

MEETING
STATE OF CALIFORNIA
AIR RESOURCES BOARD
SCIENTIFIC REVIEW PANEL

UNIVERSITY OF CALIFORNIA, LOS ANGELES
COVEL COMMONS, SUNSET VILLAGE
SALON A
330 DeNEVE DRIVE
LOS ANGELES, CALIFORNIA

FRIDAY, JUNE 24, 2005
9:30 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Dr. John Froines, CHAIRPERSON

Dr. Roger Atkinson

Dr. Paul Blanc

Dr. Craig Byus

Dr. Gary Friedman

Dr. Stanton Glantz

Dr. Katharine Hammond

Dr. Joseph Landolph

Dr. Charles Plopper

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Jim Aguila, Manager, Substance Evaluation Sections

Mr. Jim Behrmann

Mr. Robert Krieger, Air Pollution Specialist

Mr. Peter Mathews

REPRESENTING THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. George Alexeeff, Deputy Director

Dr. Melanie Marty, Manager, Air Toxicology and Epidemiology Section

Dr. Mark Miller, Air Toxicology and Epidemiology Section, Toxicology and Risk Assessment Unit

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1 PROCEEDINGS

2 CHAIRPERSON FROINES: I'd like to call the
3 meeting to order. The date is the 24th of June, 2005.
4 And as I look around the room, all the members of the
5 Panel are present. I don't think we need to take the roll
6 with that statement.

7 Stan pointed out something that is really quite
8 interesting. I'm assuming that we're going to bring to
9 closure today the Environmental Tobacco Smoke document.
10 And this will be the first document that we have brought
11 to closure since 1998, which was diesel. And we held the
12 meeting -- the conference that we held on diesel was held
13 in this room at that time. So many of the people in the
14 room were here for that very successful conference, and in
15 fact Kathy was testifying at it. So we have a historical
16 event occurring.

17 I have 2 things to say at the outset. And later
18 we may hear from Kirk Oliver who's the lawyer for ARB.
19 And I wanted to bring the Panel's attention, for the
20 record, to the fact that there has been a communication
21 from Dr. James Enstrom and a communication from Geoffrey
22 Kabat. Enstrom is from UCLA. Kabat is from New Rochelle,
23 New York. And both investigators have raised the question
24 about whether Dr. Glantz should serve on the Panel in
25 addressing Environmental Tobacco Smoke because of what

1 they allege to be his biases. And so the question has
2 come before is now the -- I won't characterize their
3 document -- Jim, I think everybody has it, don't they?
4 Where is Jim?

5 MR. BEHRMANN: No, they do not yet.

6 CHAIRPERSON FROINES: Oh. Well, we'll make sure
7 that everybody has it. But they claim that Dr. Glantz
8 cannot objectively evaluate the studies in the new review
9 of ETS. And I'm tempted to characterize this document,
10 but I think I won't. I think I'll leave it for people to
11 draw their own conclusions. This week we -- so the
12 question is whether there is a conflict of interest and
13 whether Stan should sit on the Panel evaluating ETS, and
14 whether he can do that objectively is the question that's
15 been raised.

16 And Jim Behrmann and I have been meeting with
17 Kirk Oliver this week to discuss the legal issues from the
18 standpoint of the Agency. Parenthetically, the issue of
19 conflict of interest is something that we need a meeting,
20 at some point, to discuss how the Panel wants to approach
21 it the issue of conflict of interest. We haven't done
22 that probably as effectively as we might. And so, at some
23 point in the future, we will have a meeting to discuss
24 administrative procedures with respect to conflict of
25 interest.

1 I'm comfortable with an approach like the
2 National Academy of Sciences where people actually
3 disclose any potential conflicts.

4 In any case, getting back to Stan. I just wanted
5 to say that based on the discussions with Kirk Oliver,
6 it's my conclusion and Kirk -- and the ARB legal staff's
7 conclusion that Dr. Glantz does not, does not, and I
8 emphasize, have a conflict of interest in the matter at
9 hand, and that Stan can -- we believe that Stan, and he
10 has stated at such, can fairly and objectively participate
11 in the Panel's review of the draft report. And given
12 Stan's assurances, I believe the Panel should move forward
13 to consider the draft report on the basis that Stan will
14 be an active participant within the deliberations. And
15 so, as far as I'm concerned, we should move ahead on that
16 basis. And I have nothing more to say unless some members
17 of the Panel have comments.

18 The second thing I wanted to say is slightly
19 personal, but not entirely. And that is that at the last
20 meeting, which I think personally was a very, very
21 successful meeting, I think we accomplished a great deal.
22 And I think that the document we have before us reflects
23 the accomplishments that grew out of that meeting.

24 I would also say that at times during that
25 meeting some of us, including me, were very outspoken.

1 And things were said, perhaps even harshly at times, and
2 so I wanted to apologize for any outspokenness that
3 occurred. And I want to assure the agencies that the
4 success of this panel and the interaction with the agency
5 depends on the ability to have collegial discussions. And
6 I want to assure them and the Panel that we will work to
7 make sure that the testiness that arose at various times
8 won't happen in the future. And I think that's enough
9 said. I don't know if anybody wants to comment on that.

10 But I wanted to have an apology on the record, so
11 everybody is aware that we recognize that we -- that there
12 was some outspokenness -- and outspokenness being perhaps
13 a euphemism, but we'll leave it at that. But I think that
14 the collegial nature of the interaction is really quite
15 crucial, and we should proceed on that basis.

16 Comments?

17 Stan.

18 PANEL MEMBER GLANTZ: I just had one just for the
19 record, collegial doesn't mean uncritical. It means
20 polite.

21 CHAIRPERSON FROINES: Yes.

22 PANEL MEMBER GLANTZ: So just so no one -- I
23 don't want anyone to misread the record to think you're
24 saying that this panel is somehow rubber stamping what the
25 agency is saying.

1 CHAIRPERSON FROINES: Well, I would go further.
2 I think the legislation is clear in that the legislation
3 wants this panel to be critical. We can't do our job if
4 we're not critical. So that it doesn't mean that we have
5 to do it in a way that's offensive to people, but we have
6 to be able to be critical if we're going to serve the
7 purposes of doing a thorough review of the science. And
8 so I agree, I think that's well said.

9 So let's proceed now that we've had all of the
10 fun we're going to have this morning.

11 (Laughter.)

12 CHAIRPERSON FROINES: Seriously, Janette, I think
13 you were going to start.

14 The plan for the Panel, Janette and Melanie and I
15 talked, and what we're going to do is have a brief
16 discussion -- I think brief is accurate -- from ARB as to
17 where they are. And then Melanie is going to discuss the
18 changes in the document. She's going to talk about Thun's
19 comments -- am I leaving anything out -- and the basic
20 conclusions, I guess.

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah, and
22 also responses to some panel comments.

23 CHAIRPERSON FROINES: And then if the Panel is
24 comfortable with where we've gotten to, we will then take
25 up our own Findings that you've received by Email. So

1 Janette, you're on board.

2 ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

3 We're going to have Robert Krieger start out with Part A,
4 a portion of it so he's going to be very brief.

5 (Thereupon an overhead presentation was
6 Presented as follows.)

7 ARB AIR POLLUTION SPECIALIST KRIEGER: Thank you,
8 Janette.

9 Good morning, Dr. Froines and members of the
10 Panel. As Janette mentioned and Dr. Froines agrees as
11 well, this presentation will be short and brief, since it
12 only incorporates comments made by the -- on the March
13 version of the report Dr. Atkinson and Dr. Hammond.

14 I'll briefly summarize the few comments on the
15 next few slides.

16 --o0o--

17 ARB AIR POLLUTION SPECIALIST KRIEGER: For Dr.
18 Atkinson's comments, we have revised Table 6-1 in the
19 report, to incorporate the more increased information on
20 that recent atmospheric average lifetimes for several of
21 the TACs listed in the report.

22 We've also added a reference by Krol, which is
23 suggested about the lifetimes as well. And added more
24 detail on the atmospheric fate of nicotine. And on Table
25 III that some of the compounds are present in the gas

1 phase. These are very detailed comments, but they're all
2 highlighted in the Part A report. So if you take a look
3 at those, you can see the changes there.

4 And finally for Dr. Atkinson's comments, there's
5 just several little minor changes.

6 Next slide.

7 --o0o--

8 ARB AIR POLLUTION SPECIALIST KRIEGER: Dr.

9 Hammond submitted several comments on the March draft
10 report. And one of the most important comments that we
11 addressed was the comment about adding the number of
12 samples, averaging times and the sample locations where
13 appropriate, into our text of tables. And this deals with
14 the fact that ETS in a lot of the studies that we have,
15 some where they're averaged over 24 hours, some were
16 long-term averages, some were short-terms and some were
17 realtime averages.

18 So it would be appropriate, and we agree too,
19 that that's most important to put into our tables and our
20 text so the reader knows that if you look at one average
21 over 24 hours, it's going to be different from, you know,
22 the spikes that do occur in a few minutes or even an hour.
23 So we put that in.

24 And we also -- in doing so, we've also revised
25 our scenario calculations to include a little bit more

1 realistic activity pattern Data. And in doing so, we also
2 included an in-vehicle -- actual in-vehicle concentrations
3 per Dr. Hammond's suggestion. And we used one of the
4 higher vehicle concentrations in our exposure estimation
5 to calculate this.

6 Our exposure scenarios kind of ended up being a
7 little lower at the low end and a little higher at the
8 high end. So we really didn't change much, but it did
9 change a little bit to use those, so we thought those were
10 appropriate.

11 This is more of a minor comment, Table III-2, 3
12 in Chapter 3, we included information on the noncancer
13 health effects for several of those toxic air contaminants
14 that are listed in Chapter 3.

15 And we also added Dr. Hammond's reference of
16 1995.

17 Next slide.

18 --o0o--

19 ARB AIR POLLUTION SPECIALIST KRIEGER: Okay. As
20 far as the few clarifications that we made to the report.
21 It was a little confusing to the reader sometimes and to
22 Dr. Hammond too, and we recognize this too as well, that
23 the approach we used to search literature was based on the
24 initial reasons why we updated the 1997 NCI Report, but we
25 tried to coincide with OEHHA on this as far as an update,

1 and we realized this. So we tried to make that a little
2 more clear to the reader too, because of those studies
3 were reviews of other studies that had different dates,
4 earlier dates than 1997. So it was a little confusing in
5 the text, so we tried to clarify that in our report.

6 We also clarified some of the workplace exposure
7 studies, again, taking into account the average times of
8 samples. We included that as well.

9 And you see Dr. Hammond also had other minor
10 changes. And you can see it in the Executive Summary, we
11 indicated that the relative range of exposure was less
12 than .01 for a nonsmoker in a nonsmoking home. Also, it's
13 not on the slide, but the higher end also went up a little
14 bit in the exposure scenario, as I said before in the
15 previous slide.

16 And there were also some minor corrections to the
17 references. Again, we added Dr. Hammond's reference, and
18 there were a few other typos and minor corrections to the
19 report, which we hope made this, in the end, we believe a
20 much stronger report.

21 --o0o--

22 ARB AIR POLLUTION SPECIALIST KRIEGER: The
23 summary of all these revisions, overall the conclusions
24 reached in the report that have been presented to the
25 Panel have not changed. And I think that's all we had for

1 our part.

2 Any questions?

3 CHAIRPERSON FROINES: I was going to go ask Roger
4 and you for comments. At this point, let's just have any
5 questions for the presentation.

6 PANEL MEMBER HAMMOND: I just wanted to thank
7 you. I think you did a very good job. I appreciate your
8 tolerance with me, based on the extensive remarks. I
9 think it's a very nice job. I just have a few minor typo,
10 very minor corrections, so I'll just get those to you on
11 Monday, but it's a excellent work. It's a lot of work.

12 Thanks.

13 ARB AIR POLLUTION SPECIALIST KRIEGER: Thank you.

14 CHAIRPERSON FROINES: Roger.

15 PANEL MEMBER ATKINSON: I have no problems with
16 this.

17 CHAIRPERSON FROINES: Anyone else from the Panel
18 have comments to make at this point?

19 Great.

20 I should say that you guys really have made a
21 major effort in terms of trying to deal with the exposure
22 issue and should be applauded for that. That wasn't easy.
23 And we had a lot of early meetings talking about that, and
24 so it really was a challenge.

25 PANEL MEMBER GLANTZ: I just have one -- and I

1 mentioned this at an early meeting. I think that the
2 outdoor measurements you made are really unique and I hope
3 you guys will submit it to a peer reviewed publication to
4 get it into the regular scientific literature.

5 ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: We
6 do plan to do that.

7 CHAIRPERSON FROINES: And you don't have to put
8 all of us on as authors.

9 (Laughter.)

