

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

**Public Teleconference
May 8, 2012**

Minutes of the Meeting

ATTENDANCE

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

Dr. Agnes Kane (Chair)	Dr. Michael Pennell
Dr. John Balmes	Dr. Julian Peto
Dr. James Bonner	Dr. Carrie Redlich
Dr. Scott Ferson	Dr. Andrew Salmon
Mr. John Harris	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
Dr. Lee Newman	

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 during the May 8, 2012 teleconference 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/E556958D703C18B2852579C20051C8C9?OpenDocument>

PURPOSE

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

DATE AND TIME

The teleconference was held on May 8, 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*¹ and generally followed the meeting agenda². The meeting continued discussions from the May 1, 2012, teleconference of the Libby Amphibole Asbestos (LAA) Review Panel. 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, Chair of the LAA Review Panel.

Panel Discussion on Responses to EPA's Charge Questions

The Panel turned to discussion of its draft document, dated April 11, 2012,³ and member comments⁴ and proposed revisions.⁵ The Panel chair announced that the RfC subgroup needed more time to revise the response to charge question 3 in Section 3.2.4, and informed the Panel that May 25, 2012, would be the next deadline for the Panel members to submit revised response to charge questions to the DFO.

The Panel discussed whether geometric mean or arithmetic mean should be used for the development of a cumulative exposure metric. Dave Bussard of EPA clarified that in EPA's assessment, the geometric mean was used in the estimation of the benchmark dose.

The Panel Chair asked Dr. Jim Webber and Dr. Susan Woskie to work together to develop a recommendation on the issue of whether geometric mean or arithmetic mean should be used, and send the writeup to the DFO by May 25. She also asked Dr. Scott Ferson to write text to clarify his comments on uncertainty on line 2-4, page 4, and line 28-31, page 24.

The Panel then discussed Section 3.2.5. Inhalation Unit Risk.

Dave Bussard of EPA asked if it is easy or valuable to do uncertainty analysis on the full cohort. Panel members suggested EPA should consider conducting uncertainty analysis, and it is up to EPA to decide how far to go.

The Panel discussed the revised response to Question 3 in this section. The Panel would like greater discussion of justification for assumption of independence. This should not involve more analysis. Dr. Mike Pennell agreed to revise the recommendations and send the revised text to the DFO by May 25.

For the response to Question 5, the subgroup had revised text to address comments.

Section 4, Long-Term Research Needs:

Mr. John Harris volunteered to write a section on future development of a transmission electron microscopy (TEM) method for phase contrast microscopy (PCM) equivalency.

Appendix B:

The Panel agreed that individual comments in Appendix B are not endorsed by the entire Panel, and would not be included in the next draft.

The Panel discussed whether smokers are a sensitive subgroup and agreed that literature does not support smokers as a sensitive subgroup for LPT. There is need to propose changes in wording on pg 29, line 10, and executive summary in page 5, line 23.

The Panel agreed that on pg 4, line 5, the phrase “WR Grace exfoliation plants“ should be omitted. Also on pg 4, line 8-10, regarding estimation of human exposure, Dr. Jim Webber and Dr. Susan Woskie agreed to work on both the body of the text and the executive summary on the issue of geometric mean vs. arithmetic mean.

For pg. 8, line 1-6, Dr. Katherine Walker agreed to make changes in the executive summary in accordance with changes in response to question 3, pg 36.

For pg 28, Dr. Mike Pennell agreed to make changes to the text on gender. Dr. Lianne Sheppard and Dr. Mike Pennell would take another look at the response to Question 4 in Section 3.2.4 to clarify the analysis of confounders.

Uncertainty Factors:

EPA asked for clarification regarding SAB’s recommendation on the use of uncertainty factors. Dr. Andy Salmon and Dr. John Balmes agreed to work on a response to this question.

EPA also asked for clarification regarding modeling of combined X-ray anomalies endpoints. Panel members clarified that modeling combined X-ray anomalies is more important for future studies, and major changes in analyses already done are not recommended.

The Panel also agreed the last bullet on page 10 was to provide clinical completeness, and that the sentence on page 11, line 1-3 should be deleted.

Next Steps

For Section 3.2.4, RfC, responses to Charge Question 3, 4, and 6 will be revised. Dr. Sheppard will take the lead to revise response to question 3 and 4. Drs. Susan Woskie, Andy Salmon, and Mike Pennell will also be involved in revising responses to question 3. Drs. Mike Pennell and John Neuberger will work with Dr. Sheppard on the response to Question 4. Drs. Andy Salmon and Jamie Bonner will take the lead to revise the response to Question 6. The Panel will also look at the response to question 7 on page 31.

David Bussard asked the Panel to frame the relevance of other amphiboles on page 11. The Panel agreed that epidemiological studies from literature on other amphiboles will be useful for model selection for dose-response assessment of LAA.

The DFO announced that the next public teleconference to discuss the SAB draft report would be on July 25, 1-4 p.m., Eastern Time, and adjourned the meeting.

Respectfully Submitted:

Certified as Accurate:

/signed/

/signed/

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

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.

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
Suresh Moolgavkar, Exponent
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
Michael Showwalter, SchiffHardin
Jenny Hopkinson, Inside EPA
Jim Rollins, PNG
Randy Rabinowitz
Resha Putzrah, Navy and Marine Corps Public
Health Center
Thomas Hale-Kupiec, George Washington
University
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
Debra Taylor, Ca EPA/DTSC
Vivek Mathrani, Ca EPA/DTSC
Dr. Klein, Ca EPA/DTSC
Dr. Endlich, CaEPA/DTSC
Jeffery Camplin, Camplin Environmental
Services
Michelle Hartly, Libby resident
Suzy Rios, Libby resident

Materials Cited

The following meeting materials are available on the SAB Web site, <http://www.epa.gov/sab>, at the [May 8, 2012, Libby Amphibole Asbestos Review Panel Meeting](#) page.

¹ Federal Register Notice Announcing the Meeting (77 FR 18808)

² Meeting Agenda, Libby Amphibole Asbestos Review Panel, May 8, 2012

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

⁴ Comments from Dr. Jim Webber, SAB Panel Member, Dated May 8, 2012

⁵ Draft Text For Panel Deliberations To Develop Draft Report

- Revision to the Draft SAB Report on Section 3.2.5 Inhalation Unit Risk (IUR) by SAB IUR Subgroup
- SAB Subgroup Revised Response to Question 3 & § under Section 3.2.3 of SAB Draft Review Report of EPA's Draft Toxicological Review of Libby Amphibole Asbestos