industry also refer to delays in negotiating agreements with AHCs, arising not only from the IRB review process but also from grants management procedures that may not be attuned to the needs of industry sponsors.
- Higher costs. According to one study, academic researchers had 25 percent higher costs and were 12 percent less efficient in enrolling patients than were non-academic investigators.⁴⁴

- Problems with the quality of data. Compared with investigators outside academic institutions, academic researchers made 15 percent more errors in data recording.⁴⁴
- Limited managerial training and experience. In spite of the complex nature of multi-site, interdisciplinary research projects, AHC faculty receive little or no training in the management of such research.
- Inadequate management information systems. Anecdotal information gathered from case studies suggests that AHCs lack state-of-the-art management information systems.

These considerations—along with numerous complaints from industry sources about the slowness and lack of responsiveness of academic administrators and scientists—suggest that, if AHCs want to compete effectively for clinical trials, they will need to undertake major reforms in the way they organize their clinical research enterprise.

In addition to charges of inefficiency at AHCs, a report by the Inspector General of the Department of Health and Human Services suggests that IRBs—at AHCs and elsewhere—may not be adequately protecting the interests of patients involved in clinical research.^{45, 46} The report indicates that IRBs are now expected to review too many protocols with insufficient discussion of the risks to patients. Also, IRB members may not have sufficient expertise in areas such as genetic testing, gene therapy, and xenotransplantation to understand and make judgments concerning the ethical implications of proposed research. Perhaps most compelling, the study found that advertisements used by investigators and sponsors to recruit patients may be misleading, since they “lure people with promises of free treatments or cash payments, but often make no mention of the risks.”

Needed improvements in non-clinical research

Multiple case studies by the Task Force have demonstrated that improvements in organization and management could enhance the efficiency and productivity of fundamental investigation at AHCs. For example, AHCs frequently purchase

Improvements in organization and management could enhance the efficiency and productivity of fundamental investigation at AHCs.

expensive equipment and supplies for their fundamental research investigators, but few have explored opportunities for joint purchasing to improve prices in this area.

A second area deserving scrutiny is the manner in which AHCs have traditionally allocated internal resources, including space and discretionary funds. Space is an expensive and

scarce internal resource, but until recently it has been distributed in many AHCs through private negotiations between department chairs and individual investigators and administrators. In many AHCs, this has resulted in a highly political and unsystematic process of space allocation. Scientific merit often takes a back seat to historical deals, backed by the political and economic clout of clinical leaders and faculty.

Needed improvements in cross-disciplinary research

Another area of concern is the management of cross-disciplinary or interdepartmental research agendas. Academic departments remain the primary mechanisms for faculty governance, including hiring and promotion, in AHCs. Yet modern science is increasingly interdisciplinary, making departmental distinctions less relevant. The contribution of the physical sciences to biomedical advances is a case in point. The development of computerized axial tomography (CAT scans) would not have occurred without innovations in the fields of mathematics, high energy physics, engineering, and computer science. AHCs are only now addressing the difficult organizational, financial, and academic issues involved with pursuing these new research paradigms.

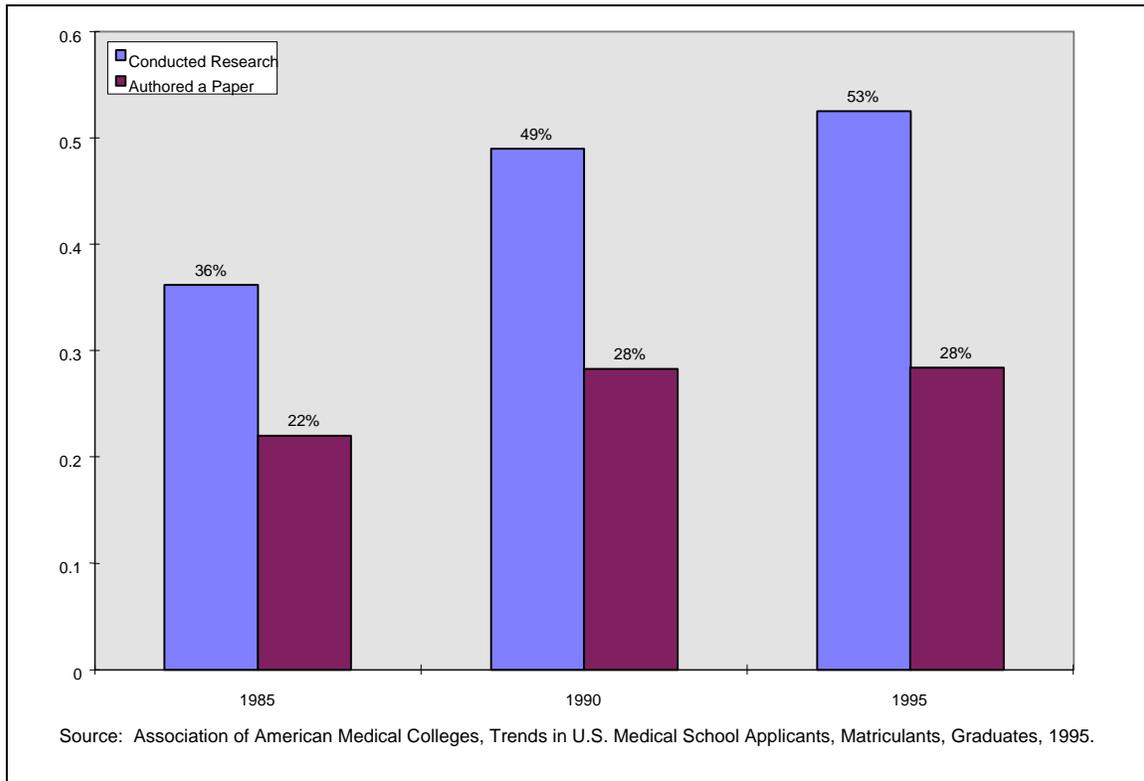
Finding 14. Academic health centers provide substantial amounts of research training.

Most of the nation's health care researchers receive at least some formal training at one or more institutions that make up academic health centers. Three broad categories of health-related researchers receive training at AHCs: medical students, resident physicians and fellows, and doctoral students.

Training for medical students

In recent years, undergraduate medical students' exposure to research training has increased dramatically. Between 1985 and 1995, the percentage of graduating medical students who had participated in a research project during medical school grew from 36 percent to 53 percent (figure 16).⁴⁷ Despite this increase, medical students' output in publications has increased only moderately. The percentage of graduating medical students who authored a research paper during medical school increased from 22 percent in 1985 to 28.4 percent in 1995.⁴⁷

Figure 16. Trends in Medical School Graduates Participating in Research Activities, Selected Years, 1985–95



Training for physicians and fellows

AHCs sometimes offer graduate fellowships, usually in the later years of subspecialty training, as a training mechanism for physicians interested in conducting research. In 1993, the NIH supported 2,613 physicians in postdoctoral research fellowships.¹⁴ According to estimates by the Association of American Medical Colleges, an additional 6,500 clinical fellows were receiving subspecialty clinical training without NIH support in short-term, non-federal hospitals in 1993. Although many of these clinical fellows were ultimately bound for careers in practice, some were preparing for careers in research.

Training for Ph.D.s and M.D./Ph.D.s

In 1995, medical schools or their faculty members sponsored or advised approximately 12,250 students in 629 doctoral degree programs.⁴⁸ An estimated 18,597 students were enrolled in medical school-sponsored Ph.D. and M.D./Ph.D. programs—equivalent in number to 25–30 percent of all medical students enrolled in U.S. accredited medical schools. Further, an estimated 60 percent of all Ph.D.s awarded in 18 biomedical-related disciplines were earned by students whose primary advisor was a medical school faculty member.⁴⁸

Financial support for research training

The federal government, primarily through the NIH, is the primary supporter of research

training in AHCs.³⁹ In 1994, the NIH distributed \$381.5 million in research training support, of which 90 percent (\$342.6 million) went to institutions of higher education, including medical schools and university-owned hospitals. Medical schools alone received \$219.3 (57.5 percent) of all NIH research training awards.¹⁵ In addition, 36 independent (not university-owned) hospitals received \$17.6 million in NIH training awards in 1994. Although the total amount that went to AHCs cannot be ascertained precisely, AHCs received between \$236 million and \$360 million in NIH training awards in 1994.*

Some research training in AHCs is indirectly subsidized through research grants from external sources and from institutional funds, such as patient care revenues. For example, about 30 percent of all Ph.D. students in medical school-sponsored programs were supported by research grants and contracts from the NIH in 1994–95.⁴⁸ Also, about 40 percent of all support for students in medical school Ph.D. programs in 1995 came from institutional sources. This suggests that clinical and philanthropic funds play an important role in sustaining the supply of Ph.D.s in the health care research sector.

