



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
EPA SCIENCE ADVISORY BOARD

November 14, 2006

MEMORANDUM

SUBJECT: Science Advisory Board (SAB) Ethylene Oxide Carcinogenicity Review Panel–
Documentation for Panel Formation Determinations

FROM: Sue Shallal, Ph.D., Designated Federal Officer
Science Advisory Board Staff Office (1400F)

TO: Vanessa Vu, Ph.D., Director
Science Advisory Board Staff Office (1400F)

THRU: Daniel Fort, Ethics and FACA Officer
Science Advisory Board Staff Office (1400F)

This memorandum documents the steps taken in regard to forming the SAB *Ad Hoc* Panel to conduct a peer review of EPA's Draft Assessment of the Carcinogenicity of Ethylene Oxide. It provides background information on this SAB review activity and addresses:

- The expertise needed to address the charge;
- Conflict of Interest Considerations and Appearance of Lack of Impartiality;
- How individuals were selected for the Panel.

EPA's Office of Research and Development (ORD) requested that the Science Advisory Board (SAB) peer review its external draft assessment entitled, "Evaluation of the Carcinogenicity of Ethylene Oxide" (August 2006). EPA last published a human health effects assessment of the potential carcinogenicity of ethylene oxide (EtO) in 1985. EPA's Office of Research and Development (ORD) has now completed a review of the more recent database on the carcinogenicity of EtO, pertinent data from the 1985 assessment, and several reviews and assessments issued by other organizations. This draft assessment evaluates the potential cancer risk from inhalation exposure to EtO.

1) Charge to the SAB: The SAB is being asked to comment on the scientific soundness of EPA's "Evaluation of the Carcinogenicity of Ethylene Oxide". Specific charge questions are provided in Attachment 1.

2) Panel Formation: The peer review will be conducted by a SAB *Ad Hoc* Review Panel. This Panel, known as the Ethylene Oxide (EtO) Review Panel, will be composed of SAB members and invited outside experts. A federal register notice was published on March 1, 2006 (widecast) requesting nominations of individuals with the following expertise, especially with respect to the potential human carcinogenic effects of ethylene oxide: Respiratory/pulmonary physiology and exposure; epidemiology; toxicology, including genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; risk assessment and statistical evaluation of epidemiological and toxicological data (see Attachment 2). On the basis of the candidates' credentials and willingness to serve on the panel, the SAB Staff Office identified thirty one (31) nominees for the "short list" of candidates.

On May 26, 2006, the SAB Staff Office posted a notice on the SAB Web site inviting public comments on the prospective candidates being considered for the Panel. (Attachment 3) In particular, the notice on the Web site stated that the Staff Office would welcome any information, analysis or documentation that the SAB Staff Office should consider in evaluating the candidates on the "Short List". The notice also asked that any advice, observations or comments which would be helpful in selecting the final candidates be provided to the SAB Staff Office no later than June 16, 2006. The SAB Staff Office received four submissions with comments on "short list" candidates for the EtO Review Panel. (Attachment 4)

3) Conflict of Interest and Appearance of a Lack of Impartiality Considerations:

For financial Conflict of Interest (COI) issues, 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 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 a lack of impartiality guidelines” may still apply and need to be considered.

Personal and Substantial Participation:

Participating personally means participating directly. Participating substantially refers to involvement that is of significance to the matter. [5C.F.R. 2640.103(a)(2)]. For this review, panel members will be participating personally in the matter through attendance at meetings, teleconferences and other means. SAB Review Panel members will provide advice that might influence the Agency’s carcinogenicity assessment of EtO.

Direct and Predictable Effect:

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)].

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)].

The work of this SAB Advisory Panel qualifies as a particular matter 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 and does involve specific parties. That group of people is the set of people that are employed or have significant financial interests in organizations that could be considered part of the life-cycle of the chemical (Ethylene Oxide) to be considered by the panel (including, but not limited to, manufacture, use, treatment and disposal).

Additionally, 5 CFR 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.

The number of manufacturers or users of Ethylene Oxide are limited in number and represent a discrete and identifiable class of people or specific parties. Therefore, the

work to be done by the Panel meets the criteria for a particular matter involving specific parties.

4) Appearance of a Lack of Impartiality Considerations

The Code of Federal Regulations [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 received authorization from the agency designee.”

Further, 5 C.F.R. 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.”

As noted above, the subject of this SAB review can be considered as a particular matter involving specific parties. Each potential advisory panel member was evaluated against the 5 C.F.R. 2635.502(a)(2) general requirements for considering an appearance of a lack of impartiality. Information used in this evaluation has come from information provided by potential advisory panel members (including, but not limited to, EPA 3110-48 confidential financial disclosure forms) and public comment.

For prospective advisory panel members who hold grants, cooperative agreements or contracts or are involved with organizations that can be considered specific parties, the “reasonable person” criterion is met in the following manner:

- i) Those who are or have previously been employed by the regulated community were considered to meet this criterion.
- ii) Those who have a pending grant, cooperative agreement, or contract whose funds could be directly received from specific parties as part of a prospective advisory panel member’s salary for efforts to research the health and ecological effects of EtO were considered to meet the criterion.

To evaluate any potentially appearance of a lack of impartiality, the following five (5) questions were posed to prospective advisory panel members:

- 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 with the issue(s) or document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify those activities.
- c) Have you served on previous advisory panels or committees that have addressed the topic under consideration? If so, please identify those activities.
- d) Have you made any public statements (written or oral) on the issue? 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 issue under consideration? If so, please identify those statements.

5) Conflict of Interest and Appearance of a Lack of Impartiality Determination for Review Panel Members

Prospective advisory panel members were required to submit a confidential financial disclosure form (EPA Form 3110-48, “Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency). As a result of a review of these forms, the responses to the five questions above, along with other information provided by each prospective advisory panel member and public commenters, the Deputy Ethics Official of the Science Advisory Board, in consultation with the SAB Ethics and FACA Policy Officer, has determined that there are no conflict of interest or appearance of a lack of impartiality for the members of this panel.

6) How individuals were selected for the final Panel: The SAB Staff Office Director makes the decision about who serves on this Review Panel during the “Panel Selection” phase. Members of the Panel were selected from the “short list” candidates. Selection criteria included: scientific credentials and expertise; willingness to serve on the Panel, and availability to meet during the proposed time period; absence of conflict of interest and absence lack of appearance of impartiality issues, and balance of relevant expertise and diversity of scientific viewpoints. Based on the above specified criteria, the membership of the EtO Review Panel includes the following experts:

1. Dr. Stephen Roberts, University of Florida (Chair)
2. Dr. Steven Belinsky, University of New Mexico
3. Dr. Timothy Buckley, Ohio State University
4. Dr. Norman Drinkwater, University of Wisconsin
5. Dr. Montserrat Fuentes, North Carolina State University
6. Dr. Dale Hattis, Clark University
7. Dr. Steven Heeringa, University of Michigan
8. Dr. James Kehrer, Washington State University
9. Dr. James Klaunig, Indiana University
10. Dr. Ulrike Luderer, University of California-Irvine
11. Dr. Mark Miller, CalEPA
12. Dr. Maria Morandi, University of Texas
13. Dr. A. Robert Schnatter, ExxonMobil Biomedical Sciences
14. Dr. Ann Sweeney, Texas A&M University

- 15. Dr. James Swenberg, University of North Carolina (Chapel Hill)
- 16. Dr. Vernon Walker, Lovelace Respiratory Research Institute

Concurred,

Date

Vanessa Vu, Ph.D., Director
EPA Science Advisory Board Staff Office (1400F)

ATTACHMENTS

Attachment 1	Charge Questions
Attachment 2	Federal Register Notice- Request for nomination of experts
Attachment 3	Invitation for comments on the “Short List” candidates
Attachment 4	List of public commenters on the “Short List” candidates

ATTACHMENT 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
National Center for Environmental Assessment
Washington, DC 20460

October 27, 2006

NCEA Washington Office (8623D)

MEMORANDUM

SUBJECT: Request for SAB review of the Draft Ethylene Oxide (EtO) Carcinogenicity Assessment

David A. Bussard

FROM: David A. Bussard, Director
National Center for Environmental Assessment-Washington (8623D)
Office of Research and Development

TO: Sue Shallal, Ph.D.
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400F)

This is to request a review by the Science Advisory Board of the draft document entitled "Evaluation of the Carcinogenicity of Ethylene Oxide". This document is an assessment of the carcinogenicity of ethylene oxide (EtO). The assessment was prepared by the National Center for Environmental Assessment (NCEA), which is the health risk assessment program in the Office of Research and Development. The document has been made available for public comment on the Agency's NCEA web site at the following URL:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=157664>. The assessment broadly supports activities authorized in the 1990 Clean Air Act and is of particular interest to EPA's Office of Air and Radiation. However, the assessment should also be applicable to the needs of all program Offices and Regions in evaluating the carcinogenicity of EtO.

EPA last published an assessment of the potential carcinogenicity of EtO in 1985. The current assessment reviews the more recent database on the carcinogenicity of EtO. The scientific literature search for this assessment is generally current through June 2004, although a few later publications are included. This assessment focuses on lifetime cancer risk from inhalation exposure.

EtO is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and as a fumigating agent for spices. The largest sources of human exposure are in occupations involving contact with the gas in plants (facilities) and in hospitals that sterilize medical equipment. EtO can also be inhaled by residents living near production or sterilizing/fumigating facilities. This document describes the derivation of inhalation unit risk estimates for cancer mortality and incidence based on human epidemiological data.

Attached is a draft of a charge to the Science Advisory Board that identifies the questions and issues we want the Science Advisory Board to address in reviewing the document.

CHARGE QUESTIONS FOR EPA'S SCIENCE ADVISORY BOARD (SAB) REVIEW OF THE ETHYLENE OXIDE (EtO) CARCINOGENICITY ASSESSMENT

EPA's Office of Research and Development (ORD) has requested that the Science Advisory Board (SAB) review its document entitled "Evaluation of the Carcinogenicity of Ethylene Oxide". This document is EPA's draft of the evaluation of the carcinogenicity of ethylene oxide (EtO). The assessment was prepared by the National Center for Environmental Assessment which is the health risk assessment program in the Office of Research and Development. The assessment broadly supports activities authorized in the 1990 Clean Air Act and is of particular interest to EPA's Office of Air and Radiation. However, this review also should be applicable to the needs of all program Offices and Regions in evaluating the carcinogenicity of EtO.

