



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460**

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

December 22, 2011

MEMORANDUM

SUBJECT: Formation of Science Advisory Board (SAB) Panel for Review of EPA's draft Toxicological Review of Libby Amphibole Asbestos

FROM: Diana Wong, Ph. D. /signed/
Designated Federal Officer (DFO)
Science Advisory Board Staff Office

THRU: Wanda Bright /signed/
SAB Ethics Officer
Science Advisory Board Staff Office

TO: Vanessa Vu, Ph.D.
Director
Science Advisory Board Staff Office

The EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD) has requested the SAB to review EPA's Draft Toxicological Review of Libby Amphibole Asbestos in Support of Summary Information on the Integrated Risk Information System (IRIS).

This memorandum addresses the set of determinations that were necessary for forming the SAB Libby Amphibole Asbestos Review Panel, including:

- (A) The type of review body that will be used to conduct the review, and the nature of the review;
- (B) The list of candidates to be considered for the panel;

- (C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
- (D) How regulations concerning “appearance of a lack of impartiality,” pursuant to 5 C.F.R. § 2635.502, apply to members of the Panel; and
- (E) The selection of Panel members.

DETERMINATIONS:

- (A) The type of review body that will be used to conduct the review, and the nature of this review.

An *ad hoc* panel, composed of subject matter experts, will be formed under the auspices of the SAB to provide advice and recommendations to EPA through the chartered SAB on the scientific and technical soundness of EPA’s draft Toxicological Review of Libby Amphibole Asbestos.

- (B) The list of candidates to be considered for the Panel.

The SAB Staff Office sought in a *Federal Register* Notice (Volume 76, Number 103, Pages 30939-30940) published on May 27, 2011 public nominations of nationally recognized and qualified experts in one or more of the following areas, particularly with respect to asbestos: mineralogy, industrial hygiene, air sampling and detection methods, exposure assessment, occupational medicine, pulmonary medicine, radiology on asbestos related disease, pulmonary pathology, epidemiology, toxicology, statistical modeling, risk assessment, and uncertainty analysis.

The SAB Staff Office identified 62 candidates based on their relevant expertise and willingness to serve. On August 9, 2011, the SAB Staff Office posted a notice on the SAB Web site inviting public comments by August 31, 2011 on the List of Candidates for the Panel. The SAB Staff Office received 7 comments on the candidate list. The commenters and their affiliations are listed below:

Gary Paul	American Association for Justice
David Landin	Self
Brooke Mossman	University of Vermont College of Medicine
Marianne Roose	City-County Board of Health for Lincoln County
Salvatore LaRosa	NYCO Minerals, Inc.
Jennifer Sass	Natural Resources Defense Council
William Walsh	Self

(C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed.

(a) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: The principal interested and potentially affected parties for this topic may include: (1) federal, state, and local government agencies involved in decisions relating to Libby Amphibole Asbestos; (2) private or public organizations or individuals that may be affected by potential decisions on the basis of EPA's assessment concerning Libby Amphibole Asbestos.

(b) Conflict of interest considerations: For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. § 208 provision states that: "An employee is prohibited from participating *personally or substantially* in an official capacity in any *particular matter* in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a *financial interest*, if the particular matter will have a direct and predictable effect on that interest [emphasis added]." For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing, the issue does not involve a formal conflict of interest; however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

(i) Does the general charge to the SAB Libby Amphibole Asbestos Review involve a particular matter? A "particular matter" refers to matters that "...will involve deliberation, decision, or action that is focused upon the interest of specific people, or a discrete and identifiable class of people." It does not refer to "...consideration or adoption of broad policy options directed to the interests of a large and diverse group of people." [5 C.F.R. § 2640.103 (a)(1)]. A particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties [5 C.F.R. § 2640.102(m)]. Additionally, 5CFR 2637.102(a)(7) defines a particular matter involving specific parties to mean any judicial or other proceeding, application, request for ruling or other determination, contract, claim, controversy, investigation, change, accusation, arrest or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest.

In providing advice for the draft IRIS Toxicological Review of Libby Amphibole Asbestos, the Review Panel's activity will qualify as a *particular matter involving specific parties* because the resulting advice will be part of a deliberation, and under certain circumstances the advice given might affect the legal rights of the specific party named, such as parties involved in the mining, manufacturing, use, and disposal of Libby Amphibole Asbestos and products containing Libby Amphibole Asbestos.

