

**U.S. Environmental Protection Agency**  
**Science Advisory Board**  
**Radiation Advisory Committee (RAC)**  
Summary Minutes of Public Conference Call Meeting<sup>1</sup>  
December 18, 2006

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**Committee:** Radiation Advisory Committee (RAC ) of the U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB). (See Roster - Attachment A.)

**Date and Time:** Monday, December 18, 2006 from 12:00 noon to 3:00 p.m. eastern standard time (See Federal Register Notice - Attachment B).

**Location:** This is a conference call with no location announced. All participants were connected via the conference lines.

**Purpose:** The purpose of this public conference call meeting is for the RAC to continue activities related to preparation of an advisory on the Environmental Protection Agency's (EPA) Office of Radiation and Indoor Air (ORIA) draft White Paper entitled "*Modifying EPA Radiation Risk Models Based on BEIR VII*," dated August 1, 2006. During the public conference call, the RAC plans to discuss and suggest edits to their December 12, 2006 public draft advisory.<sup>2</sup> (See Meeting Agenda - Attachment C.)

**SAB/RAC Attendees:** RAC Members Dr. Jill Lipoti, RAC Chair, Dr. Bruce Boecker, Dr. Thomas B. Borak (new member), Dr. Antone L. Brooks, Dr Brian Dodd, Dr. William C. Griffith, Dr. Shirley A. Fry, Dr. Helen A. Grogan (logged on the International line from Switzerland and was on the line until 11:57 am EST), Dr. Richard W. Hornung, Dr. Jonathan M. Links, Mr. Bruce A. Napier (new member), and Dr. Richard J. Vetter were present. (See Attachment A); Dr. K. Jack Kooyoomjian (Designated Federal Officer of RAC) - SAB Staff Office, and Dr. Anthony F. Maciorowski, SAB Staff office Deputy Director participated. Dr. Daniel O. Stram (new member) was in Japan and unable to participate.

**Agency Staff Attendees:** ORIA, Washington, DC: Dr. Mary E. Clark, Dr. Jerome Puskin and

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<sup>1</sup> NOTE: Please note that these minutes represent comments that are individual statements and opinions and are not necessarily consensus comments at this stage of the process in the review of any given topic. In all cases, the final SAB report to the EPA Administrator represents the consensus on the topic.

<sup>2</sup> See the December 21, 2005 minutes where the RAC was initially briefed by the Agency's ORIA staff on the proposed draft White Paper concepts in a face-to-face meeting of the RAC at Montgomery, AL. The RAC held its first formal review public conference call meeting to initiate the review of the Agency's draft White Paper on December 6, 2006, followed by a face-to-face review meeting on September 26-28, 2006. The November 28, 2006 and December 18, 2006 public conference calls are a follow-up to those meetings.

Dr. David Pawel.

**Public Attendees:** Mr. Lynn Howard Ehrle, Senior Research Fellow with the Cancer Prevention Coalition, Ms. Lisa Ledwidge and Dr. Arjun Makhijani, President of the Institute for Energy and Environmental Research (IEER) provided public comments.

**Meeting Summary:** The meeting followed the issues and general timing as presented in the meeting Agenda (See Meeting Agenda - Attachment C). Committee correspondence pertaining to edits and public comments can be found in Attachment K.

**Welcome and Introductions:** Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 12:02 p.m. with identification of the participants logging into the call and with opening remarks. He introduced himself as the DFO for the Radiation Advisory Committee (RAC), explained the purpose of the call, indicating that the RAC operates under the requirements of the Federal Advisory Committee Act (FACA) and is chartered to conduct business under the SAB Charter. He explained that, consistent with FACA and with EPA policy, the deliberations of the RAC are conducted in public meetings, for which advance notice is given. He explained that he is present to ensure that the requirements of FACA are met, including the requirements for open meetings, for maintaining records of deliberations of the RAC, and making available the public summaries of meetings, as well as providing opportunities for public comment.

