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U.S. ENVIRONMENTAL PROTECTION AGENCY  
  
SCIENTIFIC ADVISORY BOARD (SAB)  
  
QUALITY REVIEW TELECONFERENCE

Monday, November 22, 2010

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1 P R O C E E D I N G S

2 DR. NUGENT: -- Angela Nugent, and I'm the  
3 designated Federal officer for the chartered EPA  
4 Science Advisory Board.

5 We begin these calls by taking roll, and I  
6 will do that when the chair of the chartered SAB  
7 joins the call.

8 If there are chartered SAB members on the  
9 phone right now, I ask them to identify themselves.  
10 Are there any chartered SAB members on the call?

11 DR. DOERING: Otto Doering is here.

12 SPEAKER: Steve (inaudible).

13 DR. NUGENT: Otto and Steve. Right?

14 DR. GIESY: John Giesy is here.

15 DR. NUGENT: Hello, John.

16 Andy Burke is here? Thanks.

17 DR. KIM: Nancy Kim is there.

18 DR. NUGENT: Nancy, great.

19 SPEAKER: James Mihelcic is here, Angela.

20 DR. NUGENT: Thank you. Thank you, James.

21 DR. PATTEN: Duncan Patten.

22 DR. NUGENT: Oh, great. Thanks, Duncan.  
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1 DR. EIGHMY: Angela, this is Taylor.

2 DR. NUGENT: Hi, Taylor.

3 DR. ALLEN: This is Dave Allen.

4 DR. NUGENT: Dave Allen?

5 DR. ALLEN: Yes.

6 DR. NUGENT: And I missed an SAB member  
7 who identified herself.

8 DR. KHANNA: This is Madhu Khanna.

9 DR. NUGENT: Hello, Madhu. Thank you.

10 SPEAKER: Bernd Kahn.

11 DR. NUGENT: We have a lot of people on  
12 this call, even among our chartered SAB members. So  
13 I heard Bernd Kahn's name.

14 DR. KAHN: Yes.

15 DR. NUGENT: And was there another member  
16 who identified themselves?

17 DR. MURPHY: Yes. Eileen Murphy.

18 DR. NUGENT: Hi, Eileen.

19 DR. DZOMBAK: David Dzombak.

20 DR. NUGENT: Hi, Dave. Okay, great.

21 DR. MILFORD: This is Jana Milford.

22 DR. NUGENT: Thank you.  
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1 PAM: This is Pam (inaudible).

2 DR. NUGENT: Pam. Oh, yes. I should have  
3 said SAB members and liaisons. Thank you, Pam.

4 DR. BURKE: And I'm not sure if you heard  
5 me. Indy Burke.

6 DR. NUGENT: Yes, Indy, thanks.

7 DR. CORY-SLECHTA: Hi. This is Deborah  
8 Cory-Slechta.

9 DR. NUGENT: Oh, great. Okay.

10 DR. KANE: This is Agnes Kane.

11 DR. NUGENT: Thank you.

12 DR. FAUSTMAN: Angela, did you hear? This  
13 is Elaine Faustman, and I joined as well. Thank  
14 you.

15 DR. NUGENT: Excellent, great. Thank you.

16 DR. SANDERS: Hi. This is Jim Sanders.

17 DR. NUGENT: All right.

18 DR. TOLBERT: And Paige Tolbert.

19 DR. NUGENT: Thank you, Paige.

20 DR. SEGERSON: Kathy Segerson.

21 DR. NUGENT: Thanks, Kathy.

22 I haven't heard our chair yet. Deb

1 Swackhamer, are you on?

2 (No response.)

3 DR. NUGENT: Not yet, okay.

4 DR. ROBERTS: Steve Roberts.

5 DR. NUGENT: Okay. Thanks, Steve.

6 DR. POPE: Arden Pope just joined.

7 DR. NUGENT: Thank you, Arden.

8 DR. McMULLEN: L.D. McMullen.

9 DR. NUGENT: I heard L.D. and there was  
10 another -- was there another SAB member on the line?

11 DR. SWACKHAMER: This is Deb. I just  
12 joined.

13 DR. NUGENT: Oh, thanks, Deb. We've had,  
14 you know, a big chorus of SAB members on. So this  
15 is a big call. I think we have enough members on  
16 it, now that you're on it, that I can call a proper  
17 roll. This helps me get oriented to the call.  
18 Maybe I can say a few words.

19 First, I'm Angela Nugent, the Designated  
20 Federal Officer for the chartered EPA Science  
21 Advisory Board, and we opened the call by announcing  
22 that it's a public call. We expect to have a lot of

1 participants on this call. So what we typically do  
2 is just take roll for the chartered SAB members and  
3 liaison members. And I think there may be one  
4 member of the work group who is not currently a  
5 member of the chartered SAB. So I will call those  
6 names.

7 We don't call roll for members of the  
8 public, but I do include their names in the minutes.  
9 So if you have not individually contacted me to let  
10 me know that you're on this call or haven't  
11 contacted me to get the teleconference access  
12 information, please send me an email and I will  
13 include your names in the minutes.

14 Let me quickly go through the roster of  
15 the chartered SAB, the names of the individual  
16 members who were going to participate. Then I'll  
17 call the names of the liaison members who are going  
18 to participate and the work group members.

19 So Dave Allen?

20 DR. ALLEN: Here.

21 DR. NUGENT: Claudia Benitez-Nelson?

22 DR. BENITEZ-NELSON: Yes.

1 DR. NUGENT: Thank you.  
2 Tim Buckley?  
3 DR. BUCKLEY: Yes.  
4 DR. NUGENT: Thank you.  
5 Indy Burke?  
6 DR. BURKE: Yes.  
7 DR. NUGENT: Tom Burke was going to try to  
8 call from Spain. Are you on, Tom?  
9 (No response.)  
10 DR. NUGENT: Terry Daniel?  
11 DR. DANIEL: Yes.  
12 DR. NUGENT: Thank you.  
13 George Daston?  
14 DR. DASTON: Here.  
15 DR. NUGENT: Thank you.  
16 Costel Denson?  
17 DR. DENSON: Yes.  
18 DR. NUGENT: Thanks.  
19 Otto Doering?  
20 DR. DOERING: Here.  
21 DR. NUGENT: Let's see. Duncan Patten?  
22 DR. PATTEN: Yes.  
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1 DR. NUGENT: Dave Dzombak?  
2 DR. DZOMBAK: Here.  
3 DR. NUGENT: Taylor Eighmy?  
4 DR. EIGHMY: Here.  
5 DR. NUGENT: Thank you.  
6 Elaine Faustman?  
7 DR. FAUSTMAN: Yes. Here.  
8 DR. NUGENT: John Giesy?  
9 Thank you, Elaine.  
10 DR. GIESY: Here.  
11 DR. NUGENT: John.  
12 Jeff Griffiths?  
13 (No response.)  
14 DR. NUGENT: Jim Hammitt?  
15 DR. HAMMITT: Yes.  
16 DR. NUGENT: Thank you.  
17 Bernd Kahn?  
18 DR. KAHN: Here.  
19 DR. NUGENT: Agnes Kane?  
20 DR. KANE: Here.  
21 DR. NUGENT: Madhu Khanna?  
22 DR. KHANNA: Here.

1 DR. NUGENT: Nancy Kim?  
2 DR. KIM: Here.  
3 DR. NUGENT: Thanks.  
4 Kai Lee?  
5 DR. LEE: Present.  
6 DR. NUGENT: Thank you.  
7 Cecil Lue-Hing?  
8 DR. LUE-HING: Yes.  
9 DR. NUGENT: Thank you.  
10 L.D. McMullen?  
11 DR. McMULLEN: Here.  
12 DR. NUGENT: James Mihelcic?  
13 DR. MIHELICIC: Yes.  
14 DR. NUGENT: Jana Milford?  
15 DR. MILFORD: Here.  
16 DR. NUGENT: Keith Moo-Young?  
17 DR. MOO-YOUNG: Here.  
18 DR. NUGENT: Eileen Murphy?  
19 DR. MURPHY: Here.  
20 DR. NUGENT: Let's see. Arden Pope?  
21 DR. POPE: Here.  
22 DR. NUGENT: Steve Roberts?

1 DR. ROBERTS: I'm here.

2 DR. NUGENT: Thank you.

3 Amanda Rodewald I believe will be calling  
4 in at 3:00, unless she's here now. No. Okay.

5 Jim Sanders?

6 DR. SANDERS: Here.

7 DR. NUGENT: Thanks.

8 Jerry Schnoor?

9 (No response.)

10 DR. NUGENT: Kathy Segerson?

11 DR. SEGERSON: Here.

12 DR. NUGENT: Let's see. Paige Tolbert?

13 DR. TOLBERT: Yes.

14 DR. NUGENT: John Vena?

15 DR. VENA: Present.

16 DR. NUGENT: Thank you.

17 Tom Wallsten?

18 DR. WALLSTEN: Here.

19 DR. NUGENT: Thank you.

20 Robert Watts?

21 (No response.)

22 DR. NUGENT: Tom Zoeller? Tom? Tom

1 Zoeller?

2 (No response.)

3 DR. NUGENT: And let's see. On liaison  
4 members, do we have Steve Heeringa on the line?

5 (No response.)

6 DR. NUGENT: Okay. I think he said he did  
7 have a conflict. Okay.

8 And Pam Shubot?

9 DR. SHUBOT: Yes, I'm here.

10 DR. NUGENT: Thank you.

11 And I know we have one work group member,  
12 Deb Cory-Slechta. You're on the line?

13 DR. CORY-SLECHTA: Yes.

14 DR. NUGENT: Thank you.

15 Well, it's a long list, and I thank you  
16 all for being on.

17 Let me just briefly say my other required  
18 statements because this is a Federal advisory  
19 committee meeting for the chartered Science Advisory  
20 Board. I want to say the SAB is an independent  
21 expert Federal advisory committee chartered under  
22 the authority of the Federal Advisory Committee Act.

1 It's empowered by law to provide advice to the EPA  
2 Administrator on scientific and technical issues  
3 that support EPA's decisions.

4 FACA and the EPA policy require that all  
5 SAB meetings be announced to the public in the  
6 Federal Register and that SAB substantive  
7 deliberations and interactions with the EPA and the  
8 public be conducted in open sessions where a  
9 designated officer is present to ensure that the  
10 requirements of the Federal Advisory Committee Act  
11 are met.

12 We have followed the procedures of the  
13 Federal Advisory Committee Act in setting up this  
14 teleconference. We provided public notice of the  
15 meeting in the Federal Register. We've provided an  
16 opportunity for public comment. Members of the  
17 public have asked for time on the agenda to make  
18 oral statements, and I received written comments  
19 that I have provided to SAB members and posted on  
20 the SAB website for SAB members' consideration.

21 Let's see. I should also say that all the  
22 members of the SAB who are participating in this

1 call have met the requirements of the Ethics in  
2 Government Act, and we've determined that it's  
3 appropriate for them to participate in this  
4 teleconference.

5 I'll work with the chair after the  
6 teleconference to prepare minutes of the meeting to  
7 summarize the discussions and action items in  
8 accordance with the requirements of FACA. And you  
9 all should find those minutes available. The FACA  
10 requires that they be posted 90 days after the  
11 meeting date.

12 So I've already noted the names of the SAB  
13 members participating. We're not going to ask  
14 members of the public to identify themselves, but I  
15 know that there are representatives of the agency  
16 who have asked to make oral comments and public oral  
17 speakers. So when we get to that part of the  
18 agenda, we'll just confirm that they're on the line.

19 Because this is a big teleconference call,  
20 I ask people to help us out with one housekeeping  
21 issue. To ensure audibility, please put your phone  
22 on mute when you're not speaking, and then when you

1 do speak, please use the handset and not a speaker  
2 phone and that will help everybody out on the call.

3 So that's all the FACA official business,  
4 and I would like to turn the agenda over to our  
5 chair, Deborah Swackhamer. Deb, would you like to  
6 take it from here?

7 DR. SWACKHAMER: Yes, I would. Can you  
8 all hear me all right?

9 SPEAKER: Yes.

10 DR. SWACKHAMER: Okay.

11 Welcome, everyone, to this meeting. We do  
12 have a fairly long meeting and it's focused  
13 exclusively on conducting a quality review of the  
14 inorganic arsenic report. We have the request for  
15 many external outside speakers, public speakers, and  
16 so we will be running the meeting as efficiently as  
17 possible to make sure that we hear everyone, but  
18 then we want to make sure that we have sufficient  
19 time at the end for a discussion and then a  
20 disposition of the report.

21 It is my understanding that we have 10  
22 official speakers, and we've had a request for two

1 additional public speakers, and when we get to that  
2 part, we'll accommodate those speakers as well.

3 We're going to start out by first hearing  
4 from Dr. Faustman, who chaired the work group, and  
5 she will be giving us a brief overview of the report  
6 and leaving some time for clarifying questions from  
7 the board. So, Elaine, I'm going to turn things  
8 over to you.

9 Well, one more thing. Sorry. We have so  
10 many new folks on the line, on the board, and I  
11 haven't had a chance to meet all of you individually  
12 and personally. And I'm guessing that for many of  
13 you, this is your first quality review. So I want  
14 to make it very clear what the purpose of this  
15 meeting is.

16 We essentially conduct a review of the  
17 work group report. We're not doing a review of  
18 EPA's documents. And so we're not reviewing the  
19 cancer revision assessment. We are reviewing the  
20 work group's report. We're reviewing the review.

21 We are supposed to focus on four specific  
22 questions: whether the original charge questions to

1 the SAB Work Group was adequately -- were they  
2 adequately addressed. Were there any technical  
3 errors or omissions in their report? Were the  
4 committee's report -- the work group's report -- was  
5 it clear and logical, and were the conclusions drawn  
6 by the work group supported and recommendations  
7 provided -- were they supported by the body of that  
8 report?

9 So we're really just talking about  
10 reviewing the review. This could easily get into a  
11 whole discussion of the work group's work. We are  
12 not to redo the work group's work. We are supposed  
13 to review the work group's work.

14 So with that, Elaine, if I could ask you  
15 to spend a few minutes talking about the draft  
16 report.

17 DR. FAUSTMAN: Yes. Thank you very much.

18 Can everyone hear me?

19 SPEAKER: Yes.

20 DR. FAUSTMAN: I think that was a yes. So  
21 I'm going to proceed unless someone says otherwise.

22 So again, thank you very much, and I

1 reiterate the idea that people would identify who  
2 they are because it makes it very difficult in a  
3 large group like this.

4           So I was asked to present some context for  
5 our work. The Scientific Advisory Board received a  
6 request from the Office of Research and Development,  
7 National Center for Environmental Assessment, to  
8 evaluate and comment on the agency's implementation  
9 of the SAB 2007 recommendations regarding EPA's  
10 revision of the cancer assessment of inorganic  
11 arsenic. So as Deb mentioned, this is a review of a  
12 review of a review.

13           In response, I was asked to chair a work  
14 group of the chartered SAB and I was convened to  
15 review the agency's document that was entitled  
16 "Toxicological Review of Inorganic Arsenic in  
17 Support of the Summary Information on the Integrated  
18 Risk Information System." We were asked to focus on  
19 three areas: evaluation of the epidemiological  
20 literature, dose-response modeling approaches, and  
21 the sensitivity analysis of the exposure assumptions  
22 used in the risk assessment. We were not asked to

1 conduct a full peer review of the assessment.

2 The SAB commended the agency on its  
3 efforts to be responsive and responsible to our  
4 previous 2007 recommendations, and in keeping with  
5 the SAB practice, presentations by the EPA  
6 representatives and comments from the members of the  
7 public were considered during several deliberations  
8 and the development of this report.

9 The SAB has made a number of  
10 recommendations to improve the clarity and  
11 transparency of the 2010 draft assessment and to  
12 strengthen the scientific basis of EPA's findings  
13 and conclusions. Key recommendations are  
14 highlighted in the report, and I'm going to mention  
15 them very, very briefly.

16 In 2007, the Scientific Advisory Board  
17 recommended the use of the epidemiological data on  
18 the Taiwanese population for estimating human cancer  
19 risk from exposure to inorganic arsenic. The SAB  
20 also suggested that the agency consider other  
21 epidemiological studies from the U.S. and other  
22 countries and utilize a uniform set of evaluation

1 criteria.

2           The SAB supports its previous  
3 recommendations that the Taiwanese data set remains  
4 the most appropriate set for determining cancer risk  
5 from exposure to inorganic arsenic. Although EPA's  
6 2010 draft assessment presents a comprehensive  
7 overview of the epidemiological literature on  
8 arsenic and cancer up to 2007, we asked for a  
9 clarification of the set of criteria that EPA used  
10 in evaluating and presenting the studies.  
11 Additionally, we asked that EPA should consider  
12 including an addendum describing major  
13 epidemiological studies that were published after  
14 2007.

15           The SAB was also asked to talk about dose-  
16 response approaches. The SAB supported the agency's  
17 choice of using a linear default approach, given the  
18 complexity of the mode of action of arsenic.  
19 Although extensive new research has been done in  
20 this area, there was not enough information in the  
21 literature to definitively describe a mode of action  
22 for all of the multiple cancer endpoints (inaudible)

1 for this assessment. The SAB in particular  
2 highlighted effects in the lung. The SAB and action  
3 for all of the multiple cancer endpoints of  
4 relevance -- excuse me.

5 The SAB in 2007 also recommended that the  
6 EPA consider using alternative dose-response models  
7 and perform a sensitivity analysis on the Taiwanese  
8 data with different exposure metrics. EPA's 2010  
9 draft assessment uses a default linear low-dose  
10 extrapolation and evaluates the differences between  
11 a linear model and three nonlinear models,  
12 quadratic, quadratic exponential, and linear  
13 exponential.

14 The SAB finds that while the sensitivity  
15 analysis did respond to the 2007 recommendation, a  
16 more detailed description of the data sets used in  
17 developing the risk model is needed. (inaudible)  
18 providing the distribution of variability of arsenic  
19 concentrations in well water and the data and  
20 parameters used in the modeling would help to make  
21 EPA's document more transparent.

22 In 2007, the SAB recommended the agency

1     conduct a sensitivity analysis to determine the  
2     potential impact of different choices of exposure  
3     assessment, both water and non-water consumption for  
4     estimating arsenic cancer potency. The SAB finds  
5     that the agency was partially responsible to  
6     previous recommendations. The SAB recommends that  
7     the agency revise its assessment to provide a more  
8     detailed and transparent explanation of the  
9     scientific rationale for the choice and use. They  
10    also asked for a variety of ways to -- recommended  
11    some ways to enhance the rigor and transparency of  
12    the sensitivity analysis through further  
13    documentation.

14                 I think that that highlights the key  
15    points that our report found, and I'm going to, in  
16    the interest of time, stop here and open up for, I  
17    believe, Deborah, you said questions from the board,  
18    clarifying questions from the board.

19                 DR. SWACKHAMER: That's correct. Thank  
20    you very much, Elaine.

21                 We would be happy to have a few clarifying  
22    questions, if there are any, from board members.

1     Anyone?

2                     (No response.)

3                     DR. SWACKHAMER: All right. Then we'll  
4 use a few extra minutes to move ahead in the agenda.

5                     I assume that Dr. John Vandenberg is on  
6 the phone?

7                     DR. VANDENBERG: Yes. This is John  
8 Vandenberg speaking.

9                     DR. SWACKHAMER: Very good. So Dr.  
10 Vandenberg is from the EPA Office of Research and  
11 Development, and John, you had asked to make some  
12 remarks also. So the floor is now yours.