AHCs also subsidize a portion of the costs of clinical fellows. More than three-quarters of the funding for clinical fellows in non-federal hospitals came from institutional funds in 1995–96. Specifically, of the institutional funds used to support the training of clinical fellows, 63 percent came from patient revenues and general operating support, 8 percent came from physician fee revenues, and 6 percent came from medical school and university funds.⁴⁹ While only a minority of clinical fellows may enter careers in research, those who do are important to sustaining the supply of clinical researchers.

Finding 15. Health services research is undersupported by the federal government at the present time.

With tumultuous changes occurring in the organization and financing of health care, demand has grown for information to inform policymakers and managers about ways to decrease the cost and improve the quality of health care services. The development of new knowledge in this area depends on the relatively new field of health services research, which includes a wide variety of studies that examine the natural history of illness, develop better ways to measure the effects of treatment, and study methods to improve the efficiency or quality of health services through organizational or financial interventions. The Agency for Health Care Policy and Research (AHCPR) has been the primary supporter of work in these areas, although NIH has contributed some funds in recent years.

* The lower estimate is the sum of all training awards to medical schools and independent hospitals. The upper estimate is the sum of all awards to higher education institutions (medical schools, university-owned hospitals, and other higher education units) plus awards to independent hospitals.

Federal funding for health services research has generally been modest compared with other types of investigation and has followed an unpredictable course in recent years. Total appropriations for the AHCPR were \$143 million in 1997, or equivalent to 1.13 percent of the NIH appropriation (table 3). Three NIH institutes (the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism) are required by Congress to devote 15 percent of their funding to health services research related to mental health and substance abuse. These allocations totaled \$212 million in 1997.⁵⁰ In addition, the NIH reports that other subunits provided an additional \$154 million in health services research funding in 1997, bringing total NIH support to \$366 million.⁵⁰

Table 3. Trends in Federal Appropriations to the National Institutes of Health and the Agency for Health Care Policy and Research, FY 1977–97

Year	National Institutes of Health (NIH)		Agency for Health Care Policy and Research* (AHCPR)		AHCPR as a Percentage of NIH
	\$ million	% Change	\$ million	% Change	
1977	\$2,582	15.3%	\$31	-4.8%	1.19%
1978	\$2,828	9.5%	\$33	7.7%	1.17%
1979	\$3,185	12.6%	\$33	0.5%	1.05%
1980	\$3,429	7.7%	\$27	-19.3%	0.78%
1981	\$3,573	4.2%	\$29	8.6%	0.82%
1982	\$3,643	2.0%	\$16	-44.6%	0.44%
1983	\$4,013	10.1%	\$16	-0.5%	0.40%
1984	\$4,494	12.0%	\$18	9.5%	0.39%
1985	\$5,122	14.0%	\$19	7.5%	0.37%
1986	\$5,297	3.4%	\$23	18.8%	0.43%
1987	\$6,175	16.6%	\$42	84.3%	0.67%
1988	\$6,610	7.1%	\$43	4.0%	0.65%
1989	\$7,158	8.3%	\$50	14.6%	0.69%
1990	\$7,581	5.9%	\$98	97.2%	1.29%
1991	\$8,154	7.6%	\$115	17.8%	1.41%
1992	\$10,010	22.8%	\$120	4.1%	1.20%
1993	\$10,328	3.2%	\$128	6.9%	1.24%
1994	\$10,911	5.6%	\$154	20.6%	1.42%
1995	\$11,341	3.9%	\$159	3.2%	1.41%
1996	\$11,881	4.8%	\$125	-21.5%	1.05%
1997	\$12,747	7.3%	\$143	14.6%	1.13%

Sources: 1970–89 NCHSR data from AHCPR (unpublished); 1990–97 AHCPR data available at <http://www.ahcpr.gov/news/apphis99.htm>; 1990–96 NIH data available at <http://www.nih.gov/welcome/almanac97/chapt3/toc.htm>; 1997 NIH data at <http://www.hhs.gov/cgi-bin/waisgate?WAISdocID=403361365+25+0+0&WAIAction=retrieve>.

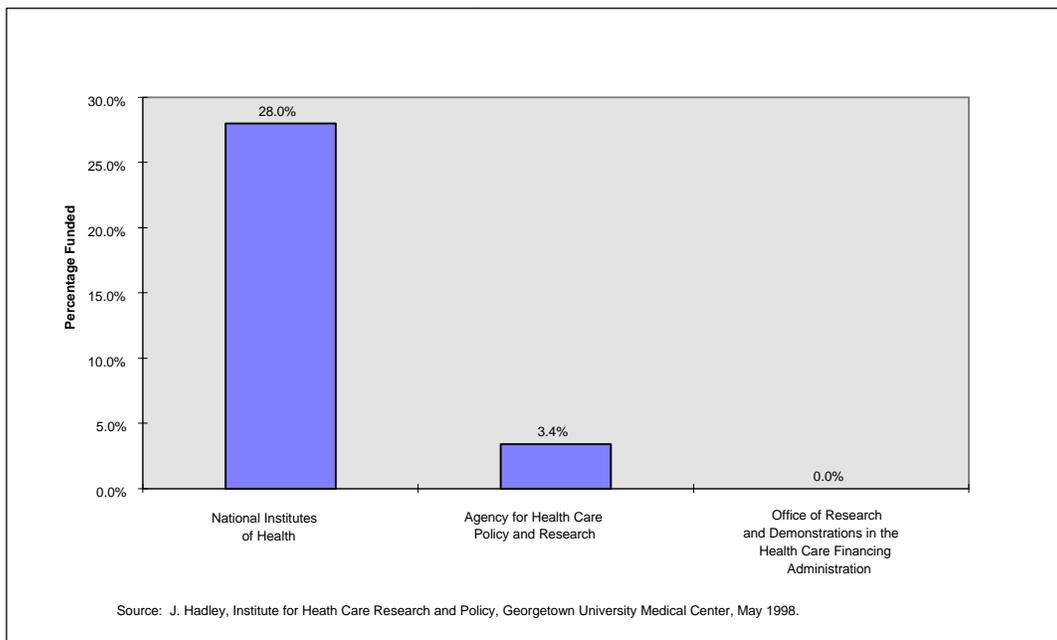
* Formerly the National Center for Health Services Research and Health Care Technology Assessment.

Additional funding for health services research comes from the Health Care Financing Administration (HCFA) through the Office of Research and Demonstrations (ORD) and the

Department of Veterans Affairs (VA). In 1995, HCFA invested \$74 million in health services research, and the VA invested \$32 million.⁵¹ Thus, in 1997 the federal government invested a total of approximately \$615 million in health services research. This amount represents an estimated .065 percent of all personal health care spending in 1997. Health services research supported by the NIH, HCFA/ORD, and the VA has not been reviewed to see how it compares with work supported by AHCPR. To date, most major methodological advances in such fields as outcomes research, quality of care research, and cost-effectiveness analysis have derived from AHCPR-funded studies.

Figure 17 compares the success rates for investigator-initiated grant applications in 1997 for the NIH (28 percent), AHCPR (3.4 percent), and HCFA/ORD (0 percent).⁵¹ (The HCFA/ORD may be explained by a 1998 note to prospective applicants, posted on the HCFA home page, stating “because of limited funding, at this time HCFA is not planning any general solicitations for grants or cooperative agreements for the purpose of supporting research studies or demonstration projects.”*)

Figure 17. Success Rates for Investigator-Initiated Grant Applications, FY 1997



SUMMARY AND CONCLUSIONS

Collectively, the Task Force findings point toward summary findings in four areas: the market for clinical care, the market for clinical research, trends in public policy, and research trends. Changes now taking place in each area may have profound effects on the future of biomedical research at AHCs.

* Text available at <http://www.hcfa.gov/ord/ordhp1.htm> (downloaded June 2, 1998).

