NATURAL RESOURCES DEFENSE COUNCIL
THE EARTH'S BEST DEFENSE

May 13, 2009

In response to the March 9, 2009 Presidential Memo on Scientific Integrity: Request for Public Comment

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Submitted by electronic mail to scientificintegrity@ostp.gov

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INTRODUCTION

We are extremely pleased that the President and the Office of Science and Technology Policy (OSTP) are responding to the evidence of scientific mismanagement, suppression, and secrecy that has clouded the last Administration. The flat-earth science that drove the Bush Administration led to scientifically indefensible policies that weakened community health, worker protections, and environmental integrity.

In these comments we will make recommendations for the enforcement of strong and effective policies to identify and disclose and prevent financial conflicts and competing interests among government scientific and technical experts.

The improper influence of scientific and technical experts having conflicts of interest has become front page news, and a major embarrassment to government agencies, scientific journals, and professional societies.[1] The practice of promoting biased or even inaccurate data that defend funders' interests has become so widely recognized in the medical field that it is no longer contestable. Marcia Angell, former editor of the *New England Journal of Medicine*, published a book in 2005 in which she criticized the drug industry for its use of public funds and its relationship with regulatory agencies to first create a market for its products and then fast-track commercialization.[2]

Although the construction and promoting of bad science has been well documented for the tobacco and pharmaceutical industries, its use to avoid regulatory restrictions of hazardous industrial chemicals is no less common. In fact, during the Bush Administration, bad science has been documented for industry-supported research on hazardous industrial chemicals, including the low-dose effects of the plasticizer bisphenol A[3], perchlorate toxicity[4], and atrazine toxicity[5]. In his compendium of bad science, *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*, Professor

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[1] David Armstrong, "Amid Suits Over Mold, Experts Wear Two Hats," *Wall Street Journal*, Jan. 9, 2007; Christopher Rowland, "Medical Group Puts Stop to Talks on Drug Firm Ties," *Boston Globe*, Dec. 27, 2006; David Armstrong, "Financial Ties to Industry Cloud Major Depression Study," *Wall Street Journal*, July 11, 2006; Reed Abelson, "Charities Tied to Doctors Get Drug Industry Gifts," *New York Times*, June 27, 2006; Tinker Ready, "Divided Loyalties?" *Washington Post*, Feb. 7, 2006; Erika Check, "Journals Scolded for Slack Disclosure Rules," *Nature*, Jan. 18, 2006.

[2] Angell M., *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House Publishing Group, 2005).

[3] vom Saal FS, Hughes C. 2005. An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment. Environ Health Perspect 113(8):926-933.

[4] Sass J, Solomon G. Inappropriate influence by industry on EHP news article. Environ Health Perspect 2005 Feb;113(2):A87-8. http://ehp.niehs.nih.gov/docs/2005/113-2/correspondence.html; Sass J. U.S. Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution. Int J Occup Environ Health. 2004 Jul-Sep;10(3):330-4. www.ijoeh.com/pfds/1003_Sass.pdf

[5] Sass, JB, Colangelo A. European Union bans atrazine, while the United States negotiates continued use. Int J Occup Environ Health, 2006 July;12:260-267. www.ijoeh.com/pfds/IJOEH_1203_Sass.pdf

David Michaels documents with amazing accuracy how industries manipulate science to influence regulatory agencies so as to weaken or delay the regulation of their products.[6]

Effective disclosure and conflict of interest policies play an essential role in protecting government and its experts from becoming agents of propaganda, distortion, corporate marketing, and other types of scientific and technical misinformation.

PRESIDENTIAL MEMORANDUM

On March 9, 2009 the White House issued a *Presidential Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity*. It required that within 120 days from the date of its issue, "the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles":

> (a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;
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> (b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;
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> (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;
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> (d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;
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> (e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and
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> (f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decision-making or otherwise uses or prepares.

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[6] Michaels D., *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health* (New York: Oxford University Press USA, 2008).

The Office of Science and Technology Policy (OSTP) followed this memorandum with a request for comments from the public on how to effectively implement the principles of the memorandum.[7] Public comment was also requested through the issue of a Federal Register notice.[8] Here we provide comments intended to facilitate the effective implementation of the principles as stated in the memorandum.

SPECIFIC COMMENTS

In response to Principle (b) we comment on specific rules and procedures that provide assurances of integrity of scientific processes.

