THE Annual Meeting of the Council of Academic Societies will be held at the Conrad Hilton Hotel, Tuesday, November 12, 2:00 p.m., in the Waldorf Room. By now you should have received the preliminary program for the entire AAMC Meeting, which also contains registration cards for the meeting and a hotel reservation form. If you have not yet sent these forms in, please do so immediately.

THE theme of the AAMC Annual Meeting is "Educating the Public About Health". Two plenary sessions will center about this challenge; our professional societies and academic health centers have a great deal to offer and a great deal to gain in developing a greater degree of sophistication in the public about health matters.

THE major item for discussion at the CAS Business Meeting will be the Report of the Association's Task Force reviewing the National Board of Medical Examiners Goals and Priorities Committee Recommendations. The Task Force has completed its work and a draft of the report will be sent to you as soon as it is finalized. Information derived from discussions by the three Councils and the Organization of Student Representatives will be utilized by the Task Force and the Executive Council in developing a position for the Association on the GAP Report.

THE Council Meeting has particularly focused on two major national issues of concern to the academic community. Programs for two half-days of discussion of these issues are attached. PSROs and Quality Assurance programs of various types are of great moment to the academic community, both because our teaching hospitals must participate and also because improvement in the quality of health services will, to a significant degree, require educational programs for physicians now in practice. The issue of physician distribution, both by geography and specialty, is of paramount concern to many in the public and private sectors. Current manpower bills being considered by the Congress have sections directed towards establishing the total number of residency positions available and the distribution of those positions across the specialties. Legislative proposals to modify the geographic distribution of physicians have been contained in every bill introduced in Congress. Clearly, the member societies of the CAS have a great deal at stake in these areas of high national interest.
On Monday evening, November 11, at 8:00 p.m., Ruth Hanft, Director of the Institute of Medicine Social Security Study, will address a special session of the Meeting. Ms. Hanft, who previously served as Director of the Cost of Medical Education Studies recently completed by the Institute, will present a progress report and discuss the issues involved in the studies which were authorized by the Congress in the Social Security Amendments of 1973 and are as follows:

1) appropriate and equitable methods of reimbursement for physicians services in hospitals which have teaching programs;

2) the extent to which funds expended under Medicare and Medicaid are supporting the training of medical specialists which are in excess supply;

3) how the funds could be expended to support more rational distribution of physician manpower both geographically and by specialty;

4) the extent to which such funds support or encourage teaching programs which tend to disproportionately attract foreign medical graduates;

5) the existing and appropriate role of such funds which are expended to meet in whole or in part the cost of salaries of interns and residents in teaching programs.

We hope you can attend the CAS Meeting.

August G. Swanson, M.D.
Director of Academic Affairs

Attachments

Council of Academic Societies
Program on Quality Assurance and PSRO's
Tuesday, November 12, 1974
9 a.m. - 12 noon

"Opportunities in the PSRO Program for Teaching, Research, and Service"

Moderator: Robert J. Weiss, M.D.

9:10 Introductory Remarks - John A. D. Cooper, M.D.

9:20 PSRO Implementation at the National Level - Ruth M. Covell, M.D.

9:40 DHEW Activities in Quality Assurance - Henry E. Simmons, M.D.

10:00 Opportunities for Education in PSRO - Clement R. Brown, M.D.

10:20 Coffee Break

10:30 Opportunities for Evaluation and Research in PSRO - Sam Shapiro and Paul M. Densen, Sc.D.

11:10 Evaluation of National PSRO Program - Michaël J. Goran, M.D.

11:30 Summation - Robert J. Weiss, M.D.

11:40 Questions and Answers

12:00 Adjournment
CAS-COD-COTH JOINT MEETING

AAMC ANNUAL MEETING
Wednesday, November 13, 1974
2:00 - 5:15 P.M.

SPECIALTY DISTRIBUTION OF PHYSICIANS

2:00 - 2:30 P.M. A Congressional Perception of the Problem

   Mr. Stephen E. Lawton
   Counsel for the Subcommittee on
   Public Health & Environment
   of the House Interstate and
   Foreign Commerce Committee

2:30 - 3:00 P.M. Redistribution of Specialty Training
   Opportunities - Options for the Private Sector

   Arnold S. Relman, M.D.
   Chairman, Department of Medicine
   University of Pennsylvania
   School of Medicine

3:00 - 3:30 P.M. Redistribution of Specialty Training
   Opportunities - Options for the Government

   Theodore Cooper, M.D.
   Deputy Assistant Secretary for Health
   Department of Health, Education and
   Welfare

3:30 - 3:50 P.M. Intermission

3:50 - 5:15 P.M. Panel Discussion

   The panel discussion will take the form
   of a question and answer session during
   which the following three individuals
   will direct questions to the above
   speakers.

   Chairman: Julius R. Krevans, M.D., Dean
   University of California, San Francisco
   School of Medicine

   Robert A. Chase, M.D., Chairman
   Department of Anatomy
   Stanford University School of Medicine

   Charles B. Womer, Director
   Yale-New Haven Hospital

   Christopher C. Fordham, III, M.D.
   U. of North Carolina School of Medicine
DECEMBER 2, 1974                  CAS BRIEFS                  NO. 26

FEDERAL HEALTH MANPOWER EDUCATION SUPPORT POLICY

AT THE ANNUAL MEETING IN CHICAGO THERE WAS VIGOROUS DISCUSSION OF THE DIRECTIONS THE HEALTH MANPOWER LEGISLATION PRESENTLY BEING DEVELOPED IN CONGRESS IS TAKING. THE COUNCIL OF ACADEMIC SOCIETIES AGENDA FOR THAT MEETING INCLUDED A MEMORANDUM SUMMARIZING THE PROBLEMS POSED TO THE ACADEMIC MEDICAL COMMUNITY BY THE NEW LEGISLATIVE PROPOSALS. PLEASE READ THAT MEMORANDUM BEFORE RESPONDING TO THE ATTACHED QUESTIONNAIRE. THE VIEWS OF THE COUNCIL OF ACADEMIC SOCIETIES MEMBERS ARE NEEDED AND I URGE YOU TO RESPOND AS QUICKLY AS POSSIBLE. THE RESPONSE WILL BE CONSIDERED YOUR PERSONAL VIEW AS AN INDIVIDUAL ENGAGED IN MEDICAL EDUCATION AND NEED NOT REPRESENT THE CONSENSUS OF YOUR SOCIETY.

PLEASE RETURN THE QUESTIONNAIRE IN THE ENCLOSED ENVELOPE.

AUGUST G. SWANSON, M.D.
DIRECTOR OF ACADEMIC AFFAIRS

COUNCIL OF ACADEMIC SOCIETIES
Memorandum # 74-44A

To: Council of Academic Societies
From: John A. D. Cooper, M.D., President
Subject: Health Manpower Questionnaire

December 2, 1974

In connection with the Assembly's discussion of Association health manpower policy, certain information is needed from U.S. medical faculty on currently favored legislative approaches to providing federal assistance for health professions education. Responses should be based on your best personal judgment. This questionnaire has been prepared in a form that can be processed by computer; if you wish to make additional comments, please feel free to do so.

1. There was considerable discussion in meetings of the various Councils and of the Assembly about conditions established by the House or Senate for the receipt of capitation support. Should the Association position be to --

   a) continue opposing any requirements for basic capitation support for the cost of medical education? ___ ___ (1)

   b) accept the inevitability of conditions on capitation and seek to limit them to those to which most schools can respond? ___ ___ (2)

2. Regardless of your answer to question 1, of the following conditions that have been included in recent or current health manpower bills, which ones do you believe the schools should do in order to receive capitation or should not do even if it meant loss of capitation?

   a) One-time medical student enrollment increase of 5% or 10 students, whichever is greater ___ ___ (3)

   b) Offering or increasing a program for the training of physicians' assistants ___ ___ (4)

   c) Secure national service agreements from all entering students, with selection of graduates required to serve through a lottery ___ ___ (5)

   d) Secure national service agreements from 25% of entering students ___ ___ (6)
<table>
<thead>
<tr>
<th>Should do</th>
<th>Should not do</th>
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<tr>
<td>e) Secure national service agreements from 25% of entering students, with each such student entitled to federal support for tuition costs and living expenses</td>
<td>![ ] (7)</td>
</tr>
<tr>
<td>f) Secure agreements from students to repay the school for federal capitation payments in connection with the student's enrollment</td>
<td>![ ] (8)</td>
</tr>
<tr>
<td>g) Secure agreements from students to repay the government for capitation payments in connection with the student's enrollment, unless the student serves in the National Health Service Corps</td>
<td>![ ] (9)</td>
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<tr>
<td>h) Prepare a federally approved plan for the training of undergraduate medical students at a site away from the medical center, supported by an amount equivalent to at least 25% of the school's capitation payment</td>
<td>![ ] (10)</td>
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<tr>
<td>i) Establish a specified academic unit for primary care training whose faculty size and curriculum duration also would be specified</td>
<td>![ ] (11)</td>
</tr>
<tr>
<td>j) Establish residencies in family medicine or comparable primary care field, with program size specified</td>
<td>![ ] (12) (13)</td>
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<tr>
<td>k) Reduce the percentage of foreign medical graduates in affiliated graduate training programs to specified levels</td>
<td>![ ] (13)</td>
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3. Would you favor eliminating capitation with conditions and substituting direct subsidy to students, which would permit schools to increase tuition to meet more closely the costs of education?  

4. If your answer to question 3 was "yes," would you still prefer direct student subsidy if conditions were attached to it similar to existing conditions associated with capitation?  

5. Would you favor last-dollar support (a varying amount, individualized for each school, for that portion of the operating budget not covered by income from other sources), with federal requirements for certain institutional financial and other records, to --  

a) capitation without conditions  

b) capitation with conditions  

Yes No
c) direct student subsidy without conditions  __  __  (18)

d) direct student subsidy with conditions  __  __  (19)

6. Do you believe there should be a reduction in the number of residency training slots to 125 percent of U.S. medical school graduates, with no change in the distribution of slots among specialties, in order to reduce the number of FMGs?

7. Do you believe there should be control over the distribution of residency training slots among the various specialties (particularly to increase the proportion devoted to preparation of primary care physicians) and over the number of slots (limiting them to 125 percent of U.S. medical school graduates in order to reduce the number of FMGs)?

8. If the answer to question 6 or 7 was "yes," would you prefer that the control be exercised by --

   a) a federal commission whose members would be appointed by the HEW Secretary?  __  __  (22)

   b) the private sector, through a non-government group such as the Coordinating Council on Medical Education?

   __  __  (23)

# # # #

The questionnaire should be completed by December 13, 1974, and returned to --

John A. D. Cooper, M.D.
President
Association of American Medical Colleges
Suite 200
One Dupont Circle
Washington, D.C.  20036

If you have any questions, contact Prentice Bowsher, AAMC Director of Federal Liaison, whose phone number is 202-466-5190.
The Assembly is the highest legislative body of the Association; by virtue of a recent change in the Bylaws, the Council of Academic Societies now has a sufficient number of seats in the Assembly to accommodate all 57 member societies. It is important that a representative from each society be present at the Assembly Meeting in the Williford Room on Thursday, November 14, from 1:00 to 4:00 p.m. at the Conrad Hilton Hotel in Chicago, Illinois. While both representatives from a society may attend, each society has only one vote.

