ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL OF DEANS
ANNUAL BUSINESS MEETING
Monday, November 7, 1983
2:00 - 5:00 p.m.
Jefferson East
Washington Hilton Hotel
Washington, D.C.

AGENDA

FEATURED PRESENTATION

"Health Care Cost Containment"

William Luginbuhl, M.D.
Dean
University of Vermont
School of Medicine

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL OF DEANS
SPRING BUSINESS MEETING

SESSION I
WEDNESDAY, APRIL 6, 1983
5:30 P.M. - 7:00 P.M.

SESSION II
SATURDAY, APRIL 19, 1983
8:30 A.M. - 12:00 NOON

THE BALLROOM, MEETING & HOTEL CENTER
THE COTTONWOODS
SCOTTSDALE, ARIZONA

I. Call to Order

The meeting was called to order at 5:30 p.m. by Richard Janeway, M.D.

II. Quorum Call

Dr. Janeway announced the presence of a quorum.

III. Chairman's Report

Dr. Janeway welcomed all new members to the Council of Deans and wished them success on their new positions. He then provided a brief overview of the meeting sessions. He gave special thanks to Dr. Louis Kettel for arranging the workshop on personal computers.

Dr. Janeway reviewed several of the issues addressed by the Administrative Board since the Annual Meeting, highlighting the discussion of the proposed sliding scale for the award of NIH research grants with proponent H. George Mandel and opponent, William Raub, Deputy Director of NIH. Dr. Janeway commented that although there was sympathy with the desire to "stretch" research dollars, there was broad agreement within the Board and Executive Council that the sliding scale proposal would threaten the integrity of the peer review system. AAMC Staff was asked to prepare an AAMC position paper reflecting the Council's deliberations. The paper has been completed and distributed by AAMC memorandum number 83-20 dated March 7, 1983.

IV. President's Report

Dr. Cooper set out five major topics to be reviewed in his report:

1. Status Report on Medical Education
2. Projects and Activities of the AAMC
3. Requests for Nominees for Research and Flexner Awards
4. Legislative Issues
5. Issues of General Importance to the Deans

Status Report on Medical Education

Dr. Cooper reported that for the first time in 20 years, the 1982 entering class into medical college schools showed a reduction of 77 students over the preceding year. This reduction of 77 positions is the net result of decisions to reduce the enrollment at 35 medical schools. Dr. Cooper noted that a recent survey conducted by staff revealed a projected decrease in 1983-84 of 47 students and an additional decrease of 85 students in 1984-85. Although the decrease is not as substantial as recommended by the Graduate Medical Education National Advisory Committee (GMENAC), it is a reversal of the trend line. The number of applicants to medical schools declined in 1982 by 1,000 as compared to 1981, a 3% decrease. Similar decreases are anticipated in 1983-84. The applicant pool peaked in 1974, leveled off, and has since declined. In the peak year, 35% of the applicants were admitted to medical schools; in 1982, 48% of the applicants were admitted. Dr. Cooper noted that the Association's work plan, approved at the Fall Retreat, suggested that the applicant pool be monitored. If the downward trend continued unabated, some AAMC intervention might be warranted. Dr. Cooper commented that the number of male applicants had fallen rapidly and had it not been for the increase in female applicants, the overall pool would have been seriously depleted. Currently, one-third of all applicants are female; there has been no substantial increase in the number of minority applicants.

Dr. Cooper reported that tuition costs continue to rise. In 1982-83, public school tuition increased by 16.2% and private school tuition increased by 15.5% over the previous year. It is anticipated that tuition will continue to rise more rapidly than the CPI.

Dr. Cooper announced that the AAMC position on the evaluation of foreign medical graduates, adopted in 1981 as a result of the recommendations of the task force chaired by Dr. William Luginbuhl, was beginning to be implemented. The AAMC recommended that the current ECFMG exam no longer be considered as an adequate evaluation of the USFMG's. As a result, the ECFMG has been stimulated to develop, in conjunction with the NBME, a new exam which will be administered in July 1984. The exam, entitled "Foreign Medical Graduate Exam of Medical Sciences" will be more nearly equivalent to Parts I & II of the National Boards. It will permit FMG's to take the exam in two parts. The exam will be required for all FMG's - alien and U.S. The ACGME, the accreditation body which establishes criteria for admission into accredited residency programs, will review the new ECFMG exam. If it is considered acceptable, it will fulfill the criteria in the new Essentials for a comprehensive exam approved by ACGME. The ACGME has reaffirmed that students graduating from schools accreditated by the LCME need not pass any standardized national exam to be eligible to enter or continue in residency programs.

With respect to another recommendation made by the task force, Dr. Cooper reported that the ECFMG is now conducting studies regarding methods for evaluating the clinical skills of FMG's through direct

observation of their performance. Dr. Cooper noted that skepticism has been expressed regarding the possibility of developing such an evaluation process, but the AAMC examination of the matter persuaded us that it is feasible.

Dr. Cooper reported that the number of positions offered in the NRMP is continuing to decrease. In 1982, positions offered decreased by 31. In 1983 there was an additional decrease of 348 positions. Had it not been for new programs in Emergency Medicine, the number of opened positions would have declined by 530. It is critical to maintain an adequate number of residency positions to fill the needs of all graduates of U.S. medical schools. He observed that the number of FMG's is rising and suggested that political pressure will be exerted to assure that all FMG's are able to complete their training in qualified programs. Dr. Cooper noted a new phenomenon: some positions not matched initially were withdrawn from the program before there was an opportunity for unmatched students to apply. Dr. Cooper reported that the process used to distribute the match books had gone smoothly and no complaints were received regarding premature releases of the information.

Activities of the AAMC

Responding to concerns expressed by clinical faculty regarding their ability to accurately measure and report on the clinical competence of their students during clerkships and residency programs, the AAMC has undertaken a clinical competence assessment project. This project, designed to analyze this evaluation process, has now completed its first phase and has published its observations in Evaluation of Clerkships - Perceptions of the Clinical Faculty - Survey of Issues and Proposed Action. The project, directed by Xenia Tonesk, Ph.D., is based on communications with 519 clinical programs representing all major specialties and site visits to 14 schools. Phase II of the project will develop guidelines which institutions can use for self-study. Dr. Cooper noted that the evaluation of students' knowledge, skills and attitudes in a clinical setting is a major responsibility for all those involved in the educational process and that he hopes the project will be helpful in assisting them in this important task.

Dr. Cooper reported that Phase I of the RIGME (Regional Institutes on Geriatrics and Medical Education) project--the conduct of four regional institutes--had been positively received by the participants. The recommendations would be published soon in the form of proceedings. He hoped that they would be useful in assisting schools prepare students to meet the needs of the elderly patient population.

The General Professional Education of the Physician (GPEP) project, in its second year, had conducted hearings at three sites. The hearings stimulated active participation among faculty, students and administrators. Working papers are being developed by the three Working Groups (Essential Knowledge, Fundamental Skills and Personal Qualities, Values and Attitudes) and will be discussed at a retreat in July.

Dr. Cooper reported on the Association's study of the characteristics of teaching hospitals conducted by the Department of Teaching Hospitals. The study, resulting in four publications, examined 33 teaching hospitals in an effort to delineate the unique characteristics of teaching hospitals. The publications will be widely circulated, especially to congressional staff.

The Association's Office of Minority Affairs is taking an active role in implementing the recommendations of the Task Force regarding methods for increasing opportunities for minority students in medicine. The office received an 18 month contract from HHS to increase the activities of the Health Careers Opportunity Program. Regional workshops which address issues of financial aid, student admissions, retention and learning skills are continuing; and over 255 medical students and personnel have attended. In addition, Dr. Cooper reported that at the 1983 Annual Meeting, the staff will distribute a report on Minorities in Medical Education. Supported by the Robert Wood Johnson Foundation, the report addresses issues relating to minority applicants' enrollment and retention, minority faculty participation and characteristics of the minority applicant. The Minority Affairs office is also collaborating with the Josiah Macy Foundation to determine the extent to which minority applicants participate in enrichment and preparatory programs, and the effects of these programs on their ability to achieve their goal to enter a career in medicine.

Dr. Cooper reported that several staff members are presently writing books, all to be published by Jossey-Bass Publishing Company as part of an AAMC series on various aspects of academic medicine. Staff include James Schofield, M.D., Davis Johnson, Ph.D.; and Emanuel Suter, M.D. In addition, Marjorie Wilson, M.D., has completed a book on the governance and organizational structure of the academic medical center which she initiated while on sabbatical at Johns Hopkins. Dr. Cooper invited deans to encourage faculty interested in writing on issues related to academic medicine to become part of the series.

Dr. Cooper announced that the staff was developing a survey on faculty appointment policies and practices and that it would be mailed to all the deans and business officers by mid-summer. The survey will seek to identify the variations in policies currently in force as well as identify new approaches being considered to address pressing institutional issues.

Research and Flexner Awards

Dr. Cooper urged the deans to submit nominations for the Research and Flexner Awards. He noted that the Association has honored distinguished scholars in the past and urged them to consider the identification of potential nominees as deserving of their attention.

Legislative Issues

Dr. Cooper stated that the effectiveness of the advocacy by the AAMC with members of Congress is dependent upon the degree to which each dean worked with his own Congressional delegation. The leaders of academic medical centers can and do exert significant influence on legislative outcomes and he urged the deans to be as active and as vocal as possible.

Dr. Cooper discussed indirect costs and the potential "wedge" between faculty and administration over the distribution of funding to direct and indirect costs. He stated that faculty do not seem to understand the impact of indirect cost on the institution's ability to conduct biomedical research. He suggested that the deans continue to engage in dialogue with their faculties regarding this issue. Dr. Cooper also reported that a number of strategies for distributing federal dollars for research were presently under discussion. He highlighted the sliding scale proposal and cautioned that this method could have a serious effect on the peer review system. He stated that the most effective strategy would be to work toward maintaining the present level of funding effort, and to provide institutions with enough funds to cover both their direct and indirect costs of conducting research.

Dr. Cooper provided a brief progress report on the V.A.'s MEDIPP project. Most of the district plans were sensitive to the need for effective affiliation agreements between the V.A. medical centers and medical schools. Several were not; these were returned to the district for reworking in appropriate consultation with the local deans' committee.

Dr. Cooper highlighed the current interest in the matter of the supervision of residents in V.A. medical centers. He stated that it is unfortunate that a few cases attract national attention and thus distract attention from the overall effectiveness of graduate training experiences. Dr. Cooper noted that Dr. Custis had sent letters to all facilities calling their attention to this critical issue and the responsibility on the part of all the staff to supervise students. Dr. Cooper also reported that the GAO is presently conducting a review of this at the request of Senator Alan Cranston. Senior GAO officials will meet with the Association's staff to discuss the issues.

W. Marcus Newberry, M.D., Dean at the Medical University of South Carolina, discussed the events surrounding an incident at a V.A. medical center involving the lack of supervision of a surgical resident. He suggested that it was, in part, a resource constraint problem and identified a need to inform Congress of the resources that are necessary to effectively operate a training program.

IV. Discussion Items

A. Medical College Admission Test: Projects and Studies

At its September 1982 meeting, the Council of Deans' Administrative Board reviewed the status of the MCAT Program. The Board considered the

material of sufficient importance to warrant consideration by the entire Council of Deans.

Dr. James Erdmann, Director of the Association's Division of Educational Measurement and Research, discussed: (1) studies recently conducted on the validity of the MCAT; (2) test performance of examinees who participated in repeated administrations of the test; (3) impact of commercial review courses on the performance of repeaters; and (4) possible changes and additions to the examination program, i.e., adding an essay section to the exam and developing a Diagnostic Services Program.

Content Validity

Dr. Erdmann explained that the original content of the new MCAT, which was first administered in 1977, was determined by an elaborate process of science topic selection followed by an extensive rating of the importance of each topic by over 150 medical school faculty. The stability of these ratings over time was reviewed during the 1981-82 academic year. This content review included 278 medical school faculty and students representing 63 medical schools and 7 academic societies. In addition, 427 undergraduate college faculty were surveyed to insure that the science topics still remained a part of the first-year sciences curriculum.

The results of the surveys affirmed that all major MCAT topics in the science areas continued to be judged as the necessary and most relevant prerequisites for the study and practice of medicine. Suggestions were made to introduce minor modifications in certain subtopic areas and corresponding changes in questions will be incorporated in the 1984 MCAT.

Predictive Validity

Dr. Erdmann stated that one of the primary objectives of the Interpretive Studies Program is to develop national statistics on the overall value of MCAT scores and their role in the admissions process. Presently, at 30 medical schools, performance data are being collected on students as they progress through their medical education. The study has at this point addressed three major validity questions:

1. How does the predictive value of MCAT scores compare to that of the undergraduate academic record using basic sciences performance measures as criteria?

2. Does the MCAT contain unique information, not already provided by undergraduate GPA, that aids in the prediction of students' performance? To what degree?

3. What is the relative value of the various individual MCAT scores in predicting overall performance in the basic sciences?

Dr. Erdmann noted that the response to the first question varies with the criterion considered. When the criteria are medical school course grades, MCAT subtest scores as a group are comparable to undergraduate

grades in predictive value although no single MCAT score correlates as highly as undergraduate science GPA. When the criteria are NBME-Part I scores, combinations of MCAT scores and several MCAT scores individually are substantially better predictors of performance.

Dr. Erdmann also discussed the degree to which MCAT scores provide unique and useful information to the admissions process. Multiple correlations with medical school course grades are consistently higher when based on a combination of MCAT scores and undergraduate GPA than those based on either predictor group separately. The increase in the average multiple correlation when MCAT is added to GPA to predict performance is 11-16 points when course grades are the criteria and 27 points when NBME scores are the criteria. These comparisons are usually expressed as the "proportion of variance explained (the multiple correlation values squared). In these terms, MCAT scores improved predictability by 65 percent with course grades as the criteria and nearly 300 percent for NBME scores.

In addition, Dr. Erdmann referred to the following correlations that offered interesting information:

1. the MCAT science scores (except Physics) are more highly correlated with performance in the first year than the skills subtest scores.

2. the correlations with second-year grades as the criterion are lower than those with first-year grades with the SA: Reading score being an interesting exception.

3. there is a particularly strong relationship between the MCAT science areas of assessment and performance in two subjects in the first-year curriculum: physiology and biochemistry.

4. SA: Reading (and to a lesser extent SA: Quantitative) scores are relatively highly correlated with performance in behavioral science courses.

5. MCAT scores are generally more highly correlated with scores on Part I of the NBME--the National Board of Medical Examiners--than with local performance.

6. A major factor in the magnitude of observed validity coefficients is the depressing effect of sample homogeneity, since those for whom criteria are available are a highly selective subset of those initially taking the MCAT.

