

**Ensuring
Independence
and
Objectivity**
at
The National Academies



CENTER FOR
Science IN THE
Public Interest

Ensuring Independence and Objectivity

at
The National Academies

CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Washington, DC

Acknowledgements

The Integrity in Science Project of the Center for Science in the Public Interest gratefully acknowledges the financial support of the Beldon Foundation, the Richard and Rhoda Goldman Fund, the Rockefeller Family Fund, the Saperstein Family Fund, and the Arkay Foundation.

This report was co-written by Integrity in Science project director Merrill Gozner and program manager Corrie Maudlin. The report was reviewed by CSPI executive director Michael F. Jacobson, Ph.D. Design by Cheryl Halterman.

Copyright © 2006 by Center for Science in the Public Interest

The Center for Science in the Public Interest (CSPI) founded in 1971, is a nonprofit health-advocacy organization. CSPI conducts innovative research and advocacy programs in the areas of nutrition, food safety, and alcoholic beverages and provides consumers with current information about their own health and well-being. CSPI is supported by almost one million subscribers in the United States and Canada to its *Nutrition Action Healthletter* and by foundation grants.

1875 Connecticut Avenue, NW, #300
Washington, DC 20009
ph: 202-332-9110 fax: 202-265-4954
www.cspinet.org

Preface

This report is written out of great respect for the National Academies. Each year, Congress and government agencies call upon the NAS to provide the best scientific advice possible on important and controversial topics. NAS reports invariably earn high marks from the scientific community, and this study, which did not evaluate the quality of any particular NAS report, makes no effort to question that consensus view.

Rather, because commercial pressures on the conduct of science have grown exponentially in recent decades, we focused on the process of nominating committees, as well as the composition of committees, both of which strongly influences the conclusions and recommendations of reports. We focused on the committee selection process because of the importance of protecting NAS committees from those pressures. Only through preventing the appearance of bias, imbalance, and conflicts of interest can the NAS ensure that the high quality and reputation of its reports will be maintained in the future.

Unfortunately, we found serious deficiencies in the NAS's committee-selection process that could jeopardize the quality of future NAS reports. The NAS has allowed numerous scientists (and others) with blatant conflicts of interest to sit on committees. Compounding that problem, those conflicts of interest usually are not disclosed to the public. Whether complete avoidance of conflicts of interest on committees would have improved the committees' recommendations is impossible to know. At the very least, though, improving the process of committee formation and excluding individuals with conflicts or balancing them with individuals having sharply contrasting views, would provide added insurance that Academy recommendations will continue to be both top-notch and merit respect throughout the world.

Michael Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest

TABLE OF CONTENTS

Executive Summary	i
I. The Evolving Role of the National Academies	1
II. Conflicts of Interest on NAS Committees	2
III. Policy Comparison: NAS and Selected Federal Agencies	5
A. NAS.....	5
B. Environmental Protection Agency	7
C. Food and Drug Administration	7
IV. Analysis of NAS Committees.....	9
A. Eliminating Direct Conflicts of Interest	9
Sidebar: Hiding Ties to Industry Is a Risky Business	12
B. Balancing Ideological Biases.....	11
C. Disclosing Conflicts of Interest and Biases.....	15
V. Recommendations	18
Appendix A – The Federal Advisory Committee Act	20
Appendix B – The 21 Committees.....	22
Notes	23

Executive Summary

BACKGROUND:

The National Academies — now comprised of the National Academy of Sciences, the Institute of Medicine, the National Academy of Engineering and the National Research Council (hereafter referred to collectively as NAS) — plays a prominent role in setting national policies. Each year, the NAS selects over 8,000 scientists to serve on more than 500 committees that produce more than 200 scientific analyses, many of them crucial to the nation's health and environment.

This report focuses only on the selection process for and composition of NAS panels. In 1997, NAS committees funded by the federal government came under the jurisdiction of the Federal Advisory Committee Act (FACA). Congress required the agency to avoid using scientists with direct conflicts of interest on study panels (unless their expertise is deemed essential and not available elsewhere) and to seek balance on points of view. This report found serious breaches of both of those rules.

STUDY FINDINGS:

1. A Failure to Eliminate Direct Conflicts of Interest

For the purposes of this study, CSPI defined a direct conflict of interest as a financial tie within the last five years to a company or industry that is relevant to the committee topic. A five-year window is comparable to policies at leading academic journals that require conflicts of interest disclosure in published articles. Among the 320 professionals on 21 NAS committees investigated by CSPI over the past three years, at least 56 (18 percent) had direct conflicts of interest.

Finding: Nearly one out of every five scientists appointed to an NAS panel has direct financial ties to companies or industry groups with a direct stake in the outcome of that study. This consistent pattern of appointing scientists with conflicts of interest clearly violates the spirit of the Federal Advisory Committee Act amendments that apply to NAS.

2. A Failure to Achieve Balance

Independent background checks by CSPI investigators found at least 66 scientists whose employment, significant and long-term financial relationships, published writings, think-tank membership, or courtroom testimony demonstrated pro-industry positions. On the other hand, only nine of the 320 scientists worked for or were closely identified through their writings or published studies with environmental or public interest groups.

Finding: NAS did a poor job of balancing points of view on a majority of the study panels examined. The NAS does not appear to consider information about potential bias or conflicts of interest prior to nominating individuals to a committee. As a result, about half the panels examined had scientists with identifiable biases who were not offset by scientists with alternative points of view.

3. A Failure to Disclose Information about Conflicts of Interest

Among the 320 scientists and other professionals examined in this study, nearly a fifth had some ties to industries that might be affected by the study. Yet the NAS revealed

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

those ties to the public (via its website) in only 46 percent of those cases.

Finding: The NAS provides brief biographies of nominees to its committees on the agency's website. Such biographies could assist people who were considering commenting on a committee's composition. However, those biographies are woefully inadequate because, in a majority of cases, they fail to provide crucial data regarding conflicts of interest and points of view.

RECOMMENDATIONS

To achieve its stated goal of “ensuring independent, objective advice” for federal agencies, Congress, and the general public, the NAS should take the following steps:

- The NAS should expand its definition of conflicts of interest to include any financial ties within the past five years with companies that might be affected by the committee's work, either directly or indirectly.
- If it allows a scientist with a conflict of interest to serve on a committee, the NAS should publish prior to the first meeting of the committee a waiver documenting the nature of the conflict and the reason for the waiver.
- The NAS should expand its definition of balance on committees to include bias and point of view, in addition to areas of expertise. The definition of point of view should be expanded to include scientists with extensive ties to industry as having a “pro-industry” bias. Balance should be defined as never having more than three such scientists on any committee and always balancing pro-industry scientists with at least an equal number of public health-oriented scientists.
- To encourage compliance, the NAS should adopt sanctions, such as a three-year ban from serving on any NAS panel, when a committee member fails to disclose appropriate information on the NAS disclosure forms.
- The NAS should make a much greater effort to expand the pool of candidates for committees by reaching out to the broader scientific community and not relying on existing boards, committees and routine contacts. It should publicly announce through its website and other outreach channels that it is forming a new study committee; that announcement should occur at least three months before the first meeting of the committee and include an invitation to the public to submit nominations for membership on the committee.
- Twenty days before a panel's first meeting (or at the same time that it posts the tentative roster for the committee), the NAS should publicly disclose all conflicts of interest, biases, and points of view of the scientists chosen for that panel. Only after consideration of public comments should NAS staff make that roster final.
- The NAS should maintain a listserv that notifies interested individuals when a committee is being formed and when it has chosen a tentative list of nominees. The latter notice should include a link to the proposed list of nominees.

I. The Evolving Role of the National Academies

For over 140 years, the National Academy of Sciences (NAS) has played a prominent role in setting national policies that are based on science. A congressional charter signed by President Abraham Lincoln on March 3, 1863, established the original NAS as a non-profit corporation made up of distinguished academics willing to provide free technical and scientific advice to the government. In its first decades of existence, the largely voluntary NAS created committees on a wide variety of subjects with the twin goals of furthering science and technology and promoting the general welfare.

Over the course of the 20th century, the NAS expanded its role in science and technology policy-making. The need for sophisticated technological expertise during World War I led to the formation of a full-time National Research Council (NRC) to serve as the principal operating agency for the NAS. The growing industrialization of society in the post-World War II era led to the formation in 1964 of the National Academy of Engineering, which also came under the NRC umbrella. The growing importance of health care in the U.S. economy led to the formation of the Institute of Medicine (1970), the last expansion of the National Academies' structure. (For the remainder of this report, NAS refers to the four national academies.¹)

Today, reports from the NAS influence national policies concerning virtually every area of modern life, from space and nanotechnology to global warming and nutrition. Each year, the NAS selects more than 8,000 academics and other experts to serve on over 500 committees, which collectively produce more than 200 reports. While none of the committee members are paid, the budget of the 2,000-person organization reached \$218 million in 2004, largely for staffing and sup-

porting the various committees. Over 80 percent of that budget came from government agencies.²

The NAS can initiate the study process on a particular subject by using its own funds, generated mostly from sales of reports and contributions. But this accounts for less than 20 percent of its budget. Most requests come directly from federal agencies, which often look to NAS for outside scientific support for new policy initiatives. Sometimes two or more federal agencies will ask the NAS to serve as an outside arbiter of an inter-agency dispute. A recent example was an NAS panel evaluating the environmental effects of the rocket fuel component perchlorate on local communities, which pitted the Defense Department and giant contractors like Lockheed Martin against the Environmental Protection Agency (EPA) in a dispute over the pollution level that would require extensive clean-up operations.

