

U.S. Environmental Protection Agency
Science Advisory Board
Radiation Advisory Committee (RAC)
Augmented for Review of the Agency's Radiogenic Cancer Risk Assessment
Summary Minutes of Public Conference Call Meeting^a
June 18, 2009

Committee: U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB) Radiation Advisory Committee (RAC) augmented for review of EPA's radiogenic cancer risk assessment. (See Roster - Attachment A)

Date and Time: Thursday, June 18, 2009 from 1:00 p.m. to 4:00 p.m. eastern daylight time (See Federal Register Notice¹).

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 to conduct edits^b to the latest (June 10, 2009) working draft of the augmented RAC^b. During the public conference call, the augmented RAC will also receive public comments in review of "*EPA's Radiogenic Cancer Risk Models and Projections for the U.S. Population*," draft December 2008 (also referred to as the "Blue Book"²).

SAB/Augmented RAC Attendees: Dr. Bernd Kahn, RAC Chair, Dr. Susan Bailey, Dr. Thomas Borak, Dr. Shirley A. Fry, Dr. Ethel Gilbert, Dr. William C. Griffith, Dr. Peter Groer, Dr. David Hoel, Dr. Richard Hornung, Dr. Jonathan Links, Dr. William F. Morgan, Mr. Bruce Napier, Dr. Dale Preston, Dr. Genevieve Roessler, and Dr. Daniel Stram. (Drs. David, Dodd, Field and Matanoski were not present.)

Designated Federal Officer: Dr. K. Jack Kooyoomjian, SAB Staff Office

Agency Staff Attendees: Members of the EPA Office of Radiation and Indoor Air (ORIA) Washington, DC Staff Office included Dr. Mary E. Clark, Dr. David Pawel, and Dr. Jerome Puskin.

^a 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.

^b See the February 27, 2009 conference call minutes pertaining to the beginning of the formal review of this activity, the March 23-25, 2009 face-to-face meeting minutes where the presentations and review took place and, this June 18, 2009 teleconference call to review the June 10, 2009 public working draft report. POSTSCRIPT: The July 22, 2009 teleconference call reviewed the July 15, 2009 public working draft report.

Public Attendees: The members of the public included Mr. Douglas P. Guarino, Associate Editor of Inside EPA (Inside Washington Publishers), and Mr. Daniel Hirsch, Committee to Bridge the Gap.

Meeting Summary: The meeting followed the issues and general timing as presented in the meeting Agenda³. No written public comments were provided to the augmented RAC. The augmented RAC members were focused on fine-tuning the edits to the latest (June 10, 2009) working draft⁴ of their report, and after some discussion, made assignments to its Sub-Groups and members, and reached consensus on many of, but not all edits.

Welcome and Introductions: Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 1:04 pm 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) augmented for the review of the EPA's radiogenic cancer risk assessment, explained the purpose of the call, indicating that the augmented RAC operates under the requirements of the Federal Advisory Committee Act (FACA) and conducts business under the auspices of the chartered SAB. He explained that, consistent with FACA and with EPA policy, the deliberations of the augmented 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 augmented 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 Panel's compliance with Federal ethics and conflict-of-interest laws. The augmented 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 person on the augmented RAC has complied with all these provisions; hence, there are no conflict-of-interest or appearance issues, nor did any individual need to be granted a waiver or be recused. Dr. Kooyoomjian further noted that the Form 3110-48 Financial Disclosure (or the SGE-450 Form for government employees) and Ethics Training was completed by all augmented RAC participants and is on file at the SAB. He advised that there is no particular matter that may pose a potential conflict of interest. He also noted that the biosketches of each participant are posted on the SAB website. Dr. Kooyoomjian noted that there is no need for disclosure from individual members at this time, since the individual participants had introduced themselves and their relation to the topic at the earlier meetings, unless any public participant had not heard of their introductions earlier; otherwise we would re-introduce the participants. Hearing no request for this, we proceeded directly with the meeting.