10 CHAIRPERSON FROINES: Thank you very much.

11 (Thereupon an overhead presentation was
12 Presented as follows.)

13 CHAIRPERSON FROINES: Well, here we are again.
14 Welcome.

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: I had a
16 couple of little items that I'll put at the end, but I
17 have a slide show now that's going to run through the
18 revisions we made to Chapter 1, the revisions we made to
19 Chapter 7, response to panel comments, and response to
20 comments submitted by Dr. Michael Thun to the Panel.

21 This is the first time somebody's told me I'm not
22 loud enough.

23 (Laughter.)

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: We
25 addressed the comments basically from all the Panel

1 members on Chapter 1. A lot of them were given to us
2 orally at the last meeting. So we combed through the
3 transcript to make sure we caught all of the important
4 issues. And Dr. Blanc provided a lot of comment, but also
5 other members of the Panel, Dr. Glantz and Hammond in
6 particular, gave me additional comments and Dr. Byus.

7 So the changes are shown in the track changes
8 mode in the SRP review draft. So they should have been
9 pretty obvious what we did. And they essentially focused
10 on clarifying OEHHA's process for reviewing studies on ETS
11 health effects and evaluating the weight of evidence. And
12 by the way, I think the chapter is a lot better now.

13 --o0o--

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: We
15 clarified the use of consultants in Section 1.1, to note
16 that yes, we did use consultants to draft some of the
17 chapters or parts of chapters, and in our meta-analyses,
18 but we take ownership of this document.

19 And we clarified in Section 1.4.1 how we
20 identified studies. And in 1.4.3 we clarified the
21 weight-of-evidence evaluation and we expanded the
22 description of "criteria for causality" with more text,
23 more explanatory text and examples.

24 And in section 1.4.4 we clarified how we went
25 about evaluating studies, both qualitatively looking for

1 inconsistencies and so on, and quantitatively looking at
2 individual risk estimates, whether or not they were
3 statistically significant, and conducting, in some cases,
4 meta-analyses of a couple of the endpoints and also
5 reporting meta-analyses that were in the literature.

6 --o0o--

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: In section
8 1.5 we elaborated on smoker misclassification and how
9 that's different than exposure misclassification, and the
10 overall importance of exposure assessment in environmental
11 epidemiology and ETS in particular.

12 We elaborated further on the case-control design
13 and cohort-study design, what they are and the advantages
14 and disadvantages. We added more text to the discussion
15 of publication bias and also other confounding.

16 And finally, we updated Table 1, Attributable
17 Risks. There were a couple of little changes primarily in
18 the risk estimates for breast cancer. And there was
19 another minor change in the estimate of SIDS deaths. I've
20 forgotten now, I've got to go back and look.

21 --o0o--

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: And that's
23 all we had to say about, in general, what we did. So if
24 there are additional comments from the Panel now, we'd
25 like to hear that.

1 CHAIRPERSON FROINES: Yeah. Let's take each
2 section. Are there comments, and Paul you clearly were
3 the lead on this one. Do you have any?

4 PANEL MEMBER BLANC: Yeah, I have a few comments.
5 I want to put them in context first. I do agree I think
6 that the chapter is very improved and serves the purposes
7 that I think you wanted. So all the suggestions I'm going
8 to make are either questions for clarification or minor --
9 potentially minor issues that I don't think would impact
10 approval of the document. It would be in the category of
11 things that I would say are minor changes that you could
12 consider for the final version.

13 One of them you actually reiterated in your oral
14 comments the comment which was down on page 1-3. You say
15 OEHHA takes ownership and full scientific responsibility.
16 I understand the full scientific, but taking ownership is
17 sort of California pyscho-babble.

18 (Laughter.)

19 PANEL MEMBER BLANC: And I'm sure you want to --

20 PANEL MEMBER GLANTZ: Weren't you the one who
21 suggested that language?

22 PANEL MEMBER BLANC: I don't think so.

23 (Laughter.)

24 PANEL MEMBER FRIEDMAN: Is the administration
25 offering to have an ownership society.

1 (Laughter.)

2 PANEL MEMBER BLANC: No, I mean -- how could you
3 have legal ownership. I really don't -- but if what you
4 mean is the sort of the common usage, I would --

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Take it
6 out.

7 PANEL MEMBER BLANC: -- take it out.

8 CHAIRPERSON FROINES: We could put it in
9 Schwarzenegger's ballot this fall.

10 PANEL MEMBER BLANC: On page 1-7 when you talk
11 about the strength of the association, which I fully agree
12 with, the public health perspective, there are 2 parts you
13 say the very last line of the section that, the first
14 point is that "From a public health perspective such small
15 magnitude associations for common disease can mean large
16 numbers of people affected by the health outcome."

17 It's 2 things. It's small magnitude associations
18 and a frequent exposure? Right.

19 In the dose response section, which is also good
20 and clearer, when you say that, on page 1-8, "Absence of a
21 graded responses is not necessarily evidence against a
22 causal relationship." It is evidence against it. It's
23 not very strong evidence. I mean, I think you want to
24 reword that. It doesn't exclude a causal relationship.

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Oh, yeah.

1 Okay.

2 PANEL MEMBER BLANC: Do you know what I'm saying?

3 OEHHA SUPERVISING TOXICOLOGIST MARTY: Um-hmm.

4 It is not necessarily, but it does not exclude it.

5 PANEL MEMBER BLANC: You can word it some other
6 way.

7 And similarly, again these are minor points, but
8 I just wanted to have this be as clear as possible. A
9 little bit farther down on this page, it says, "This
10 assumption is problematic when a particular biomarker..."
11 Do you mean that this assumption is problem ridden or this
12 assumption is open to question?

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: Open to
14 question.

15 PANEL MEMBER BLANC: So that's the correct usage
16 of term. That's fine then. Because people are going to
17 read it and say -- think you mean problem ridden and
18 you -- okay.

19 This little section on natural experiments on the
20 next page, which is nice. And I think you should say
21 that, "Even so, those natural experiments are not usually
22 considered experimental evidence." They're usually
23 considered some kind of epidemiological study. I mean,
24 they're not -- when people talk about experimental
25 evidence as a causal -- traditionally it's a causal -- as

1 a piece of causal evidence. They're not talking about
2 natural -- what we would call natural experiments. Those
3 would somehow come --

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's
5 right.

6 PANEL MEMBER BLANC: The point is well taken.
7 And again this is just trying to be as precise as
8 possible. On page 1-10 where you're talking about the
9 body of evidence approach. And this is something I should
10 have caught, because it's not underlined so it was in
11 there before. And I might have said something, but when
12 you say, "The evidence must satisfy several of the
13 guidelines...", now many people will read "several" as
14 meaning 3 exactly. I'm not saying that that is the
15 correct definition of several, but that is how many people
16 will read it. So if you would like a word, which is less
17 open to that interpretation there -- I mean, you might
18 like multiple or something else you want to say. But just
19 think about what it is, you know -- people are likely to
20 understand.

21 Similarly on page 1-11 where you're talking about
22 we have this new discussion or expanded discussion talking
23 about why some studies -- a well done study may be, you
24 know, have a lot of influence and on the other hand there
25 could be negative studies which are not very impressive

1 because of their limitations. I mean, these are generally
2 papers which are in the published literature. So actually
3 you can't stay so unequivocally that their results arose
4 from bias. If it was that clear, they would have been
5 published.

6 But what you could say is that they're more
7 likely to be attributable to bias or, you know, some --
8 you have to soften that. You see where I'm saying in the
9 very last paragraph.

10 OEHHA SUPERVISING TOXICOLOGIST MARTY: Um-hmm.

11 PANEL MEMBER BLANC: And then here's the most
12 substantive question I have that confused me. Continuing
13 in that section, it's just before Section 1 --

14 PANEL MEMBER GLANTZ: What page?

15 PANEL MEMBER BLANC: 1-12. Just before 1.4., you
16 have a paragraph talking about a group of studies and the
17 direction of the risk, right, is it below one or above
18 one. It precedes the beginnings of your discussion about
19 meta-analysis. Is the implication that you did analyses
20 that weren't really meta-analyses, they weren't weighted
21 for study size. They were just -- there was 7 studies and
22 4 were positive and 3 were negative, is that what you're
23 trying to say there? Because it's not really clear.

24 When I first read it, I thought well okay then
25 why don't you have a sentence here saying, you know,

1 weighting for study size as a technique is, you know,
2 commonly called meta-analyses. But then you have a whole
3 section on meta-analysis. So what was the intent here?

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, the
5 intent was less a quantitative analysis, like a
6 meta-analysis, and more a qualitative overview of the
7 data. So if you take all the studies that have been, at
8 that time, in health, and you plot them in the same
9 figure. If the affect is not really there, you would
10 expect about half the point estimates above one and half
11 of them below one. And you know with a. --

12 PANEL MEMBER BLANC: Then I thin it would be
13 helpful to have some kind of sentence there that says now
14 we're going to be talking later about more formal
15 met-analysis. This is just more qualitative or something
16 like that.

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

18 PANEL MEMBER BLANC: There's a part on page 1-15
19 where you talk about why sometimes you did the
20 meta-analysis and sometimes you didn't. I thought that
21 was very good to say that upfront. You said there was an
22 analysis performed on childhood asthma that's presented
23 only in summary, since this has been waiting for
24 publication. So what you're meaning -- is this because of
25 the Ingelfinger rule, you don't want to prevent its

1 publication.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Exactly.

3 PANEL MEMBER BLANC: And this was done by one of
4 your consultants?

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: It was
6 actually done by staff. Kathleen Vork was the lead and
7 she is here. We have submitted it now.

8 PANEL MEMBER BLANC: Okay, but you'd still have
9 the same problem. Could you just make that sentence more
10 explicit, because I don't think a regular reader is going
11 to understand why that meant that you couldn't do more
12 than...

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

14 PANEL MEMBER BLANC: And then I didn't dwell on
15 the part about the smoking and all that, because I didn't
16 want to -- I'll let Kathy Hammond talk about that. But
17 what I would say is that when you get to the very end, and
18 this may not have been an issue before when it was, you
19 know, shorter and not as good, but when you get to the
20 end, it just sort of ends.

21 And I think 2 or 3 sentences that just say, you
22 know, in summary we have delineated in this chapter, blah,
23 blah, blah, and blah and that would make it -- I wasn't
24 clear when I got to the end and then there's the table.
25 It's like well, you know,

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: And so...

2 (Laughter.)

3 PANEL MEMBER BLANC: Just --

4 CHAIRPERSON FROINES: Add a summary.

5 PANEL MEMBER BLANC: Yeah, just some kind of --

6 I'm not saying, you know, extensive word-smithing, but I

7 think you could just...

8 OEHHA SUPERVISING TOXICOLOGIST MARTY: Sure.

9 PANEL MEMBER BLANC: Because I think you do that
10 in most chapters, right?

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: We did.

12 PANEL MEMBER BLANC: I think you just got

13 fatigued and said I'm done with Chapter 1.

14 (Laughter.)

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, we

16 did.

17 (Laughter.)

18 CHAIRPERSON FROINES: That's unusual. Yeah, it

19 shouldn't end with just other confounding after a long

20 methodological discussion.

21 Other comments?

22 PANEL MEMBER GLANTZ: I have a few. I would echo

23 what Paul said, these are points of clarification. And I

24 have a few that I'll just give you, they're just minor

25 grammatical things. But I did have a couple questions.

1 CHAIRPERSON FROINES: Well, let's try and keep
2 your grammatical ones to a limit.

3 PANEL MEMBER GLANTZ: I'm sorry, I'm looking at
4 the Executive Summary here.

5 Okay, this is if you go to pages 1-6 and 1-7.
6 And this is -- and we've had some discussion about this.
7 I personally have a -- really don't like drawing this
8 bright line at a risk of 2 and saying that's big and
9 things less than 2 are little. I think it's very
10 arbitrary.

11 So I would just like to see the last paragraph --
12 the last little bit on 1-6 to just say small magnitude
13 associations and then delete the parenthetical statement.
14 And then the latter -- and at the top of the next page,
15 the same place, I would just delete the 1 to 2. I mean,
16 if people feel strongly they like it, I'm not going to
17 fight about it. But, you know, a lot of -- if you apply
18 that criteria, most of commonly used medical therapy would
19 be considered weak.

20 CHAIRPERSON FROINES: It's worse than that at one
21 level, since the relative risk for diesel was 1.4. You're
22 actually putting diesel into a weaker category by using 2,
23 so I agree with Stan.

24 PANEL MEMBER GLANTZ: Yeah. And I actually would
25 get rid of the word weak. I mean, I think that there's 2

1 different things that are kind of mixed up here. One is
2 the magnitude of the risk, and the other is the certainty
3 with which you can say the risk is elevated. And so I
4 would also talk about, you know, moderate elevations in
5 risk or something. But I think you need to be careful to
6 avoid confusing the magnitude of the risk estimate with
7 the significance of the test of the hypothesis that it's
8 not one.

