October 9, 2003

Dr. Bruce Alberts
President, National Academy of Sciences
2101 Constitution Ave., NW
Washington, DC 20418

RE: **Project Title:** Committee to Assess the Health Implications of Perchlorate Ingestion

Project Identification Number: BEST-K-03-05-A

Responsible Staff Officer: Ellen Mantus

Dear Dr. Alberts:

These comments are being submitted on behalf of the Natural Resources Defense Council (NRDC), the Center for Science in the Public Interest (CSPI), and Environmental Working Group (EWG). Together, these organizations represent over one million Americans.

The NAS announced on its website September 22, 2003 the committee appointments for the National Academies of Science (NAS) *Committee to Assess the Health Implications of Perchlorate Ingestion*. [1] The deliberations of this committee have clear ramifications for the regulation and control of the widespread water contaminant, perchlorate, a topic of central concern to NRDC's members, and to Americans.

NRDC has carefully reviewed the NAS panel selection for this important topic. We write to strongly urge you to revise the proposed panel membership to eliminate any individuals with real or perceived conflicts of interest. We also urge you to more fairly balance this panel by adding scientists who better represent the public health community, including pediatricians, scientists with expertise in thyroid development, and public health professionals, in order to counterbalance the many members of the panel with industry ties. Nothing in this letter is intended to impugn the integrity or morals of any of the members of the committee. We are concerned, however, about the apparent lack of balance on the panel, and urge NAS to more carefully consider and redress all potential conflicts of interest of all panelists, so as to better comply with applicable law and NAS policy.

The Problem of Unbalanced Panels

The mission of the NAS is to provide credible and independent scientific analysis and advice to government. The NAS cannot accomplish this vital mission if its objectives and deliberations include those who have a financial stake in the outcome or strong bias. Committees whose members have

[1] Members of the National Academies of Science Committee to Assess the Health Implications of Perchlorate Ingestion available electronically at http://www4.nas.edu/webcr.nsf/CommitteeDisplay/BEST-K-03-05-A?OpenDocument

conflicts of interest or a strong bias toward the perspective of polluting industries undermine the cherished credibility of NAS advice. In the words of the NAS, "The reputation of the National Academies for objectivity, integrity, independence, and competence is one of its most valuable assets."[2] Conflicts of interest or significant bias or imbalance on the committee must be avoided.

Congress has therefore provided that the Academy must ensure that "no individual appointed to serve on [a] 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." 5 U.S.C. App. §15(b)(1)(A). Thus, panelists should be free of any personal or institutional financial interest in the issue under review, and should not serve where s/he personally could be economically benefited or harmed by the outcome of the review, or if his/her family member, employer, clients, or significant funder could be similarly affected. *See*, NAS, "Policy on Committee Composition and Balance and Conflicts of Interest," (2003) The only exception to this rule is available only if the Academy publicly determines that a conflict is unavoidable, and asks for public comment upon that determination. No such determination was made here, nor could a finding that a conflict is unavoidable be justified.

Even where scientists may not have a disqualifying conflict of interest, they may nevertheless harbor a strong industry bias. Congress has required that NAS determine that "committee membership is fairly balanced…." 5 U.S.C. App. §15(b)(1)(B). NAS has stated "it is essential that the work of committees…not be compromised by issues of bias and lack of objectivity. …Questions of lack of objectivity and bias ordinarily relate to views states or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group." NAS, "Policy on Committee Composition and Balance and Conflicts of Interest," at 4 (2003). Panelists who are or often have been employed by or consultants to industry, are active participants in associations that have taken a position on the issue at hand, and others with strong industry ties, may seek to downplay the toxic effects of an agent on human health and well-being, or to overemphasize or focus solely upon the benefits of the agent, and may not be open to discussion of other alternatives. This committee and all NAS committees must be composed in order to ensure that this perspective will not unduly influence panel decisions.

NAS Policies and Procedures for Selecting Committee Members

To ensure transparency, credibility, and the public's ability to adequately judge the biases of prospective panelists, NAS must disclose more complete information about each nominee's research funding and other potential sources of financial conflict of interest. This is an issue that has not been adequately addressed by the NAS's efforts to improve the panel formation process during the past two years, and the information provided on the NAS website on these committee members is inadequate to evaluate the committee's balance (as we have repeatedly brought to the attention of NAS/IOM officials[3]). Without more comprehensive information about funding and potential conflicts of interest, the public cannot fully evaluate whether or not committee members reflect a reasonable composition of perspectives.