<u>New Projects</u>

1. ESSAY

   Dr. Erdmann stated that the Association's staff is investigating the feasibility of having all examinees complete a 30-35 minute essay during each MCAT administration. The objective of the essays is to provide information to medical faculty regarding candidates' ability to express themselves in writing. The source for stimulus materials

is expected to be general experience, subject matter areas that are familiar to average college students. Dr. Erdmann stated that some reduction in the length of the MCAT now seems possible, to provide time for the essay, without compromising test quality or comprehensiveness. Exact copies of the submitted essay will accompany each reported MCAT score to a school. The AAMC does not intend to score the essay and may recommend that no quantitative index be assigned by the shcool. Staff were in favor of introducing the essay on an experimental basis.

2. DIAGNOSTIC SERVICES PROGRAM

Dr. Erdmann stated that staff is investigating the possibility of developing a method for helping students who are considering a career in medicine to assess their areas of strengths and weaknesses in those areas tested in the MCAT. Diagnostic assessments of knowledge and skills would be obtained by means of modules of test questions selected to provide specific feedback on levels of accomplishment which could be compared to the norms of typical MCAT examinees.

B. Regional Institutes on Geriatrics and Medical Education

Dr. John Sherman provided a status report on the Association's project on geriatrics and medical education. In describing the origins of the project, Dr. Sherman stated that the changing demographics of the geriatric population is presenting new challenges to the health care community. The pervasiveness of the problems and issues inherent in the care of this population suggested to the governance structure of the Association that we needed to depart from our usual reluctance to involve ourselves with categorical issues and mount a project to address geriatric issues in medical education. He stated that the staff examined the issues for several months and concluded that it would be helpful to develop guiding principles that schools may want to consider in addressing geriatric concerns. The staff wanted to avoid anything that looked like the advocacy of a model curriculum, yet sought to encourage an approach that would integrate materials into existing curriculum.

Dr. Sherman continued to report that a Steering Committee was convened, chaired by Joseph Johnson, M.D. Under the direction of the committee, four regional institutes were held. Dr. Sherman commented on the diversity of faculty that attended the institutes and stated that nearly all medical schools were represented. The papers presented at the four plenary sessions were being published and distributed to deans, faculty, Members of Congress and appropriate organizations. The publication describes activities believed to be useful in the teaching of geriatric issues to medical students.

Now that Phase I of the program has been completed, Dr. Sherman stated that the next challenge is to facilitate the implementation of the recommendations. A series of limited visiting lectureships in geriatrics has been developed. Dr. Sherman distributed two pamphlets, one describing the lectureship program and the other listing individuals who agreed to participate as faculty. Dr. Sherman concluded by stating that the combination of interested institutions and carefully selected faculty could be an effective method of implementing important recommendations.

C. Trends in the National Residency Matching Program

Dr. August Swanson reported that there were 17,952 positions offered in the 1983 match--a decrease of 348 from 1982. He stated that major factors indicated that a decreasing trend would continue. The number of active applicants in the match increased from 18,410 in 1982 to 20,044 in 1983. There were 13,969 active U.S. graduates; 12,874 were matched (92.16%). In reference to alien and U.S. foreign medical graduates, Dr. Swanson stated that of the 1,305 active U.S. FMG's, 644 were matched. Alien FMG's had the lowest match rate of 26.23% but the total number matched increased from 751 to 949. The increase in the number of alien FMG's over the last two years may be explained by the fact that up until now they were required to take the ECFMG, not the Visa Qualifying Exam. Cognizant of the fact that a new ECFMG exam will be in place next year, many of the alien FMG's are trying to enter the graduate education process through the match as quickly as possible. Dr. Swanson stressed that this phenomena needed to be carefully monitored.

Dr. Swanson noted that the NRMP is now a 30 year-old institution which had sucessfully managed to reduce the stress for students that occurs at the interface of graduate and undergraduate medical education. Observing that several specialty programs had chosen to withdraw from the NRMP and involve themselves in a private match program, he expressed a concern that this threatened the integrity of the NRMP as well as the welfare of the students. Dr. Swanson reported that the NRMP now has the capability to match graduating seniors for both their first-and second-year program choices. The lack of this capacity was reportedly one of the factors leading to the decision of the specialties which withdrew.

Dr. Swanson emphasized the need to work with the organizations representing those specialties who withdrew from the NRMP and to convince them of the importance of being part of the national program.

D. Applicant and Matriculant Trends

At the January 1983 meeting of the COD Administrative Board, there was an interest in projecting 1982 enrollment of medical schools. Staff was requested to send a survey to all U.S. medical schools to determine projected enrollment for 1983-84 and 1984-85. Mr. Keyes reported that 126 institutional responses indicated a decrease in enrollment of 47 students in 1983-84 and 85 students in 1984-85. Analysis of the data by regions revealed that the largest decrease would occur in the Midwest/ Great Plains region with a decrease of 47 students in 1983-84 and 71 students in 1984-85. The Southern region schools projected an increase of 20 students in 1983-84 and a decrease of 2 students in 1984-85.

Mr. Keyes noted that although the data did serve to confirm the expectations that first-year enrollment was decreasing, the decrease of 122 students over a two-year period was not as significant as might have been anticipated.

E. Current Legislative Issues

In response to a request from the Chairman, Dr. Kennedy gave a brief presentation on the Congressional budget process which: 1) described the reasons for the continued importuning of the AAMC staff on what might have appeared to be the same issue, and 2) stressed the necessity of the leaders of academic medical centers to establish relationships with their congressmen and senators. He observed that deans become ex-officio persons of great influence in Washington who collectively can significantly influence legislative outcomes.

Turning to other matters, Dr. Kennedy stated that for the third time since 1979, Congress has initiated another effort to reach a concensus on legislation to renew a number of expiring authorities for the National Institutes of Health. As in the past, the House and Senate have adopted divergent approaches. The Senate bill introduced provides for rather simple reauthorization of expiring authorities. The House bill includes a large number of disease-specific "baubles", managerial directives and a major recodification of Title IV of the Public Health Service Act.

Dr. Kennedy reported that Mr. Madigan (R-IL) is considering the introduction of a substitute measure which would provide an approach similar to the Senate bill.

The positioning of the two bills creates a dilemma: Mr. Waxman's bill with high authorization ceilings is attractive to many in the scientific community for that reason; Mr. Madigan's bill which will not match those ceilings, would be far more attractive in every other respect.

Dr. Kennedy stressed the need for the deans to "educate" their faculty regarding the difference between authorizations and appropriations ceilings and to caution faculty to contain their enthusiasm for the Waxman bill.

Dr. Kennedy stated that Mr. Walgren (D-PA) was successful in his efforts to append animal welfare amendments to the House NIH renewal legislation. Although these amendments represent an improvement over other versions, they still pose significant problems: 1) the separate authorization of alternative methods represent another intrusion into the flexibility of the scientific process and 2) the regulatory standards for proper care and treatment could compel the NIH to transform its guidelines governing the care and treatment into regulation.

Mr. Madigan offered a substitute amendment which would have required a comprehensive 18-month study of current animal welfare activities by the National Academy of Sciences. Unfortunately, the amendment narrowly lost in the Subcommittee. It may be introduced again on the floor.

On the Senate side, Senators Hatch (R-UT) and Kennedy (D-MA) are sponsoring legislation mandating a study similar to the one proposed by Mr. Madigan.

The Association hopes to develop a large coalition of representatives to persuade the Committee to adopt the Madigan study and defeat the Walgren amendments.

V. Information Items

Mr. Keyes provided an update on the impact of the new Social Security Amendments which now requires non profit employers and employees to make contributions to FICA. If the institution has a 501(C)(3) Practice Plan, the Corporation will now be required to make its 6.3% contribution to FICA. If the university and the practice plan both compensate the employee, both entities must contribute FICA up to the level of the base. Employees who contribute twice to FICA will receive refunds, but the employer contributions will not be refunded. While private corporations may resort to a "Common Paymaster Rule" in similar situations, no such provision is available in the case of state institutions and separately incorporated practice plans. To correct this anomoly, Section 125 was included in the Social Security Amendment. Section 125 (Treatment of Certain Faculty Plans) identifies practice plans and state universities as related organizations under certain conditions. If these conditions are met there is deemed to be one employer for purposes of the FICA tax and the double payment of the employer contributions is avoided under "Common Paymaster Rules".

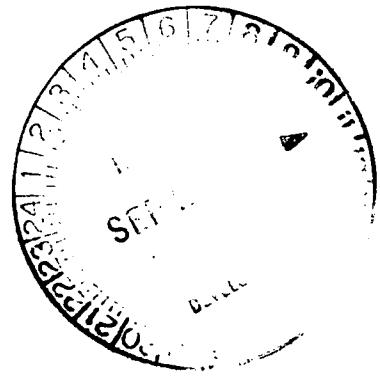
Mr. Keyes indicated that staff had two reservations or uncertainties regarding this approach: 1) whether its limitation to state institutions inappropriately narrowed the scope of the provision (i.e., were private schools adequately covered under existing provisions) and 2) whether the definition of the practice plan and the medical schools as "related corporations" would be disadvantageous in other contexts. The private school deans in attendance expressed no concern about the limitation of the provision. The deans were informed that the AAMC would provide updated information on this as it became available. All were encouraged to explore the implications of the matter back home.

Adjournment

The business meeting adjourned at 11:15 a.m. on Saturday, April 19, 1983.

RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER 1753 WEST CONGRESS PARKWAY, CHICAGO, ILLINOIS 60612

HENRY P. RUSSE, M.D.
VICE PRESIDENT FOR MEDICAL AFFAIRS
DEAN, RUSH MEDICAL COLLEGE



September 27, 1983

Mr. Joesph A. Keyes, Jr., Director
Department of Institutional Development
Association of American Medical Colleges
One DuPont Circle, N.W.
Suite 200
Washington, D.C. 20036

Dear Joe:

This will confirm our telephone conversations of the past several days regarding the COD Nominating Committee's recommendations.

I have confirmed, in personal conversation, all of these recommendations.

For Chairman Elect of the Assembly:	Dick Janeway
For Chairman Elect of the COD:	Arnold Brown, Jr.
For representative to the COD: (Executive Council) each to serve a 3-year term:	John Naughton Richard H. Moy
To serve as members at large (Administrative Board) in a 1-year term:	Bob Daniels Bill Butler Kay Clawson

Thank you for all of your help in this extended process.

Sincerely,

Henry P. Russe, M.D.

HPR/ds

LEGISLATIVE UPDATE
September 1983

FY 1984 HHS Funding

The Appropriations Committees of both chambers tackled the FY 1984 Labor/HHS/Education bill promptly after returning from the summer recess. On Thursday, September 16, the full House Appropriations Committee and the Senate Subcommittee on Labor/HHS/Education Appropriations each marked up its version of the FY 1984 funding proposal. On the whole, the picture is very positive, particularly for the NIH which would receive more than an 11 percent increase under both bills.

NIH

As is evident in the accompanying chart, only a $6.1 million difference exists between the House and Senate NIH proposals,with the former coming in at the higher level. These funding levels are adequate to cover full direct and indirect costs on all grants and to provide for funding of 5,000 new and competing grants in FY 1984. Moreover, the report accompanying the House bill expressly states that: "The Committee welcomes the [administration's] decision to fund 5,000 new and competing grants but does not agree with the proposal that the strength of one NIH support mechanism should be maintained by seriously weakening others." The report continues: "The Committee has restored virtually all of the cuts made in the other programs and provided the funds originally requested for them in the January budget estimates." Additionally, the report reads: "The Committee does not agree with a policy which inflates the number of projects supported by underfunding each project." Finally, the report urges that the indirect cost problem be addressed on a government-wide basis and recommends that the Administration consult with the academic community in taking steps to formulate a government-wide plan.

As they have not yet been reauthorized, the National Research Service Award and Medical Library Assistance programs remain unfunded in the current proposals. Should these programs remain unauthorized, as is likely for some time, appropriations will be accommodated through a continuing resolution.

The more than 11% increase over the FY 1983 level slated for NIH is obviously a very significant improvement over the less than 2 percent proposed by the Reagan Administration. It should be noted however that the final "bottom line" for NIH could be less than an 11% increase if Congress chooses to take the lesser of each chamber's proposal, as was done in FY 1982, rather than "splitting the difference" as is more common.

ADAMHA

Generous increases are in store for research on mental health and on alcohol and drug abuse with the House proposing 13.5% and the Senate 19.6% over the FY 1983 level. While the Senate figures are above the President's request, the House evidenced less optimism in the ability of the NIDA and NIAAA to absorb the 20 and 37 percent increases proposed by the Administration. Nonetheless, the lower House figures will cover full indirect costs as is directed in the House report.

Additionally, despite the Administration's goal of "zeroing-out" clinical training, both panels provided funding close to last year's figures. Again, funding for research training has been deferred.

Health Resources and Services Administration

Highlights in the areas under the jurisdiction of the Health Resources and Services Administration include: Allocations of $8.0 and $5.6 million for National Health Service Corps Scholarships by the House and Senate respectively, which will allow for the support of new scholarships (the Administration had requested no funds); the lack of any new capital for Health Professions Student Loans; the $5.6 million slated by both panels for Exceptional Financial Need Scholarships, despite the Administration's request for closing this program out; and the total rejection by the House of any limit on borrowing under the Health Education Assistance Loan Program and a $225 million limit slated by the Senate compared to the stringent $175 million limit requested by the Administration.

Prospective Payment Assessment Commission

The House has included $1 million for funding of the Prospective Payment Assessment Commission. The Senate Subcommittee mark is $2.5 million and the full Senate Appropriations Committee is expected to accept that mark.

Outlook

The next move in the House will be floor action which is expected toward the end of the week of September 19. Senate full Committee mark up is not yet scheduled.

The long range outlook is murky. Whether there will finally be an official Labor/HHS/Education Appropriations bill this year, or whether funding will yet again be maintained by a continuing resolution, will depend in good part on how quickly Congress moves in the coming weeks, and on the Administration's response to any final bill. Regarding the potential for a veto, the danger of this eventuality may have been lessened by a last minute meeting between Senate Subcommittee Chairman Lowell P. Weicker (R-CT) and OMB Director David Stockman. The upshot of the meeting was a discouraging downward negotiation of several Senate figures. Nonetheless, this action may increase the likelihood of sources for the total package.

NIH Reauthorization

House. The effort to restrain Congressional micro-management of the NIH has been vitalized by the offering of a substitute measure to the pending House reauthorization bill, H.R.2350. This new bipartisan substitute, sponsored by Representatives Madigan (R-IL), Broyhill (R-NC) and Shelby (D-AL), embodies the simple reauthorization approach to expiring NIH authorities that the AAMC favors, though it also creates an Arthritis and Musculoskeletal Disease Institute, a proposal whose absence would doom it to instant defeat, and authorizes 25 centers for health promotion and disease prevention, a proposal reportedly a sine qua non for securing the support of Richard Shelby, a member of the Committee on Energy and Commerce and its Subcommittee on Health and the Environment. The authorization ceilings in H.R.2350 are matched by those contained in the substitute, thus forcing a debate and decision on principle, not money. The AAMC persists in its opposition to H.R.2350. The bill has created

a great deal of controversy, and there is a slight possibility it simply will not go back to the floor. However, it is much more likely, and imperative to assume, that the bill will move to the floor for a vote imminently. In that case, a number of amendments will be offered. These include measures to: prohibit research on fetuses scheduled for abortion; re-attach the set-aside provisions of the Small Business Innovation Act which are effectively gutted by H.R.2350; create a new Institute of Nursing; and authorize additional funds for research on Reye's Syndrome.