Requests for new study committees often originate on Capitol Hill through a legislator responding to requests from interest groups. As a result, the NAS often finds itself involved in the most contentious issues of the day and subject to significant political pressure. For instance, an industry group opposed to an imminent action by a regulatory agency may ask a friendly legislator to obtain funding for an NAS study reviewing the scientific reasoning behind the agency's decision. Public interest groups may lobby legislators to authorize money for an NAS study that might help build support for new public health policies. Legislators seeking controversial laws or regulations favoring a special interest or constituent may seek an NAS study hoping it will justify their proposals. In most such cases, the make-up of the NAS committees, which could have a major impact on their recommendations, comes under intense scrutiny.

II. Conflicts of Interest on NAS Committees

Public concern about conflicts of interest on NAS panels evaluating health and environmental policies is not new. In 1980 the NAS Food and Nutrition Board issued a report stating that Americans did not have to reduce their intake of cholesterol and saturated fat except to achieve and maintain a normal body weight, despite rising concern about the association between blood cholesterol levels and heart disease.³ After the report's release, the media revealed that three members of the committee were food company officials while two others had served as consultants to egg producers.⁴ The media condemned the report for being radically at odds with prevailing scientific opinion, and, in response, NAS overhauled the Food and Nutrition Board. The threat that outside pressure – whether from industry or health and environment advocates – might someday influence NAS reports had become real. Yet the brouhaha appeared to have little lasting impact on internal NAS policies that guard against commercial or public interest advocacy influence over its reports.

Even before that report raised concern about NAS procedures, the NAS began opening its committees to greater public scrutiny. That was partially in response to the 1972 passage of the Federal Advisory Committee Act (FACA). That law applied open-meeting and conflict-of-interest rules to the thousands of scientists and other professionals that served on the nearly 1,000 federal advisory panels that make up “the fifth branch” of government. While the architects of the law expressly excluded NAS from its provisions,⁵ the quasi-governmental agency adopted several of the law's provisions, including open-

ing its data-gathering meetings to the public and publishing advance notice of meetings in a monthly newsletter.⁶ But fearing a loss of independence to the government agencies that provided funds, NAS officials vigorously objected to coming under the FACA umbrella, a stance that did not change in response to the controversial Food and Nutrition report.

However, a lawsuit filed in 1989 by Public Citizen called the NAS' cherished independence into question. Public Citizen wanted American Bar Association meetings brought under FACA because of the Justice Department's habit of asking the ABA for judicial recommendations. In denying the claim, the Supreme Court drew a distinction between independent groups like the ABA, which were clearly outside government, and those whose mission and charter included the need to respond to government requests. The high court offered the NAS as a “paradigmatic example” of the latter because it was “in receipt of public funds” and was an organization “created or permeated by the Federal government.”⁷

Legal ambivalence about NAS' independence officially came to an end in the 1990s. In one of the periodic protests against special interest-influenced NAS committees, the Animal Legal Defense Fund and two other animal rights groups sued the National Research Council over a care guide for research animals prepared for the U.S. Department of Health and Human Services. The groups claimed that the NRC violated FACA when it denied the public access to the committee's deliberations. In January 1997, the U.S. Appeals Court in the District of

Columbia reversed a lower court decision and declared that NAS was subject to FACA.

NAS immediately protested that its independence would be severely compromised by government officials and lobbying groups if it were subjected to FACA rules. The science community rose to NAS' defense. An editorial in *Science*, one of the nation's most respected scientific journals, claimed that federal agencies that provided funds would inappropriately influence NAS studies and that committee deliberations would be subjected to cumbersome regulations.⁸

Responding to those pleas, Congress in December of 1997 passed a new section of FACA covering NAS whenever one of its committees received federal funds. In those cases, the new rules required NAS to:

- Make names and brief biographies of committee members public;
- Post notice of open meetings;
- Make available written materials presented to the committee;
- Open data-gathering meetings to the public;
- Post summaries of meetings that are not data-gathering meetings;
- Make copies of the final committee report available to the public;
- Make available the names of the principal non-Academies reviewers of the draft report;
- Follow conflict-of-interest and balance requirements that were similar to those established by FACA for advisory committees.⁹

The NAS was also directed to offer the public a reasonable amount of time to comment on the scientists selected to serve on committees, since the committees now had to be "fairly balanced" and not include any individual with a conflict of interest "relevant to the functions to be performed" unless the conflict was "publicly disclosed" and deemed "unavoidable" (see Appendix). The NAS responded by requiring panelists at a committee's initial meeting to disclose all poten-

tial conflicts of interest and biases to fellow committee members. In theory, this would result in exclusion of panelists whose conflicts were deemed too extensive by other committee members. In practice, this closed process may not result in full disclosure, let alone dropping conflicted members, especially when it takes place at a first meeting of the committee where the participants may barely know one another. It is likely that the potential effects of biases and conflicts of interest only manifest themselves much later in the process, when a committee's recommendations are being drafted, for instance.

A General Accounting Office (now the Government Accountability Office or GAO) review of NAS' compliance with the new law less than a year after its passage found only a few minor violations of its provisions, mostly having to do with incomplete or inaccurate postings.¹⁰ But the outside auditors remained concerned. The 1998 GAO report noted that fully 24 percent of all NAS panel members in that year hailed from industry, typically from companies or trade associations with an interest in the committees' topics and recommendations. The report raised serious concerns about undue industry influence over the NAS study process.

In the late 1990s, protests about industry influence over federal advisory committees intensified, largely due to frustration with government agencies rolling back or delaying environmental, health and safety regulations. Little of this anger was aimed at the NAS. A 2001 GAO report, issued in response to a request from Rep. Henry Waxman (D-CA), called on the EPA to improve its policies and procedures for advisory committees to ensure independence and balance. The auditing agency reviewed the work of four committees established by the EPA's Scientific Advisory Board in 1999 and found numerous conflicts of interest involving industry-funded scientists. The report compared EPA's policies unfavorably to the relatively new NAS disclosure requirements. However, the GAO noted that the National Academies' definition of conflicts of interest was less stringent than the rules imposed on

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

federal agencies by the Office of Government Ethics.¹¹

During the George W. Bush administration's first term, protests over the make-up of federal advisory committees focused on alleged political interference in their deliberations. Editorials appeared in leading science and medical journals attacking the administration for ideologically packing committees and subjecting potential members to political litmus tests. For instance, in 2003 the Center for Science in the Public Interest (CSPI) and 21 academics sent a letter to the Office of Government Ethics protesting the absence of enforceable conflict of interest rules at the EPA, the Food and Drug Administration (FDA), the Interior Department, and other federal agencies. Democratic legislators asked the GAO to once again review the issues of conflict of interest and bias on advisory committees.

In April 2004 the GAO called for a thorough overhaul of the rules.¹² Numerous agencies had evaded conflict-of-interest rules entirely by calling committee appointees constituency "representatives" instead of "special government employees," the usual designation for science-oriented appointees. Only EPA collected and evaluated information about advisors' biases to ensure that advisory committees were properly balanced in terms of points of view. The GAO recommended that other agencies adopt similar guidelines.