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah, we
10 definitely don't mean to do that.

11 PANEL MEMBER GLANTZ: Well, I think it's -- the
12 way it's worded could -- it needs to be stated more
13 precisely.

14 PANEL MEMBER BLANC: Would it help, Stan, if they
15 said in that first part that when they're saying strong
16 association they put in a phrase, you know, "...has often
17 historically or by convention...". You know, I think the
18 very first part where they say that people often talk
19 about a relative risk greater than -- or an odds ratio
20 greater than 2. I think it's useful. But out front there
21 that, you know, if you look back at the terminology people
22 have used without getting into an extensive discussion of
23 it, then I agree with your comments. I'd rather that they
24 would just say a smaller relative risk. Relative to that
25 it's smaller, but that's not saying it's inconsequential

1 or whatever.

2 PANEL MEMBER GLANTZ: Yeah, if you want. I mean,
3 I just personally don't like this habit people have of
4 calling 2 some magical -- I mean, why not use Pi or
5 something. If we worked in Base E, it would be 2.7.

6 PANEL MEMBER BLANC: Well, I just want -- it's
7 important for them, though, to make it clear that they
8 understand what's generally out there, and that's why it's
9 useful to have that. The reason why 2 I think exists has
10 to do with the attributable risk in the individual, if you
11 will. Because one raises a relevant his of greater than
12 2, then you -- for that individual more likely than not
13 that risk factor accounted for their disease, right. I
14 mean I think that's the origin of it, if you want.

15 PANEL MEMBER GLANTZ: I guess. I mean, I don't
16 know -- I think it's -- I mean just this is maybe me
17 personally, but I think people get way -- that's become
18 too much of a bright line for some people. And I just
19 would rather not reinforce what I consider to be bad
20 thinking.

21 And I think if you just -- I mean, if you want to
22 do it the way Paul is saying, that's okay to relate it.
23 But I think you don't want to characterize risks under 2
24 as weak. If you have very strong evidence that the risk
25 is there -- you know, if you're very certain that a risk

1 of 1.1 isn't due to chance or confounding, to me that's a
2 strong statement. You know, it's strong statement about a
3 not huge risk. So I just think cleaning -- that's a place
4 where I think just more precision in the language would be
5 helpful

6 CHAIRPERSON FROINES: But I think that in fact
7 there's another issue that's true and that is that -- and,
8 by the way, Sander Greenland has written about this issue
9 of 2, and so has David Ozonoff, so there's some literature
10 on it. But the other point is that historically people
11 talked about the number 2 in terms of strength of
12 association. We've all been through that for years and
13 years and years.

14 But historically what we've done in the recent
15 past, and diesel is a good example, the actual number
16 became less important than the consistency of the 40
17 studies that showed basically consistent results. So that
18 we drew the conclusion recognizing that 1.42 was not 2,
19 but we drew this -- we felt confident in the Findings
20 because of the weight of the evidence of the 40 studies.
21 So we're making decisions differently now than we did even
22 10 or 20 years ago.

23 So we don't look at a specific study, look at it
24 being 2 and say when we're into these environmental
25 carcinogens, we look at -- because of the controversial

1 nature of them, we look at multiple studies to reaffirm
2 our conclusions and not just at the value of a particular
3 study. Although, obviously a study with a number of
4 greater than 2, we have more confidence in.

5 But I think that there is a different paradigm
6 that we're operating within. So the question is, how do
7 we address both those issues?

8 PANEL MEMBER BLANC: No, I think the chapter does
9 that. I think there are some wording change here. I
10 think Stan is overstating the point. He's just saying
11 don't -- you know, make it clear that you recognize that
12 this is out there, but don't so much go into the same
13 language that you say something you don't need to say.
14 That's all you need to say.

15 PANEL MEMBER GLANTZ: I don't want to like beat a
16 dead horse. But the other problem here is exactly what
17 the word "weak" refers to. Because it's used sometimes to
18 mean a small effect and other times it's used to mean not
19 high confidence in the conclusion of an effect. So I just
20 think avoiding that word will -- and just be very precise.

21 It's sort of some of the points Paul was making
22 earlier. I think if you're very precise about what you
23 mean at getting rid of that word and using some more
24 precise language would be better.

25 CHAIRPERSON FROINES: I should point out that one

1 of the best and most quoted studies in recent years is
2 Arden Pope and George Thurston's 2 studies on particulate
3 matter. And in the most recent Arden Pope study, which of
4 course has an enormously large population, they're looking
5 at 8 percent lung cancer excess risk. So they have an
6 odds ratio of 1.08. And so -- and I think there's nobody
7 that would say that that study isn't a really very fine
8 study. And the 1.08 reflects the size of the population
9 that was in the study. So that, in fact, the value of 2
10 depends on more than simple views of it.

11 PANEL MEMBER FRIEDMAN: So to summarize the word
12 weak has certain connotations which you don't like, so
13 maybe you just use the term "small magnitude". That would
14 be very precise, and it wouldn't have any of those other
15 connotations.

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

17 PANEL MEMBER GLANTZ: Okay. And then page 1-14,
18 the -- by the way, I think at the top of page you're
19 talking about the unpublished meta-analysis, the Johnson
20 meta-analysis, but I think that's out now. But at the
21 bottom of the page at 5 lines from the bottom, you say,
22 "In our analyses no single study may a significant
23 difference in the final pooled estimates."

24 And I would suggest you change the word
25 "significant" to "substantial", because significant could

1 be read as statistically significant and that you did some
2 formal analysis to see, you know -- and then on the top of
3 the next page -- no, never mind. Paul already did that
4 one.

5 Then if you go to 17, I think the -- at the end
6 of the first paragraph the sentence you added where you
7 say, "Studies that have more detailed exposure assessments
8 generally have higher precision and are considered of
9 higher quality. Imprecision in the measurement blurs the
10 distinction among the groups and results in a
11 misclassification error."

12 And I was confused by that, because I think one
13 of the things you did well here was to, as you pointed out
14 in your slide, is to separate exposure problems from
15 smoker misclassification. So I would suggest you
16 change -- and I'll give you this -- change results and
17 misclassification error. And I would change that to say
18 "Biases the estimates of effect size toward the null,"
19 which I thought was what you were trying to say. Am I
20 reading it correctly?

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah.

22 PANEL MEMBER GLANTZ: Yeah, I think that would be
23 clearer.

24 And then I was confused in the next paragraph --
25 and maybe fixing the previous paragraph will fix this, but

1 it wasn't totally clear to me when you were talking about
2 non-differential misclassification. It wasn't clear to me
3 if you're talking about exposure misclassification or
4 smoker misclassification. So I think you need to just
5 clarify that. I mean what were you talking about there?

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: No, it's
7 actually more exposure misclassification.

8 PANEL MEMBER HAMMOND: The paragraph starts
9 exposure, right?

10 PANEL MEMBER GLANTZ: Okay. Well, maybe I just
11 was tired.

12 And let's see in the middle of page 1 -- I have a
13 couple other little things, but in the middle of page
14 1-18 -- in the -- You say, "The misclassification of
15 smokers as nonsmokers affects a very small percentage of
16 the nonsmoking referent group in the majority of studies
17 (less than 5 percent)." And could you tell me what you
18 were trying to say there?

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: That
20 there's very few people who are classified as nonsmokers
21 who are actually smokers, that end up in the nonsmoking
22 referent group.

23 PANEL MEMBER GLANTZ: Okay. But did you go back
24 and like look at the studies and find of the studies that
25 were done a majority of them -- do you see what I'm

1 saying? Maybe, I was reading this too precisely, but it
2 sounded to me like you looked at it study by study and 50
3 percent plus one of them had -- this wasn't a problem. I
4 mean, what --

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: You know,
6 we should put the citation there because we got that
7 figure from a specific paper who had done just that.

8 PANEL MEMBER GLANTZ: Okay. Well, I think you
9 should just be more precise about that.

10 CHAIRPERSON FROINES: Melanie, can I go back to
11 the issue of misclassification that Stan raised?

12 We routinely in almost every document we ever
13 have, we have this, what's become rhetorical at some
14 level, we talk about non-differential misclassification
15 biasing towards the null. And it's like motherhood and
16 apple pie.

17 But there's a literature Domenci from NCI, Pat
18 Stewart from NCI and other people have written about how
19 differential misclassification can affect the relative
20 risk estimates. And so that whereas we tend to talk about
21 differential misclassification as bias towards the null.
22 There is an entire literature that looks at the issue
23 different. And even Harvey Checkoway in his book talks
24 about it.

25 And I wonder if it would be useful to have just a

1 sentence in the document that said, "As we've reviewed the
2 literature, we find no evidence for differential
3 misclassification that might have a more complex
4 relationship to the relative risk." Just so that you've
5 covered yourself. And I don't know whether it's
6 necessary, but it's -- we have, I think at sometimes
7 over-simplified the issue. And I think it's one sentence.
8 And I don't know what Kathy thinks.

9 PANEL MEMBER HAMMOND: I think if it's true, if
10 John's statement is true, I think that's a good statement
11 to put in. But I'm not sure whether that is.

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah.

13 CHAIRPERSON FROINES: What the what?

14 PANEL MEMBER HAMMOND: I'm not sure if that
15 statement is true.

16 CHAIRPERSON FROINES: Which statement?

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: That we
18 reviewed the literature looking for evidence of
19 differential misclassification.

20 PANEL MEMBER HAMMOND: I don't know how --

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: To me it's
22 a form confounding.

23 PANEL MEMBER HAMMOND: I'm thinking that -- the
24 reason -- we're talking about smoker, at this point,
25 right?

1 CHAIRPERSON FROINES: Yes.

2 PANEL MEMBER HAMMOND: And in terms of smoking
3 status, I don't know, but I guess -- I haven't looked at
4 it in quite that way to be sure that that's true. I think
5 its possible that there might be more people who are
6 diseased saying they were never smokers than people who
7 are not diseased, but I don't know that. Do you know?

8 OEHHA SUPERVISING TOXICOLOGIST MARTY: I don't
9 know that.

10 PANEL MEMBER FRIEDMAN: John, for clarification
11 in the minutes, you're talking about non-differential
12 being like motherhood and apple pie, and then -- I think
13 then you switched to differential, did you mean all to
14 totally switch to differential.

15 PANEL MEMBER HAMMOND: I think you want to
16 dismiss the differential. He wanted to make it clear.

17 CHAIRPERSON FROINES: I wanted to just basically
18 say -- you see, the problem we get into is this -- I feel,
19 and I've written this myself, so that I'm as guilty as
20 anybody else, that we tend to say misclassification that
21 we observe -- we believe is non differential, therefore
22 that will bias the relative risk towards the null, and
23 that says the risks are probably higher. But we have
24 misclassification.

25 And there is a literature that says the relative

1 risk can go up or down if you have different --

2 PANEL MEMBER FRIEDMAN: Differential.

3 CHAIRPERSON FROINES: -- differential no
4 misclassification.

5 And so I think that some of this language becomes
6 something that we throw in as like a protective device.
7 And it's not necessarily based on an analysis. It's based
8 on a belief.

9 PANEL MEMBER HAMMOND: No, I actually would
10 disagree with some of that.

11 CHAIRPERSON FROINES: That's good.

12 PANEL MEMBER HAMMOND: First of all, in terms of
13 the differential, what I can talk to is when I was on the
14 U.S. EPA's report was the section reviewing that. The
15 discussion of that point was about the different and there
16 was a differential, at least a postulated differential
17 misclassification of smoker status. And so there has
18 generally been a contention out there that those people
19 who are diseased with what are possible tobacco related
20 diseases, it's like lung cancer, would might be more
21 likely to deny that they smoked in the past than people
22 who were not diseased.

23 And so that would be a differential
24 misclassification. And so in the analysis -- and then
25 that also might carry over into the passive smoking

1 analysis in doing that. And so in the U.S. EPA analysis,
2 they actually did some calculations. And when they did
3 their risk estimates, they actually took that into
4 account. And they made an estimate of the degree of that
5 misclassification and adjusted the results downward,
6 because that would -- that type of differential
7 misclassification would lead towards bias away from the
8 null. And to an elevated relative risk, a falsely
9 elevated relative risk.

10 And so the U.S. EPA revised their estimates
11 downward based on their analysis of the extent of such
12 differential misclassification.

13 Do you follow what I'm saying?

14 Now, Melanie, I don't know, but I think that
15 that's still the status of things, isn't it, that there's
16 still the thought -- I don't even know, you know, that
17 there's probably some differential misclassification of
18 former smoking status.

