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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

October 15, 1996

MEMORANDUM FOR CHRISTOPHER JENNINGS, SPECIAL ASSISTANT
TO THE PRESIDENT FOR HEALTH POLICY
OFFICE OF POLICY DEVELOPMENT, DPC

JENNIFER KLEIN, SPECIAL ASSISTANT
TO THE PRESIDENT FOR DOMESTIC POLICY
OFFICE OF POLICY DEVELOPMENT, DPC

NANCY-ANN MIN
ASSOCIATE DIRECTOR FOR HEALTH, OMB

LAURA D'ANDREA TYSON
ASSISTANT TO THE PRESIDENT FOR ECONOMIC POLICY
OFFICE OF POLICY DEVELOPMENT, NEC

FROM: ERNEST J. MONIZ

SUBJECT: MEETING WITH ACADEMIC HEALTH CENTER REPRESENTATIVES, OCTOBER 16

The purpose of this memorandum is to provide you with information in preparation for the meeting tomorrow with representatives of academic health centers (AHCs). We have asked them to provide us with their current perspective on the changing environment, impacts, and possible responses.

The meeting will take place in Conference Room 472, from 1 to 3 p.m. I propose to open the meeting with introductions and to give each of you the opportunity to describe briefly your interest and involvement in policy development related to the research and teaching missions of the AHCs. My office will prepare a summary of the discussion which we will distribute to you.

Attachments:
1. List of attendees
2. Letter of invitation
3. Tentative agenda proposed by AHCs
4. November 8, 1995 letter from the President's Committee of Advisors for Science and Technology
5. National Institutes of Health paper, "Managed Care and Medical Research: An Overview"
6. Washington Post article (Spencer Rich, 8/18/96)

List of Participants for the Academic Health Centers Brainstorming Session

Conference Room 472 of the Old Executive Office Building
October 16, 1996
1 to 3 p.m.

Peter Kohler **(tent)**
President
Oregon Health Sciences University

Herbert Pardes
Vice President for Health Sciences
and Dean of the Faculty of Medicine
College of Physicians and Surgeons
Columbia University

Ellen Smith
Assistant Vice President and Director
for Federal Relations
Columbia University Office of Public Affairs

Samuel Silverstein
Professor and Chairman
Department of Physiology and Cellular Biophysics
Columbia University

Donald E. Wilson
Dean
School of Medicine
University of Maryland

Dr. Kenneth Berns
R.A. Rees Pritchett Professor and Chairman
Department of Microbiology
Cornell University Medical College

Dr. Roger Bulger
President
Association of Academic Health Centers

David Korn
Distinguished Scholar in Residence
Association of American Medical Colleges

Joseph Keyes
Senior Vice President
Association of American Medical Colleges

Haile T. Debas **(via conf call)**
Dean
School of Medicine
University of California, San Francisco

Michael Johns
Executive Vice President for Health Affairs
Emory University

Ralph Muller
President
University of Chicago Hospitals
and Health Systems

Frank Butler
Hospital Director
University of Kentucky Hospital

Jeffrey Cossman
Professor and Chairman
Department of Pathology
School of Medicine
Georgetown University Medical Center

Harold Varmus
Director
National Institutes of Health

EOP Staff:

Ernest J. Moniz
Associate Director for Science
Office of Science and Technology Policy

Rachel E. Levinson
Assistant Director for Life Sciences
Office of Science and Technology Policy

Laura D'Andrea Tyson (cannot attend)
Assistant to the President for Economic Policy
Office of Policy Development, NEC

Christopher Jennings, Special Assistant (will attend first hour)
to the President for Health Policy
Office of Policy Development, DPC

Jennifer Klein, Special Assistant
to the President for Domestic Policy
Office of Policy Development, DPC

Nancy-Ann Min (cannot attend)
Associate Director for Health, OMB

October 1, 1996

Dear salutation~:

Last year the President's Committee of Advisors on Science and Technology (PCAST) identified a number of concerns related to the impact of changes in our national health care system on academic health centers (AHCs). These concerns and a set of recommendations were conveyed to the President in a November 8, 1995 letter report. The recommendations focused on sustaining federal support for direct and indirect medical education and care for indigent or uninsured patients, and the need for an expert commission to address the preservation of AHCs research and educational capacities.

The Office of Science and Technology Policy, in response to PCAST's 1995 initiative, has joined with other components of the Executive Office of the President in monitoring the vitality of our biomedical research and education enterprise as the health care system evolves. Accordingly, we are holding an informal gathering of AHC representatives to provide us information and perspectives gained from current, real world experiences.

Given your extensive experience with these issues, we would very much appreciate hearing your views and invite you to participate in this meeting. It will be held on Wednesday, October 16, 1996, from 1 to 3 p.m. in Conference Room 472 of the Old Executive Office Building (17th Street and Pennsylvania Avenue, N.W.) in Washington, D.C. Please notify Donna I. Coleman by fax on (202) 456-6027 (Phone: 202/456-6130) with your name and date of birth for admittance into the building.

Sincerely,

Ernest J. Moniz
Associate Director for Science

inside address~

Suggested Agenda

October 16, 1996

I. The Changing Environment and Academic Health Centers

A. What is happening in various areas of the country?

1. Mergers of hospitals/mergers of medical schools
2. Penetration of managed care organizations

B. What is happening in the research area?

1. Amount of funding
2. Other administrative issues

II. Impacts

A. Impact of change on the continuum of biomedical research
   1. Basic
   2. Clinical
B. Impact of change on training of future researchers
C. Impact of change on teaching the next generation of physicians

III. Academic Health Center Responses to Changes

EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COMMITTEE OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20500

November 8, 1995

President William J. Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

The significant accomplishments in American biomedical research and our innovations in medical care are widely respected throughout the country and, indeed, the world. These achievements have occurred primarily at our Nation's academic health centers. Since World War II, the Federal government has played a vital role in the support of academic health centers and has done so on a bipartisan basis.

Your Administration's 1994 health care reform plan acknowledged the important contribution to our quality of life made by academic health centers and provided a mechanism to mitigate the loss of significant revenue that these institutions are now experiencing. In the absence of comprehensive health care reform, academic health centers are beginning to show signs of serious stress. Although they represent only six percent of the Nation's non-Federal acute care hospitals, these institutions provide more than half of the care for the indigent and uninsured populations. The prospect of sharp reductions in Medicare, Medicaid, and Disproportionate Share (DSH) expenditures, coupled with the erosion of clinical revenues resulting from the emergence of managed care, could have a devastating impact on the Nation's capacity to support medical research and education and the system that provides medical care to its most vulnerable citizens.

Academic health centers develop the biomedical knowledge and clinical techniques needed for new and improved treatments, train the Nation's physicians and provide unique patient care resources. In the long term, biomedical research conducted in these centers offers our citizens the best potential to enhance their quality of life and control medical expenditures with cost-effective methods for disease prevention and management.

Historically, the Federal government has assumed responsibility for a majority of the support for fundamental biomedical research and graduate medical education as a public investment that contributes broadly to the health of Americans. In 1995, the Federal investment in academic health centers for biomedical research and education was about one percent of total health care expenditures. Measured by any standard, this very modest rate of investment in an area of extraordinarily rapid advancement in knowledge and technology has had a remarkable yield. In addition, the Federal government provides, through the Medicaid and DSH programs, significant support for low-income patient care delivered in academic health centers.

Clinical revenues derived from medical practice programs conducted by the faculty of academic health centers have been another very significant source of funds for these programs of research, education and indigent care. Current changes in the health care system, including Medicare and Medicaid reform, driven by Federal and State fiscal concerns and the emergence of managed care, also threaten to eliminate this critical support for biomedical research and medical education.

We recognize the need to slow the rate of growth in health care costs and endorse efforts to address this need. Both public and private elements of the health care system need to be carefully examined and restructured to enhance medical efficacy and cost-effectiveness. However, it is also essential that in this process, the crucial public benefits that are contributed uniquely by academic health centers be recognized, and that their continued strength remain an important priority in the ongoing health care debate.

A panel of your Committee of Advisors on Science and Technology (PCAST) examined these issues and reached the following conclusions:

- Sharing the Responsibility – The education of competent physicians and scientists, and the production of new biomedical knowledge and technologies, represent vital public necessities. To date, only the Federal government has supported these functions explicitly through the Graduate Medical Education (GME) mechanisms of the Medicare program. With a few notable exceptions, other payers do not contribute to this support. We affirm the principle that responsibility for supporting the missions of academic health centers and their contributions to the well-being of society should be broadly shared by all who benefit.

- Care for the Indigent and Uninsured -- Historically, academic health centers have provided care for a disproportionate share of the indigent and uninsured populations and have received a Medicare payment adjustment for this service. It is likely that this responsibility can only increase in the developing private and public medical care marketplaces. With the trend toward managed care, others are even less likely to provide this service because of its resource-intensive nature.

- Current Debate -- A satisfactory disposition of these critically important and complex issues is unlikely to emerge from the heat of the current public debate, with its intense and narrow focus on budgetary concerns.

To support and sustain the Nation's academic health centers in the immediate future and over the longer term, PCAST therefore respectfully suggests that you consider the following recommendations:

- **Expert Commission** -- We recommend that an expert commission, credible to the President, the Congress and the public, be established to develop and recommend specific policies to address the preservation of the research and educational capacity of the Nation's academic health centers, and the supply, composition and support of the future health care work force. The commission should carefully consider the implementation of an equitable mechanism to achieve these objectives. The commission should also determine the most effective way to allocate training funds in furthering the goals of a rational workforce policy to ensure that the numbers and competencies of health care professionals are responsive to the Nation's needs. We believe that such an approach can best ensure the future vitality of our biomedical research enterprise and the highest quality of our Nation's medical care.

- **Graduate Medical Education (GME)** -- In the interim, in revising the Medicare program, the Administration should continue to resist disproportionate decreases in the GME accounts. Further, the funds for GME that are currently melded into the premiums paid to all Medicare managed care providers (the Average Adjusted Per Capita Cost formula) should be redirected to accomplish their intended objectives. This may entail developing a process that provides these payments directly to caregivers and institutions that are involved in graduate medical education.

