

**U.S. Environmental Protection Agency**  
**Science Advisory Board**  
**Radiation Advisory Committee (RAC)**  
Summary Minutes of Public Conference Call Meeting<sup>1</sup>  
November 28, 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:** Tuesday, November 28, 2006 from 10:00 a.m. to 1:00 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 November 15, 2006 public draft advisory activity.<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), Dr. Daniel O. Stram (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. Vanessa Vu, SAB Staff office Director participated.

**Agency Staff Attendees:** ORIA, Washington, DC: Dr. Mary E. Clark, Dr. Jerome Puskin and Dr. David Pawel (Drs. Puskin & Pawel attended the Beebe Symposium that day and connected

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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 public conference call is a follow-up to those meetings.

around 12:00 noon).

**Public Attendees:** Mr. Lynn Howard Ehrle, Senior Research Fellow with the Cancer Prevention Coalition, Mr. Daniel Hirsch, Committee to Bridge the Gap, Nuclear Information and resource Service, Public Citizen, and Ms. Lisa Ledwidge, 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. Written comments were provided by one member of the public just prior to the meeting (See Attachment I-1) and verbal comments were provided to the Committee by three members of the interested public during the course of the conference call meeting (See summary in minutes, below). There was follow-up in the form of additional public comment (See Attachment I-2), as well as additional public correspondence (See Attachment J).

**Welcome and Introductions:** Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 10:02 am 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 provided some brief opening remarks at 10:13 am, welcoming members and participants (Roster, Attachment A), reviewed the meeting agenda (Attachment C), and then asked that Dr. Mary Clark and the ORIA Staff provide some opening remarks. After some brief remarks by Dr. Lipoti, she asked the members starting with the new

members, to introduce themselves. Mr. Lynn Ehrle, representing the Cancer Prevention Coalition, interjected a comment in the middle of the introductions asking about the new members and Dr. Kooyoomjian, as an informational courtesy, briefly described the annual membership cycle of the members on all the standing committees.

At 10:23 am, Dr. Lipoti began review of the November 15 ,2006 draft starting with page 7, Section 3 on Philosophy of Approach to the Charge. The RAC members discussed this item, looking primarily toward clarifying terminology and inconsistencies. The Committee moved toward laying out the things they agree with and agreed to define such terms as LNT for radiation protection purposes in the context of this advisory. Dr. Links agreed to offer language for the next round of edits.

A discussion followed on the nuclear worker study and other sources of data. The Committee agreed that they needed to define what they mean by low dose, and to be clear enough in the edited text so that it is understandable to the layman.

A discussion followed on areas needing further clarification for what is in the draft White Paper, such as caveats and references to the size of the group(s) being sampled, the organ receiving the dose, low dose rates for internal emitters, exposures that are acute one-time doses or low doses over time and the different results that are likely to occur.

Another topic that was addressed was the audience who will be reading the SAB advisory. It was thought that what would be helpful to a general audience is the Section 3 philosophy of the approach to the charge, where some background and logic will be helpful to a broad readership. It was thought that some items may be more helpful to explain in an Appendix to the advisory, rather in the core of the text.

Some of the revised text should touch on the current state of scientific knowledge. It would be helpful to explain there is considerable uncertainty remaining beyond the use of the LNT model.

ORIA Staff Comments: At 11:21 am, Dr. Lipoti asked Dr. Mary E. Clark, Assistant Director for Science at ORIA for any comments. (At this time Drs. Puskin and Pawel of ORIA were still attending the Beebe Symposium at the NAS). Dr. Mary Clark thanked the RAC for the discussion, and acknowledged that the current draft White Paper perhaps did not do as good a job to clarify the low dose limitations. She offered some commentary on page 15, Section 5.8 of the current SAB/RAC draft advisory in reference to non-melanoma skin cancer & bone cancer. A new member of the Committee took the opportunity to seek clarification on Table #2 in the draft White Paper, asking if it would be okay to engage the EPA staff directly for clarification on this matter. Some discussion occurred on clarifying the units.

Public Comment: At 11:27 a.m., Dr. Lipoti asked if there were any members of the public who wished to address the RAC. At this time, three individuals identified themselves as wishing to comment. These were Mr. Lynn Howard Ehrle of the Cancer Prevention Coalition, Mr. Daniel Hirsch, President of the Committee to Bridge the Gap, and Ms. Lisa Ledwidge of the

Institute for Energy and Environmental Research (IEER).