At 1:17 p.m., Dr. Bernd Kahn, Chair of the augmented RAC, provided some brief introductory remarks, thanked the augmented RAC and the three Sub-Groups, their Leads and Scribes for their contributions to this June 10, 2009 working public draft, and outlined the process for completing this review. At 1:20 p.m., Dr. Kahn asked if Dr. Mary Clark and the

ORIA Staff wished to make any remarks at this time. Dr. Clark passed for the present.

Dr. Kahn opened up the discussion to the augmented RAC, noting the discussion items⁵ he had identified. (NOTE: section and page references are to the Committee's June 10, 2009 draft report³). Dr. Preston commented on the first item listed, namely Section 2.4, page 8 regarding the term, "equivocal evidence." He observed that the evidence for childhood cancer is not very "equivocal." He cited the Wakeford paper, which he believes states it properly. He recommended that we drop the term "equivocal." Dr. Gilbert agreed with this recommendation.

Section 3.2.2, p. 11, Lines 40-42 (Item #2 of discussion items): Dr. Roessler thought that this needs a discussion on Relative Biological Effectiveness (RBE). Dr. Fry suggested that it might be helpful for cohorts who have received diagnostic doses. Dr. Puskin thought the ORIA staff could come up with a reference on RBE. There was additional discussion on this point. Some points raised included the concern that the issue pertaining to diagnostic cancer doses could come back to "bite us." There was consensus to re-examine this paragraph and to provide appropriate references to support the statements referring to diagnostic cancer doses. It was thought that if an RBE greater than 1.0 is to be used, then it needs good justification. Dr. Roessler indicated that she would follow through on this.

Section 3.4.3, p. 14, Line 1 (Item #3 of discussion items): Dr. Gilbert observed that there is no BEIR VII model for non-melanoma skin cancer (NMSC). Dr. Puskin recalled from the March 23-25, 2009 meeting discussions that there is a model from the atomic bomb survivors, but that it appears to not be appropriate for the U.S. population, because the baseline rates are different. Since then, he has drafted a whole new section on Western populations with consistent relative risk populations and similar age dependence. Sub-Group B will get this new text from Dr. Puskin, and he will provide this to Dr. Kooyoomjian, the RAC DFO who will post it to the SAB Web site and provide it to the augmented RAC, either as a separate file, or integrated into the revised text for the next public discussion scheduled for July 22, 2009, depending on the logistics.

Section 3.4.5 Lung, p. 15, 1st Paragraph (Item #4 of discussion items): Dr. Gilbert observed that it is almost impossible to estimate the RBEs for females. We could cite the RBE estimates in a 2004 paper (Gilbert et al.), or the RBEs for males. Dr. Roessler suggested that the whole paragraph needs to be re-written. Dr. Links also supported the need for editing and to provide evidence and/or supporting references for the statements whether EPA should use an RBE of 20, and if so, why. The fundamental question on RBE is what should they be? He also cited the diagnostics issue, and what RBE do we think EPA should use. The Committee sought a recommendation on this point, and after some discussion, it evolved to a statement and recommendation that EPA should prepare and publish a paper in a peer-reviewed journal on this topic, and incorporate the recommendations coming out of such a peer review.

Public Comments:

At 1:45 p.m., Dr. Kahn asked if there were any members of the public who wished to

address the augmented RAC at this time. Mr. Daniel Hirsch, President of Committee to Bridge the Gap, referred to his earlier submission to the Augmented Radiation Advisory Committee, dated February 20, 2009 and what he referred to as “Bush Administration Comments.” [POSTSCRIPT: The title of the February 20th submission from Mr. Hirsch contained in the February 27, 2009 FACA file is “*Draft EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population’ and the Bush EPA Politicization of Science.*”] Mr. Hirsch’s contention is that none of the draft text of the June 10, 2009 Working Draft of the Augmented RAC addresses his comments raised in the June 20, 2009 submission.

