

**Memorandum**

Date MAR 23 1994

From June Gibbs Brown
Inspector General *June Gibbs Brown*

Subject Review of the National Institutes of Health's Controls Over
Advisory Committees' Potential Conflicts-of-Interest
(A-15-93-00020)

To Philip R. Lee, M.D.
Assistant Secretary for Health

The attached final report addresses weaknesses in internal control procedures designed to detect and prevent actual and perceived conflicts-of-interest involving the National Institutes of Health's (NIH) 235 advisory committees. Advisory committees consist of outside experts and professional peers who provide advice about biomedical research direction and how research monies should be spent. We found that NIH's internal control procedures were not sufficient to detect potential conflicts-of-interest in its advisory committees. Specifically, we found that NIH needed to:

- o comply with its own requirement regarding reviewing members' financial disclosure forms to identify perceived or actual conflicts-of-interest related to general matters addressed by advisory committees;
- o require an ongoing review to identify changes in a member's financial interests and/or advisory roles at NIH which may result in a perceived or actual conflict-of-interest;
- o revise the financial disclosure form to request information on the member's involvement in nonfederal grants and contracts;
- o provide updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers should be sought to obtain the essential services of these members;
- o ensure that qualified officials, independent of those involved with advisory committee activities, periodically test a sample of all approved waivers

to determine if the controls are followed and result in only appropriate waivers being granted for members; and

- o perform a follow-up review within 1 year after completing the corrective actions relating to the internal control weaknesses discussed herein, and conduct future internal control reviews as required by the Federal Managers' Financial Integrity Act program.

We believe the corrective actions you outlined in your response to a draft of this report should, when fully implemented, significantly strengthen internal controls related to conflicts-of-interest.

Copies of the attached report are being sent to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce and to the Chairman, Subcommittee on Labor, Health and Human Services and Education, House Committee on Appropriations.

We would appreciate being advised within 60 days on the status of corrective actions planned or taken on each recommendation. Should you wish to discuss the issues raised by our review, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301) 443-9742.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF THE NATIONAL INSTITUTES
OF HEALTH'S CONTROLS OVER
ADVISORY COMMITTEES' POTENTIAL
CONFLICTS-OF-INTEREST**



MARCH 1994 A-15-93-00020

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Subject Review of the National Institutes of Health's Controls Over
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To Philip R. Lee, M.D.
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This final report addresses weaknesses in control procedures designed to detect and prevent actual **and** perceived **conflicts-of-interest** involving the National Institutes of Health's (NIH) 235 advisory committees. Advisory committees consist of outside experts and professional peers who provide advice about biomedical research direction and how research monies should be spent. We found that **NIH's** procedures were not sufficient to detect conflicts-of-interest in its advisory committees that provide advice and direction to the directors of NIH Institutes, Centers, and Divisions (ICD). Specifically, we found that NIH needed to:

- o comply with its own requirement regarding reviewing members' financial disclosure forms to identify perceived or actual conflicts-of-interest related to general matters addressed by advisory committees;
- o require an ongoing review to identify changes in a member's financial interests and/or advisory **roles** at NIH which may result in a perceived or actual conflict-of-interest;
- o revise the financial disclosure form to request information on the member's involvement in nonfederal grants and contracts;
- o provide updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers should be sought to obtain the essential services of these members;
- o ensure that qualified officials, independent of those involved with advisory committee activities, periodically test a sample of all approved waivers

to determine if the controls are followed and result in only appropriate waivers being granted for members; and

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perform a follow-up review within 1 year after completing the corrective actions relating to the internal control weaknesses discussed herein, and conduct future internal control reviews as required by the Federal Managers' Financial Integrity Act (FMFIA) program.

We informed NIH of our findings during the audit, and it has taken corrective actions which we believe should, when fully implemented, significantly strengthen internal controls.

BACKGROUND

The NIH is the principal biomedical research agency of the Federal Government. Its mission is to improve the Nation's health by increasing the understanding of processes underlying human health, disability and disease; advancing knowledge regarding the health effects of preventing, detecting, and diagnosing and treating disease; and disseminating research results for critical review and medical application. In Fiscal Year (FY) 1993, Congress appropriated about \$10.4 billion to NIH to carry out biomedical research and research-related activities.