Summary Finding 1. Changes in clinical markets may reduce the ability of academic health centers to subsidize research and enroll patients in clinical investigations.

Although many AHC hospitals appear to be doing well financially, this is not true of all teaching hospitals. Publicly owned hospitals in particular remain hard-pressed. Faculty practice plans, another source of discretionary income to support mission-related activities, seem to be doing less well than hospitals, especially in competitive markets. AHC hospitals face new requirements to invest in clinical infrastructure in order to compete clinically. These investments may reduce the resources available to support the research mission.

A key question for health care research policy is whether to await more definitive evidence on the effects of market forces on the research mission of AHCs or to act now to assure the continued strength and vitality of the AHC research enterprise. Better data on the effects of markets on AHCs are urgently needed. However, the ability of AHCs to perform health care research is sufficiently important to the nation's health and economic strength that immediate preventive action may be required.

Summary Finding 2. Increased competition from clinical research organizations, most of them privately owned, is creating new challenges for academic health centers.

The advent of competition is forcing AHCs to review their role in clinical research and their management of clinical research activities. Responding to competition will require substantial changes in the organization and management of clinical research at AHCs.

Summary Finding 3. The federal government's reliance on academic health centers to share the direct and indirect costs of performing health-related research demands reexamination.

The NIH has consistently underfunded the direct costs of conducting health-related investigation. It has also terminated nearly all direct support for AHC infrastructure, relying instead on indirect payments associated with awarded grants. The adequacy of indirect costs to cover infrastructure expenses is hotly debated. Anecdotal evidence suggests that AHCs subsidize indirect costs from clinical revenues, and that clinical revenues are also essential to AHCs' ability to get loans for construction at competitive rates. Better data on the status of AHC infrastructure are needed to resolve this dispute. Nevertheless, recent trends in capital construction raise questions about whether AHCs are adding to and modernizing their capital plants at an appropriate rate.

Summary Finding 4. After several decades of extraordinary progress in basic investigation, the potential for translating accumulated new knowledge depends on increased national investment in clinical investigation.

To optimize the nation's investment in basic knowledge, AHCs and federal agencies will need

to address the underdevelopment of clinical research in AHCs. The problem has several causes, including difficulties encountered by young physicians in obtaining federal support to start clinical research careers and cultural biases within AHCs that have favored fundamental over clinical research. Strengthening the capabilities of AHCs in this area will require new NIH initiatives in training researchers and funding clinical research. AHCs will also need to improve their internal management and culture.

Another recent trend has been the maturation of new areas of investigation in the fields of outcomes research, clinical epidemiology, and health services research. These new fields have great potential to contribute to the effectiveness, efficiency, and quality of health care services but have been consistently underfunded by federal agencies.

3. RECOMMENDATIONS

The recommendations of the Task Force with respect to preserving and strengthening the research mission of AHCs address issues in three areas: (1) the manner in which academic health centers manage their own research enterprises, (2) the allocation and management of extramural biomedical research expenditures of the National Institutes of Health, and (3) the allocation of federal health care research funds generally.

Several recommendations call for increased funding of certain types of research functions or activities at AHCs. The Task Force believes that, with the exception of health services research, funds for these increases should be found within the NIH budget. The recent, substantial increase in NIH funding should facilitate the implementation of several recommendations.

MANAGEMENT OF RESEARCH AT ACADEMIC HEALTH CENTERS

Many AHCs have already made important improvements in managing their research enterprise.

- At Duke University, academic leaders have launched a strategic planning exercise to map the future of their health sciences enterprise. Historically, many AHCs have relied almost exclusively on a bottom-up approach to managing the direction of research.
- At Massachusetts General Hospital, part of Partners HealthCare System in Boston, management has empowered an executive committee of research leaders to plan and govern the hospital's research enterprise. The executive committee on research has initiated programs to rationalize space allocation, conduct peer review of applications for institutional research support, and plan regular reviews of the quality of internal research.
- At Oregon Health Sciences University, the academic health center has consolidated basic biology programs scattered through many clinical departments into a single basic medical sciences department, hoping to improve efficiency and spark interdisciplinary cooperation.

Opportunities for management improvements are most apparent in the area of clinical research. Efforts to improve the management of preclinical research are also needed, however, and deserve the attention of AHC managers. If AHCs expect to receive greater support from public sources for their research activities, they have the reciprocal obligation to use that support with maximal efficiency and effectiveness. Whether or not governmental research

funds are increased, AHCs wishing to sustain their research mission in the face of stringent economic circumstances should make the best possible use of the funds available to them.

Recommendation 1. Academic health centers should improve the management of their clinical research enterprise.

Management of clinical research within AHCs

AHCs should comprehensively and systematically examine the organization and management of clinical research at their institutions. They should take steps to reengineer the processes that support research so as to improve efficiency and reduce costs. Improved instruction and supervision of faculty in the management of clinical trials should be included in this new approach.

A number of AHCs are taking steps to address problems in the management of clinical research. For example, some have explored the option of creating centralized clinical trials units. These organizational innovations show some promise in improving the efficiency of clinical research and the ability of AHCs to compete for industry-sponsored clinical research.

The appropriateness of AHC clinical research

AHCs should develop policies and procedures to guide managers and faculty in their efforts to attract new clinical research to AHCs. These policies and procedures should assure, insofar as possible, that clinical trials have significant academic purposes and are appropriately performed at AHCs.

As AHCs reengineer their clinical research operations, they should also address another important consideration: the scope of clinical research that is appropriate to each AHC. AHCs vary in their capability and capacity to conduct clinical research. Some AHCs are evolving into academic health systems with ambitions to enroll millions of patients in their networks. Others have much more modest goals for their clinical enterprises, and some are even selling clinical facilities. Some AHCs may restrict themselves to working on methodological issues, while others may address only translational clinical investigation, which requires moderate numbers of patients. Large academic health systems may chose to address the full gamut of potential clinical research, from methodological work to large-scale phase III clinical trials. Whatever the strategy, it should be consciously chosen and carefully managed.

A strong argument can be made that clinical research conducted by AHCs should have the potential to contribute significantly to knowledge concerning health and disease. Trials that fail to meet this standard may, in fact, be more appropriately run outside AHCs. A final point related to the management of clinical trials concerns the potential need and opportunity for AHCs to look beyond their walls in developing new strategies for managing clinical research.

Large study populations and other trends in clinical research

AHCs need to strengthen their ability to learn from experience, respond quickly to trends in research and the research marketplace, and innovate. For example, AHCs should consider the impact of the growing need for large study populations in clinical research.

AHCs need to strengthen their ability to learn from experience, respond quickly to trends in research and the research marketplace, and innovate.

Clinical genetic research is revealing that individuals with the same apparent illnesses often have different genetic bases for those diseases and may benefit from different treatments. The division of illnesses into multiple new subcategories will mean that more patients will be needed in the future to conduct cutting-edge clinical research. Although it is unlikely that even an AHC with a large network will be able to accumulate the required numbers of candidates, it is vital that AHCs contribute their unique capabilities in fundamental and clinical research to these investigations.

Several potential approaches to gaining access to larger patient populations should be carefully examined by AHC managers:

- establishing consortia of AHCs that pool their clinical research capabilities for selected projects
- creating partnerships between individual AHCs and clinical research organizations that have the ability to recruit patients outside AHCs
- developing alliances between AHCs and networks of clinicians in multiple locations, including managed care organizations and providers in other countries

The need to consider such options emphasizes the dynamic and evolving character of the clinical research enterprise at the current time, and the need for AHCs to upgrade their capabilities to respond to a changing clinical research marketplace.

Professional management training

AHCs should invest in the development of a highly skilled cadre of professional clinical research managers, who are also committed to the preservation and enhancement of academic values. Advanced management training could lead to improvements in the conduct of clinical research at AHCs and to enhanced opportunities for industry funding.

Recommendation 2. Academic health centers should take steps to ensure the academic standing and prestige of clinical and health services researchers.

AHCs should consider at least three measures to improve the academic standing of clinical

research and clinical researchers at their institutions:

- improve training and mentoring for medical students, residents, and young faculty interested in clinical research careers
- include clinical researchers on internal promotion committees
- encourage academic leaders to participate in clinical research

Recommendation 3. Academic health centers should strengthen the management and organization of their basic research enterprise, including investment in and reliance on cross-disciplinary research programs.

