

March 10, 2003

Amy L. Comstock, Director  
United States Office of Government Ethics  
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Washington, D.C. 20005-3917

Dear Director Comstock:

As you know, federal agency advisory committees play a central role in informing science-based public policies that affect the public's health and safety. Recently, concern has been voiced about the potential for financial conflicts of interest to bias the committee process, especially at the Department of Health and Human Services (HHS). We are writing to urge the Office of Government Ethics (OGE) to establish uniform guidelines across all federal agencies to strengthen the independence, transparency, and public trust in the federal advisory-committee process.

In this letter we recommend that guidelines:

- broaden the array of relevant financial interests to be reported on Form 450 and disclosed to the public,
- establish a presumption against conflicts of interest and discourage the use of waivers,
- clarify and disclose which committee members are "representatives" and "Special Government Employees,"
- require "representative" members to report relevant financial and other relationships,
- require consent to public disclosure by all committee members as a condition of participation,
- improve and ensure public access to information about committee members and conflicts of interest through the FACA database, and
- promote public participation in the committee selection process.

## **Statutory Background: Independence, Transparency, and the Public Trust**

The main law governing federal advisory committees, the Federal Advisory Committee Act (FACA), emphasizes independence, transparency, and procedural requirements that promote an objective and trustworthy process. FACA promotes independence by requiring that membership be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."<sup>1</sup> FACA requires that adequate provisions be in place "to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment."<sup>2</sup> FACA emphasizes transparency by requiring that meetings be open to the public and meeting materials be available to enable the public to provide input to the committee's work.<sup>3</sup> Finally, FACA fosters consistency and public trust in the functioning of advisory committees by requiring that "standards and uniform procedures ... govern the establishment, operation, administration, and duration of advisory committees" and that each agency "establish uniform administrative guidelines and management controls" over its advisory committees.<sup>4</sup>

Beyond those requirements, FACA is silent on key details crucial to establishing *how* the government fulfills its mandate to ensure independence, transparency, and uniformity throughout the advisory-committee process. FACA says nothing about requiring advisory-committee nominees to report potentially biasing conflicts of interest; it does not provide criteria for assessing "balance"; and it does not offer specific guidance on preventing the "inappropriate influences of ... any special interest." (The use of the term "disclosure" often creates confusion; here the term "reporting" will be used to refer to an individual providing financial information to an agency and the term "disclosure" to an agency providing the information to the public.) As a

result of FACA's silence, those key issues are addressed by a set of laws and rules that produce inconsistencies in agency implementation that are at odds with FACA's goal of creating an independent, transparent, and credible advisory committee system.

Most important for federal agencies seeking to ensure that advisory committees are independent and free of inappropriate special-interest influence are the federal financial-reporting requirements. The Ethics in Government Act (5 U.S.C. Appendix) and financial conflict-of-interest statute (18 U.S.C. Sec. 208) require persons serving in an official government capacity, such as advisory committee members who are considered special government employees (SGEs), to report their financial interests to the federal government. Those reporting requirements are the primary means by which government ethics officials ensure that the federal government operates according to ethical standards.

### **Inadequacies in Reporting Requirements**

Members of federal advisory committees may not be required to report their relevant financial interests because of loopholes in the Ethics in Government Act and the criminal conflict-of-interest statute. Those loopholes concern (1) "representative" members, (2) the narrowness of prohibited conflicts of interest, (3) inadequate information collection, and (4) confidentiality of collected information.

#### **1. "Representative" Members Do Not Report Financial and Other Interests**

An advisory-committee nominee or member is not required to report any financial interests to the government if the responsible federal agency expects the person to represent the views, or "particular bias," of a nongovernmental organization, such as a trade association,

industry-funded think tank, environmental organization, or charity. Because such a person is considered a "representative" member of an advisory committee, not an SGE, the person is not required to report financial interests to the agency.<sup>5</sup>

If the federal agency does not collect financial reports from nominees and members, neither the agency nor the public can adequately assess whether the agency has met the FACA requirement for balance on a particular advisory committee and for independence of members. The "representative" designation is available to each federal agency using advisory committees under FACA. The United States Department of Interior (DOI), for instance, treats members of *all* its advisory committees as representative members. DOI does not collect information about – and does not consider in any formal conflict-of-interest process – the industry or other special-interest ties of committee members.

