



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
EPA SCIENCE ADVISORY BOARD

February 1, 2008

**MEMORANDUM**

**SUBJECT:** Science Advisory Board (SAB) Acrylamide Toxicological 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 IRIS Toxicological Review of Acrylamide. 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, "Toxicological Review of Acrylamide" (August 2006). Acrylamide polymer is primarily used in waste water treatment, paper and pulp processing, and mineral processing. Other uses include as a water soluble polymer in crude oil production, as a cosmetic additive, for soil and sand stabilization, grouting agents for sewer line sealing and manhole sealing, and in electrophoresis gels used in research. Acrylamide has been detected in a wide range of baked and fried foods. The detection of acrylamide in food prompted intense international interest and on-going research to better characterize its hazard effects, and to modify cooking practices to minimize levels in processed foods. EPA's National Center for Environmental Assessment, within the Office of Research and Development, has been updating the human health hazard and dose-response assessment for Acrylamide. EPA previously developed an oral reference dose (RfD) for non-cancer effects and a cancer oral slope factor for Acrylamide which are described in EPA's Integrated Risk Information System (IRIS) assessment (1988). An inhalation reference concentration (RfC) was added to IRIS in 1990. The current EPA draft assessment incorporates more recent studies and methods to derive an oral RfD and inhalation RfC for non-cancer effects, and an oral slope factor and inhalation unit risk for carcinogenic effects. ORD requested that the SAB comment on the scientific soundness of EPA's "Toxicological Review of Acrylamide".

1) Panel Formation: The peer review will be conducted by a SAB *Ad Hoc* Review Panel. This Panel, known as the Acrylamide Review Panel, will be composed of SAB members and invited outside experts. A federal register notice was published on March 29, 2007 requesting nominations of individuals with the following expertise, expertise in one or more of the following areas, especially with respect to the health effects of Acrylamide: neurotoxicology; epidemiology; toxicology, including reproductive/developmental toxicology, genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; and exposure and risk assessment (see Attachment 1). On the basis of the candidates' credentials and willingness to serve on the panel, the SAB Staff Office initially identified twenty one (21) nominees for the "short list" of candidates and later identified four (4) additional candidates.

On July 24, 2007, 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 2). 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 August 13, 2007. On September 18, 2007, the SAB Staff Office posted an updated notice on the SAB Web site inviting public comments on the additional prospective candidates being considered for the Panel; comments were due no later than October 2, 2007. The SAB Staff Office received three submissions with comments on "short list" candidates for the Acrylamide Review Panel (Attachment 3).

## 2) Conflict of Interest 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 Acrylamide.

### 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)].

While acrylamide has been detected in a wide range of baked and fried foods and may be considered a *particular matter of general applicability*, IRIS toxicologic reviews typically focus on health effects and do not include exposure estimates or make any conclusions regarding the risk associated with such exposures. 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 (Acrylamide) 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 Acrylamide 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.**

### 3) 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 Acrylamide 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.

#### 4) 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.

5) 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 of a 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 Acrylamide Review Panel includes the following experts:

Dr. Deborah Cory-Slechta, University of Rochester (CHAIR)  
Dr. Alfred Branen, University of Idaho  
Dr. Daniel Doerge, Food and Drug Administration- National Center for Toxicological Research  
Dr. James Felton, Lawrence Livermore National Laboratory  
Dr. Timothy Fennell, Research Triangle Institute (RTI) International

Dr. Pennelope Fenner-Crisp, Consultant  
Dr. Jeffery Fisher, University of Georgia  
Dr. Sean Hays, Summit Toxicology  
Dr. Steven Heeringa, University of Michigan  
Dr. Richard LoPachin, Montefiore Medical Center  
Dr. Lorelei Mucci, Harvard University  
Dr. Jerry M. Rice, Georgetown University  
Dr. Dale Sickles, University of Georgia  
Dr. Gina Solomon, National Resources Defense Council  
Dr. Anne Swenney, Texas A&M University  
Dr. Lauren Zeise, California EPA

Concurred,

Date

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/s/

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February 1, 2008

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

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## ATTACHMENTS

Attachment 1	Federal Register Notice- Request for nomination of experts
Attachment 2	Invitation for comments on the "Short List" candidates
Attachment 3	List of public commenters on the "Short List" candidates

ATTACHMENT 1

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

[Federal Register: March 29, 2007 (Volume 72, Number 60)]  
[Notices]  
[Page 14804-14805]

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ENVIRONMENTAL PROTECTION AGENCY  
[FRL-8293-3]

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

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

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

DATES: Nominations should be submitted by April 19, 2007, per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Request for Nominations may contact Dr. Suhair 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](mailto: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: Acrylamide polymer is primarily used in waste water treatment, paper and pulp processing, and mineral processing. Other uses include as a water soluble polymer in

crude oil production, as a cosmetic additive, for soil and sand stabilization, grouting agents for sewer line sealing and manhole sealing, and in electrophoresis gels used in research. Acrylamide has been detected in a wide range of baked and fried foods. The detection of acrylamide in food prompted intense international interest and on-going research to better characterize its hazard effects, and to modify cooking practices to minimize levels in processed foods. EPA's National Center for Environmental Assessment, within the Office of Research and Development, has been updating the human health hazard and dose-response assessment for Acrylamide. EPA previously developed an oral reference dose (RfD) for non-cancer effects and a cancer oral slope factor for Acrylamide which are described in EPA's Integrated Risk Information System (IRIS) assessment (1988). An inhalation reference concentration (RfC) was added to IRIS in 1990. The current EPA draft assessment incorporates more recent studies and methods to derive an oral RfD and inhalation RfC for non-cancer effects, and an oral slope factor and inhalation unit risk for carcinogenic effects. ORD has requested that the Science Advisory Board (SAB) review its draft assessment entitled ``Toxicological Review of Acrylamide''.