The integrity of the scientific process can best be protected by enforcing rules and procedures that ensure public transparency and rigorous scientific or technical review by experts without financial or other nonmonetary relevant competing interests. To assure scientific integrity, while each agency should have its own rules, here we describe basic government-wide minimal standards that no Agency should be able to fall below.

Interactions between regulating and regulated agencies should occur at arm's length

Scientific integrity can also suffer when the regulated entity is another federal agency rather than a private industry or party. Indeed, the involvement of other agencies presents special problems for the regulatory process given the inherently close relationship between departments of government and the interagency partnerships allowed by certain statutes, such as NEPA, to improve the efficiency of environmental analysis. The risk to scientific integrity is particularly high where the regulated agency ostensibly holds greater power within the government than the regulator. For example, such a situation has persisted for several years between the National Marine Fisheries Service ("NMFS") and the Department of Defense over the taking of marine mammals under the Marine Mammal Protection Act. In three major rulemakings concerning the biological impacts of mid-frequency active sonar, NMFS' positions on purely scientific questions, such as the thresholds at which marine mammals are harmed, were negotiated with and in some cases vetoed by the Department of the Navy. Similarly, the Navy was able to overrule NMFS staff on establishing appropriate sound thresholds as a "primary constituent element" for Puget Sound killer whales, pursuant to designating critical habitat for that population under the Endangered Species Act.

We recommend that guidelines be adopted that strictly delimit interactions between regulated and regulating agencies. Such guidelines should distinguish between important regulatory functions such as data-gathering that necessitate communication between the agencies, and the scientific review and decision-making processes that should remain the exclusive function of the regulator. To ensure transparency, they

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[7] OSPT request for public comment on the March 9, 2009 Presidential memorandum on scientific integrity. http://www.whitehouse.gov/blog/09/04/27/Give-Your-Comments-on-Scientific-Integrity/

[8] Federal Register /Vol. 74, No. 77 /Thursday, April 23, 2009, p. 18596

should require that interactions between the agencies be treated as *ex parte* communications, with mandatory reporting requirements. Finally, conflict-of-interest rules similar to those that apply to private lobbyists who join the federal government should also apply to staff that transfer between regulated and regulating agencies.

In response to Principle (c) we provide comments on peer review procedures and scientific processes

Evaluate and take action in response to worst-case scenarios as a routine scientific process

Effective risk management strategies must assume worst-case exposure scenarios in order to prevent unsafe human exposures and releases to the environment, and must be flexible, iterative, and responsive as new information becomes available. This approach is scientifically established and appropriate for Agencies charged with the protection of human health and environmental sustainability. Such a precautionary regulatory approach places the burden on the manufacturer to provide evidence of safety prior to widespread use, rather than on regulators to prove harm. This would drive policy-relevant research that informs risk management decisions in a timely manner, and supports the innovation of sustainable and socially-beneficial materials and safer or inherently safe technologies.

Establish effective enforceable disclosure and conflict policies

Science plays a critical role in arbitrating the safety and efficacy of consumer and industrial chemicals and products. Just as critical is the role of peer review, which can give scientific and technical assessments the imprimatur of independence and therefore credibility. Approval by a peer review or federal advisory committee is a forceful argument that a scientific assessment is trustworthy. Effective disclosure policies play an essential role in protecting journals from becoming unwitting agents of propaganda, distortion, corporate marketing, and other types of misinformation, thereby constituting an important cornerstone of the journals' credibility and reputation.

The integrity of the scientific process can best be protected by enforcing rules and procedures that ensure public transparency and rigorous scientific or technical review by experts without financial or other nonmonetary relevant competing interests.

We recommend that all government scientific or technical advisors, including peer reviewers and federal advisory committee members adhere to a strict policy on disclosure and conflicts, including not just disclosure of conflicts but also elimination of experts with financial or other nonmonetary relevant competing interests from serving as experts.

Disclosures should be objective

As much as possible, disclosures must be objective. For example, the National Academies asks the expert to report if research funding and support could be directly affected for the expert, or his or her close research colleagues and collaborators.[9] This requires the expert to speculate about whether the funder would be vindictive and withdraw support if the decision goes badly for the funder. It also might be a moot point, as the funding has already been received and spent. Instead, ask, as the World Health Organization does, whether there are any research support ties with a company that has an interest.[10] This can be answered yes or no and doesn't require speculation on the part of the expert.