Changing markets for clinical services and clinical research are forcing AHCs to consider cooperative, cross-institutional efforts to improve the productivity and competitiveness of their work in these areas. However, like the clinical research side of AHCs, the basic research enterprise must also adapt to changing financial and scientific circumstances. If AHCs are to receive increased support for research infrastructure, they have an obligation to use that support as effectively as possible. Therefore, AHCs should strongly consider several reforms in the organization and management of basic research.

For example, inter-institutional consortia can be valuable for purchasing very costly research equipment and supplies. Whether research consortia could provide benefits in other areas—for example, cooperative development of information systems and software to support fundamental investigators—also deserves investigation.

Formal internal peer review can be used to allocate discretionary funds and space, thereby avoiding the inefficiencies associated with more traditional methods of allocation. To meet their obligation to the public and, even more important, to capitalize on new scientific opportunities, AHCs must devise open and accountable systems of space distribution in which the scientific promise of the work is the primary consideration. Similar systems are needed to allocate discretionary resources from clinical revenues and endowments.

Increased investment in and reliance on cross-disciplinary programs in basic research could begin to break down traditional academic barriers. AHCs should rely more on cross-disciplinary centers and departments to organize and govern faculty activities. Academic governance should evolve to reflect the changing nature of the scientific work of AHC faculty, so that faculty can be confident that they will be judged for promotion and other rewards by peers and mentors who appreciate interdisciplinary investigation. Exposing researchers to cross-disciplinary training programs may accelerate the rate of innovation in new diagnostic

therapies, surgical procedures, drug delivery systems, and other novel technologies.

Recommendation 4. Academic health centers should promote and invest in applied research and development to increase the dissemination of new and emerging cost-reducing technologies and improve the delivery of health care services.

Like the federal government, AHCs have not historically given sufficient priority to research that can improve the delivery of routine patient care services. This includes studies of the cost-effectiveness of new and existing medical technologies, measures and methods to improve quality of care, alternative approaches to organizing and financing the provision of routine health care services, and many other matters that could make health care better and more efficient. New projects should be promoted in these areas, as well as pharmacoeconomics, outcome management, and clinical evaluation.

New information in these areas is likely to be a high priority for clinicians working in integrated health care systems, who are struggling to maintain the quality of service and their own incomes in the face of lower health care prices. Even more important, new knowledge in these areas is essential to improving the competitiveness of AHCs and the functioning of the health care system generally.

Some academic health centers have taken tentative steps in this direction. Often, these steps take the form of small centers that measure quality and cost of care and feed data back to medical center clinicians. Few AHCs have extended this capacity to serve their integrated health systems more broadly. Opportunities for members of such units to gain academic promotion remain unclear, but their work deserves a much higher priority than it has received in the past within the portfolio of AHC research activities.

Recommendation 5. Academic health centers should adopt measures to assure the status and viability of research within academic health care systems being challenged by the growth of managed care.

Participation in research, both basic and clinical, can and should be a competitive advantage for academic health systems in local clinical markets. However, the payoff for these mission-related activities may not be immediately evident to decision makers in complex, changing organizations. Leaders of the research mission of AHCs must be included in the senior management of academic health systems so they can represent the interests of the research enterprise and educate community-based providers on the value of research. Further, academic health systems should designate senior, respected research leaders to concentrate on managing the research mission.

The participation of research leaders in the governance of academic health systems may facilitate communication between the clinical and research enterprises. In the past, communication between researchers and clinicians occurred naturally in AHCs. However, under pressures to increase productivity in both research and clinical services, AHCs can no longer assume that researchers and clinicians will understand and respect one another's interests and concerns. Such understanding is essential to preserving the commitment of AHCs to their research missions but will also keep research leaders informed about research that can assist clinicians in improving health care delivery and competing effectively in local health care markets.

Under pressures to increase productivity in both research and clinical services, AHCs can no longer assume that researchers and clinicians will understand and respect one another's interests and concerns.

POLICIES OF THE NATIONAL INSTITUTES OF HEALTH

Since the establishment of the National Institutes of Health during the post-World War II period, the federal government has had the luxury of knowing that, in a pinch, AHCs could rely on cross-subsidies from clinical services to cover research-related costs that the federal government did not support. The existence of such cross-subsidies has helped the AHC research enterprise to grow and prosper, despite the elimination or reduction of programs such as direct support for capital expenditures or the Biomedical Research Support Grant, which provided funds for institutional infrastructure underlying research.

Given the changes occurring in health care markets, the Task Force finds sufficient evidence to raise concerns about the adequacy of support for the research enterprise of AHCs. The federal government can no longer assume that AHCs will be able in the future to raise their clinical prices or add to clinical volumes as needed to modernize or expand their research facilities or to embark on new research initiatives.

Recommendation 6. The National Institutes of Health should provide appropriate funding for construction and renovation of research facilities, through explicit capital support and the restoration of the Biomedical Research Support Grant.

Institutional research infrastructure includes buildings that house laboratories, equipment that investigators depend on, information and other systems, and the working capital needed to pursue new scientific opportunities, such as human genomics. If the federal government significantly increases its investment in biomedical research at AHCs, it should make provisions to assure that shortfalls in clinical revenues do not prevent AHCs from making optimal use of those new investments.

Recommendation 7. The National Institutes of Health should increase the percentage of requested funds actually provided for projects and raise the maximum salaries of investigators to appropriate market levels.

The National Institutes of Health regularly provides less funding for research grants than is required to accomplish the proposed work, expecting AHCs to share the direct costs associated with a research project. Examples of cost sharing include the requirement that institutions cover the portion of investigators' salaries above the \$125,000 cap, the practice of funding grants at less than the budget approved by study group sections, and the requirement that grantees pledge matching support at the time of grant submission.

The net effect of such policies is to require that AHCs find resources to make up shortfalls in the direct costs of federally funded grants: in effect, to share the cost of conducting research. Some federal officials believe that cost sharing of this type is an appropriate and necessary requirement for institutions that receive federal grant support. The decision to seek federal research support is voluntary, they argue, and so setting conditions on receipt of that support is acceptable. Furthermore, requiring recipients to contribute promotes the development of public-private partnerships and may encourage institutions to be more efficient in their use of taxpayer dollars.

Yet the benefits of cost sharing must be weighed against competing considerations. Cost sharing may result in the allocation of research dollars on the basis of the recipient's ability to pay rather than strictly on the merits of the proposed work. This could reduce the efficiency of the public's investment in research overall. Even more important, changing clinical markets require a reexamination of old assumptions about research support in AHCs. Even institutions that could afford to match federal dollars with direct cost contributions in the past may not be able to do so as readily in the future.

Better data are needed on the amount of funding currently being deployed through cost sharing arrangements and the potential effects of policy changes. AHCs and federal officials should launch cooperative surveys to collect the data necessary to monitor the effects of such changes on both AHCs and federal budgets.

Recommendation 8. The contribution of the National Institutes of Health toward indirect cost rates should be sustained at no less than current levels to support the real costs of conducting research and maintaining laboratories and offices for investigators.

Indirect cost payments by the NIH for research facilities and administration are likely to remain the primary support for the infrastructure needs of AHCs for the foreseeable future. One major advantage of the indirect cost mechanism is that it channels funds to the institutions that compete successfully for peer-reviewed grants. This creates the equivalent of a merit-based approach to allocating F&A expenses and assures that funds flow to institutions that need and

deserve capital support. To maintain the capacity of AHCs to use federal funds effectively in the future, federal support of indirect costs should be maintained at no less than current levels.

The indirect cost mechanism has certain deficiencies, however, as an approach to maintaining the infrastructure for research at AHCs. In particular, it tends to favor strong institutions with the ability to raise capital in advance and with investigators whose research track records can attract the funds necessary to cover the up-front costs of building. Institutions without those advantages may face major obstacles to upgrading their research capabilities. Further, uncertain clinical markets may force even strong AHCs to be more cautious about borrowing large amounts of funds without greater assurances that they can attract the grants necessary to cover downstream costs. In addition, indirect costs are often used to provide a source of working capital that allows AHCs to invest in the development of new research directions. This often requires hiring new faculty and sustaining them until their grant proposals are funded.