The heightened scrutiny of federal agencies was matched by growing concern about the make-up of NAS panels. In October 2003, the Natural Resources Defense Council, the Environmental Working Group, and CSPI wrote a joint letter protesting the make-up of a panel appointed to evaluate the health implications of perchlorate ingestion. The panel included Dr. Gilbert S. Omenn, a member of the board of directors of Rohm and Haas, which owned technology for perchlorate removal, and Dr. Richard Bull, a for-

mer EPA scientist at Pacific Northwest Laboratories, whose consulting contracts included perchlorate users like the Department of Defense and its contractors.¹³ The NAS ignored that protest as well as a May 2004 protest letter from California Senators Dianne Feinstein and Barbara Boxer. A month later a group representing perchlorate users heralded a separate new report commissioned by the Defense Department's contractors that claimed trace amounts of perchlorate were harmless. NAS panel member Bull had been one of its authors. An embarrassed NAS, which had previously said Bull's work for the industry had ended, forced Bull to resign from the panel.¹⁴

While that mini-scandal was unfolding, NAS moved to bring its policies more in line with federal agencies. In 2003, NAS formally unveiled a new policy governing committee formation, disclosure, and how it defined balance and conflicts of interest. The policy stated that all committee nominees' biographies will be disclosed on NAS' website 20 days before the first meeting, giving the public time to comment on the roster. It required staff to screen prospective members, who were required to complete a "Background Information and Confidential Conflict of Interest Disclosure," which included employment history, conflicts of interest, stock holdings of more than \$10,000 in a potentially affected corporation, research funding from a party that would be affected by the committee's decision, and relevant patents. Those disclosures could lead to a person's exclusion from the committee if he or she was "understood to be completely committed to a particular point of view and unwilling, or perceived to be unwilling, to consider other perspectives."¹⁵ These new rules have, over the past two years, led consumer groups to issue numerous challenges to individuals chosen to serve on NAS panels.¹⁶

III Policy Comparison: NAS and Selected Federal Agencies

As noted above, the NAS creates and manages its study committees under special rules incorporated in 1997 into the Federal Advisory Committee Act. While the rules are similar to those at such government federal agencies as the EPA and FDA, there are some important differences. A close examination of those differences highlights areas where the NAS could improve its process (see box).

practicable, in the period immediately following the appointments; provide public notice of committee meetings that will be open to the public; and make meetings and written material of the selected committees available to the public, unless NAS deems the nature of the meeting or written material is of a private nature.¹⁷

In addition, the NAS must ensure that no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and NAS determines that the conflict is unavoidable. The committee membership must also be fairly balanced regarding the functions to be performed, and individuals that NAS appoints or intends to appoint must inform the agency of any relevant conflicts of interest.

The NAS follows a four-stage process when conducting a study. The National Research Committee (NRC) Governing Board reviews and approves the study scope written by NAS staff and the study's sponsors (i.e., the group

that is requesting the study). The scope consists of a set of questions that form the "statement of task."

NAS staff has the primary responsibility for choosing the members of individual committees. It proposes a list of potential committee members, which is then reviewed and approved by the President of the NAS, who is also the Chair of the NRC. NAS then discloses

Disclosure: how three agencies compare

	<u>NAS</u>	<u>EPA</u>	<u>FDA</u>
Public notice of committee formation	N	Y	N*
Public can submit nominations	N	Y	N*
Public invited to comment on committee roster prior to first meeting	Y	Y	N
Conflicts of interest include past and present financial relationships	N	Y	Y
Conflict-of-interest data made public	N**	N	Y
Point-of-view data collected	Y	N***	N
Point-of-view data made public	N	N	N

* FDA Advisory Committees are made up of standing members and special government employees added for each meeting; the public is invited to submit nominations for the standing committees when they are periodically re-formed

** In several cases, the agency has posted conflict of interest information after public protests.

*** The Federal Insecticide, Fungicide and Rodenticide (FIFRA) Advisory Committee is an exception.

A. National Academies

According to the 1997 amendments to FACA, the NAS must provide public notice 20 days prior to a committee's first meeting of the names and brief biographies of individuals nominated to committees; provide the public an opportunity to comment on the appointments before they are made or, if the NAS determines such prior comment is not

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

es the biographies of all selected committee members on its website under “Current Projects” and allows 20 days for public comment. According to NAS, the staff tries to select a variety of experts who offer complementary experiences and perspectives to build a “reasonably balanced” committee. Balance, in most cases, refers to having the range of professional expertise that is needed for the committee to carry out its assigned task. Provisional committee members are asked to disclose their conflicts of interest and biases at the first closed meeting of the committee.¹⁸

The NAS staffers do not conduct an independent background search on potential committee members for potential conflicts of interest and biases. They rely on self-disclosure. NAS officials state that there are too many committee members selected each year to allow independent assessment by NAS staff.¹⁹ If, after posting the committee roster on the website, the public provides pertinent information, that information may be appended to the original information disclosed on their confidential disclosure form. When an NAS staffer determines a scientist with a conflict of interest has expertise that can not be found elsewhere, that conflict is deemed “unavoidable” and publicly disclosed.²⁰

Potential sources of bias are not well-defined compared to direct conflicts of interest (e.g., a full or part-time employee of a corporation with a financial interest in the issue). Potential biases generally do not disqualify an individual from participating. They are taken into account as committee composition is considered. An NAS official may ask a person to resign from the committee if the potential member is “completely committed to a particular point of view.”²¹

The NAS staff obtains information about conflicts of interest from “Background Information and Confidential Conflict of Interest Disclosure” forms filled out by prospective members. The forms state the reason for disclosure: “The individual, the committee, and the institution should not be placed in a situation where others could rea-

sonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of conflicting interest.” It is important to note that the NAS defines conflicts of interest as applying “only to current interests.” It is not a conflict for the individual if an interest has expired and “cannot reasonably affect current behavior.”²²

In other words, an industry-funded research project or consulting contract with companies directly affected by the study would not exclude a scientist from participating as long as that work was concluded prior to the start-up of the committee.

Financial conflicts of interest are defined as a relationship between the individual and (1) the sponsor or program reviewed in the study or (2) any person or organization directly affected by the outcome of the study. Examples may include a stock holding of more than \$10,000 in a potentially affected corporation, funding for research from a party that would be affected, or a relevant patent. The financial interests of a prospective member’s spouse, employer, clients, or business research partners are also considered.²³

The committee may use public meetings, information submitted by outside parties, scientific literature, and committee members’ work to produce its report. The committee meetings where reports are deliberated and written are closed. The public has access to summaries of those meetings, but interim and final drafts of the report remain confidential. “Committee members continue to be screened for conflict of interest throughout” the deliberation process.²⁴

Independent experts are chosen to review and provide anonymous comments to

The NAS staffers do not conduct an independent background search on potential committee members for potential conflicts of interest and biases. They rely on self-disclosure.

the committee once the report is produced. Reviewers are not checked for individual conflicts of interest because, the NAS states, they don't have the final say in the report; they assess the report for scientific support, effective organization, and objectivity, which the committee considers in its final decision.²⁵ Once the committee responds to the reviewer's comments, a new set of internal review monitors ensures that the review criteria have been met. Top NAS officials approve the final report before sending it to the sponsor and releasing it to the public.²⁶

B. Environmental Protection Agency

The EPA, like other federal agencies, must follow the Federal Advisory Committee Act of 1972. The EPA's Scientific Advisory Board (SAB) creates dozens of "science advisory panels" that throughout the year consider various issues facing the agency. Panel reports have a direct impact on regulations and guidelines issued by the agency. An extensive internal and external peer review process scrutinizes reports before they are issued.

While most of EPA's regulations for its SAB panels are similar to NAS', there are several significant differences. Notices that the SAB is forming an advisory panel are printed in the Federal Register and sent out to interested members of the public through an email listserv. The public can nominate people to serve on SAB committees. The SAB staff creates a short list of nominees after it reviews candidates' background information including financial ties and "other information related to conflicts of interest or appearance of lack of impartiality."²⁷ Each candidate selected for an SAB advisory committee short list must then submit a Confidential Financial Disclosure Form. Prospective board members must list employment (compensated and non-compensated), research support and funding, consulting, expert testimony, and assets and liabilities over \$10,000 owned by themselves and their spouses during the two years prior to the date of filing.

Like many federal agencies, the EPA relies on a standard Office of Government Ethics form (Form 450) to collect financial conflicts of interest information. While similar to the NAS form in the financial disclosures it requires, Form 450, according to the GAO's 2004 review of the agency's advisory committee policies, "does not request other information relevant to assessing points of view, such as previous public statements or positions on the matter being reviewed, including statements in articles, testimony, or speeches; positions taken in various legal forums, particularly in providing expert legal testimony; research conducted on the matter; interests of their employers or clients in the matter; and sources of funding for research or other activities." One EPA advisory committee – the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Scientific Advisory Panel – does collect such information independently and considers it in selecting members for its peer review panels.²⁸

C. Food and Drug Administration

The FDA maintains more than 30 advisory committees to advise the agency about scientific and regulatory issues and new products applications involving drugs, devices, biologics, veterinary medicines, and food. Most committees have a permanent roster that is supplemented, as needed, by additional members chosen because of their expertise in the topic of the meeting. Meeting notices appear in the Federal Register at least 60 days in advance of the meeting, and include the date, place, time, and agenda for the meeting. However, the full roster of the committee is not released until the day before or the day of the meeting.

Like the EPA, the FDA asks for information about conflicts of interest from the relatively recent past that may be related to the committee topic. The "Confidential Financial Disclosure Report" asks those selected if they have had "expert witness" or "speaking and writing" work related to the topic in the past year. The form also asks if "you, your spouse,

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

minor child, general partner, organization in which you serve as an officer, director, trustee, general partner or employee” have any past involvement with the meeting/task issues.²⁹ In addition, each member must disclose information related to “financial holdings and professional activities related to the product(s) or its competitor(s) that are subjects of the meeting.”³⁰

The FDA makes liberal use of clauses in FACA that allow scientists with conflicts of interest to serve on advisory panels. The agency issues waivers in situations where officials consider the conflicts to be minimal or the scientist’s expertise is considered crucial to the committee’s deliberations. Virtually all FDA advisory panels include some scientists who receive conflict-of-interest waivers. There have even been cases where a majority of the committee received waivers. When a committee is discussing a scientific or regula-

tory issue that applies to all firms in the affected industry, the FDA will grant a “general” waiver to anyone who has any financial ties to any company in that industry.