- **Disproportionate Share** -- If academic health centers are to continue their role of disproportionately caring for the indigent and uninsured populations, then appropriate resources must be provided. This will almost certainly remain a responsibility of the government.

PCAST believes that the academic health centers are a national resource that, together with our research universities, must be sustained for the good of the Nation. We hope that you will find these recommendations helpful.

Sincerely,

John A. Young
Co-Chair
President's Committee of Advisors
on Science and Technology

MANAGED CARE AND MEDICAL RESEARCH: AN OVERVIEW

I. Introduction: The Growth of Managed Care

Managed Care Organizations (MCOs)[1] are not a new phenomenon. The first managed care plan in the United States was initiated in Elk City, Oklahoma, in 1929 among rural farmers who were often unable to pay their doctor bills at the time they were due. Kaiser Permanente, the first group model Health Maintenance Organization (HMO) in the country, was established in 1942. Group Health Cooperative of Puget Sound and the Health Insurance Plan (HIP) of Greater New York followed five years later. Group Health of Minneapolis was established in 1957. Because these new organizations appeared quite successful at containing rapidly-rising health care costs, the Department of Health and Human Services provided start-up funds to spur creation of more non-profit HMOs in the late 1970s.

What is new is the recent rapid growth of MCOs, particularly for-profit MCOs. By late 1995, about 1500 MCOs were in existence, including approximately 550 HMOs. Managed care networks now deliver health care to about half of all Americans, including 58 million (22 percent of the U.S. population) who are served by HMOs and another 81 million (30 percent of the U.S. population) who are covered by other types of MCOs.[2] Close to 12 million, or 32 percent of all Medicaid recipients are enrolled in MCOs, as are about 4 million Medicare recipients (10 percent of the Medicare population).[3]

II. Why Are Medical Researchers Concerned About Managed Care?

Although the rapid growth of managed care is reducing the rate of growth in national health care costs, the continued vitality of any health care system depends on the quality of the health care it delivers. It also relies upon the continued infusion of new preventive strategies and innovative treatments, both of which emerge from medical research.

Academic Health Centers (AHCs)[4] have long been a cornerstone of the Nation's medical research and research training enterprise. They have been a driving force in developing knowledge about our country's most devastating and costly diseases, such as HIV/AIDS, schizophrenia, Alzheimer's Disease, cardiovascular disease, stroke, and cancer. While AHCs depend heavily upon Federal support in carrying out their training, service, and research missions, Federal funds are not the only source of support. Emerging changes in the health care financing system can have a profound effect upon these institutions, by reducing revenue streams used to support laboratory and clinical research and by reducing recruitment of patients into clinical trials. Ultimately, these changes may redirect young physicians away from research careers.

Reduced Revenues. In 1993/94, AHCs derived 33.2 percent of revenues from faculty practice plans, making this their single largest source of revenue.[5] Federal research grants and contracts provided another 18.8 percent of AHC revenues that year, while the AHC hospitals provided 13.3 percent. To analyze further these revenue streams, the Association of American Medical Colleges

(AAMC) surveyed member AHCs in 1994 and 1995, and found that about one-third of practice plan revenues were used to support the academic missions of the medical schools.[6] This support included direct transfers of practice plan revenues to the medical schools. In addition, practice plan revenues were used to underwrite medical school faculty time spent in the academic missions of teaching and research. For example, a clinical faculty member may derive 80 percent of compensation from faculty practice plan funds and 20 percent from AHC funds, yet spend only 60 percent of time in practice and 40 percent in research. In this case, practice plan revenues are supporting time spent on research. Revenues from faculty practice plans also provide indirect subsidies for teaching and research by supporting laboratory and hospital facilities that are used for research and teaching, as well as in clinical practice. AAMC estimated that about $816 million from practice plan revenues was used to support basic and clinical research.

Because of the need to support multiple missions, including teaching, research, and care for the poor, the costs of medical services provided by AHC faculty practice plans and hospitals are generally higher than the costs of medical services provided by community physicians, by teaching hospitals that are not closely affiliated with AHCs and by other, non-teaching hospitals. For example, in 1993, AHC teaching hospitals spent about $10,084 per adjusted admission (this is the weighted average of inpatient admissions and outpatient encounters), or 28 percent more than other hospitals, which spent an average of $7,255.[7] To cover these higher expenses, the AHC-affiliated hospitals charge higher fees. Managed care organizations are reluctant to pay these higher fees and are not referring their patients to AHCs.[8] This initiates a vicious circle--the higher cost of care at AHCs reduces referrals of patients, which further contributes to reduced revenues.

Declining Patient Accrual. The reluctance of managed care networks to refer patients to AHCs not only reduces revenues traditionally used to subsidize the costs of research, it also reduces access by researchers to patient populations that are an essential component of clinical trials and other forms of clinical research. This tendency to steer patients away from AHCs grew stronger between 1988 and 1991. The relative odds of an HMO patient being treated in an AHC teaching hospital dropped by more than 25 percent over these three years.[9] It appeared that HMOs were making greater use of teaching hospitals not closely tied to medical schools, which cost, on average, 35 percent less than AHC hospitals.

Referring patients away from AHCs has an immediate and long-range effect upon the ability of researchers to conduct basic and clinical research. In a 1994 review of the situation, commissioned by the Department of Health and Human Services, staff from Lewin-VHI interviewed clinical researchers in metropolitan statistical areas (MSAs) with above-average managed care penetration and at least one major AHC. This study identified isolated cases in which researchers were having trouble obtaining patients to participate in clinical trials, but concluded that, in general, managed care utilization procedures "have not yet had a significant impact on patient availability for clinical protocols."[10] However, the Lewin study predicted that current economic forces might have substantial impacts on future research.

By 1996, NIH-supported Cancer Research Centers throughout the nation reported that third party payers in general had become more resistant to paying the costs of patients enrolled in clinical trials, and that accruals to all kinds of clinical trials were decreasing.

Deterring the Next Generation of Researchers. The growth of managed care may have its greatest impact on new, young researchers. Young medical school faculties, who typically have little research training and few preliminary findings on which to base a grant proposal, have difficulty competing for grants from NIH or other sponsors. Until recently, however, AHCs could afford to fund some training and preliminary research from internal revenues. If the current reduction of internal revenues continues, AHCs may soon be unable to support promising young physicians and scientists seeking research careers.

III. Funds for Clinical Research

During the postwar period, basic and clinical research at AHCs grew rapidly with Federal funding. Since 1980, as Federal research funding has grown more slowly, the insurance industry has provided an increasing share of the costs of medical research. This support has taken two forms: direct and indirect. The most important source of insurance industry support is indirect, i.e., insurance companies reimburse the fees charged by AHC faculty practice plans and teaching hospitals.

Since 1980, AHCs have also begun to rely more heavily on the insurance industry for direct support of clinical research, through reimbursement of the patient care portion of the costs of experimental treatments. The insurance industry does not reimburse for direct research costs, e.g., the cost of providing an experimental drug. However, by the mid-1980s, as the costs of these experimental treatments provided by clinical researchers increased, many insurers began to challenge, and in some cases, deny such coverage. More recently, faced with growing numbers of lawsuits by patients demanding access to experimental protocols, some companies have begun to provide limited coverage. For example, in 1994, HealthNet, a California HMO, lost a high-profile suit in which a 37-year-old woman, unable to get prompt approval for experimental breast cancer treatment, paid for the treatment herself and subsequently died.[11] A jury awarded her estate $89 million in damages. A year earlier, Group Health, Inc., a Seattle HMO, began to provide coverage for bone-marrow transplants following chemotherapy, in part because of the threat of a lawsuit. To assess this situation, NIH staff surveyed representatives of nine large insurance companies and managed care plans in 1994.[12] They found that, despite language in insurance policies excluding coverage for experimental procedures, the companies frequently did provide coverage for patients enrolled in clinical research. Coverage was most likely to be provided to patients with terminal illnesses enrolled in large-scale Phase III trials of proven efficacy not using new therapies. Coverage was also more likely to be provided if the clinical trial was sponsored by NIH, CDC, or another large Federal or private funder.

The pharmaceutical and biotechnology industries are also important sources of support for medical research. By 1994, industry funded over half of all U.S. medical research.[13] Although the

pharmaceutical industry supports some basic laboratory research, a large part of its R&D investment is in clinical trials. The growing importance of industry funding can be seen in the experience of researchers based in General Clinical Research Centers (GCRCs).[14] NIH provides ongoing funding to the 75 GCRCs usually located at AHCs. In both 1990 and 1995, GCRC-based researchers obtained about 72 percent of all funding from the Public Health Service. Over the same time period, however, industry provided a larger share of these investigators' total support, growing from 9.5 percent in 1990 to 17.3 percent in 1995.

The recent rapid growth of managed care is affecting pharmaceutical industry support of medical research, particularly clinical research. Under pressure from managed care companies to control the costs of drug trials, pharmaceutical firms are scaling back research, price-shopping among AHCs, and turning to for-profit contract research organizations (CROs). Relying on patients who are professional study participants, and on large patient data bases, some CROs perform clinical trials more quickly and cheaply than AHCs.[15] A recent survey of 17 large pharmaceutical firms found that over half of all their clinical research was being conducted by CROs.[16]

Private foundations are not a major source of support for medical research. Their share of total public and private support for U.S. medical research funding has fallen from nearly 40 percent in 1940 to less than 10 percent today.[17] However, a limited amount of foundation support is available. For example, in 1996, in response to the growth of managed care and slower growth in Federal funding, the Howard Hughes Medical Institute (HHMI) announced awards of $80 million to help 30 AHCs carry out research. Unlike traditional grants, which are awarded for specific research projects, these grants are designed to strengthen overall research capabilities. The AHCs will use the funds to help young faculties set up laboratories and start up research projects. Many plan to establish or expand facilities for developing animal models of diseases and biological processes, and some will purchase advanced equipment to study the three-dimensional structures of proteins and molecules. Other foundations, such as the Commonwealth Fund, are funding studies to determine how research is being affected by changes in health care markets.