You will be receiving a copy of the Assembly Agenda under separate cover. The major topic for discussion will be a reappraisal of Association policy regarding Federal support for medical education. This issue is of importance to everyone in academic medicine.

Attachment: CAS Business Meeting Agenda

August G. Swanson, M.D.
Director of Academic Affairs

Council of Academic Societies
BORDEN AWARD FOR OUTSTANDING BIOMEDICAL RESEARCH - NOMINATIONS

THE BORDEN AWARD IN THE MEDICAL SCIENCES WAS ESTABLISHED BY THE BORDEN COMPANY FOUNDATION, INC. IN 1947 AND CONSISTS OF $1,000 IN CASH AND A GOLD MEDAL TO BE GRANTED IN RECOGNITION OF OUTSTANDING CLINICAL OR LABORATORY RESEARCH BY A MEMBER OF THE FACULTY OF A MEDICAL SCHOOL WHICH IS A MEMBER OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES.


REGULATIONS GOVERNING THE AWARD

1. THE AWARD IN ANY YEAR WILL BE MADE FOR RESEARCH WHICH HAS BEEN PUBLISHED DURING THE PRECEDING FIVE CALENDAR YEARS.

2. NO PERSONS MAY RECEIVE MORE THAN ONE BORDEN AWARD FOR THE SAME RESEARCH ALTHOUGH HE/SHE MAY RECEIVE A LATER AWARD FOR A DIFFERENT RESEARCH PROJECT.

3. IF TWO OR MORE PERSONS WHO HAVE COLLABORATED ON A PROJECT ARE SELECTED FOR AN AWARD, THE GOLD MEDAL AND CHECK SHALL BE PRESENTED TO THE GROUP, AND BRONZE REPLICA OF THE MEDAL PRESENTED TO EACH OF THE COLLABORATORS.

4. THE ASSOCIATION MAY REFRAIN FROM MAKING AN AWARD IN ANY YEAR IN WHICH NO PERSON REPORTS RESEARCH OF THE QUALITY DESERVING AN AWARD.

5. ONLY ONE AWARD SHALL BE MADE DURING ANY ONE YEAR.
6. A nominee who fails to receive the Award may be nominated for the Award for the same work in a subsequent year.

7. Materials supporting nomination should include:

   A. Six copies of a statement covering the academic history and scientific accomplishments of the nominee.
   B. Six copies of a reasoned statement of the basis for the nomination.
   C. Six copies of reprints reporting the nominee's important research.

Nominations received prior to May 15 will be forwarded to the Borden Award Committee. The Award is presented each year at the Annual Meeting. Attached is a list of prior recipients of the Borden Award.

Attachment

August G. Swanson, M.D.
Director of Academic Affairs

Council of Academic Societies
The Borden Award

Since 1947 the Association, in cooperation with the Borden Company Foundation, has presented an annual award in the medical sciences in recognition of "outstanding research in medicine conducted by a member of the faculty of an affiliated college." This award consists of $1,000 in cash accompanied by an inscribed gold medal. Recipients have been:

1973—Dr. Thomas C. Merigan, Jr., professor of medicine and chief, Division of Infectious Disease, Stanford University School of Medicine, was selected for his work with the antiviral protein interferon. In 1965 Dr. Merigan and his associates produced evidence that systematic production of interferon would protect humans against viral infections. This work consisted of demonstrating that the systemic interferon produced by infants following their live measles vaccine immunization made them resistant to challenge by an immunologically unrelated virus—the vaccinia used in their smallpox vaccination.

1972—Dr. George C. Cotzias, professor of medicine, State University of New York at Stony Brook School of Medicine and professor of neurology, Mount Sinai School of Medicine, was cited for his findings which established L-dihydroxyphenylalanine (L-dopa) as a therapeutic drug in the treatment of Parkinsonism. His findings were based on a study in which he used chronically administered high oral doses of L-dopa to produce significant improvement in the conditions of two-thirds of the study subjects.

1971—Dr. Joseph Willis Beard, professor of surgery and virology, Duke University School of Medicine, was cited for his extensive research into the etiology of cancer, his ingenuity in developing new approaches to the study of virology, and his contributions culminating in the isolation, identification, and characterization of several strains of avian viruses.

1970—Dr. Robert A. Good, Regents' Professor of Pediatrics and Microbiology, University of Minnesota—Minneapolis Medical School, and recognized physician, scientist, educator, and editor, was cited for the direction of his research and cumulative achievements, in the study of developmental and phylogenetic immunology as related to processes in both animals and man.

1969—Dr. Abraham White, professor and chairman, Department of Biochemistry, Albert Einstein College of Medicine, was the recipient for his outstanding research developments in the field of biochemistry. Dr. White's current research has resulted in the isolation of two hormones from the thymus gland. In clinical application, these two substances have vast potential for prolonging survival of first- and second-skin allografts and for the treatment of malignancies involving lymphoid tissue.

1968—Dr. Arthur Kornberg, professor and executive head, Department of Biochemistry, Stanford University School of Medicine, was presented this award for the enzymatic synthesis of DNA and the demonstration that infective viral DNA can be synthesized from pure chemical reagents and enzymes. These discoveries opened the way for the synthesis and modification of genetic material and have implications in the prevention and treatment of cancer and genetic disorders.

1967—Dr. Seymour S. Cohen, Hartzell professor and chairman, Department of Therapeutic Research, University of Pennsylvania School of Medicine, received recognition for his pioneering efforts in biochemical virological investigations. After describing the alteration of macromolecular synthesis caused by virus infection in cells, he isolated and characterized the unique phage acid constituent 5-hydroxymethylcytosine and demonstrated the induction of enzymes by viruses which are required for its synthesis. Also, Dr. Cohen's investigation of the chemical mechanisms by which therapeutic agents exert their biological effects demonstrated the inhibition of thymidylate synthetase by fluorodeoxyuridylate and in a series of studies on streptomycin showed that the lethal effects of this antibiotic were related to abnormal ribosomal RNA synthesis.

1966—Dr. Oliver H. Lowy, professor and chairman, Department of Pharmacology, Washington University School of Medicine; and Dr. Janet V. Passonneau, associate professor, Department of Pharmacology, Washington University School of Medicine, were presented the Borden Award for their teamwork in the study of the nature of the regulation of the rates for key enzyme-catalyzed reactions in the glycolytic sequence.

1965—Dr. Paul C. Zamecnik, chairman, Department of Medicine, Harvard Medical School, was cited for his research and great triumphs in the field of modern biology. It was Dr. Zamecnik and his associates at Harvard who first achieved the demonstration of protein synthesis in a well defined, cell-free system. In a series of pioneering investigations, they were able to establish much of the chemical framework for the process of protein biosynthesis.

1964—Dr. Harry Eagle, professor and chairman, Department of Cell Biology, Albert Einstein...
College of Medicine, was recognized for contributions to the growth of animal cells in culture which have been extensive and fundamental. His now classic work on the nutritional requirements and metabolic activity of human and animal cells in cultures opened broad new fields of endeavor in cell biology, virology, genetics, and cancer research.

1963—Dr. Klaus H. Hofmann, professor and chairman, Department of Biochemistry, University of Pittsburgh School of Medicine, and editor, Journal of Biological Chemistry, was cited for his work in peptide chemistry and reference to the relation between structure and function of the adrenocorticotropic and other hormones of the pituitary gland; for his research on the structural analysis and synthesis of biotin; for his discovery of a new class of long-chain fatty acids containing the cyclopropane ring; and for his work on steroids, terpenes, and proteolytic enzymes.

1962—Dr. Leon O. Jacobson, professor and chairman, Department of Medicine, University of Chicago Pritzker School of Medicine, was selected for his studies of hemopoiesis; his research on the role of the spleen in protection against radiation; establishment of foundation for the presence of a humoral system in the regulation of erythropoiesis in mammals; and for demonstrations of the importance of the kidney as a source of erythropoietin.

1961—Dr. H. M. Magoun, professor of anatomy, University of California at Los Angeles School of Medicine, was presented this award for his many contributions in the field of neurophysiology and for his discoveries revolutionizing concepts of brain organization and function.

1960—Dr. Robert F. Pitts, professor and chairman, Department of Physiology, Cornell University Medical College, received recognition for his fundamental studies on renal tubular function, for his mastery of known techniques for studying kidney function, and for his development of new methods, which were applicable to mammals, including man.

1959—Dr. Theodore T. Puck, professor and head, Department of Biophysics, University of Colorado School of Medicine, developed a method for cultivation in vitro of colonies from single mammalian cells and extended investigations which were derived from this method.

1958—Dr. Severo Ochoa, professor and chairman, Department of Biochemistry, New York University School of Medicine, received this award for his work on enzymatic synthesis of ribonucleic acid.

1957—Dr. Murray L. Barr, professor and head, Department of Microscopic Anatomy, University of Western Ontario Faculty of Medicine, was presented this award for his work on sexual dimorphism in the structure of the resting mammalian nuclei.

1956—Dr. Harry S. N. Greene, the Anthony N. Brady Professor of Pathology, Yale University School of Medicine, received recognition for his many contributions to the field of oncology, particularly in the transplanting of neoplasms.

1955—Dr. Charles B. Huggins, recipient of the Nobel Prize in Physiology and Medicine 1966, director, the Ben May Laboratory for Cancer Research; and professor of urology, University of Chicago Pritzker School of Medicine, provided outstanding contributions in the field of cancer research, particularly in the area concerning relationships between the endocrine glands and cancer.

1954—Dr. Karl F. Meyer, professor of experimental pathology and director, the George Williams Hopper Foundation, University of California, San Francisco, received this award for his contributions to knowledge of plague, the psittacosis group of viruses and brucellosis.

1953—Dr. Jean R. Oliver, distinguished service professor, State University of New York Downstate Medical Center, was presented this award for developing a technique of microscopic dissection of the kidney.

1952—Dr. William S. Tillett, professor of medicine, New York University School of Medicine, received recognition for his research in the mechanism of blood clot liquefaction and for the discovery of the streptococcal enzymes, Streptokinase and Streptodornase.

1951—Dr. Edwin B. Astwood, research professor of medicine, Tufts University School of Medicine, was cited for outstanding research in the field of endocrinology with special reference to hyperthyroidism.

1950—Dr. Gerty T. Cori, professor of biochemistry, Washington University School of Medicine, was recognized for fundamental contributions to the understanding of carbohydrate metabolism.