13                    DR. VANDENBERG: Thank you very much.  
14 Yes. This is John Vandenberg from the National  
15 Center for Environmental Assessment of EPA, and I'd  
16 like to extend our appreciation to the Arsenic Work  
17 Group for their review of the revised IRIS  
18 assessment for inorganic arsenic cancer effects.  
19 This second review clearly underscores the  
20 importance of this assessment, and we're very much  
21 looking forward to having the second review  
22 completed in a very timely manner so we can consider

1 the comments and recommendations from the Science  
2 Advisory Board, as well as the public comments we've  
3 received, as we revise the draft and post it as a  
4 completed assessment on the IRIS database.

5 I'd also like to take this opportunity to  
6 state that EPA supports EPA's staff efforts to  
7 contribute to an open and transparent discussion of  
8 scientific issues, including the publication in the  
9 scientific literature. This has become one of the  
10 comments that we received from the public, and we  
11 just want to make it clear that we do support our  
12 EPA staff and their efforts to contribute to the  
13 scientific literature and they do so.

14 Lastly, and just to be very brief, again  
15 we'd like to thank the efforts of the Arsenic Work  
16 Group, the public for their comments, and to the  
17 chartered SAB for their review of the revised draft  
18 assessment.

19 That's it.

20 DR. SWACKHAMER: All right. Thank you  
21 very much, John.

22 Do we have any clarifying questions for

1 Dr. Vandenberg from the board members?

2 (No response.)

3 DR. SWACKHAMER: All right. Hearing none,  
4 then we'll proceed with the agenda. For the next  
5 nearly an hour, we will have public comments. As I  
6 mentioned, we've had 10 folks that have formally  
7 requested to be heard on this call. We had two late  
8 requests, and I do believe we can accommodate them.

9 Is Dr. Richard Wilson on the line?

10 (No response.)

11 DR. SWACKHAMER: Is Dr. Michael Kosnett on  
12 the line?

13 DR. KOSNETT: I'm here. I'm present.

14 DR. SWACKHAMER: Okay. So we'll put you  
15 at the end of the queue, and unless we get way off  
16 with time, which means I haven't run the meeting  
17 very well, we should have time to fit you all in as  
18 well. We'd like to make sure we hear from everyone.

19 We're going to start with, as I understand  
20 it, Mr. Kevin Bromberg. He's requested to go in  
21 front of Steven Lamm, or vice versa. So we're going  
22 to start with Mr. Bromberg. Mr. Bromberg, are you

1 on the line?

2 MR. BROMBERG: Yes, I am. And thanks for  
3 changing the order. We appreciate that.

4 DR. SWACKHAMER: Yes. Go right ahead.

5 MR. BROMBERG: I was on my way to becoming  
6 Dr. Bromberg, but I had an excursion when I was  
7 getting my masters in astronomy, and I just became a  
8 lowly lawyer.

9 Anyway, but thanks for the opportunity to  
10 talk first. We thought it would be better, since I  
11 have a procedural point to make, that I go before  
12 the many scientists.

13 I'm Kevin Bromberg with the Small Business  
14 Administration, Office of Advocacy. We have a role  
15 like the SAB. We are supposed to be the independent  
16 voice to Federal agencies on Federal policy that  
17 affects small business, and as many of you know,  
18 we've been involved in arsenic science since 2001,  
19 and I previously gave testimony in June.

20 In this case, the SAB has a very important  
21 statutory role to provide sound and independent  
22 scientific advice, and the SAB has a difficult

1 assignment here because it wasn't given, in our  
2 view, adequate time to perform its job, whereas in  
3 2007 it produced a very well thought-out report on  
4 arsenic.

5 So bottom line on where we're coming out  
6 on this report is we urge the SAB not to endorse  
7 this work group report or this review process. And  
8 my suggestion at this time -- and it's a new one --  
9 is to ask the work group to meet in an open session  
10 to discuss the issues, some that I'm going to lay  
11 out and some that the many scientists that follow me  
12 will be laying out.

13 Based on the previous May and October  
14 draft review comments and discussion at the work  
15 group meeting on April 6th and 7th, we still find  
16 little evidence that the work group has seriously  
17 considered the very significant objections to the  
18 EPA assessment raised by public presenters on both  
19 occasions. Not one of the commenters supported the  
20 EPA assessment at either forum, and these presenters  
21 were among the most knowledgeable arsenic scientists  
22 in the country. And by the way, that does not

1 include me.

2           A recent Washington Post column on  
3 leadership advised that the best response to a  
4 credibility problem is to acknowledge the reality  
5 and do so quickly. The columnist once asked an  
6 executive team what they were going to do with the  
7 devastating results of an employee survey. The  
8 manager's first reaction was, well, we certainly  
9 can't post those, to which he replied, why not?  
10 Your employees already know it.

11           Acknowledging what the outside public  
12 already knows would actually help the SAB fulfill  
13 its statutory role here. And although the work  
14 group reports that it is responding to the SAB and  
15 public comments, we think it would be helpful if the  
16 work group explicitly responded to some of the  
17 comments. And in my written comments and in my oral  
18 comments, I am going to present some examples of  
19 clarifying text. And the assignment here is a  
20 simple one. Do we think it's a good idea to have in  
21 an open session a discussion among the arsenic  
22 scientists and the SAB Work Group of some of these

1 issues so we can see is it better to add additional  
2 clarifying and complete discussion to a work group  
3 review, or are we done?

4 And let me lay out why I think a public  
5 session would be a good idea.

6 We're concerned, to the extent these  
7 issues that have been raised have not been  
8 overlooked, that perhaps the work group made these  
9 determinations, well, in violation of the FACA  
10 regulations. Under FACA, you have full  
11 transparency. That requires all deliberations are  
12 made in public meetings. And the question that  
13 poses to me is, did the editing of the May report  
14 require no deliberation? Everyone was in agreement  
15 on all the key points? An additional meeting to  
16 discuss the changes to the May draft would help  
17 resolve doubts that we and others have about the  
18 adequacy of the review, potentially allow the work  
19 group to enter into a constructive dialogue with  
20 some of the country's most informed arsenic experts.  
21 Such a meeting could lead to a more complete and  
22 transparent report and would improve the process.

1 So instead of asking the full SAB, as it is now  
2 before you, to approve this report today, I think it  
3 would be preferable for the SAB to instruct the work  
4 group to resume deliberations at a public session  
5 where this could be addressed further.

6 I've come up with two examples which I  
7 think would illustrate my point, and these are  
8 examples that just deal with sensitivity analyses  
9 and dose-response modeling. So I'm going to quote  
10 an excerpt from the SAB Work Group review, and then  
11 I'm going to suggest additional language that in my  
12 view would have added to a more complete and  
13 transparent discussion and you folks be the judge of  
14 that, particularly after you hear all the other  
15 presentations that will follow.

16 So here's the SAB excerpt: "The SAB  
17 suggested the IRIS assessment include a simple table  
18 that identifies potential biases and the potential  
19 magnitude and direction for bias and inferences that  
20 are drawn from the study data."

21 So my suggestion is why don't we add this  
22 additional text, and this is my version of it. I'm

1 sure you folks can all improve upon it. "However,  
2 EPA needs to include discussion of several other  
3 studies which suggest that reliance on median well  
4 concentrations and a comparison population to model  
5 exposure could be the primary cause of the positive  
6 slope factor for low-dose exposure. These studies  
7 provide evidence that the calculated cancer slope at  
8 low doses arises from sources other than arsenic.  
9 Indeed, alternative models based on the low-dose  
10 villages strongly suggest that there is no  
11 increasing and possibly a flat or a decreasing slope  
12 in a dose-response curve at low dose approximately  
13 below 100 and 200 micrograms per liter. Such a  
14 result is consistent with many other epidemiological  
15 studies. EPA also needs to explain on page F-7 why  
16 it is not appropriate to use alternative models that  
17 do find, quote, insignificant or negative dose-  
18 response, unquote relationships."

19 And one more example and then I'm exiting.

20 Hopefully, I'm making my 5 minutes.

21 DR. SWACKHAMER: You're over 5 minutes, so  
22 please be brief.

1 MR. BROMBERG: Okay. Three paragraphs.

2 The excerpt from the report is: "Results  
3 of this analysis suggested exclusion of the  
4 reference population did have an effect on risk  
5 estimates."

6 Why not add this? Indeed, removal of the  
7 reference population and substitution of the  
8 nonlinear threshold changes the slope from a  
9 positive slope to a flat or negative slope in the  
10 low-dose range. This should be transparently  
11 explained to the reader.

12 Furthermore, care has to be taken that the  
13 comparison population data does not overwhelm the  
14 analysis. In EPA's analysis, the cancer slope is  
15 only mildly influenced by the low-dose villages, but  
16 98 percent of the weight is assigned to the single  
17 point represented by the comparison population.  
18 This also needs to be transparently explained to the  
19 reader.

20 So I thank you for your time, and I hope  
21 you will seriously consider having a public session  
22 where this conversation can occur. Thank you.

1 DR. SWACKHAMER: Thank you, Mr. Bromberg.

2 We can now hear from Dr. Steven Lamm. And  
3 I would urge all speakers to stick precisely to that  
4 5-minute time limit, or we will not be able to hear  
5 from the two additional speakers. Dr. Lamm?

6 DR. LAMM: Thank you very much. Thank you  
7 for the opportunity to speak briefly on the data  
8 analysis in this report. My name is Steven H. Lamm,  
9 M.D., MTPH. I'm a physician epidemiologist and have  
10 been interested in this issue for over 15 years. I  
11 have published research from southwest Taiwan, from  
12 Inner Mongolia, and from the United States. I have  
13 submitted multiple reports, letters, and analyses to  
14 the EPA and the SAB in these proceedings. I speak  
15 as an interested and concerned scientist and for no  
16 industrial or advocacy group.

17 There are others here who will discuss  
18 with you the issues of linearity versus  
19 nonlinearity, single study, weight of evidence, or  
20 meta-analysis, and process and procedure. I won't.

21 One topic of particular interest to me is  
22 the comparison of the analytic results from the

1 ecological studies in southwest Taiwan and the U.S.,  
2 but I will hold that for another day.

3           While all of these topics are important, I  
4 will narrow my attention at present to the more  
5 limited question that the SAB had asked of the EPA,  
6 that is, what is the dose-response relationship  
7 between bladder and lung cancer and arsenic  
8 ingestion based on the data from the southwest  
9 Taiwan study, including the southwest regional data  
10 as a reference population and in the exposure range  
11 relevant to the U.S. population?

12           There are two major problems in the EPA  
13 analysis that we have addressed.

14           One, the use of the southwestern Taiwan  
15 population as an additional study village rather  
16 than as a reference population has overwhelmed the  
17 analysis, making it insensitive to the critical low  
18 exposure. 98 percent of the information in the  
19 analysis is in that single data point. As EPA's own  
20 sensitivity analysis, table 5-11, showed, its  
21 inclusion accounts for up to 88 percent of the  
22 estimated risk. This has increased the risk by up

1 to 8 fold.

2 Two, the data are dirty or confounded, and  
3 EPA makes no cognizance of this. It is confounded  
4 both because of misclassification of villages with  
5 high arsenic levels, i.e., greater than 500  
6 micrograms per liter as low-dose villages, and  
7 because of some additional analytic factor variously  
8 proposed as fluorescent humic substance, artesian  
9 water source, or township stream. These issues have  
10 been well discussed in the public literature but are  
11 uncited in the toxicological review or cast off as  
12 arbitrary. See Brown and Chen, '95; Brown and  
13 Harod, January 2007. See Lamm et al., particularly  
14 Environmental Health Perspectives, July 2007.

15 Nonetheless, this geographic heterogeneity  
16 is clear and its solution should be a target of  
17 arsenic research.

18 The graphs we submitted last week to the  
19 SAB showed that both the low-dose villages with high  
20 arsenic levels greater than 500 micrograms per liter  
21 and those in township 3 demonstrate the cancer risk  
22 behavior of the high-dose villages, not that of the

1 low-exposure villages. The bladder cancer risks in  
2 the township 3 and high-exposure villages is about  
3 10 times greater than those in the low-exposure  
4 villages, and the lung cancer risks are about 5  
5 times greater. It is wrong to include their data in  
6 the analysis of the dose-response in the low-  
7 exposure villages, as has been done in the  
8 toxicological report.

9 We now submit an analogous graph which  
10 shows the specific SMRs for the low-exposure  
11 villages by township. Again, the cancer risks in  
12 township 3 do not behave like those in the other  
13 townships, all of which behave similarly. The  
14 bladder cancer mortality is about 10 times greater  
15 in the township 3 low-exposure villages than in the  
16 other low-exposure villages. The lung cancer  
17 mortality is 5 times greater, and the bladder and  
18 lung cancer mortality is 6 times greater. The  
19 proper data set for the low-exposure villages is  
20 that of the other four townships and their 27  
21 bladder and lung cancer deaths.

22 Based on the above and our previous

1 comments and submissions, we propose: one, that the  
2 EPA discuss the heterogeneity in the underlying data  
3 and its source; two, that the examination for the  
4 dose-response for low-level arsenic exposure be  
5 conducted on the data from the 10 low-exposure  
6 villages outside of township 3; three; that the  
7 results of that analysis be included in the meta-  
8 analysis of data from similar exposure levels in  
9 other studies, including that of northeast Taiwan  
10 and of the United States; four, that a reality check  
11 be conducted to assess the real-world likelihood of  
12 the validity of the estimate; and five, that a  
13 research goal should be the ascertaining of the  
14 reasons for the geographic heterogeneity in cancer  
15 risk in the southwest Taiwan study.

16 I hope that the panelists will have an  
17 opportunity to review those figures, as well as the  
18 letter from Professor Wilson, prior to concluding  
19 their deliberation. Thank you.

20 DR. SWACKHAMER: Thank you very much.

21 Next we have Dr. Barbara Beck. And again,  
22 I implore the speakers to please keep to 5 minutes.

1 We are now more than 5 minutes over because the  
2 previous two speakers took 7 and 8 minutes. So,  
3 please, I ask you to be sure to keep to your 5  
4 minutes, or we're going to run over by a half hour.

5 Dr. Beck, are you on the line?

6 DR. BECK: Yes.

7 DR. SWACKHAMER: Please go forward. Thank  
8 you.

9 DR. BECK: Thank you. Thank you for the  
10 opportunity to speak. My comments are going to  
11 focus on two topics: one, the adequacy of the 2010  
12 IRIS arsenic assessment's response to specific 2007  
13 SAB recommendations, particularly in the context of  
14 the narrowness of the 2010 charge questions and the  
15 decision by the 2010 work group to not go beyond the  
16 narrow charge questions; two, the lack of  
17 consideration in the 2010 assessment of important,  
18 new, since 2007, literature regarding mode-of-action  
19 and low-dose epidemiology studies, literature that  
20 has a significant impact on the dose-response  
21 assessment.

22 With respect to the response to the 2007

1 SAB recommendations and the narrowness of the 2010  
2 charge questions, my written comments provide a  
3 tabular summary of the charge questions over time,  
4 responses to the questions, and the remaining  
5 outstanding issues. I highlight some of the key  
6 points here and refer the SAB to that table for more  
7 detail.

8           The table clearly demonstrates that the  
9 work group was never asked to conduct a  
10 comprehensive review of the full IRIS assessment,  
11 both in terms of the adequacy of the report in  
12 responding to the earlier SAB comments and  
13 addressing outstanding scientific issues. The 2010  
14 work group made the decision to not deviate from the  
15 three charge questions. As acknowledged by a work  
16 group member, quote, the work group was constituted  
17 to address a narrow charge, end quote, and quote,  
18 the expertise of the group was not appropriate for a  
19 full review of EPA's toxicological assessment, end  
20 quote. Thus, the full breadth of the prior SAB  
21 comments was not considered as part of the work  
22 group review, leaving important scientific issues

1 inadequately addressed.

2           In particular, issues regarding the  
3 synthesis of mode-of-action, or MOA, information and  
4 nonlinear dose-response modeling were not addressed  
5 in any substantive manner. Although the 2007 SAB  
6 decided there was not enough definitive information  
7 on arsenic's MOA to depart from the default  
8 linearity assumption, they nonetheless concluded  
9 that all of arsenic's MOAs are likely nonlinear.  
10 They also noted that hormesis should be considered  
11 in an evaluation of a possible threshold for  
12 arsenic. Since 2005, significant new literature  
13 regarding arsenic's MOA provides further evidence of  
14 arsenic's nonlinear dose-response. While the 2010  
15 assessment includes some new MOA literature, it  
16 contains only literature published through August  
17 2007, merely tabulating the MOA studies, and  
18 provides no meaningful synthesis, particularly with  
19 respect to dose-response assessment.

20           Similarly, while the 2010 arsenic  
21 assessment includes additional epidemiological  
22 literature, the synthesis of the literature is

1 incomplete and falls short of SAB's specific request  
2 in 2007 to conduct an integrative analysis of low-  
3 dose studies to test concordance with the Taiwanese  
4 results. It is insufficient to describe each study  
5 individually. Instead, what is required is an  
6 analysis which considers the weight of evidence of  
7 the low-dose studies as a whole, evaluating  
8 consistency with predictions of risk based on the  
9 selected modeling approach.

10 Several other issues, including  
11 appropriate sensitivity analyses, were also not  
12 adequately addressed in the 2010 IRIS assessment.  
13 These outstanding issues are critical and can have a  
14 substantial impact on evaluation of arsenic risk for  
15 the U.S. population. These issues must be fully  
16 vetted for the scientific integrity of EPA's arsenic  
17 assessment.

18 I shall be briefer on the second major but  
19 related topic, noting that this point is being  
20 discussed by other commenters; namely, the lack of  
21 consideration in the 2010 document of important,  
22 new, since 2007, literature regarding mode of action

1 and low-dose epidemiology studies, literature that  
2 has a significant impact on the dose-response  
3 assessment.

4           While it is correct that new literature is  
5 always being generated and at some point the agency  
6 must finalize its assessment, in this case the  
7 impact of the new literature, specifically the dose-  
8 response mode-of-action literature and the  
9 epidemiological studies, including meta-analyses on  
10 the arsenic risk assessment, is profound.

11           In closing, in the event that Dr. Wilson  
12 is unable to speak, although we do hope he is on the  
13 call, I did want to point out that Dr. Wilson, who  
14 is an expert on arsenic research, has submitted  
15 additional comments, unfortunately after the  
16 November 15th deadline. I would hope that there is  
17 some possibility that the SAB may consider these  
18 comments, as such comments speak to important issues  
19 regarding the Taiwan study design and statistical  
20 components of EPA's dose-response modeling,  
21 expressing concerns with those of the other  
22 commenters.

1 Thank you.

2 DR. SWACKHAMER: Thank you very much, Dr.  
3 Beck.

4 Is Dr. Lorenz Rhomberg on the phone?

5 DR. RHOMBERG: I am, yes.

6 DR. SWACKHAMER: Go ahead, Dr. Rhomberg.

7 DR. RHOMBERG: Thank you. Thank you for  
8 the opportunity to make these comments. I'm Lorenz  
9 Rhomberg, a principal at Gradient. My comments  
10 today are my own, supported by the North American  
11 Metals Council.