After a controversy erupted over conflicts of interest on a panel evaluating a class of painkiller drugs known as COX-2 inhibitors,³¹ Congress in October 2005 passed an amendment to the FDA appropriations bill that required the agency to post copies of all waivers on the FDA’s website at least 15 days before the meeting date. The waivers include the nature of the conflict of interest and a range of its financial value, but not the names of companies. However, for new product advisory committee meetings, the relationship requiring a waiver is designated as being the sponsor or a competitor. In the former case, that is tantamount to disclosing the name of the company since the sponsor is known.

IV. Analysis of NAS Committees

As previously noted, in recent years the NAS has come under increased scrutiny for conflicts of interest and biases on some of its committees. Given the range of practices at federal agencies that face similar issues and some obvious differences with NAS practices, CSPI analyzed NAS practices in light of best practices at other agencies. Over the study period, CSPI researchers analyzed 21 NAS panels with a total of 320 scientists. Those committees were not randomly selected. Most of the committees addressed regulatory issues that affect health or the environment.

The committees were analyzed for:

- Direct conflicts of interest – Did the NAS allow scientists or other professionals with direct conflicts of interest to serve on the committees? If so, did the NAS tell the public why those individuals were critical to the committee’s function?
- Ideological bias – Did the NAS identify committee members with apparent biases about the subject matter at hand? Did the NAS inform the public about those members’ biases? Did the NAS seek to balance those views with members who could serve as an ideological counterweight?
- Disclosure – Did the NAS provide the public with information about panel nominees’ potential and direct conflicts of interest and their biases during the committee formation process and after the first general meeting of the committee?

A. Eliminating Direct Conflicts of Interest

Scientists’ commercial conflicts of interest are influencing the nature and quality of research at the nation’s leading universities.³² This has triggered fears that the private commercial interests are having an inordinate influence over the policies of the government’s most influential science-based agencies, including the EPA, the FDA and the National Institutes of Health.

These concerns have led to a vigorous debate over the definition of conflicts of interest at a science-based agency. NIH, for instance, defines conflicts of interest in science as “situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research.”³³ A recent call for ending conflicts of interest at academic medical centers stated that “conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised.”³⁴

Note that both definitions go beyond those rare circumstances where research outcomes have been crudely or fraudulently influenced by persons with financial ties to a business with an interest in the outcome of a particular research project. They specifically allude to situations where the conflicts may influence professional judgment, even though most researchers vehemently deny that such possibilities exist. The ambivalent posture assumed by many researchers when confront-

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

ed by the idea their financial ties might compromise their professional obligation to maintain strict objectivity was insightfully portrayed in a recent Hastings Center essay by bioethicist Carl Elliott:

The degree of dissembling and rationalization here might be funny if the stakes were not so high. “I take the money but it doesn’t influence me.” “I take the money from many different sources in order to keep my objectivity.” “I take the money but I make sure that no more than forty percent of our center’s funding comes from corporate sources.” “I take the money but I always disclose.” “I take the money but I say what I want.” Or my favorite: “I take the money but I use it to advocate for social justice.” The rationalizations always begin with the phrase: “I take the money.” No one will just say no.³⁵

Both definitions also include public perception, which involves the *appearance* of conflict of interest. Self-interested parties, including Congress, government agencies, and corporate lobbying groups, are increasingly turning to the NAS to define the scientific state of play on controversial topics, whether it is global warming, stem cell research, or a specific toxic chemical. For the NAS to maintain its credibility in this role, it must be vigilant in rooting out even the appearance of conflicts of interest among its committee members.

Conflicts of interest stem from many different types of financial arrangements. Many are not readily apparent from individuals’ positions at universities or university-affiliated centers or institutions. University-based researchers can receive personal remuneration in the form of industrial support of research contracts, grants, consulting contracts, speaking fees, honoraria, and service on corporate advisory boards. Those arrangements may be ongoing or intermittent, and they may not be disclosed on a scientist’s resumé or *curriculum vitae*. While a skilled researcher may be able to find evidence for

these ties (gleaned from disclosures in academic articles or at scientific meetings, for instance), they are generally hidden from public view.

For the public to maintain its faith in the integrity of the NAS process, it is critical that all financial ties that even appear to be a conflict of interest get disclosed on the NAS website during the panel selection process. The FACA amendments of 1997 are quite specific with regard to the NAS’ need to bar scientists with conflicts of interest from its committees: “The Academy shall make its best efforts to ensure that no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable.” (See Appendix)

For the purposes of this study, CSPI differentiated between two types of financial conflicts of interest (COI) for each member: a potential COI and an actual or direct COI. Potential COIs are defined as any financial ties to any company or industry group within the last five years, even if that private entity had no relationship to the committee’s topic. The extent of these financial ties was used to determine if that scientist was biased toward an industry or held a corporate point of view (see the next section on Balancing Ideological Biases). Direct COIs are financial ties to a company or industry within the last five years that are relevant to the committee topic, that is, where the person is an employee or has financial ties to an industry trade group, research institute, a company in the industry, or a direct competitor of a company in the industry with a direct stake in the outcome of the committee’s deliberations. While that is more stringent than the current definition employed at NAS, it is in line with policies established at many leading academic journals that require conflicts of interest disclosures to accompany published articles.

Among the 320 scientists on 21 committees investigated by CSPI, 136 (43 percent) had some ties to industry or potential COIs in the five years prior to the commit-

tee's formation (see Figure 1). At least 56 of those scientists (18 percent) had direct conflicts of interest, that is, financial ties to companies, industry trade groups, or research institutes with a stake in the outcome of the study. These figures may be underestimated since CSPI did not have access to members' disclosure forms, but relied on searching publicly available and reputable sources of information to document these financial ties.

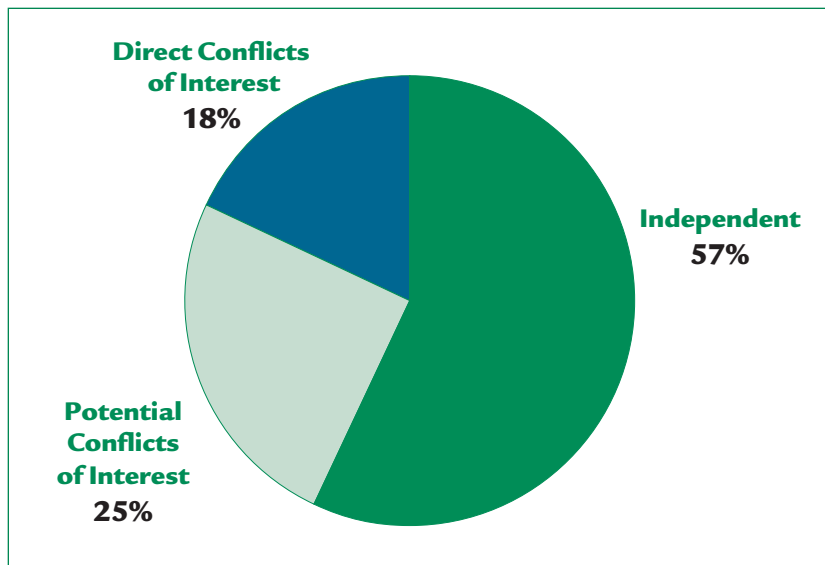


Figure 1: Conflicts of interest of members of 21 study committees (n=320)

Example: In March 2005, the IOM selected Richard Hynes of the Massachusetts Institute of Technology to chair a committee developing “Guidelines for Human Embryonic Stem Cell Research.” Hynes is a member of the scientific resource board for Genentech, the nation’s second leading biotechnology firm with extensive research capacity in stem cells and stem cell-related fields. According to NAS staff, Hynes’ tie to Genentech was not considered a conflict of interest because the topic involved bioethics questions that would have “no differential on industry.”³⁶

Example: In April 2005, the IOM appointed David C. Bellinger of the Harvard School of Public Health to a committee on “Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks,” which is weighing the relative risks methyl mercury poses to some consumers against the health

benefits of fish consumption. A few months after the panel convened, the *American Journal of Preventive Medicine* published a study co-authored by Bellinger and funded by the United States Tuna Foundation and the National Food Processors Association Research Foundation.³⁷ NAS staff said that Bellinger did not have a conflict of interest because his work on the study and its submission to the journal had been completed prior to formation of the committee. (See sidebar on next page.)