A strong case can be made that modest direct support of the infrastructure needs of AHCs should be made available during this period of uncertainty. Such funding should include both support for facilities and working capital needed to develop new research initiatives. New mechanisms for accountability should also be developed, including a peer-review system for allocation of institutional support and a system for reporting on the use of such funds within AHCs and their marginal contribution to AHCs' research activities. Institutional support should be time limited, and AHCs should be forced to compete for renewal of such grants.

The Task Force further believes that additional studies are necessary to determine more precisely the needs of AHCs for infrastructure support and the amount of funding that should be provided. These studies should include detailed, on-site surveys of representative AHCs, conducted by teams of experts that are viewed as objective and knowledgeable by policymakers, researchers, and AHC officials. The surveys should be done on a regular basis and should document the adequacy of support for AHC research infrastructures, the extent of unmet needs, and the amount of federal funding needed to assure that dollars spent on biomedical research are used to best advantage. Infrastructure support should be provided preferentially to AHCs that can document the need for support in order to accomplish research objectives of major importance to the public. Priority should also be given to institutions with less ability to cross-subsidize ongoing research because of lower overall margins and that show a substantial commitment to research on the problems of underserved populations.

Recommendation 9. The National Institutes of Health and other institutions should recognize the growing importance of clinical research by increasing support for clinical research at academic health centers.

The last decade has seen enormous strides toward a more complete understanding of basic biological processes, including genetic and molecular structures, the chemical basis of cognitive behaviors, and the functioning of the body's immune system. While this new knowledge has affected medicine in important ways, such as improvements in the treatment of patients with AIDS, many believe that the translation of basic science into actual practice could be greatly accelerated.

The Task Force believes that increased funding for clinical research is needed to evaluate current and emerging practices in patient care and medical technologies. Studies that can assess the efficacy of alternative approaches to the provision of medical services are likely to result in new and improved patient care practices and in less uncertainty for patients and providers. These studies could also lead to savings by developing cost-reducing innovations and eliminating ineffective, unnecessary, or overly expensive therapeutic regimens. Clinical innovations that have already occurred include new clinical practice guidelines, shorter hospital stays after deliveries, and minimally invasive surgical procedures such as laparoscopic cholecystectomy.

The Task Force findings reveal both opportunities and obstacles in the field of clinical research. It is difficult in any field of science to find clear, irrefutable evidence to support judgments about the proper balance between different types of investigation. Nevertheless, the Task Force believes that the volume of clinical research at AHCs should be growing faster than it is at this point in the history of the nation's biomedical research enterprise. Data on the long-term decline in physician participation in research and the difficulties facing clinical researchers in the peer-review system suggest that changing this pattern will require explicit action by public agencies and AHCs themselves.

The Task Force recommends that the National Institutes of Health should structure the proposal review process to assure thorough and effective review of clinical research proposals. Specifically, the NIH should create peer-review groups dedicated to considering clinical research proposals. At least 50 percent of the members of these groups should be experienced clinical investigators. These recommendations were also contained in the December 1997 Report of the NIH Directors Panel on Clinical Research.

The National Institutes of Health should structure the proposal review process to assure thorough and effective review of clinical research proposals.

The National Institutes of Health is currently considering reforms to its peer-review system that would reduce barriers to funding meritorious clinical research proposals. The Task Force believes that such changes are critical to restoring the real and perceived viability of the clinical research enterprise at AHCs. The peer-review process should be capable of reviewing all types of clinical research, including translational investigation, large-scale clinical trials, and epidemiological investigation. Multiple clinical research review groups, with subspecialties within areas of clinical research, may be needed.

The National Institutes of Health should increase support for general clinical research centers (GCRCs) and other clinical centers as a foundation for enhancing support for clinical research at AHCs. GCRCs currently receive \$157 million in support from the National Institutes of Health and constitute the primary dedicated source of support for the clinical research infrastructures at AHCs. GCRCs have the potential to serve as a central resource for the development of enhanced clinical research activities at AHCs. With greater support and somewhat modified priorities, these centers could provide technical capabilities that clinicians could leverage to enhance the quality and competitiveness of their requests for extramural support. GCRCs could also provide a core resource around which to build improved training programs for clinical researchers.

Recommendation 10. The National Institutes of Health should increase support for training clinical researchers at academic health centers.

There is widespread consensus that the cadre of clinical researchers at AHCs is insufficient to meet current needs in clinical investigation. Increasing the supply of qualified clinical researchers will require a long-term commitment to enhancing the attractiveness and feasibility of clinical research careers. The Task Force concurs with recommendations of the NIH Directors Panel on Clinical Research that additional NIH support for training of clinical investigators is necessary to meet this goal.

The Task Force further supports the recent decision by the NIH to establish three new clinical research training awards, including two individual awards and one institutional award.

- The Mentored Patient-Oriented Research Career Development Award, a five-year award, would provide up to \$75,000 per year in salary support and a maximum of \$50,000 in other funds to 80 young clinical investigators in 1999. Up to 400 awards would be made each year when the program is fully implemented in 2003. The total cost of the program is projected to be \$50.4 million per year by 2003.^{52*}

* Cost estimate assumes an indirect cost charge calculated at 8 percent of salaries and research support.

- The Mid-Career Investigator in Patient-Oriented Research Award, also a five-year award, would be available to young and mid-career investigators and would provide \$62,500 a year in salary support and \$25,000 in research funding over the five years. This program would support 60–80 investigators in 1999 and 300–400 a year when fully implemented, at a cost of between \$28.3 million and \$37.8 million per year, depending on the total number of awards.^{53*}
- The Clinical Research Curriculum Award would provide \$200,000 a year for two years to 20 programs (at a total cost of \$4 million per year) for development of training curricula in core disciplines that underlie clinical research.⁵⁴

Although the Task Force recognizes the need for all three types of support (early, mid-career, and institutional), it notes that the overwhelming preponderance of funding is planned for support of individual awards, with a relatively modest commitment to institutional support. The emphasis on supporting individual investigators to obtain necessary training and develop their careers may make sense in a well-developed field of investigation. However, this strategy may not be appropriate to fields as young and fragile as clinical research. Further, by stimulating AHCs to develop a centralized training capability for clinical research, the NIH might realize economies of scale in training. Therefore, in order to move toward a balance with individual grant support, the Task Force recommends the creation of more numerous, longer, and more generous institutional training grants than proposed by NIH to support and sustain core curricula and a cadre of faculty mentors in clinical research training.

The NIH has not yet responded to additional recommendations of its advisory panel suggesting support for training opportunities for medical and doctoral students and for M.D./Ph.D. training in such disciplines as epidemiology, economics, and biostatistics. The Task Force believes that the NIH should provide support for undergraduate medical training in clinical research, including mentored experiences for fourth-year medical students. In a parallel fashion, the NIH should support the training of quantitative and physical scientists who wish to pursue careers in clinical research and life sciences research. The NIH should also support training for physicians who wish to acquire advanced degrees in biostatistics, epidemiology, psychology, engineering, mathematics, physics, information technology, sociology, and economics and who plan to apply that training to clinical research.

FEDERAL SUPPORT FOR HEALTH SERVICES RESEARCH

Many of the challenges that face AHCs today—and which have brought the Task Force together—stem from societal efforts to restructure the health care system. Those efforts, in

* Cost estimate assumes an indirect cost charge calculated at 8 percent of salaries and research support.

turn, reflect the widespread conviction that the costs of health care could be reduced and its quality increased through reforms in the organization, financing, and management of health care services. Nevertheless, the federal government invests only a tiny fraction of its health care expenditures toward developing knowledge to inform this immense societal undertaking.

Recommendation 11. Federal support for health services research should be increased overall.

The primary vehicle for funding research concerning the organization and financing of health services is the Agency for Health Care Policy and Research, which had a budget of \$143 million in 1997—a figure equivalent to 1.13 percent of the 1997 NIH budget and less than one-tenth of 1 percent of national expenditures on health care services in 1996.

