

**Summary Minutes of the  
US Environmental Protection Agency  
EPA Science Advisory Board  
Libby Amphibole Asbestos Review Panel  
Public Meeting  
February 6-8, 2012**

**ATTENDANCE**

SAB Panel Members

Dr. Agnes Kane (Chair)  
Dr. John Balmes  
Dr. James Bonner  
Dr. Jeffrey Everitt  
Dr. Scott Ferson  
Dr. George Guthrie (participated by phone)  
Mr. John Harris  
Dr. Tom Hei  
Dr. David Kriebel  
Dr. Morton Lippmann (participated by phone on 2/6)  
Dr. John Neuberger  
Dr. Lee Newman  
Dr. Michael Pennell  
Dr. Julian Peto  
Dr. Carrie Redlich  
Dr. Andrew Salmon  
Dr. Elizabeth (Lianne) Sheppard  
Dr. Randal Southard  
Dr. Katherine Walker  
Dr. James Webber  
Dr. Susan Woskie

SAB Staff Office

Dr. Vanessa Vu, Director  
Dr. Diana Wong, Designated Federal Officer (DFO)

EPA's National Center for Environmental Assessment (NCEA)

Rebecca Clark, Acting Director  
David Bussard, Director, Washington Division

EPA Region 8:

Dr. Deborah McKean  
Bob Benson

Other Attendees (with their affiliations as entered on the sign-in sheets)

Thomas Brennan, SAB Staff Office  
Aaron Yeow, SAB Staff Office  
Danielle DeVoney, EPA  
Thomas Bateson, EPA  
Bob Benson, EPA  
Malcolm Field, EPA  
Charles Ris, EPA  
Krista Christensen, EPA  
Suresh Moolgavkar, Exponent  
Jay Flynn, Health Network America (Libby Medical Program)  
Jim Rollins, PNG  
Ted Larson, ATSDR  
Leonid Kopelev, EPA  
Pam Marks, Beveridge & Diamond  
Brian Pachkowski, ORISE/EPA  
Vicki Soro, NCEA  
Lisa McKenzie, CSPH  
Lyndsay Kopp, CSPH  
Bob Sonawane, EPA  
Maureen Gwinn, EPA  
Vince Cogliano, EPA  
Glinda Cooper, EPA  
Karl Bourdeau, Beveridge & Diamond  
Jonathan Gledhill, Policy Navigation Group  
Holli Feichko, W.R. Grace  
Bill Badgeley  
Lydin Duff  
Richard C. Finke  
Doug Guarino, Inside EPA  
Randy Rabinowitz  
Vicki Kapil, CDC/HHS  
Jen Mall, ASPH fellow  
Emily Cordas, NIDDK  
Victor Ketellapper, EPA Region 8  
Caroline Ganley, Tufts University  
Elizabeth Anderson, Exponent  
Paul White, EPA  
Ray Randall, Triple Canopy  
Francisco Baronk, NIH  
Dave Bayliss, EPA  
Patricia Sullivan, NIOSH (on the phone)

**MEETING MATERIALS**

The meeting materials available prior to or during the February 6-8, 2012 meeting are available on the SAB web site at, <http://www.epa.gov/sab> and specifically at the following URL:

<http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/7896D6DE96BECA7F85257956006D544B?OpenDocument>

- FEDERAL REGISTER NOTICE
- MEETING AGENDA
- PANEL ROSTER
- AGENCY REVIEW DOCUMENT  
[PDF for Toxicological Review of Libby Amphibole Asbestos in Support of Summary Information on the Integrated Risk Information System \(IRIS\) \(August 2011 Draft\)](#) (PDF, 467 pp., 4,805,784 bytes)
- CHARGE TO THE COMMITTEE
  
- AGENCY-PROVIDED BACKGROUND MATERIAL  
Memo from David Bussard, dated February 6, 2012, Additional Information on Exposure-Response Modeling in Appendix E, (PDF, 8 pp., 114,396 bytes)  
  