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

20 CHAIRPERSON FROINES: Well, maybe --

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: We have a
22 discussion of that somewhere in this behemoth. It's
23 probably in the --

24 PANEL MEMBER BYUS: I've heard this before.

25 PANEL MEMBER HAMMOND: But I didn't.

1 CHAIRPERSON FROINES: Well, maybe what we should
2 do is just take out that end of misclassification as
3 differential in the 1-17 and just not get into -- because,
4 I mean, if I thought about it, somebody else can think of
5 it.

6 PANEL MEMBER HAMMOND: And then I'd like to
7 respond to the second part of what you said, John, before
8 we go to -- yeah, I mean -- but the other part was you
9 were saying that the discussion non-differential
10 misclassification bias towards the null being like
11 motherhood and apple pie.

12 In a small select group of people, yes. But, you
13 know, even in the general epidemiologic community, I don't
14 believe that that's true. I mean, from what I've seen in
15 the literature, I don't see people taking -- most studies
16 don't take due account of that problem. So it may be that
17 we're talking amongst ourselves and we all know that. We
18 recognize that. Now, we think it's a given in the world,
19 but I don't think that's true.

20 So I think it's always important to talk about
21 it. And it needs to be emphasized, particularly -- I
22 think in this document it's totally appropriate to
23 emphasize that, because I think it's extremely important
24 in the case of Environmental Tobacco Smoke when you have
25 such a ubiquitous exposure, and one that people have

1 tended to discount for many years. So they don't even
2 remember themselves.

3 CHAIRPERSON FROINES: Well, I agree with you on
4 that.

5 PANEL MEMBER HAMMOND: And also because -- and
6 this is important, particularly in certain of these
7 things, where -- we have to look at exposure through a
8 lifetime. And people often do the exposure assessment
9 based on one point in time in the adult life and another
10 exposure are totally neglected.

11 So there are -- this particular set of analyses
12 are ripe of opportunity for substantial misclassification
13 of ETS exposure. So I think it's very important to
14 emphasize it. And I don't believe it's really recognized
15 sufficiently, even in the epidemiologic community and
16 certainly not generally.

17 CHAIRPERSON FROINES: Well, I probably run in the
18 wrong crowd, but --

19 (Laughter.)

20 PANEL MEMBER HAMMOND: No, you run in the right
21 crowd.

22 (Laughter.)

23 CHAIRPERSON FROINES: -- but the non-differential
24 therefore the risk is lower is to me becomes like a litany
25 that we should --

1 PANEL MEMBER HAMMOND: But it's a small group.

2 PANEL MEMBER BLANC: I mean, I think that this
3 comes back to what Stan was asking about. I think there
4 is a very easy solution to the omission that you're
5 calling potentially, which is on the same section that
6 Stan was asking about on 1-18 about this 5 percent of
7 smokers may be misclassified as nonsmokers.

8 PANEL MEMBER GLANTZ: Um-hmm.

9 PANEL MEMBER BLANC: Melanie, in terms of the 5
10 percent of smokers maybe misclassified as nonsmokers, I
11 mean, I think that all you need to do is then have a
12 sentence there saying this actually would be a form of
13 non-random misclassification -- what's the term you used?

14 PANEL MEMBER FRIEDMAN: Differential.

15 PANEL MEMBER BLANC: -- differential that could
16 act towards bias and towards the positive association. I
17 mean, you say it, but you don't use the term
18 non-differential.

19 And then you could have a sentence saying that
20 other than this affect which we -- which, you know,
21 available data indicated would be infrequent or small,
22 we're not aware of other -- we have not postulated other
23 substantive non-differential misclassification that would
24 lead towards a false positive or whatever you want.

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Inflated

1 risk.

2 CHAIRPERSON FROINES: But I still would take out
3 this little thing in parentheses on 1-17. I don't think
4 you really need it.

5 PANEL MEMBER HAMMOND: The less than 5 percent?

6 CHAIRPERSON FROINES: No, the misclassification
7 as non-differential. I just don't think it's necessary.

8 PANEL MEMBER HAMMOND: But back to the area where
9 Stan and Paul were discussing. I found myself confused,
10 since we're into this non-differential. Shortly after
11 where you say less than 5 percent on page 1-18, sorry.
12 Shortly after the statement is made at least for IARC
13 studies, "They found that 1.7 percent of the subjects who
14 had never smoked regularly were actually former regular
15 smokers. The misclassification was non-differential..."
16 Is that correct?

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think it
18 was non-differential with respect to disease status.

19 PANEL MEMBER HAMMOND: But was that actually
20 true? So that would be different from what I said just a
21 few minutes ago, about what was seen.

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

23 PANEL MEMBER HAMMOND: I do think if that's
24 true -- I was wondering if that's what you meant. I think
25 you should explicitly say that. It was non-differential

1 with regard to disease status, if that was in fact true,
2 which is I guess -- and then I was saying, and therefore
3 would you know --

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: It
5 therefore would tend to bias --

6 PANEL MEMBER HAMMOND: Because then that follows
7 the argument you've already been taking. This just
8 reemphasizes that.

9 PANEL MEMBER BLANC: Wait a minute. Correct me
10 if I'm wrong, but the reason why it goes in that analysis
11 as bias towards the null is because they weren't looking
12 at ETS exposures, they were looking at smoking as a risk
13 factor for certain diseases, comparing active smokers to
14 non-smokers. In that case, if you classify --

15 PANEL MEMBER HAMMOND: Is that what this was?

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

17 PANEL MEMBER HAMMOND: Oh, well I misunderstood.
18 I'm sorry.

19 PANEL MEMBER BLANC: So if bias is towards the
20 null and you're looking at smoking and disease. But if
21 you were looking at ETS and disease, it would bias in the
22 other direction.

23 OEHHA SUPERVISING TOXICOLOGIST MARTY: It was
24 actually ETS in lung cancer. These are Nyberg studies.

25 PANEL MEMBER HAMMOND: So it was ETS and not

1 smoking.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes,
3 right.

4 PANEL MEMBER BLANC: But why would that bias
5 towards the null?

6 PANEL MEMBER HAMMOND: Because you're saying 1
7 percent of the -- among the people with disease, 1.7
8 percent of the people who were classified as nonsmokers
9 actually had been former smokers. And of those that did
10 not have disease, 1.7 percent also claimed to be
11 nonsmokers, but in fact had been smokers. Is that what
12 that study had said?

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right. So
14 that --

15 PANEL MEMBER HAMMOND: So that would bias towards
16 the null.

17 PANEL MEMBER BLANC: So it's surprising. So what
18 you're trying to say there is what they found -- and let's
19 see if I really understand it. They're trying to say that
20 if you compare ETS exposed and ETS nonexposed in both
21 groups there's the same the likelihood that somebody was a
22 former smoker?

23 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's
24 what they're --

25 PANEL MEMBER BLANC: They claimed to be never

1 smokers?

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.
3 That's what their study indicated.

4 PANEL MEMBER HAMMOND: Right. That would bias
5 towards the null.

6 PANEL MEMBER BLANC: That would bias towards the
7 null. That's very interesting. That surprises me. But
8 so it may, in fact, not be -- although you would presume
9 it to be, a non-differential bias, it may, in fact, not
10 be.

11 PANEL MEMBER HAMMOND: You know, given this
12 discussion, I think -- let me back up. First of all, I
13 think you did a great job trying to tease out these 2
14 kinds of misclassifications, the exposure
15 misclassification and the smoker non-smoker
16 misclassification.

17 But right here I think this paragraph starts out
18 as being ETS exposure, and suddenly you're introducing in
19 that paragraph a smoker misclassification. So I think I
20 would actually suggest you have a separate heading for
21 exposure misclassification and smoker misclassification,
22 and that you really keep those separate, because that's
23 where we start getting confused.

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: We tried
25 that, and it kept intertwining.

1 PANEL MEMBER HAMMOND: Too hard. But I think
2 that --

3 OEHHA SUPERVISING TOXICOLOGIST MARTY: Because
4 there's both problems.

5 PANEL MEMBER HAMMOND: I understand they're both
6 problems, but I think that it's extremely important to
7 address them. So, for instance, in this case, I totally
8 missed this. I couldn't believe it was saying what it
9 apparently does say.

10 So I think it's very important in talking about
11 the smoker -- the misclassification of smokers as
12 nonsmokers has been one of the major criticisms of a lot
13 of the ETS studies. And I think that it's very important
14 to talk about how extensive that is very clearly. And
15 this is an example of differential misclassification,
16 which would bias away from the null and may falsely leave
17 an impression.

18 However, in fact this study that you're referring
19 to here makes it very clear that as a result of those
20 studies, that that type of misclassification did not exist
21 at all. And that's very important. I mean, it was not
22 differential that didn't exist at all. It existed, but it
23 was not differential, which is very important.

24 And so rather than being differential and
25 therefore biasing away from the null, it's

1 non-differential and biases towards the null. Now, all of
2 that's confusing because, in general, smoker
3 misclassification is going to be seen as differential. So
4 when you put that into the paragraph when you're talking
5 about exposure misclassification which is generally
6 non-differential, it's made even more confusing.

7 So I know it's hard, but I really would urge you
8 to try to keep at least each paragraph clean as to whether
9 it's ETS exposure misclassification or smoker
10 misclassification. But I think you've done a wonderful
11 job. I really do.

12 CHAIRPERSON FROINES: Do we want to recommend
13 that any discussion about tobacco smoke misclassification
14 be in the body of the text where it's dealing with the
15 specific studies, whereas this first chapter is meant to
16 be more general?

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.
18 And we got the opposite recommendation at the last
19 meeting.

20 PANEL MEMBER HAMMOND: No. No. I think what
21 you've done is very important. And I like it the way it
22 is. I really think -- I mean, except for what I'm saying.
23 But these are tiny little details. But I think it's very
24 important to have the general discussion.

25 CHAIRPERSON FROINES: The answer to the question

1 is no. Okay, let's move on.

2 PANEL MEMBER HAMMOND: And this is a small thing,
3 but it actually changes the meaning. On that same page at
4 the end of the first line, just move the word "only" to
5 "only at baseline".

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah.

7 PANEL MEMBER HAMMOND: Just not only evaluate it,
8 but evaluate it at baseline.

9 CHAIRPERSON FROINES: Stan.

10 PANEL MEMBER GLANTZ: I just wanted to agree with
11 that. I think treating them as separate paragraphs, I
12 mean, that is -- the fact that they were mixed together is
13 what got me confused.

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

15 PANEL MEMBER GLANTZ: And then I just have one
16 other thing in the table on page 24, which appears
17 multiple times at the very last line in the last column

18 CHAIRPERSON FROINES: What page?

19 PANEL MEMBER GLANTZ: This is page 1-24. Where
20 you say approximately 68 to 220 percent, don't you mean
21 120 percent?

22 DR. MILLER: Yes.

23 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

24 PANEL MEMBER GLANTZ: And then the other thing --
25 this table is repeated multiple times, so make sure you

1 find it everywhere.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: It's in
3 the Exec Summary also.

4 PANEL MEMBER GLANTZ: Yeah. And then why -- the
5 columns above that for Asthma, new cases, exacerbation are
6 left blank and the lower respiratory illness says NA. Why
7 didn't you just use the whole numbers, if nothing's
8 changed? Because I think --

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: The lower
10 respiratory illness we're talking about.

11 PANEL MEMBER GLANTZ: I'm talking about those 2
12 things. Every other row has numbers and then one of them
13 is blank and one says NA on it. I mean, can't you just
14 say use the old numbers and just say no additional
15 information since then or something, because I thinking
16 having those empty is going to confuse people. Or is
17 there a reason not to do that?

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, for
19 the lower respiratory illness, I don't think there's a
20 reason to not do that.

21 For the asthma, the episodes is what we actually
22 calculated in this --

23 PANEL MEMBER GLANTZ: Oh, I see.

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: -- in this
25 update.

1 DR. MILLER: That was based on the available
2 data, we couldn't replicate.

3 PANEL MEMBER BLANC: Then just put not available.

4 PANEL MEMBER GLANTZ: Well, then what I think --
5 I just think what you should do for clarity is maybe just
6 put a footnote under asthma and just say that, "Because of
7 changes in data, the availability we're computing
8 episodes, whereas in the earlier one we did it
9 differently", you know. Just so that it's clear why
10 you've got those empty cells. That's all. I think just a
11 little bit of explanation of why you did what you did.

12 CHAIRPERSON FROINES: I don't think you should
13 have empty cells with no footnote.

14 PANEL MEMBER GLANTZ: Yeah. That's everything I
15 had.

16 CHAIRPERSON FROINES: Okay. We've been through
17 Paul, Stan and to some extent Kathy. Kathy, do you have
18 further comments?

19 PANEL MEMBER HAMMOND: No.

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: But what
21 Stan --

22 PANEL MEMBER HAMMOND: Well, let me just say -- I
23 do want to say once again, I think you did a nice job on
24 doing this. I think it's very important and that it will
25 be useful.