IV. Regional and Institutional Variations in the Impact of Managed Care

Several key variables affect how extensively AHCs and clinical researchers experience the impacts of managed care. These include the speed of managed care penetration, availability of AHC cash reserves, and the success of AHCs in introducing and implementing effective administrative cost controls.[18]

Within the overall national growth of managed care, there remains substantial variation in enrollment across geographic areas. As shown in the attached maps, managed care penetration was lower in the southern and central U.S. and higher on the west coast and the northeast in both 1988 and 1993. The University-Health Systems Consortium (UHC) has developed a descriptive model capable of systematically assessing the degree of penetration of managed care into specific, local markets. The model suggests that local health care markets evolve in four stages.

- In **Stage I**, the market is "unstructured," relying primarily on traditional insurance reimbursing on a fee-for-service basis. As of 1995, UHC found that many Midwestern and southern cities fell into this category. They included: Omaha, Nebraska; Syracuse, New York; Little Rock, Arkansas; Gainesville, Florida; Chapel Hill, Winston-Salem, and Greenville in North Carolina; Charleston, South Carolina; Birmingham, Alabama; Augusta, Georgia; Shreveport, Louisiana; and Iowa City, Iowa.

- In **Stage II** of the UHC model, managed care networks appear and grow, hospitals link into provider networks, and insurance companies and self-insured companies try to negotiate discounts. The traditional reliance of AHCs on referrals from local physicians is viable only in these first two stages. In 1995, UHC estimated that about 28 cities were in Stage II. Larger cities in the east, south, and the midwest were included. For example, Cleveland and Columbus, Ohio; Hartford, Connecticut; New York City, New York; Pittsburgh and Philadelphia, Pennsylvania; Atlanta, Georgia; and Orlando and Jacksonville, Florida, were viewed as being in this stage of market penetration.

- In **Stage III**, enrollment in managed care accelerates, primary care physicians manage resources, use of specialists diminishes, and physicians' fees are reduced. According to UHC, about 20 cities, predominantly in the west, fell into this category. Major California cities, including San Francisco, Sacramento, San Jose, and Riverside were at this stage, as well as Portland, Oregon; Seattle, Washington; and Phoenix, Arizona. In addition, a few eastern cities, including Washington, D.C., and Providence, Rhode Island, were included.

- In **Stage IV** of the UHC model, managed competition dominates the market, capitation (a limited monthly payment for all of a patient's health care) is the most common form of payment for health care, and there are vertically integrated hospital and physician systems. In 1995, only four cities--Minneapolis, Minnesota; San Diego, California; Los Angeles, California; and Worcester, Massachusetts--fell into this category.

AHCs located in metropolitan areas where managed care penetration is at a Stage I or II level have felt relatively modest impacts from managed care and have had more time to prepare creative responses. For example, interviews in Atlanta in 1994 indicated that medical school faculty practice plans at Emory and Morehouse had many opportunities to ally with existing MCOs or to develop their own networks. At that time, managed care penetration was only 14 percent, and MCOs expressed a willingness to work with AHCs and allow them to help shape future managed care networks.[19]

The differences between Stages II and III are illustrated in recent case studies of Ann Arbor, Michigan, and Philadelphia, Pennsylvania. As managed care grows in southeastern Michigan, the authors of one study forecast that the University of Michigan Medical Center[20] would be unlikely to be able to obtain enough patients to sustain its 1992 level of medical school faculty with its 1992 mix of specialties. The authors of this analysis predicted that AHCs may be forced into "downplaying teaching and research in order to focus on clinical efficiency." However, this study

was primarily a projection of future trends. In contrast, when Iglehart applied the UHC model to the Philadelphia health care market, he found that the area was rapidly moving into Stage III and that local AHCs were responding by scrambling to form their own, or become part of, managed care networks. [21]

The experience of researchers at National Cancer Institute-supported Clinical Research Centers reflects these variations. The Centers most affected by market-driven reform have been those located in regions with the highest managed care penetration. For example, the southern California region has close to an 80 percent penetration rate of managed care payers. As a result, cancer researchers at the Beckman Research Institute/City of Hope, the University of California at San Diego, the University of California at Los Angeles, and the University of Southern California have acutely felt the effects of managed care on clinical research. All report that the process of enrolling patients in clinical trials has become significantly more labor-intensive.

In addition to regional variations, the differing impact of managed care is influenced by the overall financial position of the AHC. As AHCs respond to managed care, often by developing their own managed care networks, they require capital to purchase or contract with local hospitals and physicians. Publicly-funded AHCs typically lack cash reserves, as excess operating revenues must be returned to the State. In contrast, large private AHCs have experience with fundraising and some have comfortable cash reserves. AHCs with relatively larger cash reserves not only will be better positioned to pursue such strategies as developing their own managed care networks, but will also be better able to continue research activities for a time in the face of declining revenues from faculty practice plans. On the other hand, public or private AHCs, whose teaching hospitals serve a large number of poor, inner-city clients, will face particular difficulty maintaining research programs in the face of declining revenues.

V. Future Outlook

Forecasting the impact of managed care on medical research is difficult because the current situation is so unsettled and uniform data is not readily available. Comparable reporting systems are just now being considered across AHCs that will track the costs associated with research and sources of support. Lacking such hard data, information that can be used in anticipating future directions must be gleaned from a variety of anecdotal case studies and survey data (see references 5-10 and 18-22). Nevertheless, some prognoses are possible.

Reports from the field indicate that reduced revenues from faculty practice plans have already substantially reduced funds for unsponsored research. The $1 billion currently spent by AHCs to support young scientists engaged in research at a preliminary stage appears to be eroding.[22] This is of great concern because beginning medical researchers usually require a lab, technicians, and some preliminary research in order to get a grant from NIH. Thus, reduced funds are expected to affect the pool of young researchers.

Although national-level data, from a few years ago, suggest that growth in medical school revenues has continued to outrace expenses, more recent data point to a reversal of this pattern. For example, in fiscal year 1997, Johns Hopkins' medical school is expected to experience an absolute decline in faculty practice plan revenues for the first time.

Another cause for concern is the possibility of drastic reductions in Medicare and Medicaid, which pay for a large and growing proportion of fees charged by faculty practice plans and AHC hospitals. This is especially critical, since Medicare supports AHC hospitals by providing both direct medical education payments for every resident and indirect medical education payments for every patient.

Hospital mergers have become a national trend, as AHCs from New England to San Francisco are combining to reduce costs and improve operating efficiency. This increased emphasis on the "bottom line" could potentially affect the amount and type of research that is conducted. Since the 1993 merger of Philadelphia's Medical College of Pennsylvania and Hahnemann University, the number of mergers has substantially increased. The New York City health market, home to many AHCs, has experienced rapid change within the past six months, with many recent mergers. Among these, only the planned merger between New York University Medical Center and Mt. Sinai Medical Center is designed with the explicit goal of maintaining research activities, by attracting more paying patients and more public and private funding.[23] Last year, on the west coast, Stanford University Health Services and the University of California at San Francisco initiated talks, while the Oregon Health Sciences University ceased to function as a State agency and became a public corporation. The latter marks the first time that an entire AHC--medical, dental, and nursing schools and attendant research facilities--undertook such a move. The principal aim of the restructuring was to substantially reduce operational overhead, making the facility more competitive in a managed care environment. Over the next decade, many more mergers are anticipated.

In the long run, whatever strategies AHCs adopt to survive, whether through mergers, development of their own managed care networks, or cost containment, the growth of managed care can be expected to have an impact on the research focus of AHCs. Investigators may become increasingly tuned to "what the payers are willing to pay for."[24] For example, to survive in the current economic climate, AHCs and medical schools may become increasingly involved in population-based studies, and Phase II and III clinical trials may shift toward more commonly occurring conditions or toward conditions of primary interest to drug companies. A greater focus may be placed on research measuring patient outcomes, on the management of chronic diseases, and on establishing more cost-effective methods of care, mirroring the research emphases of the for-profit managed care industry. This could result in less emphasis on studies elucidating the course and mechanisms of disease as well as less emphasis on the development of new therapeutic agents, i.e., in lower overall levels of so-called "translational" research. In the short term, this orientation could slow the development of new treatments of many diseases; in the long term, reduced research capacity could substantially slow the infusion of, or even reverse, many of the public health improvements already achieved.

VI. Policy Issues

The link between medical research and improved health is more direct than ever before, with basic and clinical research providing the basis for a constant infusion of new preventive strategies and innovative treatments into the health care system. Today, even as an aging U.S. population faces new health threats, including chronic diseases and emerging infectious diseases, research that illuminates the causes of disease and leads to new therapeutic strategies stands in peril of being lost.

Recognizing the need to address the many problems facing clinical research specifically, the NIH Director convened a special Panel on the future of clinical research in May 1995. Chaired by Dr. David Nathan, President of the Dana-Farber Cancer Institute of Boston, the Panel has also taken on the issue of the rapid growth of managed care and its impact upon clinical research. The Panel identified several policy options aimed at sustaining clinical research, including programs which would make clinical research careers more attractive to young physicians and strategies to strengthen the GCRCs abilities to address the new challenges. While all of these policy alternatives mights help to encourage clinical research, funding remains a major factor in the continued viability of the national clinical research enterprise. Several policy issues emerge that need to be addressed by the stake-holders and beneficiaries of clinical research. These include:

- If clinical research is considered a "public good," does there need to be a revision of traditional fiscal roles of the various stakeholders in support of clinical research? What should be the role of the Executive and Legislative Branches of the Federal government, the managed care industry, the pharmaceutical industry, private foundations?

- Should the Federal government mandate increase fiscal support from private industry in the form of a tax on premiums or initiate tax credits? Should pharmaceutical firms, beneficiaries of the Federally-supported research training programs, be required to underwrite the training of basic and clinical researchers?

- If medical research is acknowledged to be a "public good," should the Federal government (e.g., medicare, medicaid) provide additional support for AHCs to offset revenues from other sources?

These are difficult, but very real, policy issues that must be addressed in the near future. The financing and delivery of the nation's health care are changing rapidly. The time to fully analyze the effect of these changes is being constricted in the face of the pressing need to develop solutions. Depending upon the answers, this Nation may need to face a major change in how (or if) the contributions of medical research will be employed to improve human health.