12 The 2010 IRIS draft proposes a value for  
13 the oral unit risk of 25.7 per milligram per  
14 kilogram a day that is 4.5 fold greater than the  
15 value that appeared in the 2005 IRIS draft. This  
16 represents a major change from the earlier value,  
17 one that was already in question, and its  
18 implementation would have profound impact.

19 In view of the consequences, it's critical  
20 that such a change in cancer potency represent a  
21 scientifically necessary and scientifically  
22 supportable alteration of the arsenic

1 carcinogenicity assessment and not just the adoption  
2 of a possible point of view.

3           There are really only two substantial  
4 changes actually made between the 2005 and the 2010  
5 dose-response analyses (inaudible) southwest Taiwan  
6 data; namely, one, the inclusion of a measure of  
7 dietary intake of arsenic, in addition to that  
8 coming from water; and two, the assumed amount of  
9 water consumed for U.S. versus Taiwan populations.  
10 As I've noted in previous comments, there probably  
11 should be more changes to be responsive to the 2007  
12 SAB review, but what about these two changes that  
13 were made? Several points bear mentioning.

14           First, even within this narrow focus, the  
15 2010 SAB Work Group's review expressed concern,  
16 finding the justification for dietary and drinking  
17 water assumptions inadequate, and this should  
18 probably be addressed. The importance of the values  
19 chosen is evident from the 4.5 fold total change  
20 between 2005 and 2007 that they make in the  
21 estimated potency, as well as the factor-by-factor  
22 sensitivity analysis that appeared in the 2010 draft

1 which shows that the values chosen for each factor  
2 can markedly affect the calculated potency.

3           Second, the panel expressed concern that  
4 sensitivity to combinations of assumptions was not  
5 assessed by the EPA document. Because different  
6 assumed values can affect curve shapes, the  
7 simultaneous consideration of combinations of  
8 assumptions can show sensitivity of a final answer  
9 in a way that factor-by-factor, one-at-a-time  
10 evaluations cannot. Accordingly, it's important  
11 that the work group's review evaluate the basis and  
12 impact not only on each factor individually but also  
13 as they act collectively on the final potency  
14 estimate.

15           Third and finally, it was the express  
16 opinion of the SAB Arsenic Work Group that they were  
17 not asked for and did not provide a full review of  
18 the 2010 IRIS draft. This said, the work group did  
19 express concerns about the scientific credibility of  
20 the end collective results of the components that  
21 they did evaluate. The work group called for a  
22 reality check analysis to see if the large risks

1 projected for much of the U.S. population from  
2 existing naturally occurring arsenic in drinking  
3 water can, in fact, be reconciled with the known  
4 total cancer risks for such populations.

5 To conclude, I urge the SAB to  
6 forthrightly debate the matters I have mentioned.  
7 In my view, the SAB should conclude that any  
8 candidate for a final U.S. EPA document should, in  
9 view of its major impact on arsenic assessment risk  
10 management questions, receive a full comprehensive  
11 review. This should not only review its component  
12 calculations but also assess whether the 2010 draft  
13 as a whole is scientifically credible and  
14 compelling. Anything less will mire the coming risk  
15 management process in debate and doubt stemming from  
16 the questions that have remained unanswered or  
17 unreliably answered by the risk assessment review as  
18 it now stands.

19 Thank you for your attention, and I hope  
20 the SAB will find my additional comments and more  
21 extensive written comments also of value on these  
22 issues. Thank you.

1 DR. SWACKHAMER: Thank you very much, Dr.  
2 Rhomberg.

3 Is Ms. Lynn Bergeson on the line?

4 MS. BERGESON: I am.

5 DR. SWACKHAMER: Please go ahead. Thank  
6 you.

7 MS. BERGESON: Thank you. This is Lynn  
8 Bergeson, and I appreciate the opportunity to  
9 present this statement on behalf of Drexel Chemical  
10 Company. Drexel, as a member of the Organic  
11 Arsenical Products Task Force, previously has  
12 submitted comments on both science and process  
13 issues concerning EPA's draft IRIS risk assessment,  
14 and we restate and incorporate by reference here  
15 those comments. Those comments emphasize why a  
16 thorough review by the SAB of the science behind the  
17 draft document is essential, especially because in  
18 our view EPA has not fully accounted for a  
19 substantial body of research undertaken in the  
20 decade since the 2001 NRC report was prepared.

21 Our statement today underscores another  
22 manifestation of why the SAB should not accept the

1 IRIS assessment as final until EPA has evenhandedly  
2 considered all of the relevant literature and also  
3 responded fully to the recommendations still on the  
4 table from the SAB's 2007 report. In that regard,  
5 it has recently come to our attention that several  
6 EPA scientists who have been intimately involved in  
7 developing the IRIS assessment, including the lead  
8 authors, have also been simultaneously engaged in  
9 public advocacy in favor of EPA's position on a  
10 controversial issue at the heart of the IRIS review.  
11 In the face of many rigorous new studies that argue  
12 otherwise, these EPA scientists have embraced as  
13 persuasive a body of Taiwanese data more than half a  
14 century old in assessing cancer risks from exposures  
15 to low concentrations of arsenic in drinking water.

16 This controversy is not new, of course,  
17 but there is a new twist. In October 2010, an  
18 article appeared in the journal, Environmental  
19 Health Perspectives, referred to here as EHP. In  
20 that article, EPA scientists are among its co-  
21 authors. The article reviews and rejects several of  
22 the recent studies while asserting the superiority

1 of the Taiwanese data. 6 of the 10 co-authors of  
2 the EHP article served either as lead authors,  
3 contributors, or internal EPA reviewers of the draft  
4 inorganic IRIS assessment -- excuse me -- draft  
5 inorganic arsenic IRIS assessment.

6 In our view, these scientists have  
7 inappropriately advocated a still-open issue. It is  
8 also clear from the published article that these  
9 scientists have, in our view, prejudged the issue.  
10 Since these scientists also asserted a position  
11 similar in a poster at the March 2010 SOT meeting,  
12 we believe that it is fair to conclude, based on  
13 these facts, that the scientists tasked with  
14 developing the IRIS assessment have not been as open  
15 to competing views on this pivotal issue as we would  
16 hope.

17 Drexel requests that the SAB take three  
18 steps. First, refuse to accept the draft IRIS  
19 assessment as final until EPA takes fair and open-  
20 minded account of the scientific literature that has  
21 been omitted, a directive that should be spelled out  
22 explicitly in an SAB charge. Second, direct EPA to

1 provide full answers to the 2007 SAB report  
2 recommendations, and finally, conduct its own full  
3 review of the draft assessment as it now stands.

4 Thank you.

5 DR. SWACKHAMER: Thank you very much.

6 We would like to now hear from Dr. Cohen.

7 Dr. Samuel Cohen, are you on the line?

8 DR. COHEN: Yes, thank you.

9 DR. SWACKHAMER: Yes. Please go ahead.

10 DR. COHEN: The focus of my comments will  
11 be regarding considerations of mode of action and  
12 its implications for the risk assessment of  
13 inorganic arsenic levels in the drinking water. As  
14 I've stated in my previous comments and in my most  
15 recent written comments, all of the modes of action  
16 that are being considered for inorganic arsenic  
17 toxicity and carcinogenicity are nonlinear. As has  
18 been discussed extensively, the specific mode of  
19 action for inorganic arsenic carcinogenicity has not  
20 been delineated. However, there's extensive  
21 knowledge about the mode of action. Any mode of  
22 action involving linearity such as DNA reactivity

1 has been excluded. Thus, it seems rather circuitous  
2 and disingenuous to argue that we should default to  
3 a linear risk assessment even though we do not  
4 definitively know the specific mode of action for  
5 inorganic arsenic.

6 The 2005 EPA Cancer Guidelines do not ask  
7 for definitive knowledge, but indicate that a  
8 consideration for a nonlinear risk assessment should  
9 be included if there is sufficient evidence.  
10 Clearly, there is sufficient evidence.

11 The evidence is strongest for the urinary  
12 bladder in animal models, in vitro models, and in  
13 humans. The overall mode of action includes  
14 cytotoxicity and regeneration. Ancillary changes  
15 such as oxidative damage, effects on DNA repair,  
16 effects on mitotic spindle, and others can be the  
17 cause of the consequence of the cytotoxicity.

18 The differences in the quantitative  
19 aspects between animal models and humans were  
20 indicated in the 2005 SAB review as most likely  
21 being due to differences in toxicokinetics. The  
22 subsequent evidence strongly supports this

1 conclusion.

2           Furthermore, the differences between  
3 species could well be related to the variations  
4 between species and the availability of sulfhydryl  
5 groups in specific critical cellular proteins and  
6 small molecules. There is no question that the  
7 toxicity and carcinogenicity of inorganic arsenic is  
8 due to the formation of reactive trivalent species  
9 which bind to these sulfhydryl groups. The  
10 necessity to attain critical concentrations of these  
11 trivalent forms is an obvious and well substantiated  
12 conclusion. Keep in mind that the trivalent forms  
13 include not only the methylated MMA and DMA forms,  
14 but also inorganic arsenite itself.

15           Like the urinary bladder, the evidence  
16 supports this mode of action strongly for skin.  
17 Arseniasis, the precursor change leading to skin  
18 cancer, involves evidence of toxicity and  
19 regeneration including hyperplasia, hyperkeratosis,  
20 mild (inaudible), and chronic inflammation. The  
21 evidence for this mode of action in skin is  
22 strongest in the human rather than from animal

1 models or in vitro. Evidence strongly supports  
2 cytotoxicity as a mode of action based on the in  
3 vitro studies as well. Cytotoxicity of human  
4 keratinocytes to trivalent forms of arsenic occurs  
5 at concentrations that are similar to those that are  
6 seen for urothelial cells that are seen from the  
7 urinary bladder either for humans or rats.

8           We have recently demonstrated that a  
9 similar cytotoxic response occurs for human  
10 bronchial epithelial cells also, again at similar  
11 concentrations. Add to that the high oxygen  
12 concentration present in the lung. One can readily  
13 understand why lung can be a target site for arsenic  
14 carcinogenicity. There has been considerable  
15 difficulty obtaining an animal model for lung  
16 carcinogenicity of arsenic, but this is not  
17 surprising given the significant differences between  
18 rodents and humans for lung, respiratory tract  
19 anatomy, aerodynamics and the entire carcinogenic  
20 process itself. The fact that human bronchial  
21 epithelial cells react in vitro in the same way as  
22 human urothelial cells and keratinocytes provides

1 support for cytotoxicity as a mode of action also  
2 for the lung in humans.

3 I've gone into more detail on all of these  
4 points in my written comments.

5 In summary, it is clear that the mode of  
6 action for inorganic arsenic carcinogenesis is  
7 nonlinear and likely involves various aspects of  
8 cytotoxicity and regeneration. All of the effects  
9 of inorganic arsenic occur due to formation of  
10 trivalent forms of arsenic that react with  
11 sulfhydryl groups and critical cellular molecules.  
12 These reactions are dependent on a critical  
13 concentration being attained for a toxic response to  
14 occur. The levels are not reached when exposures  
15 occur to low levels of inorganic arsenic such as in  
16 the drinking water at 10 ppb.

17 Epidemiologic evidence strongly suggests a  
18 nonlinear carcinogenic response in humans at all  
19 target sites, and current knowledge of the mode of  
20 action strongly supports that conclusion.

21 I encourage the SAB to reconsider the  
22 EPA's position regarding inorganic arsenic

1 carcinogenicity and the implications for risk  
2 assessment that derive from the draft IRIS document  
3 and EPA's responses to the previous SAB  
4 recommendations.

5 Thank you for your time.

6 DR. SWACKHAMER: Thank you very much, Dr.  
7 Cohen.

8 Next we have Dr. Joyce Tsuji.

9 DR. TSUJI: Thank you. My name is Joyce  
10 Tsuji. I'm a toxicologist with Exponent and a co-  
11 author of a meta-analysis of low-level arsenic  
12 exposures that was published in 2008 and updated in  
13 written comments submitted last week. I am  
14 presenting on behalf of the Wood Preservative  
15 Science Council.

16 Despite their narrow charge, the SAB Work  
17 Group noted some key deficiencies in EPA's arsenic  
18 cancer risk assessment. Because of these  
19 deficiencies and the weight of scientific evidence  
20 regarding the carcinogenic mode of action and  
21 epidemiological data for inorganic arsenic, EPA  
22 should show the full effect of linear and nonlinear

1 modeling assumptions without the comparison  
2 population and present a range of cancer slope  
3 factors reflecting these approaches. Studies in the  
4 past 5 years show strong convergence on a nonlinear  
5 mode of action for inorganic arsenic that  
6 corresponds to relevant human exposures in  
7 epidemiological studies. Although the SAB Work  
8 Group agreed that the choice of linear or nonlinear  
9 models or whether a comparison population was used  
10 had little effect, EPA did not present a complete  
11 sensitivity analysis in responding to comments from  
12 the 2007 SAB. The EPA 2010 revised draft report  
13 does not show the impact of a nonlinear model  
14 without the comparison population or even a linear  
15 model at low doses without the comparison  
16 population. Any of these combinations would show  
17 that the dose-response relationship is nonlinear  
18 through the full range of exposure data with little  
19 to no increase in cancer risk at low doses.

20 The draft report also does not examine the  
21 effect of using different key exposure factors such  
22 as arsenic drinking water concentration, daily water

1 intake, and dietary intake of arsenic in combination  
2 rather than in isolation as presented in the revised  
3 draft report.

4           Concerns about exposure misclassification  
5 and low power of studies appear to be the primary  
6 reasons for exclusion of all epidemiologic studies  
7 other than southwest Taiwan. However, the  
8 presumption that increased cancer risks were  
9 rendered nonsignificant in these low-exposure  
10 studies is based on an incorrect interpretation of  
11 exposure misclassification. EPA's interpretation of  
12 exposure misclassification also does not and cannot  
13 explain the consistent, although generally  
14 nonsignificant, relative risk estimates for non-  
15 smokers of less than 1.0 or in the direction of  
16 decreasing risk with arsenic exposure rather than  
17 increasing.

18           Regarding study power, the SAB Work Group  
19 noted that the use of post hoc power calculations to  
20 evaluate individual studies is inappropriate.  
21 Instead, EPA should consider the direction and  
22 precision of relative risk estimates and weight and

1 consistency of evidence at low doses from multiple  
2 studies, including southwest Taiwan. Our updated  
3 meta-analysis of low-exposure bladder cancer studies  
4 indicates relative risk estimates, particularly for  
5 non-smokers, that have upper confidence limits below  
6 a relative risk predicted by models used by EPA.  
7 The evidence from low-dose studies thus clearly is  
8 statistically inconsistent with the proposed cancer  
9 slope factor. Such inconsistency with the proposed  
10 cancer slope factor indicates that a cancer slope  
11 factor based on comprehensive nonlinear modeling  
12 should also be developed.

13 In the case of arsenic, which occurs  
14 naturally, the application of highly conservative  
15 and overestimated risks should be balanced with the  
16 use of all the available scientific information to  
17 develop a range of cancer slope factors. The  
18 currently proposed cancer slope factor will result  
19 in cancer risk estimates for arsenic that are of  
20 significant public health concern, as noted by the  
21 SAB Work Group. Such risks will complicate risk  
22 management decisions for even ordinary background

1 exposures. Thus, a full presentation of possible  
2 cancer slope factors based on the available weight  
3 of evidence using both linear and nonlinear models  
4 without a comparison population would provide more  
5 information to risk managers on the underlying  
6 science and greater transparency on the effects of  
7 modeling assumptions.

8 Thank you for the opportunity to provide  
9 these comments.

10 DR. SWACKHAMER: Thank you very much, Dr.  
11 Tsuji.

12 Ms. Tawny Bridgeford is next. Is she on  
13 the phone?

14 MS. BRIDGEFORD: Yes, I am.

15 Good afternoon. I am Tawny Bridgeford,  
16 Associate General Counsel at the National Mining  
17 Association. NMA represents the producers of most  
18 of America's coal, metals, industrial and  
19 agricultural minerals.

20 NMA is extremely concerned that if EPA is  
21 allowed to finalize the draft IRIS assessment for  
22 inorganic arsenic as written, a scientifically

1 indefensible cancer slope factor will then be used  
2 to drive cleanup levels in their Superfund and  
3 drinking water standards under the Safe Drinking  
4 Water Act to unachievable and below background  
5 levels.

6           As the SAB is aware, the IRIS program has  
7 a profound impact on domestic and international  
8 regulatory programs. Thus, it is imperative that  
9 the assessments finalized in this program are based  
10 on the best available science.

11           During the April and June SAB meetings,  
12 several renowned experts and scientists in the field  
13 expressed serious concerns with the key assumptions  
14 and modeling used to derive the cancer slope factor.  
15 Concerns were also raised related to EPA's refusal  
16 to include any studies after 2007, thereby excluding  
17 the most recent credible science. Others expressed  
18 concerns regarding the scope of the SAB Work Group's  
19 review and the lack of an independent review of the  
20 proposed cancer slope modeling in the draft  
21 assessment or the actual calculation of the cancer  
22 slope factor.

1                   NMA is disappointed that the SAB Work  
2 Group's revised report fails to thoroughly respond  
3 to these important comments. Specifically NMA  
4 believes that the SAB Work Group erred in its  
5 continue support of the linear default approach when  
6 ever-mounting research is demonstrating that there  
7 is a recognized mode of action and that a nonlinear  
8 approach is most appropriate for assessing the  
9 cancer risks of inorganic arsenic.

10                   EPA's own Cancer Guidelines support using  
11 nonlinear modeling approaches when the cancer-  
12 causing mode of action for a chemical is  
13 sufficiently understood as opposed to the draft  
14 report's apparent reliance on the criterion of a  
15 definitive demonstration. NMA submits that the  
16 research is sufficiently robust to satisfy the  
17 agency's Cancer Guidelines in the case of inorganic  
18 arsenic.

19                   Accordingly, NMA urges the SAB not to  
20 approve the work group report until the work group  
21 addresses this issue. The assessment should not be  
22 finalized until EPA appropriately revises the

1 assessment pursuant to these guidelines.

2           Finally, the SAB's choice not to conduct a  
3 full peer review of the assessment or the  
4 calculation of the cancer slope factor is equally if  
5 not more troubling given the comments SAB received  
6 through its peer review process. The SAB Work Group  
7 acknowledges that the linear approach -- and I quote  
8 -- produced a calculated upper bound cancer risk  
9 estimate for arsenic that is of significant public  
10 health concern.

11           Due to the importance of this issue, NMA  
12 strongly urges the SAB not to approve the SAB Work  
13 Group report and continue the peer review process to  
14 allow a more appropriate and thorough review of the  
15 assessment. NMA believes that the regulated  
16 community deserves such a review, given the  
17 implications it will have on their operations and  
18 the importance of ensuring that the assessment is  
19 based on the best available science.

20           Thank you.

21           DR. SWACKHAMER: Thank you very much, Ms.  
22 Bridgeford.

1 Dr. Bill Adams?

2 DR. ADAMS: Thank you. My name is William  
3 Adams. I'm an ecotoxicologist with Rio Tinto, a  
4 global mining company, and I have served on the  
5 Ecological Process and Effects Committee of the  
6 Science Advisory Board for 8 years and also served  
7 as a consultant to the board for an additional 4  
8 years. I have worked on arsenic issues related to  
9 soil, groundwater, health and ecological risk  
10 assessment, as well as remediation for the past 15  
11 years. And my area of expertise is metal  
12 toxicology, and I have extensive experience on metal  
13 levels in the environment.