At 11:27 a.m., Mr. Ehrle referred to his written public comments which were provided to the DFO, Dr. Kooyoomjian mid-day on November 27<sup>th</sup> and were emailed by Dr. Kooyoomjian to the Committee (see Attachment I-1). He referred to systemic problems and felt that his basic complaint was that the charge relates to BEIR VII, and that BEIR VII depended on ICRP. He felt that there are a wide range of studies available that could have been and should be utilized. He felt that some exposure studies may be much more significant, and that the Agency needs to go beyond BEIR VII. He asked why would you (the Agency, and the SAB/RAC) limit themselves to BEIR VII and the draft White Paper? He felt that some expanded commentary on these issues might be helpful by the SAB/ RAC.

At 10:38 a.m., Mr. Daniel Hirsch, President of the Committee to Bridge the Gap and Co-Chair of the advisory panel overseeing health studies associated with the former Department of Energy nuclear facility at Santa Susanna, CA introduced himself to the Committee. He noted that he also teaches at the University of California at Santa Cruz. He indicated that it was his view that the activity the SAB/RAC is engaged in is a political exercise and not a scientific activity. He felt that an honest critique should be forthcoming which is not a pro-industry critique. He referred to his September 22, 2006 comments which were submitted in hard copy format for the RAC's September 26-28, 2006 meeting, and asked why they were not posted on the SAB Web site (POSTSCRIPT: All comments received at the Sept, 26-28 meeting were placed as hard-copy the handouts for everyone to take off the handouts table and were provided to the RAC members during the meeting. Mr. Hirsch re-submitted the previously submitted comments following the meeting. See Attachment I-2).

It was Mr. Hirsch's view that there is a vast wealth of information pointing to the risks being higher, and that they are several multiples higher. He cited a Rocketdyne study and others. He felt that the Bush Administration and the actions of all the decision bodies present for this exercise only support and reinforce his belief that this process is politicized and is employing politics to attack LNT. He felt that there are 27 of 28 figures in the documents that, in his estimation, "relax" risk, and this should be more neutral. He suggested that those who may have, in his view, conflicts, should resign. He ended his comments at 11:44 a.m.

Mr. Ehrle interjected at 11:44 am that he agrees with the statements of Mr. Daniel Hirsch.

At 11:44 am, Ms Lisa Ledwidge, United States Outreach Director, and Editor of *Science for Democratic Action* of the Institute of Energy and Environmental Research (IEER) had verbalized four recommendations to offer the SAB/RAC. They are briefly summarized as follows:

- 1) EPA should stop averaging male and female risk and use higher risk, which would be the female risk;
- 2) EPA should change use of the "reference man" in Federal Guidance #11 and change to the most susceptible unit risk reference for each cancer;
- 3) EPA should combine BEIR VII with Federal Guidance 13 for dose conversion to provide age or age-specific risk estimates; and

- 4) EPA should modify for cancer incidence risk and not just cancer fatalities, that is, EPA should essentially give equal attention to incidence and mortality.

Dr. Lipoti asked if there were any others interested in commenting. Nobody else came forward, and the comment period closed at 11:48 a.m.

### **Continued Panel Discussion:**

The RAC continued discussion. It was clarified that Dr. Links would re-edit Section 3 up to Section 3.2 Acknowledgment.

The RAC observed in response to the last public commenter that the charge questions relating to BEIR VII in fact used incidence models as the overall approach as opposed to mortality models. A discussion followed on how other manifestations, such as skin cancer were handled. The Committee focused on edits that clarified implicit assumptions in BEIR VII, and where examples would be helpful in the text.

Dr. Lipoti directed the Committee's attention to the current text asking if edits were needed in the text for each charge question. A brief summary is as follows:

For Section 5.2 for Charge Question (CQ) #2a (deals with calculation of the risk to the life table stationary population instead of the actual U.S. population). There were no changes recommended at this time.

For Section 5.3 CQ #2b (use of more recent incidence and mortality data from SEER and/or other sources), it was noted on page 11, line #23 that the years should be 1998-2002, instead of 1995-2002, and that the text could use a clarifying discussion on incidence and mortality. A discussion followed on the fact that we do look at the changes to the risk calculations on p. 12, lines 5-7.

For Section 5.4 CQ #2c (method for combining BEIR VII's models projecting risk from Japanese A-bomb survivors to U.S. population to calculate lifetime attributable risk, LAR). There was general agreement with the draft wording.

Agency ORIA Staff Feedback: At 12:04 p.m., Drs. Puskin and Pawel joined the conference call. A discussion followed on the additional references provided by the Agency on the topic of smoking lung cancer interactions (see Attachment F-3).

For Section 5.5 CQ#2d (adoption of an alternative model for radiogenic lung cancer risk which may better account for the effects of smoking than BEIR VII). Dr. Lipoti reminded the Committee that Dr. Vu has cautioned the RAC and other Committees and Panels that they should not be doing the Agency's work for them, but giving advice for what EPA should consider and suggesting to the Agency what needs to be done; not necessarily how to do it. Some text edits toward that end were recommended by the Committee.

