



association of american  
medical colleges

# COUNCIL OF ACADEMIC SOCIETIES

## IMPORTANT MEETING ANNOUNCEMENT

**PLEASE MARK YOUR CALENDARS NOW!**

AS VOTED ON AT THE RECENT MEETING OF THE CAS, THE 1982 CAS INTERIM MEETING HAS BEEN SCHEDULED FOR JANUARY 19-20, 1982 IN WASHINGTON, D.C. THE MEETING WILL CONVENE IN THE MID-MORNING OF JANUARY 19 AND ADJOURN AROUND NOON ON JANUARY 20. ADDITIONAL INFORMATION REGARDING THE SCHEDULE FOR THE MEETING AND HOTEL ARRANGEMENTS WILL BE SENT TO YOU IN THE NEAR FUTURE.

\* \* \* \* \*

THE MEETING WILL FOCUS ON THE THEME OF THE RESEARCH PARTNERSHIP BETWEEN THE UNIVERSITY AND THE FEDERAL GOVERNMENT--A SUCCESSFUL PARTNERSHIP FOR ALMOST HALF A CENTURY, NOW THREATENED BY A NUMBER OF FACTORS. KEY CONGRESSIONAL STAFF AS WELL AS EXECUTIVE BRANCH OFFICIALS WILL BE INVITED TO PARTICIPATE IN INFORMAL DISCUSSION SESSIONS REGARDING MANY OF THESE ISSUES INCLUDING: THE GROWING ANTIVIVISECTIONIST MOVEMENT, SMALL BUSINESS SET-ASIDE LEGISLATION (SEE FALL, 1981 CAS BRIEF), REDUCTIONS IN FUNDING FOR RESEARCH AND RESEARCH TRAINING, AND AN INCREASING DEMAND FOR GREATER ACCOUNTABILITY REGARDING THE EXPENDITURE OF FEDERAL RESEARCH FUNDS.

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THIS WILL BE AN OPPORTUNITY FOR CAS REPRESENTATIVES TO MAKE THEIR SOCIETIES' VIEWS KNOWN TO MANY OF THE CONGRESSIONAL STAFF (AND, THEREBY MEMBERS OF CONGRESS) WHO PLAY IMPORTANT ROLES IN THE ENACTMENT OF HEALTH LEGISLATION. ATTENDANCE BY CAS REPRESENTATIVES AT THIS MEETING WILL DETERMINE ITS SUCCESS IN TERMS OF BEING AN INFORMATIVE AND ENLIGHTENING SESSION FOR THE CONGRESSIONAL GUESTS AS WELL AS REPRESENTATIVES TO THE COUNCIL. IT IS HOPED THAT THERE WILL BE AT LEAST ONE REPRESENTATIVE PRESENT FROM EACH SOCIETY AND SOCIETY PRESIDENTS ARE ASKED TO ASSIGN ALTERNATES TO ATTEND IN THE EVENT THAT THEIR RESPECTIVE OFFICIAL REPRESENTATIVES ARE UNABLE TO DO SO. MORE INFORMATION WILL BE SENT TO YOU IN THE NEAR FUTURE. IN THE MEANTIME, PLEASE MARK YOUR CALENDARS NOW AND PLAN TO ATTEND!!!!



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**COUNCIL OF ACADEMIC SOCIETIES  
1982 INTERIM MEETING  
REGISTRATION INFORMATION**

**Biomedical Research: A Partnership  
Between the Federal Government  
and the Academic Medical Center**

**PRE-REGISTRATION  
BY DECEMBER 28  
IS ESSENTIAL!!**

**THERE WILL BE NO REGISTRATION  
AT THE DOOR!**

COUNCIL OF ACADEMIC SOCIETIES  
INTERIM MEETING  
JANUARY 19-20, 1982  
WASHINGTON HILTON HOTEL  
WASHINGTON, D.C.

THE IMPORTANCE OF THIS MEETING CANNOT BE OVEREMPHASIZED!

The 1982 CAS Interim Meeting will focus on the theme of the research partnership between the federal government and the academic medical center--a successful partnership for almost half a century, now threatened by a number of factors. Key Congressional staff as well as Executive Branch officials have been invited to attend the plenary session and participate in informal discussion groups on the afternoon of January 19 (see schedule). A number of issues have been targeted for discussion including: potential threats to the peer review system, the antivivisectionist movement, loss of morale within the research community, communication breakdowns between the sponsors and conductors of research, and increasing demand for greater accountability regarding the expenditure of federal research funds. The main purpose of the meeting is to provide the opportunity for a free and open exchange between CAS Representatives and the invited guests regarding these generic issues. Specific pieces of legislation and details of the budget will not be the focus of the meeting; instead it is hoped that the open format will lend itself to a non-political and prospective dialogue regarding biomedical research, its development, and its future potential.