As illustrations of the problems caused by the failure to collect information from representative members, consider two groups represented on Interior's Invasive Species Advisory Committee, which examines the biological impact of non-native species on ecosystems:

1. The Nature Conservancy and the University of California, Davis, conduct a joint program on weed control funded in part by Novartis Crop Protection, Inc. The Nature Conservancy's Dr. Alan Holt is a member of this advisory committee. Interior regards Dr. Holt as a representative of The Nature Conservancy, not of Novartis, despite the close ties between them.

2. The National Fish and Wildlife Foundation, which was represented on the committee by Dr. Gabriela Chavarria, receives funding in part from Georgia-Pacific, ADM, Dupont,

ExxonMobil, Potlatch, Gallo Cattle Company, and 212 other companies. It also receives funding from the federal government. Those financial ties are neither reported to the agency nor disclosed to the public but are presumably relevant to determining the interests "represented" by the organization.

For the DOI to create balance on the invasive species committee, it must accurately assess the perspectives of the members. Yet the agency does not ask representative members to report their own or their organization's financial and other ties – such as those involving corporate funders – that might affect an individual's or an organization's positions. Due to that gap, the Interior Department and other agencies using the "representative" category cannot accurately assess the perspective of the organizations represented and overall committee balance.

## **2. Prohibited Conflicts of Interest are Defined Narrowly**

The Ethics in Government Act and relevant conflict-of-interest statute<sup>6</sup> prohibit SGEs from participating on an advisory committee only in the narrow case where the committee member (or the member's employer) would be particularly advantaged by the committee's work. Membership of a scientist employed by a lead paint manufacturer on a committee dealing with childhood lead poisoning does not qualify as a conflict of interest under current laws so long as the company's competitors also have a stake in the committee's work. This narrow definition allows companies to participate as members of scientific advisory committees that evaluate the science behind proposed safeguards that affect company and industry practices.

### **3. Relevant Information is Not Collected**

Existing procedures limit the transparency of the federal advisory committee system because they do not ensure that agencies collect the most relevant information from committee members. The main reporting form used by most agencies to comply with the financial reporting requirements (OGE Form 450) does not request information on certain direct and indirect ties that create potentially biasing conflicts of interest. For example, the form does not specifically ask filers to report direct ties such as a research grant award to a scientist, and indirect ties, such as grant support that goes to a committee nominee's university center, as was recently the case with respect to a Centers for Disease Control and Prevention (CDC) advisory committee.<sup>7</sup>

### **4. Reported Ties are not Disclosed to the Public**

Under certain circumstances, an agency may determine that someone with a conflict of interest nonetheless has expertise that is needed on a particular advisory committee. In such a case, a federal agency can issue a waiver allowing participation by the expert but must also, as a condition of the waiver, publicly disclose the member's relevant financial ties. Otherwise, the reports that members file with federal agencies about their financial and other potentially biasing affiliations are considered confidential and are not disclosed to the public. This includes those relationships creating the appearance or reality of a conflict of interest that the agency's staff decides is inconsequential, remote, or irrelevant. For example a consultant to companies that manufacture lead paint may be a member of an advisory committee on lead poisoning, but the agency may decide that the conflict is too remote to be meaningful. In such a case, the affiliation would not be disclosed to the public.

## **Inconsistent Implementation by Federal Agencies**

The integrity of the advisory-committee process is also called into question by inconsistencies in how different federal agencies manage their advisory committees.

Within HHS, for example, the CDC has no written, publicly available policy regarding the prevention of conflicts of interest on advisory committees.<sup>8</sup> Furthermore, the public has no opportunity to review and comment on the nominees to a committee or committee balance, expertise, and conflicts of interest. Without policy and procedural safeguards that promote transparency and public participation, the process occurs, for all intents and purposes, behind closed doors. In the absence of "uniform administrative guidelines and management controls for advisory committees" as required under Section 8 of FACA, recent appointments on at least two advisory committees appear to provide the opportunity for the inappropriate influence of special interests.<sup>9</sup>