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 Acrylamide Review Panel, conducting the review of the Agency's draft assessment of Acrylamide, will consist of members of the chartered SAB, SAB Committee members and additional external experts. 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 Acrylamide Review Panel is being asked to comment on the scientific soundness of this draft 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. Rob Dewoskin, at (919) 541-1089, or [dewoskin.rob@epa.gov](mailto:dewoskin.rob@epa.gov).

Request for Nominations: The SAB Staff Office is requesting nominations of nationally recognized experts with expertise in one or more of the following areas, especially with respect to the health effects of Acrylamide: neurotoxicology; epidemiology; toxicology, including reproductive/developmental toxicology, genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; and exposure and risk assessment.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals for possible service on the Acrylamide Review Panel in the areas of expertise described above. 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>. Please follow the instructions for submitting nominations carefully. To be considered, nominations should include all of the information required on the associated forms. Anyone unable to submit nominations using the electronic form and who has any questions concerning the nomination process may contact Dr. Suhair Shallal, DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than April 19, 2007.

For nominees to be considered, please include: contact information; a curriculum vitae; a biosketch of no more than two paragraphs (containing information on the nominee's current position, educational background, areas of expertise and research activities, service on other advisory committees and professional societies; the candidate's special expertise related to the panel being formed; and sources of recent grant and/or contract support).

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketchs of qualified nominees identified by respondents to the Federal Register notice and additional experts identified by the SAB Staff will be posted on the SAB Web Site at: <http://www.epa.gov/sab>. Public comments on this "Short List" of candidates will be accepted for 21 calendar days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced subcommittee or review panel includes 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. In establishing the final Acrylamide Review Panel (ARP), the SAB Staff Office will consider public comments on the "Short List" of candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for Panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, etc.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of 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/pdf/epaform3110-48.pdf>.

The approved policy under which the EPA SAB Office selects subcommittees and review 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: March 21, 2007

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

## ATTACHMENT 2

### **Invitation for Comment on the EPA Science Advisory Board Additional Short List Candidates for the Acrylamide Review Panel**

**September 18, 2007**

The EPA Science Advisory Board (SAB) Staff Office announced in a *Federal Register* Notice (Volume 72, Number 60, Pages 14804-14805) that it was forming a panel to conduct a peer review of EPA's Draft Toxicological Review of Acrylamide. To form the panel, the SAB Staff Office sought public nominations of nationally recognized experts with expertise in one or more of the following areas, especially with respect to the health effects of Acrylamide: neurotoxicology; epidemiology; toxicology, including reproductive/developmental toxicology, genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; and exposure and risk assessment. On July 24, 2007, the SAB Staff Office posted a short list of 21 candidates for public comment.

The SAB Staff Office has identified 4 additional candidates who have the relevant expertise for panel membership. Brief biographical sketches ("biosketches") on these expert candidates are provided below. We hereby invite comments from members of the public for relevant information, analysis or other documentation that the SAB Staff Office should consider in evaluating these additional candidates.

The SAB Staff Office Director makes the final decision about who serves on the review panel, based on all relevant information. This includes a review of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of a lack of impartiality. For the EPA SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual Panel member include: (a) scientific and/or technical expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, etc.

Please provide any comments you may have with respect to the "Updated Short List" candidates, no later than October 2, 2007. Please make your comments to the attention of Dr. Suhair Shallal, Designated Federal Officer. Emailing comments ([shallal.suhair@epa.gov](mailto:shallal.suhair@epa.gov)) is the preferred mode of receipt.

## List of Additional Candidates for the Acrylamide Review Panel

### Colford, John (Jack)

University of California, Berkeley

Jack Colford, MD PhD is an Associate Professor of Epidemiology at the University of California, Berkeley, School of Public Health. He is a graduate of the Johns Hopkins School of Medicine (MD 1985) and the UC Berkeley School of Public Health (PhD, Epidemiology, 1996). He completed a residency in Internal Medicine and a fellowship in Infectious Diseases at the University of California, San Francisco. He was Chief Medical Resident at Stanford University Hospital. He is board-certified in both Internal Medicine and Infectious Diseases and is also an Attending Physician at the San Francisco VA Medical Center ID clinic. Dr. Colford is the sole instructor in semester-long courses in advanced epidemiologic methods, intervention trial design, and meta-analysis and has received several teaching awards. He has taught for many years as a visiting professor each summer at the University of Michigan (meta-analysis) and the University of Zurich, Switzerland (epidemiologic methods). Dr. Colford has been an author of more than 40 peer-reviewed scientific publications, including numerous peer-reviewed articles on the health effects of waterborne diseases. He has received more than \$11.0 million in research funding. He is the Principal Investigator of four triple-blinded, randomized controlled trials of drinking water and health effects funded by the National Institutes of Health, the Centers for Disease Control, and the Environmental Protection Agency, and the University of California. These have included large trials in the United States as well as a drinking water study in 22 villages now underway in Bolivia. He was the Principal Investigator of the Mission Bay Epidemiology study of the health effects of recreational water exposure, funded by the California Regional Water Quality Control Board. He was asked by an NRC committee to review all health evidence of associations between recreational water indicators and health outcomes. Dr. Colford recently returned to UC Berkeley after a one year sabbatical at the World Health Organization (Water, Sanitation, and Health Division) in Geneva, Switzerland where he collaborated with the World Bank in a published monograph and peer-reviewed manuscript evaluating the effectiveness of drinking water treatments throughout the world.

