

**U.S. Environmental Protection Agency  
Science Advisory Board  
Libby Amphibole Asbestos Review Panel**

**Public Teleconference  
May 1, 2012**

**Minutes of the Meeting**

**ATTENDANCE**

SAB Panel Members (For full roster, see Attachment A)

Dr. Agnes Kane (Chair)	Dr. Lee Newman
Dr. John Balmes	Dr. Michael Pennell
Dr. James Bonner	Dr. Julian Peto
Dr. Jeffrey Everitt	Dr. Carrie Redlich
Dr. Scott Ferson	Dr. Andrew Salmon
Dr. George Guthrie	Dr. Elizabeth (Lianne) Sheppard
Dr. Tom Hei	Dr. Randal Southard
Dr. David Kriebel	Dr. Katherine Walker
Dr. Morton Lippmann	Dr. James Webber
Dr. John Neuberger	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)

David Bussard, Director, Washington Division

Other Attendees: Names of those who requested the teleconference call-in number are provided in Attachment B.

**MEETING MATERIALS**

The meeting materials available prior to or shortly after the May 1, 2012 meeting are available on the SAB website at, <http://www.epa.gov/sab> and specifically at the following URL:

<http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/F41FA6AC5AF02E24852579FA006B52F6?OpenDocument>

**PURPOSE**

The SAB Libby Amphibole Asbestos Review Panel held a public teleconference to discuss the SAB Panel's draft report on EPA's draft *Toxicological Review of Libby Amphibole Asbestos* (August, 2011).

**DATE AND TIME**

The public teleconference was held on May 1, 2012 from 1:00 p.m. to 4:00 p.m. Eastern Time.

## **MEETING SUMMARY**

### Convene the Meeting and Welcoming Remarks

The meeting was announced in the *Federal Register*<sup>1</sup> and generally followed the meeting agenda<sup>2</sup> unless noted otherwise in the meeting summary below. Dr. Diana Wong, Designated Federal Officer (DFO) took the roll call and opened the meeting at 1:00 p.m. She stated that the EPA Science Advisory Board (SAB) operates under the rules and regulations of the Federal Advisory Committee Act (FACA). Panel meetings are announced and open to the public, meeting minutes are prepared, all materials prepared for or by the panel are available to the public, and panel draft reports are reviewed and approved by the chartered SAB. She noted that the SAB Panel members were in compliance with federal conflict of interest and ethics requirements that apply to them. She then turned the meeting over to Dr. Agnes Kane, the Chair of the Libby Amphibole Asbestos Review Panel.

### Review of Agenda

Dr. Kane stated that the purpose of the meeting was to discuss the SAB Panel's draft review report<sup>3</sup> on EPA's draft *Toxicological Review of Libby Amphibole Asbestos* (August, 2011). (A compilation of comments from the Panel is available on the SAB website<sup>4</sup>.) Dr. Kane also described the agenda of the meeting.

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

Mr. David Bussard, Director of the Washington division of NCEA, went over questions and requests for clarification from EPA<sup>5</sup>.

### Public Comments

Dr. Kane informed the Panel and the teleconference attendees that the SAB had received 7 requests from the public to make oral comments at the teleconference. She stated that the list of registered public speakers<sup>6</sup> and written public comments and written oral comments are available on the SAB website<sup>7</sup>. Public speakers were provided an opportunity to present their comments by phone. . 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 for the derivation of RfC.
- Dr. Suresh Moolgavkar, on behalf of W.R. Grace, commented on the modeling conducted by EPA to derive the RfC.
- Dr. David Hoel, of Exponent, Inc., commented on the exposure-response models for pleural Plaque
- Dr. Lawrence Mohr, of Medical University of South Carolina, commented that localized pleural thickening is a benign marker of asbestos exposure.
- Dr. Elizabeth Anderson, of Exponent, Inc., commented on critical endpoint selection and the derivation of the RfC.
- Dr. David Fischer, of American Chemistry Council, commented that EPA's draft Libby Amphibole Assessment fell short in meeting the data evaluation procedures specified by the NAS.
- Dr. John DeSesso, of Exponent, Inc., commented on anatomical considerations of localized pleural thickenings.

### Panel Discussion on draft SAB report

The Panel chair stated that the Panel would go through the draft report section by section, and asked the lead discussants if they have comments on the response to charge questions in the draft report.

#### *Section 3.2.1. Mineralogy & Toxicokinetics*

Dr. Lippmann, the lead discussant for the toxicokinetics section, responded to EPA's question on whether or not chrysotile should be included in this section. He commented that chrysotile is very different from amphibole fibers in solubility, clearance and translocation pathways. However, deposition of chrysotile fibers in the airstream is not that different than other fibers. So the deposition of chrysotile is an exception and should be included in the section on toxicokinetics.

The lead discussants for the mineralogy section had no comments on the draft report.

#### *Section 3.2.2. Noncancer Health Effects*

##### 1. Study Population:

The Panel agreed that edits will be made as suggested by Panel members in the compilation of comments.