14 I believe the key question in front of the  
15 SAB today is whether or not the proposed change in  
16 the cancer slope factor for arsenic is supported by  
17 sufficient scientific evidence for the agency to  
18 proceed. And I believe there are four common-sense  
19 reality checks that could or should be performed to  
20 help answer that question, and I'd like to go  
21 through these four.

22 Number one, the SAB draft report notes  
Page 64

1 that the EPA's choice of a linear approach has  
2 produced a calculated upper bound cancer risk  
3 estimate for arsenic that is of significant public  
4 health concern. I ask, is it credible to believe  
5 that arsenic is the causative agent for most lung  
6 and bladder cancers in the U.S.?

7           Number two, using the proposed slope  
8 factor, one can calculate that 1 gram per day over a  
9 lifetime of common foods such as wheat flour, rice,  
10 corn meal, peanut butter, apple juice, grapes,  
11 cucumbers, lettuce, spinach, onions, carrots, and  
12 many others will exceed 1 in a million risk for  
13 cancer. I ask again, does this really make sense?

14           Based on the proposed slope factor, the  
15 concentration of arsenic in drinking water would  
16 have to be reduced to .1 ppb to achieve a cancer  
17 rate of 1 in 10,000. The current drinking water  
18 standard is 10 ppb in the U.S., which is consistent  
19 with the World Health Organization standard. The  
20 drinking water standard would have to be reduced  
21 actually to .01 ppb to achieve a cancer rate of 1 in  
22 100,000. Levels of arsenic in most drinking waters



1 stated -- and I quote -- the idea of providing a  
2 reality check on the estimated risk levels was  
3 discussed. The SAB recognizes that the IRIS  
4 toxicological reviews are not intended to provide a  
5 complete risk assessment but rather a summary and  
6 synthesis of the toxicological evidence that  
7 supports risk assessment. Hence, an estimation of  
8 risk attributable to arsenic in drinking water in  
9 the U.S. populations versus the observed incidence  
10 of cancer is not appropriate within the purview of  
11 this document.

12 Well, I offer that the primary purpose of  
13 this review may not be to stop and question whether  
14 the analysis and modeling makes sense when viewed in  
15 the context of empirical observations, but I observe  
16 there are just too many factors to ignore. I think  
17 you have to ask these kind of questions, and when  
18 you do, you will see that things don't add up.

19 I have provided four relevant checks that  
20 can easily be pursued, and in each case, the outcome  
21 of that check is that this current proposed slope  
22 factor does not pass the reality check.

1           In summary, I ask that you carefully  
2   consider the evidence that supports the use of the  
3   proposed slope factor. It's important to get the  
4   science right because highly overestimated risks do  
5   not help risk management decision-making and can  
6   result in nonsensical public health concerns. I  
7   believe further review of the approach is clearly  
8   warranted.

9           And I thank you for the opportunity to  
10   make these comments.

11           DR. SWACKHAMER: Thank you very much, Dr.  
12   Adams.

13           Next we have Dr. Michael Eldan. Is he  
14   still on the line?

15           DR. ELDAN: Michal.

16           DR. SWACKHAMER: Thank you. Michal.  
17   Sorry.

18           DR. ELDAN: Thanks for the opportunity to  
19   make comments on behalf of Luxembourg-Pamol, a  
20   producer of organic arsenical products. My comments  
21   focus on arsenic low-dose risk assessment in view of  
22   EPA's guidelines for carcinogen risk assessment, to

1 which I will refer as Cancer Guidelines.

2 In the arsenic risk assessment document,  
3 EPA asserts that the agency Cancer Guidelines compel  
4 it to use linear extrapolation for low doses because  
5 arsenic's mode of action has not been fully defined.  
6 A careful review of the guidelines clearly shows the  
7 contrary. The guidelines mandates the use of  
8 nonlinear assessments when a nonlinear mode of  
9 action is scientifically possible, even if it is not  
10 yet proven. For example, on page 19 of the  
11 guidelines, quote, if critical analysis of agent-  
12 specific information is consistent with one or more  
13 biologically based models, as well as the default  
14 option, the alternative models and the default  
15 option are both carried through the assessment.  
16 Quote.

17 The 2007 SAB review of EPA (inaudible)  
18 assessment specifically called attention to the  
19 substantial evidence and plausibility of the  
20 nonlinear dose-response and urged EPA to address  
21 that possibility in nonlinear models. For example,  
22 on page 6 of the SAB report, quote, studies of

1 indirect genotoxicity strongly suggest the  
2 possibility of a threshold for arsenic  
3 carcinogenicity. This issue is an issue that's  
4 being evaluated. Quote. The SAB recommended that  
5 nonlinear assessments should be provided in addition  
6 to linear ones to provide full characterization of  
7 the possibilities of low-exposure cancer risk.  
8 Quoting from page 44 of the report, although the EPA  
9 has chosen a linear model for the arsenic dose  
10 component of the hazard model, the panel encourages  
11 the agency to test the sensitivity of the assumption  
12 of linearity by comparing to an alternative hazard  
13 model that is nonlinear.

14 In spite of these recommendations, the  
15 current draft of EPA's arsenic assessment largely  
16 dismisses nonlinear approaches, addressing them only  
17 to justify the dismissal. It is critically  
18 important to recognize that EPA's reluctance to  
19 consider nonlinear models in spite of SAB's  
20 recommendation is in violation of its own  
21 guidelines. Most importantly, the only mode of  
22 action that would indicate low-dose linearity is a

1 direct genotoxicity by reaction with DNA. Such a  
2 mode of action has been ruled out for arsenic. So  
3 all the possible modes of action are nonlinear.

4 The 2005 EPA Cancer Guidelines address  
5 such a situation on page 322. Quote. A nonlinear  
6 approach should be selected when there are  
7 sufficient data to ascertain the mode of action and  
8 conclude that it is not linear at low doses and that  
9 the agent does not demonstrate activity consistent  
10 with linearity at low doses.

11 An argument often made against nonlinear  
12 assessment is that the guideline compels a linear  
13 extrapolation when a nonlinear mode of action cannot  
14 be fully described or modeled with precision. This  
15 is not the case. On the contrary. On page 323, the  
16 guidelines explicitly say that nonlinear  
17 extrapolation, having the significant biological  
18 support, may be presented in addition to the linear  
19 approach when the available data and the weight-of-  
20 evidence evaluation support a nonlinear approach but  
21 the data are not strong enough to ascertain the mode  
22 of action.

1           In 2007, the SAB asked the agency to  
2   consider the mechanistic evidence supporting the  
3   threshold in arsenic dose-response, as well as the  
4   lack of apparent effects in human studies conducted  
5   in the U.S. This was not only sound advice. This  
6   is the direction of EPA's own guidelines.

7           Since 2007, the scientific evidence  
8   supporting nonlinearity at low doses has been  
9   accumulating and strengthening. Thus, in its  
10   current deliberations, the SAB should not abandon  
11   the advice it gave EPA in 2007. We urge the SAB to  
12   make sure that advice it now gives the agency is in  
13   accord with EPA's guidelines, especially when the  
14   basis for the only possible linear mechanism has  
15   been excluded. It is critically important that the  
16   EPA follows SAB's advice to consider a nonlinear  
17   model as directed by its own guidelines.

18           Thank you for allowing me to present these  
19   comments.

20           DR. SWACKHAMER: You're welcome.

21           And is Dr. Richard Wilson now on the line?

22           (No response.)

1 DR. SWACKHAMER: Hearing that he is not,  
2 is Dr. Kosnett on the line?

3 DR. KOSNETT: Yes. Hi. I'm here. Can  
4 you hear me?

5 DR. SWACKHAMER: Yes. Please go ahead.

6 DR. KOSNETT: Thank you for the  
7 opportunity to address the SAB. My name is Michael  
8 Kosnett. I am a physician specializing in  
9 occupational and environmental medicine and medical  
10 toxicology. I am an associate clinical professor in  
11 the Division of Clinical Pharmacology and Toxicology  
12 at the University of Colorado School of Medicine and  
13 in the Department of Environmental and Occupational  
14 Health at the Colorado School of Public Health.

15 I've had a long-term clinical interest and  
16 research interest in the toxicology of arsenic. I  
17 served on the NRC subcommittees on arsenic in  
18 drinking water that issued reports to EPA in 1999  
19 and 2001.

20 Although I am not speaking today as a  
21 representative of the NRC, I wanted to take this  
22 opportunity to emphasize two particular points that

1 were noted by our NRC subcommittees and which remain  
2 quite valid today.

3           The first pertains to EPA's decision in  
4 the recent IRIS toxicological review to utilize a  
5 linear model to extrapolate human cancer risks from  
6 the epidemiological data. The work group accepted  
7 that ultimate decision. This was also the  
8 recommendation of the NRC subcommittee. The  
9 subcommittee noted that the human epidemiological  
10 data demonstrating cancer risk, particularly those  
11 from southwest Taiwan and Chile, are consistent with  
12 the linear dose-response and that the range of  
13 extrapolation or margin of exposure between the  
14 arsenic doses associated with observed excess  
15 cancers and the low levels of arsenic exposure from  
16 environmental sources in the U.S. is one of the  
17 narrowest for any carcinogen regulated by EPA.

18           The subcommittee also noted that in vitro  
19 studies have observed multiple genotoxic and non-  
20 genotoxic effects of arsenic in human and other  
21 mammalian cells that are consistent with a  
22 carcinogenic mode of action and that these effects

1 have occurred at concentrations that might exist in  
2 vivo at low levels of environmental arsenic  
3 exposure.

4 A key question faced by EPA is not whether  
5 these potential modes of action might follow a  
6 nonlinear dose-response at any dose, but rather,  
7 whether there is convincing evidence that they  
8 exhibit a nonlinear dose-response in the range of  
9 extrapolation relevant to contemporary environmental  
10 exposures to humans in the United States. In the  
11 absence of the demonstration of such nonlinearity in  
12 that dose range of interest, it is appropriate for  
13 EPA to utilize a linear dose-response, which is also  
14 the default choice protective of public health.

15 My second point addresses concern raised  
16 in the October 25th, 2010 SAB draft review of the  
17 EPA IRIS report regarding a reality check relating  
18 the cancer slope factors for arsenic and the  
19 observed the cancer rates in the United States.  
20 This very point was addressed by the NRC  
21 subcommittee in its 2001 report. On page 221 in a  
22 section entitled "Plausibility of Cancer Risk

1 Estimates," the subcommittee wrote, quote, although  
2 the subcommittee's risk estimates are a public  
3 health concern, they are not high enough to be  
4 easily detected in U.S. populations by comparing  
5 geographical differences in the rates of specific  
6 cancers with geographical differences in the  
7 concentrations of arsenic in drinking water. I  
8 recommend that EPA and SAB take particular note of  
9 that section of the 2001 NRC report.

10 Thank you very much.

11 DR. SWACKHAMER: Thank you very much.

12 And one more chance for Dr. Wilson. Is he  
13 on the line?

14 DR. WILSON: Hello. Can you hear me?

15 DR. SWACKHAMER: Is this Dr. Wilson?

16 DR. WILSON: This is Dr. Wilson.

17 DR. SWACKHAMER: Yes, please. You have 5  
18 minutes. Please go ahead.

19 DR. WILSON: Thank you very much for  
20 allowing me to talk.

21 I want to first emphasize that this is one  
22 of the worst problems that EPA has faced because if

1 you calculate on the 1980 guidelines with a 10 to  
2 the minus 6th risk assessment, you would have to  
3 regulate at 5 parts per trillion. Once we realize  
4 that, you've got to take it seriously.

5 I fully support the low-dose default  
6 (inaudible) 1975 EPA criteria and remind you of what  
7 was in it and that it depends on only the background  
8 cancers and the cancers caused by the pollutant are  
9 indistinguishable not only to a bad toxicologist but  
10 to any toxicologist. And it is, therefore, a  
11 default which is built in inherently into the Doll-  
12 Armitage studies and that must be recognized. So I  
13 fully support that default.

14 Now, we must now recognize that the Taiwan  
15 data are an ecological study, as has been mentioned  
16 by Jonathan Summit, but it's very clear that it's  
17 inherently impossible to derive a dose-response from  
18 that study. That should be fundamentally admitted  
19 and realize there's only one number you can get out  
20 of that with an assumed dose-response relationship.

21 On that number, you actually get it  
22 slightly better from the Chilean data, though that's

1 only at one dose, but the Chilean data have less  
2 other uncertainties.

3 Now, having said that, they're all based  
4 on this data on Movalis et al., and if you look at  
5 that data and their plots, if they do not put in a  
6 plot of zero effect at zero dose, you will not have  
7 any good evidence on that plot for arsenic-caused  
8 cancer at all. So it depends very critically on  
9 that particular point, and when you look at that  
10 point, you've got a very peculiar dose-response.  
11 The (inaudible) goes from EDR1 down to 0 in a  
12 straight line. That graph looks absolutely stupid  
13 and should give you a warning immediately that  
14 something is wrong. And what is wrong is, of  
15 course, the low-dose data in the Taiwan data.

16 Now, they mentioned that you should be  
17 able to be visible in an EPA -- in a study in the  
18 United States. Professor Lamm and myself were  
19 involved in such a study in 2004 for bladder cancer.  
20 Now, one problem with that study -- there were  
21 several problems with it, and we noted all sorts of  
22 criticisms you might make of it. In fact, I knew

1 those criticisms. We stated the criticisms  
2 ourselves. But those criticisms apply in spades  
3 much worse to all the low-dose data from Taiwan.  
4 And if you do not accept the results of Lamm and  
5 myself and others on the data in America, you should  
6 not accept the results of low-dose from Taiwan.

7           Having said that, what do you do? And the  
8 answer is you should now look at other places.  
9 We've got Chile which, of course, is one dose. You  
10 should look at other locations, which is what, for  
11 example, my conversations with C.J. Chen both in  
12 1991 when I first talked to him and this last May  
13 when I talked to him -- he is not interested any  
14 longer in that low-dose area (inaudible) with  
15 Taiwan. He's looking at other places. I think that  
16 is exactly right, and any idea that you solve the  
17 problem by more data dredging -- well, I mean, it's  
18 possible for Lamm to solve the problem, but he has  
19 in fact raised the issue that is a really difficult  
20 question.

21           So the fact (inaudible) decide on that one  
22 data set for a quantitative risk assessment is

1 completely stupid because it ends up, if you look  
2 directly at the data set and don't do anything else,  
3 you just look at the Movalis paper and you don't  
4 assume low-dose linearity, then you've not got any  
5 evidence that arsenic causes cancer, which is  
6 stupid.

7           So I called attention to go right back to  
8 the initial assumptions, repeat them, and by the  
9 way, I repeat again that the situation is really  
10 very bad. Those of us who work, as I do, in  
11 Bangladesh or Inner Mongolia to try and help the  
12 people who have got severe arsenic problems  
13 recognize this.

14           I point out that two of us, Steven Lamm  
15 and myself, were both in a meeting in Taiwan on  
16 arsenic this May. There were 200 people at that  
17 meeting, and we all went out -- we all had the  
18 opportunity of going out to actually look at the  
19 sites. As far as I know, no one from SAB was in the  
20 meeting. No one from the EPA risk assessment was at  
21 that meeting. And I think that tells you already  
22 something rather peculiar about the whole EPA

1 procedure.

2 I thank you for allowing me to talk.

3 DR. SWACKHAMER: Thank you very much.

4 This concludes our public comment period,  
5 and we now have a little more than an hour to have a  
6 discussion around this draft review -- excuse me --  
7 work group report.

8 First, I'd like to ask if there's anyone  
9 from the board who would like to ask clarifying  
10 questions of the public speakers.

11 And whoever is not on mute, please put  
12 yourself on mute.

13 Hearing none, let's now hear from the lead  
14 reviewers. We have four lead reviewers from the  
15 board -- six lead reviewers. Excuse me. We have a  
16 lot of lead reviewers to make sure that we really  
17 covered this topic as evenly as possible. We have  
18 Jonathan Samet's comments. He is not on the phone,  
19 but we have his written comments.

20 Next I will just ask each of the lead  
21 reviewers that are on the call to just briefly  
22 summarize their key points that they really want to

1 make. We have your written comments, but we'd  
2 really like to be able to have anything you think  
3 that deserves discussion while we have the board on  
4 the phone. I'm going to turn to Paige Tolbert now.

5 DR. TOLBERT: Thank you. Can you hear me?

6 DR. SWACKHAMER: Yes. Go ahead.

7 DR. TOLBERT: This is Paige Tolbert, and  
8 I'd like to provide my comments as a discussant and  
9 quality reviewer of the report by the work group.

10 The charge questions have been already  
11 sent around. The first charge question is whether  
12 the original charge questions to the SAB committee  
13 were adequately addressed, the first quality review  
14 question. And my response is that the SAB Work  
15 Group has adequately addressed the original charge  
16 questions posed to them by EPA.

17 In terms of those charge questions, the  
18 first charge question, the work group is well  
19 justified in finding that the EPA was responsive to  
20 the original SAB recommendations regarding the  
21 review of the epidemiologic literature and findings  
22 that the Taiwanese data continue to provide an

1 appropriate basis for risk models. As pointed out  
2 by the work group, there's additional work that EPA  
3 should consider embarking on in terms of more  
4 clearly stating the criteria used in evaluating the  
5 studies and presenting the review in a more  
6 systematic and synthetic way. This will make EPA's  
7 choices regarding data used in the risk models more  
8 transparent and compelling.

9 In terms of the second charge question  
10 that the work group was provided, the work group  
11 found that EPA was responsive to the 2007 SAB review  
12 in performing the requested sensitivity analyses of  
13 the dose-response modeling and concurred with the  
14 EPA rationale for choosing a linear low-dose  
15 extrapolation risk assessment approach. I find that  
16 the work group response to this charge question is  
17 adequate and that the work group request for further  
18 work and expansion of the IRIS report, as described  
19 in the work group report, is well justified.

20 And then finally for the third charge  
21 question, the work group response is again adequate.  
22 The work group provides the basis for finding that

1 the EPA report is partially responsive to the  
2 request and provides detailed suggestions for how  
3 the EPA report could be improved to be more  
4 responsive to the original SAB input and to increase  
5 transparency.

6           Regarding quality review question 2,  
7 whether there are any technical errors or omissions  
8 in the report or issues that are inadequately dealt  
9 with in the report, I did not find additional  
10 technical errors and omissions or issues that are  
11 inadequately dealt with. Minor technical concerns  
12 in the previous draft of this that we reviewed in  
13 June have been addressed. There is some additional  
14 minor editing that remains to be done. For  
15 instance, the executive summary does not fully  
16 capture the main points of the body of the report.

17           I do have some remaining concern about the  
18 work group recommendation to summarize major studies  
19 since 2007. EPA should be given wide latitude in  
20 making this determination of whether there are any  
21 transformational new studies that would dramatically  
22 change any of the conclusions of the report because

1 this cannot be done in real time, but if there are  
2 any major studies, I would rely on EPA to give them  
3 due consideration.

4 Finally, let's see. For quality review  
5 question 3, whether the report is clear and logical,  
6 I did find that the report was logical and clear.  
7 It effectively communicates the work group's  
8 assessment of the draft IRIS report with respect to  
9 the EPA charge questions.

10 And lastly, the quality review question of  
11 whether the conclusions drawn or recommendations  
12 provided are supported by the body of the  
13 committee's report. I did find that the conclusions  
14 are supported by the body of the work, the report,  
15 and that the work group has provided ample rationale  
16 for its recommendations, that the work group has,  
17 within the scope of the original charge questions,  
18 made scientifically sound and well justified  
19 conclusions and recommendations.