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[2] NAS, "The National Academies' Study Process," 2003, available online at http://www4.nationalacademies.org/news.nsf/0a254cd9b53e0bc585256777004e74d3/3e6ad00d15066e8d85256ca70072dc52?OpenDocument.

[3] Letter to NAS co-signed by over a dozen representatives of public interest groups. May, 2000. http://www.cspinet.org/new/nas_letter.html
NAS response from E.W. Colglazier. October, 2000. http://www.cspinet.org/integrity/colglazier.html

Our review of the biographical information provided by the NAS on its website, and our own limited research (mainly from documents available on the internet) raises concerns about potential industry-bias of several committee members. The publicly available biographies of panelists provide no information indicating any potential conflicts of interest or bias, but are insufficiently detailed to warrant a final determination in this regard. While we do not impugn the integrity or qualifications of any of the proposed panel members, we are deeply concerned about balance and potential bias among some members.

The panel chair has strong industry ties

Dr. Gilbert S. Omenn, the panel chair, is a paid member of the Board of Directors for Rohm and Haas (since 1987)[4], and for Amgen Inc.[5] Rohm and Haas has an estimated 30-50% of the U.S. market share for ion exchange resin technology used for water purification.[6] The company's $200-million/year ion exchange resins sales target perchlorate removal, among other pollutants.[7] It appears likely to us that Dr. Omenn would own a significant number of shares of stock in Rohm and Haas. Presumably these stock options would appreciate significantly if sales of the ion exchange resin technology were to increase in response to perchlorate contamination. Thus, Dr. Omenn could be construed as having a direct financial stake in the outcome of the deliberations of this NAS panel.

In addition to his ties with Rohm and Haas, Dr. Omenn has testified on behalf of Proctor and Gamble in FDA hearings. At a minimum, these ties and relationships with chemical manufacturers suggest bias towards an industry perspective. While the bias of any individual panel member theoretically can be balanced by biases of other panelists, it is inappropriate for the Academy to select a chair about whom significant questions of bias may fairly be raised. The chair has unique power on NAS panels and unique influence over the final report. The chair steers the entire process, frames issues to be debated, can effectively cut off certain lines of inquiry or discussion, oversees and can assign drafting of the report, and in general has far more substantial influence on the final report than any other individual panel member. For this reason, a committee chair should not harbor any significant bias. Selection of a chair with bias may undermine the credibility of the final report. As NAS has stated, "if a report is to be not only sound but also effective as measured by its acceptance in quarters where it should be influential, the report must be, *and must be perceived to be*, not only highly competent but also the result of a process that is fairly balanced in terms of the knowledge, experience, and perspectives utilized to produce it and free of any significant conflict of interest." NAS, "Policy on Committee Composition and Balance and Conflicts of Interest," at 1 (2003).

It is clear that the perchlorate issue is highly controversial and deserves a fair and impartial scientific review. This is precisely why EPA asked NAS to conduct the review. NRDC respectfully suggests that fairly or unfairly, NAS will do itself and its final report on perchlorate a significant disservice by selecting a committee chair with significant industry ties and a potential direct financial conflict of interest. This

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[4] Rohm and Haas Board of Directors website. http://www.rohmhaas.com/governance/board_comp.html

[5] International Life Sciences Summit: 2003 http://www.connectionscorp.com/cgi-bin/biotech/2003e.pl?Subject=agenda

[6] Caruana, CM. 2001. Suppliers prime pumps in niche markets. WaterGenius.com. Jan 3, 2001. http://www.watergenius.com/articledetail.asp?articleid=722

[7] Mullin, R. 2002. Basic materials keep a technology edge. CE&N, 80(46): 44-48. http://pubs.acs.org/cen/coverstory/8046/8046water1.html

selection, if maintained, will set up the inevitable outcome that many already-skeptical members of the public will discount or even attack the final report, irrespective of its validity and objectivity, based upon the committee chair. We therefore respectfully urge the Academy to select a different chair that cannot be accused of having any bias on the perchlorate issue.