Memo from David Bussard, dated February 7, 2012, on the Age Distribution and Distribution of Time of Mesothelioma Cases Among the Libby Workers Cohort or Subcohort in Libby, MT. (PDF, 1 pp., 49,807 bytes)  
  
Memo from David Bussard, dated January 31, 2012 on Data Request from the SAB on Exposure-Response Modeling in Appendix E. (PDF, 6 pp., 80,780 bytes)  
  
Memo from Robert Benson Region 8 – Industrial Hygiene Air Sampling Results in Appendix F, (PDF, 27 pp., 692,834 bytes)  
  
References Discussed by the SAB Review Panel During the Peer Review Meeting of the Draft Toxicological Review of Libby Amphibole Asbestos. (PDF, 3 pp., 233,147 bytes)  
  
References Requested by the SAB Review Panel for the Peer Review of the Draft Toxicological Review of Libby Amphibole Asbestos. (PDF, 2 pp., 63,401 bytes)
- AGENCY BRIEFING MATERIAL  
EPA Presentation – EPA Risk-based Decision Making at the Libby Superfund Site. (PDF, 12 pp, 440,554 bytes)  
  
EPA Presentation – U.S. EPA’s External Review Draft Toxicological Review of Libby Amphibole Asbestos. (PDF, 37 pp., 339,926 bytes)
- List of Public Speakers. (PDF, 1 pp., 12,217 bytes)

- **PUBLIC COMMENTS**

Presentation from Elizabeth Anderson, Exponent Inc.. (PDF, 14 pp., 464,176 bytes)

Presentation from Elizabeth Anderson, Exponent Inc. (02/07/12). (PDF, 4 pp., 230,331 bytes)

Presentation from Jay Flynn, Libby Medical Program. (PDF, 6 pp., 559,368 bytes)

Presentation from Jeffrey Mandel, University of Minnesota School of Public Health. (PDF, 4 pp., 384,691 bytes)

Presentation from Suresh Moolgavkar, Exponent, Inc., on behalf of WR Grace. (PDF, 12 pp., 385,343 bytes)

Public Comments from Clinton Maynard. (PDF, 4 pp., 23,872 bytes)

Public Comments from Elizabeth Anderson, Exponent, Inc. (PDF, 8 pp., 437,762 bytes)

Public Comments from Elizabeth Anderson, Exponent, Inc. – Addendum (02/07/12) (PDF, 7 pp., 635,357 bytes)

Public Comments from James Lockey, University of Cincinnati. (PDF, 2 pp., 339,882 bytes)

Public Comments from Jay Flynn, Libby Medical Program (PDF, 8 pp., 54,543 bytes)

Public Comments from John Adgate, Colorado School of Public Health. (PDF, 1 pp., 105,935 bytes)

Public Comments from John Adgate, Colorado School of Public Health (02/06/12). (PDF, 1 pp., 43,816 bytes)

Public Comments from Suresh Moolgavkar, Exponent, Inc. on behalf of WR Grace . (PDF, 78 pp., 1,641,054 bytes)

Public Comments from Suresh Moolgavkar, Exponent, Inc. on behalf of W.R. Grace (02/09/12). (PDF, 1 pp., 149,929 bytes)

Public Comments from Terry Trent. (PDF, 4 pp., 1,341,916 bytes)

Public Comments from Terry Trent - Additional Comments. (PDF, 2 pp., 28,261 bytes)

Public Comments Submitted to EPA Docket (PDF, 4pp., 83,601 bytes)

## **PURPOSE**

The SAB Libby Amphibole Asbestos Review Panel held a face-to-face meeting to review EPA's draft *Toxicological Review of Libby Amphibole Asbestos* (August, 2011) and discuss responses to EPA's charge questions.

## **LOCATION**

Westin Alexandria Hotel, 400 Courthouse Road, Alexandria, VA 22314

## **DATE AND TIME**

The meeting was held on February 6, 2012 from 9:00 a.m. to 5:00 p.m. (Eastern Time), February 7, 2012 from 8:30 a.m. to 5:30 p.m. (Eastern Time), and February 8, 2012 from 10:30 a.m. to 2:30 p.m. (Eastern Time).