EPA last published a health assessment of the potential carcinogenicity of EtO in 1985 (U.S. EPA, 1985). The current assessment reviews the more recent database on the carcinogenicity of EtO. The scientific literature search for this assessment is generally current through June 2004, although a few later publications are included. This assessment focuses on lifetime cancer risk from inhalation exposure.

EtO is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and as a fumigating agent for spices. The largest sources of human exposure are in occupations involving contact with the gas in plants (facilities) and in hospitals that sterilize medical equipment. EtO can also be inhaled by residents living near production or sterilizing/fumigating facilities.

The DNA-damaging properties of EtO have been studied since the 1940s. EtO is known to be mutagenic in a large number of living organisms, ranging from bacteriophage to mammals, and it also induces chromosome damage. It is carcinogenic in mice and rats, inducing tumors of the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary gland. In humans employed in EtO-manufacturing facilities and in sterilizing facilities, the greatest evidence of a cancer risk from exposure is for cancer of the lymphohematopoietic system. Increases in the risk of lymphohematopoietic cancer have been seen in several studies, manifested as an increase

either in leukemia and/or in cancer of the lymphoid tissue. In one large epidemiologic study of sterilizer workers that had a well-defined exposure assessment for individuals, positive exposure-response trends for lymphohematopoietic cancer mortality in males and for breast cancer mortality in females were reported (Steenland et al., 2004). The positive exposure-response trend for female breast cancer was confirmed in an incidence study based on the same worker cohort (Steenland et al., 2003).

In accordance with EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), EtO was characterized as carcinogenic to humans based on the total weight of evidence.

This evidence, as assessed by EPA, included:

- a) strong, though less than completely conclusive, evidence of carcinogenicity from human studies
- b) sufficient evidence of carcinogenicity in laboratory animals
- c) EtO is a direct-acting alkylating agent with clear evidence of mutagenicity/genotoxicity, and there is sufficient evidence that DNA adduct formation and the resulting mutagenic/genotoxic effects are key events in the mode of action of EtO carcinogenicity
- d) evidence of chromosome damage in humans exposed to EtO, supporting the inference that the same mode of action for EtO carcinogenicity is operative in humans

This document describes the derivation of inhalation unit risk estimates for cancer mortality and incidence based on the human data. An EC_{01} of $44 \mu\text{g}/\text{m}^3$ (0.024 ppm) was calculated using a life-table analysis and linear modeling of the categorical Cox regression analysis results for excess lymphohematopoietic cancer mortality in males reported in a high-quality occupational epidemiologic study (Steenland et al., 2004). Linear low-dose extrapolation from the LEC_{01} yielded a lifetime extra cancer mortality unit risk estimate of 5.0×10^{-4} per $\mu\text{g}/\text{m}^3$ (0.92 per ppm) of continuous EtO exposure. Applying the same linear regression coefficient and life-table analysis to background male lymphohematopoietic cancer *incidence* rates yielded an EC_{01} of $24 \mu\text{g}/\text{m}^3$ (0.013 ppm) and a preferred lifetime extra cancer unit risk estimate of 9.0×10^{-4} per $\mu\text{g}/\text{m}^3$ (1.6 per ppm). The preferred estimate is greater than the estimate of 5.0×10^{-4} per $\mu\text{g}/\text{m}^3$ (0.91 per ppm; $EC_{01} = 44 \mu\text{g}/\text{m}^3$) calculated, using the same approach, from the results of a breast cancer incidence study of the same worker cohort (Steenland et al., 2003), and is recommended as the potency estimate for Agency use.

Because the weight of evidence supports a mutagenic mode of action for EtO carcinogenicity, and in the absence of chemical-specific data on early-life susceptibility, this assessment finds that increased early-life susceptibility should be assumed and the age-dependent adjustment factors (ADAFs) should be applied, in accordance with EPA's *Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens*, hereinafter referred to as "EPA's Supplemental Guidance" (U.S. EPA, 2005b). Applying the ADAFs to the unit risk estimate of 9.0×10^{-4} per $\mu\text{g}/\text{m}^3$ yields an adjusted full lifetime unit risk estimate of 1.5×10^{-3} per $\mu\text{g}/\text{m}^3$, and the commensurate lifetime chronic exposure level of EtO corresponding to an increased cancer risk of 10^{-6} is $0.0007 \mu\text{g}/\text{m}^3$. [Note that for less-than-lifetime exposure scenarios (or for exposures that vary with age), the unadjusted (adult-based) potency estimate of 9.0×10^{-4} per $\mu\text{g}/\text{m}^3$ should be

used, in conjunction with the ADAFs as appropriate, in accordance with EPA's Supplemental Guidance.]

Unit risk estimates were also derived from the three chronic rodent bioassays for EtO reported in the literature. These estimates, ranging from 2.2×10^{-5} per $\mu\text{g}/\text{m}^3$ to 4.6×10^{-5} per $\mu\text{g}/\text{m}^3$, are about an order of magnitude lower than the estimates based on human data [unadjusted for early-life susceptibility]. The Agency takes the position that human data, if adequate data are available, provide a more appropriate basis than rodent data for estimating population risks (U.S. EPA, 2005a), primarily because uncertainties in extrapolating quantitative risks from rodents to humans are avoided. Although there is a fairly sizable difference between the rodent- and human-based estimates, the assessment infers that the similarity between the unit risk estimates based on the male lymphohematopoietic cancer and the female breast cancer results increases confidence in the use of the unit risk estimate based on the male lymphohematopoietic cancer results.

The unit risk estimates were developed for environmental exposure levels and are not necessarily applicable to higher-level occupational exposures, which appear to be subject to a different exposure-response relationship. However, occupational exposure levels are of concern to EPA when EtO is used as a pesticide (e.g., fumigant for spices). Therefore, this document also presents extra risk estimates for cancer for a number of occupational exposure scenarios.

The SAB Ethylene Oxide Review Panel is being asked to comment on the scientific soundness of this carcinogenicity assessment. The specific charge questions to the Panel are as follows:

Issue 1: Carcinogenic Hazard (Section 3 and Appendix A of the Draft)

1. Do the available data and discussion in the draft document support the hazard conclusion that EtO is carcinogenic to humans based on the weight-of-evidence descriptors in EPA's 2005 *Guidelines for Carcinogen Risk Assessment*? In your response, please include consideration of the following:

1.a EPA concluded that the epidemiological evidence on EtO carcinogenicity was strong, but less than completely conclusive. Does the draft document provide sufficient description of the studies, balanced treatment of positive and negative results, and a rigorous and transparent analysis of the data used to assess the carcinogenic hazard of ethylene oxide (EtO) to humans? Please comment on the EPA's characterization of the body of epidemiological data reviewed. Considerations include: a) the consistency of the findings, including the significance of differences in results using different exposure metrics, b) the utility of the internal (based on exposure category) versus external (e.g., SMR and SIR) comparisons of cancer rates, c) the magnitude of the risks, and d) the strength of the epidemiological evidence.

1.b. Are there additional key published studies or publicly available scientific reports that are missing from the draft document and that might be useful for the discussion of the carcinogenic hazard of EtO?

1.c. Do the available data and discussion in the draft document support the mode of action conclusions?

1.d. Does the hazard characterization discussion for EtO provide a scientifically-balanced and sound description that synthesizes the human, laboratory animal, and supporting (e.g., *in vitro*) evidence for human carcinogenic hazard?

Issue 2: Risk Estimation (Section 4 and Appendices C and D)

2. Do the available data and discussion in the draft document support the approaches taken by EPA in its derivation of cancer risk estimates for EtO? In your response, please include consideration of the following:

2.a. EPA concluded that the epidemiological evidence alone was strong but less than completely conclusive (although EPA characterized the total evidence - from human, laboratory animal, and *in vitro* studies - as supporting a conclusion that EtO as "carcinogenic to humans"). Is the use of epidemiological data, in particular the Steenland et al. (2003, 2004) data set, the most appropriate for estimating the magnitude of the carcinogenic risk to humans from environmental EtO exposures? Are the scientific justifications for using this data set transparently described? Is the basis for selecting the Steenland et al. data over other available data (e.g., the Union Carbide data) for quantifying risk adequately described?

2.b. Assuming that Steenland et al. (2003, 2004) is the most appropriate data set, is the use of a linear regression model fit to Steenland et al.'s categorical results for all lymphohematopoietic cancer in males in only the lower exposure groups scientifically and statistically appropriate for estimating potential human risk at the lower end of the observable range? Is the use of the grouping of all lymphohematopoietic cancer for the purpose of estimating risk appropriate? Are there other appropriate analytical approaches that should be considered for estimating potential risk in the lower end of the observable range? Is EPA's choice of a preferred model adequately supported and justified? In particular, has EPA adequately explained its reasons for not using a quadratic model approach such as that of Kirman et al. (2004) based? What recommendations would you make regarding low-dose extrapolation below the observed range?

2.c. Is the incorporation of age-dependent adjustment factors in the lifetime cancer unit risk estimate, in accordance with EPA's Supplemental Guidance (U.S. 2005b), appropriate and transparently described?

2.d. Is the use of different models for estimation of potential carcinogenic risk to humans from the higher exposure levels more typical of occupational exposures (versus the lower exposure levels typical of environmental exposures) appropriate and transparently described in Section 4.5?

2.e. Are the methodologies used to estimate the carcinogenic risk based on rodent data appropriate and transparently described? Is the use of "ppm equivalence" adequate for interspecies scaling of EtO exposures from the rodent data to humans?

Issue 3: Uncertainty (Sections 3 and 4)

1. EPA's *Risk Characterization Handbook* requires that assessments address in a transparent manner a number of important factors. Please comment on how well this assessment clearly describes, characterizes and communicates the following:

- a. The assessment approach employed;
- b. The use of assumptions and their impact on the assessment;
- c. The use of extrapolations and their impact on the assessment;
- d. Plausible alternatives and the choices made among those alternatives;
- e. The impact of one choice versus another on the assessment;
- f. Significant data gaps and their implications for the assessment;
- g. The scientific conclusions identified separately from default assumptions and policy calls;
- h. The major risk conclusions and the assessor's confidence and uncertainties in them, and;
- i. The relative strength of each risk assessment component and its impact on the overall assessment.