Examples: Some committees were heavily populated with scientists with ties to the affected industries. The “State Practices in Setting Mobile Source Emissions Standards” panel included at least 4 of 11 members with direct financial ties to oil or vehicle industries. Of the 11 scientists evaluating the “Department of Energy’s Carbon Sequestration Program,” launched in August 2005, 10 had ties to carbon-emitting industries. The 16-member “Food Marketing and the Diets

of Children and Youth” committee, which issued its report in 2006, included at least 7 individuals with direct ties to the food, media and advertising/marketing industries, all of which had a direct stake in the study’s contents.

Finding: Nearly one out of every five scientists appointed to an NAS panel had direct financial ties to companies or industry groups with a direct stake in the outcome of that study. This consistent pattern of appointing scientists with conflicts of interest clearly violates the spirit of the Federal Advisory Committee Act amendments that apply to NAS and in some cases may have violated the law itself.

B. Balancing Ideological Biases

FACA requires that federal agencies balance advisory committees both in terms of functions to be performed and points of view.

Hiding Ties to Industry is a Risky Business

Eating mercury-laden fish can be risky for children and pregnant women. Yet fish is an important source of omega-3 polyunsaturated fatty acids, which are good for cardiovascular health.

Where should a consumer turn to for advice?

The Environmental Protection Agency and Food and Drug Administration warn pregnant women and children to avoid eating large predatory fish (which have the highest mercury content) and limit other fish-intake to twice a week.³⁸ But the Agriculture Department's food pyramid lists swordfish, mackerel, and tuna as good sources of protein even though they have high levels of mercury. The food pyramid contains no warnings.³⁹ That isn't surprising. The department is heavily involved in promoting fish consumption through five regional aquaculture centers.⁴⁰

It is not alone. The National Oceanographic and Atmospheric Administration (NOAA) promotes off-shore fish farming.⁴¹ In late 2004 NOAA commissioned the Institute of Medicine to study the relative risks and benefits of seafood consumption. "People tell our administrator the [EPA/FDA] advisory is confusing," said Spencer Garrett, director of NOAA's National Seafood Inspection Laboratory in Pascagoula, Mississippi.

Given the high stakes nature of the debate where the public health community and the fishing industry have widely divergent views, the IOM should have ensured that the scientists and other professionals on its committee would be free from conflicts of interest. Yet when the panel was unveiled in January 2005, it included a scientist who had just completed a study of the same topic – a risk-benefit analysis of fish consumption – that was paid for by the National Fisheries Institute, an industry trade group, among others.⁴² David C. Bellinger of Children's Hospital in Boston and his colleagues at the Harvard Center for Risk Analysis concluded that pregnant women who reduced fish consumption instead of substituting low-mercury species for high-mercury species would be doing more harm than good for their developing fetuses. The study appeared in the academic literature, complete with disclosure of its funding sources, months after the committee's work got underway.

Bellinger's involvement in a fishing industry-funded study represented a conflict of interest that violated any reasonable interpretation of the NAS/IOM's conflict of interest rules. The NAS/IOM even failed to disclose his industry ties on its website or tell consumer groups who met with IOM staff in February 2005.⁴³

When later questioned about Bellinger's conflict of interest, NAS executive director William Colglazier defended his inclusion. He stated Bellinger's study had been completed and submitted for publication prior to his inclusion on the committee.⁴⁴

The language in Section 15, which applies to NAS, is less prescriptive. It states only that "the committee membership is fairly balanced as determined by the Academies to be appropriate for the functions to be performed," omitting the phrase about "points of view." (See Appendix.) However, the 2004 GAO report that reviewed federal agency

compliance with FACA included a long discussion about balance requiring detailed inquiry into scientists' points of view, and, based on interviews with NAS officials, praised the agency for its efforts to go beyond the definition of balance required by the statute. "The National Academies state that allegations of conflict of interest or *lack of*

balance and objectivity (emphasis added) can undermine the conclusions of fully competent committees.⁴⁵

While direct conflicts of interest are relatively straightforward to understand because they involve financial relationships, bias or point of view is more difficult to track. On the one hand, a scientist's employment, organizational affiliations, and published writings can indicate a perspective on issues. The chief scientist for a major corporation, a scientist who writes op-ed columns with a certain perspective, a staff scientist at an environmental group – all can and should be identified as having a particular point of view for the purpose of balancing a committee. But simply because a scientist receives research grants or speaking fees from a company or industry research institute doesn't mean that the scientist is biased in favor of industry. While studies have shown that research results tend to reflect the points of view and interests of funders, speculation as to the cause of this relationship remains precisely that – speculation.⁴⁶

On the other hand, scientists with a long history of working for industry or public interest groups can be assumed to be biased for purposes of balancing committee rosters. "A university professor who is also an official of an environmental advocacy organization may reasonably be viewed by a sponsoring agency and others as representing an environmental rather than an unaligned 'academic' perspective," the GAO said in its 2004 review. "Similarly, a university professor who is also an official of a toxicology institute that receives funding from chemical companies or who provided expert legal testimony for a corporation may reasonably be viewed by a sponsoring agency and others as providing an industry perspective." The GAO analysis clearly suggests that a committee with several industry consultants, unless they were balanced by roughly the same number of health or environmental advocates, would violate FACA.⁴⁷

The issue of bias is more clearly defined for scientists who are directly employed by organizations with an avowed point of view.

When the chief scientist of General Motors sits on an advisory panel, there can be little doubt that the positions he takes will reflect the interests of his employer. In a similar vein, a scientist employed by the Natural Resources Defense Council is safely assumed to be pro-environment.

The gray area occurs when scientists have ties with industry groups or advocacy organizations that are so extensive that they can be said to reflect that particular point of view even though they are not directly employed by those groups. As noted above, a committee dominated by such scientists would be considered unbalanced. But should agencies establishing committees take steps to counterbalance the presence of even one or two such persons on a committee? That requires independent investigation into a scientist's point of view. The GAO report suggested such bias may be inferred from published statements in press articles, public testimony and speeches, court appearances, and affiliations with ideologically-oriented think tanks or research institutes, in addition to extensive relationships with industry.

Identifying points of view of potential appointees is not aimed at barring those scientists from a panel, although that could be one approach to balancing a committee. Rather, FACA merely requires that such biases be offset by scientists with

opposing or alternative points of view. Depending on the committee's task, it is possible that the ideal panel would include a number of scientists with clashing points of view in order for the full committee to receive a complete airing of the issue at hand.

Some science policy experts do not support collecting information on possible biases for the purposes of establishing balance.

When the chief scientist of General Motors sits on an advisory panel, there can be little doubt that the positions he takes will reflect the interests of his employer.

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

Responding to complaints about political influence over the advisory committee process, a 2004 NAS panel chaired by former Congressman John Porter (R-IL) called for eliminating such questions from advisory committee appointment forms. “Scientists, engineers, and health professionals should be appointed to federal advisory committees based on their expertise and integrity,” the report said. “They should not be asked for information that would have no bearing on the scientific or technical expertise they would provide during committee discussions – such as political party affiliation, voting record, or *personal positions on particular issues* (emphasis added).”⁴⁸ That clashes directly with the spirit of FACA and the GAO view that collecting such information “would better ensure that the committees are, and are perceived as being, fairly balanced in terms of points of view – and that no one interest or viewpoint dominates.”⁴⁹

Ironically, the NAS in 2003 began soliciting such information about potential panelists’ views on its confidential disclosure forms. Candidates are asked: “List your relevant articles, testimony, speeches, etc., by date, title, and publication (if any) in which they appeared, or provide relevant representative examples if numerous. Provide a brief description of relevant positions of any organizations or groups with which you are closely identified or associated.”⁵⁰

It is impossible to know how many of the 320 scientists on the 21 panels under review disclosed information about their points of view since the completed forms remain sealed and the discussions about bias and conflicts of interest at the first meeting of panels take place behind closed doors. NAS officials told CSPI that the staff makes no attempt to investigate possible sources of bias independent of the disclosures in the forms. The CSPI investigation found few instances

where the NAS identified a point of view or bias in the panel member’s brief biography posted on the Internet.