20 Thank you.

21 DR. SWACKHAMER: Thank you very much,  
22 Paige.

1                   Next we have -- is John Vena here?

2                   DR. VENA:    Yes, I am.

3                   DR. SWACKHAMER:  Very good, John.  Would  
4 you go forward with your, again, highlighting some  
5 substantial comments that you really want the board  
6 to hear.

7                   DR. VENA:  Yes.  With regard to the three  
8 review questions -- the four review questions, the  
9 first one.  You know, I really thought the work  
10 group did a fantastic job of addressing each of the  
11 charge questions, and I thought they very  
12 systematically went through and addressed many of  
13 the issues.

14                   With regard to technical errors or  
15 omissions, to my knowledge I did not feel that there  
16 were any major technical errors or omissions.

17                   With regard to number 3, whether the  
18 committee's report is clear and logical, I thought  
19 there were several instances where the cover letter  
20 and executive summary did not -- sorry.  I forgot to  
21 leave the "not" out.  I forgot to put the "not" --

22                   DR. SWACKHAMER:  I assumed that.

1 DR. VENA: Do not adequately capture the  
2 sentiment of the statements in the body of the text  
3 responding to the charge questions. There are  
4 several statements and recommendations I thought  
5 that need to be clarified, and I had articulated  
6 those in the latter part of my report.

7 With regard to the fourth question,  
8 conclusions or recommendations are supported by the  
9 body in the committee's report, the recommendation  
10 and response to charge question 3 on page 14 that  
11 they test the effects of layered assumptions, I  
12 understand kind of the rationale for that. And I  
13 think one of the previous speakers did hit on that  
14 point, but I really didn't see much in the actual  
15 body that justified that that would be instructive  
16 to examine the set of exposure assumptions. Somehow  
17 maybe the language could be added to clarify that.

18 And with regard to some of the specific  
19 responses to the charge questions, with regard to  
20 charge question number one, on page 6, lines 10  
21 through 16, I thought that that really needs  
22 clarification and more clearly stated both in the

1 cover letter and in the executive summary. Again, I  
2 hope they could clarify what pulling any essential  
3 information from references in the text was meant to  
4 convey.

5 And also summaries of the epidemiology  
6 studies should include a quantitative presentation.  
7 I thought that was vague. And are they specifically  
8 recommending a formal meta-analysis? And also, this  
9 recommendation wasn't clearly articulated in the  
10 cover letter and executive summary.

11 Page 7, lines 25 through 33, should the  
12 SAB specifically recommend that the literature  
13 published since 2007 be incorporated in the updated  
14 assessment? And Dr. Tolbert I know expressed some  
15 reservations about that. And also I'd like to note  
16 that Dr. Samet also in his review also questioned  
17 the, I guess, rationale behind that. And it seems  
18 to me, as also I think better articulated by Dr.  
19 Tolbert, was that if you do do that, then you'd have  
20 to go through a process of evaluation of the total  
21 literature and the consequences, et cetera. So I'm  
22 not sure that that recommendation is justified. I

1 guess we adopt the current risk assessment. Then  
2 the question remains as to what's the next process  
3 after that's adopted with regard to either update  
4 the IRIS document with regard to all of the  
5 literature. So it seems to me that in order to  
6 include that literature, you'd have to go through a  
7 very systematic review and update of the IRIS  
8 document with that literature.

9           The other thing with regard to charge  
10 question 1, it specifically stated -- and this has  
11 to do, to me, with being very clear as to the -- let  
12 me see here -- excuse me. I lost my spot here.

13           DR. SWACKHAMER: While you're thinking,  
14 I'm going to ask whoever is making all that noise to  
15 please mute your line. Somebody is rattling around,  
16 and if you could please mute your line. Thank you.

17           Go ahead.

18           DR. VENA: With regard to the modeling, I  
19 think there's some specific language in the  
20 executive summary and the body that the SAB agrees  
21 with the conclusions that none of the alternative  
22 models, i.e., quadratic, quadratic exponential, and

1 linear exponential, evaluated by the EPA materially  
2 change the estimated risk levels versus the use of a  
3 linear model. So that to me seems to be a statement  
4 justifying the linear model that's in both the  
5 executive summary and the body, but it's not in the  
6 cover letter as a specific recommendation. And they  
7 seem to support, again, EPA's use of the linear  
8 model.

9           And also in the first part under charge  
10 question 1, again on page 7, there's a specific  
11 recommendation with regard to bias, assessing the  
12 bias, page 7, (inaudible) should include statements  
13 regarding differential versus nondifferential. And  
14 I'm sorry. I said "bias." I meant  
15 "misclassification." And I thought justification  
16 for the recommendations for estimating the  
17 quantitative consequences of bias should be provided  
18 and would that exercise really change the  
19 conclusions of the document.

20           More specifically, I really don't  
21 understand the recommendation to go through this  
22 process of a quantitative bias analysis for

1 epidemiologic data. It seems to me that the book,  
2 as well as the process, is a way of recalculating  
3 your confidence intervals based on the analytic  
4 approaches to the data and making certain  
5 assumptions that unless you have the individual-  
6 level data and the data analysis, I'm not sure how  
7 EPA could use this method to somehow summarize the  
8 literature. So I just don't understand it and maybe  
9 somebody could clarify it for me.

10 So I think that's it for charge question  
11 1.

12 Charge question 2, I think there's a few  
13 issues just to clarify, as I mention in my report,  
14 and most specifically, that the whole paragraph I  
15 thought was unwarranted and should be omitted on  
16 page 10. It's better worded on page 10 than in  
17 other parts of the document in terms of they said  
18 that this reality check or whatever. And they  
19 recommend that they consider this but then put it in  
20 another document. I just don't understand why it's  
21 even needed then and why that language is even  
22 needed. It should be omitted, and/or if it's

1 retained, that it be better worded in the summary  
2 and in the cover letter.

3 And I think that's it as far as my  
4 comments.

5 DR. SWACKHAMER: Thank you very much,  
6 John.

7 Is Tom Zoeller on the phone?

8 DR. ZOELLER: Yes.

9 DR. SWACKHAMER: Oh, good. You were able  
10 to join us. We're going through the lead reviewers  
11 and having people highlight any comments they'd  
12 really like to share with the board.

13 DR. ZOELLER: Yes.

14 So basically my comments were very similar  
15 to the first two lead reviewers, and generally I  
16 thought this was a very well drafted document.  
17 There are minor issues in various spots, "issues"  
18 meaning kind of points of clarification that need to  
19 be made, but I don't think that there's -- at least  
20 I didn't find anything that was fundamentally flawed  
21 about it, technical errors, et cetera. So I  
22 basically concur with the first two lead reviewers.

1 DR. SWACKHAMER: Sorry. I was on mute.

2 Very good.

3 Is Steve Heeringa on the phone?

4 DR. NUGENT: Deb, this is Angela. I

5 received word that --

6 DR. SWACKHAMER: I know he was going to --

7 he might or might not call in.

8 DR. NUGENT: I think he's not on the line.

9 DR. SWACKHAMER: He also raises the issue  
10 of this lit review post 2007. So we'll be coming  
11 back to that issue.

12 In his other comments, he has some  
13 specific comments around the executive summary and  
14 some clarity. But again, it looks like it's pretty  
15 much in line with what we've heard from folks so  
16 far.

17 Dr. Shubot, are you on the phone?

18 DR. SHUBOT: Yes, I am.

19 DR. SWACKHAMER: So if we could hear from  
20 you.

21 DR. SHUBOT: Well, as everyone else, my  
22 comments are very similar. I thought the work group

1 had a tough job. They adhered to their charge and  
2 carried it out more than adequately. I thought it  
3 was a very good job, a lot of work, and a tough job.

4 I also had a strong comment about the  
5 literature review. I think the points that have  
6 been raised by many reviewers, not just the SAB,  
7 point to the need for EPA to stay on top of all the  
8 literature. I think (inaudible) reevaluate. I  
9 agree with that, but I would recommend that the work  
10 group not suggest that this be appended to this tox  
11 review. There are other mechanisms for doing that  
12 kind of ongoing literature review, annotated review,  
13 such as an IRIS literature search. Or perhaps there  
14 are other venues too. I'm not sure. Or as each  
15 office takes up this type of data, that there be a  
16 strong recommendation to update the literature  
17 (inaudible).

18 Other than that, I think I have no novel  
19 comments. I too noticed that there was perhaps some  
20 different emphasis in the body of the report versus  
21 the executive summary versus the cover transmittal  
22 pages, but I don't know that that was a fatal flaw

1 but it's something to maybe be alert to and some  
2 folks did a much better job than I did of making  
3 some specific recommendations.

4 That's all.

5 DR. SWACKHAMER: Okay. Thank you very  
6 much.

7 So we've heard from the lead reviewers.

8 At this time, I would welcome a chance to  
9 hear back from -- I've lost my report. Goodness.  
10 I've got too many pieces of paper on my desk. What  
11 the heck did I do with my agenda? Sorry about that.

12 Okay. I would like to hear back from  
13 Elaine also on response to these comments. Also, is  
14 John Vandenberg still on the line?

15 DR. VANDENBERG: Yes, I'm still here.

16 DR. SWACKHAMER: It might be also helpful  
17 -- I should have asked you this sooner if you're  
18 willing to serve as a resource for some of these  
19 questions that might come up regarding how EPA has  
20 done things, et cetera.

21 First, I'd like to hear from Elaine, just  
22 a quick response, if you have any, to some of the

1 comments you've heard.

2 DR. FAUSTMAN: No. Other than just the  
3 fact that there's a definite consistency in what  
4 we're being asked to do by the Scientific Advisory  
5 Board comments. And I think those are well within  
6 an ability for us to respond to here. So  
7 clarification in particular about what we're asking  
8 for in the appendices, clarification of what we're  
9 asking for in this one sensitivity analysis, and  
10 making sure again that our cover letter is  
11 consistent with the documentation that we have in  
12 the report.

13 DR. SWACKHAMER: As well as the executive  
14 summary, right.

15 DR. FAUSTMAN: Yes, yes.

16 DR. SWACKHAMER: Okay.

17 Now, we have a whole number of other folks  
18 on the line in terms of other SAB members, and we  
19 have lots of written comments. And I would say,  
20 having looked at the written comments, I also see  
21 some similarities and some consistencies of some  
22 threads that need to be addressed, which have

1 already been addressed, I think, mostly by the lead  
2 reviewers. But I want to give a chance for anyone  
3 else to offer their comments if they have not had a  
4 chance to offer written comments and would like to  
5 make comments now, if any board members would like  
6 to underscore a point they've made in writing and  
7 you want to make sure that we hear this and it  
8 hasn't been articulated by the lead reviewers, then  
9 I'm happy to entertain comments from the board.

10 Anyone.

11 DR. GRIFFITHS: Deb, this is Jeff  
12 Griffiths.

13 DR. SWACKHAMER: Yes.

14 DR. GRIFFITHS: My written commentary is  
15 similar to what others have said. I think it may be  
16 appropriate in the cover letter to acknowledge, you  
17 know, the genuine passion and scientific interest in  
18 this area and that a review of what the EPA's  
19 current thinking is or will be -- that a review  
20 might be in order as more information comes in and  
21 that we acknowledge that.

22 You know, I am very mindful of the public  
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1 commentary that we've had, and I am not persuaded by  
2 it that we should leave a linear model, for example,  
3 in terms of low-dose assessment. I am, nonetheless,  
4 aware of the (inaudible) it will have and the  
5 relatively limited data sets that we have for  
6 arsenic. And so I think that the letter can state  
7 that we believe the agency has done what it was  
8 supposed to do. I think it's possible for us to  
9 note that there was a great deal of public  
10 commentary about this in some fashion. I don't know  
11 whether that belongs in a letter, a side letter,  
12 something like that, but it is indeed striking that  
13 -- well, not striking. It's just a circumstance of  
14 life that the data that we have for human exposure  
15 to arsenic in its organic form and human health  
16 outcomes is relatively limited compared to what it  
17 might be for certain other things. So I guess that  
18 would be the content of what I wanted to add.

19 DR. SWACKHAMER: Excellent comments.

20 Thank you.

21 Other SAB members?

22 DR. DOERING: Yes. This is Otto Doering.

1           Listening to this conversation and the one  
2 we had earlier in the year where there was also  
3 commentary, this is not my field. I know nothing  
4 about it. But the extent to which the people who  
5 commented on this raised what to me appeared to be  
6 very substantive issues, this just makes me very ill  
7 at ease about EPA, whether as a result of our  
8 comment on the report or not, adopts a hard and fast  
9 approach to assessing risk in this.

10           DR. SWACKHAMER: Elaine, would you like to  
11 comment on that?

12           DR. FAUSTMAN: I'm sorry. I kind of  
13 missed -- I need the last three sentences stated  
14 again. I'm so sorry.

15           DR. DOERING: Elaine, this is Otto.

16           It's just that listening to all the  
17 comments, I am just ill at ease with the thought  
18 that it may be because of what we say -- are we  
19 indicating that it is appropriate for EPA to adopt a  
20 particular data and model approach to their  
21 regulation in this area, given the controversy that  
22 surrounds it? And I'm speaking of the linear model

1 in very low doses.

2 DR. FAUSTMAN: Well, usually the default  
3 is, if there is such controversy, one uses that  
4 until more information comes forth. And I think  
5 that's what you're hearing is. Is there enough  
6 information at present to be able to deviate from  
7 that?

8 But I think your comment and the previous  
9 commenter -- it is amazing. I actually would argue  
10 the other, that we have a tremendous amount of  
11 useless data out there on arsenic and analysis of  
12 the same studies over and over again. And we have a  
13 lot of exposure for arsenic. So how come there  
14 haven't been more studies performed by many of the  
15 interested parties that are around the table here?  
16 But that's not, I think, our place to handle that.

17 I was struck by some of the comments that  
18 were made about where we need to make some more  
19 adequate reference to previous statements. In the  
20 document, we did go with the 2007 advice to continue  
21 to use the Taiwanese study. I think if anything is  
22 embarrassing is that there haven't been additional

1 (inaudible) with many other populations out there.

2 So I am struck.

3 But there is a tremendous amount of  
4 interest in this and I think previously we compelled  
5 on the call that we had this summer -- we compelled  
6 EPA to deal with this in a much broader context  
7 that's outside the setting of this value, but in the  
8 other regulation-specific aspects of their  
9 responsibility.

10 DR. DOERING: Thank you.

11 DR. BENITEZ-NELSON: Deb, this is Claudia  
12 Benitez-Nelson.

13 DR. SWACKHAMER: Yes. Go ahead.

14 DR. BENITEZ-NELSON: I just wanted to add  
15 my comment in that I agree with the previous  
16 discussion in that I think EPA has done its job. I  
17 think you've done a very good job of responding to  
18 the working group and the draft report, and there's  
19 nothing else to be done based on the data batch in  
20 hand.

21 But I would like to add my concerns and  
22 say that as being part of the SAB working group,

1 that clearly this is an issue that's been around for  
2 a while, and I think it's something that we really  
3 as the working group need to be aware of and to make  
4 sure that it's not something that again another 3  
5 years go by and we have to do a review of such a  
6 report and we find that we're in the same situation.  
7 And I find that a little disconcerting and a bit  
8 worrisome. So I do think as of now we've done what  
9 we needed to do, and I think they've done a good  
10 job, but this should be something -- a charge to the  
11 SAB to move forward on in the future.

12 DR. SWACKHAMER: Thank you for those  
13 comments.

14 Are there other board members that would  
15 like to have a chance to share their comments?

16 SPEAKER: Deb, this is --

17 DR. PATTEN: Deb? Excuse me.

18 DR. SWACKHAMER: Is that Duncan?

19 DR. PATTEN: Yes, it's Duncan. I'm going  
20 to have to leave, so I have a quick comment.

21 I agree with Otto. I'm a little concerned  
22 after listening to the public comments, but I'm not



1 John Vena.

2 DR. SWACKHAMER: Yes. Go ahead, John.

3 DR. VENA: Yes, yes.

4 And similar to Dr. Tolbert, as well as Dr.  
5 Samet, is that the IRIS risk assessments take an  
6 unbelievable amount of time to develop. SAB  
7 encouraged an expansion that could lead to further  
8 delay. So it wasn't that I wasn't saying that it  
9 shouldn't be updated. It's just it seemed to me  
10 that that's beyond the charge questions that were  
11 put to the working group, and my job was to review  
12 the working group document in response to the IRIS  
13 as it currently exists.

14 I guess it's beyond, I guess, the charge  
15 at the moment in terms of, I guess, you could  
16 clarify for me, being new to the chartered SAB, once  
17 this IRIS is adopted, then what is the next  
18 procedure with regard to, in fact, doing the update  
19 and taking the literature from 2007 and 2010. I  
20 mean, what's the process after that?

21 DR. SWACKHAMER: Perhaps that's something  
22 that John Vandenberg could address.

1 DR. VANDENBERG: Yes. Thank you very  
2 much. This is John Vandenberg from EPA.

3 We have a list of priorities for assessing  
4 different chemicals of obviously priority to the  
5 agency, and arsenic, obviously, going through this  
6 review of a second review, is very high priority.  
7 So we're aware of the literature. We're constantly  
8 surveying and interpreting the liver -- not the  
9 liver -- the literature as we move forward. And as  
10 it becomes evidence for our program needs, for the  
11 EPA program offices, for the regional offices, for  
12 the States, that arsenic yet again needs to be  
13 reviewed, it would again get into the IRIS agenda to  
14 be re-reviewed at some point in the future.

15 So it's not a fixed process except to say  
16 that we do recognize that the literature is  
17 expanding, and so at certain points in time it  
18 becomes incumbent upon us to review that literature  
19 again and revise the assessment. I can't say what  
20 point in time that would be for arsenic, but  
21 certainly this literature has expanded to a great  
22 extent, especially regarding some of the mode-of-

1 action information.

2 DR. VENA: So if I'm clear on this, the  
3 2010 document that was reviewed by the work group  
4 earlier and then this is a second, I guess, draft of  
5 their report -- is that the decision was made at  
6 that point not to update the literature up to 2010  
7 and redo it and submit it at that time for another  
8 full review. It was here's the document, review how  
9 EPA responded with the literature up to 2007, and  
10 then that would put it in the queue for processing  
11 and then it would follow that then it would be  
12 updated as needed or whatever.

13 DR. VANDENBERG: Yes, that's right. You  
14 know, this document went through a full peer review  
15 that began with the document being (inaudible) in  
16 2005 with then the 2007 report from the Science  
17 Advisory Board. We considered those comments and  
18 recommendations at that time, finished the document.  
19 It took us quite a while to get it through the  
20 internal process review of the agency and  
21 interagency, which is why it was released early in  
22 2010, using the data that was available up through

1 2007. So this is really a focused review of that  
2 data up through 2007. The assessment at its core  
3 was all reviewed. There was a full peer review of  
4 the assessment by this Science Advisory Board in  
5 2007.