ATTACHMENT 2

EPA Science Advisory Board Staff Office; Request for Nominations of Experts for the Ethylene Oxide Review Panel

[Federal Register: March 1, 2006 (Volume 71, Number 40)]
[Notices]
[Page 10500-10501]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr01mr06-53]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-8039-3]

EPA Science Advisory Board Staff Office; Request for Nominations
of Experts for the Ethylene Oxide Review Panel

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: Requesting the nomination of experts for the Science Advisory Board
(SAB) Ethylene Oxide Review Panel.

DATES: Nominations should be submitted by March 22, 2006, per instructions
below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further
information regarding this Request for Nominations may contact Dr. Sue Shallal,
Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at
(202) 343-9977; by fax at (202) 233-0643; or via e-mail at
shallal.suhair@epa.gov. General information concerning the EPA Science Advisory
Board can be found on the EPA SAB Web site at: <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background: EPA last published a health assessment of the potential
carcinogenicity of ethylene oxide (EtO) in 1985 (U.S. EPA, 1985). EPA's Office
of Research and Development (ORD) has now completed a review of the more recent
database on the carcinogenicity of EtO, pertinent data from the 1985 assessment,
and several reviews and assessments issued by other organizations. EtO is
manufactured from ethylene and used primarily as a chemical intermediate in the
manufacture of ethylene glycol. It is also used as a sterilizing agent for
medical equipment and as a fumigating agent for spices. ORD's draft assessment
focuses on lifetime cancer risk from inhalation exposure. The assessment broadly
supports activities authorized in the 1990 Clean Air Act and is of particular
interest to EPA's Office of Air and Radiation. However, this review also should
be applicable to the needs of all program Offices and Regions in evaluating the
carcinogenicity of EtO. ORD has requested that the Science Advisory Board (SAB)

review its draft assessment entitled ``Evaluation of the Carcinogenicity of Ethylene Oxide''.

The EPA Science Advisory Board (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 review panel, conducting the review of the Agency's evaluation of the carcinogenicity of ethylene oxide, will consist of members of the chartered SAB, SAB Committee members and other experts as determined to be necessary. This panel will comply with the provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies. Upon completion, the panel's report will be submitted to the chartered SAB for final approval for transmittal to the EPA Administrator. The SAB Ethylene Oxide Review Panel is being asked to comment on the scientific soundness of this carcinogenicity assessment.

Availability of the Review Materials: The EPA draft document to be reviewed by the SAB Panel will be made available by the Office of Research and Development. For questions and information concerning the review materials, please contact Dr. Henry Kahn, at (202) 564-3269 or kahn.henry@epa.gov.

Request for Nominations: The SAB Staff Office is requesting nominations of recognized experts with one or more of the following areas of expertise, especially with respect to the potential human carcinogenic effects of ethylene oxide: Respiratory/pulmonary physiology and exposure; epidemiology; toxicology, including genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; risk assessment and statistical evaluation of epidemiological and toxicological data.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals to serve on the SAB Panel(s). Nominations should be submitted in electronic format through the SAB Web site at the following URL: <http://www.epa.gov/sab>; or directly via the Form for Nominating Individuals to Panels of the EPA Science Advisory Board link found at URL: <http://www.epa.gov/sab/panels/paneltopics.html>. To be considered, nominations must include all of the information required on the associated forms. Anyone who is unable to submit nominations using this form, and who has any questions concerning any aspects of the nomination process may contact the DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than March 22, 2006.

The EPA SAB Staff Office will acknowledge receipt of the nomination. From the nominees identified by respondents to this notice (termed the ``Widecast''), the SAB Staff Office will develop a smaller subset (known as the ``Short List'') for more detailed consideration. Criteria used by the SAB Staff in developing this Short List are given at the end of the following paragraph. The Short List will be posted for public comment on the SAB Web site at: <http://www.epa.gov/sab>. The Short List will include each nominee's name and a short biographical description of expertise and professional experiences. During this comment period, the public may provide relevant information on nominees that the SAB Staff Office should consider in evaluating candidates for the Panel.

For the EPA SAB Staff Office, a balanced subcommittee 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 charge. Public responses to the Short List candidates will be considered in the selection of the Panel, along with information provided by candidates and information independently-gathered by the SAB Staff Office on the background of each candidate. Specific criteria to be

used in evaluating an individual nominee 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 and viewpoints.

Prospective candidates will also be required to fill-out the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address:

http://www.epa.gov/sab/sge_course/pdf_sge/epaform3110_48.pdf. The process by which the EPA SAB Office forms panels is described in the following document: Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board (EPA-SAB-EC-02-010), which is posted on the SAB Web site at: <http://www.epa.gov/sab/pdf/ec02010.pdf>.

Dated: February 23, 2006.
Anthony F. Maciorowski,
Associate Director for Science, EPA Science Advisory Board Staff Office.
[FR Doc. E6-2899 Filed 2-28-06; 8:45 am]
BILLING CODE 6560-50-P

ATTACHMENT 3

Invitation for Comments on the "Short List" Candidates for the Ethylene Oxide Review Panel EPA Science Advisory Board (SAB) May 26, 2006

The EPA Science Advisory Board (SAB) Staff Office announced in 71 FR 10500-10501, March 1, 2006, that it was forming an expert panel to conduct a peer review of EPA's Carcinogenicity Evaluation of Ethylene Oxide. The SAB Staff Office requested nominations for experts in the following disciplines, especially with respect to the potential human carcinogenic effects of ethylene oxide: respiratory/pulmonary physiology and exposure; epidemiology; toxicology, including genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; risk assessment and statistical evaluation of epidemiological and toxicological data. Background on the details of this advisory activity and panel nomination process appear in the above referenced Federal Register notice and are also available at the SAB website (<http://www.epa.gov/sab/>).

The SAB Staff Office has reviewed the nominations for the Panel, and has identified a list of nominees to a Short List of 31 candidates based on the qualifications and interest of the nominees. Brief biosketches of the candidates on the "Short List" are listed below. We invite comments from members of the public for relevant information or documentation that the SAB Staff Office should consider in the selection of the Panel.

The SAB Staff Office Director makes the final decision about who will serve on the panel in the "Panel Selection" phase. In that phase, SAB Staff completes its review of information regarding conflict of interest, an appearance of a lack of impartiality, and appropriate balance and breadth needed to address the charge. SAB Staff will review all the information provided by the candidates, along with any information that the public may provide in response to the posting of information about the prospective panel on the SAB website during the "Short List Phase," and information gathered by SAB Staff independently on the background of the candidates.

Please e-mail your comments no later than June 16, 2006. Please make your written comments to the attention of Dr. Sue Shallal, Designated Federal Officer at shallal.suhair@epa.gov.

Ethylene Oxide Review Panel Shortlist Biographical Sketches

Steven Alan Belinsky

Cancer Epidemiology and Control Program for the University of New Mexico Cancer

Dr. Steven Belinsky received his undergraduate training and graduate degrees at the University of North Carolina at Chapel Hill. He then did a postdoctoral fellowship and was a Senior Staff fellow at the National Institute of Environmental Health Sciences before moving to the Lovelace Respiratory Research Institute in Albuquerque, NM in 1990. He is currently Director of the Lung Cancer Program and Deputy Director of the NIEHS center that is a collaborative venture between the University of New Mexico and the Institute. He also co-directs the Cancer Epidemiology and Control Program for the University of New Mexico Cancer Center. He has served on numerous advisory boards for the National Institute of Environmental Health Sciences and the National Cancer Institute. Dr. Belinsky has worked in the field of tobacco carcinogenesis for 20 years and is internationally recognized for his work in lung cancer and translational studies for early detection of lung cancer. His laboratory was the first to demonstrate that the tobacco specific nitrosamine causes DNA adducts that accumulate in the lung and lead to mutation of the K-ras oncogene. His work has been extended to evaluate epigenetic mechanisms for lung cancer, specifically inactivation of genes through aberrant promoter hypermethylation. Key findings from his laboratory include, identifying the p16 tumor suppressor gene as an early event in lung, the detection of promoter methylation of specific genes up to 3 years prior to diagnosis of lung cancer, and the demonstration that inhibitors that block promoter hypermethylation can prevent lung cancer development. Currently, his research is focused on controlling lung cancer through the identification of gene targets and pathways that are disrupted during the development of this disease. These findings are translated into population-based studies for the purpose of developing intermediate biomarkers for predicting cancer risk, early detection, prognosis, and response to preventive interventions. In addition, his group is involved in conducting at both the animal and human level the evaluation of novel preventive and chemotherapy approaches to reduce the mortality from lung cancer. Dr. Belinsky has authored over 130 publications.

Ian A. Blair

University of Pennsylvania

Dr. Ian A. Blair is a Professor of Pharmacology and Adjunct Professor of Chemistry at the University of Pennsylvania. He obtained his PhD degree from the Imperial College of Science and Technology, University of London, UK in 1971 (Advisor, Nobel Laureate Sir Derek HR Barton). He is a member of the American Association for Cancer Research, American Chemical Society, and American Society for Mass Spectrometry (Chair, Section on Quantitative Analysis 1985-1987), American Society for Pharmacology and Experimental Therapeutics and International Society for the Study of Xenobiotics. He received the Dean's Award for Excellence in Graduate Training, University of Pennsylvania, School of Medicine in 2006. Dr. Blair is Director of the Center for Cancer Pharmacology at the University of Pennsylvania, Philadelphia, PA (<http://www.med.upenn.edu/ccp>) and is an Investigator at University of Pennsylvania Comprehensive Cancer Center (<http://www.oncolink.upenn.edu/upcc>) and Center for Experimental Therapeutics (<http://www.med.upenn.edu/CET>). He is also Scientific Director of the Genomics Institute Proteomics Facility at the University of Pennsylvania and the Director of Systems Biology at the Institute for Translational Medicine and Therapeutics. He is a member of several NIH Review Committees. His laboratory is involved in determining the factors that control lipid hydroperoxide-mediated damage to DNA, RNA, and proteins. They are also characterizing the lesions in these macromolecules using novel mass spectrometry methodology, determining how the lesions affect proliferation and apoptosis using model in vitro systems, and assessing how such processes can be prevented using novel pharmacological agents.

