

# association of american medical colleges

## MEETING SCHEDULE COUNCIL OF ACADEMIC SOCIETIES ADMINISTRATIVE BOARD

Washington Hilton Hotel  
Washington, D.C.

### January 18, 1978

5:00 p.m.	Business Meeting	Chevy Chase Room
7:30 p.m.	Cocktails	Dupont Room
8:30 p.m.	Dinner	Chevy Chase Room

### January 19, 1978

8:30 a.m.	Business Meeting (Coffee and Danish)	Chevy Chase Room
1:00 p.m.	Joint CAS/COD/COTH/OSR Administrative Boards Luncheon and Executive Council Business Meeting	Conservatory Room
4:00 p.m.	Adjourn	

AGENDA  
COUNCIL OF ACADEMIC SOCIETIES  
ADMINISTRATIVE BOARD

January 18-19, 1978

I. REPORT OF THE CHAIRMAN

II. ACTION ITEMS

1. Approval of Minutes of CAS Administrative Board Meeting  
of September 14-15, 1977 . . . . . 1
2. Appointment of CAS Nominating Committee . . . . . 9
3. Reinstatement of American Society of Hematology . . . . . 10
4. Executive Council Action Items:
  - Appointment of a Secretary-Treasurer
  - Appointment of the Executive Committee
  - Election of COTH Members
  - Approval of Subscriber
  - 1977-78 Executive Council Committees
  - Endorsement of LCME Accreditation Decisions
  - Student Representation on the LCME
  - OSR Resolution on Graduate Medical Education Directory
  - Committee on Future Staffing
  - Report of the Committee on Physician Distribution
  - Ethical Practices Governing Privately Sponsored Research  
in Academic Settings
  - Cost Containment Program of the National Steering Committee  
on Voluntary Cost Containment
  - American College of Surgeons' Letter

III. DISCUSSION ITEMS

1. CAS Interim Meeting of January 18, 1978
2. Plans for a June Public Affairs Meeting . . . . . 11
3. CAS Services Program . . . . . 12
4. Congressional Inquiry into Responsibilities of Academic  
Scientists . . . . . 13
5. Response to Dr. Kennedy of the Food and Drug  
Administration . . . . . 19

MINUTES  
COUNCIL OF ACADEMIC SOCIETIES  
ADMINISTRATIVE BOARD

September 14-15, 1977

Washington Hilton Hotel  
Washington, D.C.

PRESENT: Board Members

A. Jay Bollet\*,  
Chairman (Presiding)  
Robert M. Berne  
F. Marian Bishop  
Carmine D. Clemente  
G.W.N. Eggers  
Rolla B. Hill  
Thomas K. Oliver  
Roy C. Swan  
Samuel O. Thier\*

Staff

John A.D. Cooper\*  
Kat Dolan  
James Erdmann  
Paul Jolly\*  
Thomas Kennedy\*  
Mary Littlemeyer  
Thomas Morgan  
Mignon Sample  
John Sherman\*  
August Swanson

ABSENT: Eugene Braunwald  
Daniel X. Freedman  
Leslie T. Webster

Guests: Ivan L. Bennett\*  
Gilbert S. Omen\*\*  
Richard S. Wilbur\*\*\*

The CAS Administrative Board Business Meeting convened on September 14th at 5:15 p.m. and adjourned at 7:30 p.m. A social hour was followed by dinner at 8:30 p.m. Dr. Gilbert Omen, Assistant Director for Social and Economic Services, Office of Science and Technology Policy, joined the board for an informal discussion of current Administration concerns. Dr. Richard Wilbur, Executive Vice President of the Council of Medical Specialty Societies, was a guest of the Board for the meeting and dinner.

The meeting reconvened at 8:30 a.m. on September 15th. Following the usual custom, the CAS Administrative Board joined the other AAMC Boards for a luncheon meeting at 1:00 p.m.

---

\*For part of the meeting

\*\*Assistant Director for Social and Economic Services, Office of Science and Technology Policy

\*\*\*Executive Vice President, Council of Medical Specialty Societies

I. Adoption of Minutes

The Minutes of the CAS Administrative Board Meeting of June 22-23, 1977 were adopted with one amendment. Dr. G.W.N. Eggers should be added to the Minutes as being present at the meeting.

