



**association of american
medical colleges**

**AGENDA
FOR
COUNCIL OF DEANS**

**ANNUAL BUSINESS MEETING
MONDAY, NOVEMBER 5, 1979
2 p.m. — 5 p.m.
WASHINGTON HILTON HOTEL
WASHINGTON, D.C.**

COD SPRING MEETING

April 9-12, 1980

Hilton Inn & Conference Center

Ft. Lauderdale, Florida

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL OF DEANS
ANNUAL BUSINESS MEETING
Monday, November 5, 1979
2:00 - 5:00 p.m.
Monroe Room
Washington Hilton Hotel
Washington, D.C.

AGENDA

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PROGRAM SESSION
4:00 P.M.

"The Progressive Diffusion of Board Certified
Specialists Into Non-Urban Towns"

Albert P. Williams
Senior Economist
Rand Corporation

Session II
Wednesday, April 25, 1979
8:30 am - 12 Noon
Navajo Room
Raddison Resort & Racquet Club
Scottsdale, Arizona

MINUTES

I. Call to Order

The meeting was called to order at 8:30 a.m. by Christopher C. Fordham III, M.D., Chairman.

II. Quorum Call

Dr. Fordham announced the presence of a quorum.

III. Consideration of Minutes

The minutes of the October 23, 1978, Annual Business Meeting held at the New Orleans Hilton Hotel were approved as submitted.

IV. Chairman's Report

Dr. Fordham announced that the Executive Committee had met on the Section 223 issue and introduced Dr. Gronvall, Chairman of the Committee to report its action. Dr. Gronvall reported that the Committee had concluded that the COTH position was untenable for the reasons discussed at the Sunday session and voted not to adopt it as the AAMC position. He asked for and received the Council of Deans concurrence.

V. Discussion Items

A. AAMC Meeting of Housestaff on Report of Task Force on Graduate Medical Education.

Ms. Dolan, Special Assistant to the AAMC President announced the Executive Council's decision to hold an invitational meeting of about 30 residents to discuss and receive their input on the GME Task Force Report. Each dean would be asked to submit three nominees of residents in affiliated GME programs in various specialties and years of training; the OSR Administrative Board would also be invited to submit a list of approximately 12 names. From this pool, the thirty invitees would be selected. The meeting would be of approximately a day and one-half duration, during which the working groups reports would be presented by the working group

Chairman or members, and discussed with the residents. The meeting was scheduled for October 12 and 13.

B. Section 227 - Regulations.

Dr. Richard Knapp discussed the activities of the AAMC ad hoc committee on Section 227. A subcommittee had been formed to meet with the officials in the Health Care Financing Administration who were responsible for drafting regulations, to discuss our problems with the current draft. While there was substantial progress on a number of issues, it appeared that there was essentially no possibility of removing fiscal test entirely.

C. Report of the Task Force on Graduate Medical Education.

The current status of each of the working group reports and their major highlights and conclusions were reviewed for the Council.

Dr. Clawson discussed the report of the Working Group on Transition. He reported that it had been approved by the Executive Council and that a number of the recommendations were in process of implementation. Dr. Swanson reported on the Working Groups on Specialty Distribution, Financing, Accreditation and Quality. These were in various stages of finality, but would be acted upon by the Executive Council in time for the Assembly meeting in November. A half day session at that meeting would be devoted to a discussion and approval of the final reports of these groups. After that meeting the Task Force would prepare its final report.

D. Essentials of Approved Programs of Graduate Medical Education.

Dr. Swanson reviewed the current draft of the Essentials which appeared in the agenda book. He stated that there remained a number of steps in the approval process before they could be adopted as the policy of the LCGME. The key characteristic of the document was its emphasis on institutional responsibility for the programs, a policy initiated by the AAMC and subsequently adopted in modified form by the Coordinating Council on Medical Education.

E. Federation of State Medical Boards Proposal -- Flex I & Flex II.

Dr. Bryant Galusha, a member of the Federation and of its committee on review of the licensure process, presented a discussion of the Federation's proposal that the licensure exam system be modified. State responsibility for the quality of medical practice led the Federation to conclude that a new system was required to assure the competence of physicians. He described the reasons for their concern which included the proliferation of "off shore" schools, the movement toward

and away from the three year curriculum and the substantial expansion of medical schools and medical school enrollments in this country.

The Federation proposes to institute a new system of two FLEX exams for all physicians. Flex I would be administered prior to entry into graduate medical education and would result in the award of a licence to practice under supervision in a residency program. Flex II would qualify a physician for an unrestricted license and would be given after 1, 2, or 3 years of residency training. The FSMB Board of Directors has endorsed this proposal and work is proceeding with the National Board of Medical Examiners to develop a comprehensive qualifying exam which might be used as the Flex I.

F. Evaluating Applications for Transfer from Foreign Medical Schools.

Dr. Schofield alerted the deans to the prospect of a flood of requests for transfer that could be anticipated from students at "off shore" schools who had completed two years of their program. He suggested that the deans initiate a review of the evaluation process to assure that they would be prepared to handle the requests.

G. National Council on Health Planning and Development -- Subcommittee on Productivity and Technology.

Dr. Phillip Caper, Chairman of the Subcommittee reviewed the charge to his group and the request for assistance which he had sent on its behalf to a number of organizations throughout the United States. (A copy of his letter was in the agenda book.) He emphasized the interest of Secretary Califano in this project and his views as to its importance.

H. AAMC Health Manpower Legislation -- Options and Strategy.

Dr. Bondurant announced his resignation from the AAMC Task Force on the Support of Medical Education and the appointment of Dr. Edward Stemmler as his successor. Because of the lateness of the hour, he concluded that it would be infeasible to undertake a comprehensive review of the survey results, but announced that they had been tabulated and were available in the back of the room.

Dr. Bondurant's view was that the Association should not respond in detail to the Administration's proposal as detailed by Dr. Foley the previous day, but should simply express our general dissatisfaction with that approach. He suggested that the task ahead would be to craft a politically salable proposal which would be satisfactory to the schools. The Task Force, thus, would probably be well advised not to chisel a position in concrete in the near future, but rather remain somewhat flexible so that it could respond effectively as developments occurred.

VI. Adjournment

Dr. Fordham announced his resignation as Chairman of the Council of Deans, effective approximately August 1, 1979.

By acclamation, the Council expressed its appreciation for the effective work of Dr. Fordham in leading the Council over the past year.

The meeting was adjourned at 12:30 p.m.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL OF DEANS
SPRING BUSINESS MEETING

Session I
Sunday, April 22, 1979
5:30 pm - 7:00 pm
Navajo Room
Radisson Resort & Racquet Club
Scottsdale, Arizona

MINUTES

I. Welcome and Overview of the Meeting

Dr. Fordham opened the meeting with a welcome to the deans and their guests: Dr. S. O. Freedman, Dean of the McGill University Faculty of Medicine, and Drs. Clifford G. Grulée, William D. Mayer, and John W. Patterson, Distinguished Service Members of the AAMC. He reviewed for the group the schedule and format of the meeting which would include business sessions on Sunday evening and Wednesday morning, program sessions on Monday and Tuesday mornings, an informal session with the VA Assistant Chief Medical Director for Academic Affairs on Monday afternoon and a cookout on Tuesday evening. He announced the revision of the Tuesday program schedule to accommodate Dr. Henry Foley, Administrator of the Health Resources Administration, who had asked to address the deans on the current status of the Administration's proposals for the renewal of health manpower legislation. (See letters appended to minutes for correspondence between Dr. Fordham and Dr. Foley subsequent to the meeting.)

II. The Washington Scene

Dr. John Sherman, AAMC Vice President, reviewed the status of legislation and other national level health policy developments of interest to the deans. He discussed the substantial cuts in health programs contained in the President's FY 1980 budget proposal and the accompanying request for a rescission of funds already appropriated for fiscal 1979. In the first test of strength on this issue, the White House had pulled out all the stops in advancing its position. Nevertheless, a strong response from the health community, particularly through the Coalition on Health Funding, promised to avert a disastrous Congressional action. The Coalition's Table of Funding Recommendations, appearing in the agenda book, indicated the magnitude of the problem. Dr. Sherman detailed some of the activities of the Coalition as well as the independent efforts of the AAMC. Drs. D. Kay Clawson and William Deal were slated to present testimony on behalf of the AAMC in the near future.

Dr. Sherman reserved substantive discussion of the health manpower legislation renewal for later in the meeting. He requested that the deans complete a survey questionnaire seeking their views on potential features of such legislation so that these could be tabulated and presented as a basis for such discussion.

Dr. Sherman briefly cited the fact that the major national health insurance proposals were summarized in the agenda book. Basically, Senator Kennedy favors an immediate and comprehensive national health insurance program with cost containment utilized as a method of obtaining extra financing while the Administration prefers a phase-in approach beginning with catastrophic coverage and favoring controls. He asked that the deans review this material in preparation for an AAMC examination of its position on such legislation.

In a synopsis of other legislation, Dr. Sherman reported on:

- (1) Renewal of health planning legislation. Of the three approaches (Administration, House, and Senate), the House approach was the most attractive because it contained two features recommended by the AAMC:
(a) a requirement that if one or more accredited medical schools existed in a health service area, the dean of that school must be on the board of the health service agency and (b) a provision which requires that both HSA's and state agencies, in reviewing the proposed medical services in an area, consider the availability of resources for training health professionals.
- (2) The Dole-Bayh Patent Bill. This is of particular interest for the AAMC because it would effect a system of uniform policies throughout the executive branch. It also offered the possibility of providing a more secure statutory basis for preserving the closed system of peer review of research grants.
- (3) The Clinical Laboratory Improvement Act. This laboratory control measure is currently the subject of review by an ad hoc committee which will recommend an AAMC position.

Dr. Sherman then briefly updated the Council on the issue of compensation of human subjects injured in research. There were two related and troublesome matters. The requirement that informed consent statements specify the availability of such coverage and the possibility that such coverage would be mandated by a proposed regulation about to be issued. Most, but not all, institutions appear to have found a way to comply with the informed consent requirement although only with great difficulty and much consternation. The proposed requirement that such compensation be offered was the subject of substantial effort on the part of the AAMC and other higher education associations. Since there is currently no means to provide the requisite insurance coverage, the promulgation of such a regulation would create a chaotic situation. An ad hoc group has been formed which includes representatives of the insurance industry which is in the process of detailing the problems and of developing recommendations for steps which need to be taken prior to the issuance of a regulation. We have gotten the attention of HEW officials and are hopeful that premature action on this matter can be avoided.

Dr. Sherman also described the efforts of the AAMC in cooperation with the National Association of College and University Business Officers and the National Association of State and Land Grant Colleges in reviewing and commenting on proposed revisions to OMB-Circular A-21 governing indirect cost reimbursement for government sponsored research. The final regulation will be much improved over early proposals but is likely to contain some troublesome provisions.

Dr. Sherman mentioned the interest of several groups in utilizing the AAMC faculty roster as a means of identifying minority and women senior faculty for recruitment purposes. Two concerns lead the Executive Council to conclude that a systematic use of the faculty roster for this purpose would be unwise: (1) the possibility that the list was not sufficiently accurate for this purpose, and (2) the assurance given to faculty members that the information would be used only for statistical and study purposes, i.e., not released in personally identifiable form. To respond to this interest, however, the staff would be contacting appropriate representatives of the institutions concerned with women's and minority affairs for the purpose of improving the accuracy of the information and obtaining either the consent of each faculty member for using the information for this purpose or a denial of this consent.

At the conclusion of Dr. Sherman's presentation, Dr. Stone suggested that, if the timing permitted, the Association should consider a comprehensive reexamination of its position on the health planning legislation. It was his view that the system it enacted was fundamentally flawed and unworkable. It resulted in complex decisions with substantial local significance being made by a group of individuals under pressure to conform with national standards which could not possibly take into account all the relevant local factors. Furthermore, this process was staffed by well-meaning but inexperienced persons who were not capable of performing the task expected of them. He suggested that the efforts of the AAMC in working to improve the system at the margins while accepting its basic structure was misdirected. At this period in our nation's history, there is developing a movement toward deregulation of our economy and our affairs in general. The AAMC should associate itself with this view.

Other members of the Council echoed Dr. Stone's general dissatisfaction with the health planning system. They also raised questions about certain specifics of the AAMC position. Several questioned the wisdom of mandating that a Dean be a member of the HSA board.

As a result of this discussion, the officers of the Council made a commitment that the matter would be brought to the Executive Council for a comprehensive review at its June meeting. In advance of this, the deans would be given a complete description of the current AAMC position and would be requested to forward their comments in writing for the benefit of the Council.

III. Financial Management Seminar

Dr. Wilson announced that the first Financial Management Seminar of the Management Advancement Program would be held in October. Invitation letter would be sent to the deans in the near future.

IV. Section 223 - Classification of Hospitals

Dr. Richard Knapp reviewed the status of the Section 223 regulations which classify hospitals for purposes of Medicare reimbursement for routine services. He described a proposal that there be developed a new category in the classification scheme of "Primary Teaching Hospital of a Medical School." This proposal had been endorsed by the Council of Teaching Hospitals Administrative Board which also recommended that each dean designate the hospital or hospitals to be included in the category. The staff and leadership of the other councils feared that such a category would be unworkable and actually very troublesome. Teaching hospitals are very dissimilar on factors relevant to this kind of reimbursement. Those affiliated with some schools might include several with very complex and resource intensive care missions, while those affiliated with other schools might include no such hospital. There was thus the prospect that such a category would (1) include very dissimilar institutions which should not be compared, and (2) present the medical school with the politically impossible task of designating one affiliated hospital from a number, each of great significance to the schools program.

The Executive Committee was scheduled to meet on this matter and consider the advisability of modifying the position recommended by the COTA Board. Advice from the deans was solicited. A number of clarifying questions were raised and discussed. Several deans supported the position that the proposal was unworkable. None spoke in favor of the proposal.

The meeting was adjourned until the Wednesday morning session, at approximately 7:00 P.M.



association of american medical colleges

May 3, 1979

Dr. Henry A. Foley
Administrator
Health Resources Administration
Public Health Service
Department of Health, Education & Welfare
5600 Fishers Lane
Rockville, Maryland 20852

Dear Hank:

This letter follows up your presentations at the Spring Meeting of the Council of Deans in Scottsdale on April 24, 1979. After your departure, the Administrative Board of the Council continued the discussions initiated with you during lunch that day and at the Council's business meeting on the 25th there was a further exchange of views on these matters. As a result of all of this, I was asked to communicate to you the major themes that emerged.

I should say first and foremost that your request to appear before the Deans was a wise one. The group found it very useful to learn of the probable outline of the legislative proposal that, as we understood you, will move forward from HRA as the Administration's position within the next fifteen days. Despite the rapidity and brevity of the presentation, you succeeded, nonetheless, in identifying those authorities which the Administration intends to retain, amend, re-study or delete and what new authorities it proposes to request.

Secondly, the group felt it important to convey to you our view of the nature of the exchanges with you. The scope of the information you had to convey, describing the many provisions of the current legislation on which the Administration will take a position, coupled with the short time available and the absence of any written material on the subject matter precluded any consideration of the individual provisions in any significant detail. Thus, you will understand that none of the comments offered can be regarded as embodying an official position of the AAMC, the Council of Deans or its Board, or indeed a well thought out position of any of the individual deans. Since we were working from the barest outline, it was possible only to react to the tenor and thrust of the Administration's proposal. In this regard you will recall that only one theme clearly emerged -- the depth and breadth of the disillusionment evoked by the Administration's FY 1979 rescission proposal and its FY 1980 proposal to terminate institutional support. This action followed only a

Dr. Henry A. Foley
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May 3, 1979

few months upon the reluctant decision of medical school faculties, after acrimonious and divisive debate, to accept U.S. foreign medical students in advance standing. It has raised serious doubts, not only in the medical schools in the United States, but also among university presidents and their governing boards, and state officials upon whom many medical schools must place primary reliance, on the question of whether it is any longer possible for the schools to place any trust in or reliance on the promises of the Federal government. It is the strong conviction of many that there has been a breach in the credibility of the Federal government which cannot be repaired in the near term. The outline of the proposals which you brought, while conceptually separable from the breach of faith embodied in the rescission proposal, nevertheless reflects the same fundamental judgment that institutional support is no longer essential for the achievement of federal purposes in the government's relationship to medical schools. As must have been inescapably clear from our comments, we do not share this judgment. In fact it appears that this action will result in the inexorable dismantling of many of the initiatives that the schools have recently undertaken in response to federally identified priorities.

We are particularly distressed to learn that it was your perception that this judgment had been made not on the basis of pressing budgetary priorities but rather because federal officials had somehow arrived at the conclusion that medical schools exhibited little commitment to the public interest. This conclusion, which is contradicted by every serious examination of the medical schools response to federal programs, from the Rand Studies in 1973 to the GAO Study completed in 1979, came as an unwelcome shock to academic officials who felt that they had devoted immense energies and efforts over the past two decades to cooperate with the Federal government. By any available measure, these programs and the concomitant effort of the medical schools to implement them must be regarded as distinguished examples in any recounting of Federal government success stories. That governmental officials could not only entertain but develop policy recommendations on such ill-founded opinions was viewed by the assembled group as utterly incredible.

We did find in your remarks some grounds for hope, particularly in your recognition of the devastating effect vacillating programmatic priorities and funding decisions have on the ability of educational institutions to function. We are also gratified with your expressed willingness to continue working on ways to implement the concept first enunciated by Undersecretary Champion of a mechanism of support similar in concept and function to the Biomedical Research Support Grant. While we recognize that there is at yet no acceptable proposal, this appears to be the single promising area on which we might work to reestablish a satisfactory relationship between the schools and the Federal government.

Dr. Henry Foley
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May 3, 1979

We very much appreciate your taking the time to bring to the deans such important, if unwelcome, news. If this recapitulation of our exchanges in any way misconstrues or misrepresents your message, please get back to us as soon as possible to set the record straight. In any event, be assured of our continued willingness to meet with you as the legislative process matures.

Sincerely,

Christopher C. Fordham III, M.D.
Chairman
Council of Deans

ATTACHMENT



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH RESOURCES ADMINISTRATION
HYATTSVILLE, MARYLAND 20782

OFFICE OF THE ADMINISTRATOR

MAY 21 1979

Christopher C. Fordham III, M.D.
Chairman, Council of Deans
Association of American Medical Colleges
Suite 200
1 Dupont Circle, N. W.
Washington, D. C. 20036

Dear Dr. Fordham:

Thank you very much for your letter of May 3 regarding my presentation at the spring meeting of the Council of Deans in Scottsdale last month. I was indeed pleased to accept the Council's invitation to brief them on the forthcoming Administration health manpower legislative proposal. I keenly appreciate the significance of this legislation to the Nation's medical schools. I, therefore, appreciated very much the opportunity to begin a dialogue which will hopefully continue between us on the renewal of this legislation.

Given the time frame which was involved, I do understand that none of your comments can be regarded as the official position of the AAMC. As the legislative process goes forward, however, I do look forward to learning of your Association's official view with respect to this legislation.

In one very important respect, though, I am disturbed that in your letter you at one point raised the question of whether it is any longer possible for the medical schools to place any trust or reliance in the promises of the Federal Government; and then quickly go on to find it "utterly incredible" that some Federal officials questioned the commitment of the medical schools to the public interest. Quite frankly, I find such a negative attitude to be nonproductive. From my own perspective, it is clear that there has been an effective partnership between the medical schools and the Federal Government for many years. That partnership, among other things, called upon the schools to train an ever growing number of competent physicians. Without question the medical schools of this Nation have responded splendidly to that task now completed.

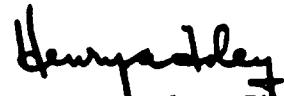
Page 2 - Christopher C. Fordham III, M.D.

If there is to be any real hope of maintaining stable Federal institutional assistance to the Nation's medical schools, then you and we must fashion a new set of performance criteria which all or some of the schools will be able and willing to meet in return for such Federal support. As I indicated in Scottsdale, I believe that the problems of geographic and specialty maldistribution as well as enhancing educational opportunities for minorities are areas which we should productively explore. I do not believe that it is possible to realistically expect undifferentiated Federal institutional assistance.

I am attaching for your information a paper which has just come to my attention entitled "Policy Termination and Policy Modification--The Case of the Capitation Grant Program." This paper was prepared by Robert D. Behn and Kim Sperduto of the Institute of Policy Sciences and Public Affairs, Duke University, and was recently presented at the annual meeting of the Midwest Political Science Association. I found it an intriguing historic analysis of the evolution of the capitation program to date. I was struck by a number of points that the authors made including particularly the notion that from the congressional perspective the capitation grant program would be seen as a lever to attack the problems of specialty and geographic maldistribution, as well as the notion that if indeed the medical schools are a national resource deserving substantial Federal assistance, perhaps the Federal Government should play a greater role in medical school operations.