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: Thank you.

2 And Stan what you were just asking for is
3 actually in the text, but what we can do is do a better
4 job of the footnotes.

5 PANEL MEMBER GLANTZ: Well, I think it's okay to
6 have it in the text too. But I mean a lot of people, as
7 you know, the only thing they're going to look at in the
8 report is this table. And so you want it to be self
9 contained.

10 CHAIRPERSON FROINES: Yeah. This is going to
11 come up later in another issue, but people look at tables.
12 I don't read -- I have papers that I don't read, I just
13 look at the tables and figures, and a little bit of the
14 discussion.

15 (Laughter.)

16 PANEL MEMBER GLANTZ: Kathy Hammond only thinks
17 you should publish tables and leave the text out entirely.

18 That was a joke.

19 (Laughter.)

20 PANEL MEMBER HAMMOND: Kathy Hammond objects to
21 this characterization.

22 (Laughter.)

23 CHAIRPERSON FROINES: The last 2 comments were
24 jokes for the record.

25 (Laughter.)

1 CHAIRPERSON FROINES: Moving on.

2 Charlie.

3 PANEL MEMBER PLOPPER: I have only one comment on
4 this. And that I came into this document with a bias that
5 OEHHA always does a very thorough job of looking at all
6 the literature and doesn't treat all studies equally,
7 because they're not equal. And my only concern is that
8 there's some judgmental comments made in here. These are
9 all peer-reviewed studies. So to say the word "well done"
10 or "well documented" or "well conducted" sort of leads the
11 reader away from the issue that they're not really
12 rigorous enough.

13 So I read that through the parts I've looked
14 through. And it just bothers me that -- why don't you
15 just say they're rigorous or they're not rigorous or
16 rigorous or less rigorous, which is what you do, right?
17 And you laid out a nice set of criteria used for rigor and
18 I happen to agree with it. And I think you should say
19 that instead of saying they're well conducted or not,
20 because it's just going to irritate people. When the fact
21 of the matter is that they're just not rigorous enough.

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.
23 We'll use rigorous and less rigorous.

24 PANEL MEMBER PLOPPER: You defined that all the
25 way throughout. I'm sorry, I've been away so long. That

1 was my bias coming back to reread parts of this. It's
2 just going to irritate a lot of people, and it's not
3 really what you do. You're put rigor and that's what I
4 was concerned about.

5 CHAIRPERSON FROINES: Good point.

6 Gary.

7 PANEL MEMBER FRIEDMAN: I have nothing to add.

8 CHAIRPERSON FROINES: Craig.

9 PANEL MEMBER BYUS: I think this chapter is much
10 much better. And I thought I understood all the ETS
11 misclassifications after reading it. Now, I'm not so sure
12 I do.

13 (Laughter.)

14 PANEL MEMBER BYUS: And if you ask me to explain
15 just what you all just said, I think I would have a
16 difficult time.

17 But I think it is much better and very clear.
18 And if you put this in there, it will be very, very clear.

19 CHAIRPERSON FROINES: You know, if you go look
20 around the country at schools of public health and other
21 institutions, this issue is not very adequately dealt with
22 in most places. It's over-simplified. And it's really an
23 important topic.

24 PANEL MEMBER BYUS: Well, it's very clear that it
25 is an extremely important topic in this document, if not

1 central to it, in my estimation. So any clarification you
2 all can bring to this issue and to write it down clearly,
3 I think, will be very beneficial to the document.

4 I couldn't agree with that more.

5 CHAIRPERSON FROINES: Joe.

6 PANEL MEMBER LANDOLPH: It's good enough. I
7 think it's been substantially improved. Lots effort into
8 it and I don't have anything to add.

9 CHAIRPERSON FROINES: Roger.

10 PANEL MEMBER ATKINSON: I don't have any
11 additions.

12 CHAIRPERSON FROINES: Melanie, I just had 2 sort
13 of generic comments. I would like -- this now becomes, in
14 essence, almost a methodology for future substances, as
15 well. In other words, what you've done is not necessarily
16 limited it, even though there's overlap. And it would be
17 useful to take Chapter 1 try and clean it, so it has
18 generic applicability and include it for other chemicals,
19 because industry and environmental groups and the public
20 won't necessarily have read this document. And to have
21 something that shows how you make decisions as a generic
22 approach, I think, would be particularly useful.

23 So you may think about its applicability in other
24 documents, because a lot of work has gone into it, and we
25 might as well take advantage of it.

1 The second thing I would say is that you
2 should -- we talked about publication. I would think
3 about taking this document and saying in some journal
4 maybe Regulatory Toxicology or I don't know Risk Analysis
5 or some journal and say here is how California is
6 approaching its decision making on toxic substances, and
7 it would be very useful if it were published, because you
8 would get a lot of feedback. And it would create a debate
9 that would be, I think, useful and interesting.

10 And so you may -- those are sort of generic
11 remarks, but I think it's worth saying that California has
12 gone to another level of trying to define causality and
13 how we make decisions. And that's useful to the broad
14 community. It certainly would be useful to other State
15 governments. And hopefully even EPA would read it and
16 benefit from it. I won't say anything further on that.

17 PANEL MEMBER BLANC: Can I ask a question about
18 the attributable risk section. I just have a brief
19 question.

20 I know you say -- it's very useful that you put
21 the simple formula that you used. I assume that there
22 were some studies for which you only had the odds ratios
23 and not the relative risk though. Let's see attributable
24 fraction -- where do you put the formula -- oh yeah --

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Page 1-15.

1 PANEL MEMBER BLANC: 1-15. This document is
2 generally calculated by the formula, blah, blah, blah,
3 blah.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: You can
5 use an odds ratio rather than relative risk. It really
6 already --

7 PANEL MEMBER BLANC: But it's a slightly
8 different formula when you use the odds ratio, right?
9 It's not that -- Stan, do you remember?

10 PANEL MEMBER GLANTZ: I thought that if the odds
11 ratio is near 1, it's a good approximation to the relative
12 risk. And so you could use the same formula.

13 PANEL MEMBER BLANC: No. In the odds ratio you
14 can use the exposure prevalence in the diseased. And in
15 this one, you can use the exposure prevalence in the
16 entire population. I just don't want you to get
17 yourselves into trouble.

18 If you look at the American Thoracic Society's
19 statement on the Burden of Occupational Exposures to
20 Airways Disease, there's really an exhaustive and boring
21 discussion of these formulae. The other thing is that --
22 and this may not be necessary for this document but were
23 you to do the things that John is suggesting it might
24 be -- there are even more rigorous ways of calculating the
25 attributable risk that also give you a 95 percent

1 confidence interval that adjusts for the covariants that
2 are looked -- that were looked at in the logistic
3 regressions if it was an odds ratio, and take that into
4 account, especially in the estimation of the confidence
5 interval.

6 Clearly, you wouldn't do that because you didn't
7 have the raw data for these studies. And so it would be
8 unlikely that there would be a situation where, you know,
9 you could do that. But it's if -- and I don't think it's
10 necessary for this document. But it's something if you
11 were going to really be more explicit, you'd need to say
12 that.

13 But I do think the other thing that's probably
14 likely is that they will be some and you only have many
15 that you had the odds ratios you use the other formula,
16 that had this based on the prevalence in the diseased.

17 DR. MILLER: You're talking about P here in the
18 formula. The Ps that were used are population based
19 exposure data prevalence. So when possible I think we
20 used California data, and sometimes it's national.

21 CHAIRPERSON FROINES: I have a question.

22 PANEL MEMBER HAMMOND: I'm sorry.

23 DR. MILLER: Well, the formula on page 15. I
24 think we're talking about P, which is the exposure
25 prevalence. And what we determined was prevalence of

1 exposure being population, either in California or
2 national statistics depending on what was available.

3 PANEL MEMBER HAMMOND: And --

4 DR. MILLER: Not in the disease, that's
5 population exposure prevalence.

6 PANEL MEMBER BLANC: All right, just double check
7 it because it depends on what --

8 PANEL MEMBER HAMMOND: Yeah, I thought that
9 was --

10 PANEL MEMBER BLANC: And that is true if you have
11 the relative risk. But if you don't have the relative
12 risk, just stick in an odds ratio --

13 DR. MILLER: Well, there they're talking about
14 relative risk comes from -- you know, is extrapolated.

15 PANEL MEMBER BLANC: From the studies.

16 DR. MILLER: From the studies and you have
17 meta-analyses.

18 PANEL MEMBER BLANC: Suppose you don't have the
19 relative risk, and you only have the odds ratio.

20 PANEL MEMBER HAMMOND: But I think if you have an
21 odds ration, and the odds ratio is close to 1, then that
22 it very close to the relative risk, and therefore you can
23 use it for the relative risk. That was the point. In
24 which case then you can also use the prevalence in the
25 population as opposed to prevalence in the disease.

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

2 PANEL MEMBER HAMMOND: And that was my
3 understanding of what you were saying.

4 DR. MILLER: That's right.

5 PANEL MEMBER HAMMOND: And perhaps -- to follow,
6 you know, Paul's point, maybe it's worthwhile to say -- I
7 mean, because what you say, you say explicitly R is an
8 estimate of the relative risk. And, you know, maybe you
9 could add that in studies that have a relative risk you
10 use the relative risk. And in studies that you have the
11 odds ratio, if the odds ratio is under X value 1.X, you
12 will use the odds ratio as of the thing the relative risk
13 refer to a document that says you can do that.

14 How about that.

15 PANEL MEMBER BLANC: Yeah, that's fine.

16 DR. MILLER: That would be more clear.

17 CHAIRPERSON FROINES: Melanie, how long do you
18 think it's going to take for you to go through the
19 revisions on Chapter 7?

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: It
21 shouldn't take that long. It's the discussion. My slides
22 will be fast.

23 (Laughter.)

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's up
25 to you guys.

1 CHAIRPERSON FROINES: I ask my wife questions and
2 she always answers whatever she feels like. She never
3 tells me the answer to my question, so this is a
4 reflection of the same thing. We've been together too
5 long, I'm afraid.

6 (Laughter.)

7 CHAIRPERSON FROINES: The question is how long do
8 you think it will take? I mean, 20 minutes because I want
9 to take a break, if we're going to take a fairly lengthy
10 time.

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: You
12 probably should take a break.

13 CHAIRPERSON FROINES: Let's take a break for 10
14 minutes.

15 (Thereupon a recess was taken.)

16 CHAIRPERSON FROINES: For the record, Peter has
17 just handed out the draft Findings, so everybody has them
18 for the discussion later. And Jim has also handed out the
19 document from Dr. Enstrom that we discussed earlier.

20 PANEL MEMBER FRIEDMAN: The draft Findings is
21 that the same ones we got by Email?

22 CHAIRPERSON FROINES: Yes. We just wanted to
23 make sure you had them in front of you.

24 Melanie.

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

1 Again, we made a number of revisions to Chapter 7 in
2 response to panel comments. We added -- all of these
3 revisions that I'm going to discuss are in the breast
4 cancer section. We added discussion or the conclusions of
5 the Surgeon General and the IARC reports, both that came
6 out in 2004, on active and passive smoking and breast
7 cancer. And we acknowledged that there are differing
8 opinions out there.

9 We edited the summary of active smoking and
10 breast cancer, condensed it a little.

11 And we clarified the origin of risk estimates
12 used in our meta-analysis. And for those that we derived
13 using data in the papers, we clarified how those were
14 derived.

15 --o0o--

16 OEHHA SUPERVISING TOXICOLOGIST MARTY:

17 CHAIRPERSON FROINES: Just for the record,
18 everybody on the Panel has received a copy of the changes,
19 so the Panel has actually seen the changed document.

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: In the
21 OEHHA summary of risk estimates section, we edited --

22 PANEL MEMBER FRIEDMAN: Could I go back. The one
23 that we got, are you talking about what you've done to the
24 one we've got or what you got done since we sent you
25 comments about that one we got.

1 (Laughter.)

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right now,
3 I'm talking about the one that you got. And in a few
4 minutes, I'll talk about additional stuff we're going to
5 do in response to particularly your comments and other
6 people.

7 So we edited this section for clarity and
8 condensed the text. And we finalized the pooled risk
9 estimates. There were some minor changes primarily
10 from -- we look at how we derived one of those estimates
11 on I mentioned earlier.

12 --o0o--

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: In the
14 section on discussion of ETS and breast cancer, we changed
15 our terminology of the studies that we thought were "most
16 informative" to "most informative" from "most
17 influential", which seemed to annoy virtually everyone.

18 (Laughter.)

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: We edited
20 the discussion of importance of exposure
21 misclassification. We clarified and condensed sections on
22 strength of the association, consistency and we added to
23 the discussion regarding confounding by uncontrolled
24 factors.