### Ginsberg, Gary

Connecticut Department of Public Health

Dr. Ginsberg is a toxicologist at the CT Dept. of Public Health within the Division of Environmental and Occupational Health Assessment. He has responsibility for human health risk assessments conducted in the state. Dr. Ginsberg serves as adjunct faculty at the Yale School of Medicine and is an Assistant Clinical Professor at the University of Connecticut School of Medicine. He recently finished serving on the National Academy of Science Panel on Biomonitoring and he currently serves on the NAS Panel that is evaluating USEPA risk methods. He has been invited to testify at Congressional hearings on toxics issues on a number of occasions. He received a Ph.D. in toxicology from the University of Connecticut (Storrs) and was a post-doctoral fellow in carcinogenesis/ mutagenesis at the Coriell Institute for Medical Research. Dr. Ginsberg's toxicology experience has involved a variety of settings: basic research, teaching, working within the pesticide and consulting industries, and now working in public health. He has published in the areas of toxicology, carcinogenesis, physiologically-based pharmacokinetic modeling, inter-individual variability and children's risk assessment.

## Heeringa, Steven

University of Michigan

Dr. 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.

## Sweeney, Anne

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. 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.

**Invitation for Comment on the EPA Science Advisory Board  
Short List Candidates for the Acrylamide Review Panel**

**July 23, 2007**

The EPA Science Advisory Board (SAB) Staff Office announced in a *Federal Register* Notice (Volume 72, Number 60, Pages 14804-14805) that it was forming a panel to conduct a peer review of EPA's Draft Toxicological Review of Acrylamide. To form the panel, the SAB Staff Office sought public nominations of nationally recognized experts with expertise in one or more of the following areas, especially with respect to the health effects of Acrylamide: neurotoxicology; epidemiology; toxicology, including reproductive/developmental toxicology, genetic toxicology and mechanisms of action for carcinogenicity; metabolism; pharmacokinetics and modeling; dose-response assessment; and exposure and risk assessment.

Background information on the project and details on the nomination process appeared in the cited notice. The notice is available on the SAB Website at <http://www.epa.gov/sab/>.

Based on qualifications, interest and willingness to serve of the nominees, the SAB Staff Office has identified 21 candidates who have the relevant expertise for panel membership. Brief biographical sketches ("biosketches") on these expert candidates are provided below. We hereby invite comments from members of the public for relevant information, analysis or other documentation that the SAB Staff Office should consider in evaluating these candidates.

The SAB Staff Office Director makes the final decision about who serves on the review panel, based on all relevant information. This includes a review of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of a lack of impartiality. For the EPA SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual Panel member include: (a) scientific and/or technical expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, etc.

Please provide any comments you may have with respect to the "Short List" candidates, no later than August 13, 2006. Please make your comments to the attention of Dr. Suhair Shallal, Designated Federal Officer. Emailing comments ([shallal.suhair@epa.gov](mailto:shallal.suhair@epa.gov)) is the preferred mode of receipt.

## List of Prospective Candidates for the Acrylamide Review Panel

### Branen, Alfred

University of Idaho

Larry Branen is the Associate Vice President for UI Northern Idaho and serves as the major spokesperson for the University of Idaho regarding Northern Idaho goals, objectives and strategies. He is the chief administrator of programs at the University of Idaho Coeur d'Alene Center and the University of Idaho Research Park. Larry also serves as a Professor of Food Science and is actively involved in the Biosensor and Nanotechnology Applications Laboratory with a focus on the development and application of biosensors to agriculture, food and health sciences. Dr. Branen is an Idaho native and grew up on a farm near Wilder, Idaho. After receiving his BS at the University of Idaho and his Ph.D. in food science at Purdue University, Dr. Branen served in faculty and administrative roles at the University of Wisconsin, Washington State University, and the University of Nebraska. He returned to the University of Idaho, College of Agriculture as associate dean and director of resident instruction in 1983 and was named dean of the College of Agriculture in 1986. Dr. Branen continued as dean until July 1993 when he returned to a faculty position in the Department of Food Science and Toxicology. He returned again to administration in 1997 as the UI Executive Director for Institutional Planning and Budget and led the development of the UI strategic plan. From 1998-2003 he served a second term as the dean of the College of Agricultural and Life Sciences. Dr. Branen is a member of several professional organizations and is the author of more than 50 publications in food science and has edited 4 books on food additives. He recently completed a review on the level of acrylamide in foods.

### Clewell, Harvey

CIIT Centers for Health Research

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.

### Cory-Slechta, Deborah

University of Medicine and Dentistry of New Jersey and Rutgers University

Dr. Deborah Cory-Slechta received her Ph.D. degree from the University of Minnesota in 1977 and worked as a junior staff fellow of the National Center for Toxicological Research beginning in 1979. She was appointed to the faculty of the University of Rochester Medical School in 1982 and rose through the ranks. In 1998, she was appointed Chair of the Department of Environmental Medicine and Director of the NIEHS Environmental Health Sciences Center at the University of Rochester. From July 2000- July 2002, she was the Dean for Research and Director of the AAB Institute for Biomedical Sciences, a newly established post at the University and as such, became the first female dean in the

history of the Medical School. Dr. Cory-Slechta has served on numerous national research review and advisory panels, including committees of the National Institutes of Health, the National Institute of Environmental Health Sciences, the Food and Drug Administration, the National Center for Toxicological Research, the Environmental Protection Agency, the National Academy of Sciences, the Institute of Medicine, and the Agency for Toxic Substances and Disease Registry, Centers for Disease Control. In addition, Dr. Cory-Slechta has served on the editorial boards of several journals including Neurotoxicology, Toxicology, Toxicological Sciences, Fundamental and Applied Toxicology, Neurotoxicology and Teratology, and American Journal of Mental Retardation. She has held the elected positions of President of the Neurotoxicology Specialty Section of the Society of Toxicology, President of the Behavioral Toxicology Society, and been named a Fellow of the American Psychological Association. Her research has focused largely on environmental neurotoxicants as risk factors for behavioral disorders and neurodegenerative disease. Specifically this has included work on the impact of lead on learning and attention and associated neurochemical mechanisms, and, more recently on the role of pesticides as risk factors for Parkinson's Disease. Currently she has also begun to examine mixtures of neurotoxic chemicals and risk modifiers for effects of neurotoxicants as well. These research efforts have resulted in over 100 papers and book chapters to date.

