



Memorandum

Date

JUN 23 1992
[Signature]

From

Richard P. Kusserow
Inspector General

Subject

Review of Alleged Conflicts-of-Interest in National Institutes of Health Consensus Development Conference on the Treatment of Destructive Behaviors in Persons with Developmental Disabilities (A-15-90-00009)

To

James O. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

Attached is a copy of our final report on the subject review requested by the Senate Permanent Subcommittee on Investigations (Subcommittee), Senate Committee on Governmental Affairs, in response to conflicts-of-interest allegations in a Legal Times article involving the National Institutes of Health (NIH) Consensus Development Conference (Conference) on the "Treatment of Destructive Behaviors in Persons with Developmental Disabilities."

The Subcommittee asked us to evaluate the potential conflicts-of-interest cited in this article in which critics claimed that the Conference's "sanctioning" of a controversial pain-inflicting electrical device, called the Self-injurious Behavior Inhibiting System, resulted from "cozy relationships and financial ties" involving Conference officials and promoters of the device.

Although many of the professional relationships and financial ties cited in the article were found to be true, we found no evidence that Conference officials gained financially. We also found no evidence that these associations influenced the Conference officials in their decisions concerning the device. Rather, the Conference concluded that the device and other aversive treatments should be discouraged and used only under restrictive conditions.

Our review did, however, disclose that NIH had not implemented the most effective internal control techniques for identifying, documenting, and evaluating potential conflicts-of-interest for Conference officials. In addition, we found that no internal control review has been conducted of the consensus development conference program as intended under the Federal Managers' Financial Integrity Act (FMFIA).

Page 2 - James O. Mason, M.D., Dr. P.H.

These internal control weaknesses were discussed with NIH officials who subsequently implemented certain corrective actions. We are recommending, however, that the effectiveness of these corrective actions be evaluated and that an internal control review be periodically conducted of the consensus development conference program in accordance with FMFIA requirements.

The Public Health Service (PHS) concurred with our recommendations. The PHS comments, dated April 8, 1992, have been incorporated in the Agency Comments and OIG Response section of this report and included in the Appendix.

We would appreciate being advised within 60 days on the status of corrective actions taken or planned on each recommendation. If you wish to discuss our findings further, please call me or your staff may contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (FTS) 443-3583. A copy of this report is being sent to The Honorable Sam Nunn, Chairman, Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs because of his interest in this subject.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF ALLEGED CONFLICTS-OF-
INTEREST IN NATIONAL INSTITUTES OF
HEALTH CONSENSUS DEVELOPMENT
CONFERENCE ON THE TREATMENT OF
DESTRUCTIVE BEHAVIORS IN PERSONS
WITH DEVELOPMENTAL DISABILITIES**



**Richard P. Kusserow
INSPECTOR GENERAL**

A-15-90-09



Memorandum

Date

JUN 23 1992

From

Richard P. Kusserow
Inspector General

Subject

Review of Alleged Conflicts-of-Interest in National Institutes of Health Consensus Development Conference on the Treatment of Destructive Behaviors in Persons with Developmental Disabilities (A-15-90-00009)

To

James O. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

This final report provides you with the results of our examination into potential conflicts-of-interest contained in a March 26, 1990 Legal Times article involving the September 1989 National Institutes of Health (NIH) Consensus Development Conference (Conference) on the "Treatment of Destructive Behaviors in Persons with Developmental Disabilities" held in Bethesda, Maryland. This review was requested by the Chairman of the Permanent Subcommittee on Investigations (Subcommittee), Senate Committee on Governmental Affairs.

The Subcommittee asked us to evaluate any conflict-of-interest situations indicated by this article in which critics claimed that the Conference's "sanctioning" of a controversial pain-inflicting electrical device, called the Self-injurious Behavior Inhibiting System (SIBIS), resulted from "cozy relationships and financial ties" involving Conference officials and promoters of the device.