Dr. Kooyoomjian also commented on the status of this Committee's compliance with Federal ethics and conflict-of-interest laws. The RAC follows the Committee and Panel Formation Process, as well as determinations made by the SAB staff and others pertaining to confidential financial information protected under the Privacy Act. Each committee member has complied with all these provisions; there are no conflict-of-interest or appearance issues for any of the Panelists, nor did any individual need to be granted a waiver or be recused. Dr. Kooyoomjian further noted that the Form 3110-48 Financial Disclosure and Ethics Training was completed by all RAC members and is on file at the SAB, that there is no need for disclosure, and that there is no particular matter that may pose a potential conflict of interest. He advised that the RAC members, including the three new members should briefly introduce themselves and how they relate to this topic. He also advised that the biosketches of each Panelist are posted on the SAB website (See Attachment M).

RAC Panelists "logged-in," and Dr. Lipoti welcomed the participants (Roster, Attachment A) and provided some brief opening remarks at 12:15 p.m., briefly summarizing the goals for today's conference call. The Committee picked up with Section 6, page 19 of the December 12, 2006 public draft advisory dealing with uncertainties not quantified in BEIR VII, particularly the use of the biophysical model (See Attachment F-4). A discussion followed on the issue of LNT, and that there are epidemiological studies of high cumulative doses at low dose rates. The ORIA Staff plan to review these studies. It was agreed that the Committee would discuss some of these issues more expansively in Appendix A of the draft advisory.

It was thought that there may not be a consensus on responding to comments pertaining

to whole tissue or single cell oncology at this time. It is clear that a cell in a tissue is much less likely to be transformed because of the cells around them. In Section 3 dealing with Philosophy of Approach to the Charge, the Committee felt it should encourage the Agency to continue to monitor the science as the literature might affect the old biophysical “one hit” model. There was consensus that LNT overestimates the risk, but does not underestimate the risk. Some discussion then took place on whether the Committee is comfortable on whether the LNT over or under-estimates risk, and cautioned that we should be careful not to over-interpret this issue. It was agreed that the current edits and word-smithing has been careful in this regard.

A discussion followed on the issues of doses and whether they are internal emitters to a single organ. (p. 20, lines 4-9). It was recognized that the current draft advisory is silent on dose-rate effects. The Committee agreed to eliminate the portion of the paragraph on page 20, lines 4-9. The Committee thought that it would be helpful to have a qualitative discussion on an alternate approach for EPA to specify a range of dose and dose-rate, and to not reach inappropriate conclusions. The Agency staff acknowledged that there is a certain range where they have data, and beyond which they have to use a model. The Committee liked the direction of this for additional text edits to the current draft. The issue of model extrapolation within the range of applicability was then discussed. The Committee liked the wording being suggested that at low doses and low dose rates, the Agency is using a model to extrapolate from higher dose rates, and being a model, there is uncertainty in the application.

It was acknowledged that certain cancers might change dramatically due to lifestyle factors. The Committee acknowledged that the current draft states this. The difficult part is how much risk is modified at low dose rates. The Committee also acknowledged that the recommendation on page 18, lines 30-32 of the current draft as conceptually a huge task; namely, to estimate the relative magnitude of the independent contribution of the additional sources of error or uncertainty identified to the overall uncertainty.

The Committee thought that it would be helpful to conduct a sensitivity analysis, and it was recognized that there is no easy short cut at doing a proper sensitivity analysis. The Committee thought that it would be helpful to make further edits to the first paragraph on page 19 dealing with this topic. A discussion followed on cellular and molecular endpoints. It was acknowledged that the statement on page 19, lines 39 and 40 needs to be edited to acknowledge that there are no reliable epidemiological data.

#### ORIA Staff Comments:

At 1:21 p.m., Dr. Lipoti asked Dr. Mary Clark if the ORIA Staff had any comments. At this juncture regarding the discussion pertaining to uncertainty, the Agency staff does not have any comments.

#### Continued Committee Discussion:

The Committee discussed Appendix A, which came out of the body of the draft advisory.

It was observed that it needs more references. A discussion took place to clarify the terminology on such items as hormesis, LNT, and the reference to ongoing research and paradigms.