Expanded support for health services research could yield a range of important techniques and information:

- risk-adjusters that could be used to assure that health plans and providers are paid fairly for treating sicker patients and thus do not discriminate against them in competitive markets
- measures of quality of care, to allow consumers and their public and private representatives to evaluate the quality of care provided under alternative health care arrangements
- information on the cost-effectiveness of different treatments for the same illnesses, so that providers and plans can make rational decisions about how to allocate health care resources
- information on how regulations placed on managed care organizations (such as minimum lengths of stay for certain procedures, required access to emergency and specialty services, or required financial disclosure by providers) will affect access to and the cost of and quality of health care services
- data on the organization and delivery of health services, including the effect of incentives on provider behavior, the influence of patient preferences, the effect of changing manpower needs, and non-financial barriers to service use
- understanding of the learning and adaptive behaviors of caregivers and the ability of institutional incentives to modify those behaviors
- applications of valuable continuous quality improvement techniques

To address these and other critical issues, the Task Force recommends that, over the next five years, the federal government should increase the budget of the Agency for Health Care Policy and Research and the Office of Research and Demonstration in the Health Care Financing Administration and commit those funds to health services research. The underfunding of AHCPR in recent years makes this recommendation considerably more pressing than proposals to increase spending on other forms of biomedical research and development.

REFERENCES

1. Office of Management and Budget and United States Government, *Budget of the United States Government*, U.S. Government Printing Office, 1998.
2. D. Malakoff and E. Marshal, "NIH Wins Big as Congress Lumps Together 8 Bills," *Science* 282, no. 23 (1998):558–560.
3. Commonwealth Fund Task Force on Academic Health Centers, *Leveling the Playing Field: Financing the Mission of Academic Health Centers*, The Commonwealth Fund, 1997.
4. E. Mansfield, "Academic Research and Industrial Innovation," *Research Policy* 20 (1991):1–12.
5. F. Narin, K. S. Hamilton, and D. Olivastro, "The Increasing Linkage Between U.S. Technology and Public Science," *Research Policy* 26, no. 3 (1997):317–330.
6. L. Zuker, M. R. Darby, and J. Armstrong, "Intellectual Capital and the Firm," working paper no. 4946, National Bureau of Economic Research, 1994.
7. Z. J. Acs, D. B. Audretsch, and M. P. Feldman, "Real Effects of Academic Research: Comment," *American Economic Review* 82, no. 1 (1992):363–365.
8. A. Jaffe, M. Trajtenberg, and R. Henderson, "Geographic Location of Knowledge Spillovers as Evidenced in Patent Citations," *Quarterly Journal of Economics* 108, no. 3 (1993):577–598.
9. A. Jaffe, "Real Effects of Academic Research," *American Economic Review* 79, no. 5 (1989):957–970.
10. M. P. Feldman and F. R. Lichtenberg, "The Impact of Organization of Publicly Funded Research and Development," 1997, available at <http://gray.nber.org/papers/W6040>.
11. Research!America, "Attitudes Toward Medical Research: A 1995 Nationwide Survey of the American Public," 1998, available at <http://researchamerica.org/about/polls.html>.
12. E. Mansfield, *Microeconomics: Theory and Applications* (New York: Nelson, 1970).
13. P. Passell, "The Tax Credit for Research and Development: Free Lunch?" *New York Times*, February 5, 1998.
14. U.S. Department of Health and Human Services and National Institutes of Health, *NIH Data Book*, 1994.
15. National Institutes of Health, *Extramural Trends: Fiscal Years 1985–1995*, 1996.

16. N. A. Causino, D. Blumenthal, and D. Saglam, unpublished analysis conducted at the Institute for Health Policy, Massachusetts General Hospital/Partners HealthCare System, Inc., 1997.
17. J. Adams and Z. Griliches, "Research Productivity in a System of Universities," National Bureau of Economic Research, 1996.
18. Association of American Medical Colleges, *Report on Medical School Faculty Salaries, 1994–95*, 1995.
19. J. J. Cohen, "Financing Academic Medicine: Strengthening the Tangled Strands Before They Snap," *Academic Medicine* 72, no. 6 (1997):520.
20. D. Korn, Association of American Medical Colleges, personal communication, 1998.
21. Office of Management and Budget, "OMB Circular No. A-21, Revised April 26, 1996," available at <http://www.whitehouse.gov/WH/EOP/OMB/html/circulars/a021/ao21.html>.
22. J. Y. Krakower, J. L. Ganem, and P. Jolly, "Review of U.S. Medical School Finances, 1994–1995," *Journal of the American Medical Association* 276, no. 9 (1996):720–724.
23. Department of Health and Human Services and HHS Working Group on the Costs of Research, "Management of Research Costs: Indirect Costs," 1991.
24. J. S. Weissman, D. Saglam, E.G. Campbell, N. Causino, and D. Blumenthal, "Market Forces and Un-sponsored Research in Academic Health Centers," *Journal of the American Medical Association* 281, no. 12, (1999):1093–1098.
25. R. F. Jones and S. C. Sanderson, "Clinical Revenues Used to Support the Academic Mission of Medical Schools, 1992–93," *Academic Medicine* 71, no. 3 (1996):299–307.
26. National Science Foundation and Science Resources Division, *Science and Engineering Indicators—1995*, 1995.
27. H. N. Beaty et al., "Research Activities of Faculty in Academic Departments of Medicine," *Annals of Internal Medicine* 104, no. 1 (1986):90–97.
28. A. Borkowski, J. J. Berman, and G. W. Moore, "Research by Pathologists Not Funded by External Grant Agencies: A Success Story," *Modern Pathology* 5, no. 5 (1992):577–579.
29. A. Borkowski, J. J. Berman, and G. W. Moore, "Unfunded Pathology Research: Its Frequency and Success in the Scientific Literature," *Laboratory Investigation* 66 (1992):100A.
30. E. Moy et al., "Relationship Between National Institutes of Health Research Awards to U.S. Medical Schools and Managed Care Market Penetration," *Journal of the American Medical Association* 278, no. 3 (1997):217–221.

31. E. G. Campbell, J. S. Weissman, and D. Blumenthal, "Relationship Between Market Competition and the Activities and Attitudes of Medical School Faculty," *Journal of the American Medical Association* 278, no. 3 (1997):222–226.
32. American Association of Health Plans, "Study Reveals That Health Plans Make Higher Payments to Teaching Hospitals," AAHP Policy Brief, April 14, 1997.
33. R. E. Mechanic and A. Dobson, "The Impact of Managed Care on Clinical Research: A Preliminary Investigation," *Health Affairs* 15, no. 3 (1996):72–89.
34. Deloitte and Touche, "The Balanced Budget Act of 1997, Public Law 105-33: Medicare and Medicaid Changes," 1997.
35. Prospective Payment Assessment Commission, "Medicare and the American Health Care System: Report to Congress, June 1997," 1997.
36. Association of American Medical Colleges, "Public COTH Member Hospitals Are at Financial Risk," fact sheet, 1998.
37. D. Blumenthal et al., "Participation of Life Science Faculty in Research Relationships with Industry," *New England Journal of Medicine* 335, no. 23 (1996):1734–1739.
38. National Institutes of Health, "The NIH Director's Panel on Clinical Research: Report of the Advisory Committee to the NIH Director," 1997.
39. Institute of Medicine, *Careers in Clinical Research* (Washington, D.C.: National Academy Press, 1994).
40. E. H. Ahrens, *The Crisis in Clinical Research* (New York: Oxford University Press, 1992).
41. G. Hughes, "CROs Under the Microscope," *Pharmaceutical Visions* 5, no. 1 (1998):45–52.
42. Institute of Medicine, "Town Meeting: Clinical Research in the Public Interest," 1997.
43. CenterWatch, "Can Academic Centers Remake Themselves?" *CenterWatch* 2, no. 3 (1995):1–11.
44. University HealthSystem Consortium, *Perspectives on Clinical Research in Academic Health Centers*, 1995.
45. Office of the Inspector General, Department of Health and Human Services, "Institutional Review Boards: A Time for Reform," OEI-01-97-00193, 1998.
46. R. Pear, "Study Finds Risks to Patients in Drug Trials: Inspector General Calls Supervision of Review Boards Inadequate," *New York Times*, May 30, 1998.