I hope this clarifies any confusion which may exist. I cannot stress enough my feeling that it is essential that we continue to work together in the context I have described in order to increase the likelihood that the renewal of the health manpower legislation will put into place a program which is in the interests of the American people and of direct benefit to the medical schools of this country, their faculties, and their students.

Sincerely yours,



Henry A. Foley, Ph.D.
Administrator

Enclosure

ELECTION OF PROVISIONAL INSTITUTIONAL MEMBER

The following school has received provisional accreditation from the Liaison Committee on Medical Education and is eligible for membership in the AAMC:

Oral Roberts University
School of Medicine

The Executive Council has recommended, contingent upon approval by the full Council of Deans, Assembly election of the school listed above to Provisional Institutional Membership in the AAMC.

RECOMMENDATION

That the Council of Deans approve the election of this school to Provisional Institutional Membership.

ELECTION OF DISTINGUISHED SERVICE MEMBERS

At its June 14 meeting, the COD Administrative Board authorized the Chairman to appoint a small committee to solicit and screen recommendations from the membership for nominations for Distinguished Service Members. The committee, consisting of Drs. Beering and Luginbuhl, met and presented its recommendations at the September 13 Board meeting. The following individuals were submitted for consideration for election to Distinguished Service Membership in the AAMC:

Edward N. Brandt, Jr.
Christopher C. Fordham III
William J. Grove
Marion Mann
Clayton Rich

The Executive Council has recommended, contingent upon approval by the full Council of Deans, Assembly election of these individuals to Distinguished Service Membership.

RECOMMENDATION

That the Council of Deans approve the election of these individuals as Distinguished Service Members.

REPORT OF THE NOMINATING COMMITTEE AND ELECTION OF OFFICERS

The Nominating Committee of the Council of Deans consisted of:

William F. Kellow, Chairman
David R. Challoner
Samuel H. Rubin
Robert L. Tuttle
Stanley van den Noort

The committee solicited the membership for recommendations of persons to fill the available positions by memorandum dated April 3, 1979. The returned Advisory Ballots were tabulated and the results distributed to each committee member. The committee met by telephone conference call on June 21, 1979. Dr. Kellow's letter report (dated July 5, 1979) of the committee's recommended slate of officers follows.

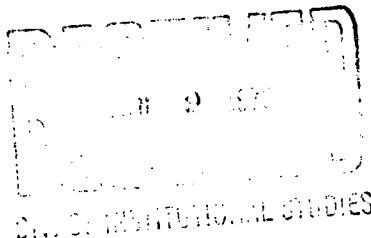
JEFFERSON MEDICAL COLLEGE
of
THOMAS JEFFERSON UNIVERSITY

Offices of the
Dean and Vice President



Philadelphia, 19107
(215) 928-6980

July 5, 1979



Christopher C. Fordham, III, M.D.
Dean, University of North Carolina
School of Medicine
Chapel Hill, North Carolina 27514

Dear Dr. Fordham:

This letter constitutes my report as Chairman of the Council of Deans' Nominating Committee to you as the Chairman of the Council of Deans. The Committee met at 1:00 p.m. EDT on June 21, 1979 by telephone conference call. At that time we had available to us the tallies of the advisory ballots submitted by the Council of Deans.

The following offices will be filled by vote of the Council of Deans. The slate proposed by your Nominating Committee is as follows:

Chairman-Elect of the Council of Deans
Steven C. Beering, M.D.
Dean and Medical Center Director
Indiana University School of Medicine

Member-at-Large of the Council of Deans
Richard H. Moy, M.D.
Dean and Provost
Southern Illinois University School of Medicine

The following offices are filled by election of the Assembly. Consequently, the slate proposed for the Assembly's consideration will be developed by the AAMC Nominating Committee, of which I am a member. Thus, these names will be submitted in the form of a recommendation from our Nominating Committee to that Nominating Committee:

Chairman-Elect of the Assembly
Julius R. Krevans, M.D.
Dean
University of California - San Francisco

Christopher C. Fordham, III, M.D. 2

July 5, 1979

Council of Deans Representatives to the Executive Council

Theodore Cooper, M.D., Ph.D.

Dean

Cornell University Medical College

Leonard M. Napolitano, Ph.D.

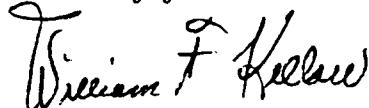
Dean

University of New Mexico School of Medicine

These nominations reflect the wishes of the members of the Council of Deans. I am confident that we have a slate which will contribute to the work of the Association, and all persons have been contacted and have agreed to serve if elected.

Thank you for the opportunity to serve in this capacity.

Sincerely yours,



William F. Kellow, M.D.

Chairman

Nominating Committee

WFK/jm

cc: David R. Challoner, M.D.

Samuel H. Rubin, M.D.

Robert L. Tuttle, M.D.

Stanley van den Noort, M.D.

Joseph A. Keyes

I. INTRODUCTION AND ASSUMPTIONS

The Ad Hoc Committee on Continuing Medical Education was appointed by the Executive Council of the Association of American Medical Colleges in July 1976. It was charged with further analyzing those issues in continuing medical education identified by the Task Force on Continuing Medical Education (William H. Luginbuhl, Chairman), and developing approaches to manage these issues, with particular reference to the Liaison Committee on Continuing Medical Education. The Ad Hoc Committee has the following membership:

William D. Mayer, M.D., Chairman
Richard Bergland, M.D.
Clement R. Brown, Jr., M.D.
Richard M. Caplan, M.D.
Carmine D. Clemente, Ph.D.
John E. Jones, M.D.
Charles A. Lewis, M.D.
Thomas C. Meyer, M.D.
Mitchell T. Rabkin, M.D.
Jacob R. Suker, M.D.
Steven Tarnoff, M.D., OSR Representative
David B. Walthall, M.D.

Staff: Emanuel Suter, M.D.
Wendy Waddell, M.A.

The Ad Hoc Committee initiated several studies which have been summarized in separate reports^{1/} and helped to formulate additional proposals for research and development^{2/}.

-
- 1/ a. Continuing Medical Education, Results of Delphi Probe with Practitioners and Faculty, DERP/AAMC, June 1978.
 - b. Continuing Medical Education, Discussions Using Nominal Group Techniques, DERP/AAMC, June 1978.
 - c. Continuing Medical Education, An Analysis Tool for Examining Options, DERP/AAMC and Pugh-Roberts Associates, Inc., Nov. 1978.
 - d. Continuing Medical Education, The Relationships of Continuing Medical Education to Physician Competencies, Final Report to the VA, Dec. 1978.
 - e. Continuing Medical Education, A Selected Annotated Bibliography, DERP/AAMC, January 1979.
-
- 2/ a. The Relationships of Continuing Medical Education to Physician Competence, Contract No. V101 (134) p. 578 by the VA, August 1977 through December 1978.
 - b. Enhancing the Application of Adult Learning Principles to Continuing Education of Health Professionals, Supported by grant, No. EMI 78-002-01, from the VA, September 1978 through August 1982.
 - c. Development of Lifelong Learning Characteristics in Physicians, Proposal for Analysis and Demonstration, under consideration by the W. K. Kellogg Foundation.

Every practicing professional should recognize:

" . . . the need to maintain competence; the need to use the theories and techniques of innovative practice; the need to understand relevant new developments in the basic disciplines; the need to apply the ethical principles required in a constantly changing work environment; the need to strengthen and sustain a responsibly coherent profession; the need to preserve an appropriate perspective on work-life and not be engulfed by it; and the need to collaborate with members of other professions whose self-conceptions and ways of work are also continuously evolving . . . "

Cyril O. Houle, 1979

Continuing medical education is in a state of rapid expansion and confusion. When rationally planned it is a complex blend of medical practice experiences, patient behavior, physician learning styles, instructional offerings, individual learning needs, and the circumstances and environments peculiar to the physician learners. However, planning for continuing medical education is subject to pressures and influences often counter to rational development, such as the market based economy, an ad hoc faculty and a burgeoning student body that is continually changing. These pressures are compounded by mandatory state and specialty requirements and the consequent need to record and monitor efforts expended by physician participants. The situation is further complicated since methodologies for applying educationally sound principles to the practice of continuing education have not been used widely. Some recently published reviews provide helpful summaries of this situation ^{3/}.

The Ad Hoc Committee identified assumptions which it felt were valid and widely accepted:

1. The ultimate goal of continuing medical education is the improvement of patient care through expansion of physician competence and performance.
2. The factors affecting the quality of care delivered in any setting are so numerous and complex as to preclude an isolated approach to continuing education. The identification and

3/ a. Richards, R.K., Continuing Medical Education, Perspectives, Problems, Professions, Yale Univ. Press, New Haven and London, 1978.
b. Egdahl, R.H., and Gertman, P.H., edit., Quality Health Care, The Role of Continuing Medical Education, Aspen Systems Corporation, Germantown, MD, 1977.
c. Coordinating Council on Medical Education, Continuing Competence of Physicians, A Report of the Committee on Continuing Competence of Physicians, Chicago, 1979.

corroboration of desirable levels of and change in performance and competence can only occur in the health care setting. Continuing education thus requires a collaborative effort between physicians, their professional organizations, the health care setting, and educational institutions. No single component can exert exclusive control.

3. Continuing education is broadly defined as those change oriented activities dealing with the interface of medical practice, competency and performance, professionalism and learning.
4. The development of methodology and mechanisms to link quality assurance of medical care to continuing education of physicians is critical for effective learning.
5. Continuing education of physicians, if done in accord with general and adult learning principles, will accomplish performance change. If currently it fails to do so it must be due to inappropriate process rather than an intrinsic inability of education to be effective.
6. Physicians as professionals are motivated to continue their education and will accept the practice of continuous assessment of their performance in comparison to established and constantly changing standards of practice, including competence and performance 4/.
7. The acquisition of the attitudes and skills for self-evaluation and self-correction can be enhanced during undergraduate and graduate medical education.
8. Physicians will continue to depend on providers of continuing medical education for satisfying at least part of their continuing education needs.
9. Although education should and does occur in the practice setting and the hospitals, medical schools, teaching hospitals and academic societies share the major responsibility for formal continuing medical education and can have a significant impact on the future of it.
10. Members of medical school faculties represent the major provider resource for continuing medical education.

4/ The Ad Hoc Committee defined competence as the capabilities necessary to perform and performance as the actual application of these capabilities to patient care.

11. The existing system of certification and accreditation will continue in the future and require improvement to realize the potential of continuing medical education.
12. A national organization is needed to develop policy and educational standards for accreditation of organizational and institutional providers of continuing medical education to assure that quality education is linked to enhanced quality care.

II. TRENDS AND ISSUES

1. The most obvious manifestation of recent developments in continuing medical education is the rapid expansion of formal programs responding to mandatory requirements by state licensing boards, specialty boards, professional and specialty societies, and hospitals. Between 1971 and 1977 the number of courses offered by accredited institutions and organizations increased by more than a factor of five (from 2,319 to 16,665) with a corresponding increase in physician enrollment (from 191,682 to 1,086,396). In California alone in 1978, 40,000 physicians registered 9,600,000 continuing medical education credit hours under the California Medical Association's certification program.
2. There is an increased reliance by physicians on community and teaching hospitals to satisfy continuing education needs. This is evident from recent trends in course offerings and physician attendance, in accreditation of increasing numbers of community hospitals and from a recently conducted survey of physician preferences for continuing education^{5/}.
3. The "currency" most commonly used for relicensure and re-certification is the category 1 credit hour of the American Medical Association's Physician Recognition Award. This credit documents registration by the physician for continuing education offered by an accredited institution or organization. The present demand for credit hours combined with a still evolving accreditation system of the Liaison Committee on Continuing Medical Education creates a continuing medical education market characterized by an ill defined and uncontrolled product and a highly pressured consumer. The result is escalating costs (an annual cost of over three billion dollars has been estimated) for a learning outcome of undetermined benefit.
4. Most medical schools are not prepared or optimally equipped to

5/ Mason, J.L., Kappelman, M.M., Hornung, C.A., and Massagli, M.P., Medical Education: Utilization and Preferences of Primary Care Physicians, Univ. of Maryland, 1979.

satisfy the demands for continuing medical education being placed on their faculties. Most schools still consider continuing medical education as an additive rather than an integral part of their institutional responsibilities. Some studies indicate that faculty members may contribute more of their time to continuing medical education offerings organized by other providers than their medical school (e.g. specialty society, hospital, commercial organizations.)

5. The direct contribution of continuing medical education to medical care cannot be assessed, or only under very special circumstances, because of the diverse characteristics of the health care environment. At the present time success is measured by the accumulation of credit hours (currency) or by the number of registrants rather than by methods to document learning accomplishment or impact on delivery of care. Frequently, providers of continuing education offer credit hours without regard to the instructional outcome or the relationship to the student's practice.

6. Physicians satisfy continuing education needs in various ways involving formal and informal activities, with formal continuing medical education offered by accredited institutions and organizations and yielding category 1 credit representing only a fraction of the physician's total continuing medical education involvement. Therefore, accreditation encompasses only a small segment of continuing medical education. Existing data do not permit judgment as to which type of educational experience is more valuable in terms of physician performance and the quality of medical services rendered to the public.

7. The impact of mandated continuing education has not been fully evaluated yet. There is widespread doubt regarding the expected desirable impact of compulsion on physicians' competence and performance and on their learning behavior^{6/}.

8. The instructional approaches used most widely in continuing medical education tend to disregard the attitudes and capabilities of physicians as adult learners. In the planning of accredited continuing medical education the priorities of accredited institutions and organizations outweigh those of the learners; there is little room for personal initiative except through the individual course selections. Few undergraduate and graduate education efforts are oriented toward the physician's preparation for the self-evaluating and self-correcting demands of professional life.

9. The state of the art of continuing medical education is characterized by a lack of data establishing causal relationships

6. Storey, P.B., Mandatory Continuing Medical Education, one step forward-two steps back, New England Journal of Medicine, 1978, 298, 1416-1418.

between learning and practice behavior, and methods for assessing performance are not yet widely available. The relationship between undergraduate, graduate and continuing medical education remains essentially unexplored. Nevertheless, demonstrable changes in the practice behavior of physicians can be achieved if the plan for instruction/learning is aimed at correcting identified deficiencies recognized by physicians and continuing education providers.

III. CONCLUSIONS AND RECOMMENDATIONS

The Ad Hoc Committee arrived at the following conclusions and recommendations applicable to general or specific aspects of continuing medical education.

A. General Conclusions

1. Continuing education is a necessary means for physicians to fulfill their professional responsibility to maintain and improve the quality of their performance. As a component of quality assurance of medical care it must be closely related to the physicians' practice.
2. Continuing medical education should encourage physicians to examine their performance and expand their competencies as determined by their individual practices, the needs of the hospitals or other health care organizations with which they are associated, and by scientific developments and societal demands.
3. Whenever possible, continuing education should be offered and carried out in close proximity to the physician's locale of patient care. Wasteful loss of time, travel and cost should be reduced.
4. Peer review on an individual or collective basis can exert quality control over the individual physician's performance and the performance of groups. Health care organizations and specialty groups carry major responsibility for developing programs to assess the quality of physicians' performance and the adequacy of their competency, and for assuring that continuing education activities are available to address determined discrepancies.
5. Continuing education is a component of professional behavior and skills for self-evaluation and self-directed learning should be acquired early in the physician's career.

6. Continuing medical education is a responsibility shared by the individual physician, the hospital or the practice organization, and the continuing education provider. It requires individual and collective initiatives.
 7. Mandated continuing education without any evidence of a beneficial effect on medical practice is senseless. The impact of relicensure, recertification, and other compulsory requirements for continuing education on physician performance and medical care cost should be thoroughly investigated.
 8. In view of the state of the art of continuing medical education, research and development must have high priority. It should address the various aspects of continuing education, such as: (a) methodologies for assessing physician performance and linking quality control of health care to continuing education; (b) impact of continuing medical education on the quality of health care; (c) consequences of mandating continuing education; (d) methods for developing self-evaluating and self-correcting attitudes in physician students; and (e) potential role of data processing and communication technology in the maintenance of physician competence and quality of performance.
 9. Accreditation in continuing medical education should recognize both formal and informal learning efforts until the impact of various types of physician learning on practice behavior can be measured, all planned and documentable learning activities should be considered of equal value.
 10. Cost is an important factor in continuing medical education, and cost effectiveness should become a paramount consideration in planning and implementing programs.
- In regard to these general conclusions the Ad Hoc Committee recommends that the AAMC:
1. *Pursue policies and activities in accord with the above conclusions.*
 2. *Promote and participate in research efforts in key areas and advocate appropriate funding of this research on the national level.*
 3. *Support the development of an independent LCCME as an instrument for national policy and quality control of continuing medical education.*

4. Assist medical schools in developing educational policy and faculty guidelines for participation as providers of continuing medical education.
5. Provide a forum on the national level for the review and resolution of issues in continuing education.
6. Expand the data base in the area of continuing education by means of the LCME part II questionnaire.
7. Provide leadership in developing and applying adult learning principles to continuing medical education.

B. Conclusions About Providers

1. The major providers of continuing medical education - medical schools, hospitals and specialty societies - should assist physicians in the planning of activities related to their competence and practice performance.
2. Medical schools should serve multiple roles in continuing education of physicians. They should (a) offer continuing education opportunities in selected areas; (b) serve as a local, regional and national resource of faculty to other providers of continuing education to physicians and other health professionals and (c) provide the focus for new developments from research and innovation.
3. Teaching hospitals should explore new ways of linking quality assurance of inpatient and ambulatory care to continuing education. They should seek to apply successful approaches to individual and group practice situations.
4. In the design of continuing education activities, providers should apply instructional designs which reinforce adult learning concepts, promote and support lifelong learning habits, and enhance the problem solving capabilities of physician students.
5. To the extent possible, individual and institutional program planning should be based on an effective educational learning cycle including needs assessment, statement of objectives, use of appropriate learning methods, evaluation and feedback.

6. Provider cost of continuing medical education should be covered from multiple sources, including physician fees, state appropriations, patient care dollars, grants and contracts from private and governmental agencies.

In regard to these conclusions the Ad Hoc Committee recommends the following:

a. Medical Schools

1. As providers medical schools should engage their unique resources collaboratively with affiliated teaching hospitals and area health education networks in developing links between quality assurance and continuing education; and seek ways to use data derived from self-assessment and recertification programs for identifying the knowledge needs of physicians.
2. As a focus for research in continuing medical education they should explore innovative approaches in continuing medical education.

3. Medical schools should develop institutional policies which (a) recognize continuing medical education at a level equivalent to undergraduate and graduate medical education, and (b) provide compensation, recognition, and other rewards to faculty involved in continuing medical education.

Revenues generated by continuing medical education programs should be managed to facilitate related institutional activities.

4. Medical schools should encourage faculty development in the field of continuing education. Faculty members should become familiar with principles of adult learning and their implication for continuing education.

5. Medical schools should examine undergraduate and graduate medical education programs for opportunities to promote self-evaluating and self-correcting behavior of the student physician. They should use data from continuing education to guide educational planning at the undergraduate and graduate levels.

b. Teaching Hospitals

1. Teaching hospitals should provide the setting in which direct links between planned formal continuing education and

health care performance of physicians can be accomplished. Hospitals should develop a mechanism to assess physician competence and performance based on assessment or recertification programs made available by specialty societies and existing audit or peer review systems. Educational programs should address carefully selected problem areas agreed upon by physicians and the hospital. Program impact on competence and performance should be assessed.

2. Teaching hospitals should use resources of the medical school for developing prototype programs.
 3. Teaching hospitals should adapt and apply these prototype programs to the needs of community hospitals through the use of regional education networks.
 4. Professional continuing education organized as an integral element of a hospital's patient care programs should be considered an operational cost of such an institution, and be reimbursed through regular patient care financing mechanisms.
- c. Academic and Specialty Societies
1. Academic and specialty societies should assure that competency and performance standards for medical practice in their area of specialization are developed and remain current.
 2. They should expand their competency assessment programs and analyze the data for identifying problem and deficiency areas as a guide for continuing education program development.
 3. The societies should encourage their members to participate in competency and performance assessment programs as a basic requirement for quality assurance in medical practice.
 4. They should develop broad curricular guidelines for their membership to define what is needed to meet national goals for delivery of quality care.

B. Conclusions About Accreditation

1. A national accreditation system should be based on a network linking regional or state agencies to the Liaison Committee on Continuing Medical Education.