Public Comments: At 1:34 p.m., Dr. Lipoti asked if there were any members of the public who wished to address the RAC. At this time, two individuals identified themselves as wishing to comment. These were Mr. Lynn Howard Ehrle of the Cancer Prevention Coalition, and Dr. Arjun Makijani, President of the Institute of Energy and Environmental Research (IEER). NOTE: *No formal written comments were provided to the RAC DFO, Dr. Jack Kooyoomjian for this meeting, and both commenters requested to provide verbal comments (See Attachment G).*

At 1:34 p.m., Mr. Ehrle referred to his position as Founder and Chairman of an International Oversight Board. He has been involved in radiation study of health effects for 34 years. He was concerned with the narrow focus and charge of the request from the Agency to the SAB/RAC. In his view, the charge should have gone one step further to accept LNT on BEIR VII, yet there is sufficient evidence of problems particularly in the low dose area, and particularly in-utero. He believes that there are statements without foundation and they may point to the other direction. It is his assertion that many prominent people dealing with these issues are not published. He mentioned Chris Buzbee, Alexi Robicoff and others. It is his view that the document expresses the ICRP model being off by factors of 100 or 1000. It is his view that there are no reliable epidemiological data. His observation is that 3/4 of the LSS cohort has exposures under 200 milliseverts, that there are definitional issues, and there is very narrow exposure on issues of low doses. He encouraged Dr. Puskin of ORIA to come up with a broader charge. He ended his comments at 1:42 p.m.

At 1:42 p.m., Dr. Arjun Makijani, President of the Institute for Energy and Environmental Research (IEER) commented. He asked whether the Panel was considering changes to the cancer risk estimates. He suggested that the Panel change its recommendations to apply to cancer incidence. He observed that the report has incidence by age and gender. He has strong opinions how in-utero exposures should be used in the report. He recommended that this Panel should not fail to point out when (his emphasis) the exposure occurs. In his view, this would compromise the stem cells and bone marrow and cause problems in childhood. He did not see age-specific exposures and risk conversion factors which are in Federal Guidance 13. He contended that if you accept the BEIR VII model, it is really the early years that matter the most and not the later years. He is a little troubled by the discussion of thyroid cancer, because there are significant gender differences, and these are recognized by the National Cancer Institute. He also commented on issues related to hormone replacement therapy, and effects on cancer models. He observed that the role of estrogen mimicking chemicals is not mentioned in the Committee's draft advisory or in the Agency's draft White Paper. To him, this is a stunning effect, and in his view there should be attention given to the pervasiveness of exposure to estrogen-mimicking chemicals, as this may have implications on pollution effects. Dr. Makijani completed his comments at 1:51 pm.

There being no additional public comments to be offered to the Committee, Dr. Lipoti thanked the commenters and closed the public comment period at 1:51 p.m.

Continued Committee Discussion:

The RAC returned to discussion of the draft Advisory. The Committee offered a number of clarifying comments dealing with multiplicative and additive risk coefficients, weighted geometric means and other terminology. The Committee turned to edits in Section 3 pertaining to the Philosophy of the Approach to the Charge. The Committee agreed to include some of Section 3 commentary into the Executive Summary. They discussed various edits to areas dealing, for instance, with breast cancer, lung cancer and where it made sense to deviate from BEIR VII. They recommended that the Agency use more illustrative examples. They then discussed Section 5 dealing with CQ # 2 on modifications and extensions to the draft White Paper. In CQ 2d dealing with adoption of an alternative model for radiogenic lung cancer risk, which may better account for the effects of smoking than the BEIR VII approach, the Committee recognized where the public was concerned with the Agency recommending a lower risk. The Committee recognized that some of this difference comes largely from the recommendations on CQ #2c in the Agency's proposed methods for combining the BEIR VII's models for projecting risk from the Japanese A-bomb survivors to the U.S. population. A discussion followed on how the various risks added up to sum up all the risks. They acknowledged that some of the Committee's current edits and commentary in the draft Advisory are in direct response to the previous comments made by the public. It was observed by the Committee that the numbers are close, but consistently smaller. In Section 5.5, in response to CQ #2d, page 12, the Committee agreed to drop lines 18-21.

The Committee discussed further recommended edits to the draft Advisory.

A discussion followed on CQ #2G pertaining to the estimation of risks for sites not specified in BEIR VII, specifically bone and skin, for which the Agency is proposing to update its current approaches.

Around 2:43 p.m., a discussion followed on logistics, the sensitivity analysis, and a variety of additional recommended edits to the draft Advisory. A number of additional references were recommended by the Committee. Also, the Committee added the acronym  $RBE_N$ , and additional edits were recommended.