The article specifically addressed four critics' allegations regarding: (1) the connection between the Director, NIH's Institute of Child Health and Human Development (NICHD)--the principal sponsor of the Conference, and the American Foundation for Autistic Children (Foundation)--whose founders were credited with inventing the device; (2) close relationships and financial ties between Conference officials from NIH and the private sector, and outside organizations; (3) the role of Johns Hopkins University (JHU) School of Medicine, which obtained a financial interest in the device and was subsequently represented on the Conference planning committee and panel by a faculty member; and (4) the Conference's "sanctioning" of the device.

We found that the NICHD Director and one other Conference official from the private sector were, in fact, members of the Foundation's scientific advisory board. We also found that certain Conference officials were associated with JHU which received royalty rights from the Foundation founders for JHU's further development of the device. However, we found no evidence that these associations influenced the Conference officials to promote the device. Rather, the Conference concluded that the device and other pain-inflicting behavior reduction procedures (aversive treatments) should be used only under restrictive conditions. Further, we found no evidence that any of the Conference officials gained financially.

Our review did, however, identify internal control weaknesses in NIH's selection of Conference planning committee and panel members from the private sector. The NIH had not been requesting written certification documents from panel member candidates concerning potential conflicts-of-interest with respect to Conference issues and had taken no action to evaluate planning committee members for potential conflicts-of-interest. Further, NIH had not been documenting its findings when conducting background checks to identify a panelist's scientific bias or financial conflict-of-interest. In addition, we found that no internal control review has been conducted of the consensus development conference program as intended under the Federal Managers' Financial Integrity Act (FMFIA).

These internal control weaknesses were discussed with NIH officials who subsequently established improved policies and procedures for identifying, documenting, and evaluating scientific and financial conflicts-of-interest involving consensus development conferences. We recommended, however, that the effectiveness of these corrective actions be evaluated and that an internal control review be periodically conducted of the consensus development conference program in accordance with FMFIA requirements.

In a separate issue, our review noted that the NICHD Director's name and NIH position title appeared on the letterhead of the Foundation. We were advised by the Department of Health and Human Services (HHS) Office of General Counsel (OGC) that inclusion of this title could be interpreted as being representative of an official act or an official view of the Department, thereby violating HHS standards of conduct. However, the NICHD Director's name without the title is permissible on the Foundation's letterhead. We discussed our finding with the NICHD Director, and in August 1990 he requested the Foundation to immediately remove his title from its letterhead and requested that the

use of this letterhead be discontinued. The Foundation's stationery was subsequently changed to delete the Director's title from the letterhead.

In commenting on our draft report, the Public Health Service (PHS) generally concurred with our recommendations and indicated they have taken or are taking actions to implement them. The PHS comments, dated April 8, 1992, have been incorporated in the Agency Comments and OIG Response section of this report and included in the Appendix.

BACKGROUND

The NIH established a program in 1977 to sponsor consensus development conferences for evaluating biomedical technologies and practices, and to disseminate results that advance the understanding of the technology or issue in question to health professionals and the public at large. From the start of the program through September 9, 1991, NIH sponsored 84 consensus development conferences at a total estimated cost of \$10.5 million. Each conference is jointly sponsored by one or more of the NIH Institutes, Centers, and Divisions (ICD) along with NIH's Office of Medical Applications of Research (OMAR). The OMAR is within the Office of the Director, and provides general supervision and administrative support for all consensus development conferences.

Topics for consensus development conferences may be suggested by the ICDs, OMAR, Federal and State government health agencies, Congress, and the public. The final selection of a topic and the decision to hold a conference is made when there is agreement between the sponsoring ICD and OMAR.

After the scientific basis for a consensus development conference is defined, a planning committee is selected which includes the conference panel chairperson, representatives from each sponsoring ICD, OMAR and selected outside experts. The planning committee has four functions: (1) to draft questions pertaining to the conference topics to be answered by the conference panel; (2) to draft the conference program; (3) to recommend conference panel members; and (4) to recommend speakers who will present relevant information to the panelists. The NIH officials also explained that if a conference is sponsored by NICHD, the planning committee may recommend scientists qualified to develop conference background information on the issues to be discussed. Federal employees are prohibited by the HHS standards of conduct from serving as planning committee members if they have a financial interest in the issues being decided by the conference.

The conference panel evaluates information and provides answers to various topical questions developed by the planning committee. The panel consists primarily of medical and scientific professionals but selection of members from the general public is also encouraged by NIH guidelines. Federal employees are prohibited from participating as panel members.