1949—Dr. Fuller Albright, associate professor of medicine, Harvard Medical School, was selected for his original contributions to the understanding of the metabolism of bone and other tissues, and its relation to renal and endocrine factors.
ENCLOSED ARE SEVERAL ITEMS THAT ARE SENT TO YOU IN ORDER TO FACILITATE REPORTING BY OFFICIAL REPRESENTATIVES OF THE COUNCIL OF ACADEMIC SOCIETIES TO THE SOCIETIES THEY REPRESENT.

AN OVERVIEW OF AAMC ACTIVITIES HAS BEEN PREPARED TO GIVE YOU CONCISE, SUCCINCT NOTES OF AAMC’S MANY PROGRAMS DURING THE PAST YEAR. MORE DETAILED INFORMATION ABOUT AAMC’S ACTIVITIES IS AVAILABLE IN THE AAMC ANNUAL REPORT WHICH WAS DISTRIBUTED TO ALL REGISTRANTS AT THE AAMC ANNUAL MEETING LAST NOVEMBER IN CHICAGO. FOR OFFICIAL CAS REPRESENTATIVES WHO DID NOT ATTEND THE ANNUAL MEETING, A COPY OF THE AAMC ANNUAL REPORT IS ALSO ENCLOSED.


IN THE VERY NEAR FUTURE A NEW EDITION OF THE CAS DIRECTORY WHICH IS CURRENTLY UNDERGOING REVISION WILL BE SENT TO YOU. IF YOU WOULD FIND ADDITIONAL INFORMATION HELPFUL IN THE MEANTIME, PLEASE WRITE:

August G. Swanson, M.D.
DIRECTOR, DEPARTMENT OF ACADEMIC AFFAIRS
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
#1 DUPONT CIRCLE, N.W., SUITE #200
WASHINGTON, D.C. 20036

ENCLS. 3
MINUTES
COUNCIL OF ACADEMIC SOCIETIES
BUSINESS MEETING

November 12, 1974
Conrad Hilton Hotel
Washington, D.C.

I. Call to Order

The meeting was called to order at 2 p.m. Dr. Ronald W. Estabrook, Chairman, presided. Seventy individuals, representing 45 of the 57-member societies, were present. Societies not represented were:

- American Association for the Study of Liver Diseases
- American College of Obstetrics/Gynecology
- American College of Psychiatrists
- American Pediatric Society
- American Society for Clinical Investigation, Inc.
- American Society of Biological Chemists
- American Society of Therapeutic Radiologists
- Association for Medical School Pharmacology
- Association of Professors of Medicine
- Association of University Radiologists
- Biophysical Society
- Society of Surgical Chairmen

II. Approval of Minutes

The minutes of the meeting held March 7, 1974 were approved as circulated.

III. Chairman's Report

A copy of the report given by the Chairman was distributed to the membership.

IV. President's Report - John A.D. Cooper

Since options for Association policy on federal funding of medical schools was on the agenda, this was not taken up as a specific item in the President's Report. Dr. Cooper commented on the Washington scene as characterized by confusion. The change from the Nixon Administration to the Ford Administration has not to date been reflected in the policies with regard to the health area. An openness, however, now exists, and it is hoped that more opportunity will be given for discussion with policy-makers of the federal government. The adversarial position between the Executive and the Congressional branches which started in the Johnson Administration continues in the Ford Administration. Mr. Ford has advocated a National Health Insurance, a stance felt to enhance his position with the nation during the remainder of his term.
Dr. Cooper spoke of the appointment of Paul O'Neill, successor to Fred Malek, as Deputy Director of the Office of Management and Budget. Mr. O'Neill is very knowledgeable about the health area, is a sound thinker, and is experienced by his previous role in OMB. He will be interested much more in program analysis and justification than his predecessor -- a fact interpreted to mean that to get its budgets through OMB, the DHEW will need to provide a much greater substantiation of programs.

Another event that will affect medical education is the enactment of the Congressional Budget and Impoundment Control Act (PL 93-344) which establishes new House and Senate Committees on the Budget and generally revises the Congressional budget review process. The law establishes a Congressional Budget Office (CBO) staffed by budget experts (without regard to political affiliation) to provide a continuing "scorekeeping" analysis of the federal budget, appropriations and authorizations bills, revenues and receipts, and changing revenue conditions. The CBO is to attempt to analyze all public bills (estimating five-year costs, compatibility with budget targets, etc.) and to provide general budget information for Congressional Committees.

In the past, each of the Appropriations Subcommittees has acted more or less independently with no real overview of the entire appropriations process by the House before the total of the appropriations comes out. The budget reform will in essence result in an examination of the health budget under closer scrutiny by the budget control committee comprised of Congressmen and Senators who are not advocates for health. They will have to approve the subcommittee recommendations before they can be enacted finally and appropriated.

V. Report of the Director, Department of Academic Affairs - August G. Swanson

Dr. Hilliard Jason, formerly of Michigan State University College of Human Medicine and most recently serving a two-year appointment as Special Education Consultant to the National Library of Medicine, joined AAMC in September heading a newly created program, the Division of Faculty Development. Dr. Jason is well-known in medical education and is especially well qualified to assume this responsibility.

Dr. Tom Morgan, now at the University of Washington -Seattle, joins the AAMC as Director of the Division of Biomedical Research effective January, 1975, succeeding Dr. Mike Ball. Dr. Morgan has extensive research experience and currently serves on the Council of the Heart and Lung Institute.

As had Drs. Estabrook and Cooper before him, Dr. Swanson expressed regret in losing Dr. Ball whose resignation becomes effective December 31, 1974.
Dr. Swanson reported on three major projects related to direct services to the medical schools and to the CAS:

1. Under the direction of Dr. William Cooper, the Educational Materials Project has made excellent progress toward the development of a clearinghouse system for nonprint multimedia learning materials. Review panels nominated by various officers of the CAS member societies have now evaluated over 2,800 items of audiovisual learning materials. It is anticipated that by next year a limited number of titles with full abstract descriptions will be available through a National Library of Medicine computer system similar to MEDLINE called AVLINE.

2. The Medical College Admission Assessment Program (MCAAP), the AAMC's program to revise the Medical College Admission Test (MCAT), is well under way. Through contract with a national testing agency, AAMC is developing an entirely new set of cognitive exams. This will be targeted on the development of exams to assess reading comprehension, quantitative ability, and achievement of knowledge in biology, chemistry, and physics. Simultaneously the MCAAP is beginning to work on developing systems and methods for exploring noncognitive variables in the assessment of students for selection to medical school.

3. Through support from the Bureau of Health Resources Development within the next year the Division of Educational Measurement and Research will be doing an in-depth study of the 3-year curriculum movement in this country. This study will concentrate on the characteristics and the outcomes of the 3-year curriculum efforts in about 17 U.S. medical schools and will match those against a control group of schools with 4-year curricula.

VI. Action Items

A. New Application

ACTION: The application for membership of the Society for Critical Care Medicine was unanimously approved.

B. Nominations for the Borden Award for Outstanding Biomedical Research

Regulations regarding nominations for the Borden Award appeared in the CAS Agenda on page 12. The CAS Administrative Board recommended that the process of nomination be expanded to provide for each society's submitting one nomination for the Borden Award. In the past solicitations for nominations were sent only to members of the Assembly.

ACTION: The recommendation by the Administrative Board that each Society submit at least one nomination for the Borden Award for Outstanding Biomedical Research was unanimously approved.
C. Report of AAMC Task Force on GAP Committee Report of NBME

CAS held a detailed discussion of the AAMC Task Force Report on the Goals and Priorities Committee recommendations to the National Board of Medical Examiners. The CAS agreed with the concept of a universal qualifying exam, to be required of all students prior to entering graduate medical education, but strongly recommended that the present Parts I, II, and III of the National Boards not be abandoned until such time as a new qualifying exam has been thoroughly tried and its validity determined. The Council also strongly recommended that the Liaison Committee on Medical Education require that in the process of accrediting medical schools, data on student achievement acquired from external evaluations be provided to the accrediting team. This recommendation grew out of a serious concern by the CAS that the basic and clinical sciences content of medical education not be further eroded. The Council also recommended that the results of a qualifying exam be transmitted to the medical schools and to the graduate programs to which students are applying.

D. Dr. Neal L. Gault, Jr., M.D., Chairman of the AAMC Task Force, Dr. Edmund Pellegrino, Chairman of the NBME Advisory Committee on Undergraduate Medical Evaluation, Dr. Robert A. Chase, President of the NBME were present to participate in these deliberations. After an extensive discussion, the CAS took the following action:

**ACTION:** The Council accepted the "Gault" Report as submitted in the Agenda on pages 23-24 with the following modifications.

1. Delete Paragraph No. 1 and substitute the following:

   The Task Force believes that the 3-part system should not be abandoned until a suitable examination has been developed to take its place and has been assessed for its usefulness in examining medical school graduates in both the basic and clinical science aspects of medical education.

2. Delete Paragraph Nos. 2 and 3 and substitute the following:

   Be it resolved that the AAMC recommend that the Coordinating Council on Medical Education and the Liaison Committee on Medical Education require as a part of the accreditation process that medical schools provide evidence of utilizing external evaluation data in the assessment of the educational achievement of students as they progress through a school's curriculum with continuing emphasis on the basic sciences.
3. Accept the first paragraph of Paragraph No. 4 with only one recommendation (g): that graduates of both domestic and foreign schools should be required to pass the exam as a prerequisite for entrance into accredited programs of graduate medical education in the U.S.

The other sub-paragraphs listed as recommendations in this item (a-f) should be transmitted to the National Board as information items. The first three of these, a-c, should be transmitted without change. Item (d) is modified to read:

The results of the exam should be reported to the students and through the students to the graduate programs to which they are applying and to the licensing boards that require certification for graduate students.

Item (e) is modified to read:

The exam results may be reported to medical schools if they request them.

Item (f) is unchanged.

4. Paragraph Nos. 5, 6, and 7 are accepted without change.

5. A final paragraph should be added to direct the National Board of Medical Examiners to administer the examination early enough in the student's terminal year that the results can be transmitted to the program directors without interference in the matching plan.

E. Options for Association Policy on Federal Funding of Medical Schools

Dr. D.C. Tosteson, Chairman of the AAMC, was present to review the options for AAMC policy on federal funding of medical schools and to respond to questions of the Council of Academic Societies. The need for the faculties to assure that the programs of medical education not be dictated by federal legislation was reiterated by Dr. Estabrook and others. The purpose of the discussion was to permit the Council of Academic Societies the greatest possible contribution to the variety of options that would be more fully developed at the subsequent meeting of the Assembly. Although an action was not required, the Council of Academic Societies wished to go on record as having taken the following action.
ACTION: The Council voted unanimously to support the following action taken by the CAS Administrative Board on September 19:

The CAS Administrative Board voted unanimously to recommend that the AAMC be advised of the faculty's concern about the portions of the proposed HPEA bill that constrain and impinge upon the integrity of undergraduate and graduate medical education even to recommend the defeat of the total bill. The CAS Administrative Board further recommends that every Dean and every Board of Trustees seek every opportunity to obtain funding through alternative means such as tuition increases, increased support from state legislatures, or a decrease in faculty size where necessary to preserve the role of the medical schools in developing and implementing educational programs.