One of the RAC members noted that there has been literature after BEIR VII which shows a pronounced change on female lung cancer and how it relates to exposure, and there should be a recommendation that this recent body of literature needs to be looked at by the Agency. The RAC members assigned this activity will edit this section as per the discussions.

One of the RAC Committee members noted that the biological data from the Russians suggest that a RBE of 20 may be high. The Agency Staff observed that Ethel Gilbert's paper has much improved dosimetry of the lungs for the Mayak workers. It suggests that it is more consistent with a RBE of 20, and perhaps guidance of "wait and see" from the RAC to the Agency might, in fact, be good advice. Some discussion followed on radon risk data for radon inhaled deep in the lung might suggest a RBE near 20. The Committee observed that a summary on page 27 of the draft White Paper encapsulates a RBE of 20. Some of the RAC members expressed favor for the use of a RBE of 20, which they believe is the most conservative approach.

For Section 5.8 CQ #2g (dealing with estimation of risks for sites not specified in BEIR VII, specifically bone and skin, for which the Agency proposes to update their current approaches). Dr. Boecker was asked to clarify the estimates for bone cancer also in 2 (f). The thought was that the Committee might want to discuss differences of a single acute exposure as compared to protracted exposures.

For Section 6, page 17-19. (dealing with uncertainty - - - and focused on uncertainties not quantified in BEIR VII). The Committee Chair suggested leaving Section 6 on Uncertainties as is for editing on December 18, 2006.

For Section 7, page 20 (dealing with radiogenic thyroid cancer), the Committee discussed the current status of the NCRP report dealing with thyroid cancer. It was estimated that in 2 or 3 months, the NCRP will likely post their draft report for public comments for the public. The Committee basically agreed that for the present they can't say anything until the NCRP report dealing with thyroid cancer is published.

At 12:45 pm, Dr. Lipoti summarized the action items (see below). It was agreed that on the December 18, 2006 telephone call, Dr. Lipoti will start with Charge Question #3 (Section 6 in the November 15, 2006 Draft Advisory). It was suggested that the Committee members complete their assignments and get their written materials to Dr. Lipoti, with a cc to Dr. Kooyoomjian no later than December 11, 2006.

Summary & Action Items from the November 28, 2006 Public Conference Call: A discussion followed on assignments, and the following captures those discussions in summary fashion:

All edits are due to Dr. Lipoti no later than Dec. 11<sup>th</sup> (earlier is better);

Overview: There are issues of clarity and philosophy for everyone to address;

Section 2.2.4 - Some rewriting to clarify the dose-response relationship, as expressed on p. 247 of BEIR VII is needed. Dr. Lipoti has agreed to make some edits in this area;

Section 3 - Dr. Links will re-write Section 3 on Philosophy (already in progress, with a first draft, comments by Dr. Fry and 2<sup>nd</sup> draft);

Section 3.1 - Dr. Brooks' biophysical model information will be placed in an Appendix along with the discussion in Section 3.1;

Section 4.1 (Response to Charge Question 1) - The answer is to be clarified to address incidence rather than mortality. This addresses, in part, the public comment that we (the SAB/RAC) recommend to the Agency to give equal weight to incidence and mortality. The consensus is to use incidence;

Section 5.2 - CQ #2a draft text is OKAY for the present;

Section 5.3 - CQ #2b draft text could use a clarifying discussion on incidence and mortality. Needs modest edits as recommended by Dr. Grogan. She volunteered to make the changes;

Section 5.4 - Dr. Brooks & Fry to clarify intent on CQ #2c. Dr. Fry will send her edits to Dr. Brooks & Dr. Grogan;

Section 5.5 - The RAC will recommend in CQ #2d that ORIA should complete the literature review and use the information they obtained in the literature review to determine if there is "compelling evidence" to justify any change from the BEIR VII approach;

Section 5.6 - CQ #2e draft text is left intact for the present;

Section 5.7 - CQ #2f: Dr. Boecker (coordination with Dr. Hornung) will rewrite. He will also include CQ #2g in reference to bone cancer;

Section 5.8 - CQ #2g: Drs. Fry & Brooks will work on text edits for skin cancer. Dr. Boecker will work on text edits for bone cancer;

Section 5.9 - CQ #2h: left as is for now;

Section 6.0 - CQ #3 in Section 6 regarding quantitative uncertainty bounds was deferred to the Dec.18, 2006 public conference call; and

Section 7 - CQ #4 will remain as is for the present.