### **Doerge, Daniel R.**

#### **Food and Drug Administration**

Dr. Doerge has been a Research Chemist in the Division of Biochemical Toxicology at the National Center for Toxicological Research, Jefferson, AR since 1992 where he conducts basic and applied research to support the regulatory mission of the U.S. Food and Drug Administration. Dr. Doerge was Assistant and Associate Professor of Environmental Biochemistry at the University of Hawaii, Manoa from 1984 to 1992. His areas of research specialization have been: chemical and biochemical mechanisms of toxicity; thyroid toxicology; toxicology of soy isoflavones; toxicology of acrylamide; and applications of modern mass spectrometry that emphasize high throughput determinations of pharmacokinetics and DNA adducts. More than 180 peer-reviewed publications have resulted from this work. Current research interests include mechanisms for cooking carcinogens and the integration of biomonitoring with PBPK modeling to better extrapolate human risks from rodent toxicity. Dr. Doerge has recently received research funding from the National Institute of Aging (Phytoestrogens and Aging) and the Joint Institute for Food Safety and Applied Nutrition (Development of a PBPK/PD Model for Acrylamide). Dr. Doerge has also served as Editor-in-Chief for Archives of Environmental Contamination and Toxicology since 1996.

### **Elwell, Michael**

#### **Covance Laboratories, Inc.**

Dr. Michael Elwell is a Principal Scientist in the Department of Pathology at Covance Laboratories in Vienna, VA. He received his PhD in pathology from the University of Kansas (1982) and both his DVM in Veterinary Medicine (1972) and his BS in biological sciences (1970) from Kansas State University. Dr. Elwell's areas of expertise and information on his service with other organizations can be found in his attached CV.

### **Felton, James S.**

#### **Lawrence Livermore National Laboratory**

Dr. James Felton is past Assoc. Dep. Director at Lawrence Livermore National Laboratory (LLNL) for Biology and Biotechnology. Currently he is Senior Biomedical Scientist at LLNL and Assoc. Director for Cancer Control at University of California, Davis Cancer Center (UCDCC). He received his Ph.D. at the State University of New York at Buffalo (Roswell Park Memorial Institute) under Kenneth Paigen and did his Postdoctoral training at NIH under Dr. Daniel Nebert. He is also an adjunct Professor at UC Davis in the Department of Applied Sciences. His research has been focused on the etiology and risk of dietary carcinogenesis for 29 years, all at LLNL. He has published more than 210 articles and book chapters on this subject and has chaired numerous International meetings on this topic. Dr. Felton

has been the President of the US Environmental Mutagen Society and served on the Board of Scientific Counselors to the NCI Division of Cancer Etiology. He is a past member of subcommittee E of the NCI reviewing PO1s, UO1s, and RO3s related to cancer prevention, control, and causation. He also in 1993 served as chair of an NCI committee to study the 10 year research accomplishments in basic cancer mechanisms. Currently, his research is looking at susceptibility to heterocyclic amine carcinogens in the diet. He has developed mass spectrometric methods to analyze human urinary metabolites of these carcinogens based on a single meal of well-done chicken or meat. He is the PI on a NCI funded PO1 grant (15th yr) to study in a comprehensive way the risks from consuming these carcinogens in our diet. This work is broad based, as it uses genomics, bio-computations, analytical chemistry, accelerator mass spectrometry, synthetic chemistry, mutation analysis, biomarkers, and epidemiology to understand this possible etiology of human cancers.

### **Fennell, Timothy**

#### **RTI International**

Dr. Timothy Fennell is currently employed as a Senior Research Chemist at RTI International in Research Triangle Park, NC. He has over 25 years of experience in drug and chemical metabolism and pharmacokinetics. Tim joined the RTI staff in July 2002. Prior to that time (1986-2002), he was a Scientist at the CIIT Centers for Health Research. He has a B.Sc. (1976) and Ph.D. (1980) in Biochemistry from the University of Surrey in England. He conducted postdoctoral research at the McArdle Laboratory for Cancer Research at the University of Wisconsin – Madison. Dr. Fennell has been involved in research on a variety of chemicals, with particular emphasis on understanding the effects of metabolism and disposition on the generation of adverse effects. He has expertise in the measurement of DNA and protein adducts. Much of his recent research has focused on the metabolism and adduct formation of acrylamide and glycidamide. Dr. Fennell and colleagues were instrumental in elucidating the metabolism of acrylamide in rodents and people. He has used adducts derived from acrylamide and glycidamide to make comparisons of internal dose between species, between route of exposure and administered dose. Dr. Fennell is a member of a number of professional societies, including the Society of Toxicology, the American Chemical Society, and the American Association for the Advancement of Science. He has served as Vice President, President Elect, President and Past President of the North Carolina Chapter of the Society of Toxicology. He has served on the editorial board of a number of journals including Toxicological Sciences, Toxicology Letters, and was Associate Editor of Biomarkers (1996-2001). He has served as an adjunct faculty member at Duke University, and the University of North Carolina at Chapel Hill.