Senate. The Senate NIH reauthorization bill also awaits floor action. The Senate calendar is very crowded and S.773 may not be considered unless an agreement can be made to approve it with unanimous consent, which will limit debate and prohibit the offering of amendments. If the Senate bill does emerge for debate and amendment on the Senate floor, an amendment to restrict fetal research, as well as one sponsored by Senator Dole to create new provisions for the use of animals in NIH-funded research, are likely to be offered.

With the outcome in each chamber so unpredictable, it is not yet possibile to define the issues for a conference on the two NIH bills. However, when such a meeting is scheduled, the AAMC will need to reassert its priorities on the legislation.

Animal Welfare

A revised "working paper" draft of S.657, "The Improved Standards for Laboratory Animals Act," has recently been released in an effort to garner additional support for the legislation.

At the hearing for his bill in July, Senator Dole expressed grave concern over the strong opposition to his bill from the scientific community and suggested that the various organizations working on this bill get together to iron out a compromise.

It appears that many of the changes requested by those groups interested in a compromise were effected. Certain offensive adjectives which were deemed too subjective, such as "proper," "adequate," and "sufficient," have been deleted with the assumption that any standards set by the USDA would be at least "minimum." A vague definition of "direct use of conscious animals" was deleted and other "unclear" sections were strengthened in terms of meaning and intent.

The changes are not significant enough, however, to alter the position held by the AAMC. Along with a substantial segment of the academic and scientific community, the AAMC continues to oppose S.657 and instead supports S.964, "The Animal Research Study Act of 1983."

The current status of S.657 is cloudy at best. The understanding is that Senator Dole will offer it as an amendment to S.773, the NIH reauthorization legislation sponsored by Senators Hatch and Kennedy. Senator Hatch's staff has informed us, however, that he is standing strongly behind his study bill and would not welcome such a move.

At this time, there is a possibility that the NIH legislation will not come to the floor in the Senate, in which case Mr. Dole may try to bring his bill through separately. Either way, the AAMC strategy is to oppose S.657 and to support the study, S.964.

On the House side, there is speculation that Representative Thomas S. Foley (D-WA) will be the sponsor of corresponding animal welfare legislation though he is currently "on the fence" with this issue. Also pending in the House is Representative Waxman's (D-CA) version of the NIH reauthorization, H.R.2350, which includes animal welfare amendments and provisions for an NAS study. In addition, Representatives Madigan (R-IL) and Broyhill (R-NC) have drawn up a substitute NIH bill that does not include animal welfare language.

Hazardous Waste Legislation

Congress adjourned in August after taking a number of steps to amend the Resources Conservation and Recovery Act (RCRA). The authorizing committees in both houses have reported out lengthy, substantive bills (H.R.2867 and S.757), and the full House has begun debate on what is probably the most controversial issue, one that greatly impacts medical schools: the nature and scope of the narrowing of the small quantity generator exemption. Both bills lower the current threshold from 1000 kg/month to 100 kg/month. Further floor consideration of the House bill is expected at any time, and the Senate bill should be taken up no later than mid-October.

House Action. As matters now stand, floor amendments to the House bill require EPA to issue regulations within 18 months of enactment regulating generators of between 100 and 1,000 kilograms of hazardous waste per month. Generators of 25 or more kg/month will be required to notify transporters and waste sites of the type, quantity and origination of the waste. Fortunately, the House dropped an onerous "hammer provision" which would have imposed the full panoply of RCRA regulations on small generators if EPA did not promulgate in a timely fashion separate regulations for waste generators of between 100 and 1000 kg/month. Instead, if EPA fails to issue required rules within 30 months of enactment, newly regulated generators will have to comply with a more limited set of requirements.

Labpacks, important to academic health centers in managing hazardous waste, are prohibited by the House bill within 12 months of its enactment unless the EPA certifies that there is no alternative waste management mechanism available, and that their use will not cause damage to human health or the environment. A final determination will be required from EPA no later than 54 months after passage of the bill.

Senate Action. The Senate Committee on Environment and Public Works reported a bill which, like its House counterpart, sets the small quantity generator exemption at 100 kg/month for regulatory requirements. However, S.757 contains the "hammer provisions" deleted from the House bill. This more extensive "paper trail" will be required of the shippers of hazardous waste in the instance that EPA does not issue prompt regulations for 100-1000 kg generators. Also, the Senate bill is stricter than the House version in its waste packaging requirements for the newly regulated generators. The Senate bill does not address the labpacks issue, and thus allows EPA to continue to determine whether their use ensures safety to human health and the environment.

Both the House and Senate bills are apt to undergo further floor amendment and the AAMC is likely to refrain from direct legislative activity until a conference meeting is pending. The 100-1000 kg generator inclusion under RCRA is well-nigh unstoppable, but hopefully during conference these bills can be further shaped to accommodate the needs of medical colleges.

APPROPRIATIONS

(in millions)

	Actual FY 1982	Estimate* FY 1983	FY 1983 Comparable	President's Request FY 1984	House** Committee Allocation FY 1984	Senate** Subcommittee Allocation FY 1984	Difference Between the House and Senate Allocations
NIH							
NCI	$ 943.0	983.6	962.6	986.7	1,044.9	1,062.0	17.1
NHLBI	559.6	622.7	595.7	637.7	665.9	681.5	15.6
NIDR	72.1	78.9	75.2	80.7	84.2	84.4	.2
NIADDK	368.2	412.2	393.2	426.4	442.3	442.8	.5
NINCDS	265.9	295.7	287.4	301.5	328.9	317.1	11.8
NIAID	235.9	273.8	270.3	289.4	307.1	300.2	6.9
NIGMS	335.4	369.8	321.0	383.1	363.4	370.2	6.8
NICHHD	226.3	253.6	244.9	256.6	265.2	264.8	.4
NEI	127.4	141.8	138.0	142.3	149.6	152.0	2.4
NIEHS	154.2	164.4	158.1	165.9	173.6	172.4	1.2
NIA	81.9	94.1	91.6	99.4	112.5	108.6	3.9
RR	184.2	213.8	213.2	201.8	253.8	230.0	23.8
FIC	9.2	10.3	10.1	9.2	11.6	11.1	.5
NLM	45.0	47.1	44.8	49.6	42.3	42.0	.3
Director	23.6	25.7	25.7	26.7	26.8	26.7	.1
Building, etc.	9.9	17.5	17.5	20.0	25.0	25.1	.1
TOTAL	3,641.9	4,004.3	3,849.6	4,077.1	4,297.1	4,291.0	6.1
(NIH Research Training)	(150.5)	(167.4)		(157.7)	defer	defer	--
ADAMHA							
NIMH							
Research	141.3	152.3		172.1	172.1	174.5	2.4
Research Training	15.2	15.4		15.5	defer	defer	--
Clinical Training	42.3	20.1		--	20.0	21.5	1.5
NIDA							
Research	41.0	47.0		56.1	52.0	57.2	5.2
Research Training	.9	.9		1.0	defer	defer	--
Clinical Training	2.7	--		--	--	--	--
NIAAA							
Research	23.3	33.3		45.8	40.0	46.4	6.4
Research Training	1.1	1.1		1.2	defer	defer	--
Clinical Training	.9	--		--	--	--	--
ADAMHA Services Block Grant	428.0	439.0		430.0	439.0	469.0	30.0
HEALTH RESOURCES & SERVICES ADMIN.							
National Health Service Corps Scholarships	42.8	11.0		--	8.0	5.6	2.4
NHSC Field Program	88.6	96.6		96.0	91.0	91.0	--
Health Professions Student Loans (HPSLs)	5.6	1.0		--	--	--	--

	Actual FY 1982	Estimate* FY 1983	FY 1983 Comparable	President's Request FY 1984	House** Committee Allocation FY 1984	Senate** Subcommittee Allocation FY 1984	Difference Between the House and Senate Allocations
HEALTH RESOURCES & SERVICES ADMINISTRATION (cont.)							
Exceptional Need Scholarships	4.7	5.8		--	5.8	5.8	--
Health Education Assistance Loans (HEAL) -- Credit Limit	200.0	225.0		175.0	No Limit	225.0	225.0
Family Medicine Training	28.9	34.0		23.7	34.0	28.0	6.0
Family Medicine Departments	7.7	8.8		7.4	7.4	8.8	1.4
General Internal Medicine and Pediatrics	16.3	11.4		12.0	17.0	18.0	1.0
Area Health Education Centers	18.2	18.0		14.7	14.7	17.9	3.2
Disadvantaged Assistance	16.9	17.2		18.2	18.2	18.2	--
Preventive Medicine Residencies	--	1.0		1.0	2.0	1.1	.9
Curriculum Development	--	2.0		7.0	3.1	2.0	1.1
Health Planning	58.2	58.2		--	defer	defer	--
ASSISTANT SECRETARY FOR HEALTH							
National Center for:							
Health Services Research	16.2	16.7		17.6	17.6	17.6	--
Health Statistics	38.1	40.3		46.0	46.1	46.1	--
Family Planning	124.2	124.1		124.1	140.0	140.0	--
Rehabilitation Services and Handicapped Research							
National Institute for Handicapped Research	28.6	30.1		30.1	defer	38.0	38.0

*This column does not reflect recent supplementals or adjustments for pay raises.

**Funding for research training and Medical Library Assistance has been deferred pending reauthorization.

Principles for Support of Biomedical Research -- A Proposal for Effective Dissemination of the Document

The document which is reprinted on the following pages was adopted as AAMC policy by the Executive Council on September 15, 1983. It was developed over the course of this calendar year in response to the desire of the Council to have a well articulated statement of principles which would provide a reference and a touchstone for AAMC positions on various proposals related to the support of research and the organization and management of NIH. The objectives of such a document are to demonstrate that the AAMC has an enduring and persistent interest in the vitality of the entire biomedical research enterprise, that there are some fundamental features of that enterprise which explain and undergird its past successes and which are deserving of preservation, and that the AAMC position on any particular proposal is not ad hoc determination, based on the current prevailing political winds, but rather a consistent and principled position based on the degree to which the particular proposal is consistent with or threatening to the health of the entire enterprise.

It is hoped that this document may become the vehicle for dialogue and the development of a consensus within the community of scientists, members of the public and their elected representatives regarding this vital topic. Toward that end, multiple copies of the document are being printed; each of the CAS member societies will be asked to consider this statement and adopt it as its own. Then, it is hoped that each society, in turn, will contact the voluntary health organization with which it is in closest contact, asking that it consider and adopt the statement.

Finally, through the actions of AAMC member institutions and societies, and the voluntary health organizations, the AAMC hopes to develop a better understanding of these principles in the minds of the public and their elected representatives.

One mechanism for bringing the document to the attention of members of the United States Congress which is suggested is that the deans of each school in a state cosign a letter forwarding the document to every member of the states' congressional delegation. If this proposal meets with the approval of the Council of Deans, the AAMC staff is prepared to provide logistical assistance. Once the language of the letter is agreed upon, the AAMC could prepare a letter addressed to each member and forward them to the deans for signature.

Recommendation:

That the Council of Deans consider and ensorse this proposal.

OCTOBER 12, 1983

PRESERVING AMERICA'S PREEMINENCE IN MEDICAL RESEARCH

Principles for the Support of Biomedical Research

The Problem

The evolution of the National Institutes of Health (NIH) into the world's most productive and prestigious biomedical research enterprise has been one of the important and remarkable developments in this country during the post-World War II period. Recent events suggest the favorable conditions that contributed to that phenomenon are changing. Most prominent among the forces influencing that change has been a significant modification in approaches to legislation under which the NIH has been funded and managed. Spurred in large part by dissatisfaction with funding levels for NIH programs in their areas of interest, both lay and professional leaders of many disease-oriented organizations have turned increasingly over the last decade to a responsive Congress. They have adopted a strategy of proposing new legislation as a means of satisfying their aspirations for greater visibility and support. This approach is epitomized by bills currently before the Congress that contain numerous specific directives to NIH which, if passed, would attain the relative permanence of statute. Conversely, the components of the NIH itself are moved toward relative impermanence because of the need for the periodic renewal of expiring legislative authorities, such as those for the Cancer and Heart Institutes. Given the almost infinite number of potential disease-oriented causes and the predictable competition among them for greater recognition, this circumstance creates a continuing opportunity for the expansion of set-asides, institutes, boards, task forces and programs. Over time, such legislation would create the antithesis of the broad, elegant authority

for biomedical research, unencumbered by detailed directives, as enacted in 1944. The consequence would be an inevitable erosion and ultimately the destruction of the delicate balance between the political and scientific forces that has been and remains so crucial to the success of NIH.

The Elements of a Successful Biomedical Research Program

With the record of repeated accomplishments and the strong promise of continued productivity, it is essential that the environment in which the research enterprise functions continues to assure that the solid record of the past will be emulated, if not exceeded, in the future. Because scientific inquiry in itself is a dynamic process, the management of the program and the instruments provided for its management must also be dynamic in character. The elimination of some diseases as major threats, the emergence of new forms of illness and the ever increasing and changing knowledge base all must be recognized as developments to which the content and direction of the program must be adapted. At the same time, certain considerations, regardless of the time or the state of change, will remain essential to the well-being of both the nation's biomedical research enterprise and its primary instrument, the National Institutes of Health. Accordingly, the following characteristics deserve recognition by those responsible for or interested in the continued vitality of the NIH and its programs. This community includes scientists themselves, as well as administrators, legislators and leaders in the commercial and public sectors.

- The greatest scientific productivity occurs when highly creative investigators are provided with appropriate resources and work in an environment free of excessive demands from external regulation and directives.

- The identification of the most promising research areas and the determination of their important dimensions are in large measure a scientific judgment requiring highly knowledgeable experts in related fields.

- The need for additional knowledge requires a major emphasis on basic research.

- Free communication among investigators is the lifeblood of science; adequate resources and means must be available to facilitate that communication.

- The continuing replenishment of the pool of intellectual talent and the maintenance of the infrastructure of research institutions are essential.

- Funding for biomedical research by the federal government is essential and must be the principal source for the scale of effort currently established.

- Funding of the research enterprise should be predicated on long-term perspectives and should minimize sudden or wide fluctuations.

- Evidence of scientific merit in proposed projects should be the key determinant in decisions relating to the award of funds for research support.

- The terms and conditions of fiscal support should be compatible with and not seriously distort the administrative processes of recipient institutions.

- o Investigators and organizations engaged in research must continually demonstrate an active sense of public and scientific accountability.