## **MEETING SUMMARY**

The discussion generally followed the meeting agenda unless it was noted in the meeting summary below.

### **February 6, 2012**

#### Convene the Meeting and Welcoming Remarks

Dr. Diana Wong, Designated Federal Officer (DFO) opened the meeting at 9:00 a.m. She stated that the EPA Science Advisory Board (SAB) operates under the rules and regulations of the Federal Advisory Committee Act (FACA) which require that all meetings where discussions and deliberations take place must be held in public. She noted that the SAB Panel members were in compliance with federal conflict of interest and ethics requirements that apply to them. Dr. Vanessa Vu, Director of the SAB Staff Office, welcomed everyone to the meeting and introduced Dr. Agnes Kane, the Chair of the Libby Amphibole Asbestos Review Panel.

#### Review of Agenda

Dr. Kane welcomed the Review Panel and asked the Panel members to introduce themselves. She stated that the purpose of the meeting was to review EPA's draft *Toxicological Review of Libby Amphibole Asbestos* (August, 2011). Dr. Kane also described the agenda of the meeting.

#### Remarks from EPA's National Center for Environmental Assessment (NCEA)

Ms. Becki Clark, Acting Director of NCEA, welcomed SAB's robust review of the Libby Amphibole Asbestos Toxicological Review. She stated that the assessment follows the

Integrated Risk Information System (IRIS) process, and had input from the National Institute of Environmental Health Sciences (NIEHS), Agency for Toxic Substances and Disease Registry (ATSDR), and National Institute for Occupational Safety and Health (NIOSH). In addition, EPA responds to the National Academy of Sciences (NAS) recommendations to strengthen IRIS assessments.

#### EPA Presentations:

- Dr. Deborah McKean, of EPA Region 8, presented EPA Risk-based Decision Making at the Libby Superfund Site.
- Mr. David Bussard, Director of the Washington Division of National Center for Environmental Assessment, presented an overview of EPA's external review draft of Toxicological Review of Libby Amphibole Asbestos.

Both presentations are posted on SAB website.

#### Public Comments

Dr. Kane informed the Panel and the meeting attendees that the SAB had received 4 requests from the public to make oral comments at the meeting. She stated that the list of registered public speakers and written public comments were available on the SAB website. Public speakers were provided an opportunity to present their comments by phone or in person. Four speakers provided written oral statements which were made available at the meeting and posted on the SAB website. Public commenters provided oral statements in the following order:

- Dr. Jay Flynn, Libby Medical Program, commented on the use of pleural plaques as non-cancer endpoint and on the comparison of the toxicity of Libby Amphibole asbestos with the toxicity of tremolite, crocidolite and amosite.
- Dr. Suresh Moolgavkar, on behalf of W. R. Grace, commented on the use of subcohort data, model choice, the use of lag time, and pleural plaque as a health endpoint.
- Dr. Elizabeth Anderson, of Exponent, Inc., commented that the proposed RfC is below background concentrations in the US, and that the analytical cost of samples at the level of proposed RfC will be high.
- Dr. Jeff Mandel, of University of Minnesota (on the phone), presented recently published findings of pleural abnormalities in a nonoccupational asbestos exposure study in which community residents in Minneapolis, MN were exposed to emissions from a plant processing Libby vermiculite.

#### Panel Discussion on Responses to EPA's Charge Questions

The Panel chair asked the lead discussants to provide responses to the charge questions. The charge questions were then opened up for discussion with other panel members.

#### *Section 2- Geology, Use, and Exposure*

Panel members found the mineralogy section generally provided a good foundation for understanding the nature of Libby amphibole asbestos as related to evaluation of potential

exposures. However, panel members commented that there are modifications to be made in this section, including application of consistent use of mineralogy terminology. In addition, all mineral formulae and mineral species definitions should be double-checked.