To help achieve its mission, NIH uses advisory committees consisting of outside experts and professional peers. The NIH relies on about 235 different advisory committees which provide advice on biomedical research direction and how NIH should expend its research resources. According to NIH, there are more than 3,800 members serving on NIH advisory committees. In FY 1992, NIH spent about \$44,371,000 to support advisory committees activities.

There are four types of advisory committees at NIH:

<u>Types of Advisory Committees</u>	<u>Number</u>
Scientific and Technical Peer Review Committees (STPRC)	155
National Advisory Councils and Boards (NACB)	21
Program Advisory Committees (PAC)	37
Boards of Scientific Counselors (BSC)	22
Total	235
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The STPRCs are established generally along lines of scientific discipline or disease area and consist mainly of nonfederal

scientists selected for their competence in particular scientific areas for which the pertinent group has review responsibilities. The STPRCs are the initial review group for research grant applications. In reviewing an application, they assign a priority score to the application based on one or more factors. These factors include scientific or technical merit, the significance of the project, qualification of the applicant, and the adequacy of the proposed methodology. Scores are used in determining if the grant will be funded. The STPRCs decisions may be appealed by the grant applicant. Conflict-of-interest on the part of an STPRC member is one justification for reevaluation of an application.

One NACB is established at each of the ICD levels. They are composed of 12 or more noted nonfederal scientists, community leaders, and other public figures. They are chosen for their expertise, interest, or activity in matters related to the individual ICD's mission and provide advice to top NIH management officials regarding medical research needs. The NACBs also provide a second-level review of research grant applications.

The PACs and BSCs are not involved in the grant approval process, but instead are primarily involved in providing advice on other NIH matters. The PACs evaluate extramural research direction related to specific medical areas being addressed within each ICD. For example, established within the National Heart, Lung, and Blood Institute is the Pulmonary Diseases Advisory Committee. The review and evaluation of research projects and investigators in the NIH intramural research program is performed by the BSCs composed of highly qualified outside scientists.

The Standards of Conduct governing Federal employees are extended to committee members; except those serving on STPRCs. Advisory committee members, not serving on STPRCs, receive appointments as temporary Federal employees and are known as "special government employees" (SGE). An SGE is defined by 18 United States Code (U.S.C.) section 202(a) as:

"...an officer or employee...who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, temporary duties either on a full-time or intermittent basis..."

The STPRC members are designated to serve without receiving SGE status and accordingly are not subject to Standards of Conduct and related conflict-of-interest statutes governing Federal employees. The NIH has, however, established procedures for the annual collection and review of financial

disclosure forms submitted by all advisory committee members in order to protect against conflicts-of-interest.

The key statutory provision relating to conflicts-of-interest is 18 U.S.C. section 208, which prohibits all Federal employees, including SGEs, from participation in any particular matter which will have a direct and predictable effect on the employee's financial interests. When necessary, Federal agencies can grant a waiver and permit an SGE member having a conflict-of-interest to participate in committee discussions. Waivers are available when the need for the individual's services outweighs the potential for a conflict-of-interest created by the financial interest involved.

There are essentially two types of waivers that may be given: a general waiver and a specific waiver. A general waiver is appropriate where the member will be dealing with general policies and recommendations that may directly and predictably affect the sector in which the member has a financial interest. For example, a member owns stock in several drug companies. It would be appropriate to issue a general waiver allowing the employee to participate in general matters that might affect the member's financial interests in the drug companies.

Although the member is given a general waiver, the member must still be disqualified from participation in particular matters that directly and predictably affect the member's financial interest in one of the drug companies unless a specific waiver is granted. A specific waiver is allowable if the conflict posed by the member's financial interest in the drug company is outweighed by the need for the member's services.

Within NIH, each ICD is directly responsible for managing its advisory committees and designates for each committee an official called the Executive Secretary who is required to assure that committee activities comply with all requirements. A Committee Management Officer is also established within the Office of the Director, NIH, and the offices of the directors of the ICDs. The Committee Management Officers monitor committee activities and provide administrative support. Potential members are required to complete a financial disclosure form before they are appointed to a committee and every year thereafter. The form, entitled "Confidential Statement of Employment and Financial Interest (HHS-474)," must be completed and returned to NIH. The Executive Secretary for the committee is required to sign the HHS-474 and document whether any conflicts-of-interest are indicated. Subsequently, the Director of the ICD also signs the HHS-474 to document his or her review for conflicts-of-interest.