- o Public expectations as to the benefits of investment in scientific activity should be realistic in terms of the unpredictabilities of research, and the substantial time lag between fundamental discoveries and their widespread impact on health problems.

The evolution of this set of working principles over a thirty year period has given the nation a highly effective model for the pursuit of an important social objective. Modification should be undertaken only on firm justification and after thorough examination of the possible consequences, lest serious harm be done to the integrity of the enterprise.

Background and History

Widespread and persistent public interest in extending the human lifespan and in enhancing the state of physical and mental well-being has prompted the establishment and maintenance of a very substantial medical research enterprise in this country. This phenomenon was predicated on the premise that only with new knowledge derived from a vigorous, diverse and high quality research effort could progress be made in reducing the toll of suffering and economic loss from cancer, heart disease, arthritis, and a host of other maladies. It was further premised that only the federal government could acquire and sustain the sizable financial resources necessary for such a venture.

These conditions and their exploitation in a responsible, visionary and cooperative manner by a small number of individuals from government, academe and the public resulted in the NIH. Its success can be attributed in

large part to four unusual circumstances, all of which were essential. They were:

- o the establishment and maintenance of a crucial balance between the political and scientific forces that influence the medical research program,
- o the relationshp between the NIH and research-intensive academic institutions,
- o the provision and reaffirmation by the Congress of general authorities to the Public Health Service for the conduct and support of medical research, and
- o the continuing appropriation of funds by the Congress for the NIH operation.

The first two involved the forging of significant and enduring relationships. One was the matching of the political appeal of categorical diseases with identified scientific opportunities. This relationship is epitomized by the nature of the names given most of the major NIH organization components (e.g., National Cancer Institute) and by the widespread use of expert scientific advisors for planning and evaluating research programs and for selecting research projects for funding. The establishment and persistence of this modus vivendi is as contributory as any other single condition because of its unquestioned influence on the congressional appropriation process. Not inconsequentially, it has been probably the greatest determinant of the productivity and quality of the agency. Unfortunately, it is also probably the most fragile. Either of two far less desirable possibilities could have occurred. The scientific community could have insisted on organizing not only the research but its funding and administration along the traditional lines of scientific disciplines (e.g., a National Institute for Biochemistry). Alternatively, those fighting the causes for specific diseases could have insisted

that the enabling legislation require that the distribution of funds appropriated for research be made proportional to the comparative levels of disease-specific mortality or morbidity. That concept would tie the appropriations, at least in terms of visibility, much closer to their identified disease interests. The first approach obviously would have lessened the emotional impact generated by serious disease, meaning far lower appropriations for research. The second would have unquestionably wasted tax-derived dollars, because scientific opportunities and the incidence of disease frequently do not coincide. Instead a remarkably ingenious confluence of interests was evolved. It is most apparent in the two-tier advisory system that was established at NIH, in part by legislative mandate and in part by administrative action. The National Advisory Councils generally are composed of individuals having some identified association with a particular categorical disease and drawn from either the professions or the public, while the technical review panels, made up of individuals with established scientific reputations, are charged with the responsibility for assessing proposals for scientific merit.

The other essential relationship was a partnership between the NIH and the bio-scientific and academic communities, represented especially by the universities. While the purposes and activities of the partners are not identical, they have been highly compatible and a relationship has developed that has been generally characterized by a high degree of mutual dependence and trust. Through federal policy and funding, this arrangement has permitted the public interest to be served by the best source for the generation of new knowledge required for the fight against disease while at the same time indirectly but definitely strengthening many institutions of higher learning. The public interest has been thereby enhanced in two notable ways.

The second contributing factor of great significance was the provision in 1944 of enabling legislation in Section 301 of the Public Health Service Act that was almost unique in its combination of no temporal or dollar ceilings and few directives to the NIH. It was ideally suited to contend with the unpredictabilities of pace, direction, opportunity and outcome in a research activity. These characteristics, so inherent in scientific inquiry, require unusual flexibility in the management of a research effort. At the same time, it was eminently clear that the NIH was to be a health agency, using science to fulfill its mission. The enactment and preservation for almost three decades of this elegant legislation reflected a remarkable degree of foresight and self-restraint by the Congress. The legislature disregarded methods previously adopted for dealing with more applied activities such as defense or commerce and selected one for the biomedical research program that recognized both congressional responsibilities and limitations. It enabled:

- the Congress to discharge its responsibilities through the processes of oversight and appropriations,
- the NIH to develop a flexible management concept and operation, based on high quality science, that facilitated and strengthened the nation's biomedical research enterprise,
- the scientist to pursue promising avenues of research, and
- the public to express its aspirations through the appropriation process and participation in the Advisory Council apparatus.

The third factor was the insistence by the agency, its advisors and the Congress that scientific merit should be the primary determinant in the

allocation of research monies. This principle assured that the research supported had the highest probability of developing valuable new knowledge and offered the greatest likelihood for the most rapid and most effective improvements in the treatment of specific diseases. Fortunately, the insistence on merit as a keystone has been broadly based and unrelenting, because well-intentioned but scientifically deficient proposals for the solution of disease problems are often vigorously promoted.

The fourth major influence was the provision by the Congress of continuing financial support for the effort. Funds have been provided annually with strong bipartisan support after an extensive hearing process and with only general instructions as to their deployment.

Accomplishments of the NIH Program

As a result of these conditions, a vast increase has occurred in our understanding of the fundamentals of health and disease and the practice of medicine has been revolutionalized. Some afflictions, especially among the infectious diseases, have all but disappeared as major threats to our citizens and the knowledge base is well on its way to a level of development that will permit major assaults on more complex, chronic ailments. Scientific fields such as endocrinology, genetics, immunology, the neurosciences and virology abound with important discoveries that offer hope of earlier diagnosis or more effective measures for prevention or treatment of numerous diseases. At a time when the costs of health care are coming under increasing scrutiny, research leading to the prevention or cure of illness represents the most rewarding approach to control or reduce those costs.

In addition to the benefits which have accrued in terms of health per se, there have been two other highly desirable consequences. The first is the very significant return on the biomedical research investment that has occurred in non-medical areas. Such biomedical discoveries as freeze-drying and its application to food preservation, genetic manipulation and its uses in agriculture, laboratory instrument computers and contributions to the development of mini-computers, fiber optics and their growing use in telecommunications, and enzyme biochemistry in the development of new types of detergents have contributed significantly to the development of whole new industries. Second, the emergence of the large and high quality biomedical research endeavor in this country established the United States as the world's leader in this field. At a time when the Nation has lost some of its preeminence in other fields, our citizens can still point with pride to the maintenance of leadership in biomedical research.

Preserving the Enterprise

Despite all the accomplishments and accolades and the appearance of an undertaking of great permanence, the continued vitality of the NIH endeavor requires constant vigilance and protection. Preserving academic values under the aegis of public funding on the one hand, or adopting the special standards of public conduct in the very private research enterprise on the other, has not been easy in the United States or in any other free society. Yet the stakes for the public good are so high that every effort should be made to devise and institutionalize workable arrangements. Our current cultural emphasis on the short-term gain and the frequent failure to distinguish between science and technology contain a constant threat to the well-being of the NIH.

The sheer size of the effort with its heavy dependency on federal funding represents another point of great vulnerability. Even its own friends and benefactors when dissatisfied with their share of the resources or degree of visibility in its operations may inadvertently cause serious problems. It behooves all to whom these considerations are addressed not only to provide support for the continued integrity and vitality of NIH but also to exert restraint during periods of temporary frustration or dissatisfaction with day-to-day decisions or outcomes. Thus:

- Biomedical scientists should keep constantly in mind their responsibilities to the public that provides the funding and determines the character of the national environment in which the scientific effort occurs. Part of this responsibility is participation in education of the public about biomedical science, its capabilities and limitations.

- The public should recognize the limitations as well as the capabilities of scientific inquiry so as to assure a climate of tolerance for the uncertainties of scientific effort.

- Individuals and organizations with disease-specific interests should consider possible negative impacts of their proposals for legislative mandates in specific categorical areas on the integrity and vitality of the NIH as a whole.

- Legislators' personal agendas should have as a high priority the preservation of that fine and difficult line between their representative and advocacy responsibilities and their fiduciary responsibilities as trustees of the nation's research enterprise.

- Administrators should recognize that facilitating the scientific effort while assuring adequate scientific, financial and ethical accountability will always remain their paramount task.

- The NIH should extend and formalize their current procedures to receive, evaluate and appropriately publicize proposals by advocacy groups for modifications in program content, emphasis or priority.

Only if these considerations are recognized and accepted will the rewards of the investment for better health be fully realized.

OCTOBER 12, 1983
10:18 A.M.

AAMC OFFICERS RETREAT

Each year, in early December, the newly elected officers of the AAMC engage in a two day retreat with senior AAMC staff. The agenda for this year's retreat is now in preparation. Members of the Council are invited to suggest issues for consideration on this occasion.

ISSUES RELATED TO COMMERCIAL SPONSORSHIP OF MEDICAL EDUCATION PROGRAMS

The attached material was brought to the attention of the Council of Deans' Administrative Board at its September 15, 1983 meeting. The Board concluded that the appropriate action would be to bring this matter to the attention of the Council membership. This material is included in this agenda in lieu of the preparation and distribution of an AAMC memorandum.

COMMERCIAL SUPPORT OF CONTINUING MEDICAL EDUCATION

In a recent communication to Dr. Cooper, Richard S. Wilbur, as Secretary of the ACCME, expressed concern that some medical schools may inappropriately co-sponsor CME activities supported by pharmaceutical companies and/or equipment manufacturers. His communication included copies of two policy statements regarding the relationship of accredited CME sponsors and commercial companies (see letter and enclosures, attached). Dr. Wilbur conveyed a ACCME request that AAMC Executive Council review these statements and consider developing an AAMC policy statement addressing this issue.

This matter is brought to the Council of Deans Administrative Board for its advice. Support of CME from commercial enterprises raises several issues and questions. The first is a general question, namely to what extent the flow of money from the commercial sector into CME may influence utilization of drugs, instruments, and accompanying procedures by physicians and patients. The answer is not readily available but advertising firms and market analyzers probably could show affirmative evidence of qualitative if not quantitative nature. On the basis of ethical or moral principles institutions or organizations may want to establish policies aimed at excluding any potential erosion of the educational integrity of the institution through commercial grants or other support of CME programs.

A second question addresses the conditions under which a CME program can receive partial or total support from a commercial source, or a CME sponsor can co-sponsor a program offered by a commercial organization without violating the principles of academic freedom and fair presentation of scientific facts. Dr. Wilbur's communication is directed at this level of concern. The most common interest of a commercial enterprise obviously is to buy exposure of a product or the firm's name in connection with diagnostic or therapeutic problems. The offense, if any, to unbiased education may be very subtle or it may be quite blatant. Many institutions and organizations have established internal policies to regulate the acceptance of financial support for CME programs from a commercial donor. Among them are medical schools (see e.g. the policy of the University of Nebraska asking Medical Center policy, attached), the American College of Physicians (attached) and others. Most of these policies specify the conditions under which continuing education programs may accept funding from commercial sources. Some of these conditions are that (1) the funds be received by the institution and used in accordance with institutional policies; (2) the CME unit retain undisputed control over program planning and execution, including topics and speakers for the presentations and the final evaluation of the program; (3) the utilization of funds be specified in advance; (4) the recognition of the grants be limited to brief statements on the activity programs without display of products or services available from the grantor; and (5) products of a donor not be mentioned unless pertinent alternatives to those products are also presented so that any suspicion of endorsement of a product be avoided.

Similar policies and procedures prevail for co-sponsorship by an accredited institution of continuing education courses or materials presented or distributed by a commercial company.

Finally, a third level of concern addresses the potential detrimental effect of moneys for CME from commercial firms on the internal functioning of CME within the institution. CME directors are particularly concerned over donations from firms to individuals or individual departments by-passing the continuing medical education unit of the institution. Another disturbing problem for some institutions is the fact that some of their faculty are lured into participating in commercially sponsored programs offered by other organizations, for instance hospitals, specialty societies, travel firms, that pay relatively generous honoraria to faculty which cannot be matched by the home institution, therefore making it more difficult for the CE provider unit of the institution to attract faculty for their own programs.

Recommendation

- That the Administrative Board of the COD review some of these issues.

- That the Group on Medical Education be asked to review these questions and to develop a recommendation regarding an appropriate stance for the AAMC.

- That the COD Administrative Board provide the CME with such advice, guidance or observations as it deems appropriate.

ACCME

Accreditation Council for
Continuing Medical Education

P.O. Box 245 Lake Bluff, IL 60044 (312) 295-1490

August 12, 1983

John A. D. Cooper, M.D.
President
Association of American
Medical Colleges
One Dupont Circle, N.W., Suite 200
Washington, DC 20046

Dear John:

The ACCME has expressed growing concern over what appears to be inappropriate co-sponsorship by some medical schools of CME activities supported by pharmaceutical companies and/or equipment manufacturers. This places the medical school in the position of appearing to recommend a particular product to the physician audience, thereby adversely affecting its credibility as a sponsor of continuing medical education. Enclosed are two statements addressing this question which the ACCME requests the Executive Council to review, with the hope that the AAMC might consider approving some similar statement.

With kindest personal regards.

Yours cordially,

Richard S. Wilbur, M.D.
Secretary, ACCME

CC: Patrick J. V. Corcoran, M.D.
Richard M. Caplan, M.D.
John N. Lein, M.D.
Henry P. Russe, M.D.

RSW/kf

American Board of Medical Specialties
[illegible] American Plaza, Suite 805
Evanston, Ill. 60201

American Hospital Association
840 N. Lake Shore Dr., Chicago, Ill. 60611

American Medical Association
535 N. Dearborn St., Chicago, Ill. 60610

Association for Hospital Medical Education
1101 Connecticut Avenue, N.W.
Washington, D.C. 20036

Association of American Medical Colleges
One Dupont Circle, N.W., Washington, D.C. 20036

Council of Medical Specialty Societies
P.O. Box 70, Lake Forest, Ill. 60045

Federation of State Medical Boards of the U.S., Inc.
2630 West Freeway, Suite 138
Fort Worth, Tx. 76102

SOCIETY OF MEDICAL COLLEGE DIRECTORS OF CME

DRAFT
JUNE 30, 1983

Approved May, 1983

THE RELATIONSHIP BETWEEN COMMERICAL COMPANIES AND CME COURSES PRESENTED BY MEDICAL SCHOOLS

It is widely recognized that financial relationships between commercial companies (pharmaceutical, equipment, publishing, etc.) and medical schools have been increasing in the past few years. The potential for mutually beneficial results from these cooperative arrangements in both research and education is excellent. Consequently, these cooperative efforts should be encouraged. However, each medical school must be careful that it does not engage in an activity that is (or appears to be) inconsistent with its academic integrity. In addition, lapses by a medical school in maintaining appropriate standards may also damage the general reputation of other medical schools.

