

CORRUPTED SCIENCE

Ethics & Science Advisory Committees



Federal Advisory Committee Law

- Executive Branch agencies have established boards, commissions, councils, and similar groups to provide technical advice directly to government administrators.
- Advisory committees are “frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.”
- “Standards and uniform procedures should govern [their] establishment, operation, administration, and duration.”
- “Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees.”
- “The function of advisory committees should be advisory only.”
- “all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.” *

* Pub. L. 92-463, Sec. 2, Oct. 6, 1972, 86 Stat. 770. www.epic.org/open_gov/faca.html

The Power and Extent of Federal Advisory Panels

- In 2003, 948 federal advisory committees were active, including 214 scientific and technical panels; 102 reviewed grants
- Dept. of Health and Human Services (HHS) had 247 committees
 - National Institutes of Health (NIH) - 144, largest of any executive branch
 - Food and Drug Administration (FDA) - 30
 - Centers for Disease Control (CDC) - 23
- Dept. of Agriculture had 54 advisory committees and the Environmental Protection Agency had 26.
- Many NIH committees serve as peer reviewers of research grant applications and advise on policies and programs.
- Advice given by FDA advisory committees on drugs and medical devices is “often pivotal” in agency decisions.

* Robert Steinbrook, M.D. Science, Politics and Federal Advisory Committees. *NEJM*, April 1, 2004.

Ethical Guidelines for Federal Advisory Committees

- For their time on the boards members are considered “special government employees” (SGEs) if they serve less than 130 days/year (18 U.S.C., sec. 202-209).
- SGE regulations apply even if consultant takes no oath, receives no pay and is not a permanent government employee.
- Federal conflict of interest laws that apply to federal employees thus apply to SGE advisory committee members:
 - They are prohibited from engaging in self-serving conduct.
 - They are designed to protect the federal government from “actual or apparent conflicts on interest” (18 U.S.C., sec. 208(a) purpose).
 - 1997 Amendments to Federal Advisory Committee Act (PL 105-153) appeared to toughen the act, explicitly forbidding participation of those with financial interests, but its application has proven otherwise.

Federal Science Advisory Committee Rules

There are two rules that seem to guide the use of scientists on federal advisory committees:

- Rule 1 states that if a scientist has a substantial conflict of interest then he or she cannot serve on a federal advisory committee.
- Rule 2 states that Rule 1 can be waived.

As a consequence, there have been many waivers for scientists who have financial conflicts of interest but are permitted to serve and vote on a federal advisory committee.

USA TODAY Investigation

In 2000, investigative journalists of *USA TODAY* studied 18 expert advisory committees established by FDA's Center for Drug Evaluation and Research that met between Jan. 1, 1998 and June 30, 2000. The newspaper reported: "more than half of the experts hired to advise the government on the safety and effectiveness of medicine have financial relationships with pharmaceutical companies that will be helped or hurt by their decisions."^{*}

Of the 1,620 member appearances at these advisory meetings, 803 (50%) had waivers for conflicts of interest. *USA TODAY* found that, about 50% of the time, advisers to the FDA have a direct financial interest in the drug they are asked to evaluate.

^{*} Denis Cauchon. FDA advisers tied to industry. *USA TODAY*, September 25, 2000.

Ethics “Reform” Act of 1989

- The Act Reduced the authority of individual agencies to issue criteria for conflict of interest waivers by giving authority to the Office of Government Ethics (OGE)
- The Act gave the OGE Director power to issue rules to exempt from COI rules employees whose “financial interests...are too remote or too inconsequential to affect the integrity of the services” they supply.
- The Act does *not* require agencies to disclose an advisory committee member’s principal employment, contractual relationships or investments that may be relevant to issues the committee will discuss.