The NIH guidance relating to conflict-of-interest and NIH advisory committee activities are found in the NIH Manual (Manual), Chapter 2300-735-2, "Procedures for Avoiding Conflicts of Interest for Public Advisory Committee Members," released in 1981, and updated in the NIH Manual, Chapter 4513, released in 1990. In addition, the NIH Committee Management Handbook (Handbook), issued in 1986, details the roles and responsibilities of NIH employees involved with advisory committee activities.

The FMFIA requires that NIH periodically review its system of internal controls and report annually on the system's status. Accordingly, an FMFIA review should cover the adequacy of policies and procedures for preventing conflicts-of-interest involving advisory committees.

The NIH advisory committees are instrumental in determining the direction and quality of the billions of dollars of NIH-funded research and indirectly the health of the Nation. Accordingly, NIH controls must be adequate for preventing perceived or actual conflicts-of-interest which may adversely influence the decisions and services that the committees provide.

The Office of the Special Counsel for Ethics, Office of General Counsel, has been assigned responsibility for advising departmental employees about legal requirements related to conflict-of-interest issues. The Assistant Special Counsel for Ethics (ASCE), NIH Branch, is directly responsible for advising NIH officials regarding conflict-of-interest issues.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of this review was to determine if NIH has implemented effective policies and procedures to protect against advisory committee members being involved in perceived or actual conflicts-of-interest. In this regard, we reviewed statutes, the Department of Health and Human Services (HHS) Standards of Conduct, regulations, policies, procedures, and guidelines relating to the conflict-of-interest requirements and the NIH advisory committees' activities.

In addition, we: (1) reviewed NIH's files and records pertaining to controls implemented over conflicts-of-interest involving advisory committees; and (2) reviewed financial disclosure forms submitted by individuals working for both NIH and the Food and Drug Administration (FDA) advisory committees to disclose differences in information being obtained.

Throughout this review, we conducted interviews with officials from NIH and FDA to obtain information relevant to policies

and procedures for identifying and preventing conflicts-of-interest involving advisory committee activities at both agencies. Except for selected financial disclosure forms, we did not review files at FDA or evaluate its controls over conflicts-of-interest.

During our review, we also discussed our findings with NIH officials so they could take quick corrective action. We also met with the ASCE, NIH Branch, to obtain guidance concerning legal requirements concerning conflict-of-interest issues and NIH advisory committees.

Our review was conducted primarily at the NIH campus, Bethesda, Maryland, during the period from February 5, 1993, through July 2, 1993, in accordance with generally accepted government auditing standards.

RESULTS OF OUR REVIEW

We found that NIH's procedures were not sufficient to detect potential conflicts-of-interest in its advisory committees. We believe this could have adversely affected the quality of the important services being provided. Specifically, NIH was not: (1) reviewing members' financial disclosure forms to identify perceived or actual conflicts-of-interest related to general matters addressed by advisory committees; (2) requiring reviews to identify changes in a member's financial interests and/or advisory roles at NIH which may result in a perceived or actual conflict-of-interest; (3) requesting information on the member's involvement in nonfederal grants and contracts; and (4) providing updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers should be sought to obtain the essential services of these members.

In addition, we found that NIH had not performed an internal control review of the NIH advisory committee activities as required by FMFIA.

We believe that the absence of appropriate NIH guidance to ICD officials who monitor advisory committee activities was a primary cause for the internal control weaknesses disclosed during our review. In addition, NIH officials need to be vigilant in monitoring compliance with conflict-of-interest policies and procedures.

The NIH Did Not Always Enforce Requirements for Identifying Potential Conflicts-Of-Interest

Our review found that NIH was not reviewing advisory committee members' financial disclosure forms, HHS-474's, to identify conflicts-of-interest related to general program and policy issues that would be discussed at upcoming meetings. The NIH Handbook requires such a review. The NIH was only reviewing these forms in conjunction with specific issues when the advisory committee members' were reviewing grant applications and contracts. The NIH did not review the advisory committee members' HHS-474's when the meetings discussed general program and policy matters.

We informed NIH officials during this review that the failure to consistently review a member's HHS-474, for all program and policy issues being addressed, could result in a member with a conflict-of-interest to go undetected. The NIH officials agreed that NIH had not applied the same scrutiny used for grant and contract matters as they did to matters involving advice on other program or policy issues.

In a March 3, 1993 memorandum, NIH's Director of Personnel Management instructed responsible ICD officials to conduct a review of SGE members' most recent financial disclosure forms. The Director informed ICD officials that the system of disqualification to prohibit a member from participating in a specific matter in which the member has a financial interest will continue. The memorandum required, however, that an analysis must also be made of all matters considered by the committees that might have a direct and predictable effect on the member's interests.