6 So part of the confusion that I'm hearing  
7 here is that the last sentence of the first  
8 paragraph of the letter seems to suggest that there  
9 was not a full peer review of the assessment. Well,  
10 in fact, there was. There was not a full peer  
11 review of the revised assessment. This is a more  
12 focused review that targets certain key issues of  
13 the revised assessment that --

14 DR. VENA: I think you're right. I think  
15 that's where the confusion is. Thanks for  
16 clarifying that.

17 DR. VANDENBERG: Sure.

18 DR. SWACKHAMER: Yes, John. Thank you  
19 very much for that clarification.

20 This might be a good time to point out  
21 that EPA requested that the SAB review the inorganic  
22 aspects of arsenic and it's reviewing the cancer

1 aspects separately. In fact, there's an FR notice  
2 out on that review panel. So the agency has split  
3 that.

4 John Vandenberg, do you have any comment  
5 on that, on why we wouldn't do a full integrated  
6 review from the agency's perspective? Or is that a  
7 possibility that we might pursue in the future?

8 DR. VANDENBERG: We're still in the  
9 development process for the noncancer assessment.  
10 That's what you were referring to here.

11 DR. SWACKHAMER: I'm sorry. Yes.

12 DR. VANDENBERG: So that development and  
13 review process, as was noted earlier, takes quite a  
14 long time. So if we were to link these together, it  
15 would lead to, again, a delay of completing the  
16 cancer assessment.

17 In the noncancer assessment, what we are  
18 doing is we are evaluating the literature to see if  
19 there can be a derivation, considering all the data,  
20 of reference dose or an inhalation reference  
21 concentration. So it's possible, and we've done  
22 this for other assessments where we can, in a sense,

1 look at the entirety of the tox evidence but pull it  
2 into two different assessments, a cancer and a  
3 noncancer assessment, that are complementary and  
4 complete. But in this case, there's a bit of a time  
5 lag between them.

6 DR. SWACKHAMER: Are there other comments  
7 from board members? I know I cut someone off early  
8 on.

9 SPEAKER: Deb, this is --

10 DR. HAMMITT: Deb, this is Jim Hammitt.

11 DR. SWACKHAMER: There's a woman's voice.

12 Let's take her first because that's who I cut off  
13 before.

14 DR. SEGERSON: That's okay. It's Kathy  
15 Segerson. But go ahead, Jim.

16 DR. HAMMITT: No. Go ahead, Kathy.

17 DR. SEGERSON: I was just actually going  
18 to just say something about the timing -- I'm sorry  
19 -- about the update to the literature as well, which  
20 has been discussed in detail. I guess I just would  
21 argue that maybe in light of the comments that we've  
22 heard from the public, that even though I understand

1 that you need to cut off at some point the  
2 information that you're going to use to make the  
3 recommendations, it might be appropriate to  
4 recognize in the letter something about the  
5 development of new data over time and how that would  
6 be incorporated just to acknowledge that 2007 is not  
7 the last date at which any information has become  
8 available about this. Sort of a plan or something.  
9 I don't know, Deb, if you had some suggestions on  
10 how to address this particular issue in the letter,  
11 but it seems as though it's something we should say  
12 something about.

13 DR. SWACKHAMER: I do have some thoughts,  
14 but I welcome other comments from the board on how  
15 to deal with this issue. It's clear that we can't  
16 just leave it as an open door and then these  
17 assessments would never get completed. On the other  
18 hand, we do need -- as you just said very well, we  
19 need to acknowledge the fact that literature  
20 continues to accrue. And so perhaps it's an  
21 acknowledgment of that and urge EPA to try to get  
22 these assessments turned around faster so that these

1 lag times don't get quite so long.

2 DR. DASTON: This is George Daston.

3 DR. SWACKHAMER: Can we hear from Jim  
4 first?

5 DR. DASTON: I'm sorry. I was just going  
6 to respond to that point, but sure.

7 DR. SWACKHAMER: Well, okay. Why don't  
8 you go ahead, George? Then we'll hear from Jim.

9 DR. DASTON: I mean, so in an ideal world,  
10 the rules for IRIS are that every assessment is  
11 updated every 10 years. And simply because of  
12 resources, that's not always possible. But arsenic  
13 is such an important compound with such an obviously  
14 controversial assessment, that maybe what we can do  
15 as an SAB is recommend to MCEA that this be put on a  
16 rotating schedule.

17 DR. SWACKHAMER: That's a good suggestion.  
18 Jim?

19 DR. HAMMITT: Yes, thank you. Jim  
20 Hammitt.

21 I guess I'm sort of surprised by this. So  
22 like Otto, I think Otto said -- well, I don't really

1 know anything specific about arsenic. But I'm sort  
2 of stunned by we had several presentations from  
3 public commenters about how nonlinear models led to  
4 very, very different results. And then question 2,  
5 the second charge question, the second paragraph of  
6 that says that EPA used a variety of different  
7 models and the sensitivity analysis showed the  
8 potency estimates were similar to a linear approach.  
9 So those two facts don't seem to align very well.

10 DR. SCHNOOR: Jim, this is Jerry Schnoor.

11 I think it has to do with the data set  
12 that's used with the linear or the quadratic models.  
13 Using the Taiwan data set, I believe -- and maybe  
14 John Vandenberg will support this. Using the Taiwan  
15 data set, they're saying they didn't have much  
16 differences. But some of the public comments were  
17 referring to use of other databases and, of course,  
18 the fact that we have very little evidence of  
19 disease or pathology in this country at drinking  
20 water rates that would be in excess of the new  
21 cancer slope factor.

22 DR. SWACKHAMER: And Elaine, I'll also ask  
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1 you to either verify that or add to that.

2 DR. FAUSTMAN: Well, I think I want to  
3 call -- there was -- one of the public commenters  
4 specifically addressed that issue about the truth  
5 sensing, and he was one of the add-ins. I think he  
6 was the 11th person to speak, Michael Kosnett.

7 DR. SWACKHAMER: Yes.

8 DR. FAUSTMAN: And I think he said that  
9 that had already been addressed and that that would  
10 not have been seen as easily as was indicated. So I  
11 think we need to be careful about assuming that  
12 that's the case.

13 Then he cited the reference in one of the  
14 previous arsenic documents, and I did not have time  
15 to pull that page up. But I believe Angela has that  
16 in the notes. So I would be cautious about saying  
17 that the truth sensing was not coming out because I  
18 think this commenter actually provided some very  
19 specific analyses that had been done by one of the  
20 previous panels.

21 DR. NUGENT: This is Angela. He's also  
22 provided some written comments during the course of

1 this teleconference that I'll post on the web and  
2 provide to chartered SAB members. Dr. Kosnett.

3 MR. BROMBERG: Why don't we ask the public  
4 speakers what they think of Dr. Kosnett's comments?

5 DR. SWACKHAMER: Who just spoke?

6 MR. BROMBERG: This is Kevin Bromberg, one  
7 of the public speakers, somebody who's --

8 DR. SWACKHAMER: This is now a board  
9 discussion. We have provided time on the agenda for  
10 you to provide your comments, but if there are not  
11 clarifying questions, this is not an open  
12 discussion. It's a board meeting.

13 MR. BROMBERG: I understand that.

14 DR. SWACKHAMER: Are there other comments?

15 DR. HAMMITT: Deb, this is Jim again. If  
16 I could just say one more thing.

17 DR. SWACKHAMER: Yes.

18 DR. HAMMITT: That is, sort of coming into  
19 this call, I had the sense that perhaps the issue  
20 was the SAB Work Group had responded to the charge  
21 questions well, but maybe the charge questions were  
22 too narrow. And as I understand it, SAB committees

1 always have the option to go beyond the charge  
2 questions if they think it's important. So I kind  
3 of had the sense that maybe the elephant in the room  
4 here is that the charge questions may have been a  
5 little too narrow and the work group didn't go  
6 beyond them, and that's where a lot of the  
7 controversy lies.

8 DR. SWACKHAMER: Jim, I think you've  
9 stated it pretty well. And actually one of the  
10 public speakers -- I think it was Barbara Beck --  
11 said the same thing. That's exactly right. We were  
12 given a set of charge questions. We constituted a  
13 work group within the SAB. And the charge questions  
14 were very specific, and they were very focused. And  
15 the work group did have a discussion. Elaine, you  
16 can pipe in here if I misrepresent the work group at  
17 all, but my understanding is the work group did have  
18 a discussion about whether to expand past the scope  
19 of those charge questions, and based on who was in  
20 the work group, the expertise within the work group  
21 that was selected to be focused on those charge  
22 questions, they felt they should focus on those

1 questions and not go beyond their charge, which is  
2 perfectly within their -- you know, they get to do  
3 that too. And so that's what they did. And I know  
4 that there are many people out there, including many  
5 of our public speakers, who would have preferred  
6 that the work group did go beyond their charge  
7 questions or would prefer that there had been a full  
8 peer review of this reviewed document, that there  
9 had been a different process followed.

10           And what I would like to suggest, given  
11 that that's not what happened and given that the  
12 work group chose to stick to their charge questions  
13 -- and we've had fairly, I would say, uniform  
14 comments back from the board that they have  
15 addressed those comments adequately and according to  
16 the criteria that we use for quality review. We do  
17 have some comments on how to improve the letter and  
18 the executive summary, and we need to deal with this  
19 recommendation around additional data past 2007.  
20 But in general, there seems to be agreement that  
21 they, in general, addressed the charge questions as  
22 they were supposed to.

1           But given that there is a fair amount of  
2   discomfort both from the public comments and from  
3   several members of the SAB around that choice to --  
4   the result of having stayed on a narrow focus, I  
5   would like to suggest that we suggest as a board in  
6   the letter to the Administrator that we, in fact,  
7   offer to review the revised cancer document at the  
8   same time that we review the noncancer documents and  
9   do an integrated review, as I alluded to just a few  
10  minutes ago, and that we offer our services to the  
11  Administrator to, in fact, do what I think everyone  
12  really had hoped we would do from the get-go.

13           Are there comments on that?

14           DR. FAUSTMAN:  Yes.  This is Elaine.

15           Can you please clarify one item of that?

16           DR. SWACKHAMER:  Yes.

17           DR. FAUSTMAN:  You're then also asking EPA  
18  to update their cancer document or not in the  
19  intermediate time period?

20           DR. SWACKHAMER:  The timing would be such  
21  that if they take the recommendations from the work  
22  group report -- okay -- then they would have another

1 revision, and we could review that is what we would  
2 offer to do; in other words, to follow up your  
3 report.

4 DR. FAUSTMAN: Thank you.

5 DR. DENSON: Deb, this is Cos Denson.

6 I like your suggestion, and I would  
7 heartily support that and would back that and go  
8 forward.

9 DR. SWACKHAMER: Very good.

10 And Elaine, I think, just to clarify any  
11 fear you may have, this wouldn't go back to the work  
12 group. Obviously, we would need to constitute an  
13 appropriate group to do this, and that would not be  
14 a problem with this much lead time.

15 DR. FAUSTMAN: That wasn't my first fear.  
16 It was more that there would be a lack of clarity to  
17 EPA as to what we were asking them to do with the  
18 comments that we've already placed on the cancer  
19 document.

20 DR. SWACKHAMER: We would not be holding  
21 back -- we would not ask them to not make those  
22 changes. We would ask them to make the changes as

1 per this report.

2 DR. SHUBOT: Deb, this is Pam. I think  
3 you're right to offer the services on the noncancer  
4 endpoints, but I'm a little bit confused. Was EPA  
5 intending -- I'm new to this, obviously. Was EPA  
6 intending to go forward with basically two tox  
7 reviews, one on cancer and release that right now,  
8 and then do the noncancer?

9 DR. SWACKHAMER: That is my understanding,  
10 but I'm going to ask John to clarify that. John  
11 Vandenberg.

12 DR. VANDENBERG: Right. So our plan here  
13 is to get the comments from the SAB on this second  
14 review of the revised assessment and move to  
15 consider those comments in the next few months to be  
16 able to take the revised document, considering these  
17 comments, through our review process which includes  
18 an agency and interagency process, and then finish  
19 the document sometime -- I'm just guessing here -- 4  
20 to 6 months perhaps.

21 And then we are moving a noncancer IRIS  
22 assessment for arsenic forward now. It has not yet

1 gone into the agency and interagency review process  
2 which precedes the peer review process. So we're a  
3 number of months away from moving that document into  
4 the peer review process.

5 DR. SWACKHAMER: So if I'm hearing that  
6 correctly, there might be -- you're expecting to go  
7 ahead and revise this document under discussion, or  
8 the IRIS document under discussion, but the timing  
9 might be a little off, but we could still offer to  
10 do an integrated review on behalf of the agency.

11 DR. VANDENBERG: What I'm trying to  
12 understand is are you saying that we should move  
13 forward and complete this document or have it as yet  
14 another draft.

15 DR. SWACKHAMER: Well, that obviously  
16 would be up to the Administrator, but I think what  
17 I'm suggesting we do is to conduct a more integrated  
18 review in general around the cancer and noncancer  
19 effects.

20 DR. ROBERTS: Deb, this is Steve Roberts.

21 As a response to that, I'm not sure -- I  
22 mean, I think we can offer to conduct a more in-

1 depth review or a broader review of the cancer  
2 assessment if the Administrator wishes. But I think  
3 linking that to the inorganic -- I mean -- I'm sorry  
4 -- the noncancer review as an integrated review.  
5 I'm not sure that's of much benefit to them, and I  
6 think what it does is then it puts the timing on  
7 whichever one of those is the slower to develop. I  
8 mean, I think we have a possibility to sort of  
9 hamstring whichever one is proceeding more quickly  
10 by tying it to the one that's proceeding more  
11 slowly. So, I mean, I think there's perhaps value  
12 in offering the services of the SAB to conduct a  
13 fuller review if the Administrator wants, but I'm  
14 not sure that we gain much by tying it to the  
15 noncancer review.

16 DR. SWACKHAMER: That's a good point, and  
17 I think we don't want to be too proscriptive either  
18 on how the process might be. I guess I just want to  
19 offer our expertise and service to the Administrator  
20 to make sure that this very important issue is  
21 really as thoroughly considered as possible.

22 DR. SCHNOOR: Deb, this is Jerry Schnoor.  
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1 I just wanted to reiterate and agree with  
2 a couple of things that have been said. I think  
3 offering to review further to the Administrator is a  
4 proper role for us, and I agree with that.

5 I also think that the work group did a  
6 great job in general of reading and responding to  
7 the EPA report.

8 And even, I think, the EPA probably  
9 followed all the procedures outlined in IRIS and our  
10 risk assessment heritage in compiling that report.

11 But as John Vandenberg said, it takes so  
12 many years to turn this thing around. We're talking  
13 about more than 5 years.

14 10 years ago, when I chair of the BOSC for  
15 ORD, I chaired a research plan, drinking  
16 water/arsenic review. And of course, we used the  
17 same Taiwanese data and we used the same default to  
18 low-dose linear staging in order to calculate the  
19 cancer slope factor. And now we're 10 years later,  
20 and there have been a lot of studies. So you can  
21 imagine that the public and others are frustrated by  
22 the lack of seeing progress or change that's

1 occurred in a very active research field.

2 And added to that, as mentioned by some of  
3 the public commenters, again at the same time as we  
4 use the same 50-year-old data set from Taiwan and  
5 apply the same basic procedures to it and continue  
6 to ratchet a more stringent cancer slope factor,  
7 nothing else has changed. And it just seems like  
8 somehow everybody is doing what they're supposed to  
9 do and programmed to do, but it may not be giving  
10 the proper result, it seems to me.

11 I don't know how to fix it, Deb, but  
12 that's my take on it.

13 DR. VENA: This is John Vena. I just have  
14 a comment.

15 I agree that submitting the report and  
16 then having EPA respond to the report and provide  
17 the final update to the IRIS makes sense.

18 I guess my question, given the significant  
19 public health concern regarding the risk assessment  
20 and the delay so far, is that I guess your  
21 recommendation to then -- is it to review the IRIS  
22 cancer document again with just an update up to

1 2007?

2           It seems to me it has gone through all  
3 kinds of peer review and now the working group has  
4 provided comments on their response. But it seems  
5 to me that it makes sense to then adopt the IRIS and  
6 move forward, but then make a specific  
7 recommendation to say that given the already delay  
8 that occurred, that it makes sense to then, instead  
9 of waiting 10 years to update it, put it on a  
10 schedule of having it updated and redone,  
11 integrating all the updated literature, makes sense  
12 and that that should be done on a regularly  
13 scheduled basis when it make most sense to do that.

14           DR. SWACKHAMER: Yes. I certainly don't  
15 want to hold up the process or re-review a review  
16 that we -- I mean, I'm not trying to make it more  
17 difficult. And it's not up to us to say that. We  
18 don't decide whether IRIS gets accepted or whether  
19 that number gets accepted. We provide this report  
20 on the three charge questions.

21           I think what I want to do is offer the  
22 Administrator a chance to open the door to have us

1 participate in additional opportunities for review  
2 around these related subjects as we go forward  
3 because of the great interest. So I have to think  
4 about how to best word that in the letter, but I  
5 certainly can work with EPA staff to make sure I get  
6 the -- the SAB staff to make sure that I have my  
7 facts straight in terms of the timing and all of  
8 that. I don't want to hamstring anybody. I just  
9 want to offer that we would play a role as this goes  
10 forward.

11 DR. VENA: I certainly agree with that.

12 DR. FAUSTMAN: You know, Deborah -- this  
13 is Elaine Faustman.

14 DR. SWACKHAMER: There are several people  
15 that are talking over one another. There are two  
16 women that are speaking. Who are they?

17 DR. FAUSTMAN: One is Elaine Faustman.

18 DR. SWACKHAMER: And who else?

19 DR. SHUBOT: Pam Shubot.

20 DR. SWACKHAMER: Pam, okay. I heard you  
21 first. Why don't you go ahead, Pam? And then we'll  
22 hear from Elaine.

1 DR. SHUBOT: I really like the idea of  
2 offering to work on the noncancer, and one of the  
3 reasons is -- and you might want to think about this  
4 for your letter -- is that in the course of looking  
5 at noncancer, there will be an opportunity to look  
6 at precursor events that again come before the  
7 development of cancer. What might be useful to ask  
8 EPA is will this open the door, looking at precursor  
9 events, to examine the newest information on mode of  
10 action and appropriate cancer evaluation.

11 DR. SWACKHAMER: Excellent way to put it.  
12 And actually I should clarify. And Vanessa, please  
13 correct me if I'm wrong, but my understanding is the  
14 noncancer panel has already -- that FR notice has  
15 gone out. So there is going to be a panel that  
16 reviews the noncancer effects. Is that correct?

17 VANESSA: Deb, this is Vanessa.

18 So in May of this year, we went out with  
19 Federal Register notice inviting the public to  
20 nominate experts to serve on the Arsenic Review  
21 Panel. This is in response to ORD's request to look  
22 at the noncancer health effects of inorganic

1 arsenic. So we are in the process of forming this  
2 expert group. So if the agency asks us to look at  
3 both cancer and noncancer, definitely we will  
4 respond to that, but that is the agency's  
5 discretion.

6 DR. SWACKHAMER: So thank you very much.

7 So, Pam, it's not a question of if we get  
8 a chance. The SAB will be reviewing the noncancer  
9 piece. So it opens the door for what you just  
10 suggested, which is good.