2. The LCCME should be financially independent from its sponsors.
3. The accreditation agency should be responsible for:
(a) establishing general principles and national policies for continuing medical education; (b) developing an effective accreditation system; (c) developing a national information system for continuing medical education; and (d) promoting R & D in key areas of concern to continuing medical education.
4. Accreditation of organizations and institutions carrying out physician education should remain separate from but clearly related to certification of the individual practitioners.
5. Accreditation should promote the provider's role in facilitating and verifying individual physician responsibility and accountability. Accredited institutions and organizations should support and assist in documenting all planned physician learning modes.
6. A single credit system should be established that recognizes planned learner- and provider-initiated activities for continuing medical education.

The Ad Hoc Committee recommends that the Liaison Committee on Continuing Medical Education:

1. Be reorganized as an independent agency with the member organizations to include all previous members, namely AHME, AAMC, ABMS, AHA, AMA, CMSS, FSMB, federal and public representatives; consideration be given to the inclusion of additional organizations.
2. Establish policies based on the principle that continuing medical education must be placed in the context of quality assurance of health care, and develop criteria and standards for the accreditation process.
3. Recognize by a single credit system all planned and documentable continuing medical education activities.
4. Accredit medical schools and national organizations directly and approve state or regional agencies for accrediting local organizations and institutions carrying out continuing medical education, but retain full responsibility for monitoring the delegated process and assuring compliance with its policies.

5. Develop specifications for an information management system supportive of continuing medical education, its planning and accreditation, to be implemented at the local, regional and national levels.
6. Encourage studies developing methods for relating continuing medical education to patient care and evaluating its impact.
7. Charge organizations and institutions providing continuing medical education an annual fee for re-registering their accreditation status. This fee may include a base rate and a rate established on the basis of number of offerings and/or enrollment. The costs of initial or re-accreditation should be borne by the organization being accredited.

REPORT OF THE AD HOC COMMITTEE ON CLINICAL RESEARCH TRAINING

In October 1978, the AAMC Assembly adopted an OSR-initiated resolution urging the development of student research experiences. This expression of concern that research opportunities for medical students are inadequate and underutilized at many schools came at a time when it was becoming clearly evident that there has been and continues to be a marked decline in the numbers of medical students and post-doctoral trainees intent upon pursuing academic medical careers. Believing that this issue deserved highest priority, the Executive Council in June 1979 authorized the appointment of an ad hoc committee to analyze the causes underlying the decline in clinical research manpower and to propose a comprehensive course of action for the Association to rectify the problem.

The Committee was appointed in June and met on June 28, 1979 under the chairmanship of Dr. Thier. (The committee membership is shown below). The Committee's draft Report is presented at this time for discussion by the Administrative Boards and the Executive Council.

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INTRODUCTION

Clear evidence now at hand demonstrates that there has been and continues to be a marked decline in the numbers of medical students and postdoctoral physician trainees intent upon pursuing careers in investigative medicine. Discussions have recently become more intense concerning the implications of the diminished numbers of physicians entering clinical research and for the future of biomedical research, patient care, and medical education. At the 1979 annual meetings of three major clinical research societies—the American Federation for Clinical Research, Association of American Physicians, and the Society of University Surgeons—the Presidential Addresses focused on the need to seek solutions to the fact that the nation will soon be faced with an acute shortage of physician investigators. Six months earlier, in October 1978, the AAMC Assembly, adopting a resolution initiated by the Organization of Student Representatives, urged the development of student research experiences. This was based on concern that research opportunities for medical students are inadequate or underutilized at many medical schools. Believing that the issue of the need for more clinical investigators deserved highest priority, the Executive Council in June 1979, authorized the appointment of an ad hoc Committee on Clinical Research Training to analyze the causes of the decline in physician investigators, and to propose a comprehensive course of action to rectify the problem.

BACKGROUND

A. Trends in Physician Research Manpower

I. Medical student interest in clinical research is declining. A recent attitudinal study of medical students at Harvard showed that the percentage of graduating students assigning high priority to research dropped from 49% in 1963 to 2% in 1976 (1). Several AAMC studies have also indicated that while 39% of medical school graduates in 1960 stated that research would be a component of their careers, only 20% expressed the intent to devote any portion of their careers to research in 1979 (2). While not showing a decline in interest, studies at the University of Iowa indicated that students at that state medical school had low levels of interest in academic careers: 78% of students who entered between 1969 and 1972 did not plan to devote much time to research, only 8% expected to spend a year or more in research training, and only 2% of these same students reported plans to devote their careers to research and teaching.

II. The number of physicians training for careers in research is declining. The number of MDs in research training programs supported by the National Institutes of Health (NIH) has fallen from approximately 4,600 in 1971 to 1,790 in 1977 (5). These 1,790 trainees filled only about 70% of the 2,450 clinical training positions budgeted by NIH. It is clear that not only are there fewer research training opportunities for MD's, but also that physician interest in research training is declining. Further, while the total number of postdoctoral research fellows supported by NIH has remained relatively constant over the past decade, there has been a gradual increase of PhD trainees and a gradual decrease of MD trainees. Consequently, the proportion of MDs in the postdoctoral research training pool has fallen from 46% in 1968 to just over 20% in 1977. As yet another indicator, the percentage of Research Career Development Awards given to MDs has decreased from 43.5% to 24.1% over the past decade (5).

Similar trends are observed in programs supported by ADAMHA for research training in Psychiatry and the behavioral sciences. Apart from a brief moment in the history of NIMH, there has never been a specific targeted program to train post-residency psychiatrists in research. Consequently, the pool of clinical researchers is far smaller in proportion to the number of practicing psychiatrists than in other clinical disciplines. The recent report of the task panel on research of the President's Commission on Mental Health indicated that only 15 psychiatrists were in research training in 1977 (6).

III. The research activity of physicians is decreasing. In 1966, approximately 44% of competing research grant awards to new principal investigators were made to MDs. In 1978, MDs received only 23% of the total number of new and competing grant awards. During this same time period, the total number of competing research grants awarded to MDs has remained relatively stable, and the success rate of MDs who submit research grant proposals has remained constant. In contrast, awards made to PhD investigators have doubled as have the number of research grant applications submitted by PhDs. Thus, the numbers of MD investigators in the total research effort has relatively decreased. Further, although the ranks of medical school faculty have grown substantially over recent years, the number of MDs seeking research support from NIH has not kept pace. Data from the AMA show that the number of physicians reporting research as a primary activity has decreased from 15,441 in 1968, to 7,944 in 1975 (7), while at the same time the number of full-time faculty at U.S. medical schools has increased by 160%.

The implications of these trends for U.S. biomedical and behavioral research and for patient care will be discussed at length in a subsequent section.

B. Basic Considerations Relating to the Research Training of Physicians

The many ways in which the interest of undergraduate and graduate physicians in research careers is developed must be understood if effective steps are to be taken to ensure adequate numbers of clinical investigators. Some students develop an interest in and talent for research during premedical training. At least 200 such students develop strong enough biomedical research interests each year to apply for federal support leading to combined MD-PhD degrees (8). These highly motivated and outstanding students are very likely to enter academic and research careers upon completion of their training if they are given the proper experience and support.

More commonly, however, students receive their first critical exposure to research in the medical curriculum either by performing laboratory experiments in basic science courses or through more formal, short-term (3 to 12 month) research electives or fellowships. These are the students who at graduation may express an interest in careers in medical research and teaching. Whether they will enter such careers almost always depends on their postgraduate medical education experiences. If sufficient interest in research is stimulated in medical school, it is likely that a student may select a postgraduate residency training program that is academically oriented and that offers the continuing opportunity to develop research experience. Similarly, the undecided student may find in the residency the challenge and support which leads to a research career. A recent study confirms that the "research" orientation of the residency is the second most powerful determinant of a physician's entry into research and success in such a career (9). Thus, the research "climate" at the academic medical centers and the presence of role models for research careers is very important for students in both undergraduate and graduate medical education.

It is at the end of most residencies (or about mid-way in surgery and surgical specialty residencies) that the very difficult decision for a research career must be confirmed and sustained by the young physician. Having shown enough clinical ability to gain the confidence of clinical superiors, the young physician must then decide whether to enter practice with its larger financial and patient-care rewards or try to establish a mark in teaching and research. Resident physicians have had sufficient clinical training to assure them that they will succeed in clinical practice. In contrast the resident has generally had little or no research experience and thus cannot assess his or her potential for success in a research and teaching career. Also, in past years research careers were held in higher esteem by the public while more recent public sentiment favors careers in patient care. While clinical incomes have soared, research funding has become more uncertain, and the federal government, by establishing the payback provision, now requires a commitment to academic careers as a condition for awarding research training funds. Obviously, these factors combine to dissuade the interested but untried researcher from taking the fellowship that may provide the first solid research foundation for an academic career.

For those who do undertake a research fellowship, the location and nature of that experience has been shown to be the most powerful determinant of the trainee's research career outcome (9). If the fellowship is taken at an institution where there is a high level of research and scholarly activity the trainee is much more likely to go on to a successful academic career with academic tenure, productivity and grant success. There remain two final critical steps for those who successfully complete research training: gaining an academic faculty position and obtaining the assurance of early career support for the chosen research endeavor. If either of these fail to materialize, clinical practice remains an attractive and lucrative alternative.

As will be discussed in more detail below, the circumstances under which clinical research training is provided to graduate physicians in the United States varies depending on the discipline involved. Further, training for clinical specialty practice has been traditionally interwoven with training for research for most of those physicians who subsequently entered careers in research and teaching. This intermixed clinical and research training is changing under a variety of pressures (e.g., federal support for trainees, specialty board requirements). To an increasing degree, clinical specialties are being pressed to separate clinical training from the research training. A major pressure for this separation has been the federal decision to limit federal funding support to research training. This has created some tensions not only because clinical and research training have traditionally been intermixed but also because many clinical research activities can be conducted in patient care settings. A notable exception has been the Veterans Administration programs although pressures are now being brought to bear within the VA to restrict support for research training and clinical investigators.

The success of three decades of federal research training programs, especially for PhDs, and limited research grant funds have created a situation in which only those clinicians most rigorously trained in research can compete successfully for research support and advance the frontiers of science. Thus, it may be that the time has come to assure the development of solid, clinical research training programs of the highest possible caliber to assure that physicians are prepared for long and productive careers in clinical investigation.

DISCUSSION

A. Implications fo the Trends in Clinical Research Manpower

If the trends described in the previous section continue, there will be serious consequences not only for biomedical research and medical education but also for patient care. The physician investigator possesses unique capabilities and perspectives that form the bridge between the research lab and the bedside. On one hand, the physician's knowledge of human disease is essential in focusing research ideas and maintaining the relevancy link between research and the treatment of patients. The MD possesses the clinical insight to transfer knowledge gained through research to the patient. Conversely, many research ideas are sparked by a physician encountering a particular patient care problem and transferring ideas about the problem back to the research laboratory. Without the physician investigator in the cross-over role, the separation between basic science and clinical science departments would be exacerbated; neither group will operate optimally in isolation from the other.

Teaching medical students is an equally important role of the physician investigator. By virtue of providing a link between science and patient care, the clinical researcher makes an important contribution to the educational and professional development of all medical students regardless of their specific career aspirations. The clinical investigator is uniquely able to demonstrate and stress the importance of the scientific basis of medical practice. In addition, the clinical researcher is an obviously important role model to students aspiring to a research career.

From the national perspective, the continuing search for new scientific knowledge to improve the nation's health depends on the constant influx of a cadre of bright and dedicated MD investigators.

It has been difficult to determine the precise number of clinical researchers needed to operate the nation's biomedical research programs and the mechanisms by which these researchers should be trained. The National Research Council of the National Academy of Sciences, charged since 1974 by Congress with determining the need for researchers in all fields including clinical research, has estimated that about 2,800 MD-postdoctoral research trainees and 700 MD-PhD predoctoral trainees should be supported by NIH each year (7). Complicating this assessment of need for and support of clinical research training is the fact that a significant but indeterminate number of clinical trainees receive some training for research careers with support from various additional sources: Veterans Administration, hospital funds, physician earning and private foundations (10). Such training is highly variable with respect to the rigor and duration of the research training provided. In many cases, it appears that training program directors involve trainees in mixed clinical and research experiences which do not provide the basic grounding needed to develop independent clinical investigators who can compete successfully for available research funds (10). Another factor complicating the decision of how many clinical researchers should be trained is the relatively short period of research productivity of MDs (as opposed to PhDs) both because their longer training programs delay their research careers and because they leave earlier for clinical or administrative activities. Therefore, the question of whether the appropriate number of clinical investigators, supported by all sources,

are currently being trained is not easily answered. However, the over-riding fact that federally-supported MD research trainees have decreased precipitously since 1975 and are now one-third to one-half below the NAS-NRC goals, indicates that the nation is attracting and training insufficient numbers of physician investigators. All of these factors make the determination of the precise numbers of clinical research trainees and their support programs difficult.

B. Probable Causes of the Trends

There appear to be numerous, interrelated causes for the current trends in clinical research manpower. No single factor, such as the vagaries of federal funding, should be examined in isolation because a one-dimensional approach to a problem of this magnitude would be simplistic and ineffective. Some causes are easily recognizable and can be supported by current data while others require considerable dissection and may be more subjective in nature; each must be addressed if the current trends are to be reversed. The approach to the causes and their solutions that follows will be organized along the continuum of medical education and practice.

Medical Students.

During medical school, the first critical career decisions are made that determine whether an individual may become a clinical investigator. If interest in research is stimulated and sufficiently nurtured in medical school, it is likely that a student will select postgraduate training that is academically oriented and offers the opportunity to continue the research experience. If a student's interest in investigation is not stimulated in medical school, it is less likely that the graduating student will seek such an experience during the postdoctoral training experience.

Other problems besetting present-day medical students are economic. Rising tuition and costs, especially in the private schools, lead to larger student debts than ever before and make it doubly important to consider the level of trainee stipends which will make research experiences attractive to medical students.

Students who accumulate a large debt burden through college and medical school will make career decisions within a framework that includes income potential. All of these factors combined with the uncertainties of federal funding of research, make a career in research less attractive economically. When the federal requirement for the research trainee to pay back, in time or money, for research training support is considered along with other economic disincentives, the likelihood of medical student commitment to a research career diminishes even further.

Though primary care and biomedical research should not be thought of as mutually exclusive types of careers, the rise in popularity of one may be related to declining interest in the other. Student career decisions appear to be heavily influenced by the national call for primary care physicians. Financial aid sources, especially at the state level, are increasingly linked to service in under-doctored areas. The curriculum in medical schools is beginning to reflect this emphasis on primary care medicine. Federal funding for generalist residency programs is on the rise and students cannot close their eyes to these incentives.

Additional factors cited by students as causes for the declining interest in an academic career include the lack of exposure to research through laboratory courses and informal interaction with faculty. In previous eras a student might become interested in research by repeating classical experiments in basic science or by casual laboratory interactions with faculty members. Today's medical school curricula, laboratory technology and the demands on faculty time are such that this type of faculty-student interaction is infrequent.

A recent AAMC survey (11) showed that research opportunities for medical students are highly variable (11). At least a few opportunities are available at most institutions but at a few schools the student demand for research experiences far exceeds available resources. In many cases students are unable to take advantage of research opportunities because of inadequate financial support, lack of laboratory facilities, or because of scheduling conflicts. The AAMC survey also found that counselling about research opportunities and careers is inadequate at most schools.

Special attention to the needs of minority medical students and faculty is required. American medical colleges would be assisted in their efforts to recruit and retain minority medical students if increased number of minority faculty members could be found. These faculty serve as important role-models for students, and their numbers should be increased by a special effort to recruit minority physicians into high quality research training programs (e.g. the Research Associate Program of the NIH Clinical Center). Such research training would make more certain early faculty appointment and the ability to compete for research funds.

Residents.

As previously noted, residency training is the time when an individual decides whether to commit an additional major block of time and effort to research training to prepare for a career as a clinical investigator. Residency programs vary in the amount of emphasis given or time allowed for research experience. Some residencies, including a number of the surgical specialties, routinely include from three months to one year of clinical research experience as an intrinsic part of the residency training program supported by the hospital. This research experience is given not so much in anticipation of producing clinical investigators, but because it is thought to be an important part in the training of a clinical specialist. Such exposure to research enables a clinician to interpret and keep up with advances in the specialty in the years ahead. The exposure is sufficient in some cases to encourage an individual to seek additional, in-depth research training beyond the usual clinical residency. It is this stimulation to obtain additional research experience which marks the commitment to a career in clinical investigation.

The pattern for including a research experience within a standard residency varies widely among specialties and even within the approved programs of individual specialties. For example, the minimum training requirement for consideration by the American Board of Surgery is four clinical years of training, but the Board encourages hospitals to offer programs of five years duration. A research experience is often included as the third or fourth year of a five year hospital-sponsored residency program with approval of the Residency Review Committee in Surgery. On the other hand, the American Boards of Pediatrics, Internal Medicine, and other primary specialties no longer consider research experience as a part of

their general training requirements. Since residency program structure is determined by board requirements those training programs that wish to encourage clinical investigation must usually find other sources of funding for the research experience outside the usual mechanisms for residency funding. In the past, this research experience was often incorporated into subspecialty fellowships, many of which were funded by federal training grants. In recent years, the debate about the need for more subspecialists has led to serious questions by federal and other funding agencies as to whether it is appropriate for public funds to be used for research training provided in connection with subspecialty training. These considerations led to a reduction in the funding of subspecialty fellowships which in turn reduced the number of opportunities for research training. To correct this trend psychiatry, perhaps pediatrics, internal medicine and other specialties should again acknowledge that opportunities for research experience are important during the general residency period and are appropriate for the education of many qualified specialists especially those who will go on to academic careers. The Boards and Residency Review Committees should adopt flexible policies to allow those physicians planning careers in research and teaching to count some early research time toward their primary Board requirements. A research component during the subspecialty training period is now permitted and should be continued.

Probable causes for the declining interest in an academic career at the residency level are similar to those experienced by medical students and have been discussed above. As residents make definitive career decisions, such disincentives as the payback provision and perceptions that the academic life is filled with funding uncertainties, much paperwork, and relatively low financial rewards, make the decision to try research difficult. Most residency schedules are inflexible and not conducive to the periodic renewal of research interests. This inflexibility together with the primary specialty board requirements previously mentioned affects the resident's inclination towards research. For a resident entering post-graduate training with an interest in research, it is at least three years before any significant laboratory experience is gained. For most residents, and especially for those with family obligations, a heavy debt burden, and pessimism about their academic future, a four-year waiting period may be the "coup-de-grace" to an initial interest in research.

Advanced Clinical Trainees.¹

The subtle disincentives that might cause medical students or residents to exclude an academic career from their career options become very tangible at the fellowship and advanced clinical trainee level. Negative attitudes conveyed by senior faculty about the problems associated with research as well as personal economic issues remain paramount on the long list of disincentives. Medical students and residents may have had some perception of the disincentives to research but physicians in advanced training see at close range the uncertainties related to funding; the continuing paperwork required to obtain grant support; the heavy workload to meet teaching, administrative, patient care, and research responsibilities;

¹ This term includes subspecialty trainees (residents and fellows) in surgical specialties and subspecialty fellows in the medical specialties.

and the knowledge that their colleagues in private practice are surpassing them in income. Added to these realities is the further fact that a six-month to one-year research experience hardly prepares an individual for a career as an independent investigator. The potential researcher must acquire an additional one to three years of research training to be assured of success as a clinical investigator.

When the potential researcher faces the decision of whether to commit an additional year or more to research training supported by federal funds, the payback provision poses an important disincentive. While it can be argued that the payback provision is not a strong disincentive to the trainee sure of his or her own research potential, it is certainly not an incentive to pursue research training to determine whether one is suited for such a career.

Junior Faculty.

The transition of the young physician from research training to faculty status requires special consideration. The local and national institutions supporting research training programs must accept responsibility for the placement of graduates of these programs in appropriate academic positions. Another problem at this stage is a lack of a smooth and orderly mechanism for a fully trained clinical investigator to identify and choose the most desirable opportunity among the nation's medical institutions to pursue a career as a junior faculty member. Finally, there is the need to nurture the neophyte faculty member, assuring research support and particularly protecting him or her from commitments of time or energy that conflict with the faculty member's desire and need to establish an independent research career.