The OMAR has established guidelines which specifically address the need to prevent the selection of panel members who have a vested interest or otherwise identified with an advocacy or promotional position regarding the conference topic.

The Conference panel reported that NIH made a broad effort to involve the greatest number of participants interested in the topic of the Conference. In July 1989, NIH mailed over 13,000 announcements inviting participation to individuals and organizations with an identified interest in this area. The Conference, which was open to the public, was also announced in the Federal Resister and in major professional journals.

The Conference was conducted in September 1989 on the NIH campus, Bethesda, Maryland and was sponsored by NICHD and OMAR. Co-sponsors included the National Institute of Neurological Disorders and Stroke, the National Institute of Mental Health of the Alcohol, Drug Abuse, and Mental Health Administration, and the Division of Maternal and Child Health of the Health Resources and Services Administration.

The results of the Conference were presented by the panel immediately following the Conference in a draft consensus statement¹ released to the news media in September 1989 which provided answers to the Conference questions. In addition, a final Conference report, which is unique to NICHD sponsored consensus development conferences, was completed by NICHD in October 1991². The Conference report includes a more detailed panel report on the Conference findings. The final Conference report also includes: (1) the consensus statement; (2) abstracts of presentations by the Conference speakers; (3) scientific background information documents; (4) listing of scientific references; and (5) comments from organizations and individuals.

¹The final consensus statement, printed by the Government Printing Office, was released in April 1990 and included only minor editorial changes.

²The final Conference report was printed by the Government Printing Office and released in early 1992.

The Self-Injurious Behavior
Inhibiting System Device

According to NIH officials, the SIBIS device is designed to deliver a small electrical shock, equivalent to the snap of a rubber band against the skin, when a person self-administers a blow to the head, or when a remote control device is activated. The SIBIS device was invented by one of the Foundation's founders who granted JHU a license to further develop the device that was to be marketed through a sublicensee. Under this license agreement, the inventor would receive 71.1 percent of the net royalties³ that JHU received from the manufacturer and seller, Human Technologies, Inc., of Tampa, Florida.

OBJECTIVE, SCOPE AND METHODOLOGY

The objective of our review was to identify and evaluate potential conflicts-of-interest that may have existed because of close professional relationships and financial ties that were reported in the Legal Times article. In this regard, we reviewed statutes, HHS standards of conduct, regulations, policies, procedures and guidelines relating to the conduct of consensus development conferences. We held discussions with two of the four critics quoted in the Legal Times article to obtain any evidence of conflicts-of-interest involving the Conference.

In addition, we: (1) reviewed NIH's files and records pertaining to the allegations raised in the article; (2) reviewed HHS Financial Disclosure forms and Request for Approval of Outside Activity forms filed for the period 1987 through 1990 for NIH employee? involved in the Conference; (3) reviewed curriculum vitae for NIH employees; (4) reviewed information from standard biographical sources, and published literature abstracts for panel members to identify any evidence of conflict-of-interest regarding the Conference issues; (5) examined audio transcripts of the Conference to identify any promotion of the device; and (6) reviewed the final consensus statement and the final NICHD Conference report for indications of promotion of the device.

³Net royalties represent gross royalties received by JHU less costs incurred by JHU related to the device.

⁴Curriculum vitae is a resume of one's career showing biographical information such as educational background; employment record; listing of publications and abstracts of such publications; organization memberships; and honors and awards.

planning committee members from the private sector, or Conference speakers for financial conflicts-of-interest. As required to provide financial disclosure forms. Although our internal controls over the NIH sponsored consensus development conference program, weaknesses during our review of the allegations reported in the Legal Times article.

Maryland, during the period from April 1990 through October standards.