II. Action Items

A. New Membership Applications

The Society of Teachers of Emergency Medicine, reviewed by Drs. Braunwald and Berne, and the Society for Surgery of the Alimentary Tract, reviewed by Dr. Hill, were considered for election to the CAS. Dr. Bishop raised a question as to whether members of the Society for Surgery of the Alimentary Tract were academic types. This prompted a discussion on how selective the CAS should be regarding membership. Historically, it has been the position of the CAS Board that it is not possible to establish rigid criteria for membership, and the Board has elected instead to individually review and approve societies seeking membership.

ACTION: The CAS Administrative Board approved the Society for Surgery of the Alimentary Tract and the Society of Teachers of Emergency Medicine for membership in the Council of Academic Societies.

B. Endorsement of LCME Accreditation Decisions

Dr. Bishop commented on the decision on the University of Oklahoma because there was so little information regarding the concerns the LCME had, most of which related to Tulsa.

ACTION: The CAS Administrative Board voted to endorse the LCME accreditation decisions.

C. Removal of Schools from Probationary Accreditation

ACTION: The CAS Administrative Board approved the LCME removal from probation of the University of Missouri-Kansas City and the Texas Tech University.

D. Election of Provisional Institutional Member

ACTION: The CAS Administrative Board approved the election of the Northeastern Ohio Universities to Provisional Institutional Membership.

E. Election of CAS Member

ACTION: The CAS Administrative Board approved the recommendation to the Assembly the election of the American Society for Clinical Pharmacology and Therapeutics, the Society of Teachers of Emergency Medicine, and the Society for Surgery of the Alimentary Tract to CAS Membership.

F. Election of Distinguished Service Members

ACTION: The CAS Administrative Board voted to consider at the June 1978 meeting whether to nominate additional candidates for Distinguished Service Membership and requested that the present CAS members be shown in the agenda for that meeting.

G. Election of Emeritus Members

ACTION: The CAS Administrative Board approved the election of Robert Ebert, M.D., and Franz Ingelfinger, M.D. as Emeritus Members.

H. Approval of Subscribers

ACTION: The CAS Administrative Board approved the Universidad Catolica de Puerto Rico and the University of Texas System as Subscribers.

I. Flexner and Borden Award Nominations

The CAS Administrative Board requested that for next year, a report be included showing the number of nominations made, by which groups, and what the response from the CAS was to the request for more quality recommendations.

ACTION: The CAS Administrative Board approved the recommendations for Dr. Paul Beeson/Flexner Award and Dr. Hugh McDevitt/Borden Award.

J. Individual Membership Dues Increase

ACTION: The CAS Administrative Board approved the recommendation that Individual Membership dues be increased to \$30 per year.

K. Amendment to the CAS Rules and Regulations

ACTION: After clarification by Dr. Bollet that the amendment was correct as it was written, the CAS Administrative Board approved the proposed amendment for forwarding to the full Council.

L. Amendment of GME Rules and Regulations

Dr. Swanson gave an historical background of the development of the Groups. The rationale for including COTH and CAS members within the different categories of the GME (i.e. graduate medical education, continuing medical education) was to allow interaction of the GME with people of similar interests. The Board discussed the problem of how to communicate with individual members and promote resource-sharing among the members. It was suggested that it would be useful to have staff meet with the different societies to provide an opportunity for exchange of information, particularly regarding AAMC activities.

ACTION: The CAS Administrative Board approved the revised GME Rules and Regulations.

M. FY 1978 CCME Budget

Dr. Thomas Kennedy reported to the CAS Board on the budget process of the CCME. There had been some conflicts with the AMA, but the objections had been satisfied and the budget was felt to be a reasonable one.

ACTION: The CAS Administrative Board voted to approve the 1978 CCME Budget.

N. Statement on Withholding of Services by Physicians

The CAS Administrative Board discussed the position statement developed by a Working Group appointed at the last Executive Council Meeting (copy attached to Archive Minutes). The general consensus of the Board was that the statement was too long and indirect. Dr. Oliver suggested that the statement begin with page five of the actual recommendations. Dr. Bollet also suggested that the last section be strengthened. Dr. Swanson emphasized that this should be the established position of the AAMC and be given widespread distribution.

ACTION: The CAS Administrative Board concurred with the principles and basic position as stated by the Working Group; however, they felt that a more concise document should be prepared.