F. Election of Nominating Committee

ACTION: The Council of Academic Societies elected the following to constitute the 1975 CAS Nominating Committee.

From the Clinical Sciences:
G.W.N. Eggers, Jr., M.D., University of Missouri
William L. Parry, M.D., University of Oklahoma
Daniel Freedman, M.D., University of Chicago

From the Basic Sciences:
Carmine D. Clemente, Ph.D., UCLA
James B. Preston, M.D., SUNY Upstate Medical Center

G. Resolution from the Society of Academic Anesthesia Chairmen

ACTION: The resolution from the Society of Academic Anesthesia Chairmen regarding the critical shortage of academic anesthesiologists was referred for consideration to the CAS Administrative Board.

H. U.S. Faculty Visiting at the Universidad Autonoma de Guadalajara

The questions posed by this situation were summarized in the Agenda on page 66. Dr. Eastwood suggested that it would be helpful if the AAMC's opinion of the Guadalajara operation could be made available to students. With regard to the major question of involvement of U.S. faculty at Guadalajara, the opinion was expressed by Dr. Relman that this issue was inappropriate for action of the CAS but rather should be a matter for attention of the individual U.S. medical school administrations. Dr. Relman's statement was accepted as the consensus of the CAS.
I. Election of Members to the 1974-75 CAS Administrative Board

ACTION: The Council elected by ballot the following to serve on the CAS Administrative Board effective 1974-75:

Chairman-Elect
Rolla B. Hill, Jr., M.D., SUNY Upstate Medical Center

For Administrative Board, from the Basic Sciences
Robert M. Berne, M.D., University of Virginia
F. Marion Bishop, Ph.D., University of Alabama

For Administrative Board, from the Clinical Sciences
David R. Challoner, M.D., Indiana University
Thomas K. Oliver, Jr., M.D., University of Pittsburgh

J. Installation of Chairman

ACTION: Dr. Jack W. Cole was installed as Chairman of the Council of Academic Societies for 1974-75.

K. Commendations

ACTION: In separate actions by acclamation the Council expressed sincere appreciation and congratulations for their leadership and service to Dr. Ronald W. Estabrook, CAS Chairman for 1973-74, and to Dr. Michael F. Ball, Director of the AAMC Division of Biomedical Research, August 1, 1972-December 31, 1974.

VII. Adjournment

ACTION: The meeting was adjourned at 5:20 p.m.
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
PROGRAMS AND ACTIVITIES*
1974 OVERVIEW

The Association of American Medical Colleges (AAMC), working with its members, engaged in a wide range of activities during 1974. Foremost among these were those in the following areas:

BIOMEDICAL RESEARCH

1. AAMC's impoundment suit was instrumental in procuring release by President Nixon of $165 million FY 1973 funds -- $29 million in health manpower special project funds and $136 million in NIH funds for research, research training, and fellowships.

2. AAMC consulted in drafting regulations on the conduct of biomedical research and took a leadership role of liaison in supporting legislation to establish a national ethics commission.

3. In discussions with key Administration and Congressional representatives, AAMC lent strong support to the system of peer review of proposals for Federal research funding.

4. In testimony before both the House and Senate Appropriations Committee, the Association stressed the importance of the NIH Research and Training Programs and the General Research Support Program, as well as the need for adequate funding for each.

*This summary has been especially prepared for the Council of Academic Societies. For greater detail, see the AAMC Annual Report, 1974, which was distributed at the AAMC Annual Meeting, November, 1974.
5. With staff of NIH Division of Research Resources, AAMC developed a cost analysis and rate setting manual for animal research facilities. In discussions with NIH, Department of Agriculture, and others, AAMC emphasized that regulations must not adversely affect biomedical research.

6. AAMC continued to support a balanced national program of high quality of biomedical research and opposed establishment of additional categorical disease institutes or institutes dedicated to one or more organ systems at the NIH.

FACULTY

1. AAMC established a Division of Faculty Development to assist faculty through programs and workshops designed to develop effective instructional strategies and improve methods of evaluating student performance.

2. AAMC, through the Faculty Roster, has provided to the medical schools data on faculty composition, mobility, and retention and initiated special manpower studies.

3. Special AAMC studies included the Financing of Medical Education, which examined the manner in which faculty allocate effort, and the annual Medical School Faculty Salary Study.

EDUCATION

1. To obtain data on the degree to which academic medical centers have moved to assume institutional responsibility for graduate medical education, AAMC conducted a questionnaire survey of all centers.

2. Based on the report of its Task Force on Foreign Medical Graduates, AAMC adopted position that all students seeking graduate medical education pass a national qualifying exam.
3. AAMC commissioned a Task Force to study the implications of the Goals and Priorities (GAP) Report of the National Board of Medical Examiners.

4. AAMC, through the Medical College Admissions Assessment Program, began development of separate tests of cognitive assessment to replace the Medical College Admission Test (MCAT).

5. AAMC held a colloquium where experts in career development met to discuss the influence of selection and education on career choice.

6. The AAMC's project with the National Library of Medicine and the American Association of Dental Schools to identify, review, and assess effective nonprint educational materials completed its first year.

7. AAMC completed a feasibility study on developing a health sciences multimedia learning advancement program.

8. AAMC published and distributed 40,000 copies of the Medical School Admission Requirements (25th ed.).

9. AAMC published the third edition of the Curriculum Directory with expanded information on the required and elective programs in the U.S. and Canada.

10. AAMC continued distribution of the AAMC Education News, a newsletter reporting on instructional innovation, assessment, and curriculum, to over 36,000 full-time medical school faculty members.

FEDERAL LIAISON

During 1974 AAMC presented testimony on the following:

1. District of Columbia Medical and Dental Manpower Act of 1970.


4. Title I (Indian Health Manpower) of the Indian Health Care Improvement Act.

5. Health planning, resource development, and regulation.

6. Fiscal 1975 budget for the medical program of the Veterans Administration.

7. National Health Service Corps and the Public Health and National Health Service Corps Scholarship Training Program.

8. DHEW appropriations regarding the President's fiscal 1975 budget.


12. Health manpower legislation regarding the distribution of health care by specialty.

HEALTH CARE

1. AAMC sponsored a national invitational Institute on Primary Care and planned subsequent regional workshops.

2. AAMC was active to support, through technical assistance and consultation, institutions involved in development of prototype HMOs.

3. AAMC initiated a program, which will involve six representative institutions, to develop model curricula for physician training based upon medical practice requirements of HMOs.

4. AAMC continued its efforts on the Longitudinal Study of the Class of 1960 and began preparation to conduct a major follow-up of the cohort to derive data on health manpower issues.

5. AAMC conducted a study on the teaching of community medicine in Colombia, Ethiopia, Thailand, and Turkey.

6. AAMC continued its study on the impact of national health service plan on medical education in Canada, the United Kingdom, and Sweden.
STUDENTS

1. AAMC expanded its analysis and reporting of data on applicant admission activity.

2. AAMC processed 268,090 applications for admission to 83 medical schools through AMCAS (American Medical College Application Service).

3. AAMC sponsored an Early Decision Plan, in which 51 institutions participated, through which 628 students were admitted without filing an application to any other school.

4. AAMC tested a pilot admissions matching plan in which all schools in California and Michigan participated.

5. AAMC developed Simulated Minority Admissions Exercises which are being used by medical school admissions officers and committees.

6. AAMC filed an amicus curiae brief on behalf of the defendant, the University of Washington, in the case of De Funis v. Odegaard, which was heard by the Supreme Court.

7. AAMC testified to recommend strongly that Federal grants-in-aid and loans to medical students be continued and that the annual limitation on grants-in-aid be increased from $3,500 to $4,500.

8. AAMC supported provisions for loan forgiveness for students who choose to serve in the National Health Service Corps or practice in a health shortage area.

9. AAMC held workshops which over 100 medical school financial aid officers attended.

10. AAMC joined the coalition pressing for modification of the Buckley Amendment dealing with accessibility of student records.

11. AAMC continued COTRANS (the Coordinated Transfer Program for U.S. citizens studying medicine abroad.)
12. AAMC strengthened its liaison with premedical advisors through
the development of an information service which makes available to them
admissions data about national and individual undergraduate school appli-
cant pools and by providing financial support to the new National Asso-
ciation of Advisors for the Health Professions.

13. AAMC continued the administration of a US/PHS Fellowship
Program for medical students in Yugoslavia.

INSTITUTIONAL DEVELOPMENT

1. AAMC continued its Management Advancement Program which consists
of a series of seminars which have attracted, in addition to the deans,
63 department chairmen, hospital administrators, vice presidents, chancellors,
and others.

2. AAMC sponsored a Delphi forecast of the future of medical
education.

3. AAMC established a file on medical school governance.

4. AAMC studied the process and authority for appointment, promotion,
award of tenure, and dismissal of faculty.

5. AAMC examined the status of collective bargaining in higher
education and its implications for medical school faculties.

6. AAMC has attempted to identify appropriate models for data
collection and documentation of personnel procedures to assure insti-
tutional compliance with federal regulations for equal opportunity for
women and minorities.
TEACHING HOSPITALS

1. In response to regulations regarding the payment of teaching physicians under Medicare, AAMC studies of reimbursement at six medical centers were instrumental in delaying implementation of Section 227 pending a more thorough analysis.

2. With regard to Section 223 of PL 92-603, an AAMC analysis of the SSA's grouping methodology demonstrated that the hospital groups established in the regulations were no better than random groupings.

3. AAMC also responded to proposed regulations seeking to implement other sections of the Social Security Amendments and directly affecting teaching hospitals.

4. AAMC organized a task force to review and analyze the 1973 revisions of the Joint Commission on the Accreditation of Hospitals.

5. AAMC undertook a survey to examine the organizational and functional arrangements of computer services in university-owned teaching hospitals.

6. AAMC conducted the sixth annual Survey of House Staff policy.

COMMUNICATIONS

The AAMC communicates its views, studies, and reports to its constituents and others through a variety of publications, news releases, press conferences, and personal interviews.

1. The major communications vehicle to constituents is the "President's Weekly Activities Report" which is issued 43 times a year and reports on AAMC activities and Federal activities that directly affect medical education, biomedical research, and health care.

2. The AAMC's major scholarly publication, which appears monthly, is the Journal of Medical Education.

3. AAMC publishes several other specialized newsletters.
The faculties of American medical schools have successfully survived another turbulent year. During this year the faculties have shown a remarkable capacity to adapt to subtle, but significant, changes imposed by both external and internal forces which have begun to attenuate their roles in fulfilling their responsibilities for medical education and biomedical research. Further, new constraints have been proposed and many of the vexing problems facing medical education have only recently come into focus, so that detailed study and constructive action can be taken in the near future. The CAS, through its Administrative Board, has attempted to reflect the concerns and interests of the faculties of our medical schools by input into the decision-making process for the establishment of AAMC policy on a broad range of topics.