CONFERENCE OFFICIALS NOT

The March 1990 Legal Times article alleged that certain financial ties with organizations and individuals which may have influenced the Conference's "sanctioning" of the device. the article alleged: (1) that the Director of

Scientific Advisory Board of the Foundation whose founders were credited with inventing the device; (2) that the JHU by helping the inventors further develop and conduct studies on the device, Conference planning committee and panel by a faculty member; and (3) that the Conference promoted use of the SIBIS and

The NICHD Director
and Other NIH Employees

who was Chairman of the Planning Committee for the Conference, Foundation's Scientific Advisory Board. However, he device. He said that his association with the Foundation was autistic children in Montgomery County, Maryland. In addition, Foundation, we found no evidence of any NIH employees' Inc.,⁵ on outside activity request forms and financial disclosure

⁵As mentioned in the background section of this report, Human Technologies, Inc., is the manufacturer of this device.

reports filed since 1987; and curriculum vitae showing education, bibliographical data and associations with professional organizations and individuals.

Although the Director stated that he was not involved with the device or its manufacturer, he told us that he supports the use of the device if it is warranted. However,- he emphasized that this device and other forms of punishment-should be used only when other forms of treatment have,been found ineffective. He added that various cases have been reported where punishment is the only treatment that will prevent destructive behavior and that the device has been reported as being very effective for this purpose.

Panel Members

We found that one Conference panel member has also been a member of the Foundation's Scientific Advisory Board for several years. Although the device was invented by one of the Foundation's founders, the Foundation had no financial interest in the device. According to statements by one of the foundation founders:

"Since AFAC's [Foundation] founding in 1967, AFAC has had a Scientific Advisory Board consisting of outstanding scientific and medical specialists. The Board holds no meetings. Individual Board members are consulted from time to time on problems relating to autism. No Board member receives or has ever received from AFAC any remuneration of any kind for any purpose or for any service."

Johns Hopkins University

The planning committee included the Director of the Psychology Department, JHU School of Medicine. He told us of his involvement in studies relating to the effectiveness of the device. He explained that the JHU Applied Physics Laboratory was responsible for further development of the device in response to a request from the founders of the Foundation. The Director stated that he does not have any financial interest in the device.

In addition to the planning committee, a JHU professor of Behavioral Biology and Neuroscience served on the Conference panel. The Conference transcripts revealed, however, that one of the speakers discussed evidence in support of the device, and the JHU professor commented that "it appears to be a good device." The NIH officials explained that this exchange, the speakers' discussion and the panelist's comments, occurred in public session of the Conference.

Promotion of the Device

The final consensus statement and the final Conference report included an analysis of the advantages and disadvantages of multiple forms of aversive and non-aversive treatment, including electric shock therapy. Although the panel's reported findings did not specifically mention the device, an abstract of one of the presentations included in the Conference report discusses the research findings on the device. In its conclusion, the consensus statement recommends that:

"Behavior reduction procedures should be selected for their rapid effectiveness only if the exigencies of the clinical situation require such restrictive interventions and only after appropriate review. These interventions should only be used in the context of a comprehensive and individualized behavior enhancement treatment package."

The two critics we spoke with believed that the Conference was promoting the use of the device, and that inadequate evidence was provided to the Conference panel against using the device and other forms of aversive treatment. Given the final outcome of the consensus statement and final Conference report, these critics still maintain that the panel's approval of the use of aversive treatment, even under restrictive conditions, will result in the use of aversive treatment when it is not necessary. Further, our review of standard biographical sources and abstracts of published literature for panel members, and Conference transcripts did not indicate promotion of the device.

INTERNAL CONTROLS

Although we found no evidence of conflicts-of-interest, we found weaknesses in NIH's internal controls for evaluating potential conflicts-of-interest in the selection of panel members, planning committee members, and formal Conference speakers. Specifically, OMAR was not requesting written certification documents from panel candidates for potential conflicts-of-interest with respect to Conference issues. The OMAR officials were, however, requesting that panel members volunteer any information that might indicate scientific biases or financial conflicts-of-interest, and also conducting literature searches to evaluate a candidate's scientific biases. No documentation was maintained to reveal the findings of NIH's inquiries and actions taken regarding the selection of Conference panel members. The Director of OMAR stated that if conflicts-of-interest or biases were disclosed, the individual would not be selected as a panelist.

Initial discussions with OMAR and NICHD officials revealed that neither OMAR nor NICHD were concerned with evaluating scientific and financial conflicts-of-interest in the selection of planning committee members and formal Conference speakers. We were told that these officials may frequently have scientific biases and even financial conflicts-of-interest because of their particular expertise and scientific background. They explained that these individuals may be required, because of the importance of their expertise, in planning the Conference and providing expert information as Conference speakers.