In contrast, the Food and Drug Administration (FDA), another agency within HHS, posts on its web site transcripts of advisory committee meetings that include conflict-of-interest disclosures. Unfortunately, those disclosures vary considerably in their detail (and therefore usefulness) and are difficult to find on FDA's web site. In 2002, prompted by a report by the General Accounting Office (GAO), FDA agreed to broaden public disclosure of information that the agency already collects about members' conflicts of interest for some of its committees.<sup>10</sup> For some relationships for which a waiver is granted, the member would have to disclose financial ties as a condition of participation. Some relationships disqualify a person from participating as a member. Despite those improvements, FDA still does not provide the public

the opportunity, prior to final committee selection, to comment on overall committee balance and nominees' background, expertise, and financial relationships with industry and others.

In 2001, the GAO documented flaws in conflict-of-interest practices at the U.S. Environmental Protection Agency (EPA).<sup>11</sup> GAO found that EPA's staff was not sufficiently familiar with the requirements of the financial conflict-of-interest statute (18 U.S.C. Sec. 208), did not routinely ensure that panelists' financial reporting forms were complete, and did not obtain information pertinent to conflict-of-interest determinations in a timely manner. In response, the Executive Committee of the EPA's Science Advisory Board (SAB) developed written procedures to strengthen conflict-of-interest procedures, transparency, and independence in the formation of SAB panels.<sup>12</sup> Nonetheless, the biographical sketches of nominees to committees still fail to consistently include key information about relevant financial ties of committee nominees and they are not adequately accessible to the public.<sup>13</sup>

### **Recommendations: OGE Should Develop High and Uniform Standards**

We urge the Office of Government Ethics to address the lack of specificity of relevant statutes, the inadequacies in reporting requirements, the lack of opportunity for public participation in the committee formation process, and the inconsistencies across agencies in public disclosure of advisory-committee nominees' and members' financial relationships with industry and other parties. OGE should ensure that every department or agency of the federal government develop standards to guard against untoward and undisclosed biases and ensure that both the agency and the public have adequate information to assess relevant affiliations of committee members. Such standards should ensure independence, transparency, uniformity,

and public trust in the federal advisory-committee system. We recommend that government-wide standards:

- **Broaden the array of relevant financial interests to be reported on Form 450 and disclosed to the public.** The Office of Government Ethics should revise its standard financial reporting form, the Form 450, to broaden the array of financial interests that filers must report. The National Academies form on “Potential Sources of Bias and Conflict of Interest” provides a useful model. Agencies should disclose to the public nominees’ and members’ affiliations relevant to the committee's work, including:
  - research grants and awards
  - consulting fees
  - leadership positions in for-profit entities or non-profit entities that receive significant industry funding
  - patents and royalty agreements
  - expert-witness testimony and other relevant public positions
  - honoraria for speaking and writing
  - stock holdings in public companies over a *de minimus* amount

Standardization of categories of interests would provide important guidance for agency staff and committee members, as well as elicit important information for agencies and the public to consider. Where agency staff determines that any of these relationships do not prohibit membership on advisory committees or where a particular financial relationship is questionable, agency staff should err on the side of public disclosure.

- **Establish a presumption against conflicts of interest and discourage the use of waivers.** Federal agencies should presume that individuals with financial and other relevant conflicts of interest are not eligible to participate as members of or consultants to advisory committees. Participation in the work of advisory committees by those with conflicts of interest should be rare and limited in scope. Agency waivers of conflict-of-interest prohibitions should be a tool of last resort.<sup>14</sup> Such participation, if allowed, should be accompanied by a written, public explanation of why the person's participation was necessary and unavoidable.
- **Clarify and disclose which committee members are "representatives" and SGEs.** The distinction between "representative" and SGE members of advisory committees often is not clear or even known to interested parties, journalists, and other members of the public. Yet, a committee of representative members and a committee of independent experts serve different purposes and different interests. Such a difference is relevant in evaluating committee balance and the committee's work and should be clearly disclosed and explained.
- **Require "representative" members to report relevant financial and other relationships.** Currently, the exclusion of representatives from reporting requirements prevents agencies and the public from adequately assessing committee balance and independence. Government-wide standards should guarantee public disclosure of relevant financial and other relationships by *all* committee members, including persons serving in both "individual" and "representative" capacities.