25 --o0o--

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: In the
2 conclusions section for breast cancer, we separated the
3 section on younger, primarily premenopausal from
4 older/postmenopausal. We condensed the writing in that
5 section in eliminating excess verbiage.

6 --o0o--

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: And the
8 conclusions are on this slide. And this is the wording
9 that's currently in the document. For the younger
10 primarily premenopausal women we have a statement that,
11 "Overall, the weight of evidence (including toxicology of
12 tobacco smoke constituents, epidemiological studies, and
13 breast biology) is consistent with a causal association
14 between ETS exposure and breast cancer in younger,
15 primarily premenopausal women." And we have a discussion
16 of why we chose those terms in there.

17 And further more, for postmenopausal women,
18 "...we conclude that further research is necessary to
19 characterize ETS associated breast cancer risk in
20 postmenopausal women, and the evidence to date is
21 considered inconclusive".

22 --o0o--

23 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's it
24 for the overview slides. I can go to the -- there's a
25 couple of slides I have for a comment that Dr. Friedman

1 made, plus I have more that I was going to say in response
2 to his comments. I don't know if you want to jump to that
3 or go around the room.

4 PANEL MEMBER BLANC: Go jump to that.

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay,
6 let's jump to that.

7 I did have some slides, I don't know if you folks
8 want to see these. These are just essentially why we came
9 to our conclusions. It's what you've heard before.

10 But for ETS and breast cancer association in
11 younger premenopausal women, there were 14 studies that
12 evaluated breast cancer risk in this strata; 13 of those
13 14 found elevated risks estimates; and 7 of those were
14 statistically significant.

15 The pooled risk estimate from our meta-analysis
16 of those 14 studies is 1.68 with a confidence interval
17 that excludes 1. And the pooled risk estimate for the
18 studies in the meta-analysis with lifetime exposure
19 information from all sources was higher. It was 2.2,
20 again with a confidence interval that excludes 1. And
21 there were some studies that provided evidence of dose
22 response.

23 --o0o--

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: And this
25 is the figure out of the document that shows those studies

1 plotted along with the summary risk estimates on the
2 right.

3 --o0o--

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: These are
5 the 6 studies that OEHHA considered most informative and
6 the results of the analysis from these studies for younger
7 premenopausal women, the relative risks and then the 95
8 percent confidence intervals. And they ranged from 1.59
9 to 3.6. And all the lower confidence limits excluded 1.

10 --o0o--

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: There was
12 evidence from 9 studies on risk to postmenopausal women.
13 And the evidence appeared inconsistent and generally null.
14 Although, there were a few studies that showed elevated
15 risk estimates. And as I noted earlier, we think further
16 research is necessary to characterize the association
17 between ETS exposure and breast cancer in postmenopausal
18 women.

19 --o0o--

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: This slide
21 just shows the premenopausal studies and postmenopausal
22 studies, sort of a birds-eye view.

23 --o0o--

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: We did get
25 comments from a couple of the Panel members. Dr. Friedman

1 sent some comments noting that we say that we didn't think
2 SES and alcohol were strongly related to either breast
3 cancer or ETS, emphasis on the strongly. And he asked us
4 to give evidence of that. So we actually planned to put
5 in a couple of paragraphs describing that.

6 In a nutshell, alcohol association is actually
7 relatively weak for breast cancer, which is not to say
8 it's not there. It's there.

9 In the collaborative study, the relative risk
10 estimate -- and this is an analysis, I think, of 53
11 individual studies. For those women consuming 15 to 24
12 grams per day, the relative risk estimate is around 1.2.
13 Johnson --

14 PANEL MEMBER GLANTZ: How much alcohol is that,
15 for those of us, 15 to 24?

16 DR. MILLER: What they say in that paper is that
17 it depends on the country, but it ranges somewhere in the
18 10 to -- I think 8 to 12 grams per drink. The United
19 States is actually more. I think there was 12 and some -
20 written was 10, or something like that. Approximately 10
21 grams of alcohol per drink.

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Johnson's
23 paper in 2000, he did look at alcohol effects and had
24 relative risks stratified by the amount of alcohol drinks
25 per week of less than a half, from a half to less than 3.5

1 and greater than 3.5. And he got a similar risk estimate
2 of 1.2 for greater than 3.5 drinks per week.

3 And then Reynolds et al., looked their teachers'
4 cohort. And from their data, their survey data, about 8
5 percent of teachers consumed more than 20 grams per day.
6 So the upshot is that confounding either uncontrolled or
7 residual for an infrequent behavior with a small magnitude
8 associated risk couldn't substantially alter or explain
9 the association noted between ETS and breast cancer in the
10 studies that we looked at.

11 And I should note that most of those studies at
12 least did some sort of confounding control for alcohol
13 consumption.

14 --o0o--

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: And also
16 some studies did some sort of control measurement for SES.
17 In this slide there is a greater --

18 PANEL MEMBER FRIEDMAN: Can I go back to alcohol
19 for a second. Do you mind if I interrupt?

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: Sure, no.

21 PANEL MEMBER FRIEDMAN: Do you have any data on
22 the association of alcohol with Environmental Tobacco
23 Smoke, because you presented one side of the issue, which
24 is pretty persuasive, but it wouldn't explain it. But I
25 think it would be also important to show whether there's

1 an association with Environmental Tobacco Smoke.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think we
3 do. In fact, it might even be discussed somewhere in
4 this. Yeah, we can pull that up. There is actually -- I
5 do. I know there are data that we can pull together for
6 that.

7 PANEL MEMBER FRIEDMAN: I think it would be good
8 to have that in there too.

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah. I
10 mean, I think that you can -- if you think about it,
11 smoking is higher -- there are higher rates smoking in
12 lower SES, and naturally you would expect higher rates of
13 ETS exposure in lower SES strata. And that's my
14 remembrance of the information that I know we have
15 somewhere.

16 PANEL MEMBER FRIEDMAN: I'm talking about alcohol
17 and ETS.

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: Sorry.
19 Okay, alcohol and ETS, yes.

20 PANEL MEMBER FRIEDMAN: The question of
21 confounding, you presented one part of the issue in terms
22 of alcohol and breast cancer. But I think it would be
23 also important if there are data to present the alcohol
24 association, if there is any with ETS.

25 PANEL MEMBER BLANC: Well, okay, but I would

1 presume that there's an association. For some reason
2 there isn't an association between alcohol and active
3 smoking, there just has to be an association between
4 alcohol and ETS.

5 PANEL MEMBER FRIEDMAN: Well if there are data on
6 that, I think it would be nice.

7 PANEL MEMBER BLANC: That means that the data
8 if -- and that would be where I would go. But if you
9 don't have the data, I would simply make a statement that
10 say even presuming some association, for example people
11 who go to bars outside of California are going to have
12 more ETS and people going to bars are more likely to drink
13 alcohol.

14 (Laughter.)

15 CHAIRPERSON FROINES: I have a procedural
16 question. If you want to add a study or studies to
17 address Gary's question, I assume that we can proceed with
18 the completion of the document and a decision on the
19 assumption that you'll add those. And Gary can look at
20 them even -- in other words, I'd just as soon not want to
21 have another meeting on this topic.

22 PANEL MEMBER FRIEDMAN: Oh, that's fine.

23 OEHHA SUPERVISING TOXICOLOGIST MARTY: And we've
24 done that in the past, where we've responded to a comment
25 at the last meeting, sent the response to the Panel

1 person, and gotten agreement that way.

2 CHAIRPERSON FROINES: Good.

3 DR. MILLER: There's a paper by Reynolds that
4 looks at correlations with ETS. And I just don't remember
5 clearly off the top of my head that exact paper, but we'll
6 find that.

7 PANEL MEMBER FRIEDMAN: We even have a paper, but
8 I don't remember whether we looked at alcohol or not.
9 That was many years ago. Well, I'm sorry to interrupt,
10 but I just -- while we are on alcohol, I just wanted to
11 clarify.

12 CHAIRPERSON FROINES: No, I think that's
13 important.

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: George is
15 pointing out to me that we also have stated that in
16 studies that controlled for alcohol and SES, there was
17 little impact on the risk estimate.

18 PANEL MEMBER FRIEDMAN: Right.

19 --o0o--

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: In terms
21 of SES, there are greater rates of breast cancer in higher
22 SES women, but it's thought to be due to reproductive risk
23 factors, namely parity, age at first birth is probably a
24 big one, because you put off having children to get
25 educated. These, along with surrogates of SES, are

1 smokers and the nonsmokers. So this is not to say that
2 there isn't any anti-estrogenic effect. It's just that,
3 if there is, it hasn't been measured, and it's less than
4 smokers.

5 PANEL MEMBER FRIEDMAN: I think it would be
6 important to put that in this section too, repeat that
7 information.

8 PANEL MEMBER BLANC: Just for our edification, is
9 the anti-estrogenic effect of smoking monotonic in terms
10 of its dose response?

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: I don't
12 know. I can't answer that.

13 PANEL MEMBER BLANC: Stan, do you know?

14 PANEL MEMBER GLANTZ: The things I know are that
15 smokers have earlier menopause. There are other things
16 that are related to it. I don't know that anybody's --
17 I've never seen anything that showed the very heavy -- the
18 effects reverse among very heavy smokers. But this isn't
19 my area of expertise, but I've certainly never heard that.

20 DR. MILLER: The only things I can remember
21 reported are smokers versus nonsmokers.

22 PANEL MEMBER BLANC: Because if there was a study
23 which showed that if you smoke half a pack or less a day,
24 it doesn't appear to have substantive anti-estrogenic
25 effects than by extrapolation you could say it's unlikely

1 that passive smoking as active.

2 Whereas, you know, if it's a sort of straight
3 linear line, rather than having an upswing when you start
4 to get to 1 pack and 2 packs a day or something. It's
5 been looked at in terms of intensity -- smoking intensity.

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: We can
7 look at that, and see if we can find anything, and then
8 add that into the discussion.

9 PANEL MEMBER FRIEDMAN: I think your argument that
10 a comparison group of smokers contains some passive
11 smokers is fairly weak, because certainly a smoking group
12 has a lot of passive smoking going on. So I'm not -- I
13 don't think that's a very strong argument suggesting that
14 passive smoking is not -- does not affect estrogen.

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's
16 true.

17 CHAIRPERSON FROINES: This is an aside. Have
18 there been any studies that you're aware of where people
19 have looked at endocrine disruptors and passive smoking?

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: Not that
21 I'm aware of.

22 CHAIRPERSON FROINES: That's an interesting issue
23 isn't it, when you think about estrogen.

24 PANEL MEMBER BYUS: And as I said at the last
25 meeting, I'm still -- I think this discussion of the

1 anti-estrogenic effects is all well and good, and it's all
2 nice, but it's not clear the role of estrogen in really
3 breast cancer. And it's very complex, both added estrogen
4 and the dose response issue is extremely complicated. And
5 you're going to get into all kinds of issues with it. I
6 mean, it's a nice thing to do. It makes -- you know, it's
7 kind of intellectually satisfying. But I think the more
8 you discuss this, the more you could potentially go down
9 the wrong path.

10 CHAIRPERSON FROINES: Well, I think that's why
11 some of the --

12 PANEL MEMBER BYUS: That's all. You know, it's a
13 nice thing to say, but not to get too carried away with.

14 PANEL MEMBER FRIEDMAN: Well, it's so key,
15 because the first thing people react to when they see the
16 passive smoking association with breast cancer, they say
17 well what about active smoking, why isn't that? So, yes,
18 there is a small association, but it's no greater. And
19 that's the rational for why the active smoking is not
20 greater than the passive is because active smoking
21 suppresses estrogen.

22 So that is such a key point in this whole
23 discussion that even though it's -- Craig, I take your --
24 I understand what you're saying, and, you know, I agree
25 with it, but that's so much of the basis of their

1 conclusion.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, let
3 me say something --

4 PANEL MEMBER BYUS: The epidemiology data is
5 solid based on the classification of who smokes and
6 doesn't, and whether you're exposed to passive smoke truly
7 or not. I mean, the data that is epidemiological that
8 persuades me is very clearly laid out.

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think
10 we've only said that the antiestrogenicity is one argument
11 that's out there.

12 PANEL MEMBER BYUS: That's all. It's not --

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: And it
14 doesn't -- you know, we're not hanging our hat on that.

15 PANEL MEMBER BYUS: No, don't hang your hat.

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: We just
17 are saying that the dose response is nonmonotonic because
18 for sure of this effect, but it certainly can be argued
19 that it may play a role.

20 PANEL MEMBER FRIEDMAN: Well, if it wasn't
21 estrogen, what other reason would you have for active
22 smoking, which includes a lot of passive smoking, not
23 having a stronger association with breast cancer than pure
24 passive smoking?