Timothy Buckley

The Ohio State University

Dr. Timothy J. Buckley is an Associate Professor and Chair of the Division of Environmental Health Sciences in the School of Public Health at Ohio State University. He was an Assistant Professor of Environmental Health Sciences and Epidemiology at the Johns Hopkins Bloomberg School of Public Health. Dr. Buckley joined the Hopkins faculty in 1996 after five years with the U.S. EPA's National Exposure Research Lab. His research has focused on assessing total human environmental exposure through measurements in multiple environmental media and biomarkers. Over his research career, Dr. Buckley has been responsible for the concept, design, implementation, and management of several major studies involving human exposure to PAHs, metals, VOCs, pesticides, and PCBs through multiple environmental media. These large-scale projects complement laboratory-based studies where controlled exposures are used to more fully investigate relationships between exposure, body burden, and effects. Dr. Buckley's current research includes community-based exposure assessment, evaluation of chemical treatment to reduce lead bioavailability, the role of exposure to indoor air pollution and allergens in asthma among inner-city children, exposure and effects from mobile source related air pollution, improving methods to assess dermal exposure, and the development and evaluation of exposure biomarkers. While with the U.S. EPA, Dr. Buckley received awards for his role and efforts in the National Human Exposure Assessment Survey (NHEXAS) and the Lower Rio Grande Environmental Exposure Study. His published research was recognized in 1996 with a U.S. EPA Scientific and Technology Achievement Award and again in 1999 by the Walter G. Berl Award given the Johns Hopkins Applied Physics Laboratory. Dr. Buckley is a certified industrial hygienist and has been elected to leadership positions among his professional associations including chair of the American Industrial Hygiene Association's Biological Monitoring Committee and Academic Counselor of the International Society of Exposure Analysis. Dr. Buckley received his Ph.D. in Environmental Science from Rutgers University and a Masters of Health Science in Industrial Hygiene from the Johns Hopkins Bloomberg School of Public Health. Dr. Buckley is currently a member of the EPA Science Advisory Board Integrated Human Exposure Committee.

Harvey J. Clewell III

CIIT Centers for Health Research

Dr. Harvey J. Clewell III is the Director of the Center for Human Health Assessment at the CIIT Centers for Health Research. He has over twenty-

five years of experience in research and consulting in the areas of environmental quality, toxicology, risk assessment, and hazardous materials management. His current research interests include the application of physiologically based pharmacokinetic (PBPK) modeling to the interpretation of human biomonitoring data, the incorporation of genomic dose-response information in a cancer risk assessment for arsenic, and the application of biologically based dose response modeling approaches in risk assessments for inhaled irritants. Prior to joining CIIT, he worked as a consultant in chemical risk assessment, where he gained an international reputation for his research on the application of PBPK modeling to chemical risk assessment and pharmaceutical safety assessment. He played a major role in the first uses of PBPK modeling in cancer and non-cancer risk assessments by EPA, ATSDR, OSHA, and FDA, for such chemicals as methylene chloride, vinyl chloride, trichloroethylene, and retinoic acid. He also served for 20 years as an officer in the U.S. Air Force, where his duties included Deputy Director of the Air Force Toxic Hazards Research Unit, Director of Hazardous Materials Safety for the Air Force Aeronautical Systems Center, and consultant to the Air Force Surgeon General on Chemical Risk Assessment. He is an adjunct professor in the Department of Toxicology, University of Louisiana, Monroe, as well as in the Center for Environmental Toxicology and Technology, Colorado State University, Fort Collins, CO.

David Coggon

University of Southampton

Dr. David Coggon is Professor of Occupational and Environmental Medicine at the MRC Epidemiology Resource Centre, University of Southampton, UK. He graduated in mathematics and medical sciences from Cambridge University (1972), and completed his undergraduate clinical training at Oxford University (1976). After hospital jobs in internal medicine, he joined the MRC in Southampton in 1980 as a clinical scientist. Here he completed specialist clinical training in occupational medicine while developing a career in epidemiological research. His main research interest is the epidemiology of occupational and environmental health hazards, and he leads a programme of research aimed principally at informing the management of risk in the workplace and the wider environment. This has included studies on various suspected occupational carcinogens including ethylene oxide, formaldehyde, styrene, phenoxy herbicides and mineral acid mists. He has published some 180 papers in peer-reviewed journals, as well as editorials, commentaries, book chapters, and two textbooks. In recent years his research funding has been from the UK Medical Research Council, UK government departments, the European Union, and the Colt Foundation. He also has a major interest in the evaluation of research and its translation into public policy. He is currently chairman of the Depleted Uranium Oversight Board (Ministry of Defence), and from 2000-05 chaired the UK government's Advisory Committee on Pesticides. He is also a member of the Advisory Group on Non-Ionising Radiation (Health Protection Agency), and in the past was a member of the Industrial Injuries Advisory Council, the Expert Panel on Air Quality Standards, the Stewart Committee on Mobile Phone Technology, and of three monograph committees for the evaluation of industrial chemicals at the International Agency for Research on Cancer. He is a fellow of the Academy of Medical Sciences.

George Corcoran

Wayne State University

Dr. George Corcoran is Chairman, Department of Pharmaceutical Sciences, and Professor of Pharmaceutical Sciences at the Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University in Detroit, MI. He is also Adjunct Professor of Pediatrics in the School of Medicine of Wayne State University. Dr. Corcoran earned his B.A. in Chemistry from Ithaca College (1970), M.S. in Chemistry from Bucknell University (1973), and Ph.D. in Pharmacology and Toxicology from George Washington University (1980), before completing Post-Doctoral training in Toxicology at Baylor College of Medicine and The Methodist Hospital (1981). Prior to his appointment at Wayne State University in 1996, Dr. Corcoran served as Assistant Professor of Pharmaceutics at the State University of New York at Buffalo, followed by 9 years at the University of New Mexico in Albuquerque, NM as Associate Professor and later Professor, and Director of the Toxicology Graduate Program. Throughout his professional career, Dr. Corcoran has been active in numerous professional societies, including as Secretary of the Society of Toxicology, Scientific Council Member and Chairman of the Division of Toxicology of the American Society for Pharmacology and Experimental Therapeutics, and Member of the Research and Graduate Affairs Committee of the American Association of Colleges of Pharmacy. He is also a member of the Michigan Society of Toxicology and the Michigan Pharmacists Association. In addition, Dr. Corcoran is currently Associate Editor of Toxicology and Applied Pharmacology and a member of the editorial board of Pharmacology and Toxicology, and he has served on the editorial boards of Toxicology Letters and the Journal of Toxicology and Environmental Health. He has been very active in the national peer review of research, as Member of the NIH Alcohol Toxicology-1 Study Section, Member or Chairman of several NIH Special Emphasis Panel Study Sections, and Member and later Chairman of the National Research Council Hughes Howard Pre-Doctoral Fellowship Panel in Neurology and Physiology. Dr. Corcoran is currently a member of the EPA Science Advisory Board Environmental Health Committee. His research program, which focuses on mechanisms underlying cell death in the liver caused by drugs and environmental chemicals, has resulted in over 70 peer-reviewed and other publications. His work has been supported primarily by NIH, with small amounts of supplemental foundation and pharmaceutical industry funding.

Norman Drinkwater

University of Wisconsin Medical School

Dr. Norman Drinkwater is the Chair of the Department of Oncology at the University of Wisconsin Medical School. He is also the Director of the McArdle Laboratory for Cancer Research and Associate Director for Laboratory Programs of the University of Wisconsin Comprehensive Cancer Center. Dr. Drinkwater received his B.S. in Biochemistry from the University of Wisconsin in 1974 and a Ph.D. in Oncology from that institution in 1980. After postdoctoral training at Michigan State University, he joined the faculty of the Department of Oncology at the University of Wisconsin in 1982, becoming Professor and Chair of the department in 1992. Over the years, Dr. Drinkwater's research has focused on various aspects of chemical carcinogenesis, including the metabolic activation of carcinogens, molecular mechanisms of chemical mutagenesis, and, most recently, on the genetics of susceptibility to carcinogenesis. His support for this research has been derived entirely from the National Institutes of Health. Dr. Drinkwater has served on numerous review and advisory panels. Recent activities include membership on the Board of Scientific Counselors for the National Toxicology Program (1999-2002), the CE Study Section for NIH (1999-present; Chair, 2002-2004), the American Cancer Society Council on Extramural Grants (2001-present), and the External Advisory Boards for the M. D. Anderson Cancer Center (2000-present) and Oklahoma University Cancer Center (2001-present). Dr. Drinkwater is currently a member of the EPA Science Advisory Board Environmental Health Committee.

Montserrat Fuentes

North Carolina State University

Dr. Montserrat Fuentes is an associate professor in the Statistics Department at North Carolina State University and a visiting faculty in the Center on Global Change at Duke University. She also holds an associate status in the Marine Earth Atmospheric Sciences Department at NCSU. Dr. Fuentes received her B.S. in Mathematics and also in Music from the University of Valladolid (Spain), and her Ph.D. in Statistics from the University of Chicago (1999). She spent 6 months as a postdoc in the National Center of Atmospheric Research (NCAR) before joining NC State in 1999. Throughout her professional career, Dr. Fuentes has been active in numerous professional societies, including being chair of the section on Statistics and the Environment (2003) for the Eastern North American Region (ENAR) of the International Biometric Society, chair of the General Methodology Section (2001, and 2004) of the American Statistical Association (ASA), program chair for the 2002 Southern Regional Council on Statistics (SRCOS) and ASA, serving in the scientific committee for The International Environmetrics Society (TIES) (2004) and in the program committee for the Institute of Mathematical Science-The International Society for Bayesian Analysis (IMS-ISBA) joint conference (2005). She was also chair of the scientific committee for the International Statistical Institute (ISI) Conference on Environmental Statistics and Health (July, 2003). She is a member-elect of the ISI, and also member of the Regional Advisory Board (RAB) for ENAR (2003-2006). Dr. Fuentes is an associate editor for the Journal Biometrics (2003-2006). She received the Abdel El-Shaarawi Young Research's Award in recognition of outstanding contributions to environmetric research (2003). Dr. Fuentes is currently a member of the EPA Science Advisory Board Integrated Human Exposure Committee. Dr. Fuentes has maintained her own research group, currently with eight Ph.D. graduate students working on projects sponsored by the National Science Foundation (NSF), the US Environmental Protection Agency (EPA), the US Department of Transportation (DOT), the National Oceanic and Atmospheric Administration (NOAA) and the US Department of Defense (DOD). Dr. Fuentes has developed new statistical methods that she applied to air pollution and weather prediction problems in collaboration with the air quality modelers and scientists at EPA and NCAR. This work has led to numerous publications in top statistical journals and books, as well as top journals in atmospheric sciences. Her current research focuses on the development of novel spatial-temporal statistical methodology to quantify uncertainties about the impacts of fine particles exposure on mortality and illness.