- **Require consent to public disclosure of relevant affiliations by all committee members as a condition of participation.** All federal agencies should require, as a condition of participation on advisory committees, that representative members as well as members serving in an individual capacity consent to public disclosure by the agency of relevant affiliations that may bias the judgment of the member.
- **Improve and ensure public access to information about committee members and conflicts of interest through the FACA database.** Agencies should provide affirmative disclosure of information regarding the financial and other interests of advisory committee nominees and members including those conflicts that have been waived and those relevant interests that were not considered conflicts. Such disclosures should be readily accessible via the General Service Administration Committee Management Secretariat's FACA Database ([www.fido.gov/facadatabase](http://www.fido.gov/facadatabase)), a central location on each agency's web site, meeting transcripts and minutes, committee rosters, committee reports, and other sources of committee information.
- **Promote public participation in the committee selection process.** In addition to publicly soliciting nominees to serve as members of advisory committees, federal agencies should give the public the opportunity to review a list of final nominees and their backgrounds and to comment on issues of balance and expertise *prior* to the final selection of the committee. As part of their new procedures on forming study panels, EPA's Science Advisory Board includes

public feedback on nominees' backgrounds prior to final selection of committee members.<sup>15</sup> Although not a federal agency, the National Academy of Sciences also routinely provides the public the opportunity to comment on appointments to its study committees in accordance with requirements under the 1997 amendments to FACA.<sup>16</sup>

FACA calls for federal advisory committees to have substantially consistent policies and procedures. We, therefore, urge you to establish clear, government-wide guidance to prevent conflicts of interest and to strengthen the transparency, accountability, integrity, and credibility of the committee process.

We look forward to your reply. (Please direct correspondence to Virginia A. Sharpe, Ph.D., Project Director, Integrity in Science, Center for Science in the Public Interest, 1875 Connecticut Avenue, NW, Suite 300, Washington, DC 20009-5728)

Sincerely,

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cc: Spencer Abraham, Secretary, Department of Energy  
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Ann M. Veneman, Secretary, United States Department of Agriculture  
Christie Todd Whitman, Administrator, Environmental Protection Agency  
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## ENDNOTES

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1. 5 U.S.C. Appendix 2 Sec. 5(b)(2). On the impartiality test in ethics regulations, see 5 C.F.R. Sec. 2635.502(a). See also "Conflict of Interest Basics for New HHS Employees," Ethics Division, Office of General Counsel, Department of Health and Human Services, April 2001.
2. 5 U.S.C. App. 2 Sec. 5(b)(3).
3. 5 U.S.C. App. 2 Sec 10.
4. "... standards and uniform procedures..." 5 U.S.C. Appendix Sec. 2(b)(4); "... establish uniform administrative..." 5 U.S.C. Appendix Sec. 8(b)(1).
5. Memorandum of the President, "Preventing Conflicts of Interest on the Part of Special Government Employees," May 2, 1963, as quoted in Office of Government Ethics Informal Advisory Letter 82 x 22, "Memorandum from J. Jackson Walter, Director of the Office of Government Ethics, to Heads of Departments and Agencies of the Executive Branch regarding Members of Federal Advisory Committees and the Conflict-of-Interest Statutes," July 9, 1982. [http://www.usoge.gov/pages/advisory\\_opinions/advop\\_files/1982/82x22.pdf](http://www.usoge.gov/pages/advisory_opinions/advop_files/1982/82x22.pdf).
6. 18 U.S.C. Sec. 208(a).
7. Representative Edward J. Markey (D-MA), "Turning Lead Into Gold: How the Bush Administration is Poisoning the Lead Advisory Committee at the CDC," October 8, 2002; Dan Ferber, "Overhaul of CDC Panel Revives Lead Safety Debate," *Science* 2002:298:732 referring to Dr. Kimberly Thompson's affiliation with the industry-funded Harvard Center for Risk Analysis.
8. CSPI phone communication with Burma Burch, CDC Committee Management Officer, October 24, 2002.
9. The Secretary of HHS has recently attempted to appoint to key public health committees members who have connections to the industries affected by those committees' recommendations. That office recently replaced a majority of members of the CDC's Advisory