The officials were told that when waivers are needed, waiver justifications should be submitted to the NIH Committee Management Office for review and approval--when the NIH Director or the Secretary of HHS appointed the committee members. The justifications should be submitted to ICD directors when the ICD director appointed the committee members. A copy of each approved waiver and disqualification statement was also required by the March 3, 1993 memorandum to be submitted to the ASCE, NIH Branch. We confirmed with ASCE that these approved waivers and disqualification statements were being submitted and that comments were provided.

¹ Only STPRC and NACB members are involved in reviewing grant applications and contracts.

The NIH Needs an Ongoing System to Identify
a Member's Current Financial Interests

We found that NIH was not requiring that members provide updated information on their financial interests before each committee meeting in order to disclose conflicts-of-interest as intended by the conflict-of-interest statute, 18 U.S.C. section 208.

During discussions in the initial stages of this review, we informed NIH officials and ASCE, NIH Branch, that we had learned that FDA had implemented policies and procedures that appeared to be more effective in obtaining updated information on a member's financial interests. Before each committee meeting, FDA requires each member to provide an updated financial disclosure form. Whereas NIH obtains an annual financial disclosure form and provides each member with information concerning the member's responsibilities regarding compliance with conflict-of-interest requirements, it does not actively pursue updated financial information before each committee meeting.

In response to these discussions of FDA's process, ASCE, NIH Branch, and NIH officials told us that they had been considering new policies and procedures to obtain the most updated information on a member's financial interests. On February 10, 1993, ASCE issued a statement which addressed the need for NIH to more actively pursue and review information on the members' changing financial holdings and NIH advisory roles.

In the March 3, 1993 memorandum, NIH's Director of Personnel Management also asked responsible NIH officials to provide advice for developing an ongoing review process to obtain updated information on SGE members' financial interests and NIH advisory roles. On April 28, 1993, ASCE, NIH Branch, approved the use of a standard form to obtain updated information on the members' financial interests. The NIH told us that the Executive Secretary will review this updated information on the member's financial interests along with the agenda of the upcoming meeting. The Executive Secretary will determine if a conflict exists and determine if new or revised waivers should be issued, or if a member should be disqualified during the discussion of a particular issue.

The NIH Is Not Always Obtaining
All Essential Information for
Identifying Conflicts-of-Interest

We found that NIH does not obtain all the data related to committee members needed to assure that members do not have conflicts-of-interest. A comparison of information obtained

from members serving on advisory committees for NIH and FDA revealed that FDA was obtaining certain essential information that was not being provided by members to NIH officials. For example, the financial disclosure form developed by FDA requested that the member list all nonfederal-funded research grants and contracts with which the member has direct involvement or over which the member has control (such as the department head) or which the member is negotiating. The HHS-474 financial disclosure form being used by NIH did not specifically request this information.

Information provided by members serving both FDA and NIH revealed that these members were sometimes involved as principal investigators or otherwise controlled grants received from various drug and/or medical device companies. For example, one member reported to FDA that the member was the principal investigator on grants received from four different companies regulated by FDA.

This matter was discussed with NIH officials who said that they were in the process of developing a revised financial disclosure form which would also include wording similar to that on the FDA form regarding nonfederal grants and contracts. In commenting on a draft of this report, NIH officials stated that they will soon be pursuing formal rule making procedures required by the Office of Government Ethics to obtain final approval of their revised financial disclosure form for SGE members and would implement the necessary steps to seek similar information from STPRC members.

The NIH Needs to Improve Guidance
Regarding Conflicts-Of-Interest
and When to Seek Waivers

We found that NIH guidance for NIH officials monitoring advisory committee activities and conflicts-of-interest issues was incomplete. Guidance provided in the NIH Manual, Chapter 2300-735, "Procedures for Avoiding Conflicts-of-Interest for Public Advisory Committee Members" (updated in the NIH Manual Chapter 4513), and the NIH Handbook, refer primarily to conflicts-of-interest which may arise during the member's review of proposed grants and contracts. The NIH officials agreed with our observation that the guidance provided in the Manual and the Handbook referred primarily to conflicts-of-interest which may arise during the member's review of proposed grants and contracts and therefore could have contributed to the member's other advisory activities not being properly monitored for potential conflicts-of-interest. These officials informed us that NIH guidance will be revised to assure that responsible NIH employees are aware of the need to identify all potential conflicts-of-interest in all situations.