Michael Gargas

The Sapphire Group

Dr. Michael L. Gargas, Managing Principal of The Sapphire Group™, is a toxicologist with over 28 years of related environmental experience. Dr. Gargas oversees and prepares human health risk assessments, conducts toxic tort support investigations, serves as an expert witness, interacts with regulatory agencies, and addresses critical toxicological issues through applied and basic research on behalf of clients. Dr. Gargas' area of expertise is in human health risk assessment and biochemical toxicology research with emphasis in the areas of inhalation toxicology, chemical metabolism, physiologically based pharmacokinetic (PBPK) modeling, and chemical dosimetry, with specific application of these approaches to risk assessments. Prior to joining The Sapphire Group™, Dr. Gargas served as a VP and Principal Health Scientist with a risk assessment and toxicology consulting firm, a senior research scientist at the Chemical Industry Institute of Toxicology (CIIT), and as a toxicology research scientist with the U.S. Air Force (as a civilian) and on active duty with the U.S. Navy. Dr. Gargas completed undergraduate degrees in Medical Laboratory Technology and Biology from George Washington University and Wright State University, respectively and his doctorate in Biomedical Sciences (Toxicology Specialty) is from Wright State University. Dr. Gargas has been an active member in the Society of Toxicology since 1989 and the Society for Risk Analysis since 1992 and has served on the editorial board of Toxicology and Applied Pharmacology. He is also a member and has served as a Councilor to the Risk Assessment Specialty Section of the SOT and is currently serving as the President of that Specialty Section. Dr. Gargas has been invited to present numerous guest lectures on toxicology and risk assessment topics, including a number of international seminars and conferences as a member of the organizing group and has close contacts with regulators in many parts of the world including the USA, Canada, and Europe. Dr. Gargas has served on review and advisory panels, including as an outside reviewer on the USEPA IRIS risk assessment for vinyl chloride, a USEPA special review team regarding an IRB issue, as a member of a technical advisory team for a Superfund Grant to the Oregon Health & Science University, and several other special project reviews on behalf of USEPA. He has published seven book chapters and over 70 peer-reviewed articles on a wide range of health and toxicologic topics. Dr. Gargas is also an Adjunct Assistant Professor of Toxicology at Wright State University, serving as director for a yearly graduate course in biokinetics and toxicology.

David Garrabrant

University of Michigan

David Garrabrant, MD MPH is Professor of Occupational Medicine and Epidemiology at the University of Michigan, School of Public Health. He holds degrees in chemical engineering (BS, Tufts University, 1972), medicine (MD, Tufts University School of Medicine, 1976), public health (MPH, Harvard School of Public Health), and physiology (MS, Harvard School of Public Health, 1980). He completed a residency in internal medicine at Georgetown University Hospital (1976-78) and Boston University Hospital (1980-81) and is board certified in internal medicine. He completed a residency in occupational medicine at the Harvard School of Public Health (1978-80) and is board certified in preventive medicine/occupational medicine. He is an attending physician at the University of Michigan Medical Center and holds an appointment as Associate Professor of Emergency Medicine at the University of Michigan School of Medicine. He teaches courses in occupational and environmental disease, research methods in occupational and environmental epidemiology, field methods in epidemiology, and risk assessment. He is the author of over 130 publications. His research focuses on epidemiologic studies of long term health effects of chemicals to humans. Recent work includes studies of environmental risks to pancreatic cancer focusing on DDT and related chemicals, cohort mortality studies of automobile manufacturing workers focusing on cancer risks related to machining fluid exposures, long term neurologic effects of chlorpyrifos exposure, and environmental exposures to dioxins. He has received grant support totaling approximately \$20 million from the NCI, NIEHS, NIOSH, UAW-Ford Motor Company National Joint Committee, corporate sponsors, and charitable institutions. He served on the Safety and Occupational Health Study Section of the CDC in 1992-96, and was appointed Chair of that study section in 1995-96 by Secretary of HHS Donna Shalala. He was a visiting faculty member at the University of Indonesia School of Medicine while on sabbatical in Jakarta, Indonesia in 1995-96. In addition to his other duties, he is currently Director of the Center for Risk Analysis and Communication at the University of Michigan.

Dale Hattis

Clark University

Dale Hattis is Research Professor with the Center for Technology Environment and Development (CENTED) of the George Perkins Marsh Institute at Clark University. For the past twenty-nine years he has been engaged in the development and application of methodology to assess the health, ecological and economic impacts of regulatory actions. His work has focused on the development of methodology to incorporate interindividual variability data and quantitative mechanistic information into risk assessments for both cancer and non-cancer endpoints. An important focus in recent years has been on age-related differences in pharmacokinetic processes and susceptibility for carcinogenesis. Specific quantitative risk assessment studies have included hearing disability in relation to noise exposure, renal effects of cadmium, reproductive effects of ethoxyethanol, neurological effects of methyl mercury and acrylamide, chronic lung function impairment from coal dust, four pharmacokinetic-based risk assessments for carcinogens (for perchloroethylene ethylene oxide butadiene and diesel particulates), an analysis of uncertainties in pharmacokinetic modeling for perchloroethylene and an analysis of differences among species in processes related to carcinogenesis. He is a member of the Environmental Health Committee of the EPA Science Advisory Board and for several years he has served as a member of the Food Quality Protection Act Science Review Board. In the recent past he has served as a member of the National Research Council Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations. Current major sources of research support include the Department of Energy and the U.S. Environmental Protection Agency. He has been a councilor and is a Fellow of the Society for Risk Analysis and serves on the editorial board of its journal Risk Analysis. He holds a Ph.D. in Genetics from Stanford University and a B.A. in biochemistry from the University of California at Berkeley.

Steven Heeringa

University of Michigan

Steven G. Heeringa is the Director of the Division of Surveys and Technologies at the University of Michigan Institute for Social Research (ISR) where he oversees research design and operations for population-based studies in the social sciences, education, demography, public health and medicine. Steve has a Ph.D. in Biostatistics from the University of Michigan and is a specialist in statistical design and analysis for studies of human and animal populations. Steve Heeringa has over twenty-five years of statistical sampling experience directing the development of the ISR National Sample design as well as sample designs for ISR's major longitudinal and cross-sectional survey programs. During this period he has been actively involved in research and publication on statistical methods and procedures such as sample design methods and procedures, such as weighting, variance estimation and the imputation of missing data that are required in the analysis of sample survey data. He is an advisor to panels of the National Institutes of Health (NIH) and the World Health Organization (WHO). Since 2000, Steve has served as an ad hoc member of more than 10 EPA Scientific Review panels. He has been a teacher of survey sampling methods to U.S. and international students and has served as a sample design consultant to a wide variety of international research programs based in countries such as: Russia, the Ukraine, Uzbekistan, Kazakhstan, India, Nepal, China, Iran, Chile and Egypt.

Rogene Henderson

Lovelace Respiratory Research Institute

Dr. Rogene Henderson is a Senior Scientist Emeritus at the Lovelace Respiratory Research Institute. Dr. Henderson earned her Ph.D. in chemistry from the University of Texas in 1960 and her B.S./B.A. in chemistry/biology from Texas Christian University in 1955. She was a Fulbright Scholar in physical chemistry in 1955-1956 and held fellowships at the Universities of Texas and Arkansas. Dr. Henderson's research interests are in three major areas: (1) biochemistry of the lung, particularly the surfactant lining layer — she has developed in vivo screening tests for pulmonary toxicants based on analysis of bronchoalveolar washings for biomarkers of lung injury and repair; (2) the mechanisms by which pulmonary inflammation leads to repair or to chronic disease (fibrosis, emphysema); and (3) the pharmacokinetics of inhaled xenobiotics (particularly vapors) and chemical-specific biomarkers of chemical exposure. She has recently conducted studies on the health effects of low-level sarin exposures in rats. Dr. Henderson is currently a member of: the U.S. Army Deployment Toxicology Science Working Group, a member and Vice-Chair of the Board of Scientific Councilors (BOSC) for the U.S. Environmental Protection Agency (EPA) Office of Research and Development; and a member of the American Cancer Society (ACS) Advisory Group on Cancer and the Environment. Dr. Henderson is a National Associate of the NAS. Since October 2004, she has served as the Chair of EPA's Clean Air Scientific Advisory Committee (CASAC).

Greg Kedderis

Consultant

Dr. Gregory L. Kedderis received a B.S. in chemistry from Worcester Polytechnic Institute, Worcester, MA, and a Ph.D. in biochemistry in 1982 from Northwestern University Medical and Dental School, Chicago, IL. He was a postdoctoral fellow at the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from 1982 to 1984 and subsequently joined Merck Sharp & Dohme Research Laboratories in Rahway, NJ as a senior research biochemist. Dr. Kedderis returned to CIIT as a staff scientist in 1988, where he was Director of the Chemical Carcinogenesis Research Program (since 1998) and the Division of Biochemistry and Molecular Genetics (since 2000) until 2002. He is currently a consultant in biochemistry, pharmacology, and toxicology. He is also a Visiting Research Professor in the Nicholas School of the Environment and Earth Sciences and in the Integrated Toxicology Program at Duke University, Durham, NC. Dr. Kedderis is author or co-author of 69 publications. He has served on a number of international committees and workshops sponsored by ILSI, ECVAM, and other organizations. He has also served on several editorial boards, including Drug Metabolism and Disposition and the Journal of Pharmacology and Experimental Therapeutics, and was Reviews Editor for Chemico-Biological Interactions. His research interests include the relationship between chemical dosimetry and biological effects, mechanisms of toxicity of drugs and xenobiotics, and mechanisms of genotoxicity and chemical carcinogenesis. Recent research funding has come from the U.S. Environmental Protection Agency and the Electric Power Research Institute. Dr. Kedderis is a member of the Society of Toxicology, the Chemical Substances Threshold Limit Values Committee of the American Conference of Governmental Industrial Hygienists, and the National Occupational Research Agenda Cancer Research Methods Team.