Another goal of the meeting is the establishment of personal contacts between CAS Representatives and the health aides of their respective Congressional Representatives. To facilitate this interaction, CAS Representatives and the staff person(s) for their respective home district Congressmen and Senators will be assigned to the same discussion group. IF THE DISCUSSION GROUPS ARE TO BE EFFECTIVELY ORGANIZED IN THIS MANNER, THE CAS STAFF MUST KNOW IN ADVANCE OF THE MEETING WHICH CAS REPRESENTATIVES AND SOCIETY OFFICERS PLAN TO ATTEND. PRE-REGISTRATION IS VITAL TO THE SUCCESS OF THE MEETING!!!

A registration form appears on the following page. Please complete the form and return it by December 28. Also enclosed is a Hilton Hotel reservation card. This should be completed and returned to the hotel by December 28. Any questions regarding the purpose or format of the meeting should be directed to Lynn Morrison or Diane Plumb at 202-828-0480. Agenda materials will be sent to you in late December.

MEETING SCHEDULE

January 19

11:00 a.m.

Plenary Session  
(CAS and AAMC Staff Only)

Thoroughbred Room

Presentation of legislative update  
and other important background  
information

12:30 p.m.

Lunch

2:00 p.m.

Plenary Session  
(CAS, AAMC Staff and Invited Guests)

Thoroughbred Room

Stewardship of the Biomedical Research  
Enterprise: A View from the Research Community

*Bernadine Healy Bulkley, M.D.*  
*Professor of Medicine*  
*Johns Hopkins University School of Medicine*

An Informed Observer's View of Federal/Public  
Expectations for Biomedical Research

*John K. Iglehart*  
*Special Correspondent*  
*NEW ENGLAND JOURNAL OF MEDICINE*

3:30 p.m.

Small Group Discussion Sessions

(Rooms to be Assigned)

5:30 p.m.

Cocktail Reception

Thoroughbred Room

January 20

9:00 a.m.

CAS Meeting  
(CAS and AAMC Staff Only)

Jefferson East Room

12:30 p.m.

Adjournment

REGISTRATION INFORMATION

To cover the cost of the January 19 reception, a registration fee of \$20 is being charged. Checks should be made payable to "AAMC." Please complete the form below and return it along with the registration fee by December 28 to:

Lynn Morrison  
Department of Academic Affairs  
AAMC  
One Dupont Circle, N.W. Suite 200  
Washington, D.C. 20036

Council of Academic Societies  
1982 Interim Meeting

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

\_\_\_\_\_

SOCIETY: \_\_\_\_\_

I will attend the Interim Meeting and have enclosed my \$20 registration fee.

Reminder: Hotel reservations must be made by returning the enclosed Hilton reservation card to the hotel.



## association of american medical colleges

ENCLOSED ARE BACKGROUND MATERIALS FOR THE JANUARY 19-20 INTERIM MEETING OF THE COUNCIL OF ACADEMIC SOCIETIES. REGARDLESS OF WHETHER YOU PLAN TO ATTEND THE MEETING, THESE MATERIALS (PARTICULARLY THE BRIEFING SHEETS ON ISSUES) SHOULD BE KEPT ON HAND FOR REFERENCE. IF YOU DO PLAN TO ATTEND THE MEETING:

1) READ CAREFULLY THE ENCLOSED MATERIALS

- You should have a basic understanding of all of the issues outlined in the briefing sheets. You may wish to become particularly knowledgeable about two or three of the issues of greatest concern to you.
- Additional information on any of these issues may be obtained by calling Diane Plumb at 202-828-0480 in advance of the meeting.

2) BE PREPARED TO DISCUSS THE RESEARCH PROGRAMS AT YOUR OWN INSTITUTION

- Convey this information in an anecdotal manner and try to avoid highly technical descriptions.
- Highlight particularly exciting research breakthroughs which have taken place at your institution as well as research projects which your institution aspires to conduct in the future.

3) IF YOU RECEIVED THE NAMES OF STAFF MEMBERS FROM YOUR CONGRESSIONAL DELEGATION WHO HAVE BEEN INVITED TO THE MEETING OR RECEPTION AND YOU HAVE NOT YET CONTACTED THEM, YOU SHOULD DO SO IMMEDIATELY!!