The NIH officials also agreed with our observation that the Manual issuances and the Handbook did not address the provision under 18 U.S.C. section 208, which allows a member to be granted a waiver if the need for the member to be on a committee outweighs the potential for a conflict-of-interest. The NIH officials agreed that the Manual and the Handbook should address the specific policies and procedures to be followed regarding waivers. They informed us that, under the revised policies and procedures being developed, waivers are to be granted only after review and approval of a written waiver request that details the member's financial interests and the facts demonstrating that the need for the member's advice outweighs any potential conflict-of-interest.

The NIH Needs to Perform Reviews Required by FMFIA

The FMFIA requires Federal agencies to periodically review their systems of internal control and to report annually on the system's 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.

Subsequent to the initiation of this review, NIH developed an action plan that addressed the deficiencies identified during our review, including: (1) the need for obtaining current financial interest information from members; (2) developing improved financial disclosure forms; and (3) new procedures and guidance for avoiding conflict-of-interest by NIH advisory committee members.

Responsible NIH officials informed us that following implementation of all the new policies and procedures identified in NIH's action plan, NIH will initiate an internal control review in compliance with FMFIA to evaluate the effectiveness of these newly implemented internal controls over conflicts-of-interest related to advisory committees. We were informed that the new controls are targeted for full implementation by September 24, 1994.

CONCLUSIONS AND RECOMMENDATIONS

The NIH policies and procedures were not adequate to protect the Government from potential conflicts-of-interest that may exist when NIH advisory committee members are advising NIH regarding various matters. Specifically, NIH guidelines emphasized potential conflicts-of-interest involving the review of proposed grants or contracts and therefore contributed to the impression that monitoring of the committees' other activities was not required. However, conflicts-of-interest could also exist related to other activities involving the members. Furthermore, actions taken

by NIH to identify conflicts-of-interest could have failed because the information being reviewed was not necessarily current or complete regarding the members' NIH advisory roles and related financial interests.

We also believe that the absence of appropriate NIH guidance to **ICD** officials who monitor advisory committee activities contributed to these weaknesses in internal controls. Specifically, the guidance provided emphasized only those members involved in reviewing proposed grants and contracts. Furthermore, no guidance was provided to NIH officials that addressed the waiver provisions and the procedures to be followed to obtain approved waivers.

Responsible NIH officials told us they have initiated various corrective actions which should, when fully implemented, improve the internal controls over conflicts-of-interest. However, in order to assure the adequacy of internal controls, we recommend that you instruct the Director of NIH to:

1. expedite the completion of corrective actions to:
 - a. enforce the requirements that members' financial disclosure forms be reviewed for all committee activities to identify any perceived or actual conflicts-of-interest;
 - b. require an ongoing review to identify changes in a member's financial interests and/or advisory roles which may result in a perceived or actual conflict-of-interest;
 - C.** revise the financial disclosure form to request information on the member's involvement in nonfederal grants and contracts;
 - d. provide updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers should be sought to obtain the essential services of these members; and
 - e. ensure that members with potential conflicts-of-interest are disqualified from participating in the related advisory committee meeting or receive a properly reviewed and approved waiver.
2. ensure that qualified employees independent of those involved with advisory committee activities periodically test a sample of all approved waivers to determine if the controls are followed and result

in only appropriate waivers being granted for members; and

3. perform a follow-up review within 1 year after completing the corrective actions relating to the internal control weaknesses discussed herein, and conduct future internal control reviews as required by FMFIA program.

PUBLIC HEALTH SERVICE'S RESPONSE AND OFFICE OF INSPECTOR GENERAL COMMENTS

In a memorandum dated January 5, 1994, the Assistant Secretary for Health (ASH), Public Health Service (PHS), provided comments to the Office of Inspector General (OIG) which stated agreement with all our findings and recommendations. The PHS comments are included in the Appendix to this report in their entirety. We have also paraphrased and highlighted the PHS comments in the following paragraphs.

The ASH concurred with the need to enforce the requirements that members' financial disclosure forms be reviewed for all committee activities to identify any perceived or actual conflicts-of-interest. In this regard, reference was made to a February 12, 1993 meeting and a March 3, 1993 follow-up memorandum in which the Director, Division of Personnel Management, NIH, reminded various responsible NIH officials of the need to enforce these requirements for all SGE advisory committee activities including those involving general program and policy issues.