Following our discussion of these findings with NIH officials, the Director of OMAR issued, in September 1991, specific policies and procedures which require that: (1) panel members provide a certified statement disclosing any personal financial interests, publications, public positions, or memberships related to the issues under discussion at a consensus development conference; (2) planning committee members from the private sector report all activities that would indicate a scientific bias and/or financial interest involving the conference topic; (3) planning committee members from the Federal Government be warned that the HHS standards of conduct prevents them from participating as committee members if they have a financial interest in the conference topic; and (4) the panel and audience be specifically encouraged to ask conference speakers during the recorded public sessions about any financial interests that they might have related to the conference topic. The Director of OMAR informed us that actions taken concerning the above matters will be clearly documented and readily available for examination.

In keeping with NIH's stated longstanding policy, these newly established policies and procedures restate that individuals with a scientific bias or financial conflict-of-interest cannot serve as panelists. However, individuals from the private sector could serve as planning committee members if their expertise is deemed required. The Director of OMAR said that under the new procedures, any existing conflicts-of-interest will be documented and therefore, known by OMAR and other NIH officials when assessing the advice provided by private sector members of the planning committee.

We also found that NIH has not conducted an internal control review for the consensus development conference program as intended under the FMFIA. The FMFIA requires Federal agencies to periodically review their systems of internal control and to report annually on the systems' status. These reviews are

to be made according to the policies and procedures contained in the Office of Management and Budget Circular A-123, Revised.

Separate Issue Concerning the NICHD Director's Name and Title on the Foundation's Letterhead

We found that the NICHD Director's name and NIH title were listed on the Foundation's letterhead. The HHS standards of conduct state that:

"Employees shall avoid any action whether or not specifically prohibited by this part, which might result in or create the appearance of...(e) Making a Government decision outside official channels."

We were instructed by HHS, OGC, Business and Administrative Law Division that this section has been interpreted as preventing any activity that may give the impression that the activity is an official act of the Department or represents an official view. The attorneys stated that the NICHD Director's name and NIH title on the Foundation's letterhead could leave this impression and accordingly violate this section of the standards of conduct. However, the NICHD Director's name without the title is permissible on the Foundation's letterhead.

The NICHD Director told us that he was unaware of this matter and expressed concern that his title was being used in this manner. In an August 29, 1990 memorandum, the NICHD Director asked the Foundation to immediately remove his title from its letterhead and requested that the use of this letterhead be discontinued. The Foundation's stationery was subsequently changed to delete the Director's NIH title from the letterhead.

CONCLUSION

We found that the NICHD Director and one other Conference official from the private sector were, in fact, members of the Foundation's Scientific Advisory Board. We also found that certain Conference officials were associated with JHU which received royalty rights from the founders of the Foundation for JHU's further development of the device. However, we found no evidence that these associations influenced the Conference officials to promote the device. Rather, the Conference concluded that the device and other pain-inflicting behavior reduction procedures (aversive treatments) should be discouraged and used only under restrictive conditions. Further, the critics provided no evidence that any of the Conference officials gained financially.

Our review did, however, disclose internal control weaknesses in NIH's selection of Conference planning committee members and panel members from the private sector. The NIH had not been requesting written certification documents from panel member candidates for potential conflicts-of-interest with respect to Conference issues and documenting its findings when conducting background checks to identify a candidate's scientific bias or financial conflict-of-interest. Further, NIH needed to implement procedures for identifying conflicts-of-interest for planning committee members. In addition, NIH was not assuring that actions taken to address conflicts-of-interest related to consensus development conferences were clearly documented and such documentation was readily available for examination.

The policies and procedures recently issued should, if properly implemented, improve internal controls over conflicts-of-interest involved with consensus development conferences. However, NIH will allow individuals from the private sector to participate as planning committee members if their expertise is required. Accordingly, NIH needs to assure that individuals from the private sector identified as potentially involved with conflicts-of-interest be selected for the planning committee only after all appropriate written justifications have been made and are approved regarding their participation.