A number of programs have recently been introduced by both the federal government and private foundations which recognize these problems. These five-year programs provide realistic salaries and require institutional commitment in terms of support and protection of the young faculty member's time for research. The programs are, however, limited in number. Although these clinical investigator award programs address the problem of junior faculty support in a positive way and should be expanded, they raise another problem. Most research training fellowships provide stipends in the range of \$15,000 to 17,000 per annum. The clinical investigator awards, on the other hand, provide \$25,000 per year thus creating two levels of support for what may be identical training experiences. However, the higher level is more realistic in view of the clinical income which could be earned. It has been suggested that the \$25,000 level should be awarded for 3 to 5 years based upon the candidate's record of research ability and the institution's commitment. The ad hoc Committee is divided on this point.

It is during the first five or so years of faculty experience that many well trained clinical investigators are lost. Problems at this level include difficulties in obtaining funding for independent research, the paperwork and restrictions that continue to increase related to grant applications and compliance with a variety of regulations. The increasing demands of the medical centers for the faculty to commit more time and effort to individual clinical practice impacts severely on the junior faculty, and in many institutions a heavy part of the teaching load is placed on the junior faculty. Also, the negative attitudes of senior faculty about research and financial issues impact particularly upon the junior faculty at this point.

RECOMMENDATIONS

Since the etiologies of the declining interest in clinical research are varied and interrelated, a broad effort at several levels--the AAMC, the local institutions, state and federal governments, and private foundations and corporations--must be undertaken to solve the identifiable problems.

The two times along the continuum of medical education which appear to offer the most fruitful opportunities for change and attitude adjustment are medical school and the advanced trainee or research fellowship phase. In order to stimulate a stronger interest in clinical research, faculty need to provide positive and exciting research experiences during undergraduate medical education. Any interest sparked must then be carefully nurtured and encouraged since it is unrealistic to expect students to retain an interest in research when faced with a myriad of disincentives, competing attractions, and sacrifices. During the advanced clinical trainee period, research opportunities should be improved and fellows should be enabled to pursue research in a protected and supportive environment. Program directors at institutions whose goals include the education of clinical investigators must accept the responsibility for counselling, encouraging, and finding funding to support the additional research experience which will assure competitive research careers.

The recommendations which follow are grouped according to the various organizations and entities affecting the supply of clinical research manpower. Within each major category, recommendations are targeted at the chronological stages in the medical education continuum where changes and adjustments might be made.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

General:

- 1) The Association should document the decline in clinical research manpower and report the implications for medical education and health care if this trend continues. Position papers should be widely distributed to the academic medical community, to governmental agencies, and to the public. Further, the AAMC should highlight the issue of clinical research manpower in a positive and constructive way at national meetings and in its publications.
- 2) The AAMC should assume a liaison role with the public and private sectors to assure adequate research training support at all levels.
- 3) The AAMC should emphasize research training opportunities for minority medical students and residents as an adjunct to affirmative action programs.

Medical Students:

- 1) The AAMC should urge the LCME to examine student research programs in the accreditation process.

- 2) The AAMC should develop a publication describing sources of research support, both public and private, available to students. To support this publication the AAMC should augment its data on MD-PhD programs, research support for medical students, and other areas providing insight into the problems in clinical research.
- 3) The AAMC should develop a definition of what constitutes an appropriate research experience for students to provide guidance to institutions designing research programs.

Residents, Fellows and Advanced Clinical Trainees:

- 1) The AAMC should include in its publications data and sources of support for advanced research trainees.
- 2) The AAMC, recognizing the distinction between clinical subspecialty training and research training, should develop a definition of the essential features of research experiences for postdoctoral fellows to prepare them for productive research careers.
- 3) The AAMC should adopt a position on the economic differential for MD and PhD research trainees. It is clear that MD trainees and PhD trainees make decisions about research experiences and ultimate career goals within a different economic matrix, and there should be recognition of this fact in stipend levels, in application of the payback provision, etc.
- 4) The AAMC should obtain precise information about the payback provision--how it is viewed by NIH and ADAMHA and how it is being enforced--for distribution to the constituency.

Faculty:

- 1) The AAMC should gather data describing sources of research and career support, both public and private, for faculty.
- 2) The AAMC should encourage cooperation and communication between individual societies examining the issues of clinical research manpower. Professional societies representing clinical department chairman should particularly be encouraged to become involved with the issue.

MEDICAL SCHOOLS

Students:

- 1) Medical schools should design student research programs that provide students with stimulating research experiences.
- 2) Medical schools should develop advisory systems to inform students about careers in clinical research and about opportunities for research experiences while in school. Faculty should encourage bright and promising students with research interests.

- 3) Medical schools should examine their own capacity to expand MD-PhD programs, clinical scientist programs, etc. where these are consistent with institutional goals.
- 4) Those medical schools whose goals include education of future investigators should examine their curricula to ensure exposure to research whether through reintroduction of laboratory courses, summer or short-term fellowships, thesis requirements, or electives.
- 5) Medical school admission committees should identify for special encouragement after admission those students who have done productive research as undergraduates.

Residents, Fellows and Advanced Trainees:

- 1) Medical schools should encourage program directors to provide flexibility in residency schedules for trainees desiring research experience.

THE FEDERAL GOVERNMENT

Students:

- 1) The federal government should develop an additional program with reasonable stipend levels to support medical student research specifically. This program should not compete for funds with present research training programs.
- 2) The NIH and ADAMHA should change its policy against providing stipend support to medical students receiving academic credit for a research elective or fellowship.
- 3) The federal government should increase its support of the Medical Scientist Training Program since there are more qualified applicants than places for MD-PhD positions.
- 4) The NIH and ADAMHA should more widely publicize its intramural student elective program. Special emphasis should be given to minority medical students.

Residents, Fellows and Advanced Research Trainees:

- 1) The NIH and ADAMHA should establish a flexible policy with regard to stipend levels and not force institutions to reduce the number of research training positions to increase stipend support.
- 2) The government should modify or eliminate the payback provision for MD research trainees (as opposed to clinical trainees for which federal support is not and should not be available).

- 3) Veterans Administration support for research training should be maintained.
- 4) The advantages of research training in the NIH Intramural Program should be publicized more widely to minority students and physicians.

Faculty:

- 1) The federal government should consider structural changes (such as lengthening the grant period) in its research programs to reduce paperwork and improve grant conditions.
- 2) The federal government should provide stable and adequate funding for research resource programs such as the Clinical Research Centers Program and Biomedical Research Support Grant Program.
- 3) The federal government should increase its support for clinical research faculty through long term support mechanism (e.g., RCDAs, and VA career investigators). The very successful VA career investigator program should be continued and expanded.
- 4) The federal government should examine its research training programs thoroughly to ascertain which have been most effective and productive.

PRIVATE SECTOR

- 1) Specialty certifying boards should examine whether some research training is appropriate and, if so, should grant credit for research training toward primary specialty board requirements.
- 2) Private foundations and corporations which depend upon physician investigators to carry out their activities and help them to achieve their goals should be made aware that there is a crisis in clinical research manpower. The private sector also depends heavily upon clinician investigators in some fields to advance the objectives of the corporations involved in medical and research related activities. These foundations and corporations should be encouraged to provide long-term support for physician research training and MD-generated clinical investigation at all levels. Creative approaches to solving the problems, a hallmark of foundation support in the past, is sorely needed.

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S.988-HEALTH SCIENCE PROMOTION ACT OF 1979

The Health Science Promotion Act of 1979, introduced in April 1979 by Senators Kennedy, Schweiker, Williams, and Javits is moving forward slowly through the Senate. Hearings were held in May at which Dr. Richard S. Ross testified on behalf of the AAMC. Following this, the bill was modified in a number of respects, the most significant of which were: to eliminate the sunset provisions which would have put all of the institutes of the NIH out of business in 1984; and to include research training in the mission statement of the NIH.

(The AAMC staff received what appears to have been the first draft of the revised bill, and the enclosed analysis is based on that. Subsequently, and without our knowledge, a final draft, the one currently extant at the time of this writing, was released. The only difference that the staff has been able to ascertain between the early and late draft revisions relates to the composition of the Council: In the first draft, the composition of the Council was composed of 5 biomedical, 5 behavioral and social scientists, and 5 non-scientific members; in the second draft revision, this was changed to 6 biomedical, 5 behavioral and social scientists, and 4 non-scientific members.)

Attachment I is the AAMC staff analysis and critique of S.988. In summary the staff recommendations are that:

- The President's Council on the Health Sciences, as proposed in Title I of the Act, is unacceptable. Its function, that of a planning body, is inappropriate and its charge to report simultaneously to the Secretary, the Congress, and the President is not only unworkable but counter-productive, since it compromises the traditional separation of powers between the Executive and Legislative Branches of Government. Alternatively, the AAMC staff recommend that the Council be established as an advisory body, located within and reporting to the Congress. While the difficulty of accommodating such an arrangement within the structure and tradition of the legislative branch presents difficult problems, nonetheless it is felt that since one major hiatus in the Government's scientific advisory apparatus is the absence of a formal scientific advisory apparatus for the Congress, a President's Council, advising to the Congress was highly desirable.
- The recommendations of the AAMC staff with respect to Title II are modest. The need for Title II in its entirety is seriously questioned, as also are the desirability of several of the "experiments" recommended. Particularly, reservations were expressed about the inclusion of social scientists and non-scientists on study sections, the provision of discretionary funds to the Director, NIH to support "under developed and under funded areas" as well as "unconventional and innovative research", and the requirement to establish an appeals process.

The AAMC staff applauds the intent behind the provision which gives the Director authority to establish advisory committees---a clear attempt to "end around" the Federal Advisory Committee Act. However reservations were expressed about the adequacy of this provision to accomplish the desired ends. The Commission's statements of the various institutes were viewed to be too narrowly cast and very likely to create serious operational problems.

- The provisions in Title III to reduce paperwork were applauded, even though authority to carry out the proposed "experiments" is already available to the federal agencies. Minor reservations are voiced on specifics.
- The AAMC analysis and critique ended up with the overall assessment that the proposed statute did very little to actually promote the health sciences and cited the critical need of that functional activity for meaningful assistance.

The staff analysis was sent to the members of the AAMC Biomedical Research Committee, together with a copy of the revised version of S.988. Attachment II is a brief distillate of the comments of the members of this committee.

Drs. David Blumenthal and Donald Nutter, who up until now have borne major responsibility for the development and modification of this legislation have now passed the baton on to Dr. Robert S. Graham. The Senate staff is in the process of collecting and collating the comments on the currently extant text of the bill and expect to revise it still further by the end of the year. Additional hearings this year are unlikely. As yet, there is no evidence of any comparable legislative proposal in the House of Representatives.

INTRODUCTION

On April 26, 1979, Senators Kennedy, Schweiker, Williams, and Javits introduced S. 988, the Health Science Promotion Act of 1979. On May 2, Dr. Richard S. Ross, Dean, Johns Hopkins University School of Medicine testified on this bill for the Subcommittee on Health and Scientific Research of the Senate Human Resources Committee, presenting a tentative AAMC position and assuring the Subcommittee that this would be followed by a more definitive one, based on a more thoughtful and considerate analysis than had been possible to prepare in the brief interval between the introduction of the bill and the hearings. This staff paper represents such an analysis, based, it is important to note, on a revised version of the original bill that did not become available to the AAMC until July 13, 1979.

TITLE I - THE PRESIDENT'S COUNCIL ON THE HEALTH SCIENCES

Title I of the bill establishes an entity entitled the President's Council on the Health Sciences, a fifteen-member body composed of five biomedical, five behavioral and social scientists together with five non-scientific members. With the advice and consent of the Senate, the President would appoint all members and designate one as Chairman. The major responsibility of the Council would be to develop each year---after review of plans submitted by the Departments health research agencies---a five-year "national health sciences plan" that would recommend a one-year budget for all health science areas within the purview of the DHEW and would assign priorities for expenditures in these areas for the next four years. In formulating the plan, the Council would be expected to take into consideration criteria such as the mortality and morbidity of specific diseases, the opportunities for research, the extent of support available from federal agencies other than DHEW and the level of public concern. The format of its recommendations would be to specify expenditures for research in terms of: fundamental knowledge of health and disease; primary and secondary prevention; treatment and rehabilitation; support for regulatory agencies in DHEW and other federal departments; and training. In addition, the plan would also identify areas of health science research that are relatively underfunded and underdeveloped and propose measures to promote research in those areas; for the first three years of the plan, epidemiology, behavioral sciences, and the environmental health sciences are deemed underfunded or underdeveloped. Budget submissions based on either no change from, or 5, 10, and 15% increases over the previous years budget authority would be required. Each year, the Secretary/DHEW would be required to submit simultaneously with the President's budget a response

to the Council's plan, including an explanation of differences in funding levels and disagreements on spending priorities between the Council's recommendations and the President's budget. The plan would simultaneously be made available to the President, the Secretary/DHEW, and the Congress. The statute would permit the Council to undertake or support a variety of proposals to improve methodologies for the evaluation of completed research and for the planning of future research. The Council is required to regularly monitor and report on the current status of the physical facilities and the equipment/instrumentation for health science research throughout the nation. The annual authorization ceiling for the Council would be 1/4 of the funds available for evaluation of Title IV programs under Section 513 through FY 1985. The Council would cease to exist on December 31, 1985.

General Critique

The AAMC staff has reviewed the basic concept inherent of Title I in the context of: the recommendations of the 1976 Report of the President's Biomedical Research Panel; the Association's reaction to that Report; the national effort recently stimulated by the Secretary/DHEW to develop a set of planning principles; the critique of that effort by the Institute of Medicine (IOM); and the current as well as the historic administration of biomedical and behavioral research programs in the DHEW. The staff has also explored alternative concepts on which such a Council might be built. Finally, a recommendation for modification has been formulated.

The basic concept proposed in S. 988 is that the President's Council on the Health Sciences function as a planning body for all of the health research responsibilities assigned to the DHEW. Presumably, jurisdictional boundaries on the scope of the Senate Human Resources Committee preclude assigning the Council a broader compass, including the health research activities of other Federal Agencies, such as the Veterans Administration (VA), the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), the Department of Energy (DOE), the National Science Foundation (NSF), and other Federal Agencies engaged in health research. A large, complex and sophisticated apparatus for planning already exists within the National Institutes of Health (NIH), even though most of it is not so labeled and may therefore not be easily recognized by the casual observer; comparable functions of substantial size exist in other Federal science agencies. Planning must, of course, be an integral and inescapable component of any organization assigned important responsibilities and trusted with the stewardship of large amounts of public funds. Whatever the fate of S. 988, planning will necessarily continue in the Executive agencies. S. 988 proposes an additional planning process. To evaluate the desirability of this replication, a number of factors must be considered.

The Nature of Scientific Planning.

Any discussion of scientific planning must immediately draw a fundamental distinction between planning for scientific research and planning for resources for scientific research. The former is complex and difficult, as will be elaborated in a moment; the latter is quite feasible, once decisions on some of the several important parameters of a program have been made. For instance, once the level of investment in a research program has been established, the requirements that must be met to conduct the program---of physical facilities, number and type of scientific and technical personnel, etc.,---can be specified with considerable accuracy. Additional resources---equipment, supplies, information and data, supporting services, and a host of other requirements can be approximated with reasonable accuracy by experts. Obviously, resource requirements will depend on the field of research, the "state-of-the-art" in that field, and other cognate issues. But in general the extent to which these variables modulate resource requirements are well understood.

On the other hand, planning for scientific research is fundamentally a "bottom-up" process. The most significant determinant of scientific progress and the most dependable harbinger of scientific opportunity is new discovery. New discovery is an unpredictable outcome of the efforts of highly intelligent and carefully trained scientists who have mastered---often at a very tender age---the ineffable art of being able to recognize a problem that is both soluble and significant in a field that is ready and ripe for penetration and progress. When perceived---often after a lag period of shorter or longer duration---and to the extent of its importance, new discovery causes working scientists to modulate their plans---in the aggregate, "THE PLAN"---and moves administrators and legislators to reallocate resources. Meaningful scientific planning must be based on intimate knowledge of the past and current status of the scientific disciplines that comprise the effort and that are expending, coalescing, fragmenting and evolving at a very rapid rate. While change in the corpus of a discipline may appear small over a short (one year) period, the cumulation of discovery at the edges of it produces very substantial revision over a longer epoch (a decade). In this context, scientific planning imposes characteristic requirements.

The Scale of the Effort. Planning must be on a large scale in that familiarity with domain as large as health science can only be encompassed by a large number of experts. While the tasks of planning and allocating resources need not and probably should not be their full time activity, the vast substantive content of the domain precludes any reduction in the total number of scientists involved in the basic effort. One full time science administrator, isolated from science and scientists, cannot take the place of twenty working scientists devoting five percent of their effort to this function.

Continuity. The planning function must be a continuous one, adjusting resource allocations to keep pace with discovery. The organization responsible for a national plan must be so constituted to enable it to respond rapidly and continuously to the dynamism of science.

Information requirements. A truly useful and meaningful plan must be based on early information about discovery but even more importantly about how working scientists perceive discovery and how they propose to exploit it to advance their field.

However expertly the planning is performed within a domain of science whose content is within the ken of a manageable sized group of scientists and scientific administrators, the problems associated with establishing the *relative importance* of a whole series of such domains are formidable both in theory and in practice. An enterprise as large as the current national biomedical research enterprise---incidentally just one, albeit the largest, component of global endeavor---that presently engages the full- or part-time energies of probably more than 50,000 bright and well trained scientists is essentially far beyond the comprehension of any individual or group. The judgments of relative importance of different fields that are required to construct a budget must not prescind from the scientific realities identified in the detailed planning in a specific domain but must at the same time utilize additional criteria that are less objective and definable. Planning, at least for basic or applied research, if not for development, should be recognized for what it really is and is not. It is a formal catalogue of the best guesses that can be made by scientists and scientist administrators whose track record for predicting the future is good. It is a congeries of scientific facts, probabilities, intuitions and aesthetic judgments, highly conditioned by the personal experience of the individual planners as well as by the interactions among planners. The decisions embodied in it are not, and cannot be, either "right" or "wrong." Moreover, in most instances, the outcome of having decided otherwise will never be known. More than anything else, it is a process to insure that the final outcome---the budget recommended---has been developed through expert, disciplined and thoughtful analysis and forecast.

Existing Federal Apparatus for Planning Biomedical Research.

The mechanism for planning most familiar to the constituency of the AAMC is the one that has been operating for the last three decades at the NIH. It encompasses: a significant fraction of the time and effort of scientist administrators in the Office of the Director, NIH and in the Institutes and research Divisions which comprise that organization; the part-time assistance of a very large body of external advisors, drawn from the community of biomedical research workers, to serve as members of study sections, National Advisory Councils, *ad hoc* advisory committees, or to participate in a variety of

"state-of-the-art" conferences and workshops; and the massive flow of new ideas contained in research proposals submitted for funding.

This planning apparatus is continually functioning, is of critical mass, deploys a wide range of expertise and has available to it a host of new ideas. The formal planning documents---annual budget submissions and annual five year plans---prepared by the Institutes are modulated by the Director, NIH and forwarded to higher eschelons, where further modulation occurs. The lower the administrative level of planning, the greater the importance of purely scientific and technical considerations; the higher the level, the greater the influence of social, economic, and political forces. But even within an Institute of the NIH, non-scientific criteria must per force come into play. No theoretical framework exists for allocating an increment or decrement of, say, \$5 million between, say, examination of the next group of high priority compounds for their carcinogenicity vs. undertaking additional clinical trials of new chemotherapeutic agents against possibly responsive tumors vs. investing in studies on the basic biology of neoplasia vs. the host of other choices that could lay claim on the funds. Moreover, the logic that might be persuasive for a \$5 million marginal change might be totally unacceptable for one of \$1 million or \$50 million. Faced with these choices, non-scientific factors, including intuition and taste, begin to come into play. At the level of the Director, NIH, the degree to which decisions are based entirely on scientific and technical factors is further reduced. While few would be willing to say it publicly---lest they be charged with "fouling the nest"---probably half of the biomedical scientists in the US (and elsewhere) are convinced that too much money is available for cancer research; the other half would hold that there was either too little or just enough. A major task of the Director, NIH is to recommend allocation, across the whole spectrum of medical diseases, of the expected or desired appropriation request to research that is most likely to lead to the solution of problems, taking into account not only the factors mentioned in the proposed new Section 492 (b)(1)(A) of S.988, but also a host of others.

The Office of the Director, NIH, is the final site in the development of a budget or a research plan at which modulation on scientific and technical grounds takes place. In the DHEW and the OMB, only economic, fiscal, social and political criteria are invoked. This highlights one major deficiency in the budgeting and planning processes for biomedical research: the need for scientific and technical expertise to contribute to the discussions on the relative priorities and fund allocations between the various health components of the DHEW and between DHEW and other Federal agencies engaged in the conduct or support of biomedical research. This deficiency was addressed by the Report

of the President's Biomedical Research Panel in the section entitled "Science Advice." The recommendations that emerged from this body's deliberations were directed at: providing expert scientific advice to the President on NIH and ADAMHA programs; assuring coordination and consistency between a mechanism within the Executive Office of the President to assure "the integration of biomedical and behavioral interest in the total science enterprise." The creation of the Office of Science and Technology Policy (OSTP) in 1976 provided an organizational locus for the latter function. Mechanisms for achieving the others remain informal.