Panel members also noted that while the definition of mineral species embodied specific structures and composition, the use of mineral-species names in other studies (epidemiological, toxicological) may be ambiguous due to analytical difficulties. Most analytical results were based on phase contrast microscopy (PCM), which detected fibers longer than 5  $\mu\text{m}$ , but could not identify chemical composition.

The meeting was recessed for lunch at 12:15 p.m. and was reconvened at 1:15 p.m. The Chair resumed the discussion as follows:

### *Section 3- Fiber Toxicokinetics*

Panel members commented that this section did not distinguish between chrysotile and amphibole fibers, and that the translocation of fibers to the pleura should be looked at since the proposed RfC is based on pleural plaque. The Panel suggested the reference by Broaddus et al. (2011) should be useful in providing background information.

### *Section 4- Hazard Identification*

#### A. Noncancer Health Effects:

##### 1. Charge Question II.A.1. Study Population

The Panel commented that the Marysville cohort provides sufficient basis for the derivation of the RfC, despite some limitations - there is uncertainty in the exposure data prior to 1972, and the cohort is not representative of the general population (e.g. the cohort is all adult, mostly male, and Caucasian).

The Panel recommended that EPA include the Minnesota cohort since their exposure level was below the Marysville cohort, and the cohort includes women and children, so is more representative of the general population. The study does provide individual-level modeled exposures. In addition, EPA should look at the Larson study.

EPA commented that Dr. Lockey from University of Cincinnati has conducted follow-up studies which have spirometry data, that may be electronically available.

##### 2. Charge Question II. A.2. Selection of Critical Effect

The Panel commented that pleural thickening is an appropriate endpoint. If pleural thickening is not selected, there are other endpoints, such as asbestosis. Pleural thickening is not confounded by smoking. The idea of looking at all changes in the x-ray, and not just pleural thickening was considered. Usually, there is diffuse pleural thickening before decreased lung function is detected.

The Panel considered whether the observation of pleural plaque would mean adversity. The Panel agreed that in animal studies, simple pathological finding

such as structural change by itself is regarded as a severe effect. In risk assessment, structural change is not considered as a biomarker. In patients, the presence of pleural plaque is a risk factor for development of other asbestos-related diseases, e.g., asbestosis. However, one Panel member expressed the view that there is no need for an RfC because the noncancer effect is less frequent than cancer. The Panel also considered that a community-based study shows increased evidence of pleural thickening in Libby residents.

3. Section 4.2, 4.3, 4.4 – Animal and Mechanistic Studies

Panel members commented that these sections were well written. There are no animal inhalation or oral studies using Libby Amphibole. All endpoints are from short term studies and do not show preneoplastic or neoplastic changes. Animals exposed via intratracheal instillation do not have pleural lesions as found after whole body animal inhalation exposure. Hence, projections of health effects were based on animal studies using tremolite, which has been investigated in human epidemiology studies also. However, Libby Amphibole asbestos contains only 6% tremolite.

Panel members noted that additional studies on mechanisms of fibrosis should be included, although these studies were not based on Libby Amphibole asbestos. Long term fibrosis should be emphasized. The study by Cyphert et al. (2012) on rats exposed to Libby Amphibole by intratracheal instillation compared to amosite showed that a single dose of Libby Amphibole asbestos was sufficient to cause fibrosis. The Shannahan et al. (2012) study on spontaneously hypertensive (SH) rats and SH heart failure rats instilled with Libby Amphibole should be cited also.

4. Section 4.5 – Synthesis of Non-Cancer Effects

Panel members commented that this subsection focused on the lack of sufficient evidence to establish the non-cancer mode of action specific to Libby Amphibole asbestos. However, a great deal is known about the mechanisms of injury, inflammation, and fibrosis due to asbestos. The question to consider is whether there are any reasons to suspect that the mechanisms for Libby Amphibole asbestos may be different when compared to other asbestos fibers.