Disclosures should be comprehensive and transparent

All government scientific or technical advisors, including peer reviewers and federal advisory committee members adhere to a strict policy on disclosure and conflicts. As a general rule of thumb, disclosures must include any financial interests that could constitute a potential source of bias or perceived bias in the eyes of the general public, the media, the scientific community, peer reviewers, or editors. The disclosure policy should address both financial and nonmonetary relevant competing interests. We therefore recommend the following language for requesting disclosures:

> *All financial interests must be disclosed. This includes but is not limited to employment, clients, honoraria, travel expenses, grants, and litigation support. The approximate monetary value of any financial interests must be declared and should distinguish between funding for research and monies paid to the nominee. Disclosures should include anticipated future competing interests and past competing interests going back a minimum of three years. Any other competing interests or potentially competing interests, financial or otherwise, should be disclosed if these interests, when known to the public, could compromise the standing or integrity of the nominee, the committee and its work, or the Agency.*

The public statement (as well as the detailed listing of competing interests) should be written in language such that the average person would be able to identify a potential competing interest. A mere listing of funding sources for a study or the author's salary or honoraria is not adequate if the average person is not able to establish the link to a potential source of bias.

Agency staff should clearly identify how far back they wish their disclosure policy to extend, as well as considering future potential competing interests. For example, the Journal of the American Medical Association, *JAMA,* asks its authors to disclose competing interests that go back five years <u>and</u> into the foreseeable future.[11]

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[9] National Academies Policy on Committee Composition and Balance of Conflict of Interest For Committees Used in the Development of Reports. May 12, 2003.

[10] Cogliano VJ, Baan RA, Straif K, Grosse Y, Secretan MB, El Ghissassi F, Kleihues P. The science and practice of carcinogen identification and evaluation. Environ Health Perspect. Online June 3, 2004

[11] From *The Journal of the American Medical Association*'s "Instructions for Authors," under "Conflicts of Interest and Financial Disclosures," available at http://jama.ama-assn.org/misc/ifora.dtl#ConflictsofInterestandFinancialDisclosures

The EPA Peer Review Handbook recommends asking potential reviewers about "work and clients, both current and prior, that might create conflicts or the appearance of a lack of impartiality." [12] However, regarding future work the Handbook is much too vague, suggesting only that some restrictions may be placed on the approval of future work while the current peer review is underway. [13]

The Federal Advisory Committee Act must be strictly enforced

The Federal Advisory Committee Act (FACA) imposes specific requirements on the approximately 1,000 federal advisory committees with about 65,000 members that span all government offices. These advisory committees are so influential that they have sometimes been called an additional arm of government. FACA requirements include public announcement of meetings and balanced perspectives among membership. Specifically, when an agency seeks to obtain such advice or recommendations, it must ensure the advisory committee is "in the public interest," *id.* App. II, § 9(2), is "fairly balanced in terms of points of view represented and the function to be performed," *id.* § 5(b)(2), and does not contain members with inappropriate special interests. *Id.*§ 5(b)(3).

Peer review that is conducted by formal or chartered Federal advisory committees is always subject to FACA provisions. Examples include the Science Advisory Board (SAB) and the Scientific Advisory Panel (SAP) that reviews pesticide assessments. [14]

In 2004, and again in 2008 the Government Accountability Office (GAO) issued its review of the independence and balance of advisory committees that are subject to FACA (GAO-08-611T). Its 2008 report confirmed its earlier findings that many agencies were ignoring, misapplying, or avoiding FACA requirements.[15] For example, in many cases members were being appointed as "representatives" to advocate for stakeholder positions, rather than as "special government employees" that are subject to FACA disclosure and conflict requirements. In many other instances, waivers were issued to members with obvious conflicts.