APPENDIX

I. Consolidation in the Managed Care Industry

In order to gain market share and increase profits, MCOs and insurance companies are going through a wave of mergers and acquisitions. Once small new MCOs attain a size of between 50 and 100 thousand enrollees, they rapidly become prime candidates for acquisition by larger MCOs. In what seems to be something of a trend, managed care companies have recently begun to aquire insurance companies with large numbers of customers in traditional lines of fee-for-service coverage. In such instances, the insurers also hope to broaden their appeal to employers by offering a broader variety of products -- with the aim of eventually converting their customers to managed care, under which, both the payer's costs are lower, and the insurer's profits higher. For instance, in 1995, United Healthcare Corporation, a large Minneapolis-base MCO, purchased Metrahealth, (a joint health insurance venture of the Metropolitan Life Insurance Company and of the Travelers Life Insurance Company) in a deal valued at $1.65 billion. Smaller acquisitions of insurance companies by HMOs included the purchase of Massachusetts Mutual Life Insurance Company by California-based Wellpoint Health Networks; the purchase of Emphesus Financial Group of Green Bay, Wisconsin, by Humana, Inc., of Louisville, Kentucky, and the purchase of the Provident Life and Accident Insurance Company of Chattanooga, Tennessee, by HealthSource, based in Concord, New Hampshire. While some Wall Street analysts had earlier predicted that HMOs would constitute a short-lived fad, ultimately to be taken over by the insurance companies, it now appears, at least in these instances, that the little fish ate the big fish.

The largest purchase of 1995, however, reversed this scenario when Aetna Life and Casualty Company, an old-line insurance company, purchased U.S. Healthcare, Inc., for the sum of $8.9 billion.[25] Aetna purchased U.S. Healthcare after divesting itself of its property and casualty business in order to focus on the more profitable business of managed health care and after an extensive search for the best HMO which could provide Aetna with state-of-the-art information technology, aggressive marketing, and excellent skills in controlling medical costs. U.S. Healthcare had healthy profits based on its expertise in tracking the detailed performance of physicians and hospitals, penalizing those scored as wasteful and financially rewarding those whose quality scores were high. This expertise stands in sharp contrast to the lack of strong cost accounting and management systems in Academic Health Centers.

While Aetna had installed many managed care features into its health-insurance plans, it lagged in the development of HMOs. Although it could have tried building more HMO networks on its own, such a strategy would have been slow going at best, in a marketplace that was moving very fast. Aetna, like other conventional health insurers, had been slow to catch onto the popularity of HMOs, thereby allowing smaller companies to gain crucial early footholds in the market. But even when Aetna began establishing HMOs, the mindset of management remained, as it had historically been, to collect premiums, invest, and pay claims. In contrast, the mindset of new,

cutting-edge HMOs, to closely monitor physician and hospital performance using intensive data crunching, represented a new, highly aggressive, totally different way of doing business, which Aetna felt it needed to learn.

Aetna became determined to acquire a company with state-of-the-art information technology, aggressive marketing and excellent management skills to control medical costs. U.S. Healthcare seemingly fit the bill. Its profits had been amongst the industry's most robust: Last year, it posted a net income of $380.7 million on revenue of $3.61 billion in sharp contrast to Aetna's health care segment, which had reported a net of $286 million on revenue of $7.6 billion. At the same time, U.S. Healthcare's membership is rapidly expanding (by 25 percent over last year in New Jersey, 19 percent in New York, and 20 percent in Pennsylvania) and it has been highly successful in the new and growing area of providing HMOs to Medicare recipients. However, because U.S. Healthcare has been concentrated in the northeast, by joining forces with Aetna, U.S. Healthcare now will gain the strategic advantage of access to Aetna's employer business. Thus, U.S. Healthcare, which already has networks with 12,000 primary care doctors in 13 states, will now be able to form combinations with Aetna in an additional 21 states where the Hartford-based insurer has 20,000 primary care physicians in its networks. This is important, because historically, independent HMOs have had a very difficult time reaching out beyond their own geographic boundaries, in order to provide services to national accounts.

Renowned for tightly controlling medical costs, U.S. Healthcare keeps a significantly larger percentage of every premium dollar (between fifteen to twenty cents, versus five cents, for example, for Kaiser Permanente) than do its peers. It manages this by zealously tracking the detailed performance of physicians and hospitals, penalizing those scored as wasteful and financially rewarding those whose quality scores are high. Like other managed care companies, it has designed proprietary practice guidelines tied to financial incentives which go far beyond what is clinically indicated in traditional fee-for-service medical settings. What is unusual about U.S. Healthcare, however, is the degree of assiduousness with which they pursue their goals. For instance, the company has hired more than one hundred physicians on the management side alone, in order to continue to develop and refine assessment and treatment guidelines, and to devise ever more accurate and efficient ways of tracking them. The treatment algorithms the company has already developed are entirely resource based, such that the lowest cost procedure or agent gets specified as "most preferred." The guidelines integrate the variable of financial consideration into each and every clinical decision to be made in the health care arena. Financial awards accrue to those physicians who utilize the least expensive alternatives and who earn the most favorable ratings by patients. Many physicians have bridled under U.S. Healthcare's tight monitoring of medical decisionmaking among providers in its network, and may not applaud the company's vastly strengthened position.

II. The Role of Managed Care in Support of Research

The early non-profit staff model HMOs like Kaiser and Group Health of Puget Sound have long been committed to clinical, epidemiologic and outcomes research and have heavily invested in the

development of a clinical research infrastructure. For example, in 1995, Kaiser Permanente spent a total of $8.3 million on research projects in its Southern California region.[26] Eighty percent of funds for the conduct of specific projects were derived from federal and private foundation grants ($3.4 million supported 18 projects) and from pharmaceutical companies and equipment manufacturers ($3.7 million supporting 30 projects). The Kaiser Foundation Hospitals sponsored ten clinical research groups in 1995, including Cardiology, Cardiovascular Surgery, Urology, Pharmacy and Pharmacoeconomics, Allergy, Orthopedics, and Vaccine Studies. The NCI sponsors Kaiser's Community Cooperative Oncology Program and Cooperative Pediatric Cancer Group, and NHLBI sponsors Kaiser's Childhood Asthma Management research program. In 1995, in its Southern California region alone, Kaiser investigators published more than 165 scientific papers in well refereed research journals.

In 1995, under auspices of the Centers for Disease Control (CDC) and secondarily the Agency for Health Care Policy Research (AHCPR), a larger group of similar, primarily non-profit, HMOs with strong research interests and investments were brought together to form "The HMO Research Network." The network has staged two national research conferences and is presently exploring issues pertaining to collaborative multi-site studies, information system cross-walks, the staging of clinical trials, and potential collaborative ventures with private, for-profit sponsors, including pharmaceutical and biotechnology companies. Together with the trade association representing the MCO industry--the American Association of Health Plans (AAHP)--the HMO Research Network has been awarded two CDC contracts to develop research linkages with Public Health Service agencies and the private sector.

Responding to changes in the health care market, in recent years, NIH has broadened its extramural research portfolio to include managed care organizations as well as AHCs. In addition to the many NIH-funded clinical research projects at Kaiser, Puget Sound HMO currently conducts research projects funded by NCI, NHLBI, NIA, NIAAA and NIMH.[27] Most MCO research projects are population-based studies of outcomes and cost-effectiveness. For example, Group Health Cooperative of Puget Sound is systematically reviewing the geriatric and chronic disease literature to identify the most cost-effective programs for elderly care. Kaiser Permanente in northern California is using internal pharmacological data bases to study the effectiveness of combined hormone replacement surgery in reducing the risk of breast cancer.

Newer, for-profit MCOs have also expressed an interest in supporting research and NIH has held initial discussions with the industry about their interest.

ENDNOTES

1. Managed Care Organizations (MCOs) take a variety of forms, but share the common goal of containing health care costs through such techniques as relying on primary care physicians and limiting hospital stays. A Health Maintenance Organization (HMO) is a type of MCO which controls health care costs tightly by providing or arranging for comprehensive care.

2. Milton Freudenheim, "Health Care in the Era of Capitalism," The New York Times, April 7, 1996. Earlier estimates of total HMO enrollment, in 1994 and 1995, ranged from 51-53 million.

3. Milton Freudenheim, "Health Care in the Era of Capitalism," The New York Times, April 7, 1996.

4. Academic Health Centers are generally made up of a medical school, a faculty practice plan, outpatient clinics, and a teaching hospital.

5. Janice L. Ganem, et al., "Review of US Medical School Finances, 1993-1994," Journal of the American Medical Association, Vol. 274, no. 9 (September 6, 1995).

6. Robert F. Jones and Susan C. Sanderson, "Clinical Revenues Used to Support the Academic Mission of Medical Schools, 1992-93, "Academic Medicine, Vol. 71, No. 3 (March 1996), pp. 300-307.

7. James Reuter et al., "HMOs' Use of Academic Health Centers," IWP #96-103 (Washington, DC: Institute for Health Care Research and Policy, March 1996), p. 1.

8. Other studies suggesting that MCOs are unwilling to pay the higher fees traditionally charged by AHC doctors and hospitals include: D. Blumenthal, G. Meyer, "The Response of Academic Health Centers to Health Care Reform," presentation at the Association of Academic Health Centers Meeting, October 1994; Richard Culbertson, "Policy implications for future viability of clinical service, education and research," A Report to the Robert Wood Johnson Foundation; and MR Gold et al., "Financing of Academic Medical Centers and Graduate Medical Education Under Competitive Systems with Managed Care, Vol. 1, II. (Mathematica Policy Research, Inc., 1994).

9. James Reuter et al., "HMOs' Use of Academic Health Centers," IWP #96-103 (Washington, DC: Institute for Health Care Research and Policy, March 1996), p. 1.