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Committee to the Director of the National Center for Environmental Health (NCEH), apparently ignoring input of the NCEH director and the chair of the committee. (See Rick Weiss, "HHS Seeks Science Advice to Match Bush Views," *Washington Post*, September 17, 2002, A1; Dan Ferber, "Environmental Health: Critics See a Tilt in a CDC Science Panel," *Science* 2002;297:1456-7; David Michaels et al, "Advice Without Dissent," *Science* 2002;298:703; Editorial, "Keeping Scientific Advice Non-Partisan" *Lancet* 2002;360:1525; Donald Kennedy, "An Epidemic of Politics," *Science* 2003;299:625) Newly appointed members include Dennis Paustenbach, a vice president of Exponent, Inc., who has served as an expert witness and consultant for numerous companies on controversial environmental issues. Also on the committee are Retired Vice Admiral Harold M. Koenig, president of the Annapolis Center, which has received 80% of its financial support from the National Association of Manufacturers, according to the *Wall Street Journal* (1/17/1997); and Dr. Roger McClellan, former president of the Chemical Industry Institute of Toxicology, a research organization whose member companies include W.R. Grace, Chevron, Dow Chemicals, Dupont, ExxonMobil, and Union Carbide. Membership list and affiliations provided by the Centers for Disease Control and Prevention; Weiss, op. cit.; Center for Science in the Public Interest, "Integrity in Science Database," <http://www.cspinet.org/integrity>, accessed November 14, 2002.

Several scientists who have ties to the lead industry were nominated to the CDC's Advisory Committee on Childhood Lead Poisoning (ACCLPP). Dan Ferber, "Overhaul of CDC Panel Revives Lead Safety Debate," *Science* 2002:298:732. Dr. Joyce Tsuji is a scientist at Paustenbach's consulting company, Exponent, Inc., whose clients include a company in a dispute with EPA over lead pollution. (Dr. Tsuji has withdrawn her nomination.) Dr. William Banner has been an expert witness for the lead industry and believes lead is safe at levels many times higher than current standards. Dr. Kimberly Thompson is affiliated with the Harvard Center for Risk Analysis, which has 22 corporate funders with ties to the lead industry. Representative Edward J. Markey (D-MA), "Turning Lead Into Gold: How the Bush Administration is Poisoning the Lead Advisory Committee at the CDC," October 8, 2002.

A key ingredient in preventing even the appearance of a conflict of interest is strong policy and procedural safeguards. In CDC's case, such protections are inadequate. While the "policies and procedures" document internal to the lead-poisoning-prevention committee does assure the participation of the chair of the advisory committee and CDC staff in reappointing or replacing members, that process appears to have been ignored in the recent committee membership changes. "Policies and Procedures: Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP)," June 26, 1998. It is unclear how many other HHS advisory committees have their own policies and procedures and whether they are consistent with one another and with FACA.

10. Food and Drug Administration, "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," January 2002, <http://www.fda.gov/oc/guidance/advisorycommittee.html>.

11. General Accounting Office, "EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance," GAO-01-536, June 2001. <http://www.gao.gov/new.items/d01536.pdf>.

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12. Environmental Protection Agency Science Advisory Board, "Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board," EPA-SAB-EC-02-010, September 2002. <http://www.epa.gov/sab/pdf/ec02010.pdf>.

13. For example, EPA committee members' biographies – as well as biographies and public conflict-of-interest disclosures at other agencies – are not included in the Committee Management Secretariat's FACA Database, the centralized clearinghouse operated by the General Services Administration for information about FACA committees, members, background materials, costs, and other information.

14. The statute on conflicts of interest allows agencies to waive the prohibition against conflicts of interest for persons working in an official government capacity, including advisory committee members, by providing a written justification of the waiver. 18 U.S.C. Sec. 208(b) In the waiver, the agency must assert that one of several conditions are met. One condition allows a member to serve if the responsible agency certifies that the need for the person's input outweighs the conflict of interest. Agency waivers must be made available to the public.

15. Environmental Protection Agency Science Advisory Board, *Op. Cit.*

16. P.L. 105-153 – H.R. 2977, Federal Advisory Committee Act Amendments of 1997, 12/17/97, which apply specifically to the National Academy of Sciences and the National Academy of Public Administration.