5. Section 4.7 – Susceptible Population

Regarding the issue of Age-Dependent Adjustment factor, one Panel member commented that it is wrong to say that because asbestos is not mutagenic, an Age-Dependent Adjustment factor is not applied. It was noted that a study on long-term lung outcome in children exposed to Libby Amphibole is available.

6. Section 4.6 – Weight of Evidence Evaluation of Carcinogenicity and Mode of Action

The Panel found that the weight of evidence adequately supports the conclusion that Libby Amphibole asbestos is carcinogenic to humans. There was concern among Panel members for potentially greater susceptibility in

children, although EPA did not identify Libby Amphibole asbestos as mutagenic.

The meeting was recessed at approximately 5:00 p.m.

## **February 7, 2012**

The meeting was reconvened at 8:35 a.m.

### *Section 5 – Exposure-Response Assessment*

#### A. Section 5.2 and 5.3 - Inhalation Reference Concentration (RfC) and Uncertainties

##### 1. Charge Question III A.1. Exposure Reconstruction and Development of Exposure Estimates used in the Analysis

The Panel found that the methodology and uncertainties associated with the reliance on imperfect exposure indices and expert judgement were well described and appropriate. The Panel commented that the use of phase contrast microscopy (PCM) count has limitations. Resolution in the 1970's was 0.4  $\mu\text{m}$  compared to 0.2  $\mu\text{m}$  currently. Transmission electron microscopy (TEM) was not widely available in the 1980's, and may have provided a better estimate of true exposure. However, the Panel recognized that available data use PCM method. In the future, TEM should be used. The PCM samples can be archived and analyzed in the future, using TEM.

##### 2. Charge Question IIIA.2. Exposure Response Modeling

The Panel commented that the EPA selected model with the lowest Akaike information criterion (AIC) is justified from a statistical standpoint. There was no mention of fit within the region of the benchmark response (BMR). If the draft technical guidance of benchmark dose (BMD) modeling were strictly followed, a different model would have been selected. These issues should be addressed in the assessment.

The Panel discussed whether biological plausibility of the selected model should be discussed. The underlying theory in BMD is that there is no biological significance in the models. The Panel found the use of a model with a plateau does not make a lot of sense with only 8 years of exposure. The Panel commented the fitted Michaelis-Menten model should be better described with some consideration of epidemiological/biological plausibility.

The Panel discussed the EPA's selected BMR of 10%, which is the default choice for quantal responses for animal studies. However, EPA's *Draft Benchmark Dose Technical Guidance* mentioned that a BMR of 1% extra risk is typically used for epidemiological data, so the selected BMR should be better justified.

3. Charge Question IIIA.3. The panel discussed alternative modeling using the full Marysville cohort and a Cumulative Normal Michaelis-Menten model that incorporates both cumulative exposure and time from first exposure as explanatory variables. The Panel commented that the rationale for the complete cohort analysis is scientifically justified and clearly described. The Panel discussed better ways to incorporate time since first exposure (TSFE) into the analyses.

The Panel was not convinced about the use of cumulative normal distribution and suggested various approaches for handling TSFE.

4. Charge Question IIIA.4. Confounders and Covariates  
The Panel suggested that a table be included to summarize the results of the various sensitivity analyses of potential confounders and covariates. Time since first exposure is not a confounder, but an important issue. The Panel did not find smoking to be a strong confounder for localized pleural thickening.
5. Charge Question IIIA.5. Cumulative Exposure Estimate  
In general, the Panel found the approach to be reasonable, although the Panel did not agree with subtracting 10 years from 70 years in the conversion to continuous exposure.
6. Charge Question III A.6. Uncertainty Factors  
The Panel found EPA's choice of uncertainty factors reasonable based on standard risk assessment practice. However, one Panel member preferred a data base uncertainty factor of 3. Effects on the cardiovascular system and autoimmunity are not likely to occur at very low exposure. On the other hand, another Panel member thought that the data base uncertainty factor should be 10. The Panel mentioned that Section 5.3 should be revised to state that inhalation studies have not been performed in animals, so an RfC cannot be based on animal studies. The charge question stated that there is a lack of data on effects other than in the respiratory system, including other effects observed in community and laboratory animal studies (cardiovascular disease and autoimmune effects). The Panel discussed the implication for Libby residents of elevated autoantibodies against mesothelial cells. Autoantibodies against mesothelial cells may represent a biomarker of Libby Amphibole exposure.
7. Charge Question IIIA.7. Characterization of Uncertainties  
The Panel commented that the approach taken is reasonable. However, for several uncertainty categories, additional sensitivity analyses can be conducted. Some of this was done, but the approach could be applied more thoroughly. Additional discussion should be added on background exposure in other communities, with reference to the Alexander et al. (2012) study.