The ASH stated that NIH is implementing a management control review which should determine if NIH procedures are being adequately followed to detect and prevent conflicts-of-interest for members designated to serve on STPRCs. Our report recognizes that NIH has had a long-standing procedure for the annual collection and review of financial disclosure forms for advisory committee members which also requires disqualification when conflicts-of-interest are identified. We agree with NIH's efforts to further review this important area to assure that controls are adequately implemented to protect against conflicts-of-interest involving STPRC members.

The NIH should ensure, however, that procedures established for STPRC members are similar to those required to be followed for those committee members designated as SGEs. The NIH should ensure procedures are adequate to protect against conflicts-of-interest involving not only STPRC reviews of grants and contracts, but also for identifying and protecting against any future instances that may arise when STPRC members are involved in general program and policy issues.

The ASH also commented that the NIH has developed a process, for SGE members, to implement our recommendation **to require an** ongoing process to identify changes in a member's financial interests and/or advisory roles which **may result in a** perceived or actual conflict-of-interest. According to ASH, within 30 days prior to each advisory committee meeting, NIH will obtain from each SGE advisory committee member an updated financial disclosure form and ask the member at the time of the upcoming meeting if further changes are required. The NIH will review such updated information to identify any current conflicts-of-interest which must be resolved to protect NIH interests. He indicated that similar procedures will be implemented for STPRC members.

The ASH said that efforts are continuing to obtain approval of the revised financial disclosure form developed during our audit to request information on the SGE member's involvement in nonfederal grants and contracts. The NIH will also obtain such information from STPRC members.

The NIH, according to the comments, is nearing completion of efforts to provide updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers should be sought to obtain the essential services of these members. Although NIH officials have been briefed on most of these requirements, the PHS comments stated that the OIG recommendations regarding needed related revisions to the NIH Manual and related handbooks and guidelines are currently in process and will be completed in the near future.

The ASH stated that NIH will ensure that members are disqualified from participating in activities that specifically and predictably affect the member's financial interest. A general waiver will, however, be prepared to obtain the essential services of a member whose activities are limited to general matters.

In response to our recommendation that a qualified employee, independent of those involved with advisory committee activities, test the propriety of waivers granted, PHS stated that the independent ASCE, NIH Branch, will review and concur with each proposed waiver before final approval is granted.

The ASH also stated that PHS will perform a follow-up review within 1 year after completing corrective actions related to internal control weaknesses discussed in this report and conduct future internal control reviews as required by the FMFIA program. He stated that NIH has already identified the issue of conflicts-of-interest involving advisory committees as a management control area and has initiated a risk assessment as an initial step in the FMFIA review process.

Page 14 - Philip R. Lee, M.D.

We believe that the actions indicated in the PHS comments should, if properly implemented, significantly improve the internal controls required to protect against conflicts-of-interest. .

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. Should you wish to discuss the issues raised by our review and recommendations, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301)443-3582.

APPENDIX



Rockville MD 20857

JAN 5 1994

MEMORANDUM

From: Assistant Secretary for Health

Subject: Office of Inspector General (OIG) Draft Report
"Review of the National Institutes of Health's
Controls Over Advisory Committees' Potential
Conflicts-of-Interest," A-15-93-00020

To: Inspector General, OS

Attached are the PHS comments on the subject OIG draft report. We concur with the report's recommendations. Our comments outline the actions being taken to implement them.

Philip R. Lee
Philip R. Lee, M.D.

Attachment

IG	<input checked="" type="checkbox"/>
SAIG	<input checked="" type="checkbox"/>
PDIG	<input type="checkbox"/>
DIG-AS	<input checked="" type="checkbox"/>
DIG-EI	<input type="checkbox"/>
DIG-OI	<input type="checkbox"/>
AIG-MP	<input type="checkbox"/>
OGC/IG	<input checked="" type="checkbox"/>
EXSEC	<input checked="" type="checkbox"/>
DATE SENT	1-6

RECEIVED
 OFFICE OF INSPECTOR
 GENERAL
 JAN 11 - 6 PM 1994

COMMENTS OF THE PUBLIC HEALTH SERVICE ON
THE OFFICE OF INSPECTOR GENERAL DRAFT REPORT
"REVIEW OF THE NATIONAL INSTITUTES OF HEALTH'S (NIH) CONTROLS
OVER ADVISORY COMMITTEES' POTENTIAL CONFLICTS-OF-INTEREST,"
A-15-93-00020, SEPTEMBER 1993

OIG Recommendation

Responsible NIH officials told us that they have initiated various corrective actions which should, when fully implemented, improve the internal controls over **conflicts-of-interest**. However, in order to assure the adequacy of internal controls, we recommend that the Assistant Secretary for Health direct the Director of NIH to:

1. Expedite the completion of corrective actions to:
 - a. Enforce the requirements that members' financial disclosure forms be reviewed for all committee activities to identify any perceived or actual conflicts-of-interest.