MANPOWER

Physician

The most obvious impact on faculty activities has occurred as a result of social and legislative pressure which is attempting to correct the
ills of the health care delivery system through modifying the educational experience of students while in medical school or in graduate training. Many of us firmly believe that erroneous assumptions have been made by those who assign all of the problems of physician distribution to their formative, education years. Pending legislation for the continuation of federal assistance for health professions education is a prime example of an attempt by an external force to mold a change in the pattern of medical education so that students graduating from medical schools today meet a perceived need in supplying health services to the population. Those in decision-making positions seem deaf to the arguments that the educational process, per se, will not markedly alter the career selection of graduating medical students with regard either to their geographic or specialty choice for the practice of medicine.

The emphasis on the development of primary care educational programs has created conflicts within our institutions and between institutions. Primary care education has been interpreted by some to mean a de-emphasis on education in the basic medical sciences. This I find particularly disturbing, because a physician assuming responsibility for continuing, comprehensive care of patients is a physician most in need of a strong basic science foundation.

**Biomedical Research Manpower**

The furor over the rapid federal retreat from research manpower training support, which was evident a year ago, has been temporarily quieted by the AAMC's successful suit for the release of impounded
research and research training funds, and the passage of the National Research Act. This immediate short-term answer has served to satisfy the present day needs of our constituency. However, there will be major efforts in the administration and on both sides of the aisles in the Congress to reduce the federal budget. Funding for research manpower training is likely to be considered a controllable variable. Unless we act together to explain the importance of a long-term research manpower training program, the biomedical research capability of this country may be seriously crippled by a rush toward federal budget cutting.

The primary product of our institutions is manpower. Physician manpower and research manpower are the two that most concern me, for the faculties must be responsible for assuring that in all the medical schools there is a strict adherence to quality standards in educating these people. There is little question that the dependency of our institutions on state and federal governments for their support places them in a vulnerable position. The faculties must decide when the demands for program changes, which are coupled with financial support, exceed the bounds of tolerance in their infringement on the traditional rights of faculties to be fully responsible for the education and training of students. Resisting such infringement cannot be left to a few administrators or to your officers and staff in the Association of American Medical Colleges.

Specific manpower problems which have engaged the CAS and the AAMC this year are the role of the foreign medical graduate in American medicine and the recruitment of greater numbers of minority representa-
tives and women in our schools as students and faculty in compliance with affirmative action requirements. These challenges are changing the scope and character of both the undergraduate and graduate medical education in our institutions. As an aside, I would urge that you each re-read both the AAMC Foreign Medical Graduate position statement and the CCME report on the same subject. Licensed foreign medical graduates practicing in our Country are very upset by these documents and have begun to organize to prevent a change in policy. We must emphasize that we are not opposed to the immigration of physicians but rather demand that they meet the same quality standards as our graduates.

Accreditation

The accreditation of both undergraduate and graduate medical education is becoming an ever-more important process. Accreditation assures both students and the public that our institutions are maintaining their excellence and are providing education programs suitable to the needs and expectations of the students they admit. The Liaison Committee on Medical Education and the Liaison Committee on Graduate Medical Education need strong input from the faculties through the CAS if the accreditation system is to accomplish its purpose. The membership of the CAS, and in particular the basic biomedical scientists, must assume a more active role in the accreditation process. I strongly urge that the CAS set this as a goal of highest priority for the future, and we seek the unselfish cooperation of all to offer your services to these important accrediting bodies and that you serve when called upon to carry out this duty.
The national policy for biomedical research remains unclear; the trend toward directed research through the contract instrument appears to be continuing, and the pressure for the establishment of more and more categorical research programs grows. Included in your Agenda is a policy statement by the Association which urges that this direction of development of national policy be carefully examined and that further growth be allowed only after careful evaluation. In this area, the self-interest of various disciplines or specialties within the CAS may come into conflict. It is my hope that such conflicts can be resolved in a manner which will further the maintenance of a strong and broad biomedical research endeavor in this country.

The ethics of human research will be heavily scrutinized during this coming year. The public demands that clear ethical boundaries be established and enforced. Our concern must be that these boundaries are reasonable and that the system for monitoring the ethical behavior of biomedical investigators and their institutions be both fair and workable. Here again, the CAS has an enormous role to play and an enormous stake in the outcome. For example, whether fetal research continues in our country cannot be just the concern of a few neonatalogists or obstetricians; the ethical guidelines for research on developing humans before and after birth must concern us all.

The importance of scholarly biomedical research in the milieu of the academic environment of our institutions is becoming a critical issue. The rapid development of new medical schools without significant research programs, the enlargement of the classes in existing...
medical schools, and the shortening of curricula in some schools, are reducing the opportunity for students to become familiar with research and the intellectual rigor research imposes. This must concern the CAS; the solution is not clear, for the pressure from the public is for the expedient production of M.D.s, not the education of learned physicians.

HEALTH SERVICES

Our institutions are on the one hand being asked to develop innovations in the delivery of health services, while on the other, they are becoming more and more dependent on the income derived from providing health services in the traditional manner. This year I, as a biochemist, learned a great deal about this dilemma. The AAMC has been at the forefront in attempting to resolve the problem of reimbursement for patient services in the educational setting. The academic community and the CAS must become even more deeply involved in the issues of health services and of national health insurance. It may well be that the 94th Congress will be the Congress that passes a National Health Insurance Act. Whether such an Act takes into account the peculiar needs of the academic medical centers is important; only the academic community can convey those needs and can convince policy-makers how important they are.

Your Administrative Board has contributed to the development of policy for the AAMC over a wide range of topics. We on the Board recognize that our constituency is broad and heterogeneous and that problems of primary importance to one group may not be necessarily
of first priority to others. A central theme has been maintained throughout your Board's discussions; that is, to foster the activities which will strengthen medical education, biomedical research, and meet the aggregate concerns of the faculty. All substantive matters are debated among representatives of Hospital Administration, Deans and Faculty. As Bob Petersdorf mentioned last year, sometimes we win, sometimes we lose, but every time our voice is heard. However, your Board and I have been disturbed by the lack of evident interest in many of these issues by our constituency. This lethargy is most disturbing; I urge that each of you as delegates to a scientific society make it your personal responsibility to contact members of the Administrative Board of the CAS and express your opinions on topics of primary concern to your membership and to the academic community.

This last year has been a rewarding, educational experience for me. As Chairman of your Administrative Board I have enjoyed the opportunity of working with the staff of the AAMC, in particular Gus Swanson and Mike Ball. Their unselfish dedication to your interests is a quality to be admired. Change can bring with it benefits that are advantageous for all. You are all scientists, and you know that very few advances are made by serendipity. Most advances come from long hours of labor and a great deal of hard work. Likewise, solutions to such problems as the impact of national health insurance on medical education, imposition of rules to effect changes in geographic and specialty distribution, establishment of means to better evaluate the basic science and clinical science programs in medical education, and the future support of fundamental biomedical research,
will not come by serendipity. The AAMC stands at the forefront in its leadership role as the spokesman for high-quality medical education and biomedical research; you are the AAMC; I wish you well in seeking the fruitful rewards of your labor.

RWE:kb
12-5-74
ENCLOSED YOU WILL FIND TWO IMPORTANT MEMORANDA TO THE ASSEMBLY.

MEMORANDUM No. 75-2


THIS REPORT WILL FORM THE BASIS OF THE ASSOCIATION'S POLICY IN THE DEVELOPMENT OF THE HEALTH MANPOWER EDUCATION ACT. IT PROVIDES FOR CAPITATION SUPPORT BASED ON THE NET EDUCATIONAL COSTS (AS DETERMINED BY THE INSTITUTE OF MEDICINE METHODOLOGIES) WITH A VARIETY OF OPTIONS FOR FULFILLING NATIONAL INITIATIVES TO MODIFY AGGREGATE PHYSICIAN SUPPLY, GEOGRAPHIC DISTRIBUTION, AND SPECIALTY DISTRIBUTION.

IT IS IMPORTANT THAT YOU AND YOUR CONSTITUENTS BECOME FAMILIAR WITH THE ISSUES RAISED BY THE MANPOWER LEGISLATIVE DEBATES. THROUGH THE WEEKLY ACTIVITIES REPORT, YOU WILL BE KEPT INFORMED OF DEVELOPMENTS.

MEMORANDUM No. 75-4

THIS MEMORANDUM ON PROPOSED MODIFICATIONS OF THE GENERAL RESEARCH SUPPORT PROGRAM DESERVES YOUR URGENT ATTENTION. IN RESPONDING TO THE PROPOSED CHANGES, PLEASE SEND COPIES OF YOUR CORRESPONDENCE TO US SO THAT WE CAN GAIN A SENSE OF YOUR VIEWS.

ENCLOSURES

August G. Swanson, M.D.
DIRECTOR OF ACADEMIC AFFAIRS

COUNCIL OF ACADEMIC SOCIETIES
IMPORTANT NOTICE

CAS SPRING MEETING WITH MEMBERS OF PRESIDENT’S BIOMEDICAL RESEARCH PANEL

MARCH 31 - APRIL 1, 1975
BETHESDA, MARYLAND

1975 HAS BROUGHT A SERIES OF EVENTS THAT WILL AFFECT BIOMEDICAL RESEARCH SUPPORT, RESEARCH MANPOWER TRAINING AND EVEN THE FUTURE DIRECTIONS OF BIOMEDICAL RESEARCH. THE CAS SPRING MEETING WILL FOCUS ON THESE PROBLEMS AND WILL PROVIDE AN OPPORTUNITY FOR MEMBERS TO EXPRESS THEIR VIEWS TO MEMBERS OF THE PRESIDENT’S BIOMEDICAL RESEARCH PANEL. CONGRESS HAS CHARGED THE NEWLY APPOINTED PANEL TO REVIEW AND ASSESS BIOMEDICAL AND BEHAVIORAL RESEARCH SUPPORTED BY NIH AND NIMH. MEMBERS OF THE PANEL HAVE ACCEPTED AAMC’S INVITATION TO MEET WITH CAS ON THE EVENING OF MARCH 31.

THE PROGRAM WILL INCLUDE DISCUSSION OF BIOMEDICAL RESEARCH FUNDING, RESEARCH MANPOWER TRAINING, BEHAVIORAL RESEARCH AND NIMH, AND THE IMPACT OF CENTERS AND APPLIED RESEARCH ON BASIC RESEARCH. THERE WILL ALSO BE A PROGRESS REPORT ON DEVELOPMENT OF THE REVISED FORM OF THE MEDICAL COLLEGE ADMISSIONS TEST.

THE MEETING WILL BE HELD IN THE BETHESDA HOLIDAY INN FROM 1:30 PM MARCH 31, TO NOON APRIL 1. ROOMS MAY BE RESERVED AT A SPECIAL DISCOUNT ONLY BY RETURNING THE ENCLOSED CARD DIRECTLY TO THE HOLIDAY INN BY MARCH 24.
HEALTH MANPOWER BILL

CONGRESSIONAL DEBATE OVER THE HEALTH MANPOWER BILL CONTINUES. IT IS EXTREMELY IMPORTANT THAT YOU WORK WITH THE DEAN OF YOUR SCHOOL TO PROVIDE ASSISTANCE IN DEVELOPING A STRATEGY FOR CONTACTING YOUR REPRESENTATIVES AND SENATORS.