O. Establishment of a Cabinet Level Department of Health

In 1972 the Executive Council established a position in support of a separate Department of Health, and since that time the Carter Administration had proposed a separate Department of Education. Dr. Bollet commented that the Administration

is more likely to go in the direction of fewer, more complex Departments. It was the consensus of the Board that the policy statement needed to be updated.

ACTION: The CAS Administrative Board agreed with the recommendation that the Executive Council reaffirm its position that a separate Department of Health be created; however, they felt that the policy statement should be reworded and updated.

P. Recognition of LCME by U.S. Commissioner of Education

The U.S. Office of Education decided to continue recognition of the LCME for two years with an interim report due in one year addressing concerns identified in the USOE staff analysis. Some of the concerns were procedural matters and others were more fundamental pertaining to the relationship between the AAMC and the LCME. The role of the LCME as a private accrediting agency is considered essential, and the USOE recommendations along with the responses were considered from this viewpoint. Dr. Swanson briefly explained the process by which representatives are appointed, their terms, approval, etc. It was generally agreed that the response should indicate that the recommendations were good and the LCME would try to comply with the request from the USOE.

ACTION: The CAS Administrative Board concurred with the recommendation that the AAMC should accept the requirements as set forth by the Office of Education and should consider what modifications should be made in the relationship between the AAMC and LCME.

Q. Proposed AAMC Testimony on NAS Report, "Health Care for American Veterans"

The CAS Administrative Board discussed this report, which was distributed to all Board members, and the outline of the proposed testimony. Dr. Bollet expressed disappointment in the report, which he considered weak and contained insufficient data. It was suggested that in the testimony a request be made to include further data.

ACTION: The CAS Administrative Board suggested that an effort be made to obtain more data and that more emphasis be placed on trying to strengthen the quality of care in affiliated VA hospitals.

### III. Discussion Items

#### 1. Task Force on Minority Student Opportunities in Medicine Interim Report

The Interim Report of the Task Force was presented to the Executive Council for its consideration. It was emphasized that this is not a final report and is not for public discussion. Dr. Clemente raised a concern regarding the Task Force's recommendation that the New MCAT not be used as a criterion for admission. It was reported that this recommendation had been revised to put emphasis on the application of data from the test rather than the test itself. Dr. Clemente also commented on several statements that he felt compounded the problems rather than solving them. In particular were the sections on Counseling at Undergraduate Institutions (page 88 of Executive Council Agenda), which he felt put applicants in the position of being viewed as incapable of responding to the application process, and the section on Student Responsibility (page 92 of Executive Council Agenda). Dr. Clemente expressed the view that the goals established ten years ago were unrealistic and that now the AAMC is being criticized for not meeting those goals.

#### 2. Status Report on DNA Legislation

Dr. Morgan reported on the status of DNA legislation in the House and Senate. The Senate (Kennedy) bill contained four main areas which were objectionable: 1) the nature of the regulatory mechanism was a free-standing commission; 2) pre-emption, states were allowed to place regulations in effect, could write stricter regulations; 3) enforcement of penalties provided for willful or negligent violations; 4) provisions for disclosure of data. In the House (Rogers) bill, pre-emption was softer, not required to allow states to regulate; penalties were stiffer and the word negligent was not included; there was provision for protecting scientists' and patent rights of institutions and industry.

At a meeting of the Senate Health Subcommittee, Senator Kennedy offered to withdraw his bill and replace it with a simple extension of the regulations on industry. Dr. Morgan expressed appreciation for the action of CAS in responding so immediately to campaign to support the Nelson bill rather than the Kennedy bill. The immediate response succeeded in slowing down the legislative process which seemed inevitable at the time.

3. Status Report on USFMS Provisions

Drs. Ivan Bennett, John Cooper and John Sherman joined the Board for a discussion of recent developments regarding the USFMS provisions. Dr. Bennett reported on the efforts of the staffs of the House and Senate Subcommittees to work out the differences between the two bills now pending to modify the USFMS provision. The CAS Administrative Board concurred with a recommendation that the AAMC publicly endorse a proposed amendment which would require a six percent enrollment increase.