### **Fenner-Crisp, Penelope**

#### **Consultant- ILSI**

Dr. Fenner-Crisp is currently a private consultant. She is the former Executive Director of the Risk Science Institute of the International Life Sciences Institute (ILSI), a global, non-profit, scientific organization dedicated to seeking scientific solutions to important public health issues related to food and nutrition, food safety, water quality, chemical safety and environmental health and assessment of human health and environmental risk. She received a B.S. in Zoology from the University of Wisconsin-Milwaukee, an M.A. and Ph.D. in Pharmacology from the University of Texas Medical Branch-Galveston and spent two years at Georgetown University Schools of Medicine and Dentistry as a post-doctoral fellow in Pharmacology-Morphology from the then-Pharmaceutical Manufacturer's Association Foundation. Dr. Fenner-Crisp's current areas of expertise include human health and environmental risk assessment, toxicology, science policy and its integration into regulatory decision-making and familiarity with environmental regulatory programs and practices, all of which are a continuation of her activities and responsibilities during her 22 years at EPA. Her current service on advisory committees and boards consists of membership on the Drinking Water Committee of the Science Advisory Board, OPPT's National Pollution Prevention and Toxics Advisory Committee and as an ad hoc member of the FIFRA Scientific Advisory Panel (February 2007) as well as a member of the board of GreenBlue, a Charlottesville, VA-based not-for-profit organization whose mission is to inspire

a transformation in the design of human industry to achieve sustainability. She has served on the board of the American Board of Toxicology. She is a Charter member of the Society for Risk Analysis (SRA), having received its first Risk Practitioner's Award in 1996, the Capital Area Chapter of SRA, and a long-time member of the Society of Toxicology and its National Capital Area Chapter.

### **Fisher, Jeffrey**

#### **University of Georgia**

Dr. Jeffrey Fisher is a Professor in the Department of Environmental Health Science, College of Public Health at the University of Georgia (UGA). He joined the University of Georgia in 2000 and served as Department Head of the Department of Environmental Health Sciences from 2000 to 2006. He now serves as Director of the Interdisciplinary Toxicology Program at UGA. Dr. Fisher's research interests are in the development and application of biologically based mathematical models to ascertain health risks from environmental and occupational chemical exposures. Dr. Fisher's modeling experience includes working with chlorinated and non-chlorinated solvents, fuels, PCB, pyrethroids and perchlorate. He has developed PBPK models for use in cancer risk assessment, estimating lactational transfer of solvents, understanding in utero and neonatal dosimetry, quantifying metabolism of solvent mixtures and developing biologically motivated models for the hypothalamic-pituitary-thyroid axis in rodents and humans. Dr. Fisher has 20 years of experience in physiological modeling and has trained several graduate students and postdoctoral fellows on the concepts and application of physiological models. Dr. Fisher's laboratory and computational research are funded through grants provided by the USEPA, CDC/ATSDR, AFOSR, DOE, and occasionally subcontracts with nonprofit organizations or trade groups. He spent most of his career at the Toxicology Laboratory, Wright Patterson AFB, where he was Principal Investigator and Senior Scientist in the Toxics Hazards Division and Technical Advisor for the Operational Toxicology Branch. He was a Visiting Scientist at the Chemical Industry Institute of Toxicology in 1996 and at the NIOSH Taft Laboratory in 1999. During this time, he also served as Adjunct Professor in the Department of Pharmacology and Toxicology at Wright State University. Dr. Fisher has published over 100 papers on pharmacokinetics and PBPK modeling in laboratory animals and humans. He has served on several panels and advisory boards for the DoD, ATSDR, USEPA and non-profit organizations. He also has been a U.S. delegate for the North Atlantic Treaty Organization. Dr. Fisher served on the International Life Sciences Institute Steering Committee, which evaluated chloroform and dichloroacetic acid using EPA-proposed Carcinogen Risk Guidelines. He is Past President of the Biological Modeling Specialty Section of the Society of Toxicology, reviewer for several toxicology journals, and was Co-Principal Investigator on a National Institutes of Health (NIH)-supported workshop on Mathematical Modeling at the University of Georgia in the fall of 2003. He is a member of the National Academy of Sciences subcommittee on Acute Exposure Guideline Levels (AEGLs) since 2004 and is a Fellow of the Academy of Toxicological Sciences. He is currently on the editorial boards for the International Journal of Toxicology and the Journal of Toxicology and Environmental Health. Dr. Fisher has a B.S. degree in biology from the University of Nebraska at Kearney, a M.S. degree in biology/ecology from Wright State University, and a Ph.D. in Zoology/Toxicology from Miami University.

### **Hays, Sean**

#### **Summit Toxicology**

Mr. Sean Hays is the President and founder of Summit Toxicology, a toxicology and risk assessment consulting firm. Mr. Hays received his B.S. in Biomedical Engineering from Texas A&M University in 1989, a M.S. in Physiology from the University of Vermont in 1992, and a M.S. in Chemical Engineering from Colorado State University in 1997. Mr. Hays specializes in conducting exposure assessments, deriving acceptable exposure limits (i.e., reference doses and reference concentrations, cancer slope factors, permissible exposure limits, and minimal risk levels), developing pharmacokinetic (PK) and physiologically based pharmacokinetic (PBPK) models, and in developing methods for interpreting biomonitoring data in a health risk context. Mr. Hays has developed PBPK models for a wide range of chemicals and metals (including collaborating with Dr. Ellen O'Flaherty to