11 Elaine?

12 DR. FAUSTMAN: Yes, Deb. I wanted to  
13 respond to your earlier statements about that this  
14 is a big problem and the extensiveness of the public  
15 comments and continued discussion of this is  
16 important for us to recognize as an SAB. And I  
17 wanted to call your attention to one of the other  
18 activities that the SAB has been involved in, and  
19 that is with Kevin and looking at the need for  
20 integration of EPA decisions across different  
21 groups. And I think if anything wreaks or calls for  
22 a need to integrate across regulatory constructs,

1 it's with arsenic. And so I would encourage us to  
2 see this not just in the narrow context that you're  
3 talking about agreeing to look at the entire  
4 document again or whatever, but I think it's in this  
5 broader context because I believe what I heard from  
6 the public comments were twofold, one from the issue  
7 of the nuances of the science in the document, but  
8 secondly and more importantly is the implications  
9 for the risk management aspects of this.

10 And so I just think that we might need to  
11 think about how one thinks about the science across  
12 the regulatory constructs within EPA and think about  
13 the challenge that we've been working with with  
14 Kevin and others in the agency about how to do those  
15 integrated assessments. Arsenic would be a study  
16 case for that.

17 DR. SWACKHAMER: A terrific comment, and I  
18 think that might be a good way to frame it within  
19 the letter.

20 Other comments? Did I hear someone else?

21 DR. DANIEL: Deb, this is Terry Daniel.

22 DR. SWACKHAMER: Yes, Terry.

1 DR. DANIEL: I just had a kind of a  
2 clarification question. With regard to this quality  
3 review -- and it seems to me like we're waffling  
4 around between the review of the -- I mean, the  
5 quality review of the SAB's review and sort of  
6 broader issues about the EPA IRIS report itself.  
7 And I'd like to just get some clarification.

8 If we in this meeting the SAB, in effect,  
9 accepts or approves the SAB review, it seems to me  
10 that in that review it specifically asks or  
11 discusses the need for some update in the literature  
12 review beyond 2007. Have we talked ourselves out of  
13 that, or will that still remain in the response to  
14 EPA? And if so, doesn't that open the door for the  
15 EPA to address some of the issues that have been  
16 raised in the public comments regarding the strength  
17 of evidence, if you will, for the procedure that  
18 they have adopted?

19 DR. SWACKHAMER: Terry, your quite right.  
20 I have, on purpose, let the conversation wander a  
21 bit. Clearly the point here is to talk about the  
22 quality review of the work group's report, and I

1 could have kept really to the straight and narrow  
2 there and we would have been done an hour ago. But  
3 I really wanted to make sure that we had a chance to  
4 discuss the fact -- I forget. Someone called it the  
5 800-pound gorilla -- to make sure that we were very  
6 clear. The work group focused on a set of very  
7 focused questions, and they have done their job  
8 well. And we can get to that. We can dispose of  
9 that report pretty quickly here I think.

10 The larger issue is there is still some  
11 discontent, and I hear that in the public comments  
12 but I also hear it in the board. And so I was  
13 trying to find a way to allow that conversation to  
14 see if there were some ways we could offer some  
15 suggestions in the letter to offer our services to  
16 the Administrator to continue to help there. My  
17 intent, of course, is to be helpful to the  
18 Administrator in offering those services as opposed  
19 to getting in the way by delaying anything unless it  
20 should be delayed.

21 So I'm just exploring the idea with folks,  
22 and yes, I am letting the conversation kind of get a

1 little free-flowing, but it was to try to judge the  
2 sensibilities around that.

3 DR. DANIEL: Good, and I'm glad that you  
4 did.

5 And I guess where I'm kind of leaning is  
6 to be sure that we convey, in the context of the  
7 quality review, the support for what the work group  
8 recommended but extend that a little bit to -- one  
9 approach I would suggest is to extend that a little  
10 bit to say that in both the suggested extension of  
11 the literature review up through -- you know,  
12 bringing that up to date and in the clarification  
13 and sort of revisiting that's recommended of the  
14 sensitivity analysis, which gets to this issue of  
15 linear or nonlinear models, that the EPA use that  
16 strongly as an opportunity to address explicitly  
17 some of the issues that have been raised by the  
18 public comments about just those issues.

19 So my reading was, I think, that bringing  
20 that literature review up to date is not a terrible  
21 thing to ask, and it seems to be particularly  
22 important in the context of a process that may be 10

1 years before they come back to it again. So I think  
2 that that's important to bring that up to date, and  
3 doing that could be used and should be used to  
4 explicitly address some of the issues that have been  
5 raised in the public comments, as well with the  
6 sensitivity, the clarifications and increased rigor  
7 that was suggested with regard to the sensitivity  
8 analysis, that too would be a format in which the  
9 EPA could quite directly address some of the issues  
10 that have been raised in the public comments.

11 DR. SWACKHAMER: I think it's the process  
12 by which the literature would be updated and whether  
13 it would be tied to the IRIS document. And so the  
14 fear from many of the SAB reviewers is that, given  
15 what John said, that this would probably be out the  
16 door maybe in another 4 or 5 months. To do a  
17 thorough lit review for the last 3 years might  
18 extend that considerably -- to do it well, and you  
19 don't want them to do it poorly.

20 DR. DANIEL: No.

21 DR. SWACKHAMER: And so if there could be  
22 a way to disconnect and somehow have the lit review

1 to be inform us on a more expedite review instead of  
2 waiting 10 years. I now forgot who suggested that  
3 we do a 5-year review, or we suggest to EPA that  
4 they consider doing a 5-year review for the IRIS  
5 document again. So I think there are a couple of  
6 different options here.

7 And I want to turn to Elaine as the chair  
8 of the work group. Having heard this discussion and  
9 the comments around that lit review, do you have a  
10 firm recommendation for how you think we might deal  
11 with that question?

12 DR. FAUSTMAN: Just the last question or  
13 all of these questions? Are you asking me -- I  
14 thought you were going to ask me do I have a plan  
15 forward, and I can answer to that, but I'm not sure  
16 I can answer just the last question.

17 DR. SWACKHAMER: Well, then go ahead and  
18 answer the plan forward. That's good.

19 DR. FAUSTMAN: Okay. I think we heard  
20 very many specific details. So it seems to me that  
21 the ball is in our court to respond adequately to  
22 these comments and put forth a revised document for

1 everyone to look at.

2 DR. SWACKHAMER: Well, actually the group  
3 needs to decide that, and so maybe this would be a  
4 good time to go ahead and outline for you what the  
5 suggested possibilities for the disposition of this  
6 document would be.

7 One would be is that the board would,  
8 after this discussion, vote to accept the documents  
9 with revisions, but leaving those revisions up to  
10 Elaine and the SAB staff.

11 The second would be to accept the  
12 documents with revisions but that the lead reviewers  
13 would need to sign off on it before it was  
14 transmitted to the Administrator.

15 A third idea would be to accept the  
16 document and have it come back to the full board.

17 And of course, there's always the option  
18 to not accept the document and send it back to the  
19 work group. But this is the second time we've seen  
20 this document, so I don't think that last option has  
21 come up in any of the written comments that I've  
22 seen.

1           So I will entertain a motion for one of  
2     the other three, which seem much more likely.

3           DR. FAUSTMAN: Are you going to open up  
4     for discussion after entertaining a motion? Because  
5     there might be one other option you could lay out.

6           DR. SWACKHAMER: Of course. I'm now going  
7     to entertain a regular motion, look for a second,  
8     and have discussion.

9           DR. BURKE: Would you review those three  
10    options one more time, please? This is Indy Burke.

11          DR. SWACKHAMER: Typically the three  
12    options would be to accept the documents and assume  
13    revisions will be made and it goes to the  
14    Administrator. You won't see it again. The lead  
15    reviewers won't see it again before it's  
16    transmitted.

17          The second option is that the lead  
18    reviewers see it and sign off on it before it goes  
19    to the Administrator, that the board essentially  
20    entrusts the lead reviewers to do a re-review.

21          And the third option is to see the  
22    document again as a whole as the board, and the

1 board revote on the document.

2 DR. BURKE: This is Indy.

3 I move that we promote option 2, which is  
4 that the lead reviewers see the document again and  
5 we entrust them with making sure that their  
6 revisions are incorporated.

7 DR. GRIFFITHS: This is Jeff Griffiths.

8 I second the motion.

9 DR. SWACKHAMER: All right. We have a  
10 motion and a second for the lead reviewers to be  
11 responsible for ensuring that the revised work group  
12 report is satisfactory.

13 I am now open for discussion, and at this  
14 point, Elaine, go ahead.

15 DR. FAUSTMAN: Well, I was just thinking  
16 that if you chose either option 1 or option 2, you  
17 could still also ask for a draft letter on these  
18 bigger issues calling the EPA's attention to the  
19 need in a larger sense to look at arsenic on a more  
20 regular basis for these broader issues and rapidly  
21 evolving field. And it might also deal with the  
22 need to integrate across programs. But that could

1 be a separate draft letter that's not associated  
2 with the modifications in this review.

3 DR. SWACKHAMER: We can have a discussion  
4 around that. My initial intent was to incorporate  
5 those ideas into the draft letter. But let's first  
6 discuss the disposition of the report and then we  
7 can perhaps entertain a separate discussion around  
8 that.

9 DR. DZOMBAK: This is Dave Dzombak.

10 The discussion here has wandered, to use a  
11 word that was used here previously, from the very  
12 specific charge to the work group to much broader  
13 issues. It would help me if Elaine maybe could  
14 summarize what are the leading revisions to be made  
15 based on the comments received from the lead  
16 reviewers and the rest of the board. You don't have  
17 to go through all of them, but in your mind if we go  
18 with option 2 here, what are the main issues from  
19 the comments received related specifically on your  
20 charge that the work group would undertake to  
21 address?

22 DR. SWACKHAMER: If I could, I really see  
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1 -- since we have something like 30 pages of  
2 comments, I'd put it in the opposite way. We have  
3 pages and pages of comments, and my reading of them  
4 is that they all should be incorporated. So I guess  
5 I'd put it to Elaine which ones of the written  
6 comments would you argue against, not comply with.

7 DR. DZOMBAK: Deb, this is Dave Dzombak  
8 again.

9 DR. FAUSTMAN: Yes, yes.

10 DR. DZOMBAK: I was trying to get a feel  
11 for where some of these larger issues fit into the  
12 specific review. I guess that broader discussion  
13 has muddied things up a little bit. I agree that  
14 all the comments will -- you know, I'm sure they'll  
15 address them all, but I guess what I was personally  
16 looking for here is some clarification of which of  
17 these larger scale issues are relevant to the  
18 specific comments that will be addressed in revising  
19 their report.

20 DR. SWACKHAMER: Well, let's be very  
21 clear. By "larger scale issues," what are you  
22 referring to?

1 DR. DZOMBAK: Well, such as the  
2 recommendations that have been proposed to be put  
3 into the letter to the Administrator about the  
4 frequency of the cycle for review of arsenic, both  
5 the cancer and noncancer effects, and those related  
6 items that have been --

7 DR. SWACKHAMER: Okay. That's very  
8 helpful. So let's put those aside for now because  
9 that really deals specifically with the letter, and  
10 let's deal with the report itself.

11 DR. DASTON: This is George Daston, and I  
12 just wanted to weigh in because I'm on the working  
13 group.

14 And as I see it, the two things that I am  
15 thinking that we're going to run into a difference  
16 of opinion on that need to be brought is this whole  
17 issue of our recommendation to at least put a  
18 bibliography of the literature since 2007. And then  
19 the second is the suggestion that we take out all of  
20 the text around the reality check. I've heard  
21 different things about both of those and seen  
22 different things about both of those in the comments

1 that we've heard. So those are the things that I  
2 think we'll spend some time discussing.

3 DR. SWACKHAMER: And that suggests that  
4 the work group would be meeting again.

5 DR. DASTON: You know, I am perfectly  
6 happy with finessing them to the extent that we've  
7 done them now, but I think that it changes things  
8 markedly if we simply omit them.

9 DR. SWACKHAMER: My take on the reality  
10 check paragraph was omit it or clarify it, that it's  
11 too vague and it doesn't fit with the letter or the  
12 executive summary.

13 DR. DASTON: If we have that kind of  
14 leeway, I think we can move forward.

15 DR. SWACKHAMER: That was my read of that  
16 comment.

17 DR. VENA: Yes, that's correct. John  
18 Vena.

19 DR. SWACKHAMER: Yes, that was yours.  
20 Right.

21 DR. VENA: Yes.

22 DR. SWACKHAMER: In terms of the lit  
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1 review, I'm hoping that if we still have time with  
2 this conversation, we can revisit that because I'm  
3 still not clear what I would recommend. So hang  
4 onto that thought.

5 DR. DZOMBAK: Yes. This is Dave Dzombak.

6 That seems to be a big issue that's  
7 floating out there, and I think maybe some guidance  
8 from the full board to the work group would be  
9 helpful there if we're going to go with option  
10 number 2.

11 DR. SWACKHAMER: Okay. And we have that  
12 motion on the floor. So any further discussion on  
13 that, on the motion?

14 DR. ROBERTS: Could the motion be reread?  
15 This is Steve Roberts. I'm sorry.

16 DR. SWACKHAMER: Angela, do you actually  
17 have a worded motion, or I can just paraphrase.

18 DR. NUGENT: Let's see. Well, the motion  
19 is to have the work group revise the draft report  
20 with a follow-up review by the lead reviewers. I  
21 don't think it was any more specific than that.

22 DR. SWACKHAMER: And they would sign off  
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1 on it before it goes to the Administrator.

2 DR. NUGENT: Right. They and you.

3 DR. SWACKHAMER: Yes. It goes without --  
4 yes, I guess I should have said that, that all of  
5 these options include my approval.

6 DR. ROBERTS: Thank you.

7 DR. SWACKHAMER: Any further discussion on  
8 this option?

9 DR. HAMMITT: Yes. This is Jim Hammitt.

10 So I really have the sense that this work  
11 group report ought to better acknowledge the  
12 concerns we heard about -- one of the public  
13 commenters or maybe two said that there's just no  
14 plausibility to linear low-dose dose-response  
15 relationship, and others said quite clearly that  
16 lots of plausible models lead to a much lower slope  
17 than the linear one that seems to be used here. And  
18 I think there needs to be just some forthright  
19 discussion of sort of what the state of evidence is,  
20 or the work group could say either EPA did  
21 adequately consider this or they didn't adequately  
22 consider this. But I think it needs to be

1 acknowledged in here.

2 DR. SWACKHAMER: Okay. And that would be  
3 another comment for the work group to consider.

4 I'm looking for discussion on the motion.

5 Any further discussion on this motion?

6 DR. DANIEL: This is Terry Daniel again.  
7 It seems to me that the last comment and several  
8 other things that have come up could suggest in the  
9 direction of revisions, which we're doing here I  
10 think -- in the direction of revisions to the work  
11 group document to emphasize in the places -- it  
12 seems to me they've identified areas where the EPA  
13 report needs to be strengthened that are directly  
14 relevant to the issues that have been raised in the  
15 public comments.

16 If we could just be explicit that that  
17 review -- or ask EPA to be explicit in updating  
18 their review that they address -- that they do that  
19 in a way to address these issues that have been  
20 raised. And certainly with regard to their  
21 revisions -- or to the suggested additions and  
22 revisions to the sensitivity analysis and model form

1 analysis, that that be responsive to the specific  
2 issues that have been raised. And then that seems  
3 to me that would show appropriate sensitivity and  
4 response to the public comments that have been filed  
5 now more than once.

6 DR. FAUSTMAN: Now, this is Elaine  
7 Faustman, Deb.

8 I think that there's a need for  
9 clarification, and I need to pull people to our  
10 specific comments in our document. I don't think  
11 there was any lack of clarity on how our group  
12 discussed this. And I call your attention to our  
13 response to mode-of-action and dose-response  
14 modeling starting on page 8, line 16. And although  
15 there may be differences of opinion about our  
16 review, we as a work group did agree on this wording  
17 here.

18 And I don't know whether you want us to  
19 read it out loud or not. But we were very clear  
20 that the SAB agrees that there are multiple  
21 potential mechanisms for arsenic carcinogenicity and  
22 potential target tissues which make it very

1 difficult to do a single risk assessment model.  
2 This complexity and limited understanding of the  
3 mode of action of arsenic should be openly  
4 acknowledged in the 2010 draft IRIS assessment.  
5 While there is an ever-increasing literature on  
6 arsenic, there is not enough information in the  
7 literature to definitively describe a mode of action  
8 for all of the multiple cancer endpoints of  
9 relevance for this assessment. SAB notes that it is  
10 a reasonable hypothesis that bladder cancer is a  
11 result of repeated cell injury, cell death, and  
12 compensatory proliferation, but there is not enough  
13 specific data at this point to confirm the  
14 hypothesis, nor are there hypotheses to explain the  
15 role of arsenic in lung cancer.

16           You know, we go on and talk about this  
17 specifically. It says, for these reasons, the SAB  
18 concurs with EPA's rationale for choosing a linear  
19 default approach for risk assessment. And it was  
20 particularly the lack of and acknowledged lack in  
21 the written testimony from the individuals on the  
22 phone today that there is speculation on the lung

1 cancer modes of action, but there is not a well  
2 defined mode of action that's been proposed for lung  
3 cancer.

4 DR. GRIFFITHS: This is Jeff Griffiths.

5 I just want to comment that I also believe  
6 that the report clearly stated -- and this is what  
7 my interpretation is also, that there is an  
8 insufficient body of knowledge to deviate from the  
9 default assumption of a linear relationship at this  
10 point. I respect a number of the points that were  
11 made by some of the public commentators. I  
12 respectfully believe that we do not have sufficient  
13 information to deviate from that. And I do believe  
14 that the SAB report does say that quite  
15 specifically. I don't know how much more you can  
16 say than we don't have enough information. This is  
17 the best we can do. The default is a linear  
18 relationship until a better model is provided. And  
19 so it's not clear to me that vast amounts of  
20 rewording here are actually required.

21 DR. SWACKHAMER: And this is Deb.

22 I would agree, and we're talking about

1 what changes to make and we've already had that  
2 discussion. Now we're talking about what to do with  
3 the report. We have a motion on the floor that it  
4 be revised and that it be re-reviewed by the lead  
5 reviewers. Many of you still have questions and  
6 comments and maybe some uncertainty, and so we need  
7 to vote on this motion. And then if you'd rather  
8 have the motion be that it goes back to the full  
9 board, then defeat this motion and then put up  
10 another motion. But we need to move on what to do  
11 with this report.

12 DR. DENSON: This is Cos Denson.

13 I'll call the question.

14 DR. SWACKHAMER: Very good. Let's vote on  
15 this motion. I just ask for yeas, nays, and  
16 abstentions, and if it's unclear, then we'll have to  
17 do a count. So all those in favor?

18 (A chorus of ayes.)

19 DR. SWACKHAMER: Those opposed?

20 (No response.)

21 DR. SWACKHAMER: Abstentions?

22 (No response.)

1 DR. SWACKHAMER: Based on a voice vote, I  
2 say the motion carries.

3 Now, I would like to spend a little bit of  
4 time on this issue of the review of the data after  
5 2007. I am assuming there must be some mechanism to  
6 ask EPA to do this but as an addendum that doesn't  
7 hold up the disposition of the IRIS document. Is  
8 that possible, John?

9 DR. VANDENBERG: This is John Vandenberg.

10 DR. SWACKHAMER: Yes, that John.

11 DR. VANDENBERG: In some other  
12 assessments, we have done what I'll call a  
13 provisional assessment -- we've done this with our  
14 integrated science assessments for some of the  
15 criteria air pollutants -- which is a document that  
16 we have used to summarize the literature that has  
17 come in since the completion of one of our  
18 integrated science assessments. So that might be,  
19 in a sense, a separate document that serves as a  
20 resource for moving forward that isn't part of the  
21 integrated science assessment because that's one  
22 model.