USDA withheld COI information among members of the US Dietary Guidelines Advisory Committee

In December 1999, the Physicians Committee for Responsible Medicine sued the USDA alleging that it intentionally withheld information about advisory committee members who had “inappropriate ties to the meat, dairy or egg industries.” US District Court Judge James Robertson ruled on October 2, 2000 that the USDA violated federal law by hiding financial COI among members of the diet advisory committee.

The USDA did not appeal the decision.*

* Physicians Committee for Responsible Medicine (PCRM). Doctors Announce Final Victory in Dietary Guidelines Lawsuit: USDA Forfeits Right to Appeal; Reveals New Conflict of Interest. News Release, December 6, 2000. www.pcrm.org/news/health001206.html

2001 GAO Investigation of EPA's Science Advisory Board

- EPA Science Advisory Board panels, over 100 non-governmental technical experts, are charged with advising the EPA on the technical bases for EPA regulations.
- The Government Accounting Office (GAO) found that the EPA's Advisory Board "procedures do not adequately ensure independence and balance:
 - One third of financial disclosure forms filed by panels members were not reviewed by EPA staff.
 - Disclosure forms were not adequate for detecting a peer reviewer's conflict of interest.
 - The public is largely kept ignorant of what appears on conflict of interest forms submitted by EPA panel members. (EPA holds public disclosure sessions for discussing COI but publishes only the minutes of those meetings, not member's COI form details.)*

* U.S General Accounting Office, EPA's Science Advisory Board Panels. Washington, DC: GAO-01-536, June 2001.

Specific EPA cases cited in GAO investigation

- The 1,3-Butadiene Health Risk Assessment Panel -1998
 - Of the 15 panelists, 10 were professors, medical directors or both; 4 worked for companies; 1 worked for a state environmental agency; 6 of 15 began on the panel with an industry perspective.
 - Not listed in disclosure forms: 2 owned stock in 1,3-Butadiene manufacturers; 2 received fees from chemical companies.
- 3 Panels on Guidelines for Assessing Health Risks of Carcinogens
 - EPA established 3 panels (between 1996-2000) with 26 panelists in total
 - GAO's summary review of the 3rd panel stated: "We believe that the [EPA] staff office would have benefited from additional information in assessing the point of view of the panels" such as "the consulting and professional fees and stocks owned by one panelist and the work another performed for the Chemical Manufacturer's Association."

* U.S General Accounting Office. EPA's Science Advisory Board Panels. Washington, DC: GAO-01-536, June 2001.

Science Panel and Statins

Newsday (July 20, 2004) reported that eight of the nine members of the government panel that published new treatment guidelines calling for a wider use of statin drugs had ties to the companies that manufacture the medications.

The financial interests of the panelists include honoraria, speaker fees, and major research grants.

The drug companies/drugs are: Pfizer's Lipitor; Bristol-Myers Squibb's Pravachol; Merck's Lovastatin; AstraZeneca's Crestor.*

* Delthia Ricks. Statin Recommenders' Drugmaker Ties, U.S. confirms panel link. *Newsday*, Long Island, N.Y. July 20, 2004

Advisors to FDA Vioxx Panel had ties to companies

The Center for Science in the Public Interest (CSPI) found that 10 of the 32 panel members of an FDA advisory panel to review the safety of Cox-2 inhibitors had ties to Cox-2 drug makers Pfizer Inc. or Merck & Co. Ties to the drugmakers included consulting fees, speaking honoraria or research funding.

* Associated Press. 10 on FDA Vioxx panel had ties to companies. February 25, 2005. www.msnbc.com/id/7031927

Panels that Write Clinical Guidelines

“In the investigation of the panels that write clinical guidelines—documents that govern the diagnosis and treatment of patients—*Nature* found that more than one-third of the authors declared financial links to relevant drug companies, with around 70% of panels being affected. In one case every member of the panel had been paid by the company responsible for the drug that was ultimately recommended.” *

* Rosie Taylor and Jim Giles. Cash interests taint drug advice. *Nature* 437:1079-80 (October 20, 2005).