10. Robert Mechanic, et al., "The Impact of Managed Care on Clinical Research: A Preliminary Investigation," (Lewin-VHI, Inc., January 1996), p. 13. For example, one researcher reported having trouble enrolling patients into a Phase I study to treat ovarian cancer, and another said that some patients participating in a Phase II trial for colon cancer, which required an annual colonoscopy for five years following treatment, were not receiving the follow-up tests because MCO reviewers felt it was medically unnecessary.

11. George Anders, "More Insurers Pay for Care That's in Trials," The Wall Street Journal, February 15, 1994.

12. National Institutes of Health, U.S. Department of Health and Human Service, Third-Party Reimbursement Policies for Clinical Trials: Survey Report (Bethesda, MD: NIH, 1995).

13. U.S. Department of Health and Human Services, NIH Data Book 1994 (Bethesda, MD: NIH, March 1995).

14. Unpublished NIH data.

15. E.S. Browning, "Change in Health Care Shakes Up the Business of Drug Development, " The Wall Street Journal, March 28, 1995, p. A1; "Many Drug Companies Scale Back Research In New Cost Climate," The Wall Street Journal, March 28, 1995, p. A-10.

16. University Health System Consortium's Clinical Practice Advancement Center: Clinical Research Program (unpublished view graphs, copyright 1995).

17. U.S. Department of Health and Human Services, NIH Data Book 1994 (Bethesda, MD: NIH, March 1995).

18. Blumenthal, D. and Meyer, G. S., "Academic Health Centers in a Changing Health Care Environment: Results of Seven Case Studies," (unpublished paper from the Health Policy Research and Development Unit, Massachusetts General Hospital, Boston, MA, January 5, 1996).

19. Richard Culbertson, "Comparison of Contracting Attributes in Maturing United States Health Care Markets," A Report to the Robert Wood Johnson Foundation, November 1995.

20. John E. Billi, et al., "Potential Effects of Managed Care on Specialty Practice at a University Medical Center," The New England Journal of Medicine, vol. 333, no. 15 (October 12, 1995).

21. John Iglehart, "Academic Medical Centers Enter the Market: The Case of Philadelphia," New England Journal of Medicine, vol. 333, no. 15 (October 12, 1995).

22. Spencer Rich, "New Frugality of Health Care Hurts Research Funding, Medical Schools Say," The Washington Post, Sunday, August 18, 1996, p. A6.

23. Esther B. Fein, "Medical Monolith for City's Future," The New York Times, June 16, 1996, p. 1.

24. Robert Mechanic, et al., "The Impact of Managed Care on Clinical Research: A Preliminary Investigation," (Lewin-VHI, Inc., January 1996).

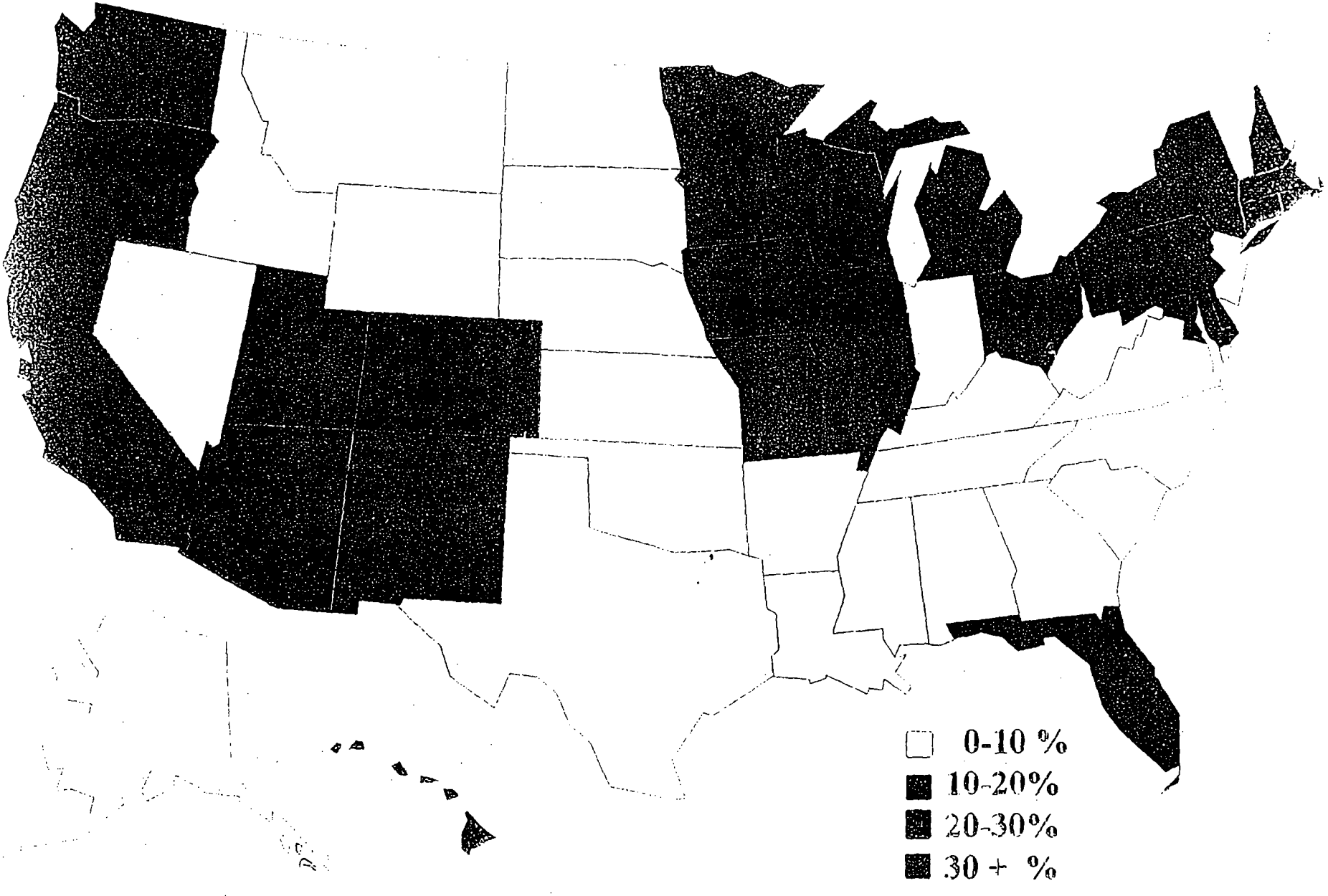
25. This discussion is drawn from the following sources: Leslie Scism and Steven Lipin, "Aetna Near $8 Billion Deal To Acquire U.S. Healthcare," The Wall Street Journal, April 1, 1996;

Leslie Eaton, "Aetna to Buy U.S. Healthcare in Big Move to Managed Care," The New York Times, April 2, 1996; Ron Winslow and Leslie Scism: "Aetna Agrees to Acquire U.S. Healthcare," The Wall Street Journal, April 2, 1996.

26. Kaiser Permanente, 1995

27. "HMO Research Network Conference Research Center Questionnaire," unpublished mimeo from the 1996 HMO Research Network Conference held in Bloomington, Minnesota, June 7 and 8, 1996.

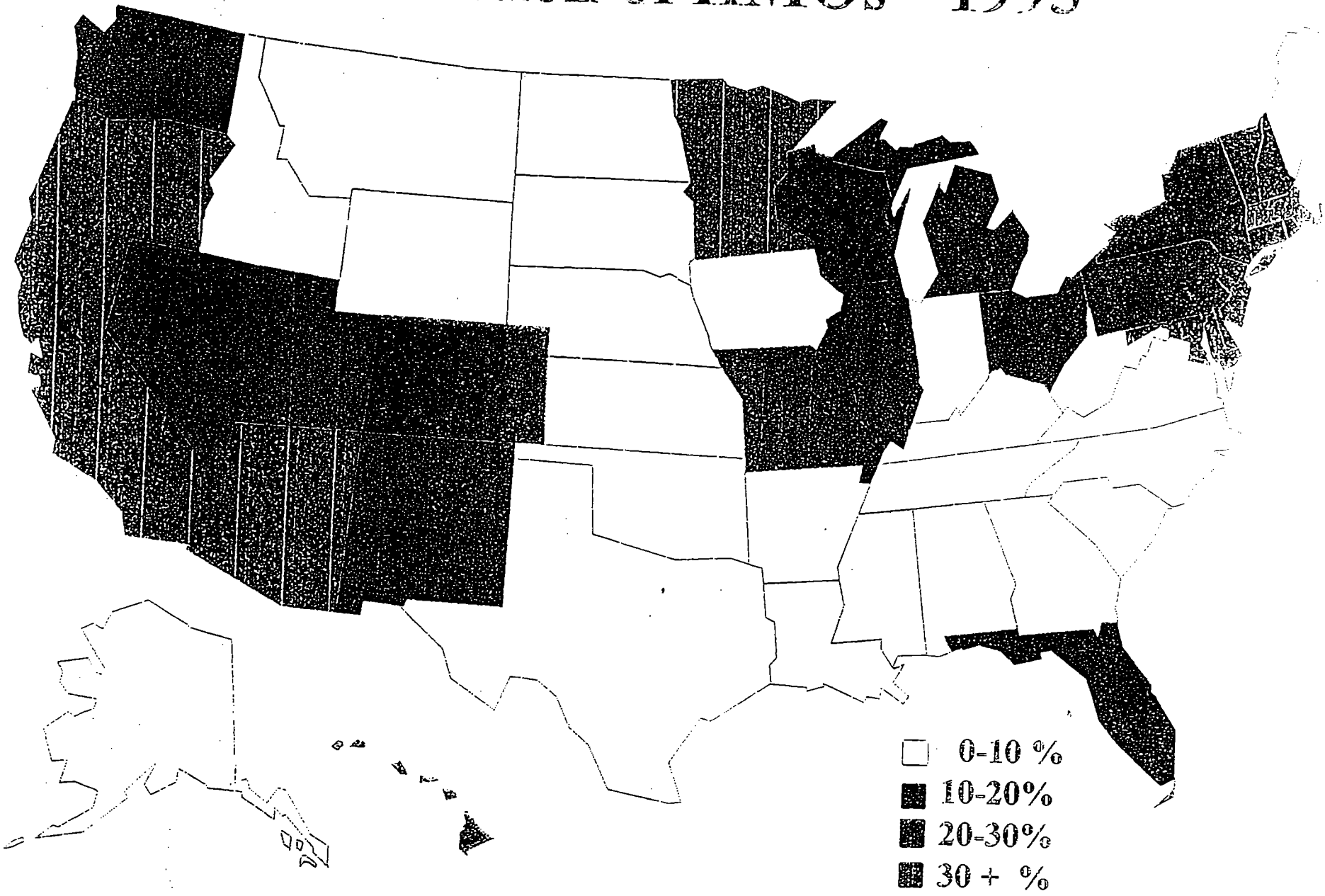
Penetration of HMOs - 1988



HMO Penetration, 1988 (by percent)

Sources: InterStudy, Group Health Association of America, Bureau of Census

Penetration of HMOs - 1993



HMO Penetration, 1993 (by percent)

Sources: InterStudy, Group Health Association of America, Bureau of Census

New Frugality of Health Care Hurts Research F nding, Medical Schools Say

By Spencer Rich
Washington Post Staff Writer

By now, almost everyone has felt the way cost-conscious insurance companies and health maintenance organizations are changing the practice of medicine in America. But medical school officials say the new frugality is having another, less visible effect: It is gradually eating away at the money available for front-line medical research.