PHS Comment

We concur. The NIH has had a long-standing procedure in place for the annual collection and review of financial disclosure forms submitted by members of advisory committee? who are appointed as Special Government Employees (SGE). The NIH has routinely reviewed financial disclosure forms for **conflicts-of-interest** for specific grant and contract matters. Where a conflict-of-interest is identified, the NIH disqualifies the SGE advisory committee member from participating in any matter that directly and predictably affects that member's financial interest.

On February 12, 1993, NIH senior officials convened a meeting of responsible staff to instruct them in reviewing financial disclosure forms for conflicts-of-interest related to general program and policy matters to be discussed at committee meetings. Staff were instructed to review before the next advisory committee meeting each SGE advisory committee member's Form HHS 474, "Confidential Statement of Employment and Financial Interests," along with each member's curriculum vitae and the next meeting agenda. The officials were provided guidance on what constitutes a conflict-of-interest for specific grant and contract matters and for general program and policy matters. Also explained were the

'Under the Ethics in Government Act of 1978, as revised, SGE advisory committee members are required to file a financial disclosure report on appointment and annually.

procedures to be used for **resolving** conflicts-of-interest, including disqualification,² or preparation of a general waiver under 18 U.S.C. Section 208. These procedures were confirmed in a memorandum of March 3, 1993. All SGE members' financial disclosure forms were subsequently reviewed before the next committee meeting. Officials also were instructed to obtain and review updated financial disclosure information and to take appropriate action to resolve any **conflicts-of-interest** identified for each SGE advisory committee member prior to every future meeting.

The NIH has had the same long-standing procedure for the annual collection and review of financial disclosure forms submitted by members designated to **serve** on Scientific and Technical Peer Review Committees (STPRC). The financial disclosure forms are reviewed for conflicts-of-interest for specific grant and contract matters **and** a member is disqualified from participating if a conflict is identified. The NIH is implementing a management control review of procedures to detect and prevent conflicts-of-interest for members designated to serve on **STPRCs**.

OIG Recommendation

1. b. Require an ongoing review to identify changes in a member's financial interests and/or advisory roles which may result in a perceived or actual **conflict-of-interest**.

PHS Comment

We concur. A process to require an on-going update of financial information and review of SGE members' financial interests was developed. Meetings were held in August 1993 with NIH senior officials, including a meeting with the NIH Institutes, Center, and Division (TCD) Directors, chaired by the Acting Director, NIH, to instruct them in **the** following procedures. Within 30 days prior to each advisory committee meeting, the NIH will: obtain from each SGE advisory committee member an updated financial disclosure form (to ensure that the information is complete, SGE members are instructed to inform the committee's designated Federal official at the meeting of any additional financial changes that have occurred after the updated financial disclosure form was submitted; and review for each SGE advisory committee

²A general waiver allows a member to participate in all general matters that may directly affect the member's financial interest, but not matters specifically and predictably affecting the member's financial interest.

member the updated financial information, taking the appropriate steps (such as disqualification or granting of a general waiver) to resolve any identified **conflicts-of-interest**.

These procedures were distributed in writing to the NIH Committee Management Officers on August 17, 1993, and they will be incorporated into a revised issuance of NIH Manual 1810, "Procedures for Avoiding Conflicts-of-Interest in the Use of NIH Advisors and Consultants" that is scheduled for publication in January 1994.

The NIH is implementing the necessary controls to obtain and review updated financial disclosure information from members designated to serve on STPRCs for review prior to each STPRC meeting.

OIG Recommendation

1. c. Revise the financial disclosure form to request information on the **member's** involvement in nonfederal grants and contracts.

PHS Comment

We concur. Effective October 1, 1993, NIH initiated the use of the Standard Form (SF) 450, "Executive Branch Confidential Financial Disclosure Report," for SGE advisory committee members. The SF 450 requires the identification of nonfederal sources of income.