The Panel discussed the exposure-response data for localized pleural thickening in workers from the Marysville, Ohio cohort in Appendix E. Some Panel members felt uneasy that an RfC was derived from one study. There is an extensive literature on

pleural plaques. If similar effects have been confirmed in other studies, then the Panel will feel more confident. Some Panel members suggested that EPA include the Minneapolis study, and the Wittenoom cohort in Australia to provide confidence in the data.

The Panel requested EPA to provide additional information regarding Tables 1 and 2 attached to EPA's February 6, 2012 memorandum, and the prevalence of localized pleural thickening for the exposure categories and time since first exposure plotted in Figures E-2 and E-3 of the External Review Draft of the Toxicological Review of Libby Amphibole Asbestos.

### **Inhalation Unit Risk (IUR)**

#### Section 5.4 Cancer Exposure Assessment – Selection of Principal Study and Endpoint

1. Charge question II.B.3. Selection of Key Study

The Panel agreed that the selection of the Libby workers cohort for the derivation of the inhalation unit risk (IUR) is adequately supported

2. Charge question IIB.4. Selection of Mortality from lung tumors and mesothelioma in the Libby worker cohort as the basis for the derivation of the IUR.

The Panel agreed that the use of the endpoints (lung cancer and mesothelioma) in the Libby worker cohort as the basis for the derivation of the IUR is appropriate.

#### Exposure Response Modeling and Confounders

1. Charge Question III.B.1. Exposure Response Modeling Approach

One Panel member commented it would be preferable to use the full data set than to throw out data points. Analyze the full Libby cohort using traditional models (and including Peto model) and characterize model uncertainty. The Panel suggested that EPA should explain why a particular model is chosen, and justify the independence assumption. The Panel also commented that the presented calculations (including lifetable analysis) look correct, but need more explanation.

The meeting was recessed for lunch at 12:15 p.m. and was reconvened at 1:15 p.m. The Chair resumed the discussion that follows:

2. Charge Question III.B.2. Smoking as confounder

The Panel discussed whether negative confounding is occurring with smoking, in which case the risk of lung cancer associated with asbestos exposure would be understated. While EPA's analysis concluded that smoking is not an important factor in the overall mortality data, this does not address the potential for smoking as an effect modifier of lung cancer.

3. Charge Question III.B.3. Derivation of Inhalation Unit Risk (IUR)

One Panel member was concerned about the assumption of independence of the mesothelioma and lung cancer IURs, which is not a good assumption since the two were estimated from the same sub-cohort. Methods that do not assume independence were suggested.

4. Charge Question III.B.4. Mesothelioma Mortality Adjustment  
The Panel found the adjustment to be reasonable, but suggested that a brief summary is needed in the document to explain what the adjustment is about.
5. Charge Question III.B.5. Uncertainties  
The Panel commented that while EPA did a nice job listing the sources of uncertainty, and did some sensitivity analysis, the uncertainty analysis conducted is largely qualitative. In accordance with NAS guidance, quantitative uncertainty analysis should be conducted. This can be done by sensitivity analysis with a list of variables, or characterization of major uncertainty using interval ranges. The Panel also commented that there should be more discussion on model uncertainty in the document.