Mr. Hirsch re-iterated his earlier remarks that he felt that the Committee has bias in the appointments, and that the draft text shows this. His contention is that the Committee (the Augmented RAC) is relaxing the risk estimates from BEIR VII. One minor positive change he cited is that the Committee is now recommending use of the arithmetic mean, instead of the geometric mean in the risk estimates. He further re-asserted his contention that most of the Committee has biases on the high end, some are neutral, but nobody is on the other end of the debate. If there were any independence on the Committee, he thought that they would comment on the 5 REM for workers being ridiculously high and that the ORIA drinking water standard in the Protective Action Guidelines should be criticized for being up to 10 REM/year. He would expect the Committee to attack the gross risk ranges that ORIA is proposing. He re-asserted that when BEIR VII report and recommendations did not come out the way the ORIA staff likes, it was changed by ORIA. He believes that the Committee doesn’t have the courage to identify the changes that they (ORIA staff) are proposing, and if you really believe that the science is with you, then you could wave a flag, but you buried it. He again re-stated that he thinks some of the Committee members should have resigned. He believes that the Committee is looking at changes that BEIR VII didn’t consider, and he recognizes this. He feels that this is a shameful exercise, and he is saddened that the exercise will lead to altering the Protective Action Guides and that people will be ending up with cancers from radiation exposures. He will take this up at a higher level. His comments ended at 1:56 pm.

Continued Discussion of Edits:

Section 3.4.6, Leukemia, p. 15 after 1st paragraph (Item #6 of discussion items): Dr. Roessler observed that the Committee needs to come up with a conclusion at the end of this paragraph. Drs. Fry and Griffith agreed with this assessment. Dr. Griffith noted that he is the author of the lung section, and he believes that the Committee needs to expand ideas to make it clear as to what is needed for the RBE. Dr. Roessler asked also that the Committee address the leukemia text.

Uncertainty Analysis, Section 4.2.3, Additional Comments on Risk Transfer, p. 20, Lines 23-25 (Item # 7 of discussion items): Dr. Gilbert thought that the sentence is not correct in regard to additive transport. She cited the logic in BEIR VII. Dr. Stram was not quite sure that he agreed with Dr. Gilbert’s comments, but that he will re-word this item. Dr. Stram agreed that the uncertainty is not symmetrical around the point estimates, and that there is more weight given to the additive model than the multiplicative model. There was discussion on observations for

stomach cancer. Dr. Gilbert thought that this would be partially fixed with use of the arithmetic versus geometric mean.

Dr. Stram agreed that he would re-work the text to explain why ERR models are better for tumor sites. Dr. Gilbert observed that this gives more weight to ERR than EAR. Dr. Stram asked if there were any other comments in the Uncertainty Analysis on this section. Dr. Kahn reminded him of Dr. Matanoski's written comments on this subject.

Section 4.2.4, Additional Comments on Risk Transfer (Item # #9 of discussion items): Dr. Borak referred to p. 21, Line 7 and observed that in the uncertainty analysis, Type I parameters random variable distribution in Bayesian analysis provide a slight bias in favor of ERR compared to EAR models. A discussion followed on Type I and Type II errors being treated as a random variable and how this might lead to an expected value of product being different. Dr. Stram thought that a simple correction might be to assume normality of the distribution. However, it was observed by others that the larger issue of displaying the logic and weighting on the point estimates might get at the whole issue of what ORIA did, and why they did it that way.

Section 5.2.3 Radiogenic Thyroid Cancer, p.23, 1st Para (Item #11 of discussion items): It was observed that the NCRP Report Number 159, "Risk to the Thyroid from Ionizing Radiation," is published now and should be referenced here, and that the Committee should reference follow-up by the ORIA staff with these recommendations. Dr. Puskin observed that ORIA knows that the relative risk was not substantially different and, in this case, adopted BEIR VII recommendations. Dr. Fry observed that there is some discussion of this issue with respect to iodine, and she thinks it is a major issue. Dr. Roessler will send the NCRP Reference No. 159 to Dr. Jack Kooyoomjian. Dr. Gilbert also cited the Chernobyl data for this subject area.