There being no additional business to be discussed, Dr. Lipoti adjourned the meeting at

12:52 pm on Tuesday, November 28, 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 dated November 15, 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 November 16, 2006 Containing the following:
F-1	Memo from K. Jack Kooyoomjian, Ph.D., DFO RAC to RAC Members entitled “ <i>Review Materials for November 28 and December 18 Conference Calls,</i> ” containing the following:
F-2	RACs 1 <sup>st</sup> Public Draft Advisory (File Address: WhitePaperpublicWkgDftAdv111506.pdf)
F-3	EPA-Supplied Data Requested by the RAC Members (File Address: Lung cancer incidence calcs101716.pdf)
F-4	November 28, 2006 Agenda for Committee Members with Toll-Free Dial-In and Pass Code Numbers (File Address: RACWhite PaperPropAgenda112806.rtf)
F-5	November 28, 2006 Public Agenda (File Address: RACWhite PaperPublicAgenda112806.pdf)
F-6	RAC Internal Roster (File Address: RAC 09IntRoster11152006.rtf)
F-7	Federal Register Notice of Nov 28 & Dec. 18, 2006 Meetings (File Address: FRN RAC White Paper Advisory Nov 28 and Dec 18, 2006.doc)
F-8	EPA’s Draft White Paper (File Address White Paper8106.pdf) , and
F-9	Charge to SAB (File Address: racwhitepaperchargefinal.pdf)
G	Email Review Information and Review Package dated November 22, 2006 containing the following:
G-1	Memo from K. Jack Kooyoomjian, Ph.D., DFO/RAC to RAC Members entitled “ <i>Additional Review and Informational Materials for SAB/RAC 11/28 and 12/18 Public Conf Call Mtgs,</i> ” and containing the following:

**Attachment**

**Description**

- G-2 Dr. A. Brooks' potential suggestion of 11/20/2006 fro answering EPA Charge Question #3 Pertaining to Quantitative Uncertainty Bounds for Each of the Risk Coefficients (File Address: EPAChargeQuestion3Brooks112006.pdf);
- G-3 Additional References Provided by EPA/ORIA as requested by SAB/RAC on Smoking Lung Cancer Interactions 11/22/2006 (File Address: additionalreferencesonsmokinglungcancerinteractions112206.pdf);
- G-4 SAB/RAC Roster: (File Address: RAC PublicRoster11222006.pdf);
- G-5 RAC 10IntRoster11222006.pdf);
- G-6 SAB/RAC Biosketches (File Address: RACBiosketchFile112206.pdf).
  
- H Email Review Information and Review Package dated November 27, 2006 containing the following:
- H-1 Email Memo from K. Jack Kooyoomjian, Ph.D., DFO/RAC to RAC Members, entitled "Public Comments & SAB/RAC Committee Edits for Nov 28, 2006 Public Conf Call," and containing the following:
- H-2 Public Comments from Mr. Lynn Howard Ehrle 11/27/2006: (File Address: Ehrle\_White Paper\_BEIR VII 112706.pdf)
- H-3 Editorial Suggestions on Nov, 15, 2006 Public Draft Advisory by Dr. Shirley A. Fry 11/27/2006; (File Address: EPA Draft White PaperFryCmnts112706.pdf)
  
- I PUBLIC COMMENTS:
- I-1 Public Comments by Lynn Howard Ehrle (See also as H-2),
- I-2 Public Comments Received from Mr. Daniel Hirsch following the 11/18/07 Public Conference Call. Subject Title: "September letter." Attachment contains the September 26, 2006 letter to Dr. Jill Lipoti Re: "EPA Office of Radiation and Indoor Air Staff Proposal to Reject the Findings of the National Academy of Sciences on Radiation Risks and Adopt Instead Relaxed Radiation protection Requirements," by Mr. Dan Hirsch, Committee to Bridge the Gap, Ms. Diane D'Arrigo, Nuclear Information & Resource Service, and Ms. Michele Boyd, Public Citizen (3 page letter).
  
- J PUBLIC CORRESPONDENCE:  
(Pre & Post Meeting Correspondence)
  
- K COMMITTEE CORRESPONDENCE:  
(Pre & Post Meeting Correspondence)
  
- L MISCELLANEOUS AND ADMINISTRATIVE  
CORRESPONDENCE:(Pre & Post Meeting Correspondence)

**Attachment**

**Description**

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| M | Biosketches of Radiation Advisory Committee  |
| N | DFO's Marked-Up Agenda of 11/28/06 Public Conference Call Meeting<br>(K. Jack Kooyoomjian) |
| O | DFO's Notes of 11/28/06 Public Conference Call Meeting                                     |

**End of Record**