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: You know,

1 the other -- well, you can probably argue the same reasons
2 that, you know, cardiovascular coronary heart disease
3 relative risks for passive smoking aren't really that much
4 lower than for active smoking. So I think the question is
5 you have a complex mixture, lots of different chemicals.
6 The mixtures are a little bit different. The exposures
7 are different, to any specific toxicological -- to any
8 particular component that's toxic in both passive and
9 active smoking. So it's a very complicated thing.
10 There's lots of synergies, antagonisms, additive stuff
11 going on. It's pretty hard to look at these things.

12 I think it's worth noting, too, that for -- well,
13 actually I have a slide in their somewhere, but that for
14 lung cancer from active smoking, you also see -- you see
15 an increase by pack years until you get to a certain
16 level, and then it flattens off and it even drops off a
17 little bit. So that's probably reflective of you've
18 already killed the sensitive people and there is old
19 geezers out there who can smoke a pack a day and they're
20 never going to die from --

21 CHAIRPERSON FROINES: Well, I think there's a
22 healthy-worker-survivor effect that you're talking about.
23 But I think there's also some biological processes. I
24 mean, you get the high doses. I can give animals low,
25 medium and high doses, and I can knockout any immunologic

1 responses at the high doses and get a U-shaped curve
2 upside that U-shaped curve. So I think that our view -- I
3 think our traditional view that our response goes up
4 uniformly with dose is so over-simplified biologically
5 that we should be thinking about it in much better terms
6 at this point.

7 PANEL MEMBER BLANC: Well, the point that you
8 make in Chapter 1 about biological plausibility is not --
9 biological plausibility doesn't mean that you have
10 explained the biological mechanism. It means can you come
11 up with some kind of plausible explanation, and that's
12 all, you know, to meet that requirement. But, you know,
13 you're on thinner ice if it's a relationship for which
14 it's, you know, very difficult in the light of the
15 biological knowledge to deposit any kind of explanation.
16 So you've done your due diligence.

17 PANEL MEMBER BYUS: And the analogy to that as I
18 was telling Katharine, is a electromagnetic field, which
19 I'm fairly familiar. There you have low-dose epidemiology
20 some evidence, but coming up with biological plausibility
21 is the problem. How those fields interact with living
22 organisms and tissues in a way that could cause increased
23 health risks.

24 You can't actually postulate a plausible testable
25 result. That doesn't mean it doesn't exist. It's just

1 that it means nobody's been able to figure out what it is
2 yet. I mean in this case, there is plenty of
3 plausibility. It's just that you don't know exactly what
4 it is.

5 CHAIRPERSON FROINES: I think we should move on,
6 because I think that the conclusion that estrogen plays a
7 role is probably reasonable, but the conclusion that we
8 know what the biochemical and biological mechanisms are is
9 a whole different issue altogether. And so we should
10 assume that we don't know, but that estrogen is one of the
11 factors that is likely to have some role and let it go at
12 that.

13 --o0o--

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: We also
15 got comments from Dr. Glantz on the chapter that you have
16 and we will be making editorial changes per his
17 suggestions.

18 CHAIRPERSON FROINES: On the chapter that what?

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: The
20 Chapter 7 the breast cancer section. So I don't know if
21 Stan wants to go over any of those points here.

22 PANEL MEMBER GLANTZ: No, I don't think -- they
23 were all editorial. There aren't any substantive -- was
24 there anything substantive?

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Is that a

1 trick question?

2 (Laughter.)

3 PANEL MEMBER GLANTZ: No.

4 CHAIRPERSON FROINES: Well, you realize that
5 every time a question like that gets raised, those of us
6 who have been on this panel for awhile remember that, and
7 that took a whole day of detail.

8 PANEL MEMBER GLANTZ: Well, that was a different
9 situation.

10 PANEL MEMBER BYUS: That was a special situation.

11 (Laughter.)

12 PANEL MEMBER GLANTZ: Yeah, that was a very
13 special situation.

14 CHAIRPERSON FROINES: So I prefer to not do it as
15 long as they're editorial. If there substantive
16 questions --

17 PANEL MEMBER GLANTZ: No, I think it was all just
18 small points of clarification, weren't they? I mean, I've
19 got them here. I could look at them.

20 PANEL MEMBER BLANC: Can I ask a question that
21 relates to --

22 PANEL MEMBER GLANTZ: I has sent them to John
23 too.

24 PANEL MEMBER BLANC: -- that relates to Chapter 7
25 to the Executive Summary.

1 CHAIRPERSON FROINES: I didn't have problems with
2 Stan's comments just for the record.

3 PANEL MEMBER BLANC: In the Executive Summary in
4 the latter part of the Executive Summary you did a good
5 job of reiterating the substance and the nuance of what
6 you were trying to say in Chapter 7.

7 I thought that in the summary of the Executive
8 Summary -- you know how the Executive Summary is
9 structured with an introductory, you know, summary of the
10 summary and then the summary. And I think that in the
11 summary of the summary, which apropos of John's comments
12 may be all that people will get to, I think there you
13 weren't as successful just because of the wording on the
14 breast cancer. And so I would -- I wanted --

15 PANEL MEMBER BYUS: Where is that?

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: ES-4, I
17 think.

18 PANEL MEMBER BLANC: Yes.

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah,
20 you're right. We were not -- we will clarify that per our
21 new wording. That's the problem.

22 PANEL MEMBER BLANC: Can you go back and make
23 that wording, because you did in the latter part of the
24 Executive Summary.

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

1 PANEL MEMBER GLANTZ: And actually, there's like
2 multiple -- there's also an Executive Summary at the very
3 beginning of the document, and then there's the Executive
4 Summary at the beginning of Part B. And you need to just
5 go make sure all of those are totally consistent with each
6 other. And I realize they've been written at different
7 times and rewritten.

8 And when I went through it -- I mean -- and I
9 would, as Paul suggested, I would take like the clearest
10 language you have in any of them and use it in all of
11 them.

12 CHAIRPERSON FROINES: Gary had a comment.

13 PANEL MEMBER FRIEDMAN: One of the first slides
14 you showed was the conclusions you drew about
15 premenopausal and postmenopausal. You use the word
16 "inconclusive" for the postmenopausal. I'm just wondering
17 if you shouldn't say it's negative so far. The data you
18 showed the points just clustered around relative risk of
19 one. I think to say it's inconclusive, I'd say so far the
20 evidence is negative for postmenopausal.

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: We
22 actually used inconclusive throughout the entire document
23 rather than characterizing something as null or negative.
24 So it --

25 PANEL MEMBER BLANC: I think inconclusive is the

1 terminology that is consistent with how they have handled
2 all the other things. So I think that since inconclusive
3 means, by their definition in Chapter 1, which means that
4 yeah, maybe there are a couple of positive studies and
5 technically speaking there are --

6 PANEL MEMBER FRIEDMAN: If you want to show that
7 slide again, the ones that you have in black that you
8 consider the better studies were actually below 1.0.

9 PANEL MEMBER BLANC: Yeah, but again, I think
10 they should be consistent. So I'm very conservative in
11 this regard. I think to use the term "inconclusive" is
12 sufficiently negative for them to use that, since that's
13 the words that they use.

14 Because technically speaking for them to say
15 negative all of them would have to be below the line.
16 Inconclusive is consistent with the terminology as they've
17 set it out. I agree with you that this is negative, but
18 the thrust of their use of the term inconclusive is that
19 it's negative.

20 PANEL MEMBER FRIEDMAN: Well, I mean I read
21 her -- it's definitely positive for postmeno --
22 premenopausal women. But postmenopausal is still
23 inconclusive, more studies are needed. It sounds like --
24 and you just emphasized the positive. You say that there
25 are some positive studies. You don't say there's negative

1 studies too. So, I mean, I just feel -- you shouldn't go
2 out on a limb.

3 CHAIRPERSON FROINES: Would it be helpful if they
4 added part of the sentence that said that there are some
5 positive studies, but by and large most of the studies are
6 negative?

7 PANEL MEMBER BLANC: Generally, null. Generally
8 null is what it says.

9 PANEL MEMBER FRIEDMAN: Well, why do you point
10 out that the few of the lower quality studies show
11 elevated risk? Why not just say a few of the higher
12 quality ones, you show the reduced risk.

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: We could
14 just leave it at generally null.

15 PANEL MEMBER BLANC: Period.

16 CHAIRPERSON FROINES: That would be okay.

17 PANEL MEMBER FRIEDMAN: Yeah, I would feel better
18 about that.

19 CHAIRPERSON FROINES: Those are good comments.

20 Melanie, are you going to go on to Thun's
21 comments?

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

23 CHAIRPERSON FROINES: I just want to make one
24 comment about Thun's comments, the document that I sent
25 him, that he made these comments from was the document

1 that we used at the last meeting. He has not -- as far as
2 I know, he has not seen -- well, I don't know whether he's
3 seen it, but he hasn't commented on the most recent
4 version. So these comments reflect what was at the March
5 meeting.

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.
7 The Panel received the comments and our responses in their
8 packets. So I'm assuming everybody --

9 PANEL MEMBER GLANTZ: I just have -- are those
10 going to be added to the web site and to Part C in the
11 front of the document?

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, they
13 are an addendum to Part C, so they will be there.

14 We have more written down, clearly in our
15 responses to comments than I'm going to cover. So I'm
16 just kind of hitting the highlights.

17 Overall, Dr. Thun thinks the report describes the
18 evidence concerning breast cancer in a manner that
19 overstates the case. At this point, Dr. Thun still
20 considers the evidence limited rather than conclusive
21 according to IARC criteria, which he is careful to point
22 out.

23 --o0o--

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: And,
25 again, he's commenting on the previous draft. And in this

1 draft we clarified the conclusion as causal for younger
2 primarily premenopausal not postmenopausal women. We
3 discussed a lot of the issues he's brought up more clearly
4 in the latest draft, particularly the potential for
5 explanation by uncontrolled or unknown confounding, which
6 he has an issue with. And we believe the evidence is
7 sufficient for younger, primarily premenopausal women.

8 --o0o--

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: Dr. Thun
10 notes that the available data leave much room for
11 uncertainty. And he expressed concern about how
12 uncertainty was addressed in the document.

13 And he also thinks that the report does not
14 consider inconsistencies among the studies, and the
15 possibility of unmeasured factors correlated with ETS
16 influencing the results.

17 --o0o--

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: And our
19 response is that we routinely recognize and deal with
20 uncertainty in any health effects assessments. In the
21 case of ETS, we have real-world exposure data in humans,
22 so there is no extrapolation uncertainty from high dose to
23 low dose or from animal to human.

24 Throughout the document OEHHA focused on study
25 quality and reasons for inconsistencies in results. And

1 exposure assessment pops up time and again as being --
2 presenting problems for ETS study.

3 We also considered for each study the reported
4 effect estimate in the 95 percent confidence interval of
5 those estimates for each study. We note that most studies
6 controlled for major known risk factors, so that
7 confounder control was considered in the studies and in
8 our document.

9 And finally, we conducted meta-analyses for women
10 overall, all ages, and premenopausal younger women both
11 had pooled estimates above 1. And in both cases the 95
12 percent low confidence limit was greater than 1. So we
13 think we actually did a pretty good job of considering
14 uncertainty in the document.

15 --o0o--

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: Dr. Thun
17 and others, I might add, note that stating that recent
18 studies have consistently found elevated risk to be
19 misleading, since some recent studies find no association.

20 And the Panel members brought this up the last
21 time, the word "recent" we meant to being published after
22 the '97 report caused a lot of confusion. So we just
23 reworded that paragraph.

24 But we do note that within the younger
25 premenopausal strata findings of elevated risk, cancer

1 risk, from recent and older studies are consistent.

2 --o0o--

3 OEHHA SUPERVISING TOXICOLOGIST MARTY: Dr. Thun
4 comments that OEHHA attributes negative findings of
5 studies to misclassification of ETS exposure and inclusion
6 of ETS exposed in the referent population. However, he
7 notes that in the Reynolds' study, only active smoking is
8 associated with breast cancer risk. And this association
9 is unaffected by inclusion or exclusion of women with
10 household ETS exposure from the referent group.

11 --o0o--

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Reynolds
13 herself notes in her cohort that from the early eighties
14 onwards, the sources of ETS exposure come primarily from
15 outside the home, which that group did not evaluate.
16 Misclassification of those exposed to ETS at work or
17 outside the home as unexposed, could actually result in
18 failure to identify an association between ETS exposure
19 and breast cancer.

20 And while it's true that for active smoking it
21 didn't seem to make a difference what referent groups you
22 used. In fact, her referent group even the one that was
23 unexposed was actually exposed. And she, herself, notes
24 this.

25 So we don't think that's a reason to refute or

1 nullify any of the other studies that found an
2 association.