4. Ad Hoc Group on Biomedical Research

Dr. Morgan reported on the establishment of a Task Force on Biomedical Research to consider the AAMC's position on biomedical research training and biomedical research in general. Dr. Robert Berne will be chairing the Task Force and the following individuals have been sent letters of invitation to serve: Drs. Philip Dodge, David Skinner, Peter Whybrow, Samuel Thier, Theodore Cooper, and Charles Sanders. The proposed procedure for the Task Force Report was outlined, the first step being collation by AAMC staff of previous AAMC positions and background material. The Task Force would then identify issues and recommendations needing revision as the basis for an issues and options paper to be prepared by staff. This paper would be distributed to CAS members for discussion and review at the January Interim Meeting and the Task Force would meet in February to prepare the final report for presentation to the Executive Council at its meeting in March.

The primary objective of the Task Force would be to update existing policies in areas which could be responsive to anticipated concerns of Congress in considering research legislation. Dr. Morgan stressed that it was important for the AAMC to have a position on these issues.

Several members of the Board had some concern about the narrow representation of the Task Force, particularly that broader concerns might not be addressed. It was the consensus of the Board that another member representing the basic sciences should be added to the Task Force, and Board members were asked to submit their recommendations to the staff.

5. Annual Meeting Plans

A summary of the schedule of activities for the Annual Meeting was reviewed, and arrangements for the CAS Business Meeting were briefly discussed.

6. Status Report on CAS Services Program

Kat Dolan reported that she has now been working with the Association of Professors of Medicine for six weeks, with the major activity involving administrative functions. As a result of the announcement of initiation of this new program, six societies (one of which is a basic science) have expressed an interest in exploring the services this program has to offer. It was decided that the Program would not offer only one or two services that societies might request because it would not enhance either the society or CAS in improving communications.

## CAS NOMINATING COMMITTEE

The change in CAS Rules and Regulations relative to selecting the Nominating Committee places the responsibility for its selection on the Administrative Board and does away with having the Nominating Committee elected at the Annual Meeting.

The Nominating Committee consists of six members (three clinical and three basic scientists) selected from amongst the representatives to the CAS. No more than two of the members may be current members of the CAS Administrative Board and only one member can be appointed from any single society. The CAS Chairman is the seventh member and the Chairman of the Nominating Committee. The Committee meets in person to develop the CAS slate, which consists of two nominees for each open position.

The Committee must meet no later than June 1. In order to allow scheduling of the meeting, the Committee should be selected in January. Six members and four alternates should be chosen so that a full Committee can be convened. The recent copy of the CAS Directory can be used for reference. In addition, the names of members of the Nominating Committees of the past three years are listed.

### 1976-77

A. Jay Bollet, M.D., Chairman  
Carmine D. Clemente, Ph.D.  
Ronald W. Estabrook, Ph.D.  
Nicholas Greene, M.D.  
Warren Stamp, M.D.  
Allan B. Weingold, M.D.  
Frank E. Young, M.D., Ph.D.

### 1975-76

Rolla B. Hill, Jr., M.D., Chairman  
Floyd W. Denny, M.D.  
Ronald W. Estabrook, Ph.D.  
William L. Parry, M.D.  
James B. Preston, M.D.  
John E. Steinhaus, M.D., Ph.D.  
Frank E. Young, M.D.

### 1974-75

Jack W. Cole, M.D., Chairman  
Carmine D. Clemente, Ph.D.  
G.W.N. Eggers, M.D.  
Daniel X. Freedman, M.D.  
William L. Parry, M.D.  
James B. Preston, M.D.  
Leslie T. Webster, M.D.

AMERICAN SOCIETY OF HEMATOLOGY

At the Annual Meeting in 1976, the American Society of Hematology was voted into membership in the CAS. Subsequently, the Society informed us that they had decided to withdraw their application for membership. In November, 1977 Samuel Rappaport, President of the Society, wrote stating that the Society now desires to have its previous application reactivated. This decision is apparently due to a change in the Society's leadership.

The American Society of Hematology has 2,300 members, of which approximately 800 are faculty. It is a scientific society and has been provided with a tax-exempt status under Section 501(c)3 of the IRS statutes.

It is proposed that the Society be readmitted as a member of the CAS without further review. It will be necessary for the Assembly to vote on its membership status at the 1978 Annual Meeting.

### Plans for a June Public Affairs Meeting

The CAS Public Affairs Representative system was created in mid-summer 1976. In December, 1976, a seminar of Public Affairs Representatives was held in Palm Beach, Florida, with congressional staff and others including Dr. Theodore Cooper, then Assistant Secretary for Health, DHEW. This legislative affairs seminar was generally considered to be worthwhile by those members of the public affairs group attending.