The AAMC agreed with the objectives of the President's Panel but dissented from its specific recommendations. The official AAMC position stated:

"Science Advice to the President. The Office of Science and Technology Policy (OSTP) as well as various advisory groups advising the President will be re-established in the near future. When OSTP begins to function, the value of the proposed President's Research Panels and their interlocking superstructure over NIH and ADAMHA is questionable. It is entirely possible that with so many advisory bodies functioning, the President may receive confused and even conflicting science advice. For these reasons, the Association believes that continuation of the President's Cancer or Biomedical Research Panels is not needed once OSTP and its staff and advisors begin functioning. However, a strong biomedical advisor to the President is needed. Therefore, the OSTP should be structured to provide biomedical and science advice. The special contributions and problems of biomedical research to the nation's science effort must be considered by this office. The information on which this advice is based should be forwarded from NIH, ADAMHA and other public agencies.

AAMC RECOMMENDATION: (5) AAMC recommends that biomedical and behavioral science advice to the President be furnished by the Office of Science and Technology Policy."

The President's Council on the Health Sciences proposed in Title I of S. 988 would not only discharge the advisory functions recommended by the President's Biomedical Research Panel but would go far beyond what that group envisaged by assuming responsibilities for budget development and long range priority setting.

When the Executive Branch has completed the planning process, it forwards its recommendations to the Congress in the form of the President's Budget. The Congress, until recently, has relied almost exclusively on the hearing process to evaluate the proposed budget, both overall and in detail. During the course of these hearings, the Congress has arranged to have scientific and technical experts from within and from without the government review and comment on the budget and has traditionally welcomed testimony from volunteer citizen witnesses, often pleading specific causes. More recently, the Congressional Budget Office has provided extensive non-partisan economic and

financial staff support. But the Congress must continue to depend heavily on the Executive Branch agencies for scientific and technical budget justifications and has no independent body to provide it, on a continuing and systematic basis, the counterpart of the scientific and technical information that the Federal agencies provide the President.

The 1976 Report of the President's Panel did not focus sharply on this problem of the Congress, but the AAMC analysis of and comment on its Report did, as follows:

"Discussion: Science Advice to the Congress. Although strengthening the biomedical science advisory apparatus in the Executive Branch is necessary, strengthening of the capability for scientific advice to the Congress is equally necessary. The Panel recommendations do not go far enough toward accomplishing a realistic increase in the kind and quality of science advice to the Congress. The Panel recommendations do not recognize the political realities of continuing tensions between Congress and the Executive. Recognizing this need, the National Science and Technology Priorities Act of 1976 (H.R.10230) suggests that the OSTP should provide science advice to Congress as well as to the Executive Branch. The Office of Technology Assessment (OTA) provides a useful parallel structure for the Congress similar to the executive Office for Science and Technology Policy. OTA should be increased in staff and responsibility so that it achieves a status and function comparable to the Congressional Budget Office. OTA advisory bodies, including advisory bodies for biomedical and behavioral science, should be chartered on a standing basis. Thus, an Office of Technology Assessment changed in function and organization could carry out an annual review, recommend priorities and describe to Congress opportunities in biomedical, behavioral and other research areas. Of particular merit in this proposal is the fact that if both congressional and executive scientific advisory bodies were established there would be adequate oversight by the Congress and a built-in system of checks and balances between the Executive and Congress.

AAMC RECOMMENDATION: (6) The Office of Technology Assessment (OTA) should be changed in function and organization to provide continuing biomedical and behavioral science advice to the Congress."

Again, while the AAMC recommendation emphasized an advisory function, the proposed President's Council on the Health Sciences encompasses an advisory function but, as previously noted, goes much further.

Evaluation of the Council Proposed in S. 988

Function of the Council. Against the background of the preceding discussion of the nature of scientific planning and the distinction drawn between a planning *versus* an advisory function, it is difficult to decide the precise functional role proposed for this Council. In the earlier (April 1979) version of the bill, it seemed clear that the Council was charged with the annual development, *de novo*, of a completely independent rolling five-year health sciences plan, including a one year health sciences budget, to be presented in

a highly stylized format. It was apparent that such a responsibility could be discharged only through a very substantial and costly planning effort, requiring a large full-time staff and the services of many *ad hoc* scientific consultants.

In the most recent (July, 1979) version, the product mandated is essentially the same, except for the additional requirement to formulate and present budgets at alternative funding levels. However, one of the changes in language suggests that the Council would be expected to have a more advisory than planning role, while another leads one to infer that a large planning task would continue to be necessary. The April language that required the Council to prepare the Plan after "consultation with the Secretary and the Assistant Secretary for Health" is replaced with the requirement that the task be carried out after "review of the health sciences plans submitted by each agency within the Department which conducts or supports health science research". This change suggests that the Council would simply be expected to critically review the planning exercises carried out within the Department and to utilize the information contained in these documents as the basis of its own recommendations. Thus, the task proposed in April would appear to have been substantially scaled down and its nature to have become more advisory than planning. On the other hand, however, the due date for presentation of the Council Plan to the Secretary, the President and the Congress has been moved from November 30 to October 1. Research agency budgets are formally scheduled to be sent to the DHEW by September 15 and do not always meet the deadline. So it would be almost impossible for the Council to review these, conduct the analyses necessary to reorganize the proposals into the categories required for the presentation format and prepare its own recommendations by October 1. The due date change could be interpreted to mean that the basic expectation of the Council is a complete planning effort, scheduled for early completion, i.e. before OMB review of the agency and Departmental recommendations; this basic task would be modulated by a quick scan of the material developed in the Agencies at the penultimate stage of the Council's work.

Thus, the AAMC staff is puzzled about the intended function of the Council. This body would, as constituted in the bill, certainly be able to fill what the AAMC views as a critically important niche in the processes of decision making on public support for health research, namely, the function of providing scientific and technical advice, free of the social, economic or political influences that inevitably and necessarily prevail during the development of the budget. It could also advise on the validity of the special interest pleadings---the "disease of the month" phenomena---that must inescapably be dealt with by the legislature. It could even provide an advocacy function for science that the Federal science agencies are restrained from performing. Finally, were the Council to view itself, or were it to be viewed, as an independent planning body, utilizing Executive Agency plans as only one of many bases for its recommendations, it could provide the whole panoply of advisory, planning and evaluative functions which now reside only in the Executive Branch.

In the last mentioned role, the Council would be enormously costly in terms of both funds and, more importantly, of demand on the time of the working scientists mobilized to advise it in a full scale planning effort. The permanent staff of scientist administrators would have to devote full time to the planning process, and, unlike their federal science agency counterparts, would be isolated almost completely from interactions with science and working scientists. Since the Council, at most, could probably be expected to recommend no more than marginal adjustments, the modest potential benefit to be derived from an unquestionably costly process would warrant careful evaluation.

Alternatively, the assignment and acceptance of a less imposing responsibility would permit the Council to base its budget and plan on its own evaluation of the raw information developed by the planners in the Executive agencies. It could begin its deliberations with a level of data and information varying from highly disaggregated to extensively preprocessed; the size of its operation would be scaled accordingly. If the choice were to deal with aggregated and preprocessed information, the function would shade imperceptibly into an advisory one.

Were the Council to operate under this type of mandate, its principal functions would be: to critique the plans developed in the Executive Agencies; to provide an independent non-partisan assessment of the proposals of special interest groups in terms of the "state of the art" in that area, the attractiveness of opportunities for progress, the magnitude and adequacy of the ongoing effort, and the reasonability of the recommendations of the special pleaders; and to bring attention to opportunities for progress that it views as promising but that, for one or another reason, had received less enthusiastic recognition in the regular planning or budget development process.

Constituency of the Council. As proposed, the Council would report simultaneously to the President, the Congress, and the Secretary/DHEW. The parallel processing (whether for planning or advising) of the Council might occasionally represent the welcome redundancy of a well designed fail-safe mechanism. However, when conflict and dissonance arise, the urge to ignore the dissenting Council will be exceeded only by the frustration that, as a free-floating agency, reporting and accountable as well as to the Congress, it is beyond the control of both the President and the Secretary. On practical grounds the Council would probably have to be assigned, for "rations and quarters" a niche in either the Legislative or the Executive Branch. This would inevitably lead to an attempt by the sponsoring Branch to "capture" the Council, or the emergence of the suspicion of the other Branch that the Council had become captive and, therefore, that it had lost its independence.

Timing of the Plan. There are interesting features about the due-date for the Council's Plan, as specified in the revised version of S. 988. For one, it comes so early in the annual budget cycle that it almost forces the Council to function as a planning rather than an advisory body, since the agency documents on which it

might otherwise rely as a substitute for a self-generated effort would in the normal course of events be available for review and analysis for only an extremely brief period. For another, the simultaneous presentation to the Secretary and to the President (i.e., the OMB) of both an Agency and an independently generated budget could stimulate additional complicating political forces and maneuvering, since the independently generated budget would be a potential instrument with which the Congress could challenge the President.

Were the Council to operate as an advisory body, but with access to Executive Branch documents, the due date would have to be later in the budget cycle than October 1. A minimum of 60-90 days after receipt of Executive Agency documents would probably be required for the Council to prepare its recommendations. If the due date were after submission of the President's budget, the Council would have the opportunity to evaluate the nature of and the basis for the modifications of the budget made, respectively, by agency heads, the Assistant Secretary of Health, the Secretary and the OMB and to reach an independent assessment of the wisdom of these revisions.

AAMC Recommendation.

The Association views it essential that the nature, purpose and functions of the President's Council for the Health Sciences in Title I of S.988 be clearly and unambiguously defined. It further strongly recommends that this clarification specify a Council whose principal function would be to *advise but not plan or develop budgets* and that would report exclusively to the Congress. This Council should be authorized access to the planning and budget information and documents in the possession of the Federal agencies on a timely basis. Its primary mission would be to provide the Congress an independent review and commentary on the short range (budget) and long-range (5 year) plans of the Executive agencies. Its Report, to be useful should be available no later than March 30 of each year to the Congressional Budget Committees, for inclusion in the debate on the First Concurrent Budget Resolution, and to the Appropriations Committees. The Council should also be available for *ad hoc* scientific advice on specific issues referred to it by the Congress or its staff.

The rationale for this recommendation is the AAMC perception that the Executive Branch is well served by its present machinery but that the Congress is not. The prevailing situation honors more in the breach than the observance the tradition of balanced powers because a clear imbalance now exists. The more dependent the Congress is on the Executive Branch for technical expertise, the higher the level of distrust it is likely to harbor. The AAMC recommendation envisages more equal actual access to expertise, with the capability of securing an independent "second opinion" from a group whose loyalty is not to the Executive Branch. Since it is the Congress that, in

the final analysis, must make the actual allocation decisions, the legislature cannot expect complete relief from the anxieties occasioned by the conflicting claims. But an autonomous advisory Council would make evident the extent to which a technical consensus did or did not prevail and would thus permit the Congress to focus on what it does best, i.e., make political choices. The mere existence of a source of independent scientific advice in the legislature might well serve to sharpen the decision-making process in the Executive branch, since the latter's decisions would become subject to "peer review" of a character not heretofore applied to it. It might also dilute any sense of proprietorship over programs that tend to develop when a single organization has an apparent monopoly in a field; two proprietors are tantamount to none. There can be no doubt that the Executive Branch will frequently be annoyed by more perceptive oversight and more penetrating challenge than it had been accustomed to experience. Perhaps serious conflict will arise on occasion. It is even possible that a strong willed Congressional advisory Council will persuade the Congress to take questionable or even mistaken actions. The consequences of the occurrence of such conflicts should not be underestimated. But the Association believes that in the long run, the advantages of providing Congress sound scientific advice and relieving it of its dependency-engendered distrust of the Executive Branch outweigh the disadvantages.

The AAMC is of the opinion that the Executive Branch process of budget development and five-year plan formulation should be allowed to run its normal orderly course, without the introduction of a perturbing influence---the Council's plan---at mid-course. The more closely and exclusive the Council is linked to the Congress, the more important it is that its actions not interfere in the Executive Branch operations. "Separation of powers" is a principle held in high regard by both Branches.

The AAMC fully appreciates the difficulty in creating an advisory apparatus within, and in specifying how it can be of service to, the Congress. The legislature is not a hierarchical organization but a collection of autonomous and independent individuals, each personally elected through a partisan political process by an electorate to whom the legislator is accountable. When individualism is prized, expected and rewarded, as it should be by the very nature of this Branch of government, a state of near anarchy will and must reign. A body truly advisory to the Congress would be faced with the very difficult assignment of finding a way to report effectively to each member of the Congress or to each member of a specific Committee. However difficult the dilemma posed by the incompatibilities between the nature of the Congress and the properties of an Advisory Committee, the Association is convinced that the potential usefulness of this advisory function warrants a determined effort to establish it under the aegis of the Legislative Branch. The effectiveness of the Congressional Budget Office (CBO), the Office of Technology

Assessment (OTA) and the General Accounting Office (GAO) encourage hope that the creation of a viable apparatus to advise one or both Houses of Congress is not beyond the realm of possibility.

The problem of the proper administrative framework for the advisory Council proposed by the AAMC is not one on which the Association is expert. Our earliest position mentioned the Office of Technology Assessment (OTA), and the Congressional Budget Office (CBO); these, together with Legislative Reference Service of the Library of Congress, might be suitable organizational loci for this activity. Arrangements might also be made for the National Academy of Medicine/National Research Council, the Institute of Medicine, or a quasi-government corporation established specifically for this purpose, modeled, for example, on the Corporation for Public Broadcasting, to discharge the function. Alternatively, the Congress might contract with an outside group such as a consortium of universities or even a private sector commercial research organization to do the job. Were the function to be performed outside the Government, advice could also be provided to the Executive Branch (the President and Secretary/DHEW) without real or apparent loss of independence.

Section by Section Comments

The Association's review of the individual sections of Title I is premised on its conviction that Title I is unacceptable, as is. However, in generic terms, these sections might be applicable to variable extent to the type of Council recommended by the Association, namely one constituted to advise but not to plan

New Section 491: The Structure of the Council.

Under any circumstances and for whatever purpose, the composition proposed in Section 491(a)(1) is seriously unbalanced, with far too few biomedical scientists in proportion to the number of behavioral and social scientists and non-scientists prescribed for this Council. The relatively restricted mission of advising the Congress over the whole sweep of biomedical science is in itself a gigantic task and would constitute an enormous challenge to the best minds in biomedicine. Behavioral science constitutes another large, albeit smaller domain. The credibility of the advisory apparatus would be seriously undermined from the start, if it failed to include a predominance of established and respected scientists in cognate disciplines, fields and specialties.

Another reason for a larger number of biomedical and behavioral scientists is that parochial interests of individual members are likely to be over-represented in decisions, unless the group is sufficiently large to encompass a broadly balanced view of reality and to engage in vigorous and informed debate.

It might be wise for the statute to specifically authorize the Council to: create sub-groups, chaired by members of the Council but composed of non-Council members; and appoint consultants.

New Section 492: Categorization of funding recommendations:

The proposed Section 492 (b) (1) (A) requires that the budget and spending priorities be specified by the Council within a highly formal set of categories related to the objectives of the research effort. This requirement appears to be relevant only if the major function of the Council is to plan and allocate rather than, as the AAMC recommends, to advise. Even were a Council of the type envisioned by S.988 created, the proposed format would be highly questionable. It is not clear that unambiguous distinctions can be made between research putatively directed at prevention, treatment, or rehabilitation. Nor is it clear that within this universe, all possible categories have been included (e.g. diagnosis). Nor is it obvious that a useful purpose is served by these distinctions. A set of recommendations in the suggested format would probably present difficult operational problems, and limit the flexibility of an Agency in exploiting opportunities. The provision has little merit, under any circumstance.

New Section 492(b) (1) (B)

This section requires the Council, as a minimum, to set forth budgets that, in comparison to the previous years budget authority, represent: no change; and 5%, 10% and 15% increases. Presumably this specification is intended to indicate the impact of small increments or---if inflation continues at the present brisk pace---decrements in funding. A 10% increase in these inflationary times may mean a decrease in actual activity. This provision could be useful in illuminating a number of problems. It could also become a sterile exercise. On balance, the benefits will probably exceed the costs. However, the level of the previous year's budget authority is not always---or more accurately not usually---available by October 1, the due date of the Council's Report.

New Section 492 (b) (2): Underfunded and underdeveloped areas:

The concept underlying the requirement that the Council specify underfunded and underdeveloped areas and identify measures to promote research deserves careful reconsideration whether this mandate be given to a planning or an Advisory Council. Underdevelopment and underfunding usually reflect intractable problems and are rarely susceptible to "easy fixes." Perhaps the most common cause is a dearth of good ideas; there are simply no handles with which to tackle the problem. The identification proposed in Section 492(b) (2) would constitute

a pressure to divert funds from projects with a high probability of productiveness to dubious ones. When "handles" on a problem are perceived, there is seldom a shortage of interested scientists or competent applications. The NIH has been emphasizing training programs in epidemiology for at least two decades, with few takers. The career of an epidemiologist is uncertain. Many epidemiological, demographic, and population biology problems require studies that must continue over long epochs. They are relatively unproductive, as measured by the frequency of publication, and as a result the epidemiological investigator remains relatively unknown and obscure---with all which that implies for tenure, salary, national recognition, etc. Since the Federal Government cannot be depended upon to honor long range commitments and has been notoriously inconstant, it is not easy to offer students interested in epidemiology any very stable and attractive career prospects. Alternatives are, of course, available to them.

New Section 493: The Response to the Plan:

The response prescribed in Section 493 is apparently intended to embarrass an Administration whose budget reflects priorities different from those of the Council. The latter's views will usually be congruent with those of the scientific community and most often with the Federal Science agencies. The Administration however will seldom have trouble, as was illustrated this year in Mr. Califano's testimony before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, in rationalizing the differences: "austerity was necessary" or some other set of activities "had higher priority than health research", etc. Moreover, a statutory requirement appears to be unnecessary; the function of Congressional hearings is to do precisely what is described in this section.

New Section 496 (b) The National Plant for Research

This section mandates that the proposed Council conduct regular national reviews of the status of the physical facilities and of technologically advanced equipment, in terms of their adequacy to meet the needs of the national biomedical and behavioral research effort, and to report the findings of these reviews.

This provision would be an extremely valuable first step to assist decision makers to arrive at judgments about needs throughout the country of one of the most basic resources upon which the mounting of a research program depends. While not sufficient, plant and equipment are absolutely necessary for a sound research activity. It has been more than a decade since the last comprehensive survey of the status---size, age, condition, etc.---of the national "plant" was undertaken. The OMB, through the

veto power over proposed federally supported surveys that it enjoys under the Federal Reports Act, is not likely to approve proposals for such surveys, since the results might create pressures for increased Federal expenditures.

Even more desirable would be authorization of research facility construction programs, with appropriations ceilings, so that positive action could be taken promptly, should the Council's review indicate acute and serious deficiencies.

TITLE II - NATIONAL INSTITUTES OF HEALTH

Title II establishes the National Institutes of Health in the Public Health Service, provides a mission statement for it and authorizes the Secretary, acting through the Institutes to take appropriate actions to achieve the stated mission. It further specifies that the Director NIH, be appointed by the President with the advice and consent of the Senate and outlines authorities available to the Director to carry out his functions. Among these is authority "to appoint one or more Advisory Committees, composed of such private citizens and officials of Federal, state, and local governments as he deems desirable to advise him with respect to his functions." (The meaning and significance of this authority is not clear, especially in terms of the requirements and the Federal Advisory Committee Act). The Director is required: to assure that no less than 45% of all funds expended by the institutes shall be used for investigator-initiated research; to establish (on an experimental basis) an appeals process for disapproved grants; to establish a program of demonstrations and experiments with alternative mechanisms for conducting peer review that would, *inter alia*, require the appointment of social scientists and other non-biomedical scientists to study sections and to include lay persons on at least five peer review study groups. The Director is authorized to deploy up to one half of one percent of all appropriated funds for evaluation of extramural and intramural research programs of the Institutes, and for research in areas deemed by the President's Council to be: relatively underfunded or underdeveloped; distinguished by its innovative or unconventional character; or of a multi-disciplinary nature concerning two or more diseases.