Panel members with ties to industry

Gilbert S. Omenn	Omenn is a long-time member of the Board of Directors for Rohm and Haas, which have an estimated 30-50% of the U.S. market share for ion exchange resin technology.[8] The company's $200-million/year ion exchange resins sales target perchlorate removal from water, among other pollutants.[9] Testified on behalf of Procter and Gamble at FDA advisory committee meeting on olestra (6-16-98). Served as chairman of Procter and Gamble's Surveillance Advisory Committee (Omenn letter to FDA, October 27, 1998)[10]
Richard Bull	In 1994 Bull worked as a senior scientist for Pacific Northwest Laboratories, managed by Battelle,[11] a "non-profit entity" holding major contracts with the US Departments of Defense (DoD) and Energy (DoE). Battelle has already begun to sponsor conferences on Perchlorate remediation[12]. Since 1984, Dr. Bull has also been a professor at Washington State University (currently half-time). At the same time he is also a principle and President of MoBull Consulting. At WSU, Bull's major research program (still ongoing) includes the DoE Low Dose Radiation Research Project (funded exclusively by DoE - Battelle's biggest client[13]). MoBull Consulting's clients include the US Department of Defense and US Department of Energy.[14] According to an EPA biosketch for Bull, dated January 2003, his research is supported by the US Air Force, the American Water Works Association (representing water utilities), the US Department of Defense, and the US Department of Energy. The work for the DoD and DoE is "focused largely upon the carcinogenic activity of trichloroethylene and other chlorinated solvents."[15]

[8] Caruana, CM. 2001. Suppliers prime pumps in niche markets. WaterGenius.com. Jan 3, 2001. http://www.watergenius.com/articledetail.asp?articleid=722

[9] Mullin, R. 2002. Basic materials keep a technology edge. CE&N, 80(46): 44-48. http://pubs.acs.org/cen/coverstory/8046/8046water1.html

[10] See website of the Center for Science in the Public Interest (CSPI), Integrity in Science Project. http://www.cspinet.org/cgi-bin/integrity.cgi

[11] http://www.battelle.org

[12] http://www.battelle.org/environment/er/conferences/chlorcon/default.stm

[13] Wash State Univ DoE Low Dose Radiation Research Program. http://lowdose.tricity.wsu.edu/

[14] Richard Bull biographical sketch for the EPA, January 22, 2003. http://www.epa.gov/sab/pdf/strpfinalbios.pdf

[15] http://www.epa.gov/sab/pdf/strpfinalbios.pdf

	Battelle donates to the WSU School of Pharmacy's endowment campaign.[16]
James Lamb	Lamb is senior vice president at Blasland, Bouck &Lee, Inc (BBL), a multi-services environmental engineering firm.[17] A partial client list includes EXXON, Aetna, Allied Signal, Amoco, AT&T, Bristol-Myers Squibb, Chevron, Chrysler, Coca-Cola, Eastman Kodak, DuPont, Enron, Ford, General Electric, GM, Lockheed Martin, Mobil, Rockwell International, many oil, gas, and utility companies, municipalities, and law firms.[18] In addition, Blasland, Bouck & Lee, Inc is listed as a DoD contractor with contracts exceeding $25,000 in FY2001.[19] On their website, Blasland, Bouck & Lee list their litigation support services.[20] This includes providing experts for chemical manufacturers, energy companies and utilities, and, most relevant, defense and aerospace clients. Litigation experience includes CERCLA/RCRA, and toxic tort and product liability claims, according to the same website. BBL states, "BBL has been successfully supporting our clients in regulatory and legal arenas alike, with results that maximize protection of the environment while minimizing client liability."[21] (underlining added) Their website claims to provide litigation "[a]ssistance in defense of Natural Resource Damage (NRD) cases".[22] Lamb was paid by the industry to appear on 20/20 to talk about bisphenol-A (BPA). (ABC-TV, 20/20, 4/19/99)[23]. In 2001, Lamb presented comments to an EPA FIFRA Scientific Advisory Panel,[24] on behalf of the EBDU/ETU (fungicides) industry task force, composed of BASF Corporation, Rhom and Haas, and the Du Pont Company.[25]
R. Michael McClain	McClain was employed as a researcher with Hoffmann-LaRoche, Inc for over two decades. He is currently an adjunct professor in the Environmental and Occupational Health Sciences Institute (EOHSI) at the University of Medicine and Dentistry of New Jersey. The EOHSI 2002 annual report indicates that funding sources included Exxon Mobil, American Chemistry Council, the Electric Power

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[16] The Endowments of Washington State University, June 30, 2002. Endowments between $100,000 and $999,999. http://catalyst.wsu.edu/pdfs/Endowments.pdf