In June, 1977, an interim meeting of the Council of Academic Societies was held in the Association headquarters in Washington, D.C. This meeting was well attended and a vigorous discussion of many legislative items occurred. On January 18, 1978, another interim meeting of the Council of Academic Societies will be held. This session will also deal largely with legislative activities relating to the support of biomedical research. It has been suggested that another public affairs seminar be held in late spring 1978, patterned after the successful session held in Palm Beach in December 1976. No decisions have been made as to time, place or format of such a meeting. The recommendation of the CAS Administrative Board relating to this proposal is being sought.

## CAS SERVICES PROGRAM

The CAS Services Program was initiated in August, 1977, to strengthen the liaison between the AAMC and CAS member societies. The first organization to join the program was the Association of Professors of Medicine.

A consortium of neurological organizations--the Association of University Professors of Neurology, the American Academy of Neurology, and the American Neurological Association--has also decided to participate in the CAS Services Program. These organizations have requested only the legislative "tracking" portion of the services package, and each will continue to provide its own administrative services. Under our agreement, which is in the final stages of negotiation, the AAMC will monitor Congressional and executive branch activities in areas which have been identified by the organizations as of interest to their constituencies. A twice monthly status report on these areas will be prepared. Additionally, AAMC will provide the Weekly Activities Report to the executive committees of each of the organizations. The CAS Brief will be mailed in bulk to each society.

We have also met several times with representatives from three pediatric societies, with the Society of Teachers of Preventive Medicine and with the Association of Anatomy Chairmen. We continue to seek ways to implement the program during the 24 month trial period.

CONGRESSIONAL INQUIRY INTO RESPONSIBILITIES  
OF ACADEMIC SCIENTISTS

Congressman Paul Rogers sent the letter which follows to Dr. Cooper. The CAS Administrative Board should discuss the nature of the response the AAMC should make. An appropriate response might be that academic medical centers and their faculties should not enter into contracts or agreements to conduct research if there are limitations set on the publication of the results of such research.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

MEMORANDUM #77-68

December 30, 1977

TO: Deans of U.S. Medical Schools

FROM: John A. D. Cooper, M.D., President

SUBJECT: Congressional Inquiry into Responsibilities of Academic Scientists

On December 23, 1977 I received the attached communication concerning responsibilities of academic scientists from Representative Paul G. Rogers. In his letter the Congressman touches upon several important issues. While the specific case he cites is nearly twenty years old, the primary issue of ethical responsibility deserves our thoughtful attention. Mr. Rogers requests my personal comment and thought; however, it would be extremely helpful to me to have your ideas on these issues so that a consensus opinion for the Association can be formulated. Your answers to the questions on pages 2 and 3 of Mr. Rogers' letter will provide me with the basis for my response.

In casting as wide a net as possible for background material, it would be useful to be able to compile data on any documents your Institution may have relative to the general issues raised by Mr. Rogers. While your replies to the questions in the Congressman's letter are of primary importance, your answers to the following will give us further supportive data.

- Does your Institution have a written policy on industrial grants, contracts and/or consultation? If "yes", please enclose a copy with your reply.
- At what level (investigator, department, school, university) does authority over acceptance of a grant or contract reside at your Institution?
- Does your Institution have any written policy relating to classified research or proprietary rights in the outcome of research supported by an industrial sponsor? If "yes", please enclose a copy with your reply.
- At your Institution what are the responsibilities of scientific investigators to publish their results? Is there a document which specifies these responsibilities? If "yes", please enclose a copy with your reply.
- Does your Institution have a written policy on "conflict of interest"? If "yes", please enclose a copy with your reply.

While I realize that the post holiday rush to catch up is now upon you, I hope that you can have your response to me by January 10 so that this matter, including your contributions, can be brought up at the next meeting of the Executive Council. Any questions you may have will be answered by Judy Braslow (202) 466-5190, Tom Kennedy (202) 466-4720 or Lew Menaker (202) 466-4747.

My best wishes to you for a happy New Year.