James Kehrer

University of Texas at Austin

Dr. James P. Kehrer is a Professor of Toxicology, and Head of the Division of Pharmacology and Toxicology in the College of Pharmacy at the University

of Texas at Austin. Dr. Kehrer received his B.S. in pharmacy from Purdue University (1974) and his Ph.D. in pharmacology/toxicology from the University of Iowa College of Medicine (1978). He did postdoctoral work in toxicology in the Biology Division of Oak Ridge National Laboratory (1978-1980). Dr. Kehrer began his academic career at the University of Texas at Austin in 1980. During 1986 he took a 1 year Faculty Development Leave at the University of Düsseldorf where he returned in 1990 and 1997 for 2 month periods of research. Dr. Kehrer has been active in numerous professional societies, and is currently a member of the American Association for the Advancement of Science, American Association for Cancer Research, American Society for Pharmacology and Experimental Therapeutics, Society of Toxicology (where he served as President of the Mechanisms Specialty Section), Society for Free Radical Biology and Medicine, and the International Society for Free Radical Research. He is currently a member of the EPA Science Advisory Board Environmental Health Committee. Dr. Kehrer received a Research Career Development Award from the National Heart, Lung and Blood Institute and the Achievement Award from the Society of Toxicology. He serves the Editor for the Americas and Japan for Toxicology Letters and currently serves as a Deputy Chairman for The Biochemical Journal. He also serves on the editorial board of Toxicology and Applied Pharmacology and Archives of Biochemistry and Biophysics. Other service has included the NIH Toxicology Study Section, and numerous NIH review panels. Dr. Kehrer maintains a large research program with numerous grants from the National Institutes of Health. He has over 125 publications, many in the areas of free radical toxicology, apoptosis, pulmonary fibrosis and cell signaling.

Christopher Kirman

The Sapphire Group

Christopher R. Kirman, M.S., Program Manager with The Sapphire Group™, is a toxicologist with over fifteen years of related experience in risk assessment. Mr. Kirman prepares human health risk assessments, interacts with regulatory agencies, and addresses critical toxicological issues through applied and basic research on behalf of clients. Mr. Kirman's area of expertise is in human health risk assessment with emphasis in the areas of dose response modeling, mechanism of action, physiologically based pharmacokinetic (PBPK) modeling, with specific application of these approaches to risk assessments. Prior to joining The Sapphire Group™, Mr. Kirman was a Senior Scientist with two other risk assessment and toxicology consulting firms, and as a laboratory research assistant as Case Western Reserve University (CWRU). Mr. Kirman completed and undergraduate degree in Chemistry, and a masters degree in Toxicology and Nutrition from CWRU. Mr. Kirman is a member in the Ohio and National Chapters of the Society for Risk Analysis. He has published ten peer reviewed articles on a wide range of health and toxicologic topics, and has received several awards from the Risk Assessment Specialty Section of the Society of Toxicology. Mr. Kirman has served as a consultant to the American Chemistry Council's Ethylene Oxide Industry Council (ACC EOIC) on ethylene oxide, including preparation of a cancer and non-cancer risk assessment for ethylene oxide that was submitted to the USEPA IRIS office in 2001. Mr. Kirman continues to consult to the ACC EOIC on ethylene oxide issues.

James E. Klaunig

Indiana University

Dr. James E. Klaunig is Professor of Toxicology and Director of Toxicology in the Department of Pharmacology and Toxicology at Indiana University School of Medicine. He received his BS degree from Ursinus College in Collegeville Pa., an MA from Montclair State University, Montclair, NJ, and his PhD from the University of Maryland in Baltimore, MD. He is the recipient of numerous awards including fellow of the Academy of Toxicological Sciences, the Otis R. Bowen, M.D. Distinguished Leadership Award, Indiana University School of Medicine and the Kenneth P. DuBois Award from the Midwest Society of Toxicology and the Sagamore of the Wabash from the Governor of Indiana. He serves as associate editor of Toxicological Sciences and on the editorial board of Toxicological Pathology. He is a Member of the NIH/NIEHS National Toxicology Program Board of Scientific Counselors. He also has served as President of the Carcinogenesis Specialty Section, President of the Ohio Valley Society of Toxicology, Member and Chair of the SOT Education Committee, and Member of the Finance and Program Committees of SOT. He is currently the Treasurer of the Society of Toxicology. He also serves the State of Indiana on the Indiana Pesticide review Board, the Governor's Council on Impaired and dangerous driving and on the Indiana Controlled Substances Advisory Board. He has trained over 50 graduate students and postdoctoral fellows. Dr. Klaunig is currently a member of the EPA Science Advisory Board Environmental Health Committee. His research interests are dedicated to understanding the mechanisms of chemically induced carcinogenesis specifically the mode of action of nongenotoxic carcinogens, role of oxidative stress in carcinogenesis and cell injury, and understanding of the multistage nature of the cancer process.

Ulrike Luderer

University of California at Irvine

Dr. Ulrike Luderer is Assistant Professor of Medicine in the Division of Occupational and Environmental Medicine at the University of California at Irvine. She also holds joint appointments in the Departments of Developmental and Cell Biology and Environmental Toxicology. Dr. Luderer's research focuses on mechanisms of action of reproductive toxicants and on protective mechanisms against those toxicants. She is a recipient of a National Institute of Environmental Health Sciences research grant (2002-2007) entitled "Glutathione: Protecting Ovarian Follicles from Oxidant Injury" and a co-investigator on an EPA grant "Latent Effects of Gestational Exposure to Heptachlor". She has published peer-reviewed journal articles and book chapters and presented research at national and international scientific conferences on such topics as the effects of solvent exposure on reproductive endocrine function, the functions of and regulation of glutathione in the ovary, the differential regulation of follicle-stimulating hormone and luteinizing hormone secretion, and reviews of reproductive and developmental and endocrine toxicology. She has served on the National Toxicology Program/NIEHS Center for the Evaluation of Risks to Human Reproduction Expert Panel on 1- and 2-Bromopropane and on the National Research Council subcommittee on methyl bromide. She is currently a member of the Environmental Health Committee of the EPA Science Advisory Board. Dr. Luderer has a Ph.D. in reproductive endocrinology and M.D. from Northwestern University and is board-certified in Internal Medicine and in Occupational and Environmental Medicine. She has a Sc.B. in biomedical engineering from Brown University.

Robert Maronpot

National Institute of Environmental Health Sciences, National Toxicology Program

Dr. Robert Maronpot is Chief of the Laboratory of Experimental Pathology in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences since 1992. He has appointments as an Adjunct Professor at Duke University, University of North Carolina and

North Carolina State University. He received his Doctorate of Veterinary Medicine in 1965 from Michigan State University, an M.S. in nutritional pathology from Michigan State University in 1966, and an M.P.H. from Harvard University in 1972. He is a Diplomate of the American College of Veterinary Pathologists as well as the American Board of Toxicology and has worked over 30 years in experimental pathology with emphasis on animal models of carcinogenesis. Dr. Maronpot previously served as President of the Society of Toxicologic Pathology, serves on several journal editorial boards, and was Editor-in-Chief of Toxicologic Pathology from 2001 to 2004. In addition to over 250 peer-reviewed publications, he has edited a comprehensive text entitled "Pathology of the Mouse" (1999) and co-edited a book entitled "Pathology of Genetically Engineered Mice" (2000). His current position is Chief, Laboratory of Experimental Pathology, National Institute of Environmental Health Sciences, National Institutes of Health.

Mark Miller

California EPA-Office of Environmental Health Hazard Assessment (OEHHA)

Dr. Mark Miller has appointments as Assistant Clinical Professor in the departments of Pediatrics and Occupational and Environmental Medicine at the University of California San Francisco. He currently serves as the director of the University of California San Francisco- Pediatric Environmental Health Specialty Unit (PEHSU) and as a public health medical officer for the California EPA Office of Environmental Health Hazard Assessment, Air Pollution Toxicology and Epidemiology Section (CA EPA). He holds an MD degree from Michigan State University College of Human Medicine and completed his pediatric residency there. He has a MPH in environmental health sciences from the School of Public Health at U.C. Berkeley and completed a residency in preventive medicine with the California Department of Health Services. Dr. Miller spent more than 13 years as a pediatrician in private practice in California. At the California EPA, Dr. Miller is working on developing risk assessment methodology that addresses the unique vulnerabilities of children. In addition, he evaluates chemical-specific epidemiology and toxicology literature for Cal/EPA for use in health effects assessments for air pollutants. Most recently he has edited a review of the health effects of environmental tobacco smoke for the California Toxic Air Contaminant listing process. He is a Fellow of the American Academy of Pediatrics (AAP) and co-chair of California Chapter 1, American Academy of Pediatrics (AAP) Environmental Health Committee. In addition, he is a former member of the AAP National Committee on Environmental Health. Dr. Miller has served as a member of advisory committees and expert panels in the area of pediatric environmental health for the state of California and federal agencies, including the "Center for Evaluation of Risks to Human Reproduction" Expert Panel on Methanol and the USEPA/USDA Pesticide Tolerance Reassessment Advisory Committee. He is currently active in international environmental issues and serves on the Commission for Environmental Cooperation Lindane Action Plan Task Force. Dr. Miller is currently a member of the EPA Science Advisory Board Integrated Human Exposure Committee. Dr. Miller's work with the University of California PEHSU is funded by grants from the Agency for Toxic Substances and Disease Registry (ATSDR) and US Environmental Protection Agency administered by the Association of Occupational and Environmental Clinics. His articles on pediatric environmental health issues have appeared in such publications as Pediatrics, the International Journal of Toxicology, and the Handbook of Pediatric Environmental Health (published by the American Academy of Pediatrics).