CONGRESS WILL BE IN RECESS FROM JUNE 27 UNTIL JULY 7 FOR INDEPENDENCE DAY. MANY MEMBERS WILL BE VISITING WITH THEIR CONSTITUENTS DURING THIS PERIOD. I AM ASKING YOU TO TAKE ADVANTAGE OF THE RECESS BY ATTEMPTING TO MEET PERSONALLY WITH YOUR SENATOR OR REPRESENTATIVE; BETTER YET, HAVE THEM VISIT YOUR SCHOOL IF YOU CAN ARRANGE IT.

THE STATUS OF THE BILLS IS THIS: THE HOUSE BILL HAS BEEN REPORTED BY THE INTERSTATE AND FOREIGN COMMERCE COMMITTEE AND FLOOR ACTION IS LIKELY SOON AFTER THE RECESS. THE SENATE HEALTH SUBCOMMITTEE IS EXPECTED TO BEGIN WORK ON ITS BILL AFTER THE HOUSE ACTS, WITH A SEPTEMBER TARGET DATE FOR REPORTING A BILL TO THE FULL SENATE. (CONGRESS WILL ALSO RECESS FOR THE MONTH OF AUGUST.)

THREE POINTS SHOULD BE EMPHASIZED. (ADDITIONAL PROVISIONS OF S 992, THE AAMC BILL, ARE ATTACHED). THE FIRST IS THE NECESSITY FOR A VOLUNTARY APPROACH TO SERVICE IN UNDERSERVED AREAS, USING AN EXPANDED NATIONAL HEALTH SERVICE CORPS, AS CONTRASTED WITH THE PAYBACK PROVISION IN THE HOUSE BILL OR THE ALL-STUDENT DRAFT PROVISION -- BOTH REQUIREMENTS FOR CAPITATION -- WHICH WAS A PART OF LAST YEAR'S KENNEDY BILL. IN A RECENT MEETING, THE SENATE SUBCOMMITTEE STAFF INDICATED THAT THEY HOPED THAT MANDATORY ENROLLMENT INCREASES AND A DRAFT OF SOME OR ALL ENTERING MEDICAL STUDENTS WOULD BE A REQUIREMENT FOR CAPITATION. THE SECOND IS THAT THE MEDICAL SCHOOL WOULD HAVE TO ACT AS THE GOVERNMENT'S AGENT IN ENFORCING EITHER OF THESE IN THE INITIAL REQUIREMENT. THE THIRD IS THE RAPIDLY INCREASING COSTS THAT CANNOT BE MET BY TUITION INCREASES WITHOUT SERIOUS EFFECTS ON THE ADMISSION OF STUDENTS FROM A VARIETY OF ECONOMIC AND CULTURAL BACKGROUNDS.

THE HOUSE BILL CAN, OF COURSE, BE AMENDED ON THE FLOOR, AND SO CAN A SENATE BILL ONCE IT IS REPORTED. YOUR SENATOR OR REPRESENTATIVE, EVEN IF NOT A MEMBER OF THE COMMITTEES WRITING THE BILLS, SHOULD BE REMINDED OF THE AMENDING PROCESS. IF YOU ARE ASKED SPECIFICALLY FOR LANGUAGE FOR AMENDMENTS, LET ME KNOW.

TIME IS SHORT, I KNOW. BUT WE MUST EXERT EVERY EFFORT IF WE ARE TO GET A CONSTRUCTIVE BILL.
KEY PROVISIONS OF AAMC BILL S. 992

CAPITATION

S.992 would authorize $3,250 per medical student. Optional enrollment increase would be permitted to meet the question of aggregate numbers. Allocation of residencies with optional undergraduate and graduate projects would be: specialty distribution approach; geographic distribution approach would be forgiveness of loans for service in shortage area; optional institutional outreach projects; strengthening of NHSC; and scholarships with service commitment. The authorization for medical, osteopathic and dental would be $244.5 million for fiscal 1976, $254.7 million for fiscal 1977 and $262.8 million for fiscal 1978.

SPECIAL PROJECTS

Present projects and project categories would be continued to improve health care personnel understanding of persons with limited English-speaking abilities, of health problems of females, and rehabilitation problems of the aged. Health personnel would be encouraged to locate in underserved areas. The authorization would be $75 million annually.

STUDENT ASSISTANCE

-- Loans: $3,000 plus tuition to students with exceptional financial need; 25% forgiveness of loan per year of practice in shortage area. Authorization: $30 million, $22.5 million, $15 million.

-- Scholarships: $3,000 plus tuition to first and second year students of exceptional financial need. Authorization: $30 million, $22.5 million, $15 million.

-- National Health Service Corps Scholarships: Approximately $7,200 a year, plus tuition, fees and other education expenses for year-for-year service requirement, minimum of two years, in the NHSC or elsewhere as designated by HEW Secretary. Authorization: $50 million, $100 million, $150 million.

AUGUST G. SWANSON, M.D.
DIRECTOR OF ACADEMIC AFFAIRS

COUNCIL OF ACADEMIC SOCIETIES
Note - This is the final in this series of CAFS Briefs.
A new series was begun in the fall, 1975.

Please note the pre-publication status of the attachment. We request that you not refer publicly to the document until after publication.
CONFIDENTIALITY OF RESEARCH GRANT PROTOCOLS

AS YOU ARE AWARE, THE ASSOCIATION HAS BEEN DEVOTING CONSIDERABLE ATTENTION TO PROBLEMS RELATED TO THE DISCLOSURE OF RESEARCH PROTOCOLS, HYPOTHESES AND DESIGNS CONTAINED IN GRANT APPLICATIONS TO FEDERAL AGENCIES. WITH THE DECISION IN THE WASHINGTON RESEARCH PROJECT, INC. V. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE AND CASPAR W. WEINBERGER, IT BECAME CLEAR THAT REMEDIAL LEGISLATION WOULD BE REQUIRED IN ORDER TO PERMIT THE FEDERAL AGENCIES TO RETAIN RESEARCH PROTOCOLS SUBMITTED WITH GRANT APPLICATIONS AS CONFIDENTIAL. THIS MATTER HAS BEEN CONSIDERED BY TWO CONGRESSIONAL COMMITTEES AND AT THEIR INITIATION IS NOW BEFORE BOTH THE PRESIDENT’S BIOMEDICAL RESEARCH PANEL AND THE COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH. IN LIGHT OF THIS WIDESPREAD ATTENTION, WE THOUGHT IT IMPORTANT THAT YOU BE WELL-INFORMED REGARDING THE ASSOCIATION’S POSITION ON THE MATTER.

THE ATTACHED ARTICLE ON THE CONFIDENTIALITY OF RESEARCH PROTOCOLS WILL BE PUBLISHED IN THE FALL. IT PRESENTS A SOMewhat MORE SCHOLARLY, INDEPTH PRESENTATION OF THE PROBLEM THAN THAT MAILED TO OTHER MEMBERS OF THE ASSEMBLY BUT COVERS ESSENTIALLY THE SAME POINTS. SHOULD YOU HAVE QUESTIONS OR RESPONSES TO EITHER OF THESE ENCLOSURES, PLEASE DIRECT THEM TO DR. THOMAS MORGAN, DIRECTOR OF THE DIVISION OF BIOMEDICAL RESEARCH.
CONFIDENTIALITY OF RESEARCH GRANT PROTOCOLS

Thomas E. Morgan, M.D.
Director, Division of Biomedical Research
Association of American Medical Colleges

Joseph A. Keyes, Jr., J.D.
Director, Division of Institutional Studies
Association of American Medical Colleges

John F. Sherman, Ph.D.
Vice President
Association of American Medical Colleges

Association of American Medical Colleges
July 14, 1975
I. Summary:

Creative efforts of individuals are the life blood of social, technological and scientific innovation and advancement. Yet creativity is a fragile attribute which needs nurturing if its potential is to be realized. This fact has been recognized in our society since the founding of the Nation. Protective structures were erected in our Constitution to foster creativity, to provide incentives for creativity, and to reward the innovator, not for his benefit alone, but primarily for the benefit of society. In response, our system of patents, trade secrets and copyrights has been developed. It is a tradition of law which permits the award of limited monopolies in order that the innovator may have sufficient commercial protection to develop his concepts for his own advancement and because this is an effective means of promoting the general welfare. But direct commercial protection is no longer by itself adequate to the task of nurturing creativity and providing incentives for the innovators. Much of our society's creative work takes place outside the commercial sector--in our colleges and universities. The reward system is different, but no less real. Within the academic community the scientist receives his professional recognition, his advancement and his personal satisfaction from the contributions of his original ideas and work to science. He requires resources for his work
but, equally as important, he requires an environment which permits him to test and prove his ideas, keeping some control of their development and publication. Only through this level of control can his own contribution be recognized and rewarded.

Until recently, the system permitted this control with no great difficulty. The governmental funding agencies recognized the need for protection of ideas and permitted the scientist to choose the timing of the public release of his work, confident that it would be made public because publication is the means by which the contribution to science and the general good is made and the scientist recognized. Now, ironically, the Freedom of Information Act, legislated to assure accessibility by the public to the conduct of its government's affairs, may become the vehicle for seriously damaging or even dismantling this system. The rationale seems to be that in dealing with the government and accepting governmental funds the scientist forfeits all private and proprietary interests in his work. (1)

Traditionally, the portion of research grant applications submitted to the National Institutes of Health/National Institutes of Mental Health (NIH/NIMH) containing the investigator's research protocols, hypotheses and designs have been treated as confidential by the funding agency. This practice was challenged by the Washington Research Project - Children's Defense Fund in a suit against DHEW under the
Freedom of Information Act. The Association of American Medical Colleges (AAMC) submitted a brief amicus curiae to the United States Court of Appeals for the District of Columbia Circuit in support of the Government's position arguing that these documents were exempt from disclosure under the Act on the grounds that they contained material of a proprietary and confidential nature procured by the government under an assurance that they would be treated as confidential. The government lost the case on a narrow interpretation of the Act's exemptions and was ordered to disclose the documents.

We are concerned that this decision, while perhaps a legitimate interpretation of the language of the statute, is an unfortunate turn of public policy which may severely erode traditional concepts of intellectual property rights and undermine the basis upon which biomedical research is conducted under support from the Federal government. We are concerned that advocates of complete access to all deliberations regarding Federal funding decisions will, in their zeal for public accountability, destroy a feature crucial to the operation of the peer review system of evaluating the scientific merits of grant applications, confidentiality of the deliberative proceedings. It is our hope that a serious study of this matter will result in a better understanding of the underlying conflict between two social objectives of great significance—the need for public accountability...
and the nurturing of scientific creativity. The following text sets out in greater detail the background of the present dilemma and the rationale for possible solutions that will be of maximum service to the public good.
II. BACKGROUND

Our perspective derives from an appreciation of the importance and proprietary nature of original ideas as recognized in the Constitution itself. Because our Nation is dependent on vigorous scientific and technological efforts, the national interest is inextricably tied to the quantity and quality of the scientists' ideas, regardless of the locus of employment or the source of financial support. Norman Latker, patent counsel of the Department of Health, Education and Welfare has eloquently summarized the events surrounding the birth of the intellectual property clause (2).