Association of American  
Medical Colleges

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

December 28, 1977

202. 466-5175

Honorable Paul G. Rogers  
Chairman  
Subcommittee on Health and the  
Environment  
Committee on Interstate and  
Foreign Commerce  
United States House of Representatives  
Washington, D.C. 20515

Dear Paul:

This letter will acknowledge receipt of your inquiry of December 6, 1977 in regard to the conduct in public or publicly-funded universities, health professions' schools and research centers of directed research funded by private, profit-making manufacturers who have a direct economic interest in the research outcome.

As you are well aware, many of the nation's academic medical centers have long been engaged in research of this character, funded by pharmaceutical, food and medical device manufacturers. The wisdom of this practice has been thoughtfully evaluated and re-evaluated over the years. Therefore, I would have to respond in the affirmative to your first question concerning its propriety.

Since I do not feel sufficient information is available at the present time to respond to the other questions you pose, I plan to solicit the views of the Council of Deans on these issues and to bring your concerns to the attention of the Executive Council of the Association when it next meets in January, 1978. Thereafter, a more definitive statement of the AAMC view will be conveyed to you.

Sincerely,

John A. D. Cooper, M.D.

NINETY-FIFTH CONGRESS

PAUL G. ROGERS, FLA., CHAIRMAN

DAVID E. SATTERFIELD III, VA.  
RICHARDSON PREYER, N.C.  
JAMES H. SCHEUER, N.Y.  
HENRY A. WAXMAN, CALIF.  
JAMES J. FLORIO, N.J.  
ANDREW MAGUIRE, N.J.  
EDWARD J. MARKEY, MASS.  
RICHARD L. OTTINGER, N.Y.  
DOUG WALGREN, PA.  
HARLEY O. STAGGERS, W. VA.  
(EX OFFICIO)

TIM LEE CARTER, KY.  
JAMES T. BROYHILL, N.C.  
EDWARD R. MADIGAN, ILL.  
JOE SKUBITZ, KANS.  
SAMUEL L. DEVINE, OHIO  
(EX OFFICIO)

ROOM 2415  
RAYBURN HOUSE OFFICE BUILDING  
PHONE (202) 225-4952

Congress of the United States  
House of Representatives

Room 2424  
225-5995

Subcommittee on Health and the Environment  
of the  
Committee on Interstate and Foreign Commerce  
Washington, D.C. 20515

December 6, 1977

John A. D. Cooper, M.D.  
President  
Association of American  
Medical Colleges  
One DuPont Circle, N.W.  
Washington, D. C. 20036

Dear Dr. Cooper:

Recent hearings conducted by the California Department of Industrial Relations looked into the manufacture, use and toxicity of the pesticide dibromochloropropane (DBCP). As you may know, DBCP has been linked with sterility among workers who handle the chemical during its production. Since August its production has been halted.

During the course of the California hearings, it was estimated that research, funded directly by the Shell Chemical Company, on the health effects of DBCP was conducted at the University of California (San Francisco) Medical School. Furthermore, the findings of that research, indicating the chemical induced sterility in the test animals, were sent directly to Shell Chemical in confidential reports. Those findings were not published for more than three years. Testimony indicated that the delay was because of Shell's desire to keep confidential the ingredients of its pesticide so that it could not be produced by competitors.

Testimony generated at the DBCP hearings raises many questions about the nature of research being con-

Document from the collections of the AAMC Not to be reproduced without permission

John A. D. Cooper, M.D.  
December 6, 1977  
Page Two

ducted at public and publicly-supported universities and medical schools. Just as importantly, it provokes questions concerning the ethical and legal responsibilities of researchers to expeditiously publish research findings such as those in the DBCP case where evidence indicates potentially serious harm to the public health.

It would be most helpful to the Subcommittee on Health and the Environment if you would provide by letter your personal comments and thoughts on the following:

1. Is it proper for public or publicly-funded universities, health professions' schools, and research centers to conduct directed research funded by private, profit-making manufacturers who have a direct economic interest in the research outcome?

2. If such directed research is conducted in public or publicly-funded universities, health professions' schools and research centers, what safeguards presently exist or could be instituted to assure expeditious disclosure of research funding indicating potential serious adverse effects on the public health?

3. Do you believe that a researcher working in a public or publicly-funded institution has any ethical responsibility to fully and expeditiously disclose any research findings of potential endangerment to the public health from a product on which he or she is performing directed research funded by the product's manufacturer? If so, how should research be monitored to assure that such ethical responsibilities are properly carried out? Does such a researcher who is also a physician have any special ethical responsibility in such a situation by reason of being a physician?