The recently increasing cooperative efforts in continuing medical education between commercial companies and medical schools are producing highly beneficial results for the companies, for the medical schools, and for course enrollees in many instances. At the same time, the causes for genuine concerns are becoming more obvious. It is recommended that medical schools use the following guidelines:

1) Medical schools should not present or cosponsor a continuing education course concentrating on products of a commercial company that is providing financial support for that course unless the pertinent alternatives to those products are also presented.
2) Medical schools should exert substantial caution before presenting or cosponsoring a continuing education course that is planned and/or implemented through a media organization employed by a commercial company.
3) Medical schools should exert substantial caution before agreeing to sponsor or cosponsor a continuing education course that is distributed by a commerical company. If the course is a correspondence course utilizing only bound books, the consistency

of the content can be more assured than in those instances when "live" discussions are included.

4) All money from commerical companies to support CME courses presented by medical schools should be paid to the respective school and handled in accordance with institutional policies.

As stated previously, cooperative efforts between commerical companies and medical schools should be encouraged and increased for the mutual benefit of the companies and the schools. The preceding guidelines are designed to maintain and enhance the credibility and reputations of both the commercial companies and the medical schools.

The Canadian Medical Association L'Association médicale canadienne

Guidelines for Acceptance of Pharmaceutical Company Financing of Continuing Medical Education Courses and Meetings

Preamble

The need for continuing medical education at all levels of practice is well recognized. Funding of continuing medical education has been helped significantly over the years by generous contributions from pharmaceutical companies. The CMA acknowledges and appreciates this financial support. Observation of a few guidelines, founded on basic principles, is vital if this valuable funding source is to be preserved.

1. The organization, content and choice of speakers must be determined by the physician organizers. The organizers may be CME directors at medical schools, CME physician organizers in community hospitals, or CME representatives for specialty and professional societies.

2. Disposal of funds should be the responsibility of the physician organizers. While the program should acknowledge the financial aid received, it should not designate the sponsor's product. It is appropriate to acknowledge the assistance of the sponsoring pharmaceutical company.

3. As a principle, the use of generic names is preferred in presentations and discussions.

4. Large scientific congresses frequently attract commercial exhibits of pharmaceutical companies. If this is the case, and it coincides with a CME session, negotiations for space or display should be conducted separately from discussions for CME sponsorship.

5. The value of social functions at CME meetings is recognized. However, they should neither compete with, nor take precedence over, central events.

Approved by the CMA Board of Directors
March 5, 1983

Post Office Box 8650 Ottawa, Ontario, Canada K1G 0G8 (613) 731-9331 Telex 053-3152

Subcommittee on Continuing Medical Education
College of Medicine
University of Nebraska Medical Center

Program Relationships with Pharmaceutical Manufacturers

Introduction:

Recognizing that pharmaceutical manufacturers and similar companies provide support for continuing education programs in a variety of ways, e.g., direct financial support, exhibits, speakers, and materials, these guidelines outline an appropriate relationship between the College and such companies for continuing medical education programs which are sponsored or co-sponsored by the College and/or a department within the College.

Guidelines:

1. Program Control - Overall responsibility for the program is vested in the College through the course chairman. This includes all aspects of the planning and selection or approval of speakers, topics and meeting sites.

2. Faculty Selection and Accommodations - Invitations to speakers, and arrangements for travel and lodging are the responsibility of the College.

3. Honoraria - Any honoraria to be paid to program faculty must meet the guidelines of UNMC and the College. Exceptions to this should be approved by the Subcommittee on CME.

4. Financial - The payment of all funds from a pharmaceutical firm should be in the form of an educational grant and made payable to UNMC or the University Foundation for the support of the program. If funds remain after a course is completed, they will be distributed in a manner determined in advance of the course.

5. Displays and Materials Distribution - Booths, exhibits, or other displays may be set up in a manner approved by the Associate Dean and the Director of Continuing Education. Materials distributed by the company such as monographs or articles should be educational in nature rather than promotional of the company's products.

6. Representatives - Pharmaceutical company representatives may be invited to attend educational programs but should make their presence unobtrusive and non-promotional.

7. Publicity - Publicity for the program should be controlled by the College and Center for Continuing Education. Pharmaceutical representatives may be asked to assist in this at the discretion of the program chairman. Recognition of support for the program may be listed in the brochure and handout materials.

8. Materials - The handout materials may not contain promotional material from the pharmaceutical company but support for the program may be acknowledged on the brochure and in the handouts.

9. C.E. Credit - All credit approvals and recording will be handled by the College and the Center for Continuing Education in the normal manner.

DRAFT: MAY, 1983
Revised: June, 1983

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1 September 1983

Ms. Kat Turner
AAMC
1 Dupont Circle #200
Washington, DC 20036

Dear Ms. Turner:

In researching your question from our phone call yesterday, I found that Dr. Beering's memory served him well, and that we do indeed have a policy on CME funding by pharmaceutical firms. It is a policy of the Board of Regents, and is attached.

I'm sorry for its informal look, but I had to lift it from a lengthy document.

I hope you find it useful.

Sincerely,

Nancy Magargal

Nancy Magargal
Research Assistant

enclosure

6. Pharmaceutical Industry Support Policy

Educational grants from pharmaceutical and other commercial companies for programmatic support are appropriate for Regional Meetings when these awards conform to the following guidelines:

a) Educational grants must be for specific educational activities (e.g., travel of speakers, honoraria, audiovisual expenses, auditorium rental, staff support, printing, buses, and coffee service for sessions and/or exhibitors).

b) The appropriate Chapter Committee will have final authority on all matters. Grantor may offer recommendations regarding format, content, and speakers for scientific events.

c) No product advertisements are allowable in conjunction with grant support of specific program features. Recognition of such grants shall be through institutional announcements, as follows: "This program is supported (in part) by an educational grant from _____."

Product advertising in the printed advance and/or final programs of the Annual Session may be accepted for financial support of program printing costs, only. Pharmaceutical industy support of scientific program features will also be noted in the final program.

d) Direct support for social events is not permissible. Grant support for the total program may be used as deemed appropriate by the program director.

association of american medical colleges

JOHN A. D. COOPER, M.D., PH.D.
PRESIDENT

September 6, 1983

202: 828-0460

Ms. Betty Lou Dotson
Director
Office of Civil Rights
Department of Health and Human Resources
330 Independence Avenue, S. W., Rm. 5400
Washington, D. C. 20201

RE Proposed Rule: Nondiscrimination on the Basis of Handicap Relating to Health Care for Handicapped Infants

Dear Ms. Dotson:

On behalf of the members of the Association of American Medical Colleges, I am writing to express our grave displeasure with the revised version of the regulation addressing the provision of health care to handicapped infants published on July 5, 1983. A federal district court judge nullified the original regulation, calling it "arbitrary and capricious" and "a hasty and ill considered (method of addressing) one of the most difficult and sensitive medical and ethical problems facing our society." After such an admonishment, it is distressing to find that the Department of Health and Human Services could reissue the regulations virtually unchanged. The implication in the regulation, particularly in the preamble, that health care providers callously allow handicapped children to die from lack of treatment or nutrition is offensive to all health care providers and particularily to those who have devoted their professional lives to caring for sick children.

Just a few decades ago, most sick newborns died within a few hours of birth and premature infants were not expected to live more than a few days. Through the efforts of many health care professionals, the prognosis for these infants has changed radically. The many technological advances and the new skills in neonatology substantially have reduced the mortality rate for the severely ill and premature infants. In fact, since 1970 infant mortalities have been halved.

It is ironic that the professionals that make it possible for infants with critical problems to have a chance at life are treated in a proposed federal regulation as if they would habitually disregard a handicapped infant's needs. This assumption is false. Hospitals and their medical staffs provide care for all patients to the best of their ability. Teaching hospitals have a particular commitment to patients in need of critical care, including the infants that are the subject of this regulation. At the 350 nonfederal teaching hospital members of the AAMC, there were more than 720,000 births in 1980. More than three-quarters of these teaching hospitals provide premature nurseries and more than 70 percent have neonatal intensive care units.

Additionally, teaching hospitals and the medical schools with which they are associated train new physicians and engage in new areas of research to perpetuate and enhance their ability to care for critically ill infants.

Suite 200/One Dupont Circle, N igton, D.C. 20036/(202) 828-0400

Traditionally, the parents and the physicians have made the very difficult decisions regarding the treatment that should or should not be rendered to children with life-threatening conditions. While some may disagree with the choice made in some of the cases, it should be recognized that the parents and physicians believed themselves to be acting in best interests of the child. The questioned raised by the case of Infant Doe and the resultant public outcry is how can the public voice its opinion regarding what is in the best interests of the child, presuming that this public voice would be less likely to concern itself with any physical or mental handicap of the child, or with the costliness of rendering continuous treatments to a child so handicapped.

The Department of Health and Human Services' answer to this question is that there ought to be an "alarm system" comprised of posted notices and toll free hot lines by which anonymous tipsters can summon teams of representatives from state child protection agencies and/or the Office of Civil Rights. This proposed approach is seriously flawed for several reasons:

- In the event there is a case in which a child is wrongfully denied treatment or nutrition, the HHS approach provides no assurance that the authorities would be called in time to take steps to protect the child.

- It is highly likely that this approach will result in a number of hospitals and physicians being falsely accused of inappropriately withholding treatment or nutrition. The few weeks in which the first "Baby Doe" regulation of the Department was in effect provided ample evidence that such false accusations would occur. These false accusations can be made either by well intentioned but uninformed people or by crank callers who may seek to harass the institutions or physicians involved.

- Perhaps the most disturbing consequence of the Department's proposed rule is the affect this method has on other infants. For example, during the period in which the original rule was in effect, an investigation was made on a "hot line" tip that Siamese twins at Strong Memorial Hospital in Rochester, New York were not receiving adequate care. This tip prompted the Office of Civil Rights to intercede. While everything possible had been done for the twins, the investigation and the investigators' lack of knowledge of the appropriate procedures to follow in conducting this inquest delayed the return of these infants to their mother. The mother, who was recovering in a nearby community hospital, was thus denied access to her infants during a significant portion of those few days they survived. The furor caused by the presence of the investigatory team and the newspaper accounts of the incident disturbed the parents of another infant so greatly that they removed their child from Strong Memorial before its treatments had been completed, thus jeopardizing its health.

- The investigations resulting from these false accusations are disruptive and time consuming and, most importantly, impair the hospital's ability to provide proper care for all of the infants in

its nurseries by usurping the time of the medical and nursing staff that would otherwise be spent in rendering care.

- Posted notices, whether they are scattered about the units or located in the nurses' station, are seen by the families of children whose care is in no way being questioned. Those families may incorrectly infer from the notice that the hospital or some of the physicians have wrongfully withheld treatment on previous occasions. This inferrence would unnecessarily increase the family's anxiety when it is already under a great deal of stress. In addition to the stress to the parents, the staff of these units are demoralized by the signs and by the parents' reaction to the signs.

- By involving the state child protection agencies in the investigation of such cases, the proposed rule would seriously drain the already inadequate resources of these agencies and involve them at a time when they can lend no expertise in deciding the best course for treatment of the child. A more appropriate time for involving such agencies would be once a decision has been made that the child is treatable, but the parents refuse to allow the treatment. Then, the state child protection agencies would be acting as they might for a child of Jehovah's Witnesses to secure the rights of the child to treatment.

It is time a more thoughtful approach to this matter was seriously considered. After much deliberation and study of the issues involved, the President's Commission on Ethical Behavior in Medicine and Biomedical and Behavioral Research recommended the establishment of ethics review boards within each institution or community to address all cases involving persons of any age group in which a decision to forego life substaining treatment must be made. Several representatives of health care provider organizations have tailored this ethics review board concept to address these cases, and the resultant Infant Bioethical Review Committees (IBRCs) are described in the proposed amendment to the Medicare Conditions of Participation submitted with the comments of the American Academy of Pediatrics. This approach offers several advantages:

- All cases of infants for whom a decision must be made regarding the provision of life sustaining treatment will be addressed by the IBRC either through determination of a hospital policy or review of the individual cases.

- The alternatives for the child can be thoroughly discussed, including the help available for people with the same disabling condition as the infant.

- The review would occur as part of normal hospital procedure for such cases, thereby minimizing the disruption of services to other seriously ill infants. Also, because the review is required for all such cases, no inferences will be made that the treatment rendered by the physician(s) and health care team involved is faulty.

- Notice of the existence and function of the IBRC can be made in such a way as to not alarm the families of infants whose care is not in question; further, the deliberations of the IBRC on a particular case shall be made in confidence, which also will minimize the anxiety to the other parents.

- Finally, the recommendation that we are advancing would be issued under the authority of the Secretary to set conditions for participation and avoids problems associated with reliance on Section 504 which is of dubious applicability.

We strongly urge you to consider withdrawing your proposed regulation and to substitute the proposal to establish IBRCs. If my staff or I may be of further assistance in helping you to consider this matter, please contact me at (202) 828-0460.

Sincerely,

Original signed by
J. A. D. COOPER, M.D.

John A. D. Cooper, M.D.

APPENDIX

CONDITION OF PARTICIPATION: Infant Bioethical Review Committee Proposed 42 C.F.R. §482.___

The governing body must appoint an infant bioethical review committee (IBRC) or must join with one or more other hospitals to create a joint IBRC for the purposes of:

(1) providing advice when decisions are being considered to withhold or withdraw from infants life-sustaining medical or surgical treatment;

(2) recommending institutional policies concerning the withholding or withdrawal of medical or surgical treatments to infants, including guidelines for IBRC action for specific categories of life-threatening conditions affecting infants; and

(3) reviewing retrospectively infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

A. Standard: Organization and Staffing.

The IBRC shall consist of at least 8 members and include the following:

(1) a practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon)
(2) a hospital administrator
(3) an ethicist or a member of the clergy
(4) a representative of the legal profession (e.g., judge)
(5) a representative of a disability group, developmental disability expert, or parent of a disabled child
(6) a lay community member
(7) a member of the facility's organized medical staff
(8) a practicing nurse

The hospital shall provide staff support for the IBRC, including legal counsel. The IBRC shall meet on a regular basis, or as required under subsection B(3), below. It shall recommend to the steering committee of the medical staff and the governing board such administrative policies as terms of office and quorum requirements.

The IBRC shall recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the IBRC and its availability on a 24-hour basis.

B. Standard: Operation of IBRC.

1. Prospective policy development.

The IBRC shall develop and recommend for adoption by the governing body institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These shall include guidelines for management of specific types of cases or diagnoses, e.g., Down's Syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, e.g., brain death and parental refusal to consent to life-saving treatment. The governing body, upon recommendation of the IBRC, may require attending physicians to notify the IBRC of the presence in the facility of an infant with a diagnosis specified by the IBRC, e.g., Down's Syndrome and spina bifida.

In recommending these policies and guidelines, the IBRC shall consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It shall also consult with appropriate committees of the medical staff, to ensure that the IBRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The IBRC shall also inform and educate hospital staff on the policies and guidelines it develops.