On the other hand, CSPI’s limited background check of the 320 scientists examined found at least 66 scientists (21 percent) whose employment, significant and long-term financial relationships, published writings, think tank membership, or courtroom testimony demonstrated a pro-industry bias (see Figure 2). In contrast, only 9 of the scientists worked for or were closely aligned with environmental, health or public interest groups. Moreover, at least 9 of the 21 panels examined had a significant number of scientists with extensive financial ties to industry who were not balanced by scientists with sig-

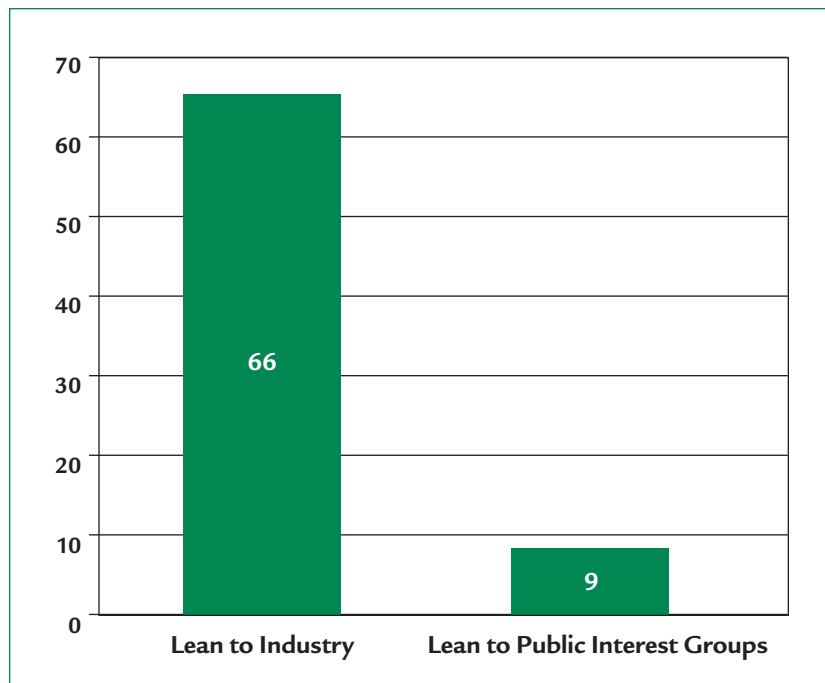


Figure 2: Committee Balance for 21 NAS Panels (number of panel members)

nificant ties to health, environmental, or other advocacy groups. Such committees should, under the GAO definition of bias that includes not only a demonstrated point of view but extensive ties to either industry or public interest groups, be categorized as imbalanced and in violation of FACA.

Example: Nine of the 19 members of the NAS committee assessing the toxicity of dioxin and dioxin-like compounds had

extensive ties to industry, mostly in the form of research contracts. Four of them conducted research for manufacturers with a stake in how regulators handle dioxin, which is a toxic by-product of the chemical, pesticide, and pulp and paper bleaching industries. Not a single scientist on the panel was directly affiliated with an environmental organization or closely aligned with environmentalist groups.

Example: In 2004 Congress asked NAS to evaluate the EPA's recently adopted "Changes in New Source Review Programs for Stationary Sources of Air Pollutants." The NAS appointed Princeton University professor William Happer, a prominent global warming skeptic whose writings have appeared in Hoover Institution publications, as chairman. The committee also included George Mason University professor Brian F. Mannix, whose writings have appeared in publications issued by the Mercatus Institute, an industry-oriented think tank that raises funds from fossil fuel industries. Mannix in 2001 wrote that the "EPA's New Source Review program is a substantial deterrent to investment in new oil refinery and power generation capacity." No scientists on the panel had a pro-environmentalist bias. Following protests against their presence on the panel, Happer and Mannix resigned.

Example: The NAS committee studying "Toxicity Testing and Assessment of Environmental Agents," impaneled in March 2004, included 12 scientists biased toward industry but only one biased toward environmental protection. The group included Gail Charnley, a private consultant to Dow Chemical who is affiliated with the Annapolis Center, an anti-regulatory think tank based in Maryland; Nancy Kerkvliet of Oregon State University, also connected to the Annapolis Center; and Abby A. Li, a former toxicologist for Monsanto who recently had joined Exponent, a private consulting firm whose clients are mainly corporations. The only environmentalist on the panel was Dr. Gina Solomon, a staff scientist for the Natural Resources Defense Council.

Example: In June 2004, the NAS' Board on Environmental Studies and Toxicology launched a 20-month review of state pollution control programs. The request was initiated by Sen. Kit Bond (R-MO), who was seeking an exemption for a major employer in his state.⁵¹ The panel included Gary Marchant, an environmental law professor at Arizona State University who once represented major automobile manufacturer trade associations in regulatory proceedings. The panel did not include any lawyers from environmental groups or state agencies. Moreover, the committee included four scientists with close ties to industry and none with ties to environmental groups.

Example: The August 2005 panel evaluating the feasibility of the Department of Energy's Carbon Sequestration Program included 10 of 11 members with recent or current financial ties to the petroleum, energy and chemical industries. The only committee member without financial ties to carbon-based industries was a university oceanographer from Rhode Island.

Finding: NAS did a poor job of balancing points of view on a majority of the 21 study panels examined. Even where an attempt was made to create balance, the results are almost always tilted toward industry dominance. The NAS makes no independent attempt to research nominees' potential biases. It relies on scientists' self-disclosure, plus whatever information is provided by the public.

C. Disclosing Conflicts of Interest and Biases

Disclosure is one means of managing conflicts of interest and bias in science and scientific publishing. Disclosure provides users of the data or readers of the publications with information that will help them evaluate the quality of the research and the conclusions of the researchers. Initially controversial, it is now considered routine at many leading science and medical journals. Most government agencies that employ scien-

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

tists as advisors require disclosure, as do medical societies at most of their meetings. However, as the controversy of requiring disclosure declined, a new debate emerged: does disclosure go far enough? “[Disclosure] serves to highlight the potential for bias, but cannot and does not eliminate the conflicts,” the editor of the *Journal of the American Medical Association* wrote in 2001.⁵²

Nor does disclosure eliminate the outright manipulations that sometimes occur. Disclosure does not prevent authors with ties to commercial entities or with their own commercial interests from delaying publication, keeping conflicting information confidential, or skewing their interpretations to fit their sponsors’ needs.⁵³

Some authors have failed to disclose relevant financial interests. The May 2005 stem cell research breakthrough announced in *Science* by Hwang Woo-Suk, Gerald Schatten and others, which was later retracted as fraudulent, failed to disclose the two scientists’ patent filings.⁵⁴ After a CSPI study identified a number of articles that failed to report relevant conflicts of interest in four prominent journals,⁵⁵ one journal, *Environmental Health Perspectives*, pledged to ban scientists from publishing within their pages for three years if fraudulent disclosure filings are later discovered.⁵⁶

These well-publicized failures to disclose conflicts of interest (well publicized in the science press at least) should have made NAS officials sensitive to the importance of disclosing on its website the conflicts of interest of committee members. Disclosure is not only a way of providing this information to the public, which is crucial to maintaining the public’s faith in the integrity of the NAS role in the science policy process, but an internal tool for preventing or managing conflicts of interest and bias on its committees, which the previous two sections showed it has consistently failed to do.

The disclosure requirements in Section 15 of FACA are quite specific, stating that no one can serve on a committee:

...who has a conflict of interest that is

relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable. (See Appendix.)

The NAS is also required by statute to give brief biographies of potential committee members to help the public comment on their qualifications. The public cannot intelligently comment on the conflicts of interest and balance aspects of committee nominees unless their biographies include that information. Yet, according to NAS officials, the biographical postings are limited to providing “an appropriate statement of the member’s qualifications to serve on the committee, highlighting the member’s expertise and technical credentials related to the committee’s charge and his or her relevant current and past affiliations.”⁵⁷

CSPI’s independent, but necessarily limited, research found that nearly one out of every five (18 percent) scientists reviewed had some ties to industry. Yet the NAS told the public about those ties in fewer than half the cases. Moreover, not a single scientist was identified as having a particular bias or point of view beyond a handful of cases where their employment by public interest/environmental groups or private firms made their biases apparent.

Example: With one exception, every scientist on the “Panel on DOE’s Carbon Sequestration Program” had a direct conflict of interest, either consulting for or being employed by oil and energy companies with a potential stake in the committee’s outcome. Only half of those ties were disclosed on the NAS website prior to the committee’s formation, or subsequently revealed by NAS.

Example: The “State Practices in Setting Mobile Source Emissions Standards” Committee, which was reviewing controversial standards, included four scientists with direct ties to oil and vehicle companies. Just two of those ties were revealed by the NAS to the public prior to formation of the committee.

Example: The “Review of the WIC [Women, Infants and Children] Food Packages” committee included five scientists with ties to the food industry or food industry-related research institutes. None of those ties was revealed to the public prior to being appointed.

Example: Excluding the reporting of direct employment by corporations or advocacy organizations, none of the biographies listed for the 21 committees reviewed by CSPI included a statement suggesting that a prospective committee member had a non-financial bias about the subject matter. CSPI’s

independent investigation found at least 3 scientists with biases that had been revealed in other forums. (See the examples of Happer and Mannix on page 15.)

Finding: The NAS provides brief biographies of prospective members of its committees on its website, and giving the public 20 days advance notice before the first meeting provides sufficient time to comment. However, those biographies are woefully inadequate for that purpose because they consistently fail to provide crucial data regarding conflicts of interest and points of view.

V. Recommendations

The CSPI review of 21 NAS committees impaneled over the past three years found that the NAS:

- Failed to keep its legal obligation to appoint scientists without conflicts of interest to its study panels.
- Failed to identify numerous proposed panel members with ideological biases; failed to balance them with panel members with opposite or alternative points of view; and allowed over-representation of industry-oriented scientists on many panels, thus failing to meet the test of balance.
- Failed to provide the public with information about the conflicts of interest and biases of prospective panel members, even though the public is encouraged to comment on those and other issues during the committee formation process.