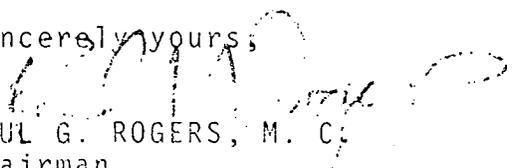
John A. D. Cooper, M. D.  
December 6, 1977  
Page Three

4. Does your association prescribe ethical or legal codes or requirements mandating that researchers involved in research projects such as described above expeditiously disclose research findings of potential endangerment to the public health? If so, how are such codes or requirements monitored and implemented? If not, do you believe such codes or requirements should be prescribed? By whom should they be prescribed and enforced?

I look forward to receiving your thinking on this issue.

Thank you for your time and cooperation.

Sincerely yours,

  
PAUL G. ROGERS, M. C.  
Chairman

PGR:lsr

Response to Dr. Kennedy of the Food and Drug Administration

During the 1977 annual meeting of the Council of Academic Societies Dr. Donald Kennedy, Administrator of the Food and Drug Administration, expressed his desire that the academic community and the Administration should come closer together for their mutual benefit. Dr. Kennedy stated that he would be glad to listen to reasonable suggestions from the academic community how the interrelationships between FDA and academe could be strengthened. The CAS Administrative Board should consider a response to Dr. Kennedy's offer. Given that the FDA is primarily a regulatory agency it is difficult to see how such relationships can be fostered and strengthened. In discussions with Dr. Kennedy's staff and others three themes have been emphasized:

First, it might be possible to increase the understanding of the Council of Academic Societies of the FDA-academe interface. Specific areas which might be studied relate to the research necessary to develop new drugs and medical devices, the education of medical students, residents, and faculty and an increased involvement of the biomedical community in the testing, development and control of drugs and devices.

Second, as Dr. Kennedy himself suggested, it might be possible to make changes in the medical curriculum to teach medical students to understand, cope and live with the FDA's increasing intrusion into the practice of medicine.

Third, it might be possible to involve the CAS in the process of the revision of FDA's legislative authority. The legal base of the FDA has evolved in a piecemeal fashion over the past forty years, and a number of legislative proposals are being put forth by both the Executive Branch and Congress to bring order out of the hodge-podge of laws affecting FDA as well as to institute some needed reforms. We might also consider whether the CAS should take a position with respect to proposals for the creation of a Drug Science Board or the creation of a National Center for Clinical Pharmacology.

STATUS REPORT  
CLINICAL EVALUATION PROJECT

The Association is currently engaged in a national study of clinical evaluation that has received the support of the Chairmen's groups in internal medicine, pediatrics, psychiatry, family medicine and surgery. The purpose of the study is to work with faculty representatives from the various departments to make more explicit the criteria used in evaluating the clinical performance of students in the undergraduate clerkships. Among these criteria, special attention will be given those related to personal characteristics that facilitate or inhibit good clinical performance. Residency evaluation will also be considered to enable the investigation of the unraveling or maturing of behaviors that are perhaps in the embryonic stages during the early phases of clinical education.

The project is divided into several phases. In the first phase, which is currently underway, evaluation forms that are used in assessing the performance of clinical clerks and residents are being requested from the appropriate faculty within each department. These faculty are being identified by the Chairmen of their departments in response to a letter supporting the project from the executive officer of their respective Chairmen's organization. This effort will result in a summary statement of what is occurring in the evaluation of a clinical clerk's performance. This document will be distributed to all participants by discipline and will serve as the point of departure for phase two.

In the second phase of the project, small groups of faculty heavily involved in clinical education and evaluation will be brought together for the purpose of testing out assumptions gleaned from previous Association efforts in this area. The goal is to arrive at the most usable (not time-consuming yet meaningful) kinds of evaluation tools, given the different uses to which the information gathered by such tools is put (e.g., acknowledgement of excellence, identification of marginal performance, compilation of legally acceptable documentation, etc.)

The third phase will involve the development and distribution of a handbook in which a number of suggestions and specific tools for testing will be presented for faculty consideration and possible adoption.

The involvement of the member societies of CAS has been crucial to getting this project underway. Staff expects to continue a close interaction with them and with the CAS Administrative Board as the project evolves.