HMOs and insurers are sharply reducing the fees they pay university hospitals and medical school doctors, which in turn shrinks the amount of "discretionary" revenue available to support promising scientists.

Across the nation, such funds total nearly $1 billion a year—an amount equal to about one-tenth of all the grants awarded annually by the National Institutes of Health.

"It's definitely a problem," said NIH Director Harold Varmus, who has appointed a committee to investigate the issue and named David Nathan, president of the Dana-Farber Cancer Institute of Boston, to head the study.

"The managed care industry has seriously injured research," Nathan said, but "it's not a conspiracy"—simply an unintended byproduct of efforts to reduce medical care costs.

Even preeminent institutions are feeling the strain. William Agnew, physiology chairman at Johns Hopkins's medical school, said that in each of the past three years, his department has lost about 25 percent of the funds it uses as seed money for cutting-edge research.

One recipient is cell biologist Jan Hoh, who is working on a technique he hopes will allow scientists to identify the characteristics of a piece of DNA in the same way a grocery store scanner uses a bar code to identify a product, improving screening for inherited diseases. Hoh's research so far has been funded principally by a commitment totaling $250,000 over three years from Agnew's discretionary fund.

The money that supports Hoh and scores of others around the country is generated by academic health centers, typically a medical school and associated hospital, whose faculty members are on salary. When those physicians treat patients, all or most of the fees—normally about the same as private-practice doctors in the area—are turned over to the medical school. Such arrangements are called "clinical practice plans."

The medical school uses some of the funds generated by practice plans to pay the salaries of faculty physicians, which are often considerably less than outside doctors earn. The funds are also used to cover teaching and other costs.

But a substantial portion at Johns Hopkins and elsewhere has been reserved to help fund basic laboratory research and clinical research (that is, research conducted on patients). In some cases, general hospital funds may also be used, and they too are becoming more scarce.

At Hopkins, Agnew said he now must use virtually all his latest allocation to maintain faculty salaries in his department. At the same time, as fee levels shrink, faculty members must devote more of their work week to bringing in the same amount of revenue, leaving less time for their own research.

Richard Grossi, Hopkins's chief financial officer, said the medical school's total revenue from faculty clinical practice plans has been rising nominally in recent years but for several years has not kept up with inflation. In fiscal 1997, he said, it will show an absolute decline.

"This is because of pressure from insurers for discounts," he said. "They don't even pressure you. They just say we're going to pay you less."

Hopkins's experience is not unique, said David Blake, senior vice president for biomedical research with the Association of American Medical Colleges, the umbrella group for the nation's medical schools.

The total of national collections from practice plans—which contributed $816 million in academic year 1992-93 to medical school research, according to an AAMC study—has been rising nominally until recently. But in the last year or so, Blake said, "the rate of increase in income from practice plans has dropped to below the rate of inflation in many institutions and is becoming negative in many cases."

"We've depended on clinical surpluses in the past to subsidize our research," said John Eisenberg, chairman of the department of medicine at Georgetown University Medical Center. "Those surpluses are decreasing. . . . Either another source of funds has to be identified or the research and teaching missions will be compromised."

Representatives of the American Association of Health Plans, a trade organization of the nation's health maintenance plans, argue that the research situation is not nearly as

imperiled as medical schools claim. They say many HMOs do considerable research with their own patients outside of a medical school or hospital setting, and are paying for many clinical trials in medical schools.

In addition, they say, HMOs are taking other steps that, in total, add up to at least $100 million and perhaps several hundred million dollars a year to support research. However, part of this goes for research on the organization and operation of health plans, not on the science of medicine.

A study conducted for NIH by the Lewin Group, a health policy analysis firm, concluded that "site visits conducted for this study suggest that managed care has had a limited impact on clinical research to date, but that the economic forces facing academic medical centers may substantially affect future clinical research."

Much of the effect involves "the way the money is used," said Eugene Braunwald, who will shortly become vice president for academic programs and faculty dean for academic programs at Partners for HealthCare, Harvard medical school.

A beginning researcher often cannot get an NIH grant immediately when he joins a medical school, he said. Usually, in order to get a grant from NIH, "you must have a structure and infrastructure—a lab, technicians and some indications it's good research," Braunwald said.

That's where seed money has real impact, he said, enabling institutions to bring along promising new researchers until they establish a record that will lead to an NIH grant.

The problem, Braunwald said, is that all this costs major research medical schools and hospitals lots of money at a time when insurers are looking for the best bargain on the cost of care.

"You've got to compete with community hospitals that don't do research" and can deliver routine care for a lower price, he said.

One possible solution to the problem is to add a special fee to health insurance premiums. In June, Sen. Daniel Patrick Moynihan (D-N.Y.) proposed a 1.5 percent fee, endorsed by the AAMC, the proceeds of which would be used for medical research and training. But Varmus and Nathan said they are not ready to support that.

In July, Nathan revealed several tentative committee recommendations: Help new graduates pay off huge accumulated medical school bills so they can afford to stay in clinical research, which is not highly paid; provide mid-career salary support for clinical researchers; and persuade the managed care and pharmaceutical industries to channel more money voluntarily into research done in medical schools.

Whatever the outcome of that debate, many physicians said, some kinds of research will still face another problem from insurers that are increasingly reluctant to pay for treatments that involve experimentation.

"Anything that smacks of being 'investigative' or 'research' they try to disallow," declaring that they will only pay for standard care, which usually is much cheaper and in many cases much less likely to help the patient, said Richard Jones, a Johns Hopkins physician who directs bone marrow transplant programs and is working on use of such transplants in leukemia treatment.

In the past, he said, insurers were much more flexible; now some balk at paying the bills for patients who are participating in formal, peer-reviewed clinical trials of promising but often expensive treatments.

Right now, Jones is focusing on ways to use transplants of a patient's own bone marrow (called autologous transplants) to help treat a disease called chronic myeloid leukemia, a blood cancer that he says is "uniformly fatal at an average of four years after diagnosis." Often very high doses of chemotherapy are needed to kill the cancer, but "too much chemotherapy would irreversibly damage the patient's cells."

In the autologous procedure, some marrow is drawn before chemotherapy and then implanted later. So far that method "does prolong life, but has not been curative," Jones said, "but we have no doubt it will be," based on laboratory findings and development of new techniques.

The problem is that the cost for an autologous procedure and follow-up hospital care can be in the range of $150,000 or more. Many insurers are unwilling to pay for it, calling it experimental; whereas they will approve conventional chemotherapy that can cost a few thousand dollars.

"Right now we have three patients we are trying to get the insurer to pay for," Jones said. "In each case they will only pay for standard treatments but not autologous."

Talmadge King and associate Cecile Rose, physicians working on lung problems at the National Jewish Center for Immunology and Respiratory Medicine in Denver, face similar problems in their work on pulmonary fibrosis, a condition in which the lung shrinks in size.

"Since 1980 I've been funded by NIH, but it's not enough money [to cover all the expenses of treatment] since clinical care is so costly," King said.

One unconventional technique King and Rose use is "lung-washing," which involves injecting a saline solution into the lung, "washing the internal surface" with it, then withdrawing the fluid and examining it under a microscope to determine conditions in the interior of the lung. "You don't need a biopsy," Rose said.

The NIH has paid for much of the cost, but there are added costs for X-rays, CAT scans, blood tests and lung-function tests that are performed before and after the washing.

In the past, the patients paid for the extra costs through insurance or Medicare and Medicaid, said King. Of late, however, the insurance companies "are separating us out as if we're enemies," he said.

He said insurers are challenging requests to pay for added CAT scans, pulmonary tests and X-rays, even when tests and X-rays the patients brought with them from their referring doctors "are not good enough to answer various scientific questions and perhaps not good enough to distinguish between various versions of the disease they might have and its severity."

This is true, he said, even though "mostly what we do is needed to care for the patient."

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Jordan J. Cohen, M.D., President

February 7, 1996

The Honorable William J. Clinton
The White House
Washington, DC 20500

Dear Mr. President:

On behalf of the Association of American Medical Colleges, I want to express my deep appreciation for the willingness of the Administration to support policies that will help preserve the quality of American medicine. We have engaged in extensive conversations with your staff, and the Medicare proposals of particular interest to academic medicine that have been developed will assure that Medicare continues to make a fair contribution to the cost of medical education, medical research, and the care for the most seriously ill and disadvantaged senior citizens. In addition to the unique needs and costs faced by academic medicine, the ability of these institutions to fulfill their responsibilities is dependent on changes in the overall health care system and on the adequacy of basic Medicare and Medicaid reimbursement. We also appreciate the sensitivity you have shown toward these issues.