Maria Morandi

University of Texas - Houston Health Science Center

Dr. Maria Morandi is an assistant professor of Environmental Sciences and Occupational Health at the School of Public Health of the University of Texas at Houston. She holds a BS degree in Chemistry from the City College of New York (1978), and MS (1981) and Ph.D. (1985) degrees in Environmental Sciences from the Norton Nelson Institute of Environmental Medicine of New York University. Dr. Morandi is also certified in Industrial Hygiene (CIH) by the American Board of Industrial Hygiene. Dr. Morandi's areas of expertise include assessment of indoor, outdoor and personal air concentrations of airborne contaminants in community and occupational environments, development of methods for personal exposure monitoring of gas and particle-phase airborne chemicals, evaluation of the effects from exposure to airborne particles and ozone on human and murine alveolar macrophages, and effects from exposure to airborne particles, ozone, and air toxics in children with asthma. She has also performed statistical modeling of PM source contributions. Dr. Morandi is a member of the Integrated Human Exposure Assessment Committee (formerly the Indoor Air and Total Human Exposure Assessment Committee) of the EPA Science Advisory Board. She was as member of the Research Strategies Advisory Committee between 1998 and 2003. Dr. Morandi has also served as member or chair of several EPA program review panels, the Agency for Toxic Substances Board of Scientific Councilors, and the National Institute of Occupational Health Study Section. Currently, she is a member of the Board of Scientific Counselors (BOSC) of the National Toxicology Program (NIEHS.), and the Chemical Exposures Working Group for the National Children Study (NCS). Dr. Morandi's sources of recent grant and/or other contract support funding include: (1) U.S. Environmental Protection Agency (several contracts on the use of passive dosimeters for monitoring indoor, outdoor and personal air concentrations of air toxics; a STAR grant on the effect of PM on murine and human alveolar macrophages; and an evaluation of the impact of attached garages on indoor and personal air concentrations of VOCs); (2) the Mickey Leland National Urban Air Toxics Research Center (impact of exposure to airborne carbonyls, PM and ozone on children with asthma); (3) The Health Effects Institute (HEI) (a population-based exposure study); and (4) NIOSH (for training Industrial Hygienists).

Walter Piegorsch

University of South Carolina

Walter W. Piegorsch is Professor of Statistics at the University of South Carolina, Columbia, SC. His research focuses on modeling and analysis for environmental data, with particular emphasis on the development of methods for estimating benchmark dose markers for use in quantitative risk analysis. He has been supported for this research for almost 10 years by the U.S. National Cancer Institute and the U.S. Environmental Protection Agency. His other areas of research interest include geo-spatially referenced disaster informatics, simultaneous inference for regression analyses including generalized linear models, and the historical development of statistical thought as prompted by problems in the biological and environmental sciences. Dr. Piegorsch has held a number of professional positions, including Chairman of the American Statistical Association Section on Statistics & the Environment (2004); Vice-Chair of the American Statistical Association Council of Sections Governing Board (1996-1999), and election to the Council of the International Biometric Society (2002-2004). For 2006-2008 he serves as Joint-Editor of the Journal of the American Statistical Association (Theory & Methods Section), the flagship journal of the association. He also has served as Co-Editor-in-Chief of the Encyclopedia of Environmetrics, a major publication in the quantitative environmental sciences published in 2002, and as a member

of many journal editorial boards including, Environmental and Ecological Statistics, Environmetrics, Environmental and Molecular Mutagenesis, Mutation Research, the Journal of the American Statistical Association, and Biometrics. Dr. Piegorsch has been honored as a Fellow of American Statistical Association (1995), a Member (by Election, 1995) of the International Statistical Institute, and has received the Distinguished Achievement Medal of the American Statistical Association Section on Statistics and the Environment (1993), and the University of South Carolina Educational Foundation Research Award for Science, Mathematics, and Engineering (2000). He earned his Ph.D. in Statistics at the Biometrics Unit, Cornell University, Ithaca, NY in 1984, after which he spent nine years as a practicing statistician with the U.S. National Institute of Environmental Health Sciences in Research Triangle Park, NC.

Stephen Roberts

University of Florida

Dr. Steve Roberts is Director of the Center for Environmental & Human Toxicology at the University of Florida, and is a Professor with joint appointments in the Department of Physiological Sciences in the College of Veterinary Medicine and the Department of Pharmacology and Therapeutics in the College of Medicine. He received his Ph.D. from the University of Utah College of Medicine in 1977, and subsequently completed a National Institutes of Health (NIH) individual postdoctoral fellowship in pharmacokinetics at SUNY Buffalo. He has previously served on the faculties of the College of Pharmacy at the University of Cincinnati and the College of Medicine at the University of Arkansas for Medical Sciences. Dr. Roberts has an active research program funded by the NIH to examine mechanisms of toxicity, primarily involving the liver and immune system. His teaching responsibilities at the University of Florida include graduate courses in toxicology and risk assessment, as well as invited lectures in other graduate and professional courses. Dr. Roberts serves as an advisor to the Florida Department of Environmental Protection on issues pertaining to toxicology and risk assessment. He has served on the committee on Bioavailability of Contaminants in Soils and Sediments for the National Research Council and he currently serves on the Board of Scientific Counselors of the National Toxicology Program.

Robert Schnatter

ExxonMobil Biomedical Sciences, Inc.

Dr. Robert Schnatter is the Senior Scientific Advisor at ExxonMobil Biomedical Sciences, Inc. (EMBSI) in Annandale, NJ. He is also a Senior Researcher at the Joint Sino-US Clinical and Molecular Laboratory at Fudan University in Shanghai, China. Dr. Schnatter received his B.S. in Biology from Rutgers University (1977), his M.S. in Biostatistics from the University of Pittsburgh (1979), his M.S. in Operations Research from Florida Institute of Technology (1980), and his Dr.PH in Epidemiology at Columbia University (1990). Prior to coming to EMBSI in 1987, Dr. Schnatter was the Corporate Biostatistician at Union Carbide Corporation since 1980, and worked for the National Center for Health Statistics in 1979. Dr. Schnatter's interests are in occupational health surveillance systems, retrospective exposure assessment, health effects of benzene and other hydrocarbons, genetic determinants of disease, and the use of epidemiologic data in risk assessments. He has been active in numerous professional societies, including the Society for Epidemiologic Research, the American College of Epidemiology (ACE), the American Industrial Hygiene Association, and the Society for Risk Analysis. He was chairman of the American Industrial Health Council's Epidemiology subcommittee from 1994 through 1997. He has published several articles on benzene health effects from a risk assessment perspective including industry's comprehensive benzene risk assessment under the EU's existing substances directive. He also serves as a reviewer for several scientific journals. He has served as a member of several advisory panels including the World Health Organization, the EPA, and the International Programme for Chemical Safety (IPCS) on benzene. Dr. Schnatter is currently a member of the EPA Science Advisory Board Environmental Health Committee. He has organized or chaired symposia for ACE, SRA, and ECETOC on the use of human epidemiological data in risk assessment. More recently, Dr. Schnatter receives funding from the University of Colorado's Health Sciences Center (UCHSC) to participate in a five year study in Shanghai, China on molecular epidemiology studies of benzene workers. Besides his annual salary from EMBSI, (part of which is covered by the UCHSC), Dr. Schnatter also has received small stipends from the Agency for Toxic Substances and Disease Registries for participating in expert panels and study reviews.

I. Glen Sipes

University of Arizona

Dr. Sipes earned a B.S. in Pharmacy from the University of Cincinnati (1965) and the Ph.D. in Pharmacology from the University of Pittsburgh (1969). After three years as a staff fellow at NIH, with Drs. B. Brodie and J. Gillette, he joined the faculty at the University of Arizona as an assistant professor in 1973. There he developed a research program with emphasis on the biotransformation of drugs and environmental chemicals and on mechanisms of chemical-induced liver and ovarian injury. He is the author of over 200 research publications and several review articles and book chapters. As an academic scientist, Dr. Sipes has trained 32 MS and 26 PhD students and mentored 25 postdoctoral fellows. Dr. Sipes currently serves as Professor and Head of the Department of Pharmacology in the College of Medicine at the University of Arizona. He is also Professor of Pharmacology and Toxicology and Anesthesiology. For 19 years he served as Head of the Department of Pharmacology and Toxicology in the College of Pharmacy and was the founding Director of the Center for Toxicology. Dr. Sipes is active in the Society of Toxicology having served as a Councilor, Secretary, Vice President and President. Dr. Sipes served as Editor of Toxicology and Applied Pharmacology, an official journal of the Society for seven years and was an associate editor of Life Sciences and on the editorial boards of Quality Assurance and Annual Review of Pharmacology and Toxicology, and Molecular Interventions. Other professional activities include serving as a Councilor for the International Society for the Study of Xenobiotics; as a Councilor and as Chair of the Pharmaceutical Sciences section for the American Association for the Advancement of Science, of which he is also a Fellow; as a member of the NAS/NRC Committee of Toxicology and Board of Environmental Studies and Toxicology and as Chairperson of the NIH Toxicology Study Section and a member of the National Advisory Environmental Health Sciences Council. He was a Burroughs Wellcome Toxicology Scholar from 1985-1990 and was elected a Fellow of the Academy of Toxicological Sciences. He served as Editor-in-Chief of the 13 volume series entitled, Comprehensive Toxicology. From 1998-2004, Dr. Sipes served as President of the International Union of Toxicology and then as Past President. He is a technical advisor (currently chair) to the Joint Expert Committee on Food Additives for the United Nations/WHO and a member of Research Institute for Fragrance Material's Expert Panel. In addition he has served as a consultant and/or on advisory committees for several pharmaceutical and chemical companies.