In its report, GAO recommended that in addition to the FACA requirement for balance, it is important that committees are perceived as balanced in order for their advice to be credible and effective. GAO provided specific recommendations to amend and improve FACA and FACA compliance, including: 1) obtaining nominations for committees from the public, 2) using clearly defined processes to obtain and review pertinent information on potential members regarding potential conflicts of interest and

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[12] EPA Science Policy Council Peer Review Handbook, 3rd Edition. 2006. Page 68. http://www.epa.gov/peerreview/

[13] EPA Science Policy Council Peer Review Handbook, 3rd Edition. 2006. Page 71. http://www.epa.gov/peerreview/

[14] EPA Science Policy Council Peer Review Handbook, 3rd Edition. 2006. Section 2-8. http://www.epa.gov/peerreview/

[15] GAO report. Federal Advisory Committee Act: Issues related to the independence and balance of advisory committees. GAO-08-611T. April, 2008. http://www.gao.gov/products/GAO-08-611T

points of view, and 3) prescreening prospective members using a structured interview.[16] Unfortunately, at the time of the report, GAO found that these recommendations had still not been fully addressed by many agencies.

All peer review should be subject to FACA provisions

It is a common practice for EPA to use a contractor to conduct an external peer review, rather than a more formal advisory committee. However, it is unclear whether an external peer review is subject to FACA provisions.

EPA's peer review process has three basic stages when an external peer review is undertaken: (1) EPA conducts its own internal peer review; (2) EPA or an EPA contractor oversees an external, independent peer review; and (3) EPA reviews the comments or report from the independent peer reviewers and determines what comments/recommendations it will adopt, after which the study is finalized. EPA typically conducts its own external peer review for smaller projects, where such reviews can involve as few as two outside reviewers and the review process may not involve a meeting between the reviewers—although, they are generally given each other's contact information—or generation of a final report by the reviewers themselves.

Use of the National Academies, task forces, and external contractors should not be exempted from FACA Compliance

When a Federal Agency seeks the advice of the National Academies, either on its own initiative or at the direction of Congress, the resulting contract between the agency and the Academies should require the application of the agency's (now presumably to be enhanced) disclosure, balance, and conflict-of-interest policies to the membership of the Academy panel whose advice is being sought. Congress has required that the National Academies determine that "committee membership is fairly balanced…." 5 U.S.C. App. §15(b)(1)(B).

Another potential problem is the creation of "task forces" reporting to the standing FACA committee that prepare the bulk of the review outside the confines of FACA and public view, after which FACA review and ratification of the findings becomes a mere formality. Agencies are barred from formally endorsing or acting on the recommendations of these task forces, but they often circulate them as if they carried some authority even before the full FACA committee has acted. New OSTP guidelines should bar this practice and make the work of such task forces subject to FACA as well.

Agencies should also be barred from turning to their own stable of in-house "task order" technical contractors to generate analyses supporting the case for whatever preferred alternative an agency is seeking, for example in the NEPA process or some

[16] GAO report. Federal Advisory Committee Act: Issues related to the independence and balance of advisory committees. GAO-08-611T. April, 2008. http://www.gao.gov/products/GAO-08-611T

other regulatory, licensing, or test and evaluation process. This happens too often, and much of this research is biased by design to favor a specific outcome.

Public interest service is not a conflict

True scientific experts in particular fields are often few in number and must choose between competing demands on their time. It is critically important therefore not to exclude those who have a public interest "knowledge bias", because of their public service in government or for non-profit public interest groups. In fact, service in the public interest is consistent with the mission of the federal agencies to serve the best interests of the public. For example, the Environmental Protection Agency is charged with protecting human health and the environment, not with protecting corporate profit interests. An individual with expertise and a public interest "knowledge bias" is essential to the functioning of an expert panel or committee and their background doing public interest or government work favors their participation. The public interest will not be served by the exclusion of such individuals.

How can one distinguish between a bias and a conflict? A public interest expert is employed because of his or her expertise and ability to serve the public interest effectively. In contrast, a conflicted expert is one whose opinion cannot be swayed by facts and evidence because it is tied to a financial benefit or competing interest. A conflicted expert has no place on any scientific or expert panel and should be barred in all cases. Below we suggest how such an expert may contribute to a deliberation as an invited specialist to address the committee, but not as a committee member.

In response to Principle (f) we suggest additional procedures to better assure the integrity of scientific and technical processes upon which Agencies rely

An example of additional procedures that are incorporated into an effective disclosure and conflict policy that is worthy of consideration is the policy that has been successfully implemented by the International Agency for Research on Cancer (IARC), the premiere chemical evaluation program of the World Health Organization. IARC strengthened and broadened its policy in 2004 after a barrage of highly public outrage over documented examples of industry-paid consultants serving as independent experts on IARC working groups.[17] IARC evaluations are used all over the world to classify chemical agents as to their cancer-causing potential, leading to regulations, liabilities, and compensation claims against manufacturers and downstream users. Recommendations

[17] Time to strengthen public confidence at IARC. Lancet. 2008 May 3;371(9623):1478.