- Let them know that you will be at the meeting and that you are hoping they plan to attend. A personalized invitation from you, the constituent, will enhance the probability that the individual(s) will in fact attend.
- If possible, invite them to join you following the reception for continued informal discussion over dinner.

YOU SHOULD BRING THESE MATERIALS WITH YOU TO THE MEETING. ANY QUESTIONS ABOUT THE FORMAT OR FOCUS FOR THE MEETING SHOULD BE DIRECTED TO LYNN MORRISON OR DIANE PLUMB AT 202-828-0480.



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**BACKGROUND INFORMATION**  
**FOR THE**  
**1982 INTERIM MEETING**  
**OF THE**  
**COUNCIL OF ACADEMIC**  
**SOCIETIES**

**“Biomedical Research: A Partnership  
Between the Federal Government  
and the Academic Medical Center”**

**JANUARY 19 - 20, 1982**

**WASHINGTON HILTON HOTEL  
WASHINGTON, D.C.**

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## MEETING SCHEDULE

January 19

11:00 a.m.

Briefing Session  
(CAS Representatives and AAMC Staff)

Thoroughbred Room

Chairman's Report

*David M. Brown, M.D.*

President's Remarks

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

Presentation of legislative update  
and other important background  
information

12:30 p.m.

Lunch

2:00 p.m.

Plenary Session  
(CAS Representatives, AAMC Staff  
and Invited Guests)

Thoroughbred Room

Stewardship of the Biomedical Research  
Enterprise: A View from the Research  
Community

*Bernadine Healy Bulkley, M.D.  
Associate Professor of Medicine  
Johns Hopkins University School  
of Medicine*

An Informed Observer's View of Federal/Public  
Expectations for Biomedical Research

*John K. Iglehart  
Special Correspondent  
NEW ENGLAND JOURNAL OF MEDICINE*

The Federal Role in the Biomedical Research  
Enterprise: Responsibilities and  
Expectations

*Edward N. Brandt, Jr., M.D.  
Assistant Secretary for Health  
Department of Health and Human Services*

3:30 p.m.

Small Group Discussion Sessions

(Rooms to be Assigned)

5:30 p.m.

Reception

Thoroughbred Room



January 20

9:00 a.m.

CAS Meeting  
(CAS Representatives and AAMC Staff)

Jefferson East Room

Discussion Group Reports

Discussion of Future CAS Initiatives

12:30 p.m.

Adjournment

## OVERVIEW OF THE PURPOSE OF THE CAS INTERIM MEETING

When the CAS decided to devote its 1982 Interim Meeting to a public affairs symposium on biomedical research, strong sentiment was expressed that this meeting should differ significantly from the previous public affairs sessions that have focused on the legislative process and on analyzing and responding to specific legislative proposals. Dialogue about the Federal budget and specific pieces of legislation have been and will continue to be important if the research community is to participate in discussions that affect their programs. But bills in Congress come and go, and much of this dialogue has been piecemeal and less than effective in the absence of a deep and meaningful understanding of the complex and delicate systems and mechanisms upon which the research enterprise is based. Consequently, the CAS felt that it would be appropriate and timely to sponsor a meeting proactive in nature and to concentrate efforts on developing a broad and mutual understanding between representatives of the Federal government and the research community about the national biomedical research program--how it was developed, how it currently functions, and what will be required for its effective continuation.

The theme of the Interim Meeting, "Biomedical Research: A Partnership Between the Federal Government and the Academic Medical Center," recognizes the symbiotic relationship between the two sectors. It is widely acknowledged that the research community depends absolutely on reliable and stable Federal sponsorship since adequate and appropriate support for the basic research mission could never be garnered from the private sector. It is equally true that the Federal government could not carry out the national research agenda without the support of the research community to provide the talent and creativity to conduct the research and to train future generations of researchers. Such a symbiotic relationship is built upon an understanding of mutual expectations, but this understanding has broken down in recent years not only because of inadequate dialogue between the two sectors but also because many decision makers on the Federal side do not have an in-depth knowledge of the systems and mechanisms upon which the enterprise is based. It is difficult to convey to a Congressional staff person how a set-aside bill, for example, could potentially dismantle a cornerstone of the national research enterprise--the peer review system--when that individual has a very limited knowledge of the intricacies of peer review. Similarly, it is difficult for the research community to respond in a meaningful way to allegations about accountability and research ethics when such questions are raised in an accusatory and inflammatory setting (such as the recent NCI hearings that were prompted by a series of Washington Post articles) rather than in rational and low-key discussions of government expectations regarding accountability and ethics.