[17] http://www.bbl-inc.com/bblinc/pressroom.cfm

[18] http://www.cwac.net/nrapreport1c.html

[19] http://www.dod.mil/dodgc/defense_ethics/resource_library/contractors01.pdf

[20] BBBL's litigation experience. http://www.bbl-inc.com/bblinc/services-litsupport.cfm

[21] http://www.cwac.net/nrapreport1c.html

[22] BBL's litigation support. http://www.bbl-inc.com/bblinc/services-litsupport.cfm

[23] See website of the Center for Science in the Public Interest (CSPI), Integrity in Science Project. http://www.cspinet.org/cgi-bin/integrity.cgi

[24] EPA FIFRA SAP meeting. Report issued November, 2001 http://www.epa.gov/scipoly/sap/2001/september7/september2001finalsapreport.pdf

[25] http://pmep.cce.cornell.edu/profiles/fung-nemat/aceticacid-etridiazole/edbc/ebdc-sr-2-92-rer.html

	Research Institute (representing the power companies), and the US Departments of Agriculture, Army, Defense (DoD), and Energy (DoE).[26]

Scientific expertise of panel is weak in critical areas

The review of perchlorate toxicology is rather unlike many chemical reviews in that the mode of action is well defined, and even the precise mechanism of toxicity is fairly well understood. Of course, there may be other mechanisms of toxicity about which little or no information is available. Nonetheless, a review of the toxicity of perchlorate will necessitate researchers who are well versed in the role of thyroid hormones during fetal and neonatal development, since the thyroid is the most well-understood and generally accepted target organ. We thus strongly suggest that the NAS appoint a substantial number of researchers that work on fetal and perinatal hypothyroidism, and have practical expertise in neonatal and pre-term infant endocrinology and developmental thyroid physiology.

We respectfully provide several names, below, for the NAS to consider as members of the committee on perchlorate toxicity. The researchers below have all published in the scientific literature in relevant areas, and would contribute considerable expertise in this area.

Gregory Brent, UCLA	Univ California Los Angeles Molecular, Cellular & Integrative Physiology Tel: 310-268-3735 gbrent@ucla.edu	Gene regulation by thyroid hormone
James E. Haddow[27]	Foundation for Blood Research P.O. Box 190, 69 US Route One Scarborough, ME 04070-0190 Phone: (207) 883-4131 Fax: (207) 883-1527	Hypothyroidism and development
Robert Z. Klein	Dartmouth Medical School, Hanover, N.H.	Hypothyroidism and development
Robert C. Smallridge	Mayo Medical School Division of Endocrinology, Jacksonville, Florida 32224, USA. smallridge.robert@mayo.edu	Hypothyroidism in pregnancy
Joanne F. Rovet	The University of Toronto Brain and Behaviour Program, The Hospital for Sick Children, Departments of Pediatrics and Psychology, Toronto, Canada joanne.rovet@sickkids.ca	Congenital hypothyroidism

Summary

Given the widespread impact of the conclusions of this committee on the regulation of perchlorate pollution, we request the following changes to the panel composition, to better ensure a credible process and a defensible outcome:

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[26] EOHSI Annual Report, 200-2001. http://www.eohsi.rutgers.edu/pdf/AnRep-0001.pdf

[27] James E. Haddow information: http://www.fbr.org/founders.html

- We strongly encourage NAS to add experts in neonatal and pre-term infant endocrinology and thyroid physiology
- We strongly encourage NAS to add scientific experts as well as others who hold a precautionary perspective for the protection of public health
- We strongly encourage NAS to remove individuals with conflicts of interest, i.e. those whose clients, employers, or major funders stand to gain from or be harmed by the outcome of the NAS deliberation
- We encourage NAS to remove other individuals with a strong industry bias in order to ensure a balance of perspectives on this committee
- We strongly urge NAS to more carefully consider and redress all potential conflicts of interest of all panelists, so as to better comply with applicable law and NAS policy

Respectfully Submitted,

Jennifer Sass Natural Resources Defense Council Washington, DC	Richard Wiles Environmental Working Group Washington, DC
Michael Jacobson Center for Science in the Public Interest Washington, DC	

cc: Dr. E. William Colglazier, Executive Officer
Dr. Warren R. Muir, Executive Director, Division on Earth and Life Studies, NRC
Dr. Ellen Mantus, NAS Responsible Staff Officer