

December 17, 2002

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue Southwest
Washington, DC 20201

Dear Secretary Thompson,

The undersigned organizations are writing to express concern about recent setbacks to the integrity of the scientific advisory process at the Centers for Disease Control and Prevention (CDC). CDC's credibility is essential for protection of the public's health. Without stronger safeguards that promote transparency, integrity, and public participation, the process for all intents and purposes occurs behind closed doors and financial interests appear to inappropriately influence the selection of members for CDC's scientific advisory committees. We urge you to direct CDC to (1) immediately disclose information about the conflicts of interest of current advisory committee members, and (2) establish uniform policy and procedural safeguards to prevent undue influence from special interests and assure transparency and public participation in the committee process.

Statutory Background

Federal advisory committees are intended to inform government decisions with the best possible expert advice and information. The credibility of the advisory committee system depends upon the expertise of committee members and the independence, transparency, and integrity of the committee process. The main law governing advisory committees, the Federal Advisory Committee Act (FACA), requires that the membership of committees be "fairly balanced," impartial, and free of inappropriate influences of "any special interest."¹ In addition, Section 8 of FACA imposes the responsibility on agency heads to "establish uniform administrative guidelines and management controls for advisory committees established by that agency"²

The legislative history of FACA documents Congress' intent to create an advisory-committee process that is transparent to the public, provides an "assurance of autonomy," and is free of "inappropriate influence."³

Recent Committee Changes Threaten CDC Credibility

Recent changes in the composition of key public health committees at CDC (and elsewhere within the Department of Health and Human Services (HHS)⁴) raise concerns about the adequacy of existing policies and procedures designed to implement the FACA.

Your office recently replaced a majority of members of the CDC's Advisory Committee to the Director of the National Center for Environmental Health (NCEH), apparently ignoring input of the NCEH director and the chair of the committee.⁵ Newly appointed members include

Dr. Dennis Paustenbach, a vice president of Exponent, Inc., who served as an expert witness for Pacific Gas and Electric; Dr. Roger McClellan, former president of the Chemical Industry Institute of Toxicology, a research organization whose members include chemical and oil companies and trade associations ; and Dr. Becky Norton Dunlop, a vice president of the Heritage Foundation, a conservative think tank in Washington, D.C.⁶

Further, several scientists who have ties to the lead industry were appointed to the CDC's Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP).⁷ Dr. Joyce Tsuji is a scientist at Paustenbach's consulting company, Exponent, Inc., and whose clients include a company in a dispute with EPA over lead pollution. (Tsuji reportedly has withdrawn her nomination.) Dr. William Banner has been an expert witness for the lead industry and has stated that lead is safe at levels many times higher than current standards. Dr. Kimberly Thompson is affiliated with the Harvard Center for Risk Analysis, which has 22 corporate funders with ties to the lead industry.⁸ Those membership changes clearly could benefit the industries most affected by the lead poisoning committee's recommendations.

Current Policies and Procedures are Inadequate

A key ingredient in preventing even the appearance of a conflict of interest comes from having strong policy and procedural safeguards. In CDC's case, such protections are woefully inadequate. According to CDC officials, CDC has no written, public policy regarding the avoidance of conflicts of interest of advisory committee members.⁹ While the "policies and procedures" document internal to the lead-poisoning-prevention committee does assure the participation of the chair of the committee and CDC staff in reappointing or replacing members, that process appears to have been ignored in the recent membership changes.¹⁰ It is unclear how many other advisory committees have their own policies and procedures and, if so, whether those documents are consistent with one another and with FACA. The recent events show that CDC does not have "uniform administrative guidelines and management controls for advisory committees," as required under Section 8 of FACA.

Without stronger policy and procedural guarantees for public participation in the member-selection process and disclosure of relevant financial ties of nominees, the committee selection process for all intents and purposes occurs behind closed doors and without public input. When your office appoints individuals with ties to industry, ignoring CDC scientists, your office only reinforces the appearance that recent turnover furthers the interests of "special interest[s]."¹¹ We urge you to:

- immediately instruct the CDC to implement interim measures to increase transparency. CDC should (1) require advisory committee members to disclose at each committee's next meeting their relevant financial ties to industry that create even the appearance of a conflict of interest, and (2) make such disclosures easily accessible on CDC's web site and in meeting minutes, membership rosters, committee reports, and other committee documents.
- instruct the CDC to establish a uniform policy and procedures for its advisory committees that prevent undue influence from special interests and assure

transparency and public participation in the committee process. Such a policy should:

1. define a disqualifying financial interest to include research grants and awards, consulting fees, and speaking and writing honoraria related to the matters addressed by the committee. Failing that, CDC's policy should require, as a condition of participation, that individuals with unavoidable conflicts of interest consent to public disclosure by CDC of their relevant financial ties; and
 2. establish procedures for meaningful public participation in the committee formation process.
- provide to us the names of individuals or entities consulted and the process used in appointing the current nominees and members of the Advisory Committee on Childhood Lead Poisoning Prevention and the Advisory Committee to the Director of the National Center for Environmental Health.