Section 4.2.2, Specific Comments, p. 18, Lines 24-39: Dr. Borak raised attention to this discussion, recommending that the draft Blue Book should clearly state and justify why one method is used to obtain a point estimate of LAR and another method based on different assumptions is used for the uncertainty analysis. The Committee agreed that this needs clarification. It was further agreed by the participants to review pages 18, 20 & 21 and edit the text appropriately.

Section 5.4.1, Low-Dose Protracted Exposure, p. 24, end of 2nd paragraph (Item #12 of discussion items): It was observed that the text needs to be revised regarding risk estimates of direct radiation exposures of protracted exposure. It was observed that the Committee does not have to enumerate every possibility. Dr. Gilbert will send recommendations for text revisions (a paragraph) to Dr. Jack Kooyoomjian.

Section 5.4.4, Holistic View of Stepwise EPA Path to FGR 13, p. 25: The Committee thought that there is a need to consider changes in the draft Blue Book in the context of its use (i.e., FGR 13). Dr. Kahn asked Dr. Links to provide a sentence or two on this subject matter to Dr. Jack Kooyoomjian to incorporate into the next round of text revisions.

Section 5.4.3, Cancer Subtypes, p. 25, 1st Paragraph (Item # 13 of discussion items): It was thought that the text needs to address brain tumors. Dr. Hoel cited Vol. 100, Part B of IARC, noting that some of the sites (e.g., kidney) that BEIR VII did not deal with. Final advice on IARC indicates that evidence on kidney cancer is not adequate. Dr. Hoel further recommended that the RAC should recommend the need to look at the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) for solid tumors and leukemia. It was observed that neither the Augmented RAC committee members, nor the ORIA staff have to agree, but they should at least recognize the UNSCEAR report pertaining to solid tumors and leukemia. A discussion followed on RBEs for animal studies and that if EPA adopts animal data, then they need to justify this and why those were chosen over others. There was also a discussion on the merits of wanting a central value, encouraging EPA to be more open on the data sources, as well as being candid regarding the logic for choice of RBE values. It was thought that some of this might be worthy of discussion in page 1 of the draft Letter to the Administrator.

Letter to the Administrator: The Committee thought that it would be nice to start out with positive comments in the letter to the Administrator. It was suggested that it might help with listing the questions, although it was acknowledged that the letter to the Administrator must be brief (usually no more than 2 pages). With regard to the charge questions, Dr. Gilbert observed that the third paragraph in the letter to the Administrator does not mention alpha emitters. There is a need to separate alpha emitters from beta/gamma, and the text could use a clear topical sentence for each paragraph. It was observed from a formatting perspective that the italicized sentence structure on the recommendations contrasts with the regular font, and might be better to be dropped. A discussion followed on alpha & beta particles and gamma rays. Dr. Kahn volunteered text edits to separate out the alphas from the betas and gammas. Dr. Gilbert offered that bone cancer is alpha, and needs to be in the first paragraph. It was also observed that the Committee should point out that this diverges from BEIR VII.

Dr. Fry thought that we might need to focus on multiple organs on p. 2 in the Letter to the Administrator. A discussion followed on prostate, uterus and breast cancer, and that colon cancer would more likely be a candidate to highlight. It was recognized that it would be helpful for the Committee to specify what cancers they have in mind, such as colon cancer. Dr. Kahn agreed to match the Executive Summary to the letter to the Administrator with the text edits.

A discussion followed on a variety of additional text edits in the Letter to the Administrator. They covered the topics of explicitly stating some of the benefits of using the arithmetic mean (e.g., additivity of the risk estimates), a recommendation to have EPA make an effort to have uncertainty estimates as consistent as possible, and if there are differences, to encourage EPA to clearly explain them. There were a number of edits to correct statements, such as reference to “equivocal.” Dr. Preston took exception with some of the draft statements and volunteered to re-write this paragraph. He also noted that the Doll & Wakeford study concludes that the evidence is quite compelling.