1                   Another might be to -- again, as George  
2   Daston, I believe, said was to put together a  
3   bibliography of literature since 2007. And we have  
4   various ways that we could do that to provide it,  
5   either again as a separate document or as part of  
6   this assessment. It just depends on what form that  
7   would best take, and there are a variety of ways  
8   that we could do that.

9                   DR. LUE-HING: This is Cecil Lue-Hing,  
10   John.

11                   What would be the easiest and most rapid  
12   model for EPA to use to produce a review of the  
13   literature post 2007?

14                   DR. VANDENBERG: The most quick would be  
15   -- or the most rapid would be to develop a  
16   bibliography. There's no doubt about that. And we  
17   have what's now the Health and Environmental  
18   Research Online System that is a means by which we  
19   can share that with the public and any interested  
20   parties. That's different than actually reviewing  
21   and integrating the information that's more recently  
22   available because at that point we would typically

1 want to integrate it with the rest of the data that  
2 was pre 2007. So that gets into actually doing  
3 another assessment. It depends on how you want to  
4 lay it out.

5 DR. LUE-HING: What you're saying then --  
6 would it be an annotated bibliography?

7 DR. VANDENBERG: Yes, something like an  
8 annotated bibliography could be developed.

9 DR. LUE-HING: Okay, thank you.

10 DR. TOLBERT: Deb?

11 DR. SWACKHAMER: Who was that?

12 DR. TOLBERT: This is Paige.

13 DR. SWACKHAMER: Paige, go ahead.

14 DR. TOLBERT: I just wanted to comment on  
15 this.

16 John, this is a generic issue -- John  
17 Vandenberg, this is a generic issue that you have to  
18 face every single time you review anything, that  
19 there is going to be more current data arising every  
20 day. I'm curious. Is this any different from all  
21 of your other situations?

22 I would assume that you have people in-

1 house who are paying attention to the current  
2 literature and keeping their eye out for anything  
3 that would be a game-changer, that would actually  
4 change your perspective or conclusions.

5 I just don't want to sort of drag this  
6 down and make work for you that is not going to be  
7 productive. So I'd be interested in John's response  
8 to that.

9 DR. VANDENBERG: And I appreciate that  
10 sentiment. We do very much keep abreast of the  
11 literature as it's coming in. The issue here is  
12 that to bring that new literature into the  
13 assessment certainly might argue to review the  
14 assessment yet again. So then we'd be into the  
15 third iteration of this and new data is coming in.  
16 So this is an unusual assessment because we did a  
17 second review. Typically we would have completed  
18 this process some time ago, but it has taken longer  
19 than certainly we expected.

20 So you're right that this is a common  
21 feature that we have new studies coming in,  
22 particularly for the most prominent chemicals that

1 we're evaluating, but we have found that we need to  
2 set a date and say the literature will be reviewed  
3 through to this point, and thereby we have a  
4 reference for saying that's the state of the science  
5 at that point in time. Here, because we're doing a  
6 second review, it's kind opened the issue up of the  
7 timing problem (inaudible) literature.

8 DR. ROBERTS: This is Steve Roberts.

9 I was just going to say -- I mean, I think  
10 the point of trying to identify "game-changing" -- I  
11 like the terminology -- in terms of studies I think  
12 is the critical part. I mean, is there a study out  
13 there that would change in a fundamental way the  
14 analysis or the estimate of cancer potency? It  
15 sounds to me like the EPA is looking for those. I  
16 am sure that the public commenters may be aware of  
17 some and can bring those to the attention of the  
18 EPA. So I would be surprised if there's one of  
19 those studies that's not at least brought to the  
20 attention of the EPA to consider.

21 So I wonder what we're really asking them  
22 to do. I mean, should we base this in terms of just

1 telling them, which I think is pretty obvious, that  
2 they need to look for and consider the presence of  
3 game-changer kinds of studies, or do we really want  
4 them to do an exhaustive compendium addition of a  
5 bunch of studies since 2007 that might expand the  
6 description of the literature but don't really  
7 change the outcome?

8 DR. LUE-HING: This is Lue-Hing again.

9 I support that discussion. One of my  
10 concerns is the public commenters have made specific  
11 and repeated references that oppose 2007 data, and  
12 my suspicion is if there were game-changers out  
13 there, those game-changers would have been at least  
14 mentioned today in their public comments and I  
15 didn't hear that. And I'm wondering if there really  
16 are game-changers out there among the data between  
17 2007 and today.

18 DR. SWACKHAMER: Perhaps the suggestion we  
19 could make or I should say the recommendation that  
20 could be made in the report, the work group report,  
21 is to modify that recommendation to say that they do  
22 an annotated bibliography from 2007 to 2010 because

1 that sounds like that could be generated fairly  
2 quickly as purely a starting point and that they  
3 continue to look for and consider, quote/unquote,  
4 game-changing literature that would trigger a new  
5 look at the assessment in the future.

6 DR. LUE-HING: I like that suggestion.

7 DR. SWACKHAMER: Any problems with that  
8 suggestion? I'm not wedded to it. I'm just looking  
9 for a solution here.

10 DR. DANIEL: Deb, this is Terry Daniel  
11 again.

12 In that context, would the recommendation  
13 coming from the work group report be that the EPA,  
14 within the IRIS report, state that that bibliography  
15 exists and reference it and state that their  
16 judgment is that looking at that literature does not  
17 change their final model or their final numbers and  
18 procedures in this IRIS report?

19 DR. SWACKHAMER: Well, since the work  
20 group didn't --

21 DR. DANIEL: They would make an active  
22 statement to that.

1 DR. SWACKHAMER: I don't believe the work  
2 group can make that statement because they didn't do  
3 the assessment and they didn't review the literature  
4 that hasn't been yet compiled. So I don't think  
5 they can make that strong of a statement.

6 DR. FAUSTMAN: Yes. As chair of the work  
7 group, yes.

8 DR. DANIEL: That we would ask them to  
9 make that statement. I mean, it seems silly to do  
10 an annotated bibliography of the literature after  
11 2007 and set it aside and not make any reference to  
12 the fact that you've done that in the report. And  
13 if you're going to admit that you've reviewed that  
14 literature, then you need at least to say that that  
15 review does not lead you to change any of the  
16 conclusions or procedures that you've presented.

17 DR. SWACKHAMER: Okay. They didn't do the  
18 review or present the procedures. That's my point.

19 DR. DANIEL: No. We've got too many  
20 "theys."

21 If the SAB Work Group report recommends to  
22 EPA that this 2007-plus review be done as an

1 annotated bibliography or whatever form it's going  
2 to take, and as has just been mentioned, this idea  
3 of game-changing reports being out there, would that  
4 not imply that in the report itself, that it would  
5 be acknowledged that that review has been done and  
6 that they did not find anything that would change  
7 the game, that would make them revisit or modify the  
8 methods and conclusions that they've arrived at in  
9 the IRIS report? The EPA would make that statement.  
10 We would recommend that the EPA would make that  
11 statement in the IRIS report.

12 DR. FAUSTMAN: So this is Elaine Faustman  
13 for the work group.

14 And I just want to remind ourselves what  
15 we have said and what we have not said. On page 7,  
16 in response to charge question 2, it says, the IRIS  
17 2010 assessment includes an extensive review of  
18 published epidemiological studies up to and  
19 including the year 2007. The SAB recognizes that  
20 the assessment cannot be continually updated with  
21 every newly published paper and it is not the  
22 purpose of IRIS to provide real-time summaries of



1 almost uniformly were not comfortable with that,  
2 thinking it would add much too much burden on EPA  
3 and would further delay the IRIS assessment. So  
4 that's what I'm trying to get at. I don't think the  
5 intent for anyone is to hold up that assessment.  
6 I'm wondering if we can just clarify that wording  
7 even more specifically, and actually, Elaine, having  
8 you reread it, it is specific.

9           John Vandenberg, I'm going to ask you  
10 again. I know you can't speak for the agency off  
11 the top of your head, but if you look at that  
12 specific language, is that something that's going to  
13 hold up the assessment in your personal opinion?

14           DR. VANDENBERG: Again, this is a personal  
15 opinion. I think that to include an appendix or an  
16 addendum -- you know, it's additional work but I  
17 think it's something that we can manage to work  
18 through. It's just maybe helpful to hear exactly  
19 what's expected there in terms of drawing the  
20 conclusions because drawing conclusions would be  
21 difficult for us versus at least identifying the  
22 literature as we scan it, which is what we do.

1 DR. DASTON: So, John, this is George.

2 I mean, one of the ways of dealing with  
3 this, I think, would simply be a statement that  
4 these epidemiology studies have been done since  
5 2007, and for each one, this is the size of the  
6 study population, that sort of thing. It doesn't  
7 have to go to the point of critical review.

8 DR. VANDENBERG: Well, with that  
9 clarification, that's very helpful because it's that  
10 critical review that would take substantial effort  
11 and time. But if it's to recognize and maybe some  
12 characterization of the size of the study or even  
13 the effect estimates, that might be certainly  
14 feasible.

15 DR. DASTON: And to be clear, I mean, the  
16 point is the one that Steve Roberts had brought up  
17 before, which is what we're looking for is -- you  
18 know, the last thing that anybody wants is for EPA  
19 to put out an assessment that's already been  
20 outdated and this is an insurance that that's not  
21 the case.

22 DR. SWACKHAMER: Okay. So I think we have  
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1 clarity in that we're going to just sort of further  
2 clarify and fine tune the language around what the  
3 work group is requesting, what the SAB is now  
4 requesting of EPA, and that would be a  
5 characterization of the major epidemiology studies  
6 that have been done since 2007. We're all okay with  
7 that?

8 DR. SEGERSON: Deb, this is Kathy  
9 Segerson.

10 Are we planning to put a statement about  
11 that in the letter or just have that clarification  
12 in the body of the report?

13 DR. SWACKHAMER: I would have to go back  
14 and specifically look at how it's worded in the  
15 letter. Right now, I think it's kind of vague. So  
16 I think we might want to be more specific, but I  
17 don't think that that's a bad thing to put in the  
18 letter is my first gut response.

19 DR. FAUSTMAN: That's my response to that  
20 as well.

21 DR. SEGERSON: I think some acknowledgment  
22 of the issue in the letter itself would be

1 important.

2 DR. SWACKHAMER: Yes. I think it has to  
3 be specific again so it doesn't sound like we're  
4 saying go out and do a 3-year lit review of  
5 everything that's ever been done, but we would  
6 specify what we're talking about.

7 Okay. We have a few more minutes, 7 more  
8 minutes. And I would very much like to see if we  
9 can reach some consensus on this letter. So,  
10 obviously, the executive summary is a short form of  
11 the report, and the letter comes from me and the  
12 chair of the committee that would essentially, for  
13 the Administrator, summarize the key points of that  
14 executive summary and report. So the main points  
15 need to be consistent from the letter to the  
16 executive summary to the full body of the report.  
17 And I will certainly work with Elaine to get that to  
18 happen.

19 But there's this issue of whether this  
20 letter to the Administrator could have some  
21 additional -- and I'm really thinking just sentences  
22 -- two or three sentences that talk about the fact

1 that we, the SAB, would welcome the opportunity to  
2 -- in the context of reviewing the noncancer IRIS  
3 document assessment, that we would also consider --  
4 we would be open to looking at an integrated kind of  
5 review, including the cancer pieces, and that we  
6 view this as an opportunity to really do integrated  
7 science and review integrated science at the agency,  
8 that arsenic is sort of this poster child for that.  
9 I wouldn't use those words.

10 DR. DZOMBAK: Deb, this is David Dzombak.

11 I think that will likely require more than  
12 two or three sentences when you really start putting  
13 it down on paper. I think it could muddy up the  
14 message about the report. I would propose if  
15 someone else -- or I would second, as someone  
16 proposed earlier, to perhaps do that in a separate  
17 letter, in a letter that could acknowledge and  
18 discuss a bit the intense public interest in this  
19 topic, the benefits of using the approach you just  
20 laid out. It doesn't have to be a long letter, but  
21 I think it's going to require more than two or three  
22 sentences.

1 DR. DENSON: I have a question, Deb. This  
2 is Cos.

3 When you say integrated science, do you  
4 mean both the cancer and noncancer arsenic review or  
5 just the cancer review?

6 DR. SWACKHAMER: The noncancer is a panel  
7 that's coming up in the next several months. So in  
8 the context of the fact that we'll already be  
9 reviewing the noncancer, I would offer that we also  
10 open the door to thinking about the health effects  
11 due to arsenic in both the context of noncancer and  
12 cancer.

13 DR. DENSON: Okay, good. Thank you.

14 DR. SWACKHAMER: And actually, Dave, you  
15 may not have ever read anything I wrote, but I could  
16 do this in three sentences.

17 (Laughter.)

18 DR. SWACKHAMER: I'm very terse.

19 DR. DASTON: This is George Daston.

20 I think that that's fine to do that, but  
21 isn't the larger issue what's done with this  
22 information? I mean, there's a whole bunch of

1 decisions that I hope are science-based that  
2 scientists in the (inaudible) office are going to  
3 have to make based on this or the Superfund offices.  
4 Isn't that also something that we'd want to see as  
5 an SAB, how this information is carried through? I  
6 mean, I would think that we'd want that in our  
7 letter.

8 DR. SWACKHAMER: I'm not sure exactly what  
9 you're trying to get at, George. Sorry.

10 DR. DASTON: Well, so I think that one of  
11 the reasons for going a little bit beyond our charge  
12 and talking about a reality check is that we really  
13 are talking about risk values that are pretty high  
14 from arsenic exposure that many people in this  
15 country actually are getting from their drinking  
16 water. And so, really, I think that the main  
17 concern, the reason why we're spending so much time  
18 on this assessment, and wanted to do a reality  
19 check, and wanted to have some communication as to  
20 what the risk estimates mean is to make sure that  
21 decisions that are based on this assessment have all  
22 of the facts that go into those various assumptions.

1 So at least the parts of that that we might have  
2 some ability to comment on and guide are the  
3 decisions within EPA that are made based on this  
4 information, and those decisions are going to be  
5 made by various program offices.

6 So I would think that as we wrote a letter  
7 offering our services, it's not just in this aspect  
8 of mode of action that we would want to comment on,  
9 but in the ways in which this is taken further into  
10 really program-specific risk assessment.

11 DR. SWACKHAMER: Maybe we could talk more  
12 about this off-line at some point. I want to honor  
13 the fact that we're a science advisory board and we  
14 want to really not get too far up that policy  
15 pathway. And I understand the difference between  
16 risk assessment and risk management and policy, but  
17 I think the paragraph in the document that talks  
18 about that reality check is excellent. And I'm  
19 still not exactly clear what you want me to say in  
20 the letter that isn't there already based on the  
21 work group report. I'm offering up just two things  
22 specific to arsenic. I might not be hearing you all

1 the way. I'm sorry, George.

2 DR. DASTON: That's okay. And I don't  
3 want to lead us -- given that it's almost 5 o'clock,  
4 I don't want to lead us further astray.

5 But it seems to me that we've talked about  
6 two very different things here. One is the work  
7 group and whether we've met our narrow charge, and  
8 the second is a lot of concern, based in large part  
9 on the public comments that have been made as to  
10 whether we've been sensitive to the alternative  
11 views of a whole bunch of scientists that we've  
12 heard from. I think that a lot of what their  
13 concern might be is in how one takes a cancer slope  
14 factor and does some sort of site-specific risk  
15 assessment on it. And those are within the purview  
16 of what EPA scientists, albeit not the ones in MCEA  
17 -- it is what EPA scientists do, and if there's some  
18 large issue that SAB can review in that area, I  
19 think that it's within our capabilities as a  
20 science, not a science policy.

21 DR. SWACKHAMER: And do you mean that for  
22 arsenic or for just in general?

1 DR. DASTON: I mean that specifically for  
2 arsenic, but obviously, you know, I mean, you could  
3 take that sort of philosophy and extend it.

4 DR. SWACKHAMER: Yes. Maybe that's where  
5 I was balking. That strikes me as a separate letter  
6 because that's getting into a whole other ball of  
7 wax. I'm really talking about some specific -- I'm  
8 giving the Administrator -- I'm opening the door to  
9 -- I'm offering for her to open the door to  
10 considering a more integrated approach from this  
11 IRIS perspective. If you have some language you are  
12 thinking of, why don't you send it to me?

13 DR. DASTON: Okay.

14 DR. SWACKHAMER: Other comments on the  
15 letter? Comfort or discomfort with adding a  
16 sentence or two about these broader issues?

17 DR. GRIFFITHS: This is Jeff Griffiths.

18 I have comfort.

19 DR. MILFORD: Deb, this is Jana Milford,  
20 and I would have comfort with what you've proposed,  
21 but I think what George is proposing is too broad  
22 and sort of ill-defined.

1 DR. MURPHY: This is Eileen Murphy.

2 I agree with Jana. I'm actually  
3 uncomfortable going into the risk management/risk  
4 policy in the letter.

5 DR. BUCKLEY: This is Tim Buckley.

6 I agree with that perspective as well.

7 But, Deborah, I also agree with the  
8 commenter who suggested that what you were proposing  
9 might muddy the message of the letter. So I would  
10 advocate for a separate letter to address that  
11 issue.

12 DR. SWACKHAMER: And again, to be clear  
13 what the issue is that I would raise is to offer to,  
14 in the context of noncancer assessment, also keep  
15 cancer in mind basically. That's really the point.  
16 And specific to arsenic.

17 DR. BUCKLEY: Yes. So maybe that will  
18 work.

19 DR. SWACKHAMER: That's really all I meant  
20 by broadening it. I'm not going to go into a  
21 philosophical discussion of what the word  
22 "integration" means.

1 DR. KIM: This is Nancy Kim.

2 Where I think something like that would  
3 work is if you focus on the mode of action because I  
4 think information that comes from the noncancer  
5 endpoints might provide information in a mode-of-  
6 action kind of thought process that would inform the  
7 cancer. So I think if you can link it that way, I  
8 can live with it.

9 DR. SWACKHAMER: And I believe that was  
10 Pam's suggestion as well.

11 DR. TOLBERT: Yes, I agree. If you focus  
12 on that, it sounds good to me.

13 DR. SANDERS: This is Jim Sanders.

14 I'm also fine with this concept.

15 DR. SWACKHAMER: Strong dissent?

16 (No response.)

17 DR. SWACKHAMER: All right. The lead  
18 reviewers will see the letter again. I would need  
19 some indication from the board if you wanted to  
20 somehow separate the approval or the report from  
21 seeing the letter, or you're going to need to sort  
22 trust me and the lead reviewers to do this letter?

1 And that's what the motion that we've passed has  
2 done.

3 DR. DZOMBAK: Dave Dzombak.

4 We passed a motion to let the lead  
5 reviewers and Deb finish it up, and so that's where  
6 we are.

7 DR. SWACKHAMER: All right.

8 We're also out of time. So thank you very  
9 much for hanging in there to the very end. Thank  
10 you for listening to all the public comments and for  
11 the very spirited and a very constructive discussion  
12 around this very important issue. So thank you all,  
13 and we will be in touch. Thank you.

14 Oh, I think Angela has to end the meeting.

15 Angela, I turn it back over to you.

16 DR. NUGENT: Thank you, Deb, and thank you  
17 all for participating. And the teleconference is  
18 adjourned.

19 (Whereupon, the teleconference was  
20 adjourned.)

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