develop a PBPK model for chromium), and has specialized in developing models for pregnancy and the developing child. He has over nine years of experience performing pharmacokinetic modeling of lead in humans and in using the O'Flaherty lead PBPK and IEUBK models to assess potential health risks for a wide range of potential exposure scenarios. Mr. Hays has used the lead PBPK model to set site-specific clean-up goals for numerous lead impacted properties, to model the potential for elevated blood lead levels among children exposed to elevated levels of lead in school drinking water supplies, and for modeling the likely changes in blood lead levels among astronauts who experience rapid and substantial bone loss while on extended space travel. Mr. Hays has experience using U.S. EPA's IEUBK model for risk assessment purposes and has performed detailed analyses to evaluate the scientific differences between the various lead pharmacokinetic models and to evaluate in which risk assessment scenarios each lead model is scientifically valid for predicting changes in blood lead levels. Mr. Hays is a member of the Society of Toxicology, the International Society of Regulatory Toxicology and Pharmacology, the American Conference of Governmental Industrial Hygienists, the International Society of Exposure Analysis, and the Society of Risk Analysis. He is currently serving as the Vice President-Elect of the Biological Modeling Section of the Society of Toxicology. Over the past two years, Mr. Hays has received funding related to lead from Wyle Laboratories (a subcontractor to NASA) to develop a lead PBPK to predict the potential impact that extended periods of exposure to microgravity would have on the blood lead levels of astronauts. He has also received funding from a large school district in the Pacific Northwest to help model the likely blood lead levels of children who had been exposed to elevated levels of lead in their school drinking water. In Mr. Hays' other consulting efforts, he has received funding from the U.S. EPA to develop PBPK models, from private industry to develop PBPK models and exposure and risk assessments for a variety of chemicals and to develop methods for interpreting biomonitoring data.

### **Kleinman, Michael T.**

University of California, Irvine

Michael T. Kleinman is a Professor of Community and Environmental Medicine at the University of California, Irvine. He is an inhalation toxicologist and has been studying the health effects of exposures to environmental contaminants found in ambient air for more than 30 years. He holds a MS in Chemistry (Biochemistry) from the Polytechnic Institute of Brooklyn and a Ph.D. in Environmental Health Sciences from New York University. He is a Professor and Co-Director of the Air Pollution Health Effects Laboratory in the Department of Community and Environmental Medicine at University of California, Irvine. Prior to joining the faculty at U.C.I. in 1982, he directed the Aerosol Exposure and Analytical Laboratory at Rancho Los Amigos Hospital in Downey, CA. He has published more than 95 articles in peer-reviewed journals dealing with environmental contaminants and their effects on cardiopulmonary and immunological systems. He has directed more than 50 controlled exposure studies of human volunteers and laboratory animals to ozone and other photochemical oxidants, carbon monoxide, ambient particulate matter and laboratory-generated aerosols containing chemically or biologically reactive metals such as lead, cadmium, iron and manganese. He recently served on two National Academy committees to examine issues in protecting deployed US Forces from the effects of chemical and biological weapons. Dr. Kleinman's current studies focus on neurological and cardiopulmonary effects of inhaled particles, including nanomaterials and ultrafine, fine and coarse ambient particles in humans and laboratory animals. His current studies have demonstrated that inhalation of combustion-generated particles can promote airway allergies and accelerate the development of cardiovascular disease and that these effects may be associated with organic and elemental carbon components of the ultrafine fraction of the ambient aerosol. His studies have also demonstrated that inhalation of ambient particles is associated with persistent inflammation in the brain and that particles associated with manganese can alter dopamine and serotonin levels in the brain and can cause changes in nerve structure during brain development. Dr. Kleinman has previously served on the U.S. EPA Science Advisory Board' Clean Air Scientific Advisory Committee (CASAC) Ozone panel and currently serves as the Chair of the California Air Quality Advisory Committee.

## Li, Abby

### Exponent Incorporated

Abby A. Li is a Senior Managing Scientist in the Health Science Practice of Exponent Inc., a scientific consulting firm. Her areas of interest include adult and developmental neurotoxicology, and risk assessment. She is currently doing research evaluating the neurotoxic potential of solvents and pesticides. Previously to joining Exponent Inc., Dr. Li was Senior Science Fellow at Monsanto, providing expertise in toxicology/risk assessment to address regulatory science issues in different world areas. She led the neurotoxicology group at Monsanto's Environmental Health Laboratory for more than ten years where she conducted pharmacokinetic, toxicology and neurotoxicology studies for industrial chemicals, agricultural products, and pharmaceuticals. Dr. Li served on the U.S. expert teams to the Organization for Economic Cooperation and Development (OECD) for the development of international test guidelines for adult and developmental neurotoxicology, and as chair of neurotoxicology expert groups for industry trade organizations (i.e., the American Chemistry Council's long-range research program and American Industrial Health Council) addressing scientific/regulatory issues in neurotoxicology. Dr. Li was a full member of the EPA's Science Advisory Board's Environmental Health Committee for 6 years, and a member of several International Life Science Institute Committees on developmental neurotoxicology and toxicity testing of pesticides. She also served on the National Academy of Science's National Research Council Committee on Toxicity Testing and Assessment of Environmental Agents. She received her Ph.D. in pharmacology and physiology from the University of Chicago.