The SF 450 does not request information concerning a respondent's involvement in nonfederal grants and contracts. To capture this information, NIH developed an alternative financial disclosure form which was submitted to the Office of Government Ethics on July 11, 1993. The Director of the Office of Government Ethics notified the Department **on** August 20, 1993, that the alternative form would have to be submitted for proposed rule-making. The NIH, through the Office of the Special Counsel for Ethics, DHHS, plans to pursue the proposed rule-making.

The NIH is implementing the necessary controls to seek similar information from members designated to serve on STPRCs.

OIG Recommendation

1. d. Provide updated guidance to responsible NIH officials for identifying perceived or actual conflicts-of-interest and determining when waivers

should be sought to obtain the essential services of these members.

PHS Comment

We concur. As discussed above, during the summer of 1993, the procedures for identifying and resolving conflicts-of-interest for SGE advisory committee members were discussed with senior NIH officials and provided, in writing, to the NIH Committee Management Officers. These procedures involve obtaining updated financial disclosure information prior to each meeting; reviewing that information for all potential conflicts-of-interest in all situations {specific grants and contracts and advice on general program and policy issues}; and preparing general waivers, as provided under 18 U.S.C. Section 208, and disqualifications. The procedures will be incorporated into a revised issuance of NIH Manual 1810, "Procedures for Avoiding Conflict-of-Interest in the Use of NIH Advisors and Consultants." That manual issuance is scheduled for publication in January 1994. Applicable sections of other handbooks and guidelines are also being revised.

The NIH will also revise all guidance regarding procedures for identifying and resolving all potential conflicts-of-interest in all situations for members designated to serve on STPRCs.

OIG Recommendation

1. e. Ensure that members with potential **conflicts-of-interest** are disqualified from participating or receive a properly reviewed and approved waiver.

PHS Comment

We concur. The NIH has had, and will continue, a long-standing practice of routinely disqualifying any SGE member from participation in any matter that directly and predictably affects that member's financial interest.

The NIH has initiated the following procedures for granting general waivers under 18 U.S.C. Section 208. If, after review of the member's financial information and the meeting agenda, the committee's designated Federal official finds that there could be a potential conflict-of-interest, the designated Federal official will request, in writing, that the appropriate NIH Deputy Ethics Counsel grant a general waiver for that member. The general waiver is based on a determination that the need for the member's advice and services outweighs the potential for a conflict-of-interest created by the financial interest involved. Each requested

waiver is reviewed by the Assistant Special Counsel for Ethics, NIH, for concurrence to ensure that only appropriate general waivers are requested. After concurrence, the request is forwarded to the appropriate NIH Deputy Ethics Counselor for decision. These procedures will be followed prior to each advisory committee meeting.

The NIH has had, and will continue, a similar long-standing practice of routinely disqualifying STPRC members from participation in any matter in which there may be a real or perceived conflict-of-interest for a specific grant or contract. The NIH is implementing a management control review of procedures to detect and prevent conflicts-of-interest for members designated to serve on **STPRCs**.

OIG Recommendation

2. Ensure that qualified employees independent of those involved with advisory committee activities periodically test a sample of all approved waivers to determine if the controls are followed and result in only appropriate waivers being granted for members.

PHS Comment

We concur. Under the delegation of authorities from the Secretary, DHHS, and Director, NIH, to grant **conflict-of-interest** waivers for SGE advisory committee members, concurrence by the Assistant Special Counsel for Ethics, NIH, must be obtained prior to approval of each requested waiver. The Assistant Special Counsel for Ethics, NIH, is a member of the DHHS Office of the General Counsel and is a person independent of those involved with NIH advisory committee activities. Thus, every requested waiver is reviewed by a qualified independent employee.

OIG Recommendation

3. Perform a follow-up review within 1 year after completing the corrective actions related to the internal control weaknesses discussed herein, and conduct future internal control reviews as required by the Federal Managers Financial Integrity Act (**FMFIA**) program.

PHS Comment

We concur. The NIH has identified Committee **Management-Conflict of Interest** as a management control area in its management control program. The NIH has initiated a risk assessment, which is the first step in the FMFIA process, of

the advisory committees conflict-of-interest area. This FMFIA review applies to SGE member committees and STPRCs.

Technical Comments

[DELETED']

¹ To avoid confusion, technical comments, which pertain to sections of our draft report that have been revised in the final report, have been deleted.