The Panel discussed the use of pleural plaque as a critical effect. The pulmonologists on the Panel have revisited the issue and found that there is a clear association between pleural plaque and reduction in lung function. The Panel was comfortable that the RfC was based on pleural plaque and agreed that pleural plaque is a structural change. Larson has conducted another study that found association of plaques with decreases in lung function. Smoking has no (or small impact) on pleural plaques. The document should clearly state that pleural plaque is a marker for the tendency to develop other asbestos-related diseases. It does not mean that pleural plaque is the gold standard. This approach does not preclude the use of more specific techniques (e.g., MRI, immune target) in the future.

The Panel also discussed early life susceptibility and mode of action. The Panel commented that Libby Amphibole asbestos has multiple modes of action. There is no evidence from the literature that Libby Amphibole asbestos is different than other amphiboles. The Panel urged EPA to include studies on other amphiboles where environmental exposure began in childhood.

#### Second Public Comments:

There were 3 public commenters:

1. Dr. Jay Flynn of Libby Medical Program presented Weill et al. (2011) and questioned if pleural plaque is an adverse health effect.
2. Dr. Suresh Moolgavkar of Exponent, Inc. commented that he has suggested three papers (Reid et al., 2007; Richardson, 2009; Testa et al., 2011) for the Panel's consideration. The paper by Richardson (2009) used a two-stage clonal expansion model to analyze lung cancer in chrysotile asbestos workers. He suggested that one way to use the entire data set is to use uncertainty distribution for the entire data set. He also found negative confounding by smoking. He was skeptical of

pleural plaque as an endpoint, and commented that the question to ask is if there is an association with exposure level.

3. Dr. Elizabeth Anderson of Exponent, Inc. commented that non-cancer hazard based on an RfC could be a risk driver rather than cancer risk based on IUR. She also commented on the sampling cost of laboratory analysis to meet the draft RfC-required analytical sensitivities.

Writing Assignments:

Panel members were assigned to writing groups to synthesize key points and recommendations related to charge questions. The lead writers were identified with their names underlined as follows:

Group 1: Hazard Characterization of Non-cancer effects  
Drs. Balmes, Bonner, Harris, Newman, Redlich

Group 2: Reference Concentration  
Drs. Kriebel, Pennell, Sheppard, Webber, Woskie

Group 3: Hazard Characterization of Cancer Weight-of-Evidence  
Drs. Everitt, Hei, Lippmann, Neuberger

Group 4: Inhalation Unit Risk  
Drs. Ferson, Peto, Salmon, Southard, Walker

The groups were asked to prepare slides in bullet form to summarize their conclusions on the strengths and weakness of EPA analyses, recommendations for EPA to strengthen the analyses, give guidance to EPA on early life susceptibility, and relevance of other literature related to amphiboles in general.

The meeting was recessed for the day at 5:30 pm.

**February 8, 2012.**

The Panel reconvened at 10:30 a.m. The Chair asked the lead writers to present a summary of their written bottom line conclusions. The slides of the presentation are posted on SAB website at:

[http://yosemite.epa.gov/sab/sabproduct.nsf/BC415BBD44C76BBA8525799E00558BF6/\\$File/Panelsummaryreview-020812-revised.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/BC415BBD44C76BBA8525799E00558BF6/$File/Panelsummaryreview-020812-revised.pdf)

Groups 1-3 gave their presentations in the morning. The meeting was recessed for lunch at 12:15 p.m. and was reconvened at 1:00 p.m.

Group 4 gave its presentation in the afternoon.

Next Steps

Dr. Kane thanked the Panel for their active participation. She asked panel members to submit revised individual comments in a week, and requested the lead writers provide revised responses to charge questions to the DFO by March 1, 2012.

Ms. Clark and Dr. Vu thanked the Panel, and the meeting was adjourned at approximately 2:30 p.m.

Respectfully Submitted:

Certified as Accurate:

/signed/

/signed/

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Diana Wong, Ph.D., DABT  
Designated Federal Officer

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Agnes Kane, M.D. Ph.D.  
Chair  
SAB Libby Amphibole Asbestos  
Review Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by panel members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

## References

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