Summary & Action Items from the December 18, 2006 Public Conference Call: A discussion followed on assignments, and the following captures those discussions in summary fashion:

- 1) Jack Kooyoomjian will send the Microsoft Word version of current December 12, 2006 public draft to the Committee for their recommended text edits;
- 2) All edits are to be completed and delivered to Dr. Lipoti with a copy to Dr. Kooyoomjian by January 19, 2007;
- 3) Jack Kooyoomjian will poll all RAC members for the next available date for a public conference call.

There being no additional business to be discussed, Dr. Lipoti thanked all the participants and adjourned the meeting at 2:58 pm on Monday, December 18, 2006.

Respectfully Submitted:

Certified as True:

\_\_\_\_\_/S/\_\_\_\_\_  
K. Jack Kooyoomjian, Ph.D.  
Designated Federal Official  
Radiation Advisory Committee (RAC)

\_\_\_\_\_/S/\_\_\_\_\_  
Dr. Jill Lipoti, Chair  
Radiation Advisory Committee (RAC)

## List of Attachments

<u>Attachment</u>	<u>Description</u>
A	Radiation Advisory Committee (RAC) Roster
B	<i>Federal Register</i> Notice: October 26, 2006, Vol. 71, No. 207, pages 62590-62591
C	Meeting Agenda for December 18, 2006
D	Agency Request for Advisory from Elizabeth A. Cotsworth, Director, Office of Radiation and Indoor Air (ORIA) to Vanessa Vu, Director, SAB Staff Office, dated August 31, 2006 and entitled “ <i>Advisory Review of the Draft White Paper: Modifying EPA Radiation Risk Models Based on BEIR VII.</i> ”
E	Proposed Project Sheet 06-16
F	E-mail Review Package Dated December 13, 2006 Containing the following:
F-1	Memo from K. Jack Kooyoomjian, Ph.D., DFO RAC to RAC Members entitled “ <i>Review Materials for the December 18 Conference Call,</i> ” containing the following:
F-2	Agenda Containing the Toll-Free and Dial-In Numbers for the RAC Members: (File Address: RACWhite PaperPropAgenda121806.rtf)
F-3	Public Agenda which is on SAB Web site: (File Address: RACWhite PaperPubAgenda121806.pdf)
F-4	Latest (Dec 12, 2006) Public Draft Advisory which is on SAB Web site: (File Address: WhitePaperWkgdftAdv121206.pdf)
G	Supplemental Information Provided by EPA to SAB/RAC for Public Discussion on November 28 & December 18, 2006
H	<b>PUBLIC COMMENTS:</b> <b><u>NOTE:</u></b> <i>No written comments were provided to the SAB’s RAC specifically for this public conference call meeting, which may be viewed by the public as a continuation of the November 28, 2006 public meeting. Please refer to the FACA file of November 28, 2006 for previously submitted written and verbal public comments.</i>
I	<b>PUBLIC CORRESPONDENCE PERTAINING TO DECEMBER 18, 2006 SAB/RAC PUBLIC CONFERENCE CALL MEETING</b> (Pre & Post Meeting Correspondence)

**Attachment**

**Description**

- J COMMITTEE CORRESPONDENCE PERTAINING TO DECEMBER 18, 2006 SAB/RAC PUBLIC CONFERENCE CALL MEETING (Pre & Post Meeting Correspondence)
- K MISCELLANEOUS AND ADMINISTRATIVE CORRESPONDENCE PERTAINING TO DECEMBER 18, 2006 SAB/RAC PUBLIC CONFERENCE CALL MEETING (Pre & Post Meeting Correspondence)
- L Biosketches of Radiation Advisory Committee
- M DFO's Marked-Up Agenda of 12/18/2006 SAB/RAC Public Conference Call Meeting (K. Jack Kooyoomjian)
- N DFO's Partial Mark-Up of December 12, 2006 PDF Draft Advisory
- O DFO's Notes of 12/18/2006 SAB/RAC Public Conference Call Meeting
- P Post-Meeting Edits and Correspondence in Review of Agency's Draft White Paper: Suggested Draft Advisory Edits Following December 18, 2006 Public Conference Call

**End of Record**