Thomas Starr

TBS Associates

Dr. Thomas B. Starr trained academically in theoretical physics, first at Hamilton College (B.A., 1966), and then at the University of Wisconsin-Madison, (M.S., 1968, and Ph.D. 1971). Following NSF postdoctoral and faculty appointments in the Institute for Environmental Studies at Wisconsin, in 1981 he joined CIIT as a senior scientist in the Department of Epidemiology, and from 1987 onward, as Director of its Program on Risk Assessment. In 1989, he joined ENVIRON International Corporation as a Principal in its Health Sciences Division, with quantitative risk assessment as his main practice area. In 1998, he became an independent consultant, founding TBS Associates. His research and consulting interests have been aimed at incorporating knowledge of toxic mechanisms into quantitative risk assessment, and improving epidemiologic methods for assessing human health. He has published over 80 scientific papers and abstracts, and given hundreds of scientific presentations. Dr. Starr is an adjunct Associate Professor in the Department of Environmental Sciences and Engineering in the School of Public Health at the University of North Carolina-Chapel Hill. He has been appointed to numerous advisory posts, including the Halogenated Organics Subcommittee of the U.S. Environmental Protection Agency's Science Advisory Board, the North Carolina Academy of Sciences Air Toxics Panel, and the North Carolina Environmental Management Commission Ad Hoc Committee for Air Toxics. Currently, he is member of the Secretary's Scientific Advisory Board on Toxic Air Pollutants for the North Carolina Department of Environmental Health and Natural Resources. He has testified before OSHA, EPA, other regulatory agencies, and Congress regarding the potential human health risks posed by various chemical exposures, including 1,3-butadiene, cadmium, dioxin-like compounds, formaldehyde, lead, methylene chloride, particulate matter, pesticides, and environmental tobacco smoke. He is a full active member of the American Statistical Association, the Society for Risk Analysis, and the Society of Toxicology. In 1988-89 he served as the first President of SOT's Risk Assessment Specialty Section, and in 1989-90 as President of the Research Triangle Chapter of the Society for Risk Analysis.

Leslie T. Stayner

University of Illinois

Dr. Stayner is currently a Professor of Epidemiology and Director of the Division of Epidemiology and Biostatistics at the University of Illinois' School of Public Health in Chicago. Previously he worked at the National Institute for Occupational Safety and Health for nearly 25 years and in his last position was the Chief of their Risk Evaluation Branch. Dr. Stayner is well recognized nationally and internationally in the area of Occupational and Environmental Epidemiology. He has approximately 100 scientific papers and book chapters. His research interests are primarily on occupational and environmental cancer, and epidemiologic methods particularly with regard to quantitative risk assessment. He has been involved in conducting research on cancer and exposure to asbestos, 1,3-butadiene, formaldehyde, diesel exhaust, hexavalent chromium, cadmium, silica and ethylene oxide. He has served or is serving as an advisor to numerous agencies including ATSDR, EPA, NRC, OSHA, MSHA and the WHO. He has also worked as a Visiting Scientist with the International Agency for Research on Cancer (IARC) in Lyon France and has participated in numerous of their monograph meetings.

Anne Sweeney

Texas A&M University

Dr. Anne Sweeney is an Associate Professor of Epidemiology at the Texas A&M University System School of Rural Public Health in Bryan, Texas. She received a B.S. degree in Nutrition and Dietetics in 1975 from Marywood College. She earned both her MPH and Ph.D. degrees in Epidemiology from the University of Pittsburgh, Graduate School of Public Health in 1988 and 1991, respectively. Dr. Sweeney served as a member of the Institute of Medicine's Gulf War and Health Study Committee, on the expert panel assessing the health effects of pesticides. She is also a member of the Fertility and Early Pregnancy Committee, assigned to the National Longitudinal Cohort Study Planning Committee, sponsored by the National Institute of Child Health and Human Development, the National Institute for Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. EPA. Dr. Sweeney is currently a member of the EPA Science Advisory Board Environmental Health Committee. Her research interests include environmental and occupational exposures to toxic agents and the relation to adverse reproductive effects, particularly infertility, early pregnancy loss, and congenital anomalies. Dr. Sweeney has had extensive experience conducting large population-based studies of cohorts exposed to endocrine active compounds, including PCBs, PBBs, dioxin, and phthalates, and their effects on pregnancy outcome. She is currently the Principal Investigator on a project under the FRIENDS Children's Environmental Health Center, awarded to the University of Illinois at Urbana-Champaign, by the National Institute for Environmental Health Sciences and the U.S. EPA, as well as a project to assess PCBs and OCs and fecundity and fertility, awarded by the National Institute for Child Health and Human Development.

James Swenberg

University of North Carolina (Chapel Hill)

Dr. James Swenberg is a Kenan Distinguished Professor of Environmental Sciences and Engineering and Professor of Nutrition, and Pathology and Laboratory Medicine at the University of North Carolina at Chapel Hill. He also serves as the Director of Center for Environmental Health and Susceptibility, and the Curriculum in Toxicology at the University of North Carolina at Chapel Hill. Before joining the University of North Carolina, he was a Department Head at the Chemical Industry Institute of Toxicology from 1978-89, Research Scientist and Section Head, Pathology & Toxicology Research Unit, The Upjohn Company from 1972-78, and Assistant and Associate Professor of Veterinary Pathology at the Ohio State University. Dr. Swenberg earned his D.V.M. degree from the University of Minnesota and his Ph.D. degree in Veterinary Pathology from the Ohio State University. He is a Diplomate of the American College of Veterinary Pathologists and a member of the American Association for Cancer Research, American Association of Neuropathologists, American Society for Investigative Pathology, Society of Toxicologic Pathologists, and the Society of Toxicology. He has served on the Board of Scientific Counselors, Division of Cancer Etiology, NCI, Board of Scientific Counselors, National Toxicology Program, NIEHS, and Board of Scientific Counselors, NIEHS, as well as a member of the FIFRA Scientific Advisory Panel, EPA, and was elected to the Society of Toxicology Council. He was awarded the George Scott Award from the Toxicology Forum, the John Barnes Prize Lectureship from the British Toxicology Society, the Distinguished Alumnus Award from The Ohio State University College of Veterinary Medicine, and the Distinguished Research Alumnus Award from the University of Minnesota College of Veterinary Medicine. Dr. Swenberg has published over 300 scientific papers and has served on the editorial boards of Cancer Epidemiology,

Biomarkers and Prevention; Cancer Research; Carcinogenesis; Chemical-Biological Interactions; Chemical Research in Toxicology; Environmental Health Perspectives; Food and Chemical Toxicology; Fundamental and Applied Toxicology; Neuro-Oncology; and Toxicologic Pathology. His research focuses on mechanisms of carcinogenesis and toxicology, with emphasis on the roles of DNA damage and repair and cell proliferation. He has published extensively on the use of mass spectrometry for DNA and protein adducts, including those arising from environmental and endogenous chemicals. Most recently, he has been investigating direct and indirect DNA damage arising from oxidative stress.

Mary Jane Teta

Exponent

Dr. M. Jane Teta is a Principal Scientist and the Practice Director of Exponent's Health Sciences practice. She has over 25 years experience in chronic disease epidemiology, particularly occupational and environmental epidemiology studies; regulatory risk assessment, particularly for cancer endpoints; and risk communication to the media and public. In addition, she has expertise in EPA/OSHA/NTP regulatory issues related to chemicals. Dr. Teta has served on numerous scientific advisory boards including those of ATSDR, EPA, The Mickey Leland Center and the Harvard Center for Risk Analysis. She is also an Adjunct Associate Professor of Epidemiology in the Department of Biostatistics and Epidemiology at the University of Massachusetts. Prior to joining Exponent, Dr. Teta was the Director of Epidemiology, Health Information, Risk Assessment, and TSCA for Union Carbide Corporation, managing epidemiology program planning and implementation, design, management, and communication of studies to employees, and providing consultation to businesses and manufacturing sites. Dr. Teta received a Doctorate in epidemiology and a Masters of Public Health in biostatistics from Yale University.

Vernon Walker

University of New Mexico; Respiratory Research Institute

Dr. Vernon Walker is a Research Scientist and Veterinary Pathologist in the Cancer Biology Program at the Lovelace Respiratory Research Institute (LRRI). He also served as a Clinical Associate Professor in the College of Pharmacology at the University of New Mexico. Dr. Walker received his DVM degree from the University of Tennessee in 1983, followed by residency training in pathology at Auburn University, College of Veterinary Medicine and the University of Alabama in Birmingham, College of Medicine and Dentistry. He received a Ph.D. degree from Duke University in 1991, followed by postdoctoral training at the University of North Carolina. Since 1994, Dr. Walker has conducted independent research first at the Wadsworth Center (at the New York State Department of Health, and as an Assistant Professor in the Department of Environmental Health and Toxicology, School of Public Health, SUNY-Albany) and now at LRRI. His research has focused on the identification and validation of biological markers that are suitable for investigating genotoxic mechanisms, determining human exposures, and evaluating human risks associated with exposure to chemical/physical agents in the environment/workplace or as a consequence of medical therapies. A major part of his research has been concerned with the characterization of the dose effects and genotoxic risks from exposures to several important industrial chemicals and environmental pollutants that are epoxide/epoxide-forming compounds (e.g., acrylonitrile, 1,3-butadiene, and ethylene oxide) known to induce lung tumors in mice and brain tumors in rats. Another aspect of his research has focused on the potential for azidothymidine, and other nucleoside analogues reverse transcriptase inhibitors (NRTIs), to be incorporated into host cell DNA and to act as clastogens or mutagens and mitochondrial toxins in children born to HIV-infected women who received highly active antiretroviral therapy. Current research is directed toward the development of a new drug-based antiretroviral therapy that both inhibits HIV replication and protects against NRTI-induced DNA damage and health risks. Dr. Walker has served on numerous review and advisory panels, with current activities including membership on the Toxicology Study Selection and Review Committee (for the NCTR/FDA) and the Board of Scientific Counselors for the National Toxicology Program. Support for his research has been derived from the National Institutes of Health, industry and private foundations such as the Health Effects Institute.

ATTACHMENT 4

List of public commenters on the “Short List” candidates

- 1- David Egilman, MD, MPH, Brown University
- 2- Suzi Goldmacher, RN, MSN
- 3- Susanna Rankin Bohme, AM
- 4- Jennifer Sass, PhD, Natural Resources Defense Council on behalf of worker and public health advocates