##### 2. Selection of Critical Effect:

The pulmonologists and lead discussants all agreed with the response to question 2. The Panel discussed the issue of including localized pleural thickening, diffuse pleural thickening and small opacity profusion together as one outcome, and agreed that combining these endpoints in the current data will have little change with the number of cases. However, in the future, it may be useful to combine all these endpoints. In addition, a panel member commented that radiographic changes by themselves are considered adverse in their own right, and these changes do not necessarily have to develop into something else to be considered as adverse.

##### 3. Laboratory animal and mechanistic studies:

The lead discussants found no need for further discussion. There was proposed word change on pg 20, line 18-22.

#### *Section 3.2.3. Carcinogenicity of Libby Amphibole Asbestos*

There were no comments for responses to questions 1 and 2.

Response to question 3. Pg 22, line 5, the Panel agreed to include possible environmental exposure as a limitation of the Libby cohort.

Response to question 4. The Panel agreed to change the sentence on page 22, line 41 to "Mesothelioma is caused by asbestos exposure", and delete "eliminating the potential for confounding." In addition, the last sentence on page 22, line 44-45 "The issue of smoking should be summarized with greater clarity" was deleted since it was not relevant.

#### *Section 3.2.4. Inhalation Reference Concentration (RfC)*

##### 1. Exposure Reconstruction

EPA clarified that although data in Appendix F, Figure F-1 is log-transformed, actual calculation of human exposure concentration did not use values that are log-transformed. The Panel agreed the paragraph on page 24, line 35-40 was probably not appropriate and should be revised.

2. Exposure-response modeling

The lead discussants agreed on the responses from page 25-26. One panel member was concerned that the wrong model was used for fitting the data in the assessment since LPT continued to develop years after asbestos exposure stopped. Other models should be considered. Since the data involves amphibole, data from similar studies on other amphiboles could be used for model selection, and does not have to be Libby Amphibole asbestos. He also commented that cumulative exposure should be plotted against incidence, not prevalence that was used in the draft assessment.

The lead discussant agreed that new text would be added in the next draft SAB report to reflect that the model used for estimating RfC should indicate incidence continued to increase after exposure stopped.

Homework Assignments

Dr. Kane asked Dr. Peto to draft his proposed approach for response to Question 3 on page 27 and send to the RfC subgroup for review.

The Inhalation Unit Risk subgroup will work together on any substantive comments made by Panel members.

The DFO will provide the revised text to the Panel no later than Monday, May 7 before the teleconference on May 8, 2012.

The teleconference was adjourned at approximately 4:00 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 not to rely on the minutes to 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.

**Attachment A. Roster**

**U.S. Environmental Protection Agency  
Science Advisory Board  
Libby Amphibole Asbestos Review Panel**

**CHAIR**

**Dr. Agnes Kane**, Professor and Chair, Department of Pathology and Laboratory Medicine, Brown University, Providence, RI

**CONSULTANTS**

**Dr. John R. Balmes**, Professor, Department of Medicine, Division of Occupational and Environmental Medicine, University of California, San Francisco, CA

**Dr. James Bonner**, Associate Professor, Toxicology, North Carolina State University, Raleigh, NC

**Dr. Jeffrey Everitt**, Director, Department of Laboratory Animal Science, GlaxoSmithKline Pharmaceuticals, Research Triangle Park, NC

**Dr. Scott Ferson**, Senior Scientist, Applied Biomathematics, Setauket, NY

**Mr John Harris**, Principal, LabCor Portland, Inc, Portland, OR

**Dr. Tom Hei**, Professor and Vice-Chairman, Radiation Oncology, College of Physicians and Surgeons, Columbia University Medical Center, New York, NY

**Dr. David Kriebel**, Professor and Chair, Dept.of Work Environment, School of Health & Environment, University of Massachusetts Lowell, Lowell, MA

**Dr. Morton Lippmann**, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

**Dr. John Neuberger**, Professor, Preventive Medicine and Public Health, School of Medicine, University of Kansas , Kansas City, KS

**Dr. Lee Newman**, Professor of Medicine, Div Env and Occup Health Sciences, School of Public Health, University of Colorado, Aurora, CO

**Dr. Michael Pennell**, Assistant Professor, Division of Biostatistics, College of Public Health, Ohio State University, Columbus, OH

**Dr. Julian Peto**, Professor, Department of Epidemiology and Population Health , London School of Hygiene and Tropical Medicine, London, UK

**Dr. Carrie Redlich**, Professor of Medicine, Internal Medicine, School of Medicine, Yale University, New Haven, CT

**Dr. Andrew G. Salmon**, Senior Toxicologist, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

**Dr. Elizabeth A. (Lianne) Sheppard**, Professor, Biostatistics and Environmental & Occupational Health Sciences, School of Public Health, University of Washington, Seattle, WA

**Dr. Randal Southard**, Professor of Soils, CA;ES Dean's Office, University of California at Davis, Davis, CA

**Dr Katherine Walker**, Senior Staff Scientist, Health Effects Institute, Boston, MA

**Dr. James Webber**, Research Scientist, Wadsworth Center, New York State Department of Health, Albany, NY

**Dr. Susan Woskie**, Professor, Work Environment, Health and Environment, University of Massachusetts Lowell, Lowell, MA

#### **FEDERAL EXPERTS**

**Dr. George Guthrie**, Dr., National Energy Technology Laboratory, US Department of Energy, Pittsburgh, PA

#### **SCIENCE ADVISORY BOARD STAFF**

**Dr. Diana Wong**, Designated Federal Officer, U.S. Environmental Protection Agency.

**Attachment B.** The following individuals requested the teleconference call-in number. Their affiliations are as entered on the registration request.