47. Association of American Medical Colleges, "Trends in U.S. Medical School Applicants, Matriculants, Graduates," 1996.
48. S. W. Ammons, Jr., and D. E. Kelly, "Profile of the Graduate Student Population in U.S. Medical Schools," *Academic Medicine* 72, no. 9 (1997):820–830.
49. Association of American Medical Colleges, *AAMC Data Book: Statistical Information Related to Medical Education*, 1996.
50. National Institutes of Health, unpublished data received from F. Little, March 26, 1998.
51. J. Hadley, unpublished remarks made at "Biomedical Research and the Policy Agenda: The Policy Agenda," a forum sponsored by The Commonwealth Fund, Washington, DC, May 11, 1998.
52. National Institutes of Health, "Mentored Patient-Oriented Research Career Development Award," 1998, available at <http://www.nih.gov/grants/guide/pa-files/PA-98-053.html>.
53. National Institutes of Health, "Mid-Career Investigator Award in Patient-Oriented Research," 1998, available at <http://www.nih.gov/grants/guide/pa-files/PA-98-053.html>.
54. National Institutes of Health, "Clinical Research Curriculum Award," 1998, available at <http://www.nih.gov/grants/guide/rfa-files/RFA-OD-98-007.html>.

APPENDIX. 1996 NIH APPROPRIATIONS TO AHCs

Total NIH \$ 1996

Rank	Institution	Per Hospital	Per AHC	% of All Awards
1	Harvard University	\$166,727,904	\$533,946,181	7.35%
	Massachusetts General Hospital	\$109,955,960		
	Brigham and Women's Hospital	\$99,967,195		
	Dana-Farber Cancer Institute	\$56,620,062		
	Children's Hospital (Boston)	\$47,877,311		
	Beth Israel Hospital (Boston)	\$33,394,050		
	New England Deaconess Hospital	\$10,833,047		
	Massachusetts Eye and Ear Infirmary	\$8,570,652		
2	Johns Hopkins University	\$279,185,690	\$294,751,299	4.06%
	Kennedy Krieger	\$7,916,188		
	Johns Hopkins Bayview Medical Center	\$7,649,421		
3	University of Washington	\$212,281,915	\$290,415,094	4.00%
	Fred Hutchinson Cancer Research Center	\$78,133,179		
4	University of Pennsylvania	\$186,727,955	\$214,193,147	2.95%
	Children's Hospital of Philadelphia	\$26,315,007		
	Graduate Hospital (Philadelphia)	\$1,150,185		
5	University of California San Francisco	\$212,877,232	\$213,097,511	2.93%
	San Francisco Gen Hosp Med Ctr	\$220,279		
6	Washington University	\$172,774,071	\$183,641,279	2.53%
	Barnes-Jewish Hospital	\$10,867,208		
7	University of Michigan	\$179,651,361	\$179,651,361	2.47%
8	University of California Los Angeles	\$156,574,520	\$177,358,442	2.44%
	Harbor-UCLA Research & Educ Inst	\$11,771,121		
	Cedars-Sinai Medical Center	\$8,618,520		
	Olive View-UCLA Education and Res Inst	\$394,281		
9	Yale University	\$174,741,782	\$174,741,782	2.40%
10	Stanford University	\$153,205,664	\$153,205,664	2.11%
11	University of Pittsburgh	\$136,204,607	\$148,447,061	2.04%
	Children's Hospital of Pittsburgh	\$7,618,995		
	Magee-Women's Hospital	\$4,623,459		
12	Duke University	\$143,358,921	\$143,358,921	1.97%
13	University of North Carolina Chapel Hill	\$140,140,193	\$140,140,193	1.93%
14	Columbia University New York	\$137,815,335	\$138,700,738	1.91%
	Columbia Presbyterian Medical Center	\$885,403		

Rank	Institution	Total NIH \$ 1996		% of All Awards
		Per Hospital	Per AHC	
15	University of California San Diego	\$135,469,556	\$135,469,556	1.86%
16	University of Minnesota	\$131,077,595	\$131,077,595	1.80%
17	Case Western Reserve University	\$124,180,639	\$124,365,858	1.71%
	Mount Sinai Medical Center	\$100,556		
	MetroHealth Center	\$84,663		
18	University of Wisconsin Madison	\$121,990,782	\$121,990,782	1.68%
19	University of Alabama at Birmingham	\$118,292,038	\$118,292,038	1.63%
20	Cornell University	\$94,291,478	\$103,870,805	1.43%
	North Shore University Hospital	\$4,807,269		
	Hospital for Special Surgery	\$3,999,678		
	Catholic Med Ctr Brooklyn Queens Nursing	\$772,380		
21	University of Colorado Health Sciences Ctr	\$83,423,416	\$102,154,755	1.41%
	National Jewish Center for Immun	\$18,562,702		
	Children's Hospital (Denver)	\$168,637		
22	University of Southern California	\$91,642,586	\$99,396,862	1.37%
	Children's Hospital of Los Angeles	\$7,754,276		
23	Baylor College of Medicine	\$90,895,535	\$90,895,535	1.25%
24	University of Chicago	\$89,200,036	\$89,200,036	1.23%
25	Yeshiva University	\$76,639,587	\$88,342,179	1.22%
	Montefiore Medical Center (Bronx, NY)	\$10,524,013		
	Bronx-Lebanon Hosp Ctr (Bronx, NY)	\$1,178,579		
26	Vanderbilt University	\$87,150,662	\$87,150,662	1.20%
27	University of Iowa	\$83,480,815	\$83,480,815	1.15%
28	Boston University	\$69,918,952	\$83,373,638	1.15%
	Boston Medical Center Newton St Campus	\$8,332,653		
	Boston Medical Center	\$5,122,033		
29	University of Texas SW Med Ctr/Dallas	\$82,900,672	\$82,900,672	1.14%
30	Emory University	\$78,300,389	\$78,300,389	1.08%
31	Northwestern University	\$68,165,506	\$73,499,101	1.01%
	Children's Memorial Hospital (Chicago)	\$3,188,254		
	Northwestern Memorial Hospital	\$1,075,855		
	U.S. Dept/Vets Affairs Lakeside Med Ctr	\$337,393		
	Rehabilitation Institute Research Corp	\$732,093		

Rank	Institution	Total NIH \$ 1996		% of All Awards
		Per Hospital	Per AHC	
32	New York University Medical Center	\$71,294,949	\$71,294,949	0.98%
33	University of Rochester Rochester General Hospital (NY)	\$70,978,006 \$137,118	\$71,115,124	0.98%
34	Indiana University	\$67,131,615	\$67,131,615	0.92%
35	Mount Sinai School of Medicine Beth Israel Medical Ctr (New York)	\$62,127,860 \$2,855,985	\$64,983,845	0.89%
36	University of Texas Health Sci Ctr Houston	\$63,809,470	\$63,809,470	0.88%
37	University of Maryland Baltimore Prof School	\$63,312,861	\$63,312,861	0.87%
38	University of Utah LDS Hospital	\$61,933,250 \$614,092	\$62,547,342	0.86%
39	Mayo Foundation	\$60,604,497	\$60,604,497	0.83%
40	Tufts University New England Medical Center St. Elizabeth's Medical Center Bay State Medical Center	\$32,261,886 \$23,499,870 \$3,607,516 \$203,644	\$59,572,916	0.82%
41	University of Virginia	\$59,289,524	\$59,289,524	0.82%
42	University of Miami Mount Sinai-Miami	\$57,665,548 \$1,482,869	\$59,148,417	0.81%
43	Oregon Health Sciences University Oregon Regional Primate Research Center	\$44,092,225 \$13,814,704	\$57,906,929	0.80%
44	University of California Davis	\$57,047,488	\$57,047,488	0.78%
45	Pennsylvania State University	\$55,995,949	\$55,995,949	0.77%
46	University of Cincinnati Children's Hospital Med Ctr (Cincinnati) Good Samaritan Hospital (Cincinnati)	\$38,449,540 \$17,008,192 \$49,136	\$55,506,868	0.76%
47	University of Massachusetts	\$55,294,182	\$55,294,182	0.76%
48	University of Arizona	\$53,161,090	\$53,161,090	0.73%
49	Wake Forest University	\$52,110,226	\$52,110,226	0.72%
50	University of Medicine and Dentistry of NJ Kessler Institute for Rehabilitation Hackensack Medical Center	\$49,977,975 \$449,608 \$310,533	\$50,738,116	0.70%