Among the key policies of concern to academic medicine that we understand the Administration will be supporting are:

- payments for the special missions of academic medicine (indirect and direct medical education and disproportionate share) will be completely removed from the calculation of the adjusted average per capita cost (AAPCC) payment methodology and paid directly to hospitals (or other appropriate entities) as originally intended;
- the current methodology for counting residents for the purpose of determining indirect medical education (IME) payments will be retained;
- updates for direct medical education payments will be made for all residency positions;
- no reductions will be made in disproportionate share (DSH) payments; and
- a National Commission on Medical Education and Workforce Priorities will be established.

We strongly endorse each of these policy positions. While we understand that final resolution of these issues will influence the specific level at which Medicare IME payments can be supported, we urge you to keep those payments at the highest level possible to enable teaching hospitals, and indeed all elements of academic medicine, to continue to assure that our country will offer the best health care in the world.

We are especially pleased that the Administration proposal modifies the method used by Medicare to determine the Adjusted Average Per Capita Cost calculation. This issue, of enormous importance to academic medicine, will increase in significance as Medicare beneficiary participation in managed care grows. The Administration proposal helps ensure Medicare's continued support of teaching hospitals' special missions. The AAMC has consistently advocated that graduate medical education, as well as the other societal missions of medical schools and teaching hospitals, be a shared responsibility of all organizations responsible for making payments for hospitals, health, and medical services on behalf of their enrollees. This commitment should include Medicare, regardless of whether Medicare patients remain in the traditional fee-for-service system or choose risk-based HMOs. The Administration AAPCC proposal ensures Medicare participation in "shared responsibility" by requiring that Medicare payments for the teaching mission go to entities that incur the costs of teaching.

In the long run, assuring healthy teaching hospitals and medical schools and high quality medical care for the American people will require a formal mechanism to assure that the private sector and the Medicaid program continue to support teaching and research, and care for the most seriously ill patients. It is for this reason the AAMC supports a graduate medical education trust fund.

Mr. President, the AAMC is grateful for your consistent support of academic medicine, and your ongoing commitment to continued American preeminence in medical education, research, and patient care. Your budget proposal clearly reflects that commitment, and we stand ready to work with you toward our mutual goal.

Sincerely yours,

Jordan J. Cohen, M.D.

Draft, 01/11/96, 4 p.m.

Estimate of CBO pricing of Major Medicare Proposals that Affect Academic Health Centers and Teaching Hospitals (in billions, 7-year totals)

Proposals	President/ Daschle	Republican Conference[1]
Update Reduction[2]	-7.1	-15.4
Indirect Medical Education (IME) Adjustment Reduction	-6.5	-11.5
Graduate Medical Education (GME) Reform[3] or DGME reduction	-3.1[4]	-1.4
Disproportionate Share Hospital (DSH) Adjustment Reduction[5]	-1.2	-3.6
AAPCC giveback of DGME/IME/DSH	+7.7 (100%, eff '98)	
GME Trust Fund (Questionable[6])		+13.5
Total Impact of Medicare Reductions	-10.2	-18.4

[1] Conference scoring does not include impact of failsafe reductions.

[2] Based on the proportion of hospital payments that go to teaching hospitals (52%).

[3] The elements of the GME reform package result in savings from both direct GME (57%) and indirect GME (43%).

[4] Does not include savings/cost estimate for provisions to count residents in non-hospital settings for purposes of IME and to pay DGME to non-hospital settings.

[5] Based on proportion of DSH payments that go to teaching hospitals (68%).

[6] The GME Trust Fund is funded through general revenue that are questionable and may not be permanent.

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TEACHING HOSPITALS AND ACADEMIC HEALTH CENTERS
December 6, 1995

CURRENT LAW:

- Medicare reimburses hospitals for the direct costs of graduate medical education (DGME) based on a hospital-specific per resident amount (an estimate of the average cost of training a resident in that hospital), the number of residents being trained, and the volume of Medicare patients served by the hospital. The FTE count of residents is weighted according to how many residents are in their initial residency (before they receive their first certification) or beyond their initial residency.

- Medicare reimburses hospitals for the indirect costs of graduate medical education (IME) with an adjustment that is based on a hospitals interns and residents-to-bed (IRB) ratio. Basically, a hospital's DRG payments are increased by 7.7 percent for every 10 percent increase in the hospital's (IRB) ratio.

- Payments to Medicare risk-contractors (AAPCC payments) include payments attributable to GME and DSH spending. Hospitals do not receive additional GME and DSH payments for Medicare risk-contract discharges.

PRESIDENT'S PROPOSAL:

IME Adjustment: Gradually reduces the IME adjustment to 6.0 percent (from 7.7 percent) over 7 years.

GME Reform: Changes the rules for reimbursing hospitals for the costs of medical education by capping the number of residents, not updating payments for specialty residents as much as for primary care residents, and increasing incentives for hospitals to place primary care residents in non-hospital settings. The changes would affect both IME and DGME payments.

Payments for Medicare Managed Care Discharges: Starting in 1998, removes GME (DGME and IME) and DSH payments from payments to Medicare risk-contractors. Pays 75 percent of this amount back to teaching and DSH hospitals and HMOs that contract with teaching hospitals or have their own medical education programs.

Establish the National Commission on Medical Education and Workforce Priorities. This Commission would advise the Secretary of HHS on issues relating to preserving the research and educational capacities of academic health centers and the future of the health care workforce.

REPUBLICAN PROPOSAL:

IME Adjustment: Gradually reduces the IME adjustment to 5.0 percent over a 4 year period.

DGME Payment Rules: Makes changes to the rules for reimbursing hospitals for the direct

costs of medical education by capping the number of residents, and decreasing payment for residents who are not in primary care training programs.

GME Trust Fund: Establishes the Teaching Hospital and Medical Education Trust Fund, which includes a large appropriation from general revenues. Apart from Medicare money, appropriated funds would primarily be distributed based on past patterns of Medicare payments to hospitals.

ANALYSIS:

The proposals in the President's Plan that would affect teaching hospitals and academic health centers (AHCs) would have a net savings of $4.2 billion according to the Administration's baseline. Teaching and DSH hospitals, AHCs, and risk-contractors with teaching programs would also share $6 billion in additional payments for GME and DSH for Medicare managed care beneficiaries. The Conference Agreement Proposals to change Medicare GME payment policies would save $9.0 billion according to CBO's baseline. However, the overall effect on the budget would be a cost of $4.5 billion if one takes into account the $13.5 billion appropriation to the Teaching Hospital and Medical Education Trust Fund. However, the future of the $13.5 billion appropriation is highly questionable.

The President's Plan offers several changes in the GME payment rules that would encourage slower growth in the number of medical residents and greater training of primary care residents, and also corrects the current inequity of teaching and DSH hospitals not receiving GME and DSH payments for Medicare managed care discharges. Although the Conference Agreement may protect the financial stability of teaching hospitals and academic health centers to some degree through the Trust Fund, the availability of this Trust Fund money and the implications of the rules regarding distribution of Trust Fund money do not ensure any protection for these hospitals. The Conference Agreement does not include any real incentives for changes in medical residency training.

Incentives for training Primary Care Doctors. Medicare payments to hospitals for graduate medical education currently provide little incentive for hospitals to limit their number of residents or train them in primary care. The Conference Agreement includes a few weak incentives for hospitals to limit their number of residents and encourage more primary care training. These incentives would have little or no effect given that the distribution of appropriated money is primarily based on past payments, and thus has little link to current behavior. The President's plan, on the other hand, explicitly caps the number of residents on a hospital-specific basis and creates several strong payment incentives for hospitals to encourage more primary care training.

Greater flexibility for Medicare GME payments. The President's plan also includes incentives for hospitals to place residents on non-hospital settings, training that is needed as a larger number of patients are being treated in managed care in less expensive settings. It would allow Medicare to pay certain non-hospital settings directly if they train medical residents. The Conference Agreement provides the opportunity for the Secretary to recognize and pay consortium of teaching facilities.

Weakens Links between Payments and Services. The method of distributing of money from the Trust Fund included in the Conference Agreement severely weakens the current links between payments and a hospital's costs and the volume of services it provides. This creates the potential for large inequities in payment as time passes.

Academic Health Center File

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The Medicare Preservation Act's Graduate Medical Education Reform Proposal: How the Teaching Hospital and GME Trust Fund Works

Summary: Beginning FY 1997 (October 1, 1996), the federal government would create a trust fund called the Teaching Hospital and Graduate Medical Education Trust Fund. The trust fund would derive its funding from two basic sources: appropriated general revenues and payments from the Medicare program. The trust fund would be subdivided into three separate and distinct accounts, each with its own funding level and payment methodology. The three accounts are: the Indirect Costs Medical Education Account; the Medicare Direct Costs Medical Education Account; and the General Direct Costs Medical Education Account.

In FY 1997, $1.3 billion in general revenues would be appropriated to the teaching hospital trust fund. In subsequent years, the following general revenues would be appropriated: $1.5 billion in FY 1998; $2.3 billion in FY 1999; $3.1 billion in FY 2000; $3.6 billion in FY 2001: and $4.0 billion in FY 2002. Starting FY 2003, the general revenues in the trust fund would be increased by the greater of the preceding year's appropriation or the amount appropriated for the preceding year times 1 plus the percentage increase in the nominal GDP.

Prior to FY 1997, teaching hospitals would continue to receive the two Medicare payments with an education label: the indirect medical education (IME) payment and the direct graduate medical education (DGME) payment. Beginning October 1, 1996, the Secretary of HHS would estimate annually what the Medicare program would have paid to teaching hospitals for IME and DGME and would transfer those amounts to the appropriate accounts in the trust fund. The estimates would be made subject to specified payment policy changes. The estimates would be affected by the extent to which Medicare beneficiaries enroll in Medicare Choice plans or choose other options and leave the fee-for-service payment system.

To receive payments from the three accounts in the trust fund, hospitals would submit payment documents to the Secretary of HHS through the Health Care Financing Administration (HCFA). Qualifying graduate medical education consortia (not described in detail in this summary) could receive payments from the Medicare Direct Costs Medical Education Account and the General Direct Costs Medical Education Account.

This analysis describes for each of the three accounts comprising the trust fund how funding would be provided to the account in each Federal fiscal year and how payments would be made from the account to the recipients.