To achieve its stated goal of “ensuring independent, objective advice” for federal agencies, Congress, and the general public, the NAS should:

- Strengthen its definition of conflicts of interest to include any financial ties to companies, industry trade groups, or industry-dominated research institutes that might be affected by the committee’s work. The NAS should consider any financial ties within the past five years when evaluating conflicts of interests, not just current ties, which is its present policy.
- Explicitly state that it is NAS policy to exclude any scientists with conflicts of interest from committees unless their expertise is crucial to successful com-

pletion of the committee’s task. In such cases, the NAS should issue and publish conflict of interest waivers documenting the nature of the conflict and the reason for the waiver.

- Change its definition of “balance” on committees to include bias or point of view (in addition to the current definition that committees will be balanced by including all the necessary types of expertise). The definition of point of view should be expanded to include scientists whose extensive financial ties to industry or public health/environmental groups (not just employment by those entities) merit their being considered as having that point of view.
- More closely evaluate scientists’ point of view disclosures to determine if candidates need to be balanced with candidates with opposite or alternative points of view. Balance should be defined as having roughly equal numbers from opposing or alternative points of view.
- Review compliance with the requirement for disclosure of conflicts of interest and points of view/bias prior to a scientist being nominated for the committee. To encourage compliance, the NAS should ban any scientist who fails to disclose appropriate information from serving on any NAS panel for three years.
- Inform scientists who are being considered for panels that their conflicts of interest will be publicly disclosed.
- Publicly announce through its website and other outreach channels that it is

forming a new study committee. That announcement should occur at least three months before the first meeting of the committee and include an invitation to the public to submit nominations for membership on the committee.

- Post on its website, after a tentative roster for the committee has been chosen, all financial conflicts of interest, points of view, and biases that are relevant to the topic being studied by the committee. Those disclosures should be published at least 20 days before the first meeting of the committee to
- allow the public sufficient time to comment.
- Publish along with the final roster an assessment of public comments regarding a committee's nominees and overall balance.
- Maintain a listserv that notifies interested individuals when a committee is being formed and when it has chosen a tentative list of nominees. The notice should include a link to the proposed list of nominees.

Appendix A

FEDERAL ADVISORY COMMITTEE ACT PROVISIONS SPECIFIC TO NAS

TITLE 5 – APPENDIX

FEDERAL ADVISORY COMMITTEE ACT

Sec. 15. Requirements relating to the National Academy of Sciences and the National Academy of Public Administration -STATUTE-

(a) In General. - An agency may not use any advice or recommendation provided by the National Academy of Sciences or National Academy of Public Administration that was developed by use of a committee created by that academy under an agreement with an agency, unless -

(1) the committee was not subject to any actual management or control by an agency or an officer of the Federal Government;

(2) in the case of a committee created after the date of the enactment of the Federal Advisory Committee Act Amendments of 1997, the membership of the committee was appointed in accordance with the requirements described in subsection (b)(1); and

(3) in developing the advice or recommendation, the academy complied with -

(A) subsection (b)(2) through (6), in the case of any advice or recommendation provided by the National Academy of Sciences; or

(B) subsection (b)(2) and (5), in the case of any advice or recommendation provided by the National Academy of Public Administration.

(b) Requirements. - The requirements referred to in subsection (a) are as follows:

(1) The Academy shall determine and

provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee. The Academy shall determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the Academy determines such prior comment is not practicable, in the period immediately following the appointments. The Academy shall make its best efforts to ensure that

(A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable,

(B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and

(C) the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed.

(2) The Academy shall determine and provide public notice of committee meetings that will be open to the public.

(3) The Academy shall ensure that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public, unless the Academy determines that a

meeting would disclose matters described in section 552(b) of title 5, United States Code. The Academy shall make available to the public, at reasonable charge if appropriate, written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy, unless the Academy determines that making material available would disclose matters described in that section.

(4) The Academy shall make available to the public as soon as practicable, at reasonable charge if appropriate, a brief summary of any committee meeting that is not a data gathering meeting, unless the Academy determines that the summary would disclose matters described in section 552(b) of title 5, United States Code. The summary shall identify the committee members present, the topics discussed, materials made available to the committee, and such other matters that the

Academy determines should be included.

(5) The Academy shall make available to the public its final report, at reasonable charge if appropriate, unless the Academy determines that the report would disclose matters described in section 552(b) of title 5, United States Code. If the Academy determines that the report would disclose matters described in that section, the Academy shall make public an abbreviated version of the report that does not disclose those matters.

(6) After publication of the final report, the Academy shall make publicly available the names of the principal reviewers who reviewed the report in draft form and who are not officials, agents, or employees of the Academy.

(c) Regulations. - The Administrator of General Services may issue regulations implementing this section.⁵⁸

Appendix B

THE 21 COMMITTEES

BEST-K-03-07-A; 06/01/04
 Division of Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*State Practices in Setting Mobile Source
 Emissions Standards*

BEES-J-04-01-D; 08/30/05
 Division on Engineering and Physical
 Sciences
 Board on Energy and Environmental
 Systems
*Panel on DOE's Carbon Sequestration
 Program*

BOGH-H-04-01-D; 01/21/05
 Institute of Medicine
 Division of Behavioral and Social
 Sciences and Education
 Board on Global Health
*Subcommittee on Care for the President's
 Emergency Plan for AIDS Relief [PEP-
 FAR] Implementation Evaluation*

HPDP-H-05-03-A; 06/24/05
 Institute of Medicine
 Board on Health Promotion and
 Disease Prevention Sciences Policy
Asbestos: Selected Health Effects

HPDP-H-04-02-A; 06/15/04
 Institute of Medicine
 Board on Health Promotion and
 Disease Prevention Sciences Policy
*Review of the National Immunization
 Program's (NIP's) Research Procedures
 and Data Sharing Program*

HSPX-H-04-06-A; 01/24/05
 Institute of Medicine
 Board on Health Sciences Policy
*Ethical Considerations for Revisions to
 DHHS Regulations for Protection of
 Prisoners Participating as Subjects in
 Research*

HPDP-H-05-01-A; 04/06/05
 Institute of Medicine
 Board on Population Health and
 Public Health Practice
*Assessment of the U.S. Drug Safety
 System*

FNBX-H-04-03-A; 08/26/04
 Institute of Medicine
 Food and Nutrition Board
 Board on Children Youth and Families
*Food Marketing and the Diets of
 Children and Youth*

FNBX-H-03-01-A; 12/23/03
 Institute of Medicine
 Food and Nutrition Board
Review of the WIC Food Packages

FNBX-H-04-04-A; 11/01/04
 Institute of Medicine
 Food and Nutrition Board
*Nutrient Relationships in Seafood:
 Selections to Balance Benefits and Risks*

FNBX-H-01-90-B; 03/23/05
 Institute of Medicine
 Food and Nutrition Board
*Committee on Military Nutrition
 Research*

DELS-O-04-01-A; 03/23/05
 Division on Earth and Life Studies
Review of NIOSH Research Programs

BLSX-K-04-03-B; 09/14/04
 Division on Earth and Life Studies
 Institute Of Medicine
 Board on Earth Sciences and
 Resources
*Guidelines for Human Embryonic Stem
 Cell Research*

BESR-U-04-06-A; 09/14/04
 Division on Earth and Life Studies
 Board on Earth Sciences and
 Resources
*Mine Placement of Coal Combustion
 Wastes*

BBXX-K-00-02-A; 03/14/03
 Division on Earth and Life Studies
 Institute of Medicine
 Board on Life Sciences
 Food and Nutrition Board
 Agriculture and Natural Resources
 Board
*Process to Identify Hazards and Assess
 the Unintended Effects of Genetically
 Engineered Foods on Human Health*

BEST-K-05-01-A; 07/13/05
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*Environmental Impacts of Wind Energy
 Projects*

BEST-K-03-08-A; 09/09/04
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
 Board on Agriculture and Natural
 Resources
 Food and Nutrition Board
*Review EPA's Exposure and Human
 Health Reassessment of TCDD and
 Related Compounds*

BEST-U-03-08-A; 03/18/04
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*Toxicity Testing and Assessment of
 Environmental Agents*

BEST-K-03-04-A; 02/25/04
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*Changes in New Source Review
 Programs for Stationary Sources of Air
 Pollutants*

BEST-K-03-02-A; 12/11/03
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*Environmental Decision Making:
 Principles and Criteria for Models*

BEST-K-03-06-A; 12/21/2004
 Division on Earth and Life Studies
 Board on Environmental Studies and
 Toxicology
*Assessing the Human Health Risks of
 Trichloroethylene*