It is therefore hoped that the Interim Meeting will provide a forum for open and broad discussion that will lay the groundwork for a greater mutual understanding between the two sectors that have built and maintained a successful biomedical research enterprise. CAS representatives should be prepared to discuss their own local research programs and to convey information of an anecdotal nature about such issues as: 1) the impact of funding uncertainties on program strength and stability; 2) loss of morale within the research community; 3) paperwork problems for individual investigators; 4) the essential role of animal experimentation; and 5) threats to the peer review system stemming from workload problems at the national level, doubts raised by some about the fairness of the system, and proposals that would alter the basic structure and purpose of peer review. If an *effective* dialogue is developed on these and other *broad* issues, discussions of specific legislative proposals will be enhanced for years to come.

The following briefing sheets provide the latest information available on issues that CAS representatives may wish to discuss with their Congressmen's health aides or individuals from the Executive Branch. Since the purpose of the small group discussions will best be achieved by focusing on broad issues and by avoiding lengthy and detailed debate on specific legislative proposals, discussions of the bills described in these briefing sheets (including their current status, prospect for passage, points of possible intervention) might best be carried out on an individual and informal basis during the reception or in follow-up conversation.

Legislative Topic: Set-Aside of Federal Research Funds for Small Business

Brief Description of Bills:

Senate Bill (S.881): Would require Federal research agencies with research and development budgets over \$100 million to set-aside 1% of their extramural research and development budgets for small business.

House Bill (H.R.4326): Would require all Federal agencies with research and development funds over \$100 million to set-aside 3% (amount phased-in over 4 years) of their budgets for allocation to small businesses.

Current Status:

S.881 adopted by the Senate by a 90-0 vote in December.

H.R.4326 approved by the Small Business Committee, but four other House Committees (Health and Environment, Science and Technology, Armed Services, and Veterans Affairs) have been granted a 45 legislative-day referral in order to allow the opportunity for these committees to consider the effects of the bill on programs within their jurisdiction.

Science and Technology will hold hearings January 26-27; other committees are expected to also schedule public hearings.

Recommended Action: Discuss with appropriate House committee staff and health aides of individual congressmen concerns about the deleterious impact of a small business set-aside on the basic research missions of NIH, NIMH, and the VA Research program. Urge that Federal funding for health research continue to be based strictly on scientific merit through the traditional peer review system.

Discuss with Senate staff concerns about the bills and urge that Senate conferees support an exemption for NIH, NIMH, and VA Research.

Legislative Topic: Health Research Funding

Brief Description of Bills:

Continuing Resolution: President Reagan recently signed a Continuing Resolution that provides funding for Federal programs until March 31, 1982. The current CR embodies a 4% reduction in spending levels for most discretionary programs; consequently most health research programs have funding levels that are close to or below last year's levels:

	<u>FY1981</u>	<u>Dec. CR for FY1982</u>	<u>Percent Difference</u>
NIH	3,569.4	3,647.7	+ 2%
NIH Research Training	176.3	157.2	-11%
NIMH Research	141.7	130.9	- 8%
NIMH Research Training	19.5	15.4	-21%

VA Appropriations: The HUD-Independent Agencies Appropriations bill provides a funding level of \$128 million for the VA medical research program--an 8.5% reduction from the 1981 budget of \$140 million.

Current Status:

Barring approval of any potential rescission requests that may be part of the President's 1983 budget, the NIH and NIMH levels mentioned above will remain stable until the CR expires and the VA research levels will be in effect until the end of Fiscal 1982.

Recommended Action: In view of the large cuts sustained this year in health research and training programs, Congress and the Administration should be strongly urged to provide increases for FY1983 to compensate, at the very least, for inflation.

Legislative Topic: Animal Research

Brief Description of Bills:

Five bills have been introduced in the House, all of which contain various provisions aimed at decreasing the use of animals in research, providing stricter guidelines for the care of research animals, and promoting the use of "alternative" in vitro methods.

Current Status:

The House Science, Research, and Technology Subcommittee held hearings in the fall on the animal research bills. The Subcommittee is proceeding with the development of a bill that presumably will address the concerns raised during those hearings. The Subcommittee bill is expected to include provisions that would not only tighten existing safeguards for the humane and proper treatment of research animals but would also provide funding by either a grant or set-aside mechanism for the development of alternative techniques.