1. The Indirect Costs Medical Education Account

How this Account Would Be Funded

FY 1996: No trust fund account exists. The Medicare program continues to make IME payments to hospitals using the prospective payment system's IME formula at the rate of 6.0 percent for every 10 percent increment in a hospital's resident-to-bed ratio (IRB).

FY 1997: This account is funded by general revenues from the U.S.Treasury and contributions from the Medicare program. General revenues (a portion of the $1.3 billion) are appropriated to this account. The portion transferred to this account is allocated based on the ratio of total Medicare IME payments to total DGME payments in FY 1994 (see note below). In addition, Medicare would transfer to this account an estimate of what the program would have paid during this year if it were still making IME payments under the prospective payment system using the 6.0 percent IME formula.

Note: For example, in FY 1994, IME payments were $3.8 billion and DGME payments were about $1.5 billion, or IME spending was 72 percent of the total of the two Medicare payments with an education label. Therefore, the IME account would get 72 percent of $1.3 billion in FY 1997, which would be $936 million. The remaining 28 percent, $364 million, would be allocated to the General Direct Costs Medical Education Account.

The projected annual Medicare IME contribution for its fee-for-service patients would be directly related to the extent to which national Medicare Choice enrollment increases. That is, each year the Medicare program would make its contribution to the Indirect Costs Account based on the number of enrollees who remain in the fee-for-service payment system ***and*** *who receive inpatient hospital services that are paid under the prospective payment system. As Medicare beneficiaries leave the fee-for-service system and join Medicare Choice Plans or participate in Medical Savings Accounts, which would pay hospitals for inpatient services using methods other than the prospective payment system, the Medicare program's transfer to this account and to the Medicare Direct Costs Medical Education Account would diminish.*

FY 1998: This account would receive 72 percent of $1.5 billion from general revenues, or $1.08 billion, plus the Medicare program's contribution for its fee-for-service patients calculated with the 6.0 percent IME formula.

FY 1999: In this fiscal year, this account would receive 72 percent of $2.3 billion, or $1.66 billion, plus the Medicare program's contribution for its fee-for-service patients using the 6.0 percent IME formula.

FY 2000: This account would receive 72 percent of $3.1 billion, or $2.23 billion, plus the Medicare contribution using the IME formula at the new and lower rate of 5.6 percent.

FY 2001: In this year, the account would receive 72 percent of $3.6 billion, or $2.59 billion, plus an amount from Medicare for its fee-for-service inpatient discharges that would be calculated using the 5.6 percent IME formula.

FY 2002: This account would receive 72 percent of $4.0 billion, or $2.88 billion, plus the Medicare contribution calculated with the IME formula at the rate of 5.6 percent.

How the Money in this Account Would Be Distributed

FY 1996: Hospitals receive Medicare IME payments for their fee-for-service discharges under the prospective payment system. The level of the IME adjustment would be 6.0 percent for every 10 percent increment in a hospital's resident-to-bed ratio.

FY 1997-FY 2002: Hospitals would receive a percentage of the money in the new Indirect Costs Medical Education Account. A hospital's percentage would be calculated as the mean average of the percentages of total IME that the hospital received in Fiscal Years 1992, 1993, and 1994. Payment would be made on an institution, not discharge, basis.

Note: The hospital's percentage would remain constant through FY 2002; only the amount available in the account for distribution would vary (see above).

2. **Medicare Direct Costs Medical Education Account**

How this Account Would Be Funded

The Medicare program would make a transfer to this account each fiscal year. Beginning in FY 1997, the contribution would be based on what the program would have paid hospitals in that year for direct graduate medical education (DGME) costs. The amount would be based on each hospital's per resident payment amount, but rules for counting full-time equivalent (FTE) residents would be subject to the following policy changes:

- FY 1996-FY 2002: Residency training positions would be capped at the number of FTE residents in the program as of August 1, 1995. The Secretary would be able to adjust programs, but the national maximum total of programs could not be exceeded.

- FY 1998: Beginning in FY 1998, payments for residents who have completed the initial residency period, or five years (whichever occurs first), would be eliminated. There would be an exception of up to two additional years for residents in geriatrics and preventive medicine.

FY 1996-FY 1998 Beginning in FY 1996, payments for certain types of residents would be gradually reduced: individuals who are not U.S. citizens or nationals; aliens lawfully admitted to the U.S. for permanent residence; aliens admitted to the U.S. as refugees; or citizens of Canada. In FY 1996, payments for FTE residents described above would be weighted at 75 percent of the full amount. In FY 1997, payments would be weighted at 50 percent and decreased to 25 percent in FY 1998 and subsequent years.

Note: As in determining the Medicare program's contribution to the Indirect Costs Medical Education Account, the program's contribution to this account depends on the number of beneficiaries who remain in the fee-for-service payment system and who receive inpatient care. This occurs because the Medicare Direct Costs transfer calculation is based on the program's fee-for-service patients' share of total inpatient days. As Medicare beneficiaries leave the fee-for-service system and join Medicare Choice Plans or participate in Medical Savings Accounts, which would pay hospitals for inpatient services using other methods, the Medicare program's transfer to this account would diminish.

How the Money in this Account Would Be Distributed

FY 1996: The Medicare program would continue to make DGME payments based on the payment policy changes described above.

FY 1997-FY 2002: Each hospital would receive a portion of this account. Qualifying graduate medical education consortia also could receive payments from this account in lieu of funds that would have been paid to teaching hospitals. Payments to hospitals would be based on the Secretary's annual estimate of what would have been paid to hospitals under the new payment policies (see above) times a hospital-specific percentage for each year. The hospital-specific percentage would be the ratio of the estimate of what the hospital would have received compared to total Medicare DME payments that incorporate the payment policy changes.

Note: Unlike the Indirect Costs or the General Direct Costs Accounts, a hospital's percentage share of the Medicare Direct Medical Education Costs account would vary from year-to-year. The Secretary would estimate payment rates for consortia using a per resident cost methodology.

3. The General Direct Costs Medical Education Account

How this Account Would Be Funded

FY 1996: No account exists.

FY 1997: This account would be funded by general revenues from the U.S. Treasury. The Medicare program would make no contribution to this account. The funding level of this account would be based on a share of the appropriated funds mandated in the Medicare Preservation Act. The proportionate share would be based

on Medicare DGME spending as a percentage of total DGME and IME spending in FY 1994.

Note: For example, in FY 1994, Medicare DGME payments were approximately $1.5 and IME payments were $3.8 billion. DGME payments were 28 percent of the total of the two Medicare payments with an education label. Therefore, the General Direct Costs Medical Education Account would be allocated 28 percent of $1.3 billion in FY 1997, or $364 million.

FY 1998: This account would receive 28 percent of $1.5 billion, or $420 million, from general revenues.

FY 1999: This account would receive 28 percent of $2.3 billion, or $644 million, from general revenues.

FY 2000: This account would receive 28 percent of $3.1 billion, or $868 million, from general revenues.

FY 2001: This account would receive 28 percent of $3.6 billion, or $1.01 billion, from general revenues.

FY 2002: This account would receive 28 percent of $4.0 billion, or $1.12 billion, from general revenues.

How the Funds in this Account Would Be Distributed

FY 1996: No account exists.

FY 1997-FY 2002: Hospitals and qualifying consortia would receive a percentage share of this account. The hospital-specific percentage would be based on the mean average of the percentages of total Medicare DGME payments that the hospital received each year in FYs 1992, 1993 and 1994.

Note: This percentage would remain constant through FY 2002; only the amount available for distribution would vary (see above). As currently set forth, this payment would be uncoupled from the number of residents training at the hospital in FY 1997 and beyond. Because Medicare would not contribute to this account, the available funding in this account would be unaffected by the trend toward enrollment in managed care or choice of other non-fee-for-service options.

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Prepared by Linda E. Fishman, Associate Vice President, AAMC. October 31, 1995.

Talking Points on Republican Senate Medicare Cuts to Medical Education

Note: because of differences between CBO and HHS baselines, direct comparison of savings or cost estimates using CBO's baseline to estimates using HHS' baseline are not appropriate.

Medicare makes substantial payments to teaching hospitals which either directly or indirectly support graduate medical education. These payments take three forms:

- direct medical education (DME) payments for residents' salaries and benefits;
- indirect medical education (IME) payments for the medical practice costs associated with teaching hospitals, such as tougher cases and more intense use of technology; and
- disproportionate share (DSH) payments to defray the cost of care to the poor and indigent frequently served by teaching facilities.

The Senate Republican Medicare Plan makes large cuts in medical education funding.
The Republican Plan:

use

- Cuts IME payment adjustments from the current level of 7.7% for each 10% increase in the ratio of interns and residents to beds to 4.5% for each 10% increase in the ratio of interns and residents to beds. CBO scores this as a $9.9 billion dollar cut over 7 years.

- Cuts DSH payments by 25%. CBO scores the DSH payment reduction as a $4.5 billion dollar cut over 7 years. Much of this cut would come from teaching hospitals.

- Removes DME, IME, and DSH payments from Medicare managed care payments, but allows hospitals serving Medicare managed care beneficiaries to apply to the government for these payments. The savings from removing DME, IME, and DSH payments from managed care reimbursement are incorporated in CBO's estimate of Medicare Choice savings, while the cost of allowing hospitals to apply for the payments is $10.7 billion over 7 years.

The President's Plan achieves more sensible reductions in Medicare's medical education costs.
The President's Plan:

- Reforms DME payments to prioritize primary care, saving Medicare $4.6 billion over 7 years (HHS estimate).

- Reduces IME payment adjustments from the current level of 7.7% for each 10% increase in the ratio of interns and residents to beds to 6.0% for each 10% increase in the ratio of interns and residents to beds. HHS estimates this will save Medicare $9.6 billion over 7 years.

- Reduces Medicare DSH payments by 10%, saving Medicare $3.4 billion (HHS estimate).

- Removes DME, IME, and DSH payments from managed care reimbursements and returns 75% of the resulting savings to teaching hospitals. HHS estimates this proposal will save $2.8 billion for Medicare over 7 years.

These are not very far from our numbers. Probably should not use.