## LoPachin, Richard M.

### Albert Einstein College of Medicine

Dr. Richard M. LoPachin is a Professor of Anesthesiology and Director of Research at the Albert Einstein College of Medicine. He holds a B.S. in Biochemistry and a M.S. in Pharmacology from the University of Georgia and a Ph.D. in Pharmacology/Toxicology from the University of Wisconsin, Madison. Dr. LoPachin has been on the faculty of the Albert Einstein College of Medicine since 1994. He is a molecular neurotoxicologist and has published over 90 research papers, reviews and book chapters on this subject. Dr. LoPachin is an Associate Editor for NeuroToxicology and he is a member of numerous editorial boards for other scientific journals. He has served extensively on scientific review panels for government (NIEHS, NIOSH, NINDS, NIMH, CDC) and private funding institutions. He has also participated in several workshops on acrylamide in food (JIFSAN/NCFST workshop). Dr. LoPachin's research over the past twenty-five years has focused on molecular mechanisms of neurotoxicity. Specifically, he has demonstrated that acrylamide (ACR) neurotoxicity is mediated by nerve terminal dysfunction in the central and peripheral nervous systems. Results from proteomic and chemical studies conducted in his laboratories have suggested that this damage occurs when ACR forms adducts with cysteine sulfhydryl groups on many presynaptic proteins that are involved in neurotransmitter uptake, release and storage. The National Institute of Environmental Health Sciences (NIEHS) has supported this research program for over 20 years. Dr. LoPachin's research interest also include defining the mechanism of axon atrophy induced by exposure to 2,5-hexanedione (HD), the active metabolite of n-hexane. His recent studies suggest that HD forms adducts with lysine residues on the "tail" portion of heavy neurofilament subunits. This impairs their incorporation into the axon cytoskeletal polymer and results in loss of caliber. This research has been funded by NIEHS for 12 years.

## McConnell, Ernest

### ToxPath, Inc.

Dr. McConnell is president of ToxPath, Inc., a consulting firm in Raleigh, NC, that specializes in experimental toxicology and pathology. Before becoming a consultant, Dr. McConnell was director of the Division of Toxicological Research and Testing Program, National Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS). He received his D.V.M. from Ohio State University and his M.S. in pathology from Michigan State University. He completed his residency in

comparative pathology at the Armed Forces Institute of Pathology, Walter-Reed Army Medical Center. Dr. McConnell's area of expertise is in toxicology comparative pathology and carcinogenesis. He is a diplomate of the American College of Veterinary Pathologists and the American Board of Toxicology. He recently completed many years of service as chair of EPA's FIFRA Science Advisory Panel. He has served two terms as a member of the National Research Council (NRC) Committee on Toxicology and on several NRC committees, including the Subcommittee on Manufactured Vitreous Fibers. He has served on a large number of other advisory panels including: Member, EPA Science Advisory Board Executive Committee, from 1993-1999; Panel Member, EPA Science Advisory Board, EPA Proposed Guidelines for Carcinogenic Risk Assessment, 1997. His years of government experience, familiarity with EPA's cancer guidelines, and his scientific expertise make him well-qualified for this review.

### **Mucci, Lorelei**

Harvard University

Dr. Mucci has joint appointments as Assistant Professor at the Harvard Medical School, Harvard School of Public Health, and the Brigham and Women's Hospital, Department of Medicine. Dr. Mucci received her ScD in Epidemiology at the Harvard School of Public Health and a MPH in Public Health from Boston University of Public Health. Dr. Mucci was a post-doctoral fellow at the Karolinska Institutet in Sweden where her focus was in cancer epidemiology. Her research program has focused on molecular predictors of prostate cancer incidence and survival to understand molecular mechanisms by evaluating, as part of a multidisciplinary team, biomarkers at the RNA, DNA, and protein levels. The goal is to molecular models that in combination with clinical parameters to be better able to distinguish aggressive prostate cancer from indolent disease. Dr. Mucci other research interest is in the potential risk of various types of cancer arising from exposure to acrylamide in foods. She has conducted and published analyses of the incidence of cancer of the kidney, colon, and breast (in women) in large populations for which acrylamide intake has been characterized in food surveys.

### **Rice, Jerry M.**

Georgetown University Medical Center

Jerry M. Rice, Ph.D., received his doctorate in biochemistry from Harvard University in 1966. His research interests include comparative tumor pathology; perinatal and transplacental chemical carcinogenesis; tumor promotion; the molecular biology of transforming and tumor suppressing genes in tumors; and the carcinogenic hazards presented by infections and infectious agents. He joined the U. S. National Cancer Institute as a commissioned officer in the U.S. Public Health Service in 1966, becoming chief of the Laboratory of Comparative Carcinogenesis in 1981, and Associate Director for the Frederick Cancer Research and Development Center and Acting Director of the Division of Cancer Etiology in 1994. In 1996 he retired from the U.S. Public Health Service and joined the International Agency for Research on Cancer in Lyon, France, where he served as Chief of the Unit of Carcinogen Identification and Evaluation and Director of the IARC Monographs Programme on Evaluation of Carcinogenic Risks to Humans. He retired from the World Health Organization in 2002, but continues to be actively involved with the WHO in various capacities. He is currently Distinguished Professor of Oncology in the Lombardi Cancer Center at Georgetown University Medical Center, Washington, where he lectures in graduate courses and does research on tobacco-related carcinogenic hazards. He also consults on issues related to carcinogenic hazard identification and carcinogenic risk assessment. He has published 180 research papers and more than 70 book chapters, reviews, and editorials, and has co-edited seven books. His awards include the Meritorious Service Medal of the U.S. Public Health Service and the Toxicology Forum's George Scott Award in Toxicology.

### **Sickles, Dale**

Medical College of Georgia

Dr. Dale Sickles is a Professor and Vice-Chair of the Department of Cellular Biology and Anatomy at the Medical College of Georgia in Augusta, GA. He received his BS in Biology and Chemistry and his

PhD in Anatomy from West Virginia University. He is also Director of Medical and Graduate Histology and Cell Biology. Dr. Sickles professional experience include a variety of neuromuscular disorders, histochemistry, and microscopic anatomical and biochemical studies of the cytoskeleton with special interests in microtubules and kinesin motor proteins. Teaching experiences include Cell Biology and Histology. Over the past 20 years his research has focused on cellular mechanisms of neurotoxicity produced by acrylamide, -diketones and organophosphorus agents. Funding for his research has been from 1) National Institutes of Environmental Health Sciences, 2) National Institute of Occupational Safety and Health, 3) National Institute of Communicative Disorders and Stroke, 4) Environmental Protection Agency, 5) American Cyanamid, 6) CYTEC Industries 7) SNF as well as the Georgia Research Alliance. Current funding examines the effects of these toxicants on kinesin, fast axonal transport and the maintenance of axonal protein support and function. Additional studies include the effects of acrylamide on mitotic kinesin motor proteins as potential genotoxic mechanisms. He is a reviewer for several toxicological publications including 1) Toxicology and Applied Pharmacology, 2) Neurotoxicology, 3) Toxicological Sciences, 4) Journal Pharmacology and Experimental Therapeutics and 5) Journal of Neurochemistry. He is a member of the Society for Neuroscience as well as the Society of Toxicology, including the Neurotoxicology Specialty Subsection.