Recommended Action: Discuss with Congressional staff the essential and irreplaceable role of animals in research. Urge that research funds not be diverted for the development of alternative in vitro methods.

Legislative Topic: Taxation of National Research Service Awards

Current Status:

Bills to permanently exempt NRSAs from taxation were not acted on in the final days of the first session of Congress because of the press of other business. Last minute efforts to extend the moratorium on NRSA taxation that expired December 31 were also unsuccessful. Consequently, NRSAs are now technically subject to taxation, but it is hoped that a retroactive moratorium or exemption will be enacted during this session of Congress.

Recommended Action: Discuss with Congressional staff the need for continuation of the tax-exempt treatment of NRSAs since taxation would diminish the attractiveness of these awards. The most preferable legislative solution would be permanent and retroactive exemption of NRSAs, but at the very least, a retroactive moratorium would provide a short-term solution.

Legislative Topic: Separate Arthritis Institute

Brief Description of Bills:

H.R.5006, introduced in November by Representative Claude Pepper, would amend the Public Health Service Act to establish a National Institute on Arthritis and Muscular-Skeletal Disorders.

S.1939, a counterpart to the above bill, was introduced in December by Senator Goldwater.

Current Status:

Both bills have been referred to the health committees (Health and the Environment in the House; Labor and Human Resources in the Senate). No hearings have been scheduled to date.

Recommended Action: The official AAMC position on these bills is opposition on the grounds that creation of a separate institute would result in increased administrative costs and further fragmentation.



Legislative Topic: Orphan Drug Development

Brief Description of Bills:

S. 1498, introduced by Senator Kassebaum, would establish an office at NIH to assist in the development of drugs of limited commercial value by granting the director the authority to undertake orphan drug development at NIH or to offer financial assistance to outside entities for such development. The NIH office would have authority to coordinate the diverse national efforts to develop orphan drugs and to conduct studies of the scientific potential, therapeutic need, and anticipated cost of drug development.

H.R.1663, introduced by Representative Ted Weiss, is identical to S.1498.

H.R.5238, introduced by Representative Henry Waxman, would promote Orphan Drug Development by amending several sections of the Federal Food, Drug, and Cosmetic Act to streamline and expedite the introduction and availability of drugs for rare diseases. H.R.5238 would establish an inter-agency committee to oversee governmental activities in this area and would provide a tax credit for industries which develop orphan drugs.

Current Status:

The Health and Environment Subcommittee held hearings on Orphan Drugs prior to the introduction of Congressman Waxman's bill. No date has been scheduled for markup by the Subcommittee.

The Senate bill is pending before the Labor and Human Resources Committee; hearings have not been scheduled.

## FUTURE CAS INITIATIVES

Despite the overwhelming success of the nation's biomedical research effort, the days of ever-increasing federal research support and limited government interference in the conduct of research appear to be at an end. Integral components of the nation's biomedical research system are increasingly threatened by funding uncertainties, legislative and regulatory proposals which have the potential to stifle the growth of biomedical and behavioral research knowledge, and a variety of other factors. If a national commitment to the research effort is to be perpetuated, it is clear that members of the academic medical community must be prepared to effectively present their views on these issues to federal policymakers. In addition, medical academicians must take responsibility for maintaining a favorable public image for the research effort in order to avert the erosion of trust that began recently with extensive press and media coverage of several isolated incidents of falsified research results.

In an effort to address these issues, the CAS Interim Meeting has been organized as a public affairs forum. The purpose of the meeting is to provide the opportunity for a free-ranging discussion between federal policymakers and representatives of the academic community. This type of interaction between medical school faculty, Congressional staffers, and executive branch officials can only serve to strengthen the research partnership between the academic medical center and the federal government. However, the Interim Meeting is just a beginning; if the partnership is to be maintained, it is vitally important for all members of the academic medical community--not just CAS Representatives--to develop and maintain a continuing dialogue with federal policymakers.

### Questions for Consideration

How can academic societies increase their public affairs effectiveness and more efficiently galvanize their members to action on specific issues?

How can the CAS heighten the awareness of all medical school faculty members regarding public affairs issues? How can the CAS encourage and facilitate increased faculty involvement?

How can faculty promote increased public affairs involvement at the institutional level?

What role can faculty play in educating the general public regarding the importance of the biomedical research effort? What steps might the CAS take to improve public understanding of the integrity of the nation's biomedical research system?