"As we all know, the Constitution was drafted in the context of a struggle with a government which had abused its obligations to defend the rights of its citizens. Thus, it was no accident that the salient portion of the Constitution drafted for the purpose of protecting your liberties made the Government the servant and protector and not the master of your individual rights.

Thus, the fifth amendment of the Bill of Rights provides that:

"No person shall be... deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation."

It appears that the absence of any one of the three words, "life" -- "liberty" -- or "property" could have the effect of negating the other two. This seems especially true if you were not guaranteed the right of "property" under the conditions specified, since private "property" is a necessity if you are to have control of your "life" and "liberty". I might add inferentially that it is contended by some that the free enterprise system is dependent on/or sprang from these words, since without the protection of private property from arbitrary intrusion, that system could not exist. Certainly the words distinguish our society from the various forms of the world's collectivist societies.
Now, we all know that the word "property", even at the time of the framing of the Constitution, included "intellectual property". But notwithstanding the generic protection of property in the fifth amendment, the framers chose to be even more explicit about this specific category of property, and provided this language in Article I, Section 8:

"The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."

There was no recorded debate in the Convention on September 5, 1787, when Article I, Section 8, was presented, and it was approved unanimously. That the products of the mind should prospectively receive legal protection, even from a centralized Government to be formed, was a principle upon which no one disagreed, probably due to some positive prior experience and examination. Within the eighteenth-century context of natural laws or rights, intellectual property had received affirmative expression not only in English and Commonwealth laws, but in the Declaration of Independence, which provided that "All men are endowed by their Creator with certain unalienable rights", and "that to secure these rights, governments are instituted among men . . . ".

Madison, the chief architect of the Constitution, did not end his interest in intellectual property with the Constitutional Convention. He made the following illuminating statements in support of the prospective Federal authority to award patents and copyrights:

In the Federalist on January 23, 1788:

"The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point by laws passed at the instance of Congress."
In a letter to Thomas Jefferson on October 17, 1788, he made a more important insight:

"Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many." (Emphasis added)

In this statement, and especially the last sentence, the answer to the need for specific protection of intellectual property, notwithstanding its generic inclusion in the fifth amendment, seems apparent. First, the use of the term "monopolies" suggests that Madison knew that the nature of an individual piece of intellectual property is such that it could be useful to all people and at the same time be susceptible of ownership by one person, while on the other hand, diversity of ownership of all other categories of property precluded the possibility of monopoly. The strong possible argument against an indefinite monopolization of valuable intellectual property and its end product under only the fifth amendment and his recognition that "The States cannot . . . make effectual provision", suggests that Madison knew that the rights of the creative few would be in danger without clarification in the Constitution. Thus, a compromise was struck under which intellectual property was to be owned for only a limited term in exchange for the creator's right to exclude. It was under these circumstances that intellectual property -- that property which makes possible the use of all other property -- obtained special consideration in the Constitution.

Although the subject is generic to many fields, our specific concern is the area of biomedical research, particularly as it is conducted in the academic community through federal grant support.

A prominent feature of the NIH almost since World War II has been the frequently studied, highly praised and often copied system of dual review for the allocation of biomedical research grant funds. At the heart of that system are the discipline-oriented Study Sections, charged
primarily with assessment for scientific merit of research project grant applications. Since the inception of that process, NIH has treated both grant applications and Study Section discussions of them as confidential information. The public good and the proprietary interests of the scientists were felt to be best served by this treatment. When the Freedom of Information Act was passed in 1966, the confidentiality of applications and discussions was supported by legal opinion as consistent with the Act and seemed to be permitted by several specific exemptions designed to preserve confidentiality where this is in the public interest.

In 1973 the Children's Defense Fund of the Washington Research Project, Inc. challenged the government's position and brought suit to compel the Department of Health, Education and Welfare to release documents related to eleven NIMH research grants sought by the plaintiff under the Freedom of Information Act (5. U.S.C. 552) (FOIA). The documents sought were: approved grant applications, site visit reports, summaries of Study Section deliberations ("pink sheets"), interim reports and renewal applications related to such approved applications. On November 16, 1973 Judge Gesell, U.S. District Court, D.C. ordered that the documents sought be made available for inspection and copying and further required the Department of Health, Education and Welfare (DHEW) to disclose upon request similar documents in all of its research grant programs.
On recommendation of the DHEW, the Justice Department entered an appeal of the decision. On September 12, 1974 the U.S. Court of Appeals for the District of Columbia handed down a decision in which it reversed the lower court in part but upheld the lower court's order requiring release to the public of research designs submitted in grant applications (3). The latter involved a narrow interpretation of Exemption 4 of the Freedom of Information Act which removes from the disclosure requirements "matters that are ... trade secrets and commercial or financial information obtained from any person and privileged or confidential." The appellate court stated:

"It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of his research design, but only that it is not a trade or commercial interest...This holding extends to all types of applications--initial, continuation, supplemental, and renewal--and to progress reports made by grantees as part of the last three kinds of applications." (3)

Consequently, from the date of that decision, all funded research applications have been required to be released upon request. The only exception to this rule is where patentable ideas may be involved. DHEW has instituted a review procedure to assure that such materials are not released.
III. FIVE PROPOSITIONS:

The Freedom of Information Act makes no requirement that persons seeking the disclosure of government documents reveal the purpose behind their request. Nevertheless, it is clear that the Washington Research Project - Children's Defense Fund had as its objective examining one aspect of governmental accountability, the degree to which the rights of human subjects of biomedical research were protected and their interests preserved in the course of governmentally funded projects. In considering the social utility of the use of the Freedom of Information Act as a means to this objective we have developed five propositions.

1) The ideas of scientists are equivalent to "trade secrets" and therefore should be protected. --We hold that ideas, the key to the vigor and productivity of the nation's scientific and technological effort, are a scientist's principal stock-in-trade. The advancement, remuneration, and prestige of a scientist, particularly of a young scientist, depend upon the soundness of these ideas and the skill with which the scientist applies them to a research problem. Furthermore, success in obtaining support for a biomedical investigator's research is mainly dependent on and proportional to the value of these ideas, as judged by the primary source of funds, the NIH/NIMH grant system.
The court decisions highlight the limited protection afforded by Exemption 4. The legislative history of the Freedom of Information Act is complex but it appears from committee reports that there may have been an intention to grant exemption from disclosure not only to commercial interests but also to ideas and to communications of persons obtained in confidence. (4) Indeed, it is logical to assume that an oversight explains the extension of protection for ideas in the commercial sector while not affording similar protection in a non-commercial environment.

Legislation is needed which will protect a scientist's ideas by holding research protocols, hypotheses, and designs confidential for a period after the initial award is made. This period should be long enough to allow the scientist to proceed deliberately along the proposed lines of investigation for a time sufficient to develop the idea. The language should protect primarily the ideas of basic (as opposed to clinical) science because basic science is the area in which new ideas are most sensitive to premature disclosure.
Preserving the confidentiality of research protocols best serves the public interest by assisting in the protection of the quality of the peer review process as used by NIH and NIMH. The hope of the public for improvement in the quality of life through biomedical research has resulted in the development in the United States of the world's leading biomedical research enterprise.

In any large activity, and especially in one involving a heavy investment of public monies, the process by which those funds are invested is of critical importance. An essential feature of the almost thirty-year history of this part of the grant system has been the unusual confidence in it of all parties involved, based in large measure on their faith that the applications presented and the discussions about them will be held in strict confidence. This arrangement has prompted the nation's finest scientists to reveal in great detail their research ideas, and the nation's leading biomedical experts to discuss in a very candid and, therefore, effective manner the content of these applications. As Attorney General Edward H. Levi has recently stated (5), "... complete disclosure would render impossible the effective operation of government. Some confidentiality is a matter of practical necessity."
A complex society cannot make decisions "in the marketplace" in the manner of simpler societies no matter how much we may wish to return to simpler days. In the same way not all citizens can or should have complete information about all decisions. Thus, decision-making must be delegated but, at the same time the decision makers must be held responsible. The complex decisions about biomedical research are now made by an extensive process which is, and must be, accountable to the public. If, however, the research protocols are disclosed and if the Study Sections should be forced in future to open their sessions, it seems probable that many investigators, particularly younger scientists seeking to establish their reputations while protecting their nascent scientific ideas from competitors, would be less willing to disclose sufficient detail to permit the present quality of assessment by Study Sections. Furthermore, as a consequence of the members being less candid in open sessions, there is no question but that the discussions would be less thorough. There is also a need to protect the privacy of the investigator whose applications are criticized and rejected and, conversely, to protect the evaluators from harassment by disappointed applicants.

There have been very few charges of "plagiarism" of ideas in the NIH Study Section system over the past twenty years. Most observers of the system concur in the conclusion that an unusual set of mores has evolved during its history which has kept such possibilities to a remarkable minimum.
This record appears to be in significant contrast to the charges which have occurred in other systems where similar attitudes have not developed.

It should be understood that the second part of the dual review system, namely the subsequent involvement of the National Advisory Councils, has always provided for the participation of individuals outside the scientific community as well as biomedical professionals. The meetings of those Councils are almost entirely open to the public, except when individual applications are being discussed.

(3) Research protocols involving human subjects require special consideration. --While the growing public concern for the protection of human subjects is relatively recent, the Advisory Councils of the National Institutes of Health recognized in the 1950's that steps should be taken to protect human subjects from "unusually hazardous procedures".

This recognition gave rise to a partial system of safeguards which was developed into a general policy statement by the National Advisory Health Council in 1965. Professional groups in the late 1960's publicly discussed and endorsed the principles of the Nuremberg and Helsinki declarations.
Biomedical researchers together with leaders at NIH set in place in 1971 detailed requirements that institutional review groups be formed in hospitals, schools, and other research institutions for the review of the conduct of research involving human subjects (6).

Although the system may not be perfect, it is clear that the earliest protection came about almost entirely in response to concerns arising within the Institutes and within the research community. As a product of this process, comprehensive regulations for the conduct of research involving human subjects were promulgated by DHEW in 1974 (7), but were not yet adopted when the Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was created and impanelled in December, 1974, as a result of Congressional concern over deficiencies which in fact were largely outside the biomedical research system or which had occurred years earlier. Those deficiencies which are properly ascribable to the system are addressed by the DHEW regulations now issued or in preparation.

Review of these historical facts relating to the research system underscores the conclusion that the protection of human subjects is an old problem and that the research community has moved responsibly to establish procedures for
the protection of human subjects. Indeed, the research community has always been in the forefront of concern for human and individual rights and particularly since World War II.