Other sections of Title II either amend or replace statutory language now contained in Title IV of the Public Health Service Act for: the National Cancer Institute (including authorization ceilings for FY 1981-83); the National Heart, Lung and Blood Institute (including authorization ceilings for the same three years); the National Dental Research Institute; the National Institute of Arthritis, Metabolism and Digestive Diseases; the National Institute of Child Health and Human Development; the National Institute of General Medical Sciences; the National Eye Institute; the National Institute on Aging; the National Institute of Environmental Health Sciences; and the National Institute of Neurological Communicative Disorders and Stroke.

General Comments

Ideally the analysis of Title II should treat the subject in two parts, the first would deal with the establishment in law of the National Institutes of Health as an umbrella organization and with the identification of the Director and his duties and authorities. The second part would speak to the provisions concerning individual institutes, their authorities, programs, scope and funding ceilings. However, there are so many themes common to both the section on the NIH and to those on the individual institutes that the ideal separation could only be observed to a limited extent.

The NIH has a history of unparalleled success under its present administrative structure and despite the absence of formal and explicit authorities for its overall operation. That circumstance has proven to have many specific advantages but most importantly, it has clearly permitted effective performance. Indeed the original authorities for the constituent institutes were all remarkably simple, affording the responsible Federal officials a high degree of flexibility while at the same time stating clearly the purposes of the organization and providing the means by which its responsibilities should be carried out. The first-order question then, is whether more explicit legislative action, which can only be more restrictive, is justified. Those who propose and support the legislation should provide greater evidence than is presently available of any significant advantages to be gained by the enactment of such legislation. Until such evidence is forthcoming and evaluated, the AAMC sees no compelling advantage for and many disadvantages to this provision.

The mission statements in S.988 of the various Institutes are surprisingly narrowly drawn. The Association does not have the expertise to review these statements in detail and would have to rely on the judgment of specialists in each field to do so. However, the listings of diseases and programs given as the mission of most Institutes on S.988 are too prescriptive. For example, Section 434 A(a) identifies diseases for which the NIAMDD has responsibility in considerable detail. Despite that circumstance, a number of other disease areas, such as those of skin, bones, joints and muscles, are omitted, thus raising doubts as to whether the Institute could continue its traditional support of research in those areas under the proposed language. In the view of the AAMC, one of the features of the legislation that accounts for the success of the NIH for the last 40 years has been the simplicity, flexibility and breadth of Section 301 of the Public Health Service Act. No better model exists for the mission statements of individual Institutes.

As a less serious reservation, the Association believes that all grants with direct costs of more than \$35,000 (rather than \$50,000 as proposed in S.988) should have the review and approval

of National Advisory Councils. The size of research grants has not changed markedly in the past ten years, and a \$50,000 limit would remove about half of all grants from the purview of the Councils.

The Association urges that two other PHS agencies deserve recognition in Title II: the Alcohol, Drug Abuse and Mental Health Administration and the National Center for Health Services Research. Lacking this explicit inclusion, S.988, even though limited to agencies in HEW, cannot be accurately called a "Health Sciences Promotion Act."

The Association also recommends that S.988 be revised to reinstate an authority for the construction of research facilities in the health sciences. Essentially no Federal funds, except those earmarked in the appropriations of the NCI for categorical cancer research facilities, have been available for this purpose in a decade and the basic general non-categorical statutory authorization for this type of assistance was repealed three years ago. During the last ten years, biomedical and behavioral research have uncovered vast new opportunities for pursuing hitherto unattainable research objectives while the facilities for conducting such work have become obsolete or unusable. The need for new construction or replacement of some existing facilities was highlighted during the recent HEW Health Research Principles exercise. Should this recommendation be adopted, the AAMC would advocate a single authority for NIH, rather than separate construction authorities for each Institute, with the program managed similarly to that previously devised for the Health Research Facilities Construction Program. In a related area, investments in equipment, especially of types that incorporate the most advanced technology, have been limited because funding for research programs has failed to keep up with inflation. As a consequence, the frequent need to use obsolete equipment or the inability to take advantage of new techniques inhibits research progress now and will do so increasingly in the foreseeable future. This problem is sufficiently urgent that the National Science Foundation has undertaken a major national study of the status of research facilities and equipment.

Section by Section Comments

New Section 400A(b) (3).

Under this provision, the Director, NIH is authorized "to appoint...advisory committees...to advise him with respect to his functions". As is well known, both the NIH and ADAMHA have long relied on external advisors to assist government officials: in scientific planning and program development; in the review and approval of project proposals; in the evaluation of the "state of the art" in various fields of science; and in a host of other

technical activities. The basic decision to involve private sector advisors reflected the wisdom of the Congress, when it provided for the first National Advisory Council---the National Advisory Cancer Council---in the statute which created the National Cancer Institute in 1937. Subsequently, as new Institutes came into being, a new National Advisory Council was established for each. By 1946, when biomedical research programs had grown to a size and complexity that made it impossible for the National Advisory Councils to review individual project proposals in depth, initial review groups, organized along scientific disciplinary lines and called Study Sections, were constituted and delegated responsibility to evaluate proposals, using scientific merit as the primary criterion, for all of the National Councils. As of today, the NIH alone uses about 140 advisory bodies, whose membership embraces about 2000 of the nation's most distinguished scientists. Each of the latter spends, on the average, about ten days each year in formal committee meetings as (part) a part-time government employee---compensated at the rate of \$125 per day---and an estimated 10-20 uncompensated days each year preparing for the committee meetings.

There is a broad consensus that the high quality of the Federal biomedical and behavioral research programs over the last 30-35 years is largely attributable to the imaginative use of advisors. Science has advanced at a dramatically rapid pace during this period. Full-time Federal employees could never have brought to the discussions of programs and projects the keen insights and finely honed judgments that were contributed by those non-government scientists who were engaged in research at the active forefront of specific fields and disciplines. And absent a deep and abiding commitment on the part of the scientific community to maintain high standards of excellence, the government could not have purchased the quality of advice it received at any price.

About a decade ago, some government agencies---specifically not the NIH or the ADAMHA---were charged with misuse of external advisory committees, principally on grounds of conflict of interest. Subsequently, P.L. 92-463, the Federal Advisory Committee Act (FACA), was crafted to regulate the roles of these committees. Procedures developed to implement FACA, especially the enormous paperwork required for the prescribed biennial rechartering, have been painfully burdensome. Perhaps even more troublesome has been the climate created by the re-chartering process---an aura that somehow there is something "unclean" about advisory committees. Finally, the FACA provided the excuse for higher authorities to revoke without any justification appointing authorities previously delegated to the Director, NIH, and the Administrator, ADAMHA; thereafter a tendency to politicize the advisory system became manifest.

The AAMC and its constituents, are strongly persuaded that the Federal Government and the American public have enjoyed the benefit---at bargain prices---of a superb mechanism for developing scientific research programs and for obtaining sophisticated judgments on the quality of research proposals submitted to the Government. Thus, the Association has attempted, by every available device, to monitor FACA's administration to make sure proper attention was accorded the key role of technical advisors in biomedical and behavioral research programs. The basic hope of the AAMC staff is that the Federal Agencies responsible for these programs be exempted from the requirements of FACA and that the operation of the advisory apparatus return to the *status quo ante*.

Against this background, the meaning and significance of the new Section 400A(b)(3) is not clear. Does this authority free the Director, NIH from the requirements of FACA and its implementing regulations? Does it authorize the Director to "establish" or only to "appoint" committee members? Is this authority intended to enable the Director, NIH (vis a vis, e.g. the Secretary, DHEW or the Assistant Secretary for Health, DHEW) to constitute all of the committees whose establishing or appointing authorities are not explicit in statute? Senator Kennedy's speech introducing S.988 indicated his intention that the authorities in this section should enable the Director, NIH to take independent action to reverse the recent erosion of the capacity of the peer review system. It is far from clear, however, that this section would be adequate to exempt advisory committees appointed under it from the very stringent and troublesome requirements of P.L. 92-463 in which the current problems of the peer review system are rooted.

New Section 400A(c).

The provision of specific authority for the Director, NIH to expend funds for research purposes is, at first glance, attractive in two ways. First, money means power and at the present time there is no stated authority which provides the Director with immediate access to funds for the purpose of supporting research or of directly related activities. Thus, the provision of a comparatively small sum of money to be used at the Director's discretion with proper safeguards would correct an internal imbalance of power which in the present situation is weighted heavily in favor of the directors of the individual institutes with their access to identified appropriations. The second reason is that it would enable the Director to take prompt action should unexpected opportunities arise under circumstances in which the regular appropriations process would be too slow a mechanism to respond. While such instances undoubtedly would be few and far between, the ability of the Director of the NIH to exploit such opportunities in prompt and vigorous fashion would greatly strengthen the entire Agency.

Having applauded the concept of this provision, it is necessary to examine it for its practical implications and restate caveats raised earlier. The causes of relative underfunding or underdevelopment of a field of biomedical and behavioral research may be multiple. For example, basic research in a given area may not have progressed far enough to warrant additional funds, or technical limitations may be holding up the advance of an area. In such cases, "throwing money" at the problem will make no real difference, but only waste public funds. In other words, great care must be exercised in employing this authority.

Innovative research should surely be supported. But the problem is how to identify the most innovative projects, i.e., how to judge the likelihood of success and make the best investment of limited funds. Peer review is one way and the Study Sections of NIH do their best to select innovative and unconventional research proposals. One must wonder about the wisdom of funding other proposals, selected presumably by a different set of evaluators, to which Study Sections had already accorded less than full merit. Moreover, a backup capability to identify worthy proposals not recognized by Study Sections already exists in the National Advisory Councils; these bodies may request reconsideration of or actually override unfavorable recommendations of Study Sections on projects deemed by staff or members of the Councils to be unusually important, innovative or unconventional. If the special set-aside of funds for the Director's use for the purpose of supporting "innovative and unconventional" research is retained, an alternative way to address this problem might be to gamble less on projects, and more on bright, well-trained young investigators who lack the proven record of research accomplishment of more senior investigators.

New Section 400A(d).

The Director, NIH, would be required to assure an annual expenditure for investigator-initiated research of at least 45 percent of all funds. The Association and its members attach extraordinarily high value to investigator-initiated research as the keystone to progress in the conquest of disease and are most anxious that large scale ventures---program projects, centers, etc.---and targeted developmental efforts not be permitted to commandeer funds better invested in the projects of individual investigators. But the level of investment in one vis a vis the other will vary from time to time and from field to field. Therefore the selection of a single level---in this case 45%---and the enshrinement of this in statute is dangerously prescriptive and needlessly restrictive. In addition, the value might, ironically, become a ceiling instead of a floor. The Association would recommend that the report on the Bill include a discussion of the issue and broad guidelines. Additionally, distribution of investments between investigator-initiated and other types of research should be monitored and made an explicit item of review in periodic oversight hearings.

New Section 400A(f).

The requirement to set up an appeals process, unless constrained in scope, could result in an enormous administrative overload. The policies and procedures governing the grants program have already been considerably modified; they now permit the release to applicants of formerly confidential reviews and have increased the availability of staff for counselling. Moreover, the members of the National Advisory Councils are increasingly sensitive to problem proposals and often request second reviews. In the final analysis, the ultimate appeal mechanism is provided by the ability of the scientist to re-apply, particularly when armed with knowledge of the criticism accorded previous applications. The danger inherent in the proposed appeals process stems from the fact that, in time of fiscal stringency, investigators have nothing to lose by appealing a disapproval or an unfavorable priority score. Thus, the load of appeals could overwhelm the system.

New Section 400A(g).

An experiment is proposed involving peer review groups whose objective is, we assume, to assure that "cronyism" does not play a part in the award of public funds for research support. The Association would abhor the emergence of any vestige of "cronyism" in the peer review process and doubts that it exists. Moreover, the mechanism proposed, i.e., the requirement that lay persons and those without expertise in the biomedical sciences be added to initial review groups would be a dubious solution to the putative problem. The reasons for opposing this provision are based both on considerations of principle and on pragmatic realities. In terms of principle, the essential function of a Study Section is to appraise the technical merit of research proposals. An individual lacking technical expertise has, by definition, no contribution to make to this basic function. The pragmatic objection relates to the reality that in recent years the number of applications reviewed by each Study Section member has risen dramatically while the number of members appointed has increased very slightly or not at all. If persons without the technical expertise to review applications were substituted for experts in appointments to initial review groups as proposed in S.988, the workload for the scientists on the panels would rise even further. The AAMC has no objection to adding lay persons in an observer status (but not as regular voting members of the chartered bodies), if the presence of such individuals would somehow reassure the Congress and/or the general public that "cronyism" did not take place. However, the Association is convinced that the only real guarantee against this evil resides in the integrity and ethical standards of the scientists on the Study Sections. The Association has, of course, long supported and encouraged the appointment of outstanding lay persons to the Advisory Councils of the Institutes where their input on policy and social priorities often has been very effective.

TITLE III - PAPERWORK

Title III authorizes the Director, NIH, to conduct experimental programs to reduce the paperwork associated with the application for and administration of research grants. The statute indicates that these experimental programs would include: the utilization of indicators of work performance other than effort reporting; delegation of authority to grantee institutions for limited carry-over of awarded funds and for transfer of funds from one grant to another; the consolidation of an Institute's biomedical research project grants into a single entity for administrative purposes; the development of alternative methods to document compliance with cost-sharing requirements; and the elimination of some reporting requirements.

General Comments

The enviable reputation of the NIH among government agencies was achieved in large part during its formative years from an insistence on high standards in all of its activities and an emphasis on innovation in its policies and operations. In the context of the extramural area, these characteristics led to the introduction of such now well-established features as the Study Sections, the graduate training grants and the Biomedical Research Support Grants. In recent years there has been little evidence of that earlier spirit of innovation and risk-taking. Undoubtedly, it has been stifled by the heavy hand of bureaucratic interference in the guise of policy coordination from higher levels in the Executive Branch and by fear of criticism, especially from Congressional oversight committees. At the same time, although it seems quite certain that the agency already possesses sufficient authorities to initiate most if not all the activities included in this part of the bill, questions on the adequacy of statutory authority might be raised to foil the exploration of desirable changes. The provisions of Title III and parts of Title II of S.988 would have distinct value were they to eliminate any ambiguities as to the existence of the necessary authorities and would serve as a stimulus to explore new and possibly better ways of doing business.

Federal efforts to assure accountability in the expenditure of public funds and to correct for isolated instances of abuse by grantees have resulted in an enormous increase in the amount of recordkeeping and reporting in recent years. These requirements involve compliance with several different categories of laws or regulations pertaining to such grants. The first category comprises those related to recognized general national social objectives and arises from minimum wage acts, affirmative action programs, non-discrimination against the handicapped and similar mandates which

affect a variety of non-federal institutions and organizations. Another derives from the obvious need to provide adequate financial accounting for the expenditure of Federal funds by non-federal organizations on behalf of individuals (i.e., scientists) who are not Federal employees. A third relates to the task of being able to provide assurance that the investment of those tax dollars has been in the best interest of the public, that is, a productive outcome.

In all of these categories, there is widespread agreement with the general objectives or the overall concepts of the programs. In operational terms, however, two substantial problems arise. The first involves, as in the third category above, the problem of assuring a pragmatically oriented, frequently impatient Congress that long-term public investments in fundamental research are of value and in meeting an expectation that their value can be

demonstrated promptly. The very nature of this type of research, unpredictable in pace, in outcome and in applicability, renders the task of matching proof of value with expectation unusually difficult. The second is the problem of applying, in any system of financial accountability, the concept and characteristics of the market place with its ease of quantification epitomized by the profit/loss statement to the significantly different realm of intellectual productivity in a non-marketplace environment. Attempts to resolve these uncertainties or difficulties have piled requirement upon requirement, in a desperate effort to provide the public and their governmental representatives with evidence for both fiscal and program accountability. The most vigorous supporters of such requirements have found the results apparently disappointing. It may be that their questions are not the right ones or that their emphases are misplaced.

While in the eyes of those critics the measures to improve the public accountability are still inadequate, the directives already imposed have modified to a significant degree the institutional environment in which federally sponsored health sciences research is conducted. Two prominent features of this change can be readily identified. The first is a considerable reduction in the operating flexibility available within the grantee institutions, especially to determine, in the light of its other institutional objectives, the most efficient and effective manner of carrying out its overall research program. The second has been the establishment of an increasingly large and costly institutional bureaucracy, both to comply with the array of Federal requirements and to shield individual investigators as best possible from the distractions and demands of those systems of accountability.

Despite the significant increases in costs resulting from those changes, there apparently has been no improvement in the ability of either the institutions or the agencies to demonstrate accountability in a fashion sufficient to satisfy the critics. While comparatively little of the regulatory burden falls directly on the individual investigator, the community of biomedical scientists is definitely affected by the proportion of total funds allocated to meet the indirect costs of research. DHEW has properly followed the tenet of reimbursing grantee institutions and organizations for the full costs of overhead as a justified part of the costs of doing research. Nonetheless, when these financial needs approximate one-third of the total dollars appropriated for research, the question inevitably arises as to whether there is a realization within the Executive and Legislative Branches of the extent to which its preoccupation with the "business" aspects of research support have eroded the availability of funding for research itself.

Because of these circumstances and the uncertainties associated with both the diversity of grantee institutional settings and the varied nature of the HEW research programs, it is commendable that the bill seeks to attack these problems through experimentation. At the same time, it must be recognized that the design and evaluation of experimental efforts to that end will be extremely difficult and must be carefully undertaken.

It is to be hoped that the Federal officials responsible for carrying out such experimentation would seek early and continuous consultation from investigators and institutional officials in the course of designing, implementing and evaluating the experiments.

Section by Section Comments

Section 301(a)(1) - Elimination or Modification of Effort Reporting by Investigators for Selected Grants.

Unquestionably, the most vexing grants management problem confronting DHEW grantees is the requirement for time or effort reporting as the basis on which salaries to be charged to research grants are reimbursed. Because of their nature, intellectual activities simply do not lend themselves readily to a system of accountability which is based on a high degree of quantification. This problem is exacerbated in biomedical or behavioral research, especially as conducted in the Nation's academic medical centers by scientists whose numerous institutional functions frequently involve joint simultaneous production activities, i.e., research, teaching, patient care and administration. The burden placed on scientists to account for the expenditure of their time and effort to a degree which would apparently satisfy the auditors and others who demand greater accountability is epitomized by the fact that in contrast to mechanical types of activities, such as involved in the production of hardware items, the truly productive efforts in research (i.e., useful ideas) may occur under any of a variety of circumstances frequently well removed from the actual locus of the research. It is to be hoped, therefore, that the subject of time and effort reporting will receive renewed attention by both Federal officials and those within the institutions, in the hope of devising a substitute to the present system which would be much more realistic and acceptable.

Section 301(a)(2) - The Delegation to Grantees of Certain Grant and Management Authorities.

The concept of placing both responsibility and authority for day-to-day management of research grants at the institutional level is an attractive one, both theoretically and practically. It has the advantage, assuming proper controls, of placing the decision making on grants management close to where the greatest knowledge and understanding, which are necessary for good decisions, are located. That location, together with appropriate institutional resources, also tends to improve the quality of intra-institutional

management, as has been evidenced by the decade of experience under the NIH study for remanding day-to-day decisions to grantee institutions.¹ A third advantage is the concomitant result of the granting agency being able to concentrate its always limited resources on the major issues for which only it can assume responsibility, such as policy making and the operation of the peer review system.

The provisions under this section for mandating carry-over and transfer authorities should materially expedite the prosecution of the research and the improvement of grants management at the institutional level, especially if developed from the results of experimental approaches.

Section 301(a)(3) - Consolidation of an Institution's Biomedical Research Project Grants for Administrative Purposes.

This proposal is a most attractive one from the viewpoint of those institution officials who must contend with the day-to-day administration of hundreds of individual grants and the rules and regulations which govern them. Theoretically, it could increase the efficiency in the use of grant funds and thereby enhance their effectiveness.

However, two concerns should be considered in any evaluation of this provision. The first is the dissension and competition possibly fostered within the grantee institution by the process of fund allocation from the "single entity" established under this authority. Scientists having competed successfully at the national level for grant support are not likely to submit willingly to locally determined modifications in availability of funds in the name of administrative tidiness.

The second consideration is more fundamental in nature. Depending on how an experiment employing this provision would be designed and implemented, there would appear to exist significant potential for inadvertently undermining the role of the peer review system in the allocation of Federal funds for biomedical research. As implied in the previous concern, the funds awarded in an NIH research grant are tied directly to the approval of the project by the peer review system. Given the understandable sense of proprietary interest in that system and its decisions, substantial modifications of those decisions by administrative actions at the institutional level could have the effect of eroding the role and value of the peer review process.