### **Solomon, Gina**

#### **Natural Resources Defense Council**

Gina Solomon is a Senior Scientist at the Natural Resources Defense Council (NRDC) and an Associate Clinical Professor of Medicine at the University of California at San Francisco (UCSF) where she is also the Associate Director of the UCSF Pediatric Environmental Health Specialty Unit. Her work has included research on air pollution and asthma, pesticides, and environmental and occupational threats to reproductive health and child development. Dr. Solomon serves on the U.S. EPA's Science Advisory Board Drinking Water Committee, the NAS Committee on Toxicity Testing and Assessment of Environmental Agents, and the California Environmental Contaminant Biomonitoring Program Scientific Guidance Panel. She previously served on the EPA's Endocrine Disruptor Screening and Testing Advisory Committee and on the California Expert Working Group on Environmental Health Tracking. Dr. Solomon has authored numerous articles and reports, and is co-author of the award-winning book, *Generations at Risk: Reproductive Health and the Environment*, published by MIT Press in 1999. Dr. Solomon attended medical school at Yale University and did her residency and fellowship training at Harvard in internal medicine and occupational and environmental medicine.

### **Tyl, Rochelle**

#### **RTI International**

Dr. Tyl was formerly Supervisor and later Manager of the Teratology Section, and continued to evaluate chemicals and pharmaceuticals for reproductive and developmental toxicity. She worked in the chemical industry from 1983-89, and then returned to RTI, where she is currently research director for Life Sciences and Toxicology and senior program director, Reproductive and Developmental Toxicology. Dr. Tyl leads reproductive and developmental toxicity studies under FDA, EPA (TSCA), EPA (FIFRA), EPA (OPPTS), OECD, and harmonized testing guidelines and GLPs, as appropriate, for industry and government. She is certified as a Diplomate with the American Board of Toxicology (Certification: 1983; Recertification: 1988, 1993, and 1998). Sources of recent grant and/or contract support : EPA

### **Weiss, Bernard**

#### **University of Rochester Medical Center**

Dr. Weiss is Professor of Environmental Medicine and Pediatrics at the University of Rochester School of Medicine and Dentistry, where he has been a member of the faculty since 1965. Before coming to Rochester, he served on the faculty of the Johns Hopkins School of Medicine, and, earlier, held an appointment at the U.S. Air Force School of Aviation Medicine. Dr. Weiss has served as a member of many committees and panels devoted to toxicology and environmental health, including those

organized by the U.S. Environmental Protection Agency's Science Advisory Board, and the National Academy of Sciences. He is especially concerned with risk assessment issues arising from the effects of environmental chemicals on brain development and brain aging. He is the editor or co-editor of seven books and monographs and author or co-author of over 200 articles. His special interests and publications lie primarily in areas that involve chemical influences on behavior; these include the neurobehavioral toxicology of metals such as lead, mercury and manganese; endocrine disrupter such as dioxin; solvents such as toluene and methanol; drugs such as cocaine; and air pollutants such as ozone.

## **Zeise, Lauren**

### **California Environmental Protection Agency**

Dr. Lauren Zeise is Chief of Reproductive and Cancer Hazard Assessment within the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. In that position since 1991, she has overseen a variety of the state's cancer, reproductive and ecological risk assessment activities. Current work addresses cancer and reproductive risk methodologies and characterizations, development of ecological risk guidance, establishment of baseline risks from gasoline use in California and guidance for evaluating risks to the fetus, children and adolescents from environmental exposures. Her group also conducts scientific evaluations mandated by California's Proposition 65. Her research has focused on cancer risk assessment methodology and applications. Dr. Zeise currently serves on the EPA Science Advisory Board (SAB), and has served previously as a member of the SAB Environmental Health Committee, Research Strategies Advisory Committee and Integrated Risk Project, and as consultant to the Clean Air Act Scientific Advisory Committee, Environmental Engineering Committee, FIFRA Science Advisory Panel, EPA Board of Scientific Counselors, and on various Ad-hoc advisory committees of the Agency. Other service includes membership on various committees of the National Institute of Medicine (IOM), National Research Council (NRC), Consumer Product Safety Commission, National Toxicology Program, Office of Technology Assessment. She currently serves on the IOM Board of Health Promotion and Disease Prevention and NRC Board on Environmental Sciences and Toxicology. She is a member, fellow and councilor of the Society of Risk Analysis and is on the editorial board for the Society's journal. The National Cancer Institute Smoking and Tobacco Smoke Monograph Health Effects of Environmental Tobacco Smoke was conceived and developed under her editorial direction. She is co-author and co-editor of the 1999 International Agency for Research on Cancer monograph Quantitative Estimation and Prediction of Cancer Risk. She received in 1977 her M.S. and in 1984 her Ph.D. from Harvard University, where she also conducted postdoctoral research on risk assessment methodology.

### ATTACHMENT 3

Adrienne Kiley      North American Polyelectrolyte Producers Association (NAPPA)

Kirsten Stade      Center for Science in the Public Interest (CSPI)

Michael Jacobson      Center for Science in the Public Interest (CSPI)