Section 3, p. 10 & 11: There was a typo on p. 11, line 41. Change “berved” to “observed.” A comment was provided on central estimates never being estimates of “best case.”

It was further suggested that this explanation needs to be in the “Blue Book.” It was also observed that point estimates differ greatly. Dr. Links will write a sentence or two on this and forward it to Dr. Jack Kooyoomjian.

Section 3.3, Response to CQ #1b, p. 13, lines 11-17: Dr. Preston observes that the text could be clearer with respect to how to switch from solid cancers as a group. He volunteered to re-write this portion of the text.

Section 3.4.2 Bone, p. 13, lines 35 & 36: Dr. Fry will re-write lines 35 & 36 regarding the nature of the exposures and their biokenetics.

Section 3.4.3, Skin (Fatal and NonFatal Nonmelanoma Cancers), p. 14, lines 7-13: Dr. Fry raised an issue on the need for the draft text edits on lines 7-13. Dr. Roessler volunteered to re-write this, to coordinate with Dr. Puskin, and to send the new re-write to Drs. Jack Kooyoomjian and Shirley Fry, so that it can be shared with the augmented RAC in the next public draft.

Page 15: There were a number of editorial corrections.

Page 16, lines 27 & 28: With respect to risk estimates for childhood and adult cancers among populations exposed in utero, there was a question and discussion as to what to do with this topic since it was in an earlier version. One member observed that it is not normally included. It was thought that we might want to consider including a level of risk for exposure from natal and pre-natal exposure. This was discussed and it was thought that the risk in-utero was treated essentially the same as early childhood, and the statement on page 16, lines 18-22 appears to be the approach that the Committee has endorsed. It appears that it is reasonable to assume at this time that cancer in-utero is similar to early childhood.

Section 4, The Uncertainty Analysis, p. 17 to 21: It appears that on p. 19, line 42, a reference is needed in reference to the Bayesian approach. Dr. Borak thought he had the reference (Bolstad), which Dr. Groer had provided earlier, but it needs to be added here. A number of edits were suggested for p. 20 & 21.

Section 5 CQ #3, p. 22-25: Dr. Borak, on p. 22, line 17 suggested changing “fine effort,” to another adjective, such as “good.”

Section 5.2.3, p. 23, line 18: A suggestion was made to include the NCRP Report #159 reference citation here. D. Borak also will get a write-up from EPA.

Section 5.4.1, Low-Dose Protracted Exposure, p. 24, line 24: This will be revised re FGR13 values.

Section 5.4.3 Cancer Subtypes, p. 25, lines 13 & 14: Dr. Fry observed that a more recent reference is needed here (e.g., Birjhead), and needs to be properly cited. (See also

references, p.32).

Section 5.3.3 SEER Data Clarification, p. 24, line7 (see also p. 55 of the draft Blue Book): Increased the LAR estimates (Re the more recent SEER data) - - -not from the models. Dr. Borak will try to sort it out so it will be in the next public draft report for discussion on July 22, 2009. Dr. Preston offered some suggested language as SEER rates from a different period and rates having changed.

