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

June 19, 2008

**OFFICE OF THE ADMINISTRATOR**
**SCIENCE ADVISORY BOARD**

# Memorandum

**SUBJECT:** Formation of Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Program Advisory Panel

**FROM:** Fred Butterfield ***/Signed/***
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**TO:** Vanessa Vu, Ph.D.
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This memorandum documents the set of determinations that were necessary for forming the EPA Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Program Advisory Panel (Panel), including:

(A) The type of advisory body that will be used to conduct the advisory activity and the types of expertise needed to address the general charge;

(B) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic concerning which advice is to be given;

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

(D) How individuals were selected for the Panel.

**BACKGROUND:**

The SAB was established by 42 U.S.C. § 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App.

In 1998, the Congress directed the Environmental Protection Agency to establish as many as five university-based PM research centers as part of the expanded Office of Research and Development (ORD) PM research program. The first PM research centers were funded from 1999 to 2005 with a total program budget of $8 million annually (see the following URL:

http://es.epa.gov/ncer/science/pm/centers.html). In the original Request for Applications (RFA), prospective centers were asked to propose an integrated research program on the health effects of PM, including exposure, dosimetry, toxicology and epidemiology. ORD's PM Research Centers program was initially shaped by recommendations from the National Research Council.

In 2002, ORD requested that the Science Advisory Board conduct an interim review of EPA's PM research centers program, the report from which is found at the following URL: http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/$File/ec02008.pdf. This review was instrumental in providing additional guidance to ORD for the second phase of the program (2005–2010). In 2004, ORD held a second competition for the PM Research Centers program. This RFA asked respondents to address the central theme of "linking health effects to PM sources and components," and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages. From this RFA, five current centers are funded for 2005–2010 with the total program budget at $40 million (see: http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19).

EPA's National Center for Environmental Research (NCER), within ORD, requested that the SAB Staff Office form an expert panel to comment on the Agency's current PM research centers program and to advise EPA concerning the possible structures and strategic direction for the program as ORD contemplates funding a third round of air pollution research centers into the future, *i.e.*, from 2010 to 2015. Therefore, in response to this request from NCER, the SAB Staff Office published a notice in the *Federal Register* (73 FR 5838) on January 31, 2008, which announced the formation of an SAB *ad hoc* panel for this advisory activity and requested public nominations of qualified experts to serve on this panel.

**DETERMINATIONS:**

(A) The type of advisory body that will be used to conduct the advisory activity and the types of expertise needed to address the general charge.

This advisory activity will be conducted by an SAB *ad hoc* panel, which will be known as the SAB PM Research Centers Program Advisory Panel.

Per the above-cited *Federal Register* notice, the SAB Staff Office requested public nominations for nationally- and internationally-recognized, non-EPA scientists with extensive research program management expertise and experience related to airborne pollution and the application of research results in reducing air pollution in protection human health and the environment. Furthermore, such experts should also have had direct research experience related to airborne particulate matter.

(B) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic concerning which advice is to be given.

(a) Identification of parties who are potentially interested in or may be affected by the topic concerning which advice is to be given: The principal interested and affected parties for this topic are: (1) EPA; (2) State, regional and local air program (or air pollution control) agencies, and State regulatory officials; and (3) the air pollution research community.

(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 and 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 statue 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 PM Research Centers Program Advisory Panel involve a particular matter? A "particular matter" refers to matters that "…will involve deliberation, decision, or action that is focused upon the interests 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)].

The SAB PM Research Centers Program Advisory Panel's activity in providing active concerning the Agency's PM research centers program will qualify as a *particular matter of general applicability* because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. That group of people constitutes those who are associated or involved with the potentially interested or affected parties, as identified in Section (C)(a) above.

(ii) Will there be personal and substantial participation on the part of Panel members? Participating personally means direct participation in this advisory activity. Participating substantially refers to involvement that is of significance to the matter under consideration. [5 C.F.R. § 2640.103(a)(2)]. For this advisory activity, the SAB Staff Office has determined that *SAB PM Research Centers Program Advisory Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations that is expected to directly influence whether ORD will fund a third round of air pollution research centers beginning as early as 2010. *Therefore, participation in this advisory activity will also be substantial.*

(iii) Will there be a direct and predictable effect on SAB PM Research Centers Program Advisory Panel members' 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 a speculative, possibility that the matter will affect the financial interest." [5 C.F.R. § 2640.103(a)(ii)]

(C) 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 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 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."

To ascertain whether there is any appearance of a lack of impartiality, the following five questions were posed to each prospective member of the SAB PM Research Centers Program Advisory Panel with respect to the forthcoming charge for the Panel:

(a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the Panel or any reason that your impartiality in the matter might be questioned?

(b) Have you had any previous involvement — including interactions with U.S. Environmental Protection Agency staff, authorship, collaboration with authors, or previous peer review functions — including with respect to:

(i) any of EPA's university-based PM research centers, as part of the Agency's Office of Research and Development (ORD) PM research program, either during the first (1999–2005) or second (2005–2010) round of solicitations and research grants; or

(ii) EPA's National Center for Environmental Research (NCER), within ORD?

If so, please identify and describe that involvement.

(c) Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so please identify those activities.

(d) Have you made any public statements (written or oral) on these issues? If so, please identify those statements.

(e) Have you made any public statements that would indicate to an observer that you have taken a position on the issues under consideration? If so, please identify those statements.

(D) How individuals were selected for the Panel.

As previously noted, on January 31, 2008, the SAB Staff Office announced in the *Federal Register* (73 FR 5838) the formation of this *ad hoc* SAB Panel and requested appropriately-qualified nominees for this expert panel. In April 2008, the SAB Staff Office published the

"Short List" of candidates for this Panel on its public Web site at: http://www.epa.gov/sab. The SAB Staff Office did not receive any comments on this "Short List" from members of the public.

The SAB Staff Office Director makes the final decision about who serves on the SAB PM Research Centers Program Advisory Panel, based on all relevant information. This includes a review of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of an appearance of a lack of impartiality. 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 for Panel membership 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; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, *etc.*

*On the basis of the above-specified criteria, the following eleven (11) experts were selected as members of SAB PM Research Centers Program Advisory Panel:*

- **Dr. David T. Allen**, **Chair**, University of Texas at Austin (TX)
- **Mr. Bart Croes**, California Air Resources Board (CA
- **Dr. Bruce Fowler**, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (GA)
- **Dr. Terry Gordon,** New York University School of Medicine (NY)
- **Mr. Daniel Greenbaum**, Health Effects Institute (MA)
- **Dr. Steven Kleeberger**, National Institute of Environmental Health Sciences (NC)
- **Dr. George Lambert [M.D.]**, Robert Wood Johnson Medical School/University of Medicine and Dentistry of New Jersey (NJ)
- **Dr. Fred Miller**, independent consultant (NC)
- **Dr. Peter Scheff**, University of Illinois at Chicago (IL)
- **Dr. Bryan Shaw,** Texas Commission on Environmental Quality (TX)
- **Dr. Barbara Zielinska**, Desert Research Institute (NV)

Concurred:

/Signed/ July 3, 2008

Vanessa T. Vu, Ph.D. Date
Staff Director
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