Total NIH \$ 1996				
Rank	Institution	Per Hospital	Per AHC	% of All Awards
51	Univ of Texas Health Sci Ctr San Antonio	\$50,733,995	\$50,733,995	0.70%
52	Thomas Jefferson University	\$50,538,675	\$50,538,675	0.70%
53	Ohio State University Children's Hospital Columbus	\$45,479,001 \$2,915,387	\$48,394,388	0.67%
54	University of Tennessee Col of Med St. Jude Children's Research Hospital	\$22,909,805 \$23,430,268	\$46,340,073	0.64%
55	University of Florida	\$45,363,593	\$45,363,593	0.62%
56	Wayne State University Children's Hospital of Michigan Sinai Hospital	\$44,900,118 \$373,000 \$47,178	\$45,320,296	0.62%
57	State University New York Stony Brook Associated Univ-Brookhaven Nat Lab Winthrop-University Hospital	\$41,284,730 \$3,914,636 \$221,854	\$45,421,220	0.62%
58	University of Illinois at Chicago	\$43,792,526	\$43,792,526	0.60%
59	Georgetown University District of Columbia Gen Hosp (Wash. DC)	\$42,987,224 \$428,231	\$43,415,455	0.60%
60	University of California Irvine	\$42,782,158	\$42,782,158	0.59%
61	Virginia Commonwealth University	\$39,758,179	\$39,758,179	0.55%
62	University of Texas Medical Br Galveston	\$38,423,580	\$38,423,580	0.53%
63	Med Col of Pennsylvania/Hahnemann Univ Allegheny-Singer Research Institute Allegheny General Hospital (Pittsburgh)	\$24,141,791 \$13,730,813 \$418,883	\$38,291,487	0.53%
64	Dartmouth College	\$35,956,117	\$35,956,117	0.49%
65	Brown University Rhode Island Hospital Miriam Hospital Roger Williams Hospital Women and Infants Hospital-Rhode Island Butler Hospital Memorial Hospital	\$19,172,389 \$7,709,219 \$2,795,254 \$1,681,473 \$1,378,938 \$1,259,678 \$1,023,697	\$35,020,648	0.48%
66	University of Kentucky	\$34,428,275	\$34,428,275	0.47%

Rank	Institution	Total NIH \$ 1996		% of All Awards
		Per Hospital	Per AHC	
67	Medical College of Wisconsin	\$34,133,766	\$34,133,766	0.47%
68	University of Connecticut St. Francis Hospital/Med Ctr (Hartford, CT) Hartford Hospital	\$31,386,301 \$634,687 \$70,584	\$32,091,572	0.44%
69	University of Kansas	\$30,558,512	\$30,558,512	0.42%
70	George Washington University Children's National Medical Center	\$23,565,458 \$6,035,804	\$29,601,262	0.41%
71	Tulane University	\$26,068,417	\$26,068,417	0.36%
72	Medical University of South Carolina	\$25,396,757	\$25,396,757	0.35%
73	University of Vermont	\$24,965,756	\$24,965,756	0.34%
74	State University of New York at Buffalo	\$24,602,128	\$24,602,128	0.34%
75	Rush University Rush-Presbyterian-St. Luke's Med Ctr	\$689,318 \$21,521,497	\$22,210,815	0.31%
76	University of New Mexico	\$21,014,803	\$21,014,803	0.29%
77	Louisiana State U Sch of Med	\$20,850,352	\$20,850,352	0.29%
78	Temple University	\$20,577,828	\$20,577,828	0.28%
79	University of Arkansas Arkansas Children's Hospital (Little Rock) Arkansas Children's Hospital Res Inst	\$19,004,571 \$1,051,228 \$122,431	\$20,178,230	0.28%
80	University of Missouri	\$20,049,823	\$20,049,823	0.28%
81	St. Louis University	\$20,044,049	\$20,044,049	0.28%
82	Michigan State University	\$19,498,760	\$19,498,760	0.27%
83	University of Oklahoma	\$18,920,256	\$18,920,256	0.26%
84	SUNY Hlt Sci Ctr Brooklyn Col of Med	\$18,277,712	\$18,277,712	0.25%
85	Northeastern Ohio Universities Col Med Children's Hospital Medical Center	\$968,460 \$17,008,192	\$17,976,652	0.25%
86	University of Puerto Rico	\$17,401,935	\$17,401,935	0.24%

Rank	Institution	Total NIH \$ 1996		% of All Awards
		Per Hospital	Per AHC	
87	Univ of Hawaii at Manoa Kapiolani Medical Center Women/Children	\$15,816,904 \$498,628	\$16,315,532	0.22%
88	Texas A&M University Health Science Ctr Scott and White Memorial Hospital VA Medical Center	\$14,699,317 \$71,859 \$49,862	\$14,821,038	0.20%
89	University of Nebraska Medical Center University of Nebraska	\$14,619,765 \$113,374	\$14,733,139	0.20%
90	Louisiana State Univ New Orleans Louisiana State Univ Med Ctr New Orleans Children's Hospital (New Orleans)	\$96,150 \$13,556,147 \$206,300	\$13,858,597	0.19%
91	Loyola University of Chicago	\$12,868,744	\$12,868,744	0.18%
92	Medical College of Georgia	\$11,257,735	\$11,257,735	0.15%
93	Howard University	\$10,412,662	\$10,412,662	0.14%
94	New York Medical College	\$10,146,223	\$10,146,223	0.14%
95	Meharry Medical College	\$10,170,265	\$10,170,265	0.14%
96	Morehouse School of Medicine	\$9,194,232	\$9,194,232	0.13%
97	Health Science Center at Syracuse	\$8,976,209	\$8,976,209	0.12%
98	University of Mississippi	\$8,809,019	\$8,809,019	0.12%
99	University of South Alabama	\$7,978,811	\$7,978,811	0.11%
100	University of South Florida	\$7,914,792	\$7,914,792	0.11%
101	Louisiana State Univ Med Ctr	\$7,558,568	\$7,558,568	0.10%
102	Medical College of Ohio at Toledo	\$7,469,135	\$7,469,135	0.10%
103	University of Louisville	\$6,867,073	\$6,867,073	0.09%
104	University of Nevada Reno	\$6,026,433	\$6,026,433	0.08%
105	University of South Carolina Richland Memorial Hospital (Columbia, SC)	\$5,251,876 \$553,670	\$5,805,546	0.08%
106	Charles R. Drew University of Med & Sci	\$5,762,903	\$5,762,903	0.08%

Rank	Institution	Total NIH \$ 1996		% of All Awards
		Per Hospital	Per AHC	
107	West Virginia University	\$5,615,659	\$5,615,659	0.08%
108	Finch Univ of Hlt Sci/Chicago Med Sch	\$5,228,249	\$5,228,249	0.07%
109	Albany Medical College of Union Univ	\$5,226,740	\$5,226,740	0.07%
110	Wright State University	\$4,887,156	\$4,887,156	0.07%
111	City College of New York	\$4,466,523	\$4,466,523	0.06%
112	Eastern Virginia Med Sch/Med Col Hamp Rd	\$3,523,700	\$3,523,700	0.05%
113	Creighton University	\$3,505,027	\$3,505,027	0.05%
114	Ponce School of Medicine	\$2,937,724	\$2,937,724	0.04%
115	Loma Linda University	\$2,919,615	\$2,919,615	0.04%
116	Texas Tech Univ Hlt Sci Ctr Sch of Med Texas Tech University	\$2,534,973 \$179,622	\$2,714,595	0.04%
117	East Carolina University	\$2,505,424	\$2,505,424	0.03%
118	Central University of the Caribe	\$2,447,176	\$2,447,176	0.03%
119	University of North Dakota	\$2,041,816	\$2,041,816	0.03%
120	Southern Illinois University Sch of Med	\$1,694,738	\$1,694,738	0.02%
121	Marshall University	\$1,027,154	\$1,027,154	0.01%
122	University of South Dakota	\$678,245	\$678,245	0.01%
123	East Tennessee State University	\$563,496	\$563,496	0.01%
124	Mercer University	\$529,562	\$529,562	0.01%
Total		\$7,267,818,639	\$7,267,818,639	100.00%

Note: In order to identify the institutions under the research umbrella of each AHC, we used lists from the Association of American Medical Colleges (AAMC) to identify all U.S. medical schools and their associated clinical facilities. Next, using publicly available data from the National Institutes of Health (NIH), we identified the total amount of awards (including research, training, fellowships, contracts, and other grants) made to each institution in 1996.

The rankings of AHCs should be used with caution for several reasons. First, in some cases we were unable to identify the amount of funding going directly to the medical school as a separate entity of its parent university. In such cases we attributed all of the funds awarded to the parent university to the medical school. Second, in other cases the NIH data did not include several affiliated clinical facilities or branch campuses.