(ii) Will there be personal and substantial participation on the part of the Panel members? Participating personally means direct participation in this review.

Participating substantially refers to involvement that is of significance to the matter under consideration. [5 C.F.R. § 2640.103(a)(2)].

Because this does constitute a particular matter, the chain of elements leading to a determination that a conflict of interest exists and there is a need to pursue the additional elements in determining the existence of a conflict of interest (i.e., Personal and Substantial Participation; Direct and Predictable Effect on Members Financial Interest).

(iii) Will there be a direct and predictable effect on a Panel member's financial interest? A direct effect on a participant's financial interest exists if "...a close causal link exists between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. ... A particular matter does not have a direct effect ... if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect." [5 C.F.R. § 2640.103(a)(i)] A predictable effect exists if, "...there is an actual, as opposed to speculative, possibility that the matter will affect the financial interest." [[5 C.F.R. § 2640.103(a)(ii)]

Candidates for the Panel were evaluated against the requirements of 5 C.F.R. § 2640.101(a), using each candidate's confidential financial disclosure form (EPA Form 3110-48), to determine whether the work of the Panel will have a direct and predictable effect on his or her financial interests.

(D) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502, apply to members of the Panel

The Code of Federal Regulations at 5 C.F.R. § 2635.502(a) states that: "Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and has received authorization from the agency designee." Further, § 2635.502(a)(2) states that, "An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."

Candidates for the Panel were evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a lack of impartiality. Information used in this evaluation included: responses to the following questions (see below), and to EPA 3110-48 confidential financial disclosure forms, and public comment.

1. Have you served on any advisory panels, committees or subcommittees that have addressed the health effects of asbestos? If so, please identify those activities.
2. Have you made any public statements (written or oral), including expert testimony (public hearing, litigation) concerning the health effects of Libby Amphibole Asbestos that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.
3. Have you had any previous involvement with the authors of EPA's draft Toxicological Review of Libby Amphibole Asbestos including collaboration, previous peer review functions?
If so, please identify and describe that involvement.
4. Have you received compensation for any work related to asbestos? If yes, please identify the sources of the funding.
5. Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?

(E) The selection of Panel members

The SAB Staff Office Director makes the final decision about who serves on the Panel, based on all relevant information, including a review of candidate's confidential financial disclosure form (EPA Form 3110-48), the responses to the five questions above, public comments, and information independently gathered by SAB Staff.

For the SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual committee member include: (a) scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, for the committee as a whole, (f) diversity of scientific expertise, and viewpoints.

On the basis of the above-specified criteria, the members of the SAB Libby Amphibole Asbestos Review Panel are as follows:

Dr. Agnes Kane, Brown University (RI), **CHAIR**
Dr. John R. Balmes, University of California (CA)
Dr. James Bonner, North Carolina State University (NC)
Dr. Jeffrey Everitt, GlaxoSmithKline Pharmaceuticals (NC)
Dr. Scott Ferson, Applied Biomathematics (NY)

Dr. George Guthrie, US Department of Energy (PA)
Mr. John Harris, LabCor Portland (OR)
Dr. Tom Hei, Columbia University Medical Center (NY)
Dr. David Kriebel, University of Massachusetts Lowell (MA)
Dr. Morton Lippmann, New York University School of Medicine (NY)
Dr. Ernest E McConnell, ToxPath, Inc.(NC)
Dr. John Neuberger, University of Kansas (KS)
Dr. Lee Newman, University of Colorado (CO)
Dr. Michael Pennell, Ohio State University (OH)
Dr. Julian Peto, London School of Hygiene and Tropical Medicine (UK)
Dr. Carrie Redlich, Yale University (CT)
Dr. Andrew G. Salmon, California Environmental Protection Agency (CA)
Dr. Elizabeth A. (Lianne) Sheppard, University of Washington (WA)
Dr. Randal Southard, University of California at Davis (CA)
Dr Katherine Walker, Health Effects Institute (MA)
Dr. James Webber, New York State Department of Health (NY)
Dr. Susan Woskie, University of Massachusetts Lowell (MA)

Concurred,

/signed/

Vanessa Vu, Ph.D.
Director
Science Advisory Board Staff Office

December 22, 2011
Date