At 3:26 PM, Dr. Kahn wrapped up the discussion, since the Committee had edited the entire June 10, 2009 public review draft in a very expeditious and thoughtful manner. He asked that all the draft edits be received in 2 weeks, preferably by July 2, 2009, and certainly no later than Close-of-Business on July 3, 2009. The intention is that all draft materials should be received by Jack Kooyoomjian and Bernd Kahn by July 3, 2009. Dr. Kahn will then try to complete the edits sometime between July 5-10, 2009. It is the intention that Dr. Jack Kooyoomjian will polish the draft for formatting edits for the next public draft no later than July 15, 2009 and have it posted to the SAB Web site for access by the Agency and the public. It was agreed to send all text edits to Dr. Kahn, with a cc to Jack Kooyoomjian, and he will send the revised working draft dated July 15, 2009 to the augmented RAC, and post it to the SAB's Web site for the Agency and the interested public for review. As a contingency, if logistics get complicated in meeting this schedule, Jack Kooyoomjian will poll everyone on the augmented RAC for an alternate date, such as an August conference call, if the Committee needs more time and the July 22, 2009 date for the next scheduled public conference call does not work for adequate public notice of the next public draft. (POSTSCRIPT: The Committee prepared a July 15, 2009 public review draft, as scheduled, posted it to the SAB's Web site, and held the public teleconference meeting as scheduled on July 22, 2009).

ADJOURN: There being no additional business to conduct, Dr. Kahn thanked all the participants, and adjourned the meeting at 3:42 p.m.

Summary & Action Items from the June 18, 2009 Public Conference Call, 1:00 p.m. – 3:42 p.m. EDT: This brief summary captures highlights items of interest to the augmented RAC in preparation for closure edits and for creating the Quality Review Draft for review by the SAB Charter Board. The action items are briefly summarized as follows:

- 1) Numerous edits were provided to polish and clarify the language in the letter to the Administrator, the Executive Summary and throughout the June 10, 2009 public draft text. The references and acronyms sections were also edited for clean-up of the text. (See above minutes text for a summary of the meeting discussion for some of these edits; see above text);
- 2) The augmented RAC was comfortable with most of the discussions and the collective edits conducted thus far. They volunteered to provide the various “clean-up” and polishing edits to Dr. Kahn and cc Dr. Kooyoomjian within the next week to 10 days;

Attachment A. Roster

**U.S. Environmental Protection Agency
Science Advisory Board (SAB) Radiation Advisory Committee (RAC)
Augmented for the Review of EPA's Radiogenic
Cancer Risk Assessment**

CHAIR

Dr. Bernd Kahn, Professor Emeritus, Nuclear and Radiological Engineering Program, and Director, Environmental Radiation Center, Georgia Tech. Research Institute, Georgia Institute of Technology, Atlanta, GA

MEMBERS

Dr. Susan M. Bailey, Associate Professor, Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO

Dr. Thomas B. Borak, Professor, Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO

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Dr. Brian Dodd, Independent Consultant, Las Vegas, NV

Dr. R. William Field, Professor, Department of Occupational and Environmental Health, College of Public Health, University of Iowa, Iowa City, IA

Dr. Shirley A. Fry, Independent Consultant, Indianapolis, IN

Dr. William C. Griffith, Associate Director, Institute for Risk Analysis and Risk Communication, Department of Environmental and Occupational Health Sciences, University of Washington, Seattle, WA

Dr. Jonathan M. Links, Professor and Deputy Chair, Department of Environmental Health Sciences, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

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Mr. Bruce A. Napier, Staff Scientist, Radiological Science & Engineering Group, Pacific Northwest National Laboratory, Richland, WA

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SCIENCE ADVISORY BOARD STAFF

Dr. K. Jack Kooyoomjian, Designated Federal Officer, US EPA, Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW, Washington, DC, 20460

Materials Cited

The following meeting materials are available on the SAB website, <http://www.epa.gov/sab> , at the [June 18, 2009 Augmented RAC Meeting](#) page.

¹ *Federal Register* Notice: Thursday, May 28, 2009, Vol. 74, No. 101, pages 25529-25530

² The Draft Blue Book entitled “*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*,” Draft U.S. Environmental Protection Agency, Office of Radiation and Indoor Air, December 2008.

³ Meeting Agenda for June 18, 2009, Radiation Advisory Committee Augmented for Review of the Agency’s Radiogenic Cancer Risk Assessment

⁴ SAB Review of "EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population," Draft December 2008

⁵ Discussion Items for June 18th Conf. Call Pertaining to June 10, 2009 Public review Draft