Other scientific, governmental, and research institutions are taking significant steps to prevent and disclose the potentially biasing ties of authors, researchers, academic institutions, and others to industry. For example,

- In the past year, the Food and Drug Administration (FDA), an agency within your department, strengthened its own conflict-of-interest procedures.¹² For some relationships, a committee member must disclose financial ties as a condition of participation. Certain relationships disqualify a person from membership on a committee.
- Last year, the General Accounting Office documented flaws in conflict-of-interest practices at the U.S. Environmental Protection Agency Science Advisory Board (SAB).¹³ In response, SAB broadened its definition of financial interest and strengthened its procedures for analyzing, mitigating, and disclosing committee members' conflicts of interest.¹⁴
- The National Academy of Sciences' policy requires disclosure of relevant financial ties of its study-panel nominees and solicitation of public feedback on the members selected for a committee.¹⁵
- Leading scientific and medical journals increasingly are requiring public disclosure when authors have financial ties to industry.¹⁶

Critics of strong conflict-of-interest policies argue that greater disclosure would have a chilling effect on experts' willingness to serve. Yet, an FDA survey of advisory committee members conducted in 2001 found that most members were willing to disclose *more* conflict-of-interest information than they currently do: Only 17 of 292 respondents (5.8%) said they would

resign or consider resigning if asked to disclose additional information.¹⁷ Thus, that argument has little merit.

The public's health and the system that promotes it depend upon credible, independent advice given free of commercial interest or influence. We urge you to stem further erosion of CDC's credibility and establish clear standards to prevent conflicts of interest from biasing the expert advice shaping our nation's public health system. In May 2003, the terms of four members of the Advisory Committee on Childhood Lead Poisoning Prevention will expire. We hope that by then CDC will have implemented a process to reappoint or replace its advisory committee members under conditions of greater transparency, public participation, and credibility.

Sincerely,

Don Ryan, Executive Director
Alliance to End Childhood Lead Poisoning

Michelle Roberts, Organizing and Campaign Director
Center for Health, Environment and Justice

Michael F. Jacobson, Ph.D., Executive Director
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Public Citizen

Jeremiah Bauman, Environmental Health Program
U.S. Public Interest Research Group

Paul Orum, Director

Working Group on Community Right-to-Know

Clifton Curtis, Director, Global Toxics Program
World Wildlife Fund

cc: Amy L. Comstock, Director, Office of Government Ethics
James L. Dean, Director, Committee Management Secretariat, General
Services Administration
Julie L. Gerberding, Director, Centers for Disease Control and Prevention
Linda Ann Sherman, M.D., Director, Advisory Committee Management and
Oversight Staff, Food and Drug Administration

1. 5 U.S.C. Appendix 2 Sec. 5(b). On the impartiality test in ethics regulations, see 5 C.F.R. Sec. 2635.502(a). See also "Conflict of Interest Basics for New HHS Employees," Ethics Division, Office of General Counsel, Department of Health and Human Services, April 2001.
2. 5 U.S.C. Appendix 2 Sec. 8(a).
3. House Report No. 91-1731, p. 20. At the time of FACA's passage in 1972, Congress declared that FACA "has the effect of assuring openness in the operations of advisory committees" and "serves to prevent the surreptitious use of advisory committees to further the interests of any special interest group." (House Report No. 92-1017, p. 3500)
4. Rick Weiss, "HHS Seeks Science Advice to Match Bush Views," *Washington Post*, September 17, 2002, A-1. Dan Ferber, "Environmental Health: Critics See a Tilt in a CDC Science Panel," *Science* 2002;297:1456-7. David Michaels et al, "Advice Without Dissent" (editorial), *Science* 2002;298:703.
5. Weiss, op. cit.; Ferber, op. cit., 1457.
6. Membership list provided by the Centers for Disease Control and Prevention; Weiss, op. cit.; Center for Science in the Public Interest, "Integrity in Science Database," <http://www.cspinet.org/integrity>, accessed November 14, 2002.
7. Representative Edward J. Markey (D-MA), "Turning Lead Into Gold: How the Bush Administration is Poisoning the Lead Advisory Committee at the CDC," October 8, 2002; Dan Ferber, "Overhaul of CDC Panel Revives Lead Safety Debate," *Science* 2002:298:732.
8. Markey, op. cit.
9. Center for Science in the Public Interest (R. Blum), phone communication with Burma Burch, CDC Committee Management Officer, October 24, 2002.
10. "Policies and Procedures: Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP)," June 26, 1998.

11. 5 U.S.C. Appendix 2 Sec. 5(b)(3).
12. Food and Drug Administration, "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," January 2002, <http://www.fda.gov/oc/guidance/advisorycommittee.html>.
13. United States General Accounting Office, "EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance," GAO-01-536, June 2001. <http://www.gao.gov/new.items/d01536.pdf>.
14. Environmental Protection Agency Science Advisory Board, "Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board," EPA-SAB-EC-02-010, September 2002. <http://www.epa.gov/sab/pdf/ec02010.pdf>.
15. National Academies, "Getting to Know the Committee Process," pamphlet, February 1998. In 1997, Congress passed into law the Federal Advisory Committee Act Amendments of 1997 (P.L. 105-153) to relieve NAS from certain requirements of FACA. 5 U.S.C. Appendix 2 Sec. 15 See United States General Accounting Office, "The National Academy of Sciences and the Federal Advisory Committee Act," GAO/RCED-99-17, November 1998.
16. For example, the International Committee of Medical Journal Editors and the Council of Science Editors adopted standards for medical and scientific journals on disclosure of conflicts of interest of authors. Davidoff, Frank et al, "Sponsorship, Authorship, and Accountability," *JAMA* 2001;286:1232-4, <http://www.icmje.org>; http://www.councilscienceeditors.org/services_DraftApproved.shtml.
17. Food and Drug Administration, "Brief Report: SGE Financial Disclosure Survey," November 14, 2001.