Danielle DeVoney, EPA  
Thomas Bateson, EPA  
Deborah McKean, EPA  
Bob Benson, EPA  
Malcolm Field, EPA  
Charles Ris, EPA  
Gina Perovich, EPA  
Krista Christensen, EPA  
Elizabeth Anderson, Exponent  
Suresh Moolgavkar, Exponent  
David Hoel, Exponent  
John DeSesso, Exponent  
Jay Flynn, Health Network America (Libby Medical Program)  
Lawrence Mohr, Medical Univ. of South Carolina  
David Fischer, American Chemistry Council  
Nancy Beck, American Chemistry Council  
Leonid Kopelev, EPA  
Pam Marks, Beveridge & Diamond  
Bob Sonawane, EPA  
Maureen Gwinn, EPA  
Vince Cogliano, EPA  
Glinda Cooper, EPA  
Samantha Jones, EPA  
Karen Hogan, EPA  
Paul White, EPA  
Louis D'Amico, EPA  
David Berry, EPA  
Helen Dawson, EPA  
Les Szabo, EPA  
Belinda Hawkins, EPA  
Linda Gaines, EPA  
Julie Wroble, EPA Region 10  
Tim Frederick, EPA Region 4  
Karl Bourdeau, Beveridge & Diamond  
William Concoran, Beveridge & Diamond  
Jonathan Gledhill, Policy Navigation Group  
Holli Feichko, W.R. Grace  
Lydin Duff, WR Grace  
Jenny Hopkinson, Inside EPA  
Jim Rollins, PNG  
Randy Rabinowitz  
Resha Putzrah, Navy and Marine Corps Public Health Center

Aubrey Miller, NIH  
Christopher Weis, NIH  
Kirstein Bowers, Montana Department of Environmental Quality  
Heidi King, House Energy and Commerce Committee  
Dale Drysdale, National Stone and Gravel Association  
Matt Stewart, Lafarge  
Matthew Brown, Associated Press Correspondent  
Robert Nolan, CUNY  
Wayne Berman, Aeolus  
Jeremy Jacobs, Greenwire  
Matt Sprinkle, Flathead Media  
Thomas Waskom, Hunton & Williams  
Lori Jarvis, Hunton & Williams  
David Landin, Hunton & Williams

## Materials Cited

The following meeting materials are available on the SAB Web site, <http://www.epa.gov/sab>, at the [May 1, 2012, Libby Amphibole Asbestos Review Panel Meeting](#) page.

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<sup>1</sup> Federal Register Notice Announcing the Meeting (77 FR 18808)

<sup>2</sup> Meeting Agenda, Libby Amphibole Asbestos Review Panel, May 1, 2012

<sup>3</sup> SAB Libby Amphibole Asbestos Review Panel Draft Report (4/11/12) on EPA's draft Toxicological Review of Libby Amphibole Asbestos (August 2011)

<sup>4</sup> Comments from the SAB Libby Amphibole Asbestos Panel Members on the Draft Report (4/30/2012)

<sup>5</sup> Agency Comments

- Questions and Clarifications from David Bussard, May 1, 2012, on SAB Draft Libby Amphibole Asbestos Review Report
- Request for Clarification from Bob Benson, Region 8, on the SAB Draft Report Reviewing EPA's Draft Toxicological Review of Libby Amphibole Asbestos Review Report

<sup>6</sup> List of Public Speakers

<sup>7</sup> Public Comments

- Oral Statement from Dr. David Hoel, Exponent, Inc.
- Oral Statement from Dr. Elizabeth Anderson, Exponent, Inc., dated May 1, 2012
- Oral Statement from Dr. John DeSesso, Exponent, Inc.
- Oral Statement from Dr. Lawrence Mohr, Medical University of South Carolina, on behalf of WR Grace,
- Public Comments from David Fischer, American Chemistry Council, April 24, 2012
- Public Comments from Dr. Lawrence Mohr, Medical University of South Carolina, on behalf of WR Grace.
- Public Comments from Dr. Suresh Moolgavkar, Exponent Inc. on behalf of WR Grace, dated April 23, 2012.
- Public Comments from National Stone, Sand & Gravel Association, April 24, 2012.
- Revised Oral Statement from Dr. John DeSesso, Exponent, Inc.