1 "A Study of Increasing the Role of Grantee Institutions in the Management of Research Projects Funded by Public Health Service Grants." Third and Final Report of a Special Study Committee Appointed by the Director, National Institutes of Health with Concurrence of The Surgeon General, Public Health Service, April 15, 1966.

It is unclear as to whether this arrangement would permit a highly desired improvement in the present use of grant funds, namely, the ability to purchase major items of equipment or to finance significant remodeling related to more than one project and justifiable as a single expenditure on the basis of that relationship as well as the simplified, less costly processing of such an expenditure. At the present time there are no arrangements whereby such costs may be covered by grant funds without considerable delay and extensive administrative maneuverings. With proper safeguards, an increasingly serious problem in research-oriented institutions and for groups of investigators involved in related projects could be resolved if such authority were available.

Section 301(a)(4) - Development of Alternative Documentation for Cost Sharing.

Another possibility should be considered for making this provision an even more effective one. That would be an examination of the true usefulness to the government of over a decade of required cost sharing. Although no evidence is available to substantiate the point, there exists the real possibility that because of significant voluntary cost sharing by most institutions prior to the mandated requirement, the net effect may well have been to increase considerably the cost of compliance, especially at the institution level in terms of required documentation, with little actual gain for the government. Therefore, it would be hoped that consideration also would be given to the total elimination of cost sharing if it were demonstrably ineffective.

Section 301(a)(5) - Simplified Accounting of Non-expended Equipment.

The selective elimination of obligating grantees to account for non-expended equipment of low cost is deserving of support. At the same time, when the cost of common items of scientific equipment now exceed \$1,500, it seems probable that the ceiling could be raised to \$5,000 so as to continue the desirable degree of accounting for major items of grant-purchased equipment while eliminating the recordkeeping for those of lesser cost.

Section 301(a)(6) - Elimination of Reporting Requirements of Unsolicited Grant Applications.

The reporting requirements on individual grants are used in inconsistent fashion by the agency, except for financial accounting documentation. It seems only reasonable, however, to expect that investigators should provide the agency with some periodic status report of scientific progress. Therefore, while this provision is attractive from the standpoint of the investigator and his institution, it does not seem reasonable when viewed from the perspective of granting agency responsibilities.

Section 301(b) - Limitations on the Research Support to be Subsumed by this Experimental Process.

In any process of experimentation, some limits should be placed on the number of units to be examined. A proposal for a dollar ceiling in the amount of no more than one-half of one percent of NIH expenditures should provide ample opportunity for assessing the value of the previous provisions in this section of the bill while maintaining a reasonable degree of restriction on the extent of the grant portfolio subject to the experimentation.

Section 301 (b) (1)

The use of "periodic peer review to determine the extent to which research projects have achieved their intended purpose" would, if implemented with a literal interpretation, very probably add as much difficulty for the research system in another dimension as the elimination of effort reporting which it seeks. To be more explicit, "peer review" would require the additional involvement of highly qualified scientists either in the present mode of the NIH Study Section apparatus or in some other as yet unidentified manner. The NIH/ADAMHA peer review system, particularly as exemplified by the Study Sections, is already grossly overloaded and the steps taken so far to alleviate the workload problem have been meager at best. Furthermore, the determination of whether or not "research projects" have achieved their intended purposes may be difficult at any time prior to the end of the period of committed support for even the most diligent and experienced peer review committee. The complexities of determining significance or even progress of a research project is eloquently described in the article by Julius H. Comroe, Jr. and Robert D. Dripps entitled "Ben Franklin and Open Heart Surgery." 2 It should be noted also that the existing process of evolution includes peer assessment when a grant is scheduled for competing renewal. On the average, the period of committed support for investigator-initiated project grants approximates slightly over three years; thus "periodic review" of research progress occurs with this frequency, within the present system. Therefore, the adoption of the provision, at least with this interpretation, may be both duplicative or difficult of attainment in itself and contributive to a serious further overloading of the peer review system.

A different interpretation might be the utilization of agency program staff for an administrative review of the manner in which the research has been carried out. Were this to be the case, the burden would not fall so seriously on members of the scientific community. On the other hand, this approach certainly could not be construed as an assessment of the scientific progress of the research.

THE PROMOTION OF THE HEALTH SCIENCES: A SUMMARY EVALUATION

The major deficiency in S. 988 is that, despite a pretentious title, it does little to promote the health sciences but instead focuses on issues of marginal importance. The bill proposes:

2 Circulation Research, Volume 25, November 1974.

- to establish a President's Council on the Health Sciences. This would per force have to be a very large and complex apparatus, if it is to carry out the statutory mandate of annually preparing budgets and rolling five-year plans for Federally supported biomedical and behavioral research, for submission to the President, to the Secretary/DHEW, and to the Congress, and will thus replicate---needlessly in the Association's view---indispensable and long standing Executive Agency functions. The AAMC's counter-proposal is that the Council be renamed, that its functional scope be narrowed to an advisory one, and that it report directly and only to the Congress.
- to give the National Institutes of Health a statutory base, even though that Agency has operated remarkably effectively without one for almost half a century.
- to confer specific authorities on the Director, NIH, most of which require no statutory authorization, some of which (e.g., those related to the peer review system and to "innovate research proposals") seem undesirable and one of which is unclear as far as meaning or significance.
- to re-write statutory authorities for the component National Institutes of the NIH in more narrow and constricting terms than are presently laid down in Title IV of the Public Health Service Act, with little if any gain to either the Institutes or the scientific community. In specifying the missions of each Institute in these narrow terms, the proposed statements would diminish flexibility and increase the problems of program operators.
- to permit and encourage experimental approaches to reducing the paperwork burden associated with Federally supported biomedical research. The AAMC heartily endorses the objectives of this provision.

In his floor statement introducing the bill, Senator Kennedy described the great advances in biomedical research over the past several decades made possible by Federal support. Despite his eloquence, he understated the accomplishments. Biomedical science is a vibrant and exciting pursuit that has captured the imagination of a generation of students and young scholars. The nation's medical and graduate schools, its teaching hospitals, and its research institutes are alive with ideas and full of ferment. Tens of thousands of bright scientists, young and old, are engrossed in research on problems of critical importance to the understanding and, thereafter, to the prevention and/or treatment of disease. Each year, at the springtime scientific meetings, the research community sits in awe as they listen to reports that show how research has extracted from nature ever more of her secrets.

"Out there," in the real world of research, progress is rapid and promise is high. This state of affairs can be attributed to an overwhelming degree to generous Federal support tendered, at least once, under reasonable terms to excellent institutions and to dedicated scientists, for research on projects deemed by scientific peers as worthy of support in terms of intrinsic quality and promise for alleviating national health problems. The role of formal "planning" and the niceties of the organization of the Federal science agencies have had little to do with the pace of progress. Only recently have heavy paperwork requirements become a burden.

The jaundiced views voiced with growing frequency in Washington relate principally to "accountability" and "responsibility in the stewardship of Federal funds". However it should be noted: that the overwhelming majority of the criticisms of research performers reflect in reality technical disputes and differences in opinions on auditing and accounting methods; that the enterprise, with extremely rare exceptions, has been characterized by unimpeachable standards of honesty and integrity; that the government has reaped a rich return on its investment in biomedical research; and that the putative mis-spending of Federal funds has almost invariably been to further research, not "to line the pockets" of investigators.

Biomedical science today, however, is in a crucial stage. Research funding has barely kept pace with inflation for the last decade, while investments in training funds have created a very large pool of capable young scientists. As a result, the NIH has in recent years been able to fund only 30-40 percent of *approved* grant applications. Each year, 10-12 percent of the pool of "principal investigators" are new, but in the relatively stable state in which research finds itself, an equivalent percent of the previous years' principal investigators drop out. Studies on the survival of cohorts of principal investigators "new" to the system in 1966 and 1968 showed that 50% had disappeared in five years. The loss is composed of scientists who were, for the most part, highly creative and productive, but who could not meet the extraordinarily high standards that prevail, especially in circumstances of severe fiscal stringency.

The attractiveness of any career diminishes sharply when the chances for advancement or even survival become small. There has been an alarming decline in the number of physicians seeking training in biomedical science over the last 3-5 years, a signal that this group has "read the tea leaves" and already "opted out", to pursue careers in medical practice. The failure to renew the pool of clinical investigators bodes ill for the future of medical science, at least. These are the scientists who built the bridges between advances in the pre-clinical biological sciences and the problems encountered at the bedside of the patient. They are usually the ones who recognize the infrequent "experiments of nature"---unique and rare variants in spontaneously occurring human disease---and exploit the opportunity these offer to illuminate new approaches to problems in basic biological science. The discouragement of physicians with the possibilities for careers in research will soon be followed by comparable perceptions and responses in other scientists who aspire to research careers in the biosciences.

As young scientists become discouraged, research funds will increasingly be controlled by older and less competitive scientists, with a gradual diminution in innovation and a slow deterioration in quality. Externally, there is likely to be little perception of change. Grants will be made, research will be conducted, papers and books will be published. But this will in reality be the triumph of "form", covering up the strangulation of "substance".

Is this present and predicted state of affairs in the public interest? Do the people of this nation desire or will they knowingly countenance the dissolution of an enterprise that has done so much to make life longer and more tolerable for so many? The Association believes not. It also believes that it is up to the Congress to take the necessary steps to insure a vigorous future for biomedical science, and it is puzzled by the resistance encountered over the last several years in persuading that Branch of Government to take appropriate action.

The epoch of generous government support for biomedical research began just before World War II and continued until about 1968. Most of the Federal officials who played key roles during that period in developing and implementing Federal policy have disappeared from public life; many of those currently active have only a vague remembrance of the relevant history. Science, including biomedical science, mobilized completely to meet the challenge of World War II. Funded by the Federal Government, its accomplishments---proximity fuses, radar, fission weapons, a myriad of useful techniques developed by operations research, antibiotics, anti-malarials, traumatic surgery, and many others---left a deep impression on the people of the United States and their representatives. The proposition that this immensely productive war time process could and should be marshalled for an assault on peace-time problems received broad and enthusiastic public support.

More by happy accident than deliberate design, the post-war effort followed the war-time pattern, according to which the bulk of biomedical research funding was channeled into academic institutions. Over the years, many Federal officials seem to have forgotten that research performed in the academic institutions of this nation is a partnership arrangement with the Federal Government to realize the aspirations of our society. Though now it has become thoroughly integrated into the academic process, and its abrupt excision would be lethal to many performer institutions, the great bulk of it is a *public service*, not essential to the core educational functions of the schools. The Association view is that this nation has created a marvelously productive and uniquely American system that has vaulted the United States to primacy in science, particularly in biomedical science, and that has brought enormous benefits to the American people.

But, increasingly, public officials seem to have forgotten the circumstances and forces that led to the forging of this partnership. Research has somehow come to be viewed by many as a gratuity to academic institutions to assist in their educational missions. Nothing could be further from the truth.

The essential prescription for continued progress and new successes is not for more planning or for more reorganization or even for less paperwork, although the latter would help. What is really needed is a dedication anew to the principle that this nation is willing, *in good times and in bad times*, to make reasonable investments in research to improve the health and well being of its people and to reduce the mortality and morbidity caused by disease. It is an inescapable reality that, unless government provides them, adequate funds will not be forthcoming. Industry, unable to rely on exploiting for its own profit the advances achieved by the basic research it might sponsor, has always under-invested in this enterprise and there is little prospect that this will change in the foreseeable future. There are no other significant sources of funds for biomedical research.

Investments by government of \$3.8 billion in FY 1978 represents only 2.0% of national expenditures for health. Indexed to health expenditures, investments have fallen steadily for more than a decade. The research enterprise despite its high esprit is under great stress.

- Bright scientists with good ideas are unable to secure financial backing for their research.
- Aspirant scientists are beginning to become discouraged by the dim outlook for careers in biomedical research.

- There is a dearth of opportunities for young and innovative academically oriented scientists to join faculties.
- Distinguished departments are beginning to contract as scientists at or just below "star" level can no longer secure support for their research, and as self renewal through the infusion of new blood becomes impossible.
- Training opportunities are rapidly disappearing.
- Much of the "plant" is aged, run down, dilapidated and functionally passe'.
- Equipment is dated and outmoded.

In short, the splendid biomedical research enterprise created by this nation since 1945 is beleagured. Without prompt and strong relief measures, this country faces the real prospect of losing its leadership position in biomedicine, just as it seems likely to be eclipsed in other areas of science and technology.

The imperative of the times is for bold, imaginative and generous rededication. The health sciences, as S.988 implies, desperately need "promotion". Their future for all practical purposes is in the hands of the Congress. The challenge to that body is to provide the authorities and the funds to sustain, to rebuild and to expand this enterprise, threatened as never before by a decade of Federal parsimony. The new conventional wisdom is that it is pointless to invest in research for its long range payoff at this time, since the expected return on investment will be discounted by inflation. The Association does not believe that better health and longer life are discountable.

A POSITION PAPER: THE EXPANSION
AND IMPROVEMENT OF HEALTH INSURANCE
IN THE UNITED STATES

The AAMC ad hoc Committee on National Health Insurance met August 2nd to review, and recommend appropriate revisions in, the Association's November 1975 policy statement on national health insurance. A position paper based on the deliberations of the Committee was presented to the Executive Council for consideration at its September meeting. The Executive Council took two actions. First it rescinded the previous position of the AAMC. Second it expressed its general approval of the approach taken in the committee draft, but having concerns on several specific items, returned the report to staff and the committee for revision in accordance with its criticisms. The attached document is the committee draft as revised by staff in accordance with the Council's request. Deleted material is indicated by strike overs; new material is in italics. In several instances, there are several formulations proposed, one of which or some variation must be chosen.

Council of Deans discussion of this matter will assist the further deliberation of the Committee and Executive Council.

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A POSITION PAPER: THE EXPANSION
AND IMPROVEMENT OF HEALTH INSURANCE
IN THE UNITED STATES

The Association
of
American Medical Colleges

August, 1979

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Introduction

Due to renewed and intensified Congressional interest in national health insurance, particularly catastrophic coverage and a phased approach toward a comprehensive program, the Association of American Medical Colleges (AAMC) appointed the AAMC ad hoc Committee on National Health Insurance in August 1979. The Committee was charged to review, and recommend appropriate revisions in, the Association's November 1975 policy statement on national health insurance. The members of the Committee were Chairman John A. Gronvall, M.D., Dean of the University of Michigan Medical School; John W. Colloton, Director and Assistant to the President for Health Services at the University of Iowa Hospital & Clinics; James F. Kelly, Ph.D., formerly Executive Vice Chancellor of the State University of New York-Albany now retired; William H. Luginbuhl, M.D., Dean of the Division of Health Sciences at the University of Vermont College of Medicine; Peter Shields, M.D., Chairman of AAMC's Organization of Student Representatives; Virginia V. Weldon, M.D., Professor of Pediatrics and Assistant to the Vice Chancellor at the Washington University School of Medicine; and Charles B. Womer, President of the University Hospitals of Cleveland.

The Committee recommended that the Association's policy be directed at "the need for expansion of health insurance in the United States" and identified three major disparities that persist in the nation's health insurance system: (1) the lack or inadequacy of basic health insurance coverage for low-income Americans; (2) the inadequacy of health insurance protection against the high costs of catastrophic illness; and (3) the lack of a generally accepted minimum standard for basic health benefit plans.

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To address these deficiencies, the Committee recommended:

- (1) The Medicaid program should be expanded and improved through the provision of federally-established incentives and disincentives to the states to foster broader eligibility of low-income people for Medicaid coverage and to *expand (in many states)* and standardize the scope of basic benefits offered. These modifications should recognize and adjust for regional differences, such as income levels.
- (2) A catastrophic health insurance program should be developed *mandating that employers shall make available to full-time employees and their families catastrophic health insurance coverage through private insurance plans meeting HEW minimum standards for adequacy of coverage and eligibility* ~~/ mandating that employers shall share the costs with employees for catastrophic health insurance coverage for full-time employees and their families through private insurance plans meeting HEW minimum standards for adequacy of coverage and eligibility~~ *which would provide incentives to encourage employers to make catastrophic health insurance coverage more publicly available. (One sentence ending must be chosen.) In addition, insurance companies should be requested to participate, as a social responsibility, in state or regional insurance "pools" that would sell approved catastrophic insurance plans to the non-employed, the self-employed, part-time workers, high-risk individuals, "Medicare beneficiaries," and others not covered by employers, all of whom would be required to purchase such coverage. (If this last phrase is added, the next sentence would be deleted.) Though these individuals would not be required to buy the catastrophic coverage, they or a government sponsor would at least be guaranteed an opportunity to buy such coverage from the industry pools.*

It should be recognized that the basic objective of catastrophic health insurance coverage is the relief of individual financial anxieties rather than the improvement of the health status of populations.

- (3) An independent certifying body or commission, composed of representatives of insurance carriers providers and consumers, should be created to establish a minimum standard basic health insurance benefits package. This Commission would review all basic health plans and provide its "seal of approval" only to those meeting the minimally acceptable standard. It is believed that the approval of health insurance policies by a voluntary body will provide a powerful incentive to insurers to offer at least minimally acceptable basic benefits packages and to employers to upgrade inadequate employee basic health plans, and will serve as a source of additional information for the protection of the public.

In addition to the above proposals for the expansion and improvement of health insurance in this country, the Committee concluded that the Association should make recommendations for: (1) the appropriate use of cost-sharing mechanisms in the financing of the nation's health insurance system; (2) the fair and reasonable reimbursement of physicians and institutional providers of services; (3) the appropriateness of financing graduate medical education through the hospitals' patient service revenue; and (4) the encouragement of philanthropic contributions to the health care system.

Expanded Eligibility and Standardizing of Benefits Under Medicaid

Since the advent of the Medicaid program in 1965, great strides have been made to expand the financial access of the poor to health care services. In

fiscal year 1978, there were approximately 24 million recipients of medical services under Medicaid, representing an increase of more than 11 percent from 1974. Despite this success in making medical services more accessible to low income persons, the Congressional Budget Office (CBO) has estimated that 18 million Americans (approximately eight percent of the total population) -- most of whom may be categorized as "poor" or "near-poor" -- still lacked any coverage for basic health services in 1978. Another 19 million Americans -- most of whom may be categorized as "working poor" (those from families with incomes of less than \$10,000 holding only individual private policies) -- were estimated to possess health insurance coverage that failed to provide adequate basic benefits for hospital and physician services.

This population of unprotected or inadequately covered low-income working Americans comprises the so-called coverage "gap"; they are not able to afford private coverage for basic health benefits or qualify for such basic protection under public assistance programs, in particular Medicaid.

Medicaid is designed to assist specified categorical groups of low-income people: the low-income aged, blind, and disabled; recipients of cash assistance under the Supplemental Security Income (SSI) program; and families receiving payments under the Aid to Families with Dependent Children (AFDC) program. The states have the option of including the medically needy, persons whose incomes are too high to be eligible for cash assistance but not sufficient to pay for needed medical care. The states must define the income limits for the medically needy within certain guidelines. Thirty-one states finance medical services for the medically needy and the definitions of income limits used for eligibility vary considerably. According to CBO, in 1975 these variations contributed to the exclusion from basic coverage under Medicaid of an estimated 8 to 10 million persons with incomes below the poverty level.

The AAMC firmly believes that a targeted approach is needed to focus basic coverage in the area of greatest need, the "gap" population. Such an approach would retain the pluralistic structure of current third party coverage, with Medicare for the aged and disabled, private health insurance for the working population and their families, and Medicaid for the low income and medically indigent. The Medicaid program should be augmented by the establishment of federal incentives and disincentives to states for (1) the extension (*in many states*) of eligibility for Medicaid to previously unqualified low-income individuals and (2) standardizing the scope of basic benefits under the program in a manner that would adequately recognize regional differences, such as income levels.

It should be the responsibility of the federal government to determine the specific nature of the proposed incentives and disincentives (financial or otherwise) offered to the states to extend financial access to the health care delivery system to the millions of low-income working Americans who cannot now afford or obtain basic health insurance protection. However, possible alternative approaches to eligibility that could be taken (individually or in combination) by the states to close the "gaps" in coverage under Medicaid include:

- all categorical requirements could be abolished and eligibility could be based solely on financial criteria (e.g., income below specified levels);
- the varying state income level definitions for eligibility of the medically needy could be eliminated, as well as the current linkage to eligibility under welfare programs that generally exclude single individuals and childless couples under age 65;

- Medicaid coverage could be extended to unemployed fathers in those 24 states that do not currently cover them; and
- the Medicaid spend-down (i.e., when medical expenses incurred are equal to the difference between the individual's income and the protected standard) program could be extended to every state, and eligibility requirements could be standardized to eliminate existing uncertainties about program requirements.