2. Retrospective record review.

The IBRC, at its regularly-scheduled meeting, shall review all interim records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed pursuant to this condition, unless the case was previously before the IBRC pursuant to subsection B(3), below. If the IBRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to the steering committee of the medical staff and hospital board for appropriate action.

3. Review of specific cases.

In addition to regularly-scheduled meetings, interim IBRC meetings shall take place under specified circumstances to permit review of individual cases. The hospital shall require in each case that life-sustaining treatment be continued, until the IBRC can review the case and provide advice.

a. Convening of interim meetings.

(i) Interim IBRC meetings shall be convened within 24 hours when there is disagreement between the family of an infant

and the infant's physician as to the withholding or withdrawal of treatment, or when a preliminary decision to withhold or withdraw life-sustaining treatment has been made, consistent with hospital policies developed pursuant to this condition.

(ii) Such interim IBRC meetings shall take place upon the request of any member of the IBRC or hospital staff or family member. The identity of persons making such requests shall remain confidential, and such persons shall be protected from reprisal. When appropriate, the IBRC or a designated member shall inform the requesting individual of the IBRC's recommendation.

(iii) The IBRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed pursuant to B(1), make the convening of an interim meeting unfeasible.

b. Conduct of interim meetings.

Interim meetings shall be open to the affected parties. The IBRC shall ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the IBRC; and the IBRC shall facilitate their access to such services and groups.

c. Treatment effect.

In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes shall be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the IBRC after complete information and due deliberation agrees with the family, the IBRC shall recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the IBRC disagrees with the family, the IBRC shall recommend to the hospital board that the case be referred immediately to an appropriate court or child protective agency, and treatment shall be continued until such time as the court or agency renders a decision or takes other appropriate action. The IBRC shall also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdraw, but the IBRC disagrees.

C. Standard: Form and Retention of Records.

The IBRC shall maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records shall be kept in accordance with institutional policies on confidentiality of medical information. They shall be made available only upon court order, or to properly authorized staff of accrediting organizations or government agencies. In such instances, patient identification shall not be disclosed.

association of american medical colleges

JOHN A. D. COOPER, M.D., PH.D.
PRESIDENT

202: 828-0460

October 11, 1983

Dr. Michael Stoto
Study Director
Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D. C. 20418

Dear Mike:

Enclosed, the views of the Association of American Medical Colleges on the organization of the National Institutes of Health. This set of comments was developed by the Association's Council at its September 15 meeting. Several of its recommendations are, I believe, novel. These were not included in the AAMC statement presented by Dr. Berne on September 19.

The Association hopes that this contribution proves helpful to the Committee.

Sincerely,

John

John A. D. Cooper, M.D., Ph.D.

Enclosures

cc: Dr. James B. Wyngaarden, NIH

Suite 200/One Dupont Circle, N.W./Washington, D.C. 20036/(202) 828-0400

The Organization of the National Institutes of Health
Comments by the Association of American Medical Colleges

Pressures for the establishment of new national institutes at the National Institutes of Health (NIH) have increased significantly in recent years. Uncertainty as to what criteria should be met to justify a new organizational unit and dis-ease as to the consequences of a rapid proliferation of new institutes brought a request to the National Academy of Sciences (NAS) and its Institute of Medicine (IOM) for advice. The latter, in turn, has invited comments from interested organizations, including the Association of American Medical Colleges (AAMC).

Historical Background

The United States Public Health Service (PHS) and its antecedents first embarked on mission-related research in 1887. Until the mid 1940's, the program emphasizing traditional public health concerns, principally communicable disease, and, to a limited extent, selected basic medical sciences; the organizational structure of both the Hygienic Laboratory (1887-1930) and the National Institute of Health (1930- 1948) reflected this scope of purpose. The activity was exclusively intramural until the PHS was authorized to award fellowships by the Randsdell Act in 1932; annual expenditures for fellowships stabilized at about $160,000 between 1938-1945. The establishment in 1937 of the NIH's first categorical institute, the National Cancer Institute (NCI), did not change the situation significantly; between 1938 and 1946, annual extramural expenditures of the NCI averaged only about $71,000 and supported an average of nine research grants.

In the immediate postwar period, the mission of the NIH was radically revised. The concept that research on the entire spectrum of human health problems was an important function of the Federal Government acheived wide public acceptability. To pursue this very broad mission, the NIH not only expanded and diversified its intramural effort, but also engaged a large community of non-government scientists, located for the most part in academic institutions throughout the Nation, to participate in a national research agenda. The prewar organizational structure was not appropriate for the new mission; accordingly between 1946 and 1950, a rapid organizational transformation was effected through the creation of seven new institutes; several more were added in subsequent years. But ever since the late forties and irrespective of its organizational structure, the NIH has assumed responsibility for the total set of problems encompassed by its new mission: to enhance human health through fostering, supporting and conducting laboratory and clinical research for the purpose of increasing the understanding of life processes and the etiology, treatment and prevention of disease.

The restructuring of the NIH could have been based on any of a number of organizational concepts. The one generally thought to have been selected was to organize by category of disease, e.g., cancer, allergy, infectious diseases, metabolic disease. On closer examination, however, other concepts are

evident in the structural evolution: disciplines of science (environmental health sciences and general medical sciences); organ and organ system diseases (heart, lung, blood, eye); biological processes (aging, human development); or some mix of these. Organizational evolution was probably more pragmatic than ideological, determined by the most viable consensus in the light of the prevailing scientific, managerial and political realities. The fact is that the scientific scope of the NIH cannot be uniquely or unambiguously encompassed in any set of discrete and nonoverlapping groupings. Most research problems are multifaceted, simultaneously embodying categorical, disciplinary, biological process and organ or organ system elements. As long as an organizational scheme permits the NIH to discharge comprehensively and effectively its entire range of responsibilities, it should be deemed satisfactory. The present structure appears to meet this specification.

The Problem of Organizational Proliferation

One major characteristic of most organizational schemes, including that of the NIH, is that they are more or less open-ended and without an inherent logical basis for limiting the number of operating units. Widespread concern that excessive proliferation of organizational units was imminent precipitated the present IOM study. The AAMC feels that a further increase in the number of national institutes would create important problems.

- The span over which an executive can exercise control is finite. The current number of institutes and institute equivalents requires that eighteen operating units report directly to the Director, NIH; this number already stretches reasonable limits.

- Institutes tend to develop an entirely proper sense of territoriality, pursuing their assigned mission with singlemindedness. Thus, their effort tend to become walled off into fixed compartments, with resources carefully husbanded for projects within, and only within, those compartments. Proliferation of institutes fragments the effort into ever smaller compartments, sequesters resources into programs of ever narrower scope, and makes it managerially difficult to reallocate them when opportunity wanes or when overlap problems commend redistribution. Thus, program and fiscal flexibility are reduced.

- With new institutes come new national advisory councils. Overall, loss of program and fiscal flexibility is enhanced by the participaticipation of these non-government advisors who, selected for their specialized expertise, are likely to have a parochial outlook. Thus, the greater the number of national advisory councils, the greater the tension between the need of the NIH for flexibility to capitalize on research opportunity wherever it emerges and the preoccupation of external advisors with the problems of single disciplines, fields or specialties.

- The narrower its scope and the more intense its focus, the more likely an institute is to underemphasize biomedical problems that,

while peripheral to its central mission, are closer to its than to that of any other institute.

Constraint on Proliferation

To resolve the dilemma of how to subdivide the mission of the NIH into manageable segments without risking crippling or destructive fragmentation, the AAMC suggests that:

> some more explicit limitation be established, de facto or de jure, on the number of operating units reporting to the Director, NIH.

However, for an arbitrary limitation such as this to solve more problems than it creates, its adoption should be coupled to the development of new mechanisms for short- and long-range adjustments to accommodate new realities brought about by scientific progress. Over long epochs, in a field as dynamic as biomedical science, the problem structure of any field is likely to be made obsolete as new knowledge is acquired. Most bioscientists are confident that, eventually, the cancer problem will be solved; when that day comes, an NCI will obviously not be needed.

To maintain concordance between organizational structure and progress in bioscience, the AAMC suggests that:

> the NIH periodically, perhaps decennially, reevaluate, reaffirm or revise its organizational structure through a process that involves the participation of a maximum number of interested government and nongoverment organizations.

This periodic reexamination would require justification of the organizational structure from a zero basis and in the light of the then prevailing realities. The range of possible actions could include: the establishment of new and the disestablishment of old institutes; the regrouping of established programs into new configurations; the addition or deletion of programs; and the addition, expansion, elimination or transfer of subunits. A definitive schedule for major review of the structure of the NIH would, it is hoped, stimulate widespread discussion within the community of interest; the predetermined constraint on proliferation would encourage collegial cooperation and negotiation among the parties of interest.

Over short periods, the annual cycles of budget development provide a reasonable basis for accommodating scientific progress. However, to improve the fidelity with which program content tracks scientific progress, the AAMC suggests that:

the NIH extend and formalize their current procedures to receive, evaluate and appropriately publicize proposals by advocacy groups for modifications in program content, emphasis or priority;

and

the strength of the Office of the Director (OD) for resolution of overlap issues be increased.

First, the forum. It is established policy at the NIH to be open to suggestions from all quarters. But interactions between special interest advocates and NIH officials have not been systematically documented, nor have the context and outcomes of the discussions been made generally available. Some special interest groups are well organized, funded and staffed; their areas of concern are concordant with major NIH program emphases; they share a large set of common interests as well as a very common information base with NIH officials; the magnitude and urgency of the problems to which they are committed, as well as the size of the NIH commitment to these problems, are matters of which the NIH, the scientific community and the public are widely aware. Clearly, these groups have no major problems, and require no special processes, to have their day in court. The proposal for some kind of a forum, however, would encourage less powerful groups to interact officially and publicly with the NIH. Thus, the NIH could reap the benefit of the information and insights of organizations focused intensely on problems of diseases that, while perhaps less frequently encountered, account for significant mortality and morbidity and profound human tragedy. Interaction with these groups would also provide the NIH the opportunity to examine and display the extent of its engagement with the problem under discussion, a mutually useful exercise. The records of such meetings, with the views of both parties on the state of research in the field, would be useful to others besides the participants: the scientific community at large should find the information valuable in assessing the validity of NIH program priorities; the higher levels in the Executive Branch should welcome the inclusion of material from these interactions in budget justifications; and the Congress should find enlightening the discussion between the NIH and the special interest advocates on the scientific issues at stake.

The absence of a formal and visible public forum for presenting claims on the NIH budget increases the credibilty of claims that access to a fair, impartial, objective hearing is not possible; and, thereby, it invites political intervention. The creation of a process of the type suggested would not only enhance the public trust in the integrity and fairness with which the national research enterprise is managed, but also increase the sensitivity with which the annual budget process adjusts program priorities.

The AAMC suggestion to strengthen the Office of the Director, NIH, relates to the fact that, in the interval between budget development cycles, as well as during the course of budget development, resolution of overlap problems depends on negotiated agreements between the involved organizational entities or on effective intervention by the Office of the Director. Several

devices might be employed to achieve the goal of strengthening the OD: a small portion---say 0.5%---of the budget of each institute's budget could be designated as reserved during the first three quarters of each fiscal year for the discretionary transfer by the Director to some other institute(s); or an equivalent---a specified fraction of National Advisory Council-approved grant applications---could be designated as transferable for award purposes from one institute to others. The value of overtly and explicitly strengthening the hand of the Director, NIH, by these or other devices may be largely symbolic since traditional mechanisms---formal reprogramming requests---would accomplish the same end. But the Association believes that the effectiveness of the Director, NIH, would be substantially strengthened if that individual were formally accorded modest discretionary authority that could be quickly and independently exercised.

Preserving the NIH

Even though the charge to the IOM has been phrased as an organizational issue, the AAMC, as was made clear in the testimony (Attachment I) presented on September 26 by Dr. Robert M. Berne, believes organizaton to be a derivative, not a primary, problem. The unchallenged preeminence of the U.S.A. in biomedical science and its wide margin of leadership in medicine is far and away more a tribute to how the NIH functioned than to how it was organized. What is most important, and what must be preserved above all, is the policy framework that has characterized NIH operations for the last several decades and the statutory authority essential for it. The enclosed statement (Attachment II), entitled "Preserving America's Preeminence in Medical Research," articulates the AAMC's convictions in this matter.

The Current Policy Framework

The criteria by which program objectives are selected and appropriated funds allocated have been crucial elements in the success of the NIH. By longstanding policy, the establishment of research programs depends on the identificaton of important scientific opportunities that are available for exploitation; that a health problem exists does not justify investments, absent opportunity. Equally longstanding is the policy that only high quality research proposals should be funded. In devising as well as in executing these policies, the NIH has relied heavily on nonfederal scientific experts for advice. National advisory councils, with both scientific experts and "consumer" representatives, have played the major role in shaping program emphasis; technical merit panels, notably the study sections, have been responsible for objective and impartial evaluation of the scientific quality of all research grant applications. The steadfast adherence to these policies over almost four decades has not only resulted in an undeniably productive research effort but earned the confidence of the scientific community, the Executive and Legislative Branches of government, and the general public in the responsibility and integrity with which public funds are expended. It is for these reasons that the AAMC strongly recommends that:

Program selection and project funding at the NIH continue to be based on scientific promise and quality.

Statutory Basis for NIH Policy

Not so widely recognized as the importance of the above policies is the fact that the statutory base which the Congress provided to the NIH has important characteristics that have enabled the NIH to function in the exemplary manner just described. Administrative flexibility not only to promulgate and implement these policies but also to develop appropriate mechanisms and to prescribe appropriate terms and conditions of support, has resulted in the emergence of a national system of research support that has been widely applauded and extensively emulated.

From 1944 until 1971, the NIH operated under broad and permanent statutory authority, without either time or dollar limits and, except in the instances of the NCI and the NHLBI, has continued to do so since 1971. Detailed legislative specification of the authorities of federal science adminstrators and of the modus operandi of federal science agencies---so difficult to get off the statute books, once enacted---limits necessary flexibility and discretion. In this context, the AAMC recommends that:

> a powerful case be made to convince the Congress to refrain from detailed statutory prescription re the NIH and to rely, instead, on general authorities coupled with oversight focused on "systems" problems.

The recently published NAS report entitled "Strengthening the Government-University Partnership in Science" deals with many of the currently troublesome aspects of the relationship between academe and the federal establishment. In one sense, it is a tribute to the wisdom with which the government has behaved for almost 40 years that the many misgivings about government support of scientific research, so widely held and vigorously articulated in the five year period preceding the activation of the National Science Foundation, did not surface in the course of this study.