The NIH also needs to periodically perform an internal control review of the consensus development conferences as intended by the FMFIA.

RECOMMENDATIONS

We recommend that the Director of NIH:

- Evaluate the effectiveness of the internal controls implemented by OMAR in identifying potential scientific and financial conflicts-of-interest involving conference officials.
- Require that planning committee candidates identified as potentially involved with conflicts-of-interest be selected only after all appropriate written justifications have been made and are approved regarding their participation.
- Assure that actions taken to address conflicts-of-interest related to consensus development conferences are clearly documented and such documentation is readily available for examination.

- Periodically conduct an internal control review of the consensus development conference program to evaluate whether relative internal control systems comply with FMFIA.

AGENCY COMMENTS AND OIG RESPONSE

The PHS, in its April 8, 1992 memorandum commenting on our draft report, generally concurred with each of our recommendations. Its response is included in the Appendix to this report and certain responses are paraphrased in this section. The PHS technical comments have been incorporated into the body of this report.

The PHS stated that an evaluation of the effectiveness of OMAR's internal controls for identifying potential scientific and financial conflicts-of-interest will be conducted by NIH's Division of Management Survey and Review during Fiscal Year 1993, and periodically thereafter in accordance with the requirements of the FMFIA. In addition, an appropriate written justification will be prepared by OMAR staff and approved by the Director of OMAR prior to a candidate's selection for a consensus development conference planning committee.

The PHS agreed to take actions to address conflicts-of-interest related to consensus development conferences. The PHS stated that these actions would be clearly documented and such documentation would be readily available for examination and review.

Although PHS agreed with our recommendations and has initiated corrective actions, they stressed in their general comments that it is sometimes necessary to allow individuals with conflicts-of-interest to participate as planning committee members in order to have the most knowledgeable people involved in the conference planning activities. The PHS believes that the separation of responsibilities for planning, conducting, and reporting the results of the conference have always provided reasonable assurance that the outcome of a conference will not be affected by a planning committee member's scientific bias or financial conflict-of-interest.

We believe that PHS should avoid choosing a planning committee member with a scientific bias and/or financial conflict-of-interest because it increases the risk of slanting the participant's viewpoint and thereby influencing the conference planning process towards his/her personal interests. Further, the critics of this particular Conference have indicated that perceived scientific bias and/or financial conflicts-of-interest influence their acceptance of the Conference results.

Page 13 - James O. Mason, M.D., Dr. P.H.

The PHS detailed comments indicate that NIH will assure that when an individual with a scientific bias and/or financial conflict-of-interest is selected, it will be properly justified in readily available documentation.

We would appreciate being advised within 60 days on the status of corrective actions taken or planned on each recommendation. If you wish to discuss our findings further, please call me or your staff may contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (FTS)443-3583. Copies of this report are being sent to interested congressional officials.

APPENDIX



Memorandum

APR 8 1992

Date

From

Assistant Secretary for Health

Subject

PHS Comments on Office of Inspector General (OIG) Draft Report
"Review of Alleged Conflicts-of-Interest in National Institutes
of Health Consensus Development Conference on the Treatment of
Destructive Behaviors in Persons with Developmental
Disabilities," A-15-90-00009, February 1992

To

Inspector General, OS

Attached are the PHS comments on the subject OIG draft report.

We concur with the report's recommendations and our comments
outline the actions planned or taken to implement the
recommendations.


James O. Mason, M.D., Dr.P.H.

Attachment

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "REVIEW OF ALLEGED CONFLICTS-OF-INTEREST IN NATIONAL INSTITUTES OF HEALTH CONSENSUS DEVELOPMENT CONFERENCE ON THE TREATMENT OF DESTRUCTIVE BEHAVIORS IN PEOPLE WITH DEVELOPMENTAL DISABILITIES," A-15-90-00009. February 1992

General Comments

In general, the report is accurate and fairly represents the process followed and the events occurring during the National Institutes of Health (NIH) Consensus Development Conference (CDC) on the treatment of destructive behaviors in persons with developmental disabilities. We are pleased that there was no evidence to indicate that the CDC was affected by bias or conflict-of-interest.