In May 21, 1975 testimony before the House Subcommittee on Health and the Environment on H.R. 7039, representatives of the Children's Defense Fund and other public interest organizations inadvertently highlighted one aspect of this subject which has received comparatively little attention. This is the failure to distinguish between the original ideas of a scientist, which constitute the intellectual heart of a research protocol, and the research grant application, which is the comprehensive document that includes the proposed protocol among other information.

This distinction becomes especially important in the context of the most elementary focus of the public interest firms active in the area of protection of human subjects involved in biomedical research. These witnesses referred frequently to alleged shortcomings in the procedures used to obtain informed consent from normal volunteers or patients involved in that research. Thousands of research grant applications have been processed by NIH. It is doubtful that the information in them which constituted the "idea" component per se would have given any lead as to the adequacy
of the informed consent procedures to be employed which
could not be made available elsewhere.

A further distinction should be made between those
protocols which describe clinical trials and those which
describe the typical investigator-initiated research pro-
ject. We should carefully protect research ideas, but in
clinical trials original research ideas are rarely involved.
Rather, the clinical trial protocol includes information
derived from previous research efforts organized so as to
permit the objective testing of specific modalities of
treatment and to assure a high degree of consistency in
the results of the study. Therefore, our concern with
respect to confidentiality is directed primarily to the
investigator-initiated research project where the testing
of original research hypotheses is basic to the nature
of the proposal.

Any legislative remedy should take cognizance of the
proposed functions of the Ethical Advisory Board which,
under the terms of Public Law 93-348, will replace the
present National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research. The
Commission and the Board will undoubtedly describe appro-
priate approaches which will afford adequate protection to
human subjects.
(4) Premature disclosure of research protocols may infringe patent rights. Some products of scientific research are patentable. Any legal remedy should protect these patent rights by specifically exempting those proposals, protocols, and designs which contain patentable ideas until the patent process has been initiated.

The award of valid U.S. patent protection is foreclosed in any case in which the invention has been described in a printed publication (a document of unrestricted availability) more than one year prior to the date of application for the patent (5 U.S.C. 102 (b)). In the case of foreign patents prior disclosure immediately forecloses patentability. Since the release by the Federal government of documents containing an "inventive disclosure" would start the running of this one year statutory bar, there needs to be some protection against this kind of disclosure. This protection is contained in the existing exemptions in the FOIA (5 U.S.C. 552 (b)). While the analogy of an investigator's ideas to trade secrets has not been adopted by the courts, there can be no question that a patent may have commercial value and thus is included in "matters that are trade secrets and commercial or financial information obtained from any person and privileged or confidential" (5 U.S.C. 552 (b)(4)). Thus, any legislation should preclude the unintended destruction of valuable property rights
by preserving the applicability of the FOIA exemptions to research protocols, hypotheses, and designs.

We do not argue that traditional procedures should be retained simply to prevent administrative workload increases. However, it is estimated that the review of applications for potentially patentable material before initial review for scientific merit (which would be required if all protocols are disclosed) would double the time required for review from 6 months to a year even if the staff necessary could be found and hired. (The sheer magnitude of complying with requests to the Justice Department has been commented upon eloquently by Attorney General Levi in his recent speech before the New York Bar Association (4)).

(5) Premature disclosure of research protocols may lead to premature release of scientific hypotheses and discoveries and harm to the public. --It has been contended that confidentiality may impede the application of research findings to national needs. We disagree for two reasons. First, the process of advancement in the academic research community requires that scientific findings be published as soon as possible. This guarantees that new ideas will be accessible to the public rapidly. Second, this process involves refereed journals and, thereby, helps to ensure that those ideas which are published will not be applied before adequate
investigation and testing. Careful, deliberate review will help prevent premature—and potentially hazardous—disclosure of scientific discoveries and hypotheses before they can be tested and proved. Premature publication of such hypotheses may create intense public pressure on practicing physicians to apply research advances before they have undergone sufficient evaluation by research scientists. In the long run, the public interest will be served best by thorough scientific investigation. Therefore, the public's understandable desire to hasten the application of research findings should not outweigh the need for responsible and adequate scientific evaluation.

IV. RESOLUTION:

We conclude from the propositions set out above that there is much to be lost if the current interpretation of the Freedom of Information Act continues to prevail without relief from the requirement that research protocols be released upon request. We hope it is clear that we support efforts to provide maximum public accessibility to the conduct of government. We believe, however, that there are occasions where the public good requires something less than complete disclosure of all documents in the hands of the government. Research protocols represent one such instance. This is so, in part, because the protocol is not, we contend, government property, but rather that of the investigator. In part this is so because to view it
otherwise is to undermine the very objectives of government support of research.

The funding of research does not represent a government purchase of the intellectual property of the scientist. Rather, it represents a public investment in an investigator's work with the hope and expectation that his work will bear fruit for the betterment of mankind and, in the case of biomedical research, for the ultimate cure or alleviation of dread disease. It is to foster, stimulate and support this work that the grant award is made. It was for this reason that the grant-in-aid became the principal funding instrument used by NIH instead of the research contract. To construe a grant application submitted for funding as governmental property is tantamount to a declaration that one forfeits all personal proprietary rights in such dealings with the government. This is manifestly not the case in other dealings with the government and there is no persuasive reason why this should occur with the submission of a grant application. While perhaps a better case can be made where the applications have been funded that the government has "bought" the idea, such an argument misses the point on two counts. First, it is not the idea which the government has bought, but rather the investigation of a particular area of social significance that the government is stimulating and supporting so that desirable objectives might be achieved. Secondly, the continued stimulation of new ideas and continued work for the advancement of science is far more important than any specific project funded. The
NIH system has proven remarkably effective in stimulating the advance of science and has in no small measure been effective precisely because it recognizes and protects the individual investigator's interests. To remove that protection is to reduce the incentive and to undermine the very governmental objectives being sought.

In our dialogue with public interest groups, both direct and through the medium of testimony before Congressional committees, the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects it has become apparent that there is a fundamental disparity between their point of view and ours. We hold that it is not only appropriate, but essential, that social objectives be implemented in our society by delegation to institutions having the means to carry them out. Those institutions should be peopled by those with the necessary expertise, and operated in accordance with procedures calculated to assure fairness in their decision-making. Such institutions should be held accountable for their work, but this accountability is to be measured by their results. Remedies for institutional deficiencies should be accomplished by disciplining or replacing their decision-makers or by refining their procedures.

The fundamental perspective of the challengers is that all citizens should have the absolute right of access to all aspects of the conduct of that business. Secrecy breeds
corruption; sunshine is the best and only disinfectant. Thus, secrecy in any but the most limited circumstances is to be avoided whatever the cost.

While we are in no way advocates of complete secrecy, we believe the costs of full disclosure are too great to bear. Proprietary rights, personal privacy, candor in decision-making, effective evaluations, incentives for innovation would all be sacrificed on this "altar of openness". Full disclosure is a formula for dismantling institutional processes of decision-making and replacing them by anarchy where no one is or can be held accountable.

"Under our Constitution, the people are the sovereign but they do not govern by the random and self-selective interposition of private citizens. Rather, ours is a representative democracy, as in reality all democracies are, and our government is an expression of the collective will of the people. The concept of democracy and the principle of majority rule require a special role of the government in determining the public interest. The government must be accountable so it must be given the means, including some confidentiality, to discharge its responsibilities." (5)

Public interest advocates who have sought to use the FOIA to gain access to information about the nature of governmentally funded biomedical research have done so with the laudable objective of examining the care with which human subjects of biomedical research have been treated and their rights preserved. They have been upheld in the courts in their interpretation of the requirements of the Act. They deny any intent to impede the progress of research or the effectiveness of the peer review system.
Furthermore, they deny that their actions may have such an unintended result. We do not challenge their statement of their intentions but we believe that their understanding of the system by which research is supported and carried out lacks sufficient thoroughness to permit them to perceive the unintended results of their actions.

We believe that there is an accommodation which, while perhaps never acceptable to advocates of unlimited disclosure, recognizes the imperatives of institutional responsibility and decision-making and which provides a new level of disclosure calculated to meet the legitimate needs and expectation of public interest advocates. It would provide full disclosure of those parts of the application which relate to, and would permit judgment about, the degrees of risks that human subjects of research would be subjected to, and the care with which their interests are provided for.

A "Notice of Research Project" is filed with the Science Information Exchange for each grant. That Notice, which is public information, together with a copy of the Informed Consent form to be used would provide sufficient information to commence an analysis by any group or individual of the adequacy of the procedures for the protection of human subjects. The NIH/NIMH could restructure their research grant application form to separate the investigator's
ideas from those parts in the application which should be disclosed to provide safeguards for human subjects. Information of a supporting nature in the application could then be made public for whatever reason at no potential harm to the investigator-applicant.

Thus, this accommodation would emphasize the improvement of the institution which has served this country so well. In addition, however, there must be a legislative component to the solution. Such legislation would assure that the protocol, the intellectual core of the application, be preserved from disclosure for a reasonable period and preserve the integrity of the peer review system. Such legislation would amend either the FOIA or other acts (e.g., Public Health Service Act). The latter approach is suggested by the FOIA (Exemption 3) and is proved effective by recent Supreme Court action. (8) Any legislation should also provide the procedural safeguards of the Freedom of Information Act.

Understandably, questions have been raised as to proof of harm to either individual scientists or to the peer review system as a result of disclosure. With no experience under such a requirement, it is, of course, impossible to provide evidence of harm. Furthermore, and not surprisingly, there is no more unanimity within the scientific community on this issue than on most others. Nonetheless, the major scientific and educational organizations with whom we have discussed the matter, support our approach at least in principle.
We strongly support measures which will provide necessary protection for the rights of individuals involved as subjects in biomedical research. We also concur in efforts to reduce secrecy in governmental activities. Paralleling these judgments, however, is the conviction that the public interest also involves incentives needed to assure the continuation of the Nation's highly productive biomedical research endeavor. We must earnestly seek -- and find -- a way to resolve these basic conflicts. We believe that our proposal offers one possibility to that end.
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1. Yale University President Kingman Brewster has commented on other aspects of increasing intrusions in non-Federal institutions through the leverage of Federal funds. Science 188: 105 (1975).

2. Latker, N.J. Presentation at Conference on "Technology Transfer - University Opportunities and Responsibilities" Case Western Reserve University - October 15, 1974.


4. Davis, K.C. The Information Act: A Preliminary Analysis, University Chicago Law Review 34:240-295(1967) The legislative history is cited on page 268, but the following conclusion by Professor Davis is also noteworthy (p 290): "Amendments most needed and least controversial .... (a) The fourth exemption is most urgently in need of amendment. It exempts from disclosure "trade secrets and commercial or financial information obtained from any person and privileged or confidential." The Act contains no exemption for privileged or confidential information which is non-commercial and non-financial. The fourth exemption should be amended to read: "trade secrets and privileged or confidential information obtained from any person.""