But for more than a decade, the role of the Congress in the governance of federally funded scientific research has become far more interventionist. Ever since the new legislative authorities for NCI and NHLBI, enacted in 1971 and 1972 respectively, periodically brought Title IV of the Public Health Service Act before Congressional legislative committees, there has been a growing tendency for the latter to assume, to a major degree, responsibility for the detailed management of the NIH's scientific research program through statutory direction. Occasional intervention by legislative committees to mandate the establishment of new institutes (Eye, Aging) is not unprecedented and the Congressional interest in conferring institute status on arthritis and musculoskeletal disease could be viewed as just the latest episode in a long saga. To take this view would, in the opinion of the AAMC, be a mistake and would be to miss a rare opportunity to examine how the Congress might most effectively contribute to the acheivement of government research objectives.

A publicly supported biomedical research program must obviously be accountable, not only fiscally and scientifically, but also politically; i.e.,

to the public and its elected representatives. Given this inescapable reality, the paramount issue, in the opinion of the AAMC, is what approach to accountability takes advantage of what the Congress is most qualified, and avoids what it is least qualified, to do. Sound decisions with respect to the national research agenda--scope, long- and short-range objectives, relative priorities and intensities, etc. -- require balanced judgments, based on the understanding of complex and extensive scientific and technical information and considerations. The inescapable responsibility of a federal science agency is to construct and to use an appropriate apparatus for making these decisions. The national legislature is not the place and national legislators are not the people to perform the task. On the other hand, Congress is eminently qualified to examine this decision-making apparatus and to determine whether the "system" meets an acceptable standard of political accountability. Is it competent, objective, fair, sensitive to public need, responsive, responsible, innovative, imaginative, etc.? Do the processes for budget development enable careful and comprehensive analysis of scientific opportunity, explicit examination of these opportunities in light of the importance of health problems, and holistic assessment of priorities by field of science and mechanism of support? Such a Congressional oversight role is entirely appropriate and highly valuable. Its adoption would match talent to task--with the Congress and the scientific community assigned roles that each does best.

The AAMC hopes the IOM would recognize that the issue before it cannot be adequately assessed without a thorough exploration of the role of the Congress in the governance of science.

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH
HISTORICAL ASPECTS

Presentation by Dr. Robert M. Berne
Chairman, Department of Physiology
University of Virginia School of Medicine

on behalf of

The Association of American Medical Colleges

26 September 1983

Mr. Chairman, Members of the Committee

I am Robert M. Berne, Chairman of the Department of Physiology at University of Virginia School of Medicine. I am speaking today on behalf of the Association of American Medical Colleges, the national voice for 127 accredited medical schools and their students for more than 400 affiliated teaching hospitals, and for over 70 academic and professional societies whose members are engaged in medical school teaching, patient care and medical research. It was my privilege to serve on the Administrative Board of the AAMC's Council of Academic Societies from 1974-1979 and as that body's Chairman in 1977-1978.

Throughout its modern history, the NIH has relied heavily on the academic community to carry out the nation's research agenda. Awards to medical schools alone account for 52% of extramural awards and their affiliated teaching hospitals another 4-5%. Thus the AAMC's constituents include institutions that perform almost 60% of NIH supported extramural research.

Before addressing specifically the issues outlined in Dr. Ebert's letter of invitation to Dr. Cooper, let me make one observation: the issue before the Committee -- the organizational structure of the NIH -- is not primary but derivative. The real issue is how the government will support research. The stimulus for the present study is the profound and relatively recent change in the manner in which one branch of government -- the Congress -- relates to the national medical research enterprise.

Until the enactment of the National Cancer Act in 1971, the programs at NIH had been funded and managed entirely under broad and simple legislation -- Section 301 of the Public Health Service Act. That basic authority, ideally suited to an activity with a heavy emphasis on basic research, was most unusual, in that it contained no time or dollar limits and was singularly free of directives to the agency. With the advent of the cancer legislation that year and of new heart legislation in 1972, a need for periodic renewals of the expiring legislation was created. Meeting the need has become the occasion for an increasing number of mandated directives and limitations on the heretofore flexible managerial prerogatives of the agency. The predictable outcome of the accumulation of narrow and specific authorities is growing rigidity and loss of discretion in program emphasis, characteristics likely to hobble a heretofore remarkably successful government organization.

My presentation this afternoon is limited to the questions asked in the letter of invitation. A more comprehensive treatment of the issues before the committee, together with several cognate recommendations,will be submitted within the next week or so.

The Association found the context of the historical questions for this hearing somewhat limiting. The implication that organizational change might have been a unique determinant of funding flows, the management and coordination of biomedical research and the quality thereof seems to be something of an oversimplification. The phenomena under investigation are a

complex of technical, social and political problems with innumerable variables playing roles. At best, the outsider can be aware of only the most gross.

Fund flows, for example, reflect judgments of Institute directors, based on detailed analysis, aided by external advisors, of scientific opportunity. These judgments are modulated by the Director of NIH, also based on scientific and technical judgments. Thereafter, the Secretary HHS, the OMB and the Congress each have their say, influenced principally by political and social forces rather than scientific and technical ones.

Even the measurement tools for answering the questions leave much to be desired. Fund flows are often defined by relative growth rates. But a "quantum" increase -- defined as the increment of funds needed to increase the workforce in a field by, say, 50 scientists, would translate into a rapid growth rate for a new and differentiating field such as aging; the same increment would accelerate growth in a mature and well funded field such as cancer by hardly a whit.

With these caveats, let me comment on the historical questions raised by Dr. Ebert. First, on the effect of organizational changes in the last fifteen years on the flow of funds into various fields.

The gross evidence for a "cause-and-effect relationship" is mixed. "Before and after" data are difficult to obtain. In the time series of Institute appropriations, there appears to be a significant short-term increase in the rate of growth of appropriations for a year or two after the establishment of a new institute or, in the case of the National Cancer Institute and National Heart, Lung, and

Blood Institute, after their new legislation in 1971 and 1972, respectively. This does, of course, have the important effect of increasing the base. However, with the exceptions of the National Eye Institute and the National Institutes of Aging, growth rates for most institutes over the longer term are close to those of other institutes and the NIH as a whole. The short-term increases are probably the consequence of both intense Congressional interest and a deliberate effort by the NIH administration to strengthen the new program once legislation has been enacted; however, in the case of NEI and NIA, rapid program growth antedated organizational change.

Based on the AAMC's admittedly limited analyses, differentially rapid growth appears to occur at times in the history of every institute, irrespective of organizational change; these spurts presumably reflect some combination of scientific opportunity and public interest. A more careful and detailed analysis of all of the forces in operation during a period of change would be of interest.

It is difficult to determine with certainty the extent to which the relatively rapid growth of new entities has been at the expense of other components, but, at least for short epochs, that appears to be the case.

As to "the effect of organizational changes in the last fifteen years on the management and coordination of biomedical research," the AAMC has been able to discover little evidence for a cause-and-effect relationship. Perhaps organizational changes over this period have not been sufficiently large, with the addition of only two entirely new entities -- Eye and Aging -- and the internal restructuring of NIADDK.

Obviously, there is a point at which a larger number of units makes management and coordination across all the components more difficult. This is especially true in a research activity that is largely basic in nature, with the frequent but unpredictable advances that exert significant influence across unit boundaries.

A major influence in this context is the subtle balance in the relationship between the Director, NIH, and the directors of the individual components. This relationship is dynamic in character and often is influenced as much by the personality and managerial style of the Director as by existing authorities. Despite some criticism of inadequate definitions of those respective authorities, the arrangement has worked remarkably well over the years.

Finally, a comment on "the effect of organizational changes in the last fifteen years on the comprehensiveness and quality of research in the affected fields."

There is, as far as we have been able to determine, no direct cause and effect relationship between comprehensiveness and organizational changes; the availability (or lack) of funds and the existence (or lack) of scientific opportunities are more important determinants than organizational changes.

The quality of research is far more likely to be determined by decisions within the centralized peer review system than by organizational changes.

Let me just speak for a moment to your second question: "the strengths and weaknesses of the current organizational structure of

disease-based Institutes, advisory councils, peer review groups, and etc., for managing and insuring high quality in relevant biomedical research."

The major strengths, as we see them, are that:

- Identification in visible fashion of major life-threatening diseases is important in securing public understanding, sustaining public enthusiasm, and thereby obtaining sizable research funding.

- The mix of organizational components between disease-oriented Institutes and non-categorical components (e.g., NIGMS and DRR) provides a rational basis for dividing funds and program responsibilities into manageable segments.

- There now exist a sufficiently large number of organizational components to:
  - provide necessary program flexibility
  - cover all relevant scientific fields and disciplines

- The two-tiered advisory apparatus provides:
  - representation of categorical interests ("relevance") through national advisory councils
  - scientific expertise ("quality") through study sections

- The centralized study section operation gains:
  - economies in use of scientific and administrative personnel
  - consistency in standards for initial review of grant applications

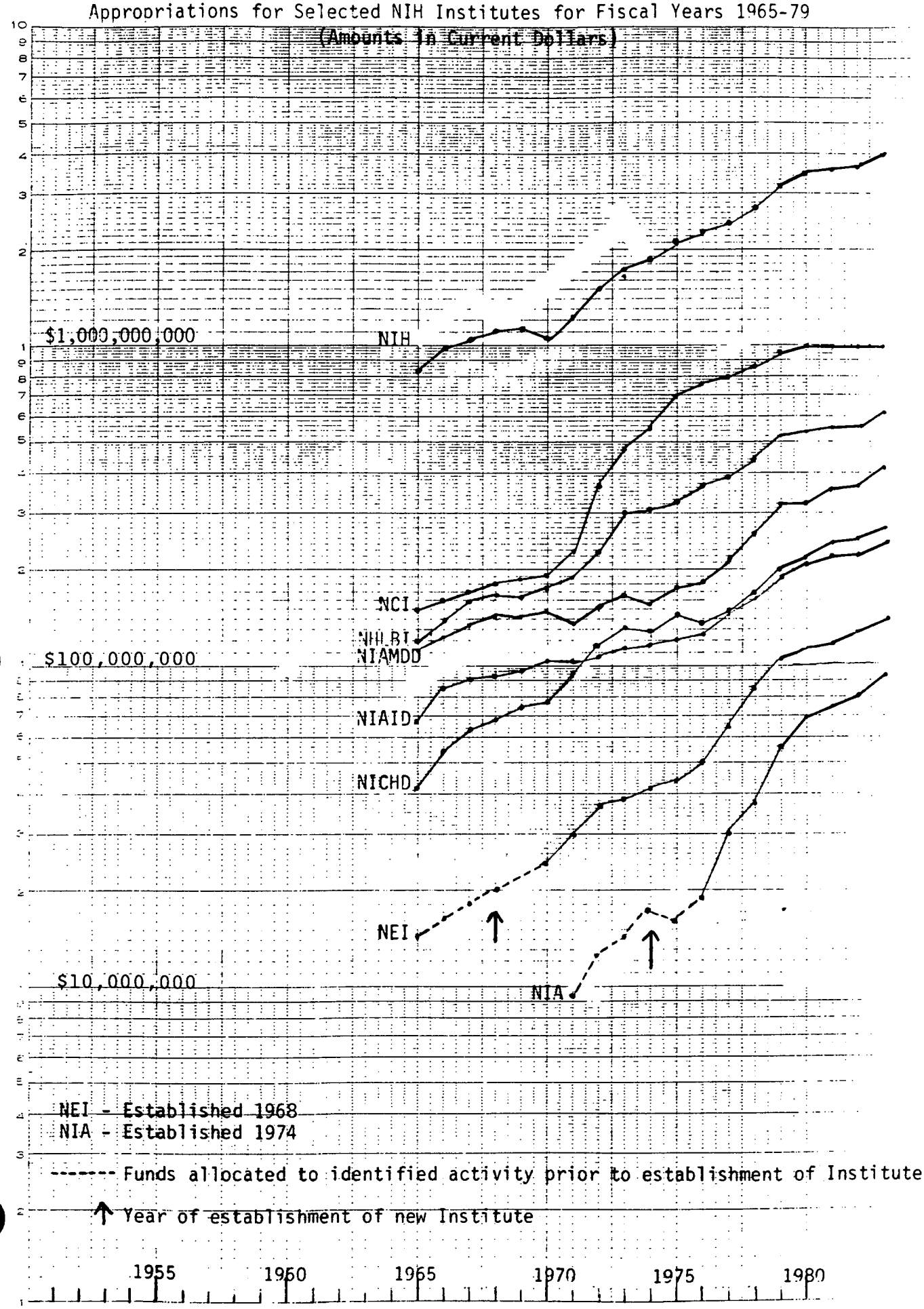
- The organization of advisors in structured panels adds to consistency in review and enhances exchange of expert opinion.

The noteworthy weaknesses are as follows:

- Disease-oriented components are potentially vulnerable to political intrusion and unless counterbalanced, may purposely or inadvertently favor applied research and development or service-oriented activities at expense of basic research.

- There is no logical limit to the number of disease-oriented institutes.

- The existing number of components must be considered as already stretching the capacity of the director's managerial span.



September 22, 1983

NATIONAL ACADEMY OF SCIENCES
INSTITUTE OF MEDICINE

Committee for the Study of the Organizational
Structure of the National Institutes of Health

Bills proposing changes or additions to the National Institutes of Health (NIH) have been introduced at every recent session of Congress. While some regard such organizational changes as a way to emphasize research in neglectd areas, others see them as administratively costly and scientifically ineffective. To develop the criteria for determining the need for change, the Congress and the NIH have called for a study of the NIH organizational structure.

In order to carry out this study the Institute of Medicine has named a committee, chaired by Dr. James D. Ebert, President of the Carnegie Institution of Washington. The other members are listed on the following page. This committee will analyze the organizational evolution of the NIH, analyze present approaches to major issues which cut across organizational lines, and recommend criteria for future organizational change.

In order to inform the committee's deliberations, separate panels have been formed to investigate 1) the effect of past organizational changes on the flow of funds into various disciplines, the scope of research in specific areas of study, and the management and coordination of biomedical research; 2) the current organizational structure of the NIH and related research agencies, and the way this structure handles management issues that cut across institute lines; and 3) alternative means for goal setting, decision making, priority setting, and budgeting that might suggest directions for organizational change. Chairmen and members of these panels, as well as a more detailed description of the charges, are listed on the following pages.

The study is funded by the National Institutes of Health. The committee held its first meeting in June 1983 and expects to release its report in late October 1984. Questions may be addressed to the Study Director, Michael A. Stoto, Ph.D., (202) 334-2268.

INSTITUTE OF MEDICINE

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September 6, 1983

Panel 1 - Historical Issues

The first panel will examine the evolution of NIH's mission and organizational structure in order to shed light on the purpose of the current structure and its reaction to organizational change. This will involve gathering information on when, why, and how new institutes were started, the flow of funds to new and remainder institutes, the effect on science, and the effect on management. The panel will also examine organizational changes below the institute level, including program structure and mix of research mechanisms. It will also include a study of changes in the political climate, and the relationship between NIH, the Department of Health and Human Services, and the Congress.