Notes

- ¹ For more background on the history of the National Academies, see <http://www.nas.org>.
- ² Personal communication, William Colglazier, NAS Executive Officer, to CSPI, October 28, 2005. See also http://www.nasonline.org/site/PageServer?page-name=ABOUT_main_page; <http://www.nationalacademies.org/annualreport/rev04.htm>.
- ³ Jane E. Brody, "Panel Reports Healthy Americans Need Not Cut Intake of Cholesterol," *New York Times*, May 28, 1980, p. 1.
- ⁴ Jane E. Brody, "Experts Assail Report Declaring Curb on Cholesterol Isn't Needed," *New York Times*, June 1, 1980, p. 1.
- ⁵ *Animal Legal Defense Fund, Inc. v. Shalala*, 104 F.3d 424 (D.C. Cir. 1997).
- ⁶ Government Accounting Office, "Federal Research: The National Academy of Sciences and the Federal Advisory Committee Act," GAO/RCED-99-17, November 1998, p. 5.
- ⁷ *Animal Legal Defense Fund, Inc. v. Shalala*.
- ⁸ M.R.C. Greenwood, "Raiders of the Last Bastion?" *Science*, July 11, 1997, p. 163.
- ⁹ GAO/RCED-99-17, p. 12.
- ¹⁰ GAO/RCED-99-17, p. 2-3.
- ¹¹ Government Accounting Office, "EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance," GAO-01-536, p. 14-19.
- ¹² Government Accountability Office, "Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance," GAO-04-328, April 16, 2004.
- ¹³ Letter from NRDC, EWG and CSPI to Bruce Alberts, President, National Academy of Sciences, Oct. 9, 2003. On file at CSPI.
- ¹⁴ Peter Waldman, "Perchlorate-Panel Member Resigns," *Wall Street Journal*, June 11, 2004, p. A3.
- ¹⁵ NAS, "Policy on Committee Composition and Balance and Conflicts of Interest," May 2003.
- ¹⁶ See, for instance, "NAS Panel Rife With Undisclosed Ties to Polluters," Center for Science in the Public Interest press release, Jan. 22, 2004 (<http://www.cspinet.org/integrity/press/200401221.html>); and "Coal Ties Tar Science Panel, Groups Say," CSPI press release, Oct. 26, 2004 (<http://www.cspinet.org/integrity/press/200410261.html>).
- ¹⁷ Federal Advisory Committee Act, Section 15, 1972.
- ¹⁸ Personal communication, William Colglazier, NAS Executive Officer, to CSPI, Oct. 28, 2005.
- ¹⁹ Personal communication, Jim Jensen, NAS Director of Congressional Relations, Oct. 28, 2005.
- ²⁰ NAS website; <http://www.nationalacademies.org/col/index.html>.
- ²¹ The National Academies' 2003 "Policy on Committee Composition and Balance and Conflicts of Interest"
- ²² Personal communication, William Colglazier, NAS Executive Officer, Oct. 28, 2005.
- ²³ NAS, "Background Information and Confidential Conflict of Interest Disclosure" forms.
- ²⁴ NAS brochure, "The National Academies Study Process: Ensuring Independent, Objective Advice."
- ²⁵ Personal communication, William Colglazier to CSPI, Oct. 28, 2005.
- ²⁶ NAS brochure, "The National Academies Study Process: Ensuring Independent, Objective Advice."
- ²⁷ See "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency," at <http://www.epa.gov/science1/pdf/epaform3110-48.pdf>, accessed Jan. 31, 2006.
- ²⁸ GAO-04-328, "Federal Advisory Committees – Additional Guidance Could Help Agencies Better Ensure Independence and Balance," April 16, 2004, p. 32-4.
- ²⁹ See <http://www.fda.gov/oc/advisory/conflictinterest/disclosure.pdf>.
- ³⁰ See <http://www.fda.gov/oc/advisory/default.htm>.
- ³¹ Gardiner Harris and Alex Berenson, "Voters on Panel Backing Pain Pills Had Industry Ties," *New York Times*, Feb. 25, 2005, p. 1.
- ³² See, for instance, Jennifer Washburn, *University Inc.: The Corporate Corruption of Higher Education*, Basic Books, 2005; and David Willman, "Stealth Merger: Drug Companies and Government Medical Research," *Los Angeles Times*, Dec. 7, 2003, p. 1.
- ³³ Quoted in Derek Bok, *Universities in the Marketplace*, Princeton University Press, 2003, p. 66-7.
- ³⁴ Troyen A. Brennan, et al., "Health Industry Practices That Create Conflicts of Interest," *Journal of the American Medical Association*, Jan. 25, 2006, p. 430.
- ³⁵ Carl Elliott, "Pharma Goes To the Laundry: Public Relations and the Business of Medical Education," *Hastings Center Report*, Dec. 1, 2004.
- ³⁶ Personal communication, Jim Jensen, NAS Director of Congressional Relations, 10/28/05.
- ³⁷ Marian Burros, "Advisories on Fish and the Pitfalls of Good Intent," *New York Times*, Feb. 15, 2006, p. F5.
- ³⁸ See <http://www.cfsan.fda.gov/~dms/admehg3.html> (accessed Jan. 19, 2006).
- ³⁹ Michael Hawthorne, "What is a consumer to do? The USDA's food pyramid recommends eating three fish that the EPA and the FDA warn are high in mercury," *Chicago Tribune*, Jan. 19, 2006.

ENSURING INDEPENDENCE AND OBJECTIVITY AT THE NAS

- ⁴⁰ See, for instance, the mission statement for the North Central Regional Aquaculture Center at <http://ag.ansc.purdue.edu/aquanic/ncrac/splan.htm> (accessed Jan. 19, 2006).
- ⁴¹ See, for instance, <http://www.nmfs.noaa.gov/media-center/aquaculture/> (accessed Jan. 19, 2006).
- ⁴² Joshua T. Cohen, PhD, David C. Bellinger, PhD, et al., "A Quantitative Risk-Benefit Analysis of Changes in Population Fish Consumption," *American Journal of Preventive Medicine*, Vol. 29, No. 4, p. 325-34. The journal reported the study was funded by the National Food Processors Association Research Foundation and the Fisheries Scholarship Fund, whose membership rosters include numerous fish processors.
- ⁴³ CSPI Integrity in Science director Merrill Gozner was present at the meeting.
- ⁴⁴ CSPI interview with William Colglazier, Oct. 28, 2005.
- ⁴⁵ GAO-04-328, op. cit., p. 43-4.
- ⁴⁶ Bekelman JE et al, "Scope and impact of financial conflicts of interest in biomedical research: a systematic review," *Journal of the American Medical Association*, Jan. 22, 2003, p. 454-63.
- ⁴⁷ GAO-04-328, op. cit., p. 33.
- ⁴⁸ "Science and Technology in the National Interest: Ensuring the Best Presidential and Federal Advisory Panel Science and Technology Appointments," The National Academies Press, Nov. 14, 2004.
- ⁴⁹ GAO-04-328, op cit., p. 40.
- ⁵⁰ The National Academies, BI/COI Form 1, "Background Information and Confidential Conflict of Interest Disclosure for Studies Related to Government Regulation," May 2003.
- ⁵¹ See, for instance, Sen. Kit Bond Press Release, "Bond Joins Workers to Celebrate Groundbreaking on Missouri Briggs and Stratton Plant Expansion," March 21, 2005 (available at <http://bond.senate.gov/atwork/recordtopic.cfm?id=234384>).
- ⁵² DeAngelis et al., "Reporting Financial Conflicts of Interest and Relationships between Investigators and Research Sponsors," *Journal of the American Medical Association*, 2001; 286:89-91.
- ⁵³ See Bekelman et al, op. cit.; and Curfman GD, et al, "Expression of Concern: Bombardier, et al., 'Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis,' *N Engl J Med*, 2000; 343:1520-8," *N Engl J Med*, 2005; 353:2813-4.
- ⁵⁴ See CSPI letter to Donald Kennedy, editor of *Science*, Jan. 12, 2006, available at: http://cspinet.org/new/pdf/science_letter.pdf.
- ⁵⁵ Center for Science in the Public Interest, "Unrevealed: Non-Disclosure of Conflicts of Interest in Four Leading Medical and Scientific Journals," July 2004 (http://www.cspinet.org/new/pdf/unrevealed_final.pdf)
- ⁵⁶ Goehl TJ, "Embracing Scutiny," *Environmental Health Perspectives*, October 2004, available online at: <http://ehp.niehs.nih.gov/docs/2004/112-14/editorial.html>.
- ⁵⁷ Personal communication, William Colglazier to CSPI, Jan. 27, 2006.
- ⁵⁸ Pub. L. 92-463, Sec. 15, as added Pub. L. 105-153, Sec. 2(b), Dec. 17, 1997, 111 Stat. 2689.



CENTER FOR
Science IN THE
Public Interest

publisher of Nutrition Action Healthletter
1875 Connecticut Avenue, N.W., Suite 300
Washington, D.C. 20009
202-332-9110
www.cspinet.org