States participating in Medicaid are required to include the following medical services: inpatient, outpatient, laboratory and X-ray, skilled nursing, physicians, home health, and EPSDT (Early and Periodic Screening, Diagnosis, and Treatment) for children under 21 years of age. Beyond these, the states may include a number of other services, such as drugs, eyeglasses, and dental services, for which federal matching funds are available. The states also have the discretion of deciding the amount or level of each service included in their programs (i.e., one state may decide to cover 30 days inpatient hospital days per Medicaid eligible person while another State may cover 90 days) and may also impose other restrictions, such as cost-sharing requirements. These types of options have led to substantial variations among the states in their expenditures for medical services for qualified individuals, as well as in the scope and duration of basic and optional benefits offered to those eligible. As states continue to face fiscal pressures, more creative ways of reducing services by means of amount, scope and durational limits can be expected. To ensure that all Medicaid recipients receive at least an adequate basic package of benefits, the proposed incentives/disincentives to be established by the federal government should encourage states to move toward standardizing a uniform set of basic benefits for those covered under Medicaid nationwide. Where fiscal constraints force a

state to make reductions in its Medicaid coverage, the potential health effects must be considered and rather than excluding any existing services entirely from coverage, states should be encouraged to place limitations on covered services.

Federally Mandated Employer-Based Plans and Voluntary Insurance Industry Pools
for Catastrophic Health Insurance Protection

"Catastrophic" health care costs are broadly defined as large unpredictable medical expenses usually associated with a major or chronic illness or serious injury. While the vast majority of Americans are protected against the costs of normal episodes of illness, a very expensive unusual or unexpected illness or accident can cause financial ruin. Consumers presently have three primary sources of assistance in meeting the costs of catastrophic health care: (1) private insurance, (2) public programs, and (3) tax subsidies. Collectively, these sources serve to reduce significantly the portion of medical expenses paid directly by the consumer and thereby decrease the incidence of catastrophic costs to the consumer. However, problems do remain in this current system of coverage.

The CBO projected that 103 million persons would have "good" catastrophic protection in fiscal 1978 through major medical plans, comprehensive major medical plans, and membership in health maintenance organizations (HMOs). In addition, while Medicaid coverage varies considerably from state to state, the CBO has reported that virtually all of the program's 24 million recipients had adequate catastrophic protection. Thus, in a nation of some 220 million individuals in

fiscal year 1978, approximately 93 million people or about 42 percent of the total U.S. population received no, or inadequate, protection against catastrophic health care costs. This clearly represents a glaring deficiency in the nation's present health insurance system.

Growing public concern about the high costs of catastrophic care has been displayed in recent years through such activities as: the rise in private health insurance plans with high coverage limits; the implementation of public catastrophic insurance programs in five states; and the introduction of numerous pieces of legislation in Congress proposing catastrophic coverage nationally. In addition to recognizing the very real potential for personal insolvency, there appears to be a growing realization that the nation may be ill-prepared to enact, afford, or administer a massive new system of comprehensive national health insurance. In light of these current trends and attitudes, and with the firm belief that the provision of adequate catastrophic protection to the entire population represents an area of pressing need that must be addressed, the AAMC advocates the development of a nationwide catastrophic health insurance program. This program would be coupled with the proposed improvements to Medicaid in the targeted approach focusing coverage in areas of greatest need.

More specifically, the Association supports a catastrophic health insurance program requiring that employers shall make available to all full-time employees and their families catastrophic health insurance coverage through private insurance plans meeting HEW minimum standards for adequacy of coverage and eligibility/ requiring that employers shall share the costs with employees for catastrophic health insurance coverage for full-time employees and their families through private insurance plans meeting HEW minimum standards for adequacy of coverage and eligibility/ which would provide incentives to encourage employers to make catastrophic health

insurance coverage more publicly available. (One sentence ending must be chosen.) Furthermore, private insurance carriers would be requested to participate, as a social responsibility, in state or regional insurance "pools." These pools would sell approved basic catastrophic insurance plans to the non-employed, self-employed, part-time workers, high-risk individuals, "Medicare beneficiaries," and others not covered by employers, all of whom would be required to purchase such coverage. (If this last phrase is added, the next sentence would be deleted.) Though these individuals would not be required to buy catastrophic coverage, they or a government sponsor would at least be guaranteed an opportunity to buy such coverage from the industry pools. *It should be recognized that the basic objective of catastrophic health insurance coverage is the relief of individual financial anxieties rather than the improvement of the health status of populations.*

Services not traditionally included in an individual's personal health care expenditures and financed instead through general revenues as public health care expenditures, such as long-term care for chronic mental illness, should be excluded from coverage under the catastrophic health insurance program. The federal Medicaid program, which now finances long-term custodial care in nursing homes in many states, should provide appropriate financial incentives to the states to accept as a responsibility of their Medicaid plans the provision of long-term care for individuals who cannot pay for it as a personal health care expenditure, recognizing that the amount spent on such care must be reasonably balanced with expenditures for acute care services. In addition, benefits which, if included, would pose unreasonable administrative burdens should be excluded from coverage under the catastrophic health insurance system.

Certification of Minimally Acceptable Basic Health Benefits Plans by a Voluntary Independent Body

This position paper has already documented data describing the disparities existing in the coverage of Americans for basic health services. There are 18 million individuals and families without any such protection at all. Moreover, the evidence is clear that even among existing basic health benefits packages there is tremendous variance in scope, amount and duration of benefits, with no certainty of at least minimal acceptability of coverage. To address this issue, the AAMC recommends that an independent certifying body or commission, composed of representatives of insurance carriers, providers, and consumers, be created to (1) establish a minimum desirable standard for a basic health insurance benefits package and (2) review all basic health plans and provide its "seal of approval" only to those meeting the minimally acceptable standard. *In identifying a desirable basic benefits package, the commission should consider, at a minimum, such coverage as inpatient care, physicians' services, ambulatory care, diagnostic laboratory and x-ray services, short-term mental health services, and home health care.* It is believed that this certification of health insurance policies by a voluntary body will provide a powerful incentive to insurers to offer at least minimally acceptable basic benefits packages and to employers to upgrade deficient employee basic health benefits plans, and will serve as a source of excellent additional information for the protection of the public interest.

Cost-Sharing Patient Co-insurance and Deductibles

The targeted approach recommended for the expansion of health insurance in the U.S. is designed to provide ready financial access to the health care system in areas of greatest need and to shift the financial burden of health care from personal expenditures to insurance coverage and public assistance.

The ideal health insurance program should, therefore, have no cost-sharing provisions. If a particular health insurance proposal includes cost-sharing mechanisms such as deductibles, coinsurance, or copayments, they should be held to minimum appropriate levels, and their effect on utilization should be evaluated. They should only be high enough to avoid over-utilization; they should not be burdensome in the aggregate to a family; and they should be waived for low-income persons. Furthermore, they should not be applicable to essential minimum and preventive services, and the cost of administering the cost-sharing should not exceed the savings from avoided over-utilization. If it is determined that some cost-sharing mechanisms should be utilized, the provider, in order to promote efficiency, should not be involved in collecting the patient's share. The provider should not be required to determine at the point of delivery whether the patient has met cost-sharing obligations in the past or whether the patient can pay any new cost-sharing obligations that may arise.

Provider Reimbursement Standards

Integral to the targeted expansion of the health insurance system is the establishment of a reimbursement policy allowing fair and reasonable payments for services. *A necessary pre-condition is the existence of a sufficient financial base to underwrite the commitments.* The policy for physicians' services should provide payment for high quality professional medical services on an equal basis irrespective of the setting in which the services are provided. Such a reimbursement policy should not impede the training and education of medical students and residents, and should recognize the team approach to professional care in the teaching setting. The policy should not, for example, in setting conditions under which fee-for-service reimbursement of teaching physicians is to be made, require the kind of financial test and other conditions imposed by Section 227 of the Social Security Amendments of 1972.

A reimbursement policy that is fair and reasonable also will meet the financial needs of the institutional providers of the services, including the replenishment of capital for the maintenance of an up-to-date facility. Allowable expenses for reimbursement should include the depreciation of capital assets, the amortization of debt, and the accumulation of an adequate operating margin. Furthermore, the reimbursement policy should reflect that there are valid differentials among providers in the cost of delivering care. The cost of services delivered in the teaching hospital, for example, will be greater for at least three reasons: (1) the severity of illness and complexity of diagnosis of patients in the teaching hospital; (2) the comprehensive and/or intensity of services provided by the teaching hospital; and (3) the teaching hospital's commitment to the incremental cost of providing the environment for medical and paramedical educational programs.

Resource Manpower Development and Distribution

It is strongly believed that an expanded and improved health insurance system in this nation would provide an appropriate mechanism for financing graduate medical education as a means of replenishing the health manpower pool. Graduate medical training includes important elements related to education and delivery of health services as integral parts of the training, and is thus appropriately financed by the health delivery system. In its financing of graduate medical education, the nation's health insurance system may justifiably be used to influence the numbers and kinds of medical generalists and specialists trained to address better the problems of maldistribution of health manpower.

Expansion of opportunities for graduate medical education in specialties deemed in short supply should continue to be encouraged through financial incentive programs. Requirements on financing policy should not be so restrictive that they inhibit desirable innovations. Special funding should provide sufficient support to meet the cost of program development and maintenance and not place an undue burden upon institutions to cover marginal costs. Plans for the subsidy of new specialty programs should include an analysis of their needs for long-term support. Reimbursement policies which make long-term financial support improbable should be altered. The financial support of ambulatory teaching clinics is increasingly dependent upon revenues generated through payments by third-party insurers. Third-party payers should be willing to pay for patient care services provided by teaching clinics at a rate equivalent to community rates with an additional allowance to support reasonable educational costs.

Philanthropy

Philanthropic contributions have provided non-profit and public hospitals with urgently needed support. Teaching hospitals, particularly, have relied upon philanthropy for support of new construction and for innovative programs. This vital support has stimulated research and development in medical care organization.

Any approach taken to addressing the need for expansion and improvement of health insurance in this country should recognize and encourage the contribution of philanthropy to the health care system. More specifically, the tax system should continue to provide deductions from corporate and individual income taxes for charitable contributions. Hospital reimbursement formulas should specifically provide that unrestricted endowment principal and income, donations, legacies,

bequests and other charitable contributions not be included in formulas establishing payment rates. Finally, expenditures of funds derived from philanthropy should be under the control of the governing board of the respective hospital.
~~subject only to the control of the state planning agency.~~

Conclusion

It is the firm belief of the Association of American Medical Colleges that adoption of the three major recommendations and four operating principles set forth in this document would result in an effective and cost efficient targeted approach to the expansion and improvement of health insurance in this nation. Furthermore, the AAMC contends that use of this approach will enable achievement of greater access to coverage by those most in need.

UNIVERSAL APPLICATION FORM FOR GRADUATE MEDICAL EDUCATION

In its Final Report of November 16, 1978, the Working Group on the Transition Between Undergraduate and Graduate Medical Education of the AAMC Task Force on Graduate Medical Education recommended that AAMC develop an application form for first-year graduate medical education programs that would request information universally accepted as essential for making selection decisions. Pursuant to this charge, AAMC developed a prototype universal application form, which was refined according to the recommendations of the Working Group on Transition, the GSA Steering Committee, the OSR Administrative Board, and AAMC Staff. The resulting "AAMC Application for First Year of Graduate Medical Education" is designed to meet the criteria established by the Working Group on Transition and thereby facilitate the process of applying for a first-year residency position.

The existence of this Universal Application is not intended to preclude institutions or programs from requiring additional information of the students in whom they are interested. The Application materials will include a return card so that their receipt by program directors can be easily verified to students.

The Association is exploring the desirability of providing these application materials to the medical schools for distribution to students planning to enter residencies in 1981.

Association of American Medical Colleges

APPLICATION FOR FIRST YEAR OF GRADUATE MEDICAL EDUCATION

FROM: Students who are or will be graduates of U.S. medical schools
TO: Graduate Medical Education Programs accredited by the Liaison Committee on Graduate Medical Education

INSTRUCTIONS – PLEASE READ CAREFULLY

The application materials include an Application Form and a Program Designation/Acknowledgement Card, which are to be used solely for applications for first-year graduate medical education programs.

1. Application Form. The Application Form is a 4-page document.

Pages 1 and 2 may be completed once and copied for distribution to all programs where an application is filed.

Pages 3 and 4 may be completed once and copied for distribution to more than one program, or they may be completed individually for each application.

For each application the pages should be assembled in sequence and stapled together in the upper left corner. THE APPLICATION FORM IS COMPLETE ONLY IF IT INCLUDES ALL FOUR PAGES AND THE APPLICANT'S SIGNATURE (NOT COPIED) ON PAGES 2 AND 4.

2. Program Designation/Acknowledgement Cards. It is essential that original Program Designation and Acknowledgement Cards be completed for each application. DO NOT SEPARATE THESE TWO CARDS. The cards indicate the starting year of the program for which the application is filed (the color of the cards also changes from year to year). Be sure to use cards intended for the appropriate year.

A. **Acknowledgement Card.** Enter your name and current mailing address on the lines provided. Place a stamp on the card. This card will be returned to you by each program to which you apply to acknowledge receipt of your application materials.

B. **Program Designation Card.** Enter the basic applicant identification information at the top of the card exactly as it appears on page 1 of your application form. Designate the appropriate institution (hospital) and program (including NRMP code) to which the application is sent.

ATTACH THE COMPLETED PROGRAM DESIGNATION AND ACKNOWLEDGEMENT CARDS (JOINED BY PERFORATION TO EACH OTHER) TO THE UPPER LEFT FRONT OF THE COMPLETED APPLICATION FORM (space is provided for this purpose on the Program Designation Card).

A complete application for a first-year graduate medical education program includes:

1. A 4-page Application Form, including original signatures on pages 2 and 4;
2. Program Designation and Acknowledgement Cards, attached to each other and to the front of the Application Form.

Application materials should be mailed in an envelope measuring at least 9 inches by 12 inches so that the Program Designation and Acknowledgement Cards do not have to be folded. (Envelopes are available with application materials.)

* * * * *

Please TYPE or PRINT LEGIBLY throughout.

PERMANENT ADDRESS AND PHONE NUMBER (items 8 and 9, page 1): Enter the name, address, and telephone number of an individual through whom you can always be contacted (parent, spouse, etc.)

INTERVIEW SCHEDULING (item 14, page 2): Indicate the general time period or specific date(s) that you are able to appear for an interview.

PERSONAL STATEMENT (item 15, page 3): Most program directors want to know about your professional interests, achievements, and plans, including your ultimate goal for a specialty and your anticipated geographic location. If you have any singular professional accomplishments such as published papers, bibliographic reference should be included. In addition, it is desirable to describe your family and household and your personal interests and activities.

REFERENCES (item 17, page 4): Most programs require a minimum of three; space is provided for a maximum of five. Do not include individuals listed in item 16.

IT IS THE APPLICANT'S RESPONSIBILITY TO ARRANGE TO SUBMIT ANY SUPPLEMENTARY MATERIALS (TRANSCRIPTS, DEAN'S LETTERS, ETC.) REQUIRED BY A PARTICULAR PROGRAM.

Association of American Medical Colleges

APPLICATION FOR FIRST YEAR OF GRADUATE MEDICAL EDUCATION
(Type or Print)

1. NAME (LAST) (FIRST) (MIDDLE)				
2. SOCIAL SECURITY NUMBER		3. DATE OF BIRTH (MO./DAY/YEAR)	4. NRMP NO. (IF KNOWN)	
5. PRESENT ADDRESS (STREET)		(CITY)	(STATE) (ZIP)	
6. PRESENT PHONE NOS. DAY () EVENING ()			7. NO. OF DEPENDENTS	
8. PERMANENT ADDRESS C/O (NAME OF PERSON THROUGH WHOM I CAN ALWAYS BE CONTACTED) (STREET) (CITY) (STATE) (ZIP)				
9. PERMANENT PHONE NO.				
10. MEDICAL EDUCATION				
MEDICAL SCHOOL(S)				
MONTH OF ANTICIPATED GRADUATION FROM MEDICAL SCHOOL				
ELECTIVES COMPLETED/PLANNED				
HONORS/AWARDS				
11. UNDERGRADUATE EDUCATION				
UNDERGRADUATE COLLEGE(S)	DATES ATTENDED		MAJOR	DEGREE (IF ANY)
	FROM (MO./YR.)	TO (MO./YR.)		
NAME				
A. CITY STATE ZIP				
NAME				
B. CITY STATE ZIP				
NAME				
C. CITY STATE ZIP				

Association of American Medical Colleges
Application for First Year of Graduate Medical Education

12. GRADUATE EDUCATION

12. GRADUATE SCHOOL	DATES ATTENDED		AREA OF STUDY	GRADUATE DEGREE (IF ANY)
	FROM (MO./YR.)	TO (MO./YR.)		
NAME				
A. CITY STATE				
NAME				
B. CITY STATE				

13. AT THE TIME I BEGIN THE GRADUATE MEDICAL EDUCATION PROGRAM FOR WHICH I AM NOW APPLYING,
I WILL/WILL NOT HAVE TAKEN THE FOLLOWING EXAMINATIONS:

A. NBME, PART I <input type="checkbox"/> WILL HAVE TAKEN <input type="checkbox"/> WILL NOT HAVE TAKEN	B. NBME, PART II <input type="checkbox"/> WILL HAVE TAKEN <input type="checkbox"/> WILL NOT HAVE TAKEN
C. FEDERATION LICENSING EXAMINATION (FLEX) <input type="checkbox"/> WILL HAVE TAKEN <input type="checkbox"/> WILL NOT HAVE TAKEN	

14. INTERVIEW SCHEDULING:

 THE FOLLOWING GENERAL TIME PERIOD(S) IS MOST CONVENIENT FOR ME:

FROM _____ TO _____

 I AM ABLE TO SCHEDULE AN INTERVIEW ON THE FOLLOWING SPECIFIC DATE(S):

_____ I AM NOT ABLE TO COME FOR AN INTERVIEWI CERTIFY THAT THE INFORMATION SUBMITTED ON THESE APPLICATION MATERIALS IS COMPLETE AND
CORRECT TO THE BEST OF MY KNOWLEDGE.

SIGNATURE OF APPLICANT

DATE

NOTE: THE SIGNATURE AND DATE ON EACH APPLICATION MUST BE ORIGINAL.

Association of American Medical Colleges
Application for First Year of Graduate Medical Education

NAME	(LAST)	(FIRST)	(MIDDLE)	NRMP NO. (IF KNOWN)
SOCIAL SECURITY NO.	DATE OF BIRTH (MO./DAY/YEAR)			
15. PERSONAL STATEMENT (SEE INSTRUCTIONS. USE ADDITIONAL SHEET IF NECESSARY)				
16. NAMES OF INDIVIDUALS AT THIS HOSPITAL WHO KNOW ME AND HAVE OBSERVED MY PERFORMANCE:				

Association of American Medical Colleges
Application for First Year of Graduate Medical Education

THE FOLLOWING INDIVIDUALS HAVE BEEN ASKED TO WRITE REFERENCES FOR ME:

A. NAME & TITLE

INSTITUTION

ADDRESS

B. NAME & TITLE

INSTITUTION

ADDRESS

C. NAME & TITLE

INSTITUTION

ADDRESS

D. NAME & TITLE

INSTITUTION

ADDRESS

E. NAME & TITLE

INSTITUTION

ADDRESS

SIGNATURE OF APPLICANT

DATE

NOTE: THE SIGNATURE AND DATE ON EACH APPLICATION MUST BE ORIGINAL.

PLACE
STAMP
HERE

Association of American Medical Colleges
APPLICATION FOR FIRST GRADUATE YEAR - BEGINNING 1981
PROGRAM DESIGNATION CARD

ATTACH

Name _____

Address _____

(DO NOT SEPARATE)

Name _____ NRMP No. _____
Last First Middle (if known)

Social Security No. _____ Date of Birth _____

Medical School _____

Date of Graduation from Medical School _____

Enclosed are first graduate year application materials to:

INSTITUTION & LOCATION: _____

PROGRAM: _____ NRMP Code _____

Signature of Applicant _____ Date _____

Association of American Medical Colleges
APPLICATION FOR FIRST GRADUATE YEAR

(name) _____

This will acknowledge receipt of your application for a first-year position,
beginning in 1981, in this graduate medical education training program.

PROGRAM _____ NRMP Code _____

INSTITUTION _____

DATE _____

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