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Panel 2 - Current Organization

The second panel will examine the current organizational structure of the NIH and related research agencies and explore a number of management issues that cut across organizational lines. This will include an analysis of the span of the Director's control, the program planning process in each institute and the Director's office, staffing profiles, the composition and role of study sections and advisory councils, and the role of staff and the role of advisors. It will also include studies of the organization and mission of agencies that have been proposed as additions to NIH so that the committee can develop criteria about whether or how they should be incorporated into NIH.

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Panel 3 - Alternatives

The third panel will examine alternatives to the current organizational structure, especially in regard to goal setting, decision making, priority setting, and budgeting. This will include a discussion of 1) "scientific opportunity" and "burden of illness" as criteria for setting research priorities; 2) the balance between basic and targetted research; 3) the balance between intramural and extramural research; 4) the balance between funding mechanisms, such as grants and contracts; and 5) how to promote and stimulate priority or neglected research areas. The panel will explore these issues in part by an examination of other research institutions, such as the NSF, foreign medical research councils, and industrial labs. Although the panel will be cognizant of political realities, it will attempt to search for alternatives to the current structure for evaluation by the full committee.

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Consensus from a meeting of faculty members and academic administrators on the current indirect cost problem.

September 6, 1983

Dear Colleagues:

Representatives of the university associations and the biomedical research community met in Washington on July 8 to discuss the future of NIH funding. The meeting was attended by a number of leaders of scientific societies as well as by university presidents and association staff.

The objective was to reach agreement on strategy and tactics for increasing future support for the biomedical research enterprise. We met for four hours of vigorous and productive discussion, at the end of which we agreed fully on the following points:

- A healthy biomedical research venture supported by full funding is a vital national objective--parallel with our need for strength in the physical sciences. There has been slowed growth in support for biomedical research since 1968 with real shrinkage over the last five years. This course of events has resulted in a substantial accumulated liability. The immediate objective of the Coalition for Biomedical Research Funding, to add $414 million to the Administration's proposal for FY 1984, is a promising start on the task of reducing this shortfall and making it possible for NIH to fund at full direct and indirect costs a minimum of 5,000 competing research grants, as well as training programs, centers, the Biomedical Research Support Grant program,--in short, a balanced program. Full funding of a sound biomedical research program would require a substantially higher figure than the additional $414 million recommended by the Coalition. We commit ourselves, the associations, and the societies to the effort of gaining Congressional support for the Coalition proposals now and greater improvements in future years.

- There is a need to resolve the problem of indirect costs, because they pose a singular threat of discord within the academic community and frequently lead to mixed messages to the public and to Congress. The NIH difficulty in reconciling an inadequate Administration budget with the real needs of research is understandable, but proposing cuts in either direct or indirect costs of research will damage the enterprise. We recognize, however, that the rise in indirect costs poses long range problems. At a meeting with PHS leadership on June 27, that some of those listed below attended, it was tentatively agreed that

the President's Science Adviser be asked to see that a study of the problem of indirect costs be undertaken. In particular, it should address the reasons for the increases in such costs over the past decade, and ways to control and, if possible, reduce them. We support that proposal. As a corollary, we urge that the Administration suspend its efforts to obtain budgetary relief either by cutting numbers of grants or by arbitrarily reducing direct or indirect costs—any of which will result in serious damage to the nation's biomedical research enterprise.

- We agreed that an important source of tension between researchers and university administrators over the indirect cost issue is the complexity of the rules and the cost-accounting measures employed, and the general failure to date to gain faculty sympathy with them. Faculty members complain that their administrations are often confusing or opaque in their explanations; and conversely, administrators sometimes feel that their faculty constituents are refractory to explanation. However one might apportion the blame, we think, the continued discord simply cannot be accepted. The University presidents present, accordingly, agreed to urge their colleagues to renew efforts to present their faculties with clear explanations of what indirect costs are and how their institutions handle them. We also agreed on the desirability of involving faculty meaningfully in the development of institutional policies respecting indirect costs, and of exchanging among institutions particularly useful explanations, documents, or accounting or budgeting procedures. For their part, the society representatives agreed to encourage among their members a receptiveness toward this proposed dialogue.

- Finally, we agreed that indirect costs as a category are particularly important targets for economy in our institutions. During the discussion, we shared some examples of institutional efforts to reduce such costs selectively. The associations will try to act as devices for communicating successful experiences, and will urge their member institutions to make such economies a matter of high priority.

We repeat that the discussion was, in our judgment, positive and highly significant. We believe it lays the foundation for strong cooperation in working for improvements in biomedical research funding, and addressing objectively our differences over the troubling matter of indirect costs. We hope you will communicate the results to your colleagues so that we can all move forward together on our main business—which is to strengthen the capacity of our faculties to do research that the Nation vitally needs, and to protect our own capacity to nurture and support that work.

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Co-chairman AAU/ACE/NASULGC Joint
Committee on Health Policy

Donald Kennedy
President, University of Stanford
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Johns Hopkins Hospital
President of the American
Federation for Clinical Research

David Cohen
Leading Professor and Chairman of
the Department of Neurobiology
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SUNY at Stonybrook
Past President of the Society
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Harlyn Halvorson
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John R. Hogness
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Centers

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Director, Planning & Policy
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Association of American Medical
Colleges

Robert Krauss
Executive Director
Federation of American Societies
of Experimental Biology

William H. Luginbuhl
Dean
University of Vermont
Association of American Medical
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Robert M. Rosenzweig
President
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Harold Shapiro
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Bob Watkins
Director of Public Affairs
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Frederico Welch
Executive Director and V.P.
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Virginia Weldon
Professor of Pediatrics
Deputy Vice Chancellor for Medical
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Member of the AAU/ACE/NASULGC Joint
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RECENT ACTION ON MEDICAL EDUCATION FINANCING BY THE ADVISORY COUNCIL ON SOCIAL SECURITY

At its August 24 meeting, the Advisory Council on Social Security adopted the following resolution calling for a three year study of medical education financing as the first step in an "...orderly withdrawal of Medicare funds from training support."

POLICY

In view of the financial crisis facing the Medicare program and the expanding supply of physicians and other health professionals, the Advisory Council on Social Security believes that there is a serious question concerning the use of the Medicare Hospital Insurance Trust Fund for the training of physicians, nurses, and allied health professionals. The Council recognizes that the Medicare program has had a significant impact upon the supply of health professionals by subsidizing the expenses of training and medical education for these groups. However, the Council thinks that the involvement of the Medicare program in underwriting these costs is inappropriate since the program is designed to pay for medical services for the elderly, rather than to underwrite the costs of training and medical education.

The Council also recognizes that the extent of public support for medical education and training health professionals is a complex and difficult matter to determine and implement. The abrupt discontinuance of the use of the Medicare Hospital Trust Fund for medical education without an analysis of the impact upon training institutions and a concomitant search for alternative public funding sources would be a disservice to the training and medical education institutions in the country and the training of prospective health professionals. The Council believes that a study on the restructuring of medical education financing should be undertaken immediately in order to provide for an orderly withdrawal of Medicare funds from training support. This study should be completed within three years under the direction of the Department of Health and Human Services.

AAMC ACTION

In light of the Advisory Council on Social Security's resolution on medical education financing, the AAMC Executive Council approved the following response:

- Believing that it is inappropriate to plan an "orderly withdrawal of Medicare funds from training support" before a comprehensive study of alternative methods for financing graduate medical education has been conducted and publicly reported, the AAMC should work to have the Advisory Council on Social Security reconsider its resolution. The Association should seek a revised resolution which recommends a study of alternative means of financing medical education and suggests that the findings of the study be used by a future advisory council to debate the reasonableness of terminating Medicare support for medical education.
- The AAMC should work with other national medical and hospital associations to develop a statement which all could endorse which opposes the present resolution on medical education financing adopted by the Advisory Council on Social Security.

On Sunday, October 16, 1983, AAMC Chairman-Elect Dr. Robert Heyssell appeared before the Advisory Committee and presented a statement of the AAMC position.

1982 ADVISORY COUNCIL ON SOCIAL SECURITY

MEMBERSHIP

1.	Otis R. Bowen, M.D. Chairman	Former Governor of Indiana, Professor of Family Medicine, University School of Medicine. (Public representation)
2.	Richard W. Rahn, Ph.D.	Vice President and Chief Economist, Chamber of Commerce of the United States. (Employer organization representation)
3.	James D. (Mike) McKevitt	Director of Federal Legislation, National Federation of Independent Business. (Employer organization representation and representation of self-employed)
4.	Stanford D. Arnold	Secretary-Treasurer, Michigan Building and Construction Trades Council (AFL-CIO). (Employee organization representation)
5.	Carlos J. Arboleya (Resigned May 1983)	President, Chief Operating Officer and Director, Consolidated Barnett Banks of Miami, Member of Numerous Civic and Community Boards, George Washington Honor Medal, Freedom's Foundation at Valley Forge, 1974-1977. (Public representation)
6.	Karl D. Bays	Chairman, Chief Executive Officer and Director, American Hospital Supply Corporation. (Public representation)
7.	Kenneth M. McCaffree, Ph.D.	Businessman and Retired Professor of Economics, University of Washington. Specialist in Long-Term Health Care. (Public representation)
8.	Samuel H. Howard	Vice President and Treasurer of the Hospital Corporation of America, Formerly Vice President for Planning for Hospital Affiliate International, a subsidiary of the Insurance Company of North America (INA), Former Associate Dean of Meharry Medical School. (Public representation)

9.	Linda H. Aiken, R.N., Ph.D.	Vice President for Research, the Robert Wood Johnson Foundation, Directs the Teaching Nursing Home and the Hospice Evaluation Projects of the Foundation. (Public representation)
10.	David W. Christopher	Partner in charge of Pittsburgh Office, Price Waterhouse and Company. (Public representation)
11.	C. Joseph Stetler	Currently with Law Firm of Dickstein, Shapiro, and Morin in Washington, D.C., Former President, Pharmaceutical Manufacturers Association. (Public representation)
12.	James Balog	Senior Executive Vice President, Drexel Burnham Lambert. (Public representation)
13.	Alvin E. Heaps	President, Retail, Wholesale and Department Store Unions. (Employee representation)

ADVISORY COUNCIL ON SOCIAL SECURITY

Medicare Educational Expense: Policy Statement

Background

The Medicare program reimburses providers a portion of their costs for various medical education programs through the Health Insurance Trust Fund. These programs are reimbursed as an identified separate cost center in each provider's cost report. Reimbursement is for the costs associated with training new physicians, nurses, and allied health care professionals. On-the-job training and continuing education programs are not reimbursed under this provision. Medicare will reimburse providers for the cost of educational programs which meet three criteria:

1. The program must be designed to enhance the quality of services or general operation of the institution;

2. The program must meet state licensure requirements; or,

3. Programs which do not require licensure must be approved by the appropriate professional organization.

Currently, thirteen medical education programs have been identified in the Medicare regulations as meeting the reimbursement criteria. The list is not exhaustive.

The Assistant Secretary for Planning and Evaluation - Department of Health and Human Services is conducting a study to determine the total cost of Medicare's medical education activities. Preliminary data indicates that these programs cost Medicare $1.3 billion in 1980 and $1.8 billion in 1983. Of these amounts the Medicare program spent $300 million in 1980 and $400 million in 1983 for the direct reported costs of medical education programs. The remaining expenditures were for indirect costs involved in the educational programs.

Studies conducted by the Department of Health and Human Services - Graduate Medical Education National Advisory Committee (GMENAC) and the Institute of Medicine suggest that there will be an oversupply of physicians, and possibly nurses, for the remainder of the century. In particular, GMENAC projected an oversupply of 70,000 physicians in 1990. By 2000 the oversupply will grow to an estimated 145,000 physicians. Other sources indicate that nursing manpower requirements and supply may be in equilibrium for the remainder of the decade.

Discussion

The Advisory Council on Social Security finds that as part of the examination of the Medicare program, due to the current financial condition of the Medicare Health Insurance Trust Fund, it is necessary for the Department of Health and Human Services and the Health Care Financing Administration to seriously question the role of this program in underwriting the cost of medical education programs. Two points need to be considered. First, whether a program such as Medicare, which is intended to assure beneficiaries financial access to health care services, is an appropriate mechanism for paying the cost of training the personnel whose services the program is designed to reimburse. The federal government through various loan programs, the Public Health Service, and the Department of Defense has the means to assure that new medical personnel receive training. These programs, unlike Medicare, are designed to train medical personnel, not reimburse them for the services that they render. The second factor is whether the Medicare program can afford to allocate between 4% and 5% of the annual Health Insurance Trust Fund expenditures for this purpose. With other programs designed to provide the means for training medical personnel the Council thinks that this is an expenditure the Medicare program should consider eliminating.

Before implementing this policy change the Council recommends that the Department of Health and Human Services and the Health Care Financing Administration conduct a study, similar in scope and depth to GMENAC, to determine the future need for and availability of medical manpower. The Council is very much aware of the impact such a change in policy by the Medicare program may have on the medical education community. Future reimbursement policy changes should reflect this study's findings.

If the Department of Health and Human Services and the Health Care Financing Administration chooses to continue reimbursing providers for the cost of medical education, changes should be made in the system for reporting this data. The Council thinks that the Department and HCFA should routinely collect and review the data on the direct cost of medical education which is already reported by providers. In this manner the Department and HCFA can evaluate the reimbursement policy in light of changing circumstances. In addition, steps should be taken to develop guidelines for reasonable indirect costs that are to be associated with various medical education programs.

AAMC CLINICAL EVALUATION PROGRAM

The AAMC Clinical Evaluation Program, designed to assist clinical faculties in assessing students during their undergraduate and graduate clinical education, is now in the implementation phase. An advisory group has been formed and will be asked to react to the materials and proposals generated by program staff. A list of the thirteen advisers is attached.

Two projects are in progress:

1. Self-assessment materials are being developed for medical schools, clinical departments, and affiliated hospitals and clinical training sites. These materials will be used by interested institutions to help identify strengths and weaknesses within their current evaluation systems, in order to determine the extent and kind of changes desired and to select the best strategy for implementing these changes. The conceptual framework for the self-assessment materials has been pre-tested in two U. S. medical schools. The initial set of materials will be piloted in the Spring of 1984. Approximately 60 medical schools have expressed interest in the self-assessment tools.

2. Information is being compiled for a paper on education and evaluation along the clinical continuum, to be available in early 1984. The paper will collate questions raised in the research literature and examine the usefulness of the findings in the context of the problems of evaluating clerks and residents posed in the booklet The Evaluation of Clerks: Perceptions of Clinical Faculty (AAMC, 1983) and the editorial "Clinical Judgment of Faculties in the Evaluation of Clerks" (JME, March, 1983). Areas under study include the identification and use of

evaluators, the handling of different types of students (e.g., failing, marginal, excellent), the purpose of evaluation, the influence of setting on the evaluation process, the different kinds of characteristics assessed and the integration of methods of assessment into a comprehensive evaluation system.

Xenia Tonesk, Ph.D.

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