Kleihues P; International Agency for Research on Cancer. Transparency at the International Agency for Research on Cancer (IARC). Lancet. 2003 Mar 1;361(9359):781.

Baines CJ; International Agency for Research on Cancer. Transparency at the International Agency for Research on Cancer (IARC). Lancet. 2003 Mar 1;361(9359):781-2.

International Agency for Research on Cancer. Transparency at IARC. Lancet. 2003 Jan 18;361(9353):189. PubMed PMID: 12547535.

below are based on the IARC policy that is now effectively enforced at all IARC Monographs meetings of scientific experts. [18]

Five recommended procedures to improve disclosure and conflict requirements for all government scientific or technical advisors, including contractors, peer reviewers and federal advisory committee members:

1. Specifically identify the relationships that might lead to conflicts of interest for a given committee; do not leave it to the candidate to decide whether a certain relationship crosses a conflict threshold and should be reported.
2. Consider the expectation of future work from an affected party to pose a financial conflict, particularly where the scientist has previously provided expert assistance in a controversy that is on-going.
3. More rigorously interpret existing FACA policy concerning the appointment of scientists where others could reasonably question whether conflicts of interest exist for a candidate.
4. Sometimes there is an expert in the field who is so knowledgeable and so prominent that the authority of the panel might be dismissed if that expert were not included. IARC acknowledges the tension between having the best experts and having impartial experts by inviting conflicted experts to address the expert committee as invited specialists, rather than by participating as a member of the committee.
5. Balance the roster of public speakers at committee meetings, and require that all speakers disclose their interests.

We strongly recommend that all government advisory committees adopt this aspect of the new IARC policy by developing a category of "invited specialist". This will allow industry employees or consultants to contribute expertise and provide critical knowledge where necessary, but not cloud the credibility of a committee as an objective adjudicator of the scientific evidence. The integrity of the scientific process can best be protected by enforcing rules and procedures that ensure public transparency and rigorous scientific or technical review by experts without financial or other nonmonetary relevant competing interests.

Conclusion

As a practical matter, regulatory agencies must protect the public and the environment from preventable risks. To do this in a systematic and scientifically supported manner, an agency collects the available data, and then fills in identified data gaps with adjustment factors, estimates, extrapolations from the observed range of data to the unobserved range, and with the use of mathematical models. All of these approaches

[18] Cogliano VJ, Baan RA, Straif K, Grosse Y, Secretan MB, El Ghissassi F, Kleihues P. The science and practice of carcinogen identification and evaluation. Environ Health Perspect. Online June 3, 2004

rely heavily on expert judgment, untested assumptions, and extrapolations. This leaves the system vulnerable to intentional manipulation through the corruption of information.

It is often the intent of the regulated industries to corrupt information regarding the harm from their products, as a mechanism of delaying or even denying regulatory action. The tobacco industry introduced the technique of manufactured doubt as a means to deny health impacts and delay regulation of its products: "*Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public. It is also a means of establishing controversy*." (1969 internal tobacco industry memo, stamped "confidential") Studies of documents from the tobacco industry archives have revealed evidence of concerted industry efforts to obscure the contribution of secondhand smoke and other environmental toxics to disease through the development of their own version of "good epidemiological practices" and "sound science", thereby infusing the scientific literature with "anti-data" intended to obfuscate scientific consensus.

The integrity of the scientific process can best be protected by enforcing rules and procedures that ensure public transparency and rigorous scientific or technical review by experts without financial or other nonmonetary relevant competing interests.

Controversies concerning the government's abilities to dispassionately evaluate scientific data and interpret the facts severely undermine the credibility of its policies. We are encouraged that President Obama, EPA Administrator Jackson, and others are giving this issue the serious attention that it deserves. Scientific integrity among federal agencies was under severe and sustained attack under the past Administration. We are enthusiastic to work with the Obama Administration to implement and enforce effective policies to protect the integrity and credibility of federal science and technical experts by ensuring that conflicts are fully disclosed and that experts with conflicts are not appointed to advisory committees.

Thank you for the opportunity to provide these comments. We look forward to working with the Obama Administration to bring scientific integrity back to the White House and federal agencies.

Respectfully,
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