We acknowledge that there were weaknesses in the practices regarding the selection of private sector people for participation in the conferences. As discussed in the report, we have taken steps to strengthen procedures in this area.

The report appears to equate an individual's scientific activities and perceived scientific bias or financial interest as conflict-of-interest. This is not necessarily correct. In order to hold a state-of-the-art scientific meeting, it is necessary to have the most knowledgeable people available involved in the conference. Although individuals with potential and actual conflicts-of-interest are permitted to participate in limited roles as planning committee members, we believe the separation of responsibilities for planning, conducting, and reporting the results of the conference; oversight by NIH's Office of Medical Applications of Research (OMAR); and, the open, public nature of the CDC process have always provided reasonable assurance that the outcome of a conference will not be affected by scientific bias or financial conflict-of-interest.

The following are the PHS comments on the OIG recommendations.

OIG Recommendation

Evaluate the effectiveness of the internal controls implemented by OMAR in identifying potential scientific and financial conflicts-of-interest involving conference officials.

PHS Comment

We concur. An evaluation of the effectiveness of OMAR's internal controls for identifying potential scientific and financial conflicts-of-interest will be conducted by NIH's Division of Management Survey and Review during Fiscal Year 1993, and periodically thereafter in accordance with the requirements of the Federal Managers' Financial Integrity Act (FMFIA).

OIG Recommendation

Require that planning committee candidates identified as potentially involved with conflicts-of-interest be selected only after all appropriate written justifications have been made and approved regarding their participation.

PHS Comment

We concur. OMAR has already established a procedure requiring private sector planning committee candidates to report all activities that may indicate a potential scientific bias or financial interest in the conference topic.

If the review of this information discloses a **conflict-of-interest**, OMAR will prepare an appropriate written -Justification which will be approved by the Director of OMAR prior to the candidate's selection to participate in the planning committee.

OIG Recommendation

Assure that actions taken to address conflicts-of-interest related to consensus development conferences are clearly documented and such documentation is readily available for examination.

PHS Comment

We concur. Documentation will be developed under the policies and procedures that were established in September 1991. This documentation will be maintained by OMAR and will be readily available for examination and review.

OIG Recommendation

Periodically conduct an internal review of the consensus development conference program to evaluate whether relative internal control systems comply with FMFIA.

PHS Comment

We concur. An evaluation of the internal systems relative to **CDCs** will be conducted by the NIH Division of Management Survey and Review during Fiscal Year 1993, and periodically thereafter in accordance with the requirements of FMFIA.

Technical Comments

Office of Audit Services note -- Comments have been deleted **at** this point because they are technical comments which have been incorporated into the body of this report.

DISTRIBUTION SCHEDULE

	<u>No. of Copies</u>
<u>Distribution Outside OIG</u>	
Deputy Secretary of HHS	1
Chief of Staff, HHS	1
Deputy Executive for Human Services and Management	1
Chairman, Council on Management Oversight, HHS	1
Assistant Secretary for Health	1
Deputy Assistant Secretary for Health	1
Internal Control Officer	1
PHS Audit Liaison	25
National Institutes of Health	5
Assistant Secretary for Management and Budget	1
Deputy Assistant Secretary for Management Analysis and Systems	1
Deputy Assistant Secretary for Finance	3
Deputy Assistant Secretary for Budget	1
Assistant Secretary for Planning and Evaluation	1
Deputy Assistant Secretary for Program Systems	1
Assistant Secretary for Legislation	<u>1</u>
Subtotal	46

	<u>No. of Copies</u>
<u>Distribution Inside OIG</u>	
Inspector General	2
Principal Deputy Inspector General	1
Assistant Inspector General for Management and Policy	
Director, Legislation, Regulations and Public Affairs	1
Congressional Liaison	1
Deputy Inspector General for Audit Services	1
Public Health Service Audits	25
Social Security Audits	1
Health Care Financing Audits	1
Human, Family, and Departmental Service Audits	1
Audit Policy and Oversight	6
Regional Inspectors General (8 Regions)	8
Deputy Inspector General for Investigations	1
Deputy Inspector General for Evaluations and Inspections	<u>1</u>
Subtotal	52
Total	<u>98</u>