3 --o0o--

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: And this
5 gets to what we were discussing earlier, Dr. Thun notes
6 the magnitude of the effect of passive smoking is said by
7 us, I mean by us, to be similar to that of active smoking.
8 While this hypothesis may be biologically possible, it is
9 not typical for a dose response relationship.

10 --o0o--

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: We note
12 that it's more important to look at dose response evidence
13 within passive smoking studies and within active smoking
14 studies, rather than between them. ETS and mainstream
15 smoke are not identical nor are the exposures of passive
16 smokers and active smokers to specific toxicological
17 substances.

18 And we also note that non-linear dose response
19 relationships are not remarkable or unusual, lung cancer
20 from active smoking we talked about, and the magnitude of
21 coronary heart disease is similar comparing active and
22 passive smoking, so there's 2 examples.

23 PANEL MEMBER BLANC: Yeah. It might be more
24 conservative to simply say are not without precedent. I
25 don't know. My, you know, definition of those other

1 things is of what's common and what's remarkable or
2 what's --

3 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

4 PANEL MEMBER BLANC: -- just diplomatic.

5 CHAIRPERSON FROINES: That's good.

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

7 --o0o--

8 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay. Dr.

9 Thun thinks that we didn't emphasize the cohort studies
10 enough. So one of his comments was that Reynolds, Egan
11 and Wartenberg cohort studies were dismissed as invalid
12 because of poor exposure assessment.

13 And he also notes that if it's true that duration
14 of exposure is important, which is seen in some studies,
15 then these cohort studies that evaluated duration of
16 exposure in a adulthood, which is Egan and Wartenberg,
17 should have been able to detect an effect.

18 --o0o--

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: Several
20 studies, mostly case controlled, but some cohorts, found
21 evidence of dose response with either duration or
22 intensity or both. And that includes Hanaoaka, which is
23 the recently reported Japanese cohort, and Jee, another
24 cohort study.

25 And we responded, we did not at all dismiss the

1 CHAIRPERSON FROINES: Any comments, questions?

2 PANEL MEMBER BYUS: I just think this is a
3 tremendous discussion to read it here. The very, very
4 critical thinking on both sides, for a very complex issue.
5 And I think you did a great job answering all of the
6 concerns. So I'm very pleased with it. It was great,
7 John, that you got him to comment here. I think this
8 really adds a level of critique to the document that is
9 very valuable.

10 PANEL MEMBER FRIEDMAN: Can I just ask for a
11 point of information. When you talk about the
12 similarities between active and passive smoking with
13 regard to risk of coronary disease, what is the risk for
14 passive smoking that you're referring to? I thought there
15 was a difference.

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: You know,
17 I meant to look that up.

18 PANEL MEMBER GLANTZ: Well, there is a
19 difference, but it's just not huge. You know, the
20 relative risks for passive smoking are about 1.3. And the
21 relative risks for active smoking are 2 to 4. But the
22 dose --

23 PANEL MEMBER FRIEDMAN: That's pretty different
24 to me.

25 PANEL MEMBER GLANTZ: Right, but the point is the

1 dose that the passive smokers get is like 1 percent. So
2 there's no proportionality. So they're not similar
3 magnitude. I mean the risks are different, but they're
4 not different in proportion to the dose, which is, I
5 think, what they're trying to say.

6 OEHHA SUPERVISING TOXICOLOGIST MARTY: Maybe I
7 overstated that.

8 PANEL MEMBER HAMMOND: Stan, I have to disagree.

9 PANEL MEMBER GLANTZ: With what?

10 PANEL MEMBER HAMMOND: About the does difference
11 between active and passive smoking. I'm saying this all
12 the time, right, that it depends on which chemical you're
13 looking at. For nicotine it's a 1 percent, for biphenyl
14 it's 15 percent. However, I think more to the point is
15 we're used to looking at the lung cancer relative risks,
16 which are what relative risk at 10 to 20 for active
17 smoking and 1.4 for passive smoking.

18 And so there's that sense that you expect to see
19 this huge difference, but we turn around and we know that
20 cardiovascular disease at that point 2.4 and 1.3 look very
21 similar, compared to the lung cancer.

22 PANEL MEMBER FRIEDMAN: Sure.

23 CHAIRPERSON FROINES: Joe.

24 PANEL MEMBER LANDOLPH: I think you did a
25 fantastic job, Melanie, and the staff scientists. I

1 looked at this chapter over many, many meetings. And you
2 condensed it as I asked you to and others have, and even
3 further still beyond that, and added all the comments.
4 I'm not too worried. I was initially worried about the
5 magnitude of the effects with the passive smoking and the
6 active smoking, because like Thun, I thought one should be
7 a small marker on the curve than the other. But that's
8 not necessarily true. They may be very different animals.

9 I think you've addressed Thun's comments -- Dr.
10 Thun's comments -- very well. You're not obligated to
11 accept his point of view, but you did what you had to do,
12 which is listen with an open mind to the comments and
13 accept those what you thought was correct.

14 So I think this chapter is getting pretty
15 complete. I think we're going to the point of diminishing
16 returns if a lot more work is invested in this. I think
17 it's pretty much close to being ready to go now, from my
18 point of view.

19 And I particularly like Figure 7.4.4 in the Table
20 7.4.1G and the Dose Response Table 7.4.1H, which shows a
21 dose response. I think that makes it crystal clear as to
22 the difference between the active and the passive smoking.
23 And passive smoking in premenopausal and postmenopausal
24 women, I think, that makes that issue very clear for me.

25 CHAIRPERSON FROINES: Kathy.

1 PANEL MEMBER HAMMOND: Just I think you've done a
2 great job. Thank you. I think this is major contribution
3 to the literature.

4 PANEL MEMBER GLANTZ: I agree.

5 PANEL MEMBER PLOPPER: I agree. I think they did
6 a great job.

7 PANEL MEMBER FRIEDMAN: I'm pleased. I'm just
8 looking forward to that one additional thing, which we can
9 take without having to hold up the vote.

10 CHAIRPERSON FROINES: Dr. Blanc.

11 PANEL MEMBER BLANC: Well, can I ask you to do
12 one thing, if it's possible, on the lengthy Table 7.0B,
13 which starts on page 7-3 and goes on to the next 5 pages.

14 PANEL MEMBER GLANTZ: You'd like it condensed to
15 one page.

16 (Laughter.)

17 PANEL MEMBER BLANC: Yeah, put that in font 6.

18 The very last row, 10, Miscellaneous. That is
19 very strangely placed. It is, after all, organic
20 chemicals. So you've got all the organics. You've got
21 all the metals, and then you've got this as if it was, you
22 know, some noncarbon based non, you know, metal. Could
23 you just put that somewhere else, please.

24 (Laughter.)

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Sure.

1 CHAIRPERSON FROINES: Which one are you talking
2 about?

3 OEHHA SUPERVISING TOXICOLOGIST MARTY: The very
4 last entry to table 7.0B is under miscellaneous and then
5 we put methyl acrylate.

6 CHAIRPERSON FROINES: Why do you have it in
7 miscellaneous?

8 OEHHA SUPERVISING TOXICOLOGIST MARTY: I can't
9 answer that.

10 CHAIRPERSON FROINES: It's an organic.

11 PANEL MEMBER BLANC: If it doesn't fit in the
12 organic chemicals, then you have classes, you should
13 carefully just put other organics or something which just
14 kind of identify it.

15 PANEL MEMBER BYUS: At least you put on there
16 miscellaneous.

17 PANEL MEMBER GLANTZ: I just had -- did you have
18 anything else, Paul?

19 PANEL MEMBER BLANC: That wasn't trivial enough.

20 (Laughter.)

21 PANEL MEMBER GLANTZ: I just have a couple of
22 little points, beyond what I already sent them.

23 In Table 7, these are just points I was confused
24 by. On table 7.0A on the very first page, if you look at
25 the breast cancer with your additional studies thing, it

1 kind of looks like the 7 meta-analysis is only applying to
2 younger premenopausal. And I don't think that's what you
3 mean.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: No.

5 PANEL MEMBER GLANTZ: So what I would suggest you
6 do here is put a blank line between the line that says
7 breast and the line that says younger, so it's clear that
8 you know that -- and then the one other thing was if you
9 look on page -- oh, wait, I'm sorry. Let me see what this
10 says on it.

11 And then if you go to page 141, and you look at
12 the statement -- and this is sort of getting, I guess, at
13 what Gary was talking about earlier. The very end you
14 say, "In contrast to the findings in younger women in
15 studies which reported statistics for women diagnosed with
16 breast cancer after menopause. A null association...is
17 apparent", which is what Gary was saying.

18 But then if you go to page 153, at the bottom
19 that's where you have the, "We conclude further research
20 is necessary, and the evidence to date is inconclusive."

21 So I think you need to just have those -- I think
22 the earlier discussion that Gary led ended up with a
23 reasonable consensus on how to deal with this. But these
24 2 statements should be made consistent with each other.
25 Because in one place you're making a null statement, and

1 in the other place you're saying more research is needed.

2 PANEL MEMBER HAMMOND: You're saying the
3 consistency statement should be consistent with the
4 summary statement.

5 PANEL MEMBER GLANTZ: Yeah.

6 PANEL MEMBER FRIEDMAN: If I ever saw data that
7 supported a null, a no association, that's what you showed
8 up there, that doesn't look inconclusive to me. That
9 looks null.

10 PANEL MEMBER GLANTZ: Well, I think that in
11 terms -- the point Paul made about the language that's
12 being used throughout the report, I think it's okay for
13 the formal conclusion to be inconclusive, but I also think
14 it's reasonable in the report to say what you said on page
15 141 about it being null.

16 PANEL MEMBER FRIEDMAN: What does -- I'm sorry to
17 drag this on, but what -- you know, aren't the data about
18 premenopausal inconclusive too because they bounce around
19 a little bit? I mean, I don't understand what
20 inconclusive means.

21 PANEL MEMBER GLANTZ: Well --

22 PANEL MEMBER FRIEDMAN: You know, it sort of
23 sounds like, well, I think there's something there, but
24 you know, we can't say anything yet. But I still am
25 suspicious. I mean I just don't get it.

1 PANEL MEMBER BLANC: Well, that would be their
2 category, which is suggestive. They have the 3 tiers.

3 PANEL MEMBER FRIEDMAN: Have they defined
4 inconclusive very clearly?

5 PANEL MEMBER BLANC: Yeah, at the beginning.

6 PANEL MEMBER GLANTZ: In Chapter 1. I just think
7 you need to make those consistent with each other and
8 consistent with the discussion that we had earlier with
9 Gary.

10 CHAIRPERSON FROINES: So I think it's --

11 PANEL MEMBER GLANTZ: I mean I think -- just to
12 be picky, I think to draw a null conclusion -- to draw a
13 negative conclusion, you need to do a power calculation,
14 you know, and all kinds of other stuff that we don't want
15 to bother with.

16 CHAIRPERSON FROINES: But I think --

17 PANEL MEMBER GLANTZ: So I think what -- if you
18 take what you wrote on page 141 and combine it with the
19 results that came out of the earlier discussion and make
20 sure that page 153 is consistent with that, everybody will
21 be happy.

22 CHAIRPERSON FROINES: And state that what that
23 will mean.

24 PANEL MEMBER GLANTZ: I think that it will -- I
25 mean, if you go back to the changes people agreed to

1 during the discussion Gary led, I think that you can make
2 page 141 and 153 match with the consensus that came out of
3 Gary's discussion.

4 CHAIRPERSON FROINES: Which will mean that there
5 will be some emphasis on null.

6 PANEL MEMBER GLANTZ: Well, I think that in the
7 table the formal conclusion using the categories of
8 Chapter 1 will be inconclusive. But in the text, I think
9 this statement here that looks -- says it looks like it's
10 null is an appropriate thing to include, which is a
11 further kind of explanation what it means in this case.

12 CHAIRPERSON FROINES: Gary, is that --

13 PANEL MEMBER FRIEDMAN: (Nods head.)

14 PANEL MEMBER BLANC: Let me give you an example
15 of what wording in that last sentence on 153, Melanie,
16 would be consistent with a null statement. Here's where I
17 think people are getting thrown off. Instead of the
18 current wording, which is, "Nonetheless, we conclude that
19 further research is necessary to characterize ETS
20 associated breast cancer risks in postmenopausal women and
21 the evidence to date is considered inconclusive."

22 If the beginning of the sentence said something
23 like, "Therefore we conclude that further research
24 indicating a positive association would be necessary in
25 order to move beyond an inconclusive finding" or something

1 like that. Because, you know, basically it's the flip
2 side of what you're saying.

3 This sentence suggests that there's more there
4 than there is there. So what you're really saying is not
5 we're -- this is more of a statement than one would expect
6 after a suggestive association. I think that's what's
7 throwing people off.

8 When you said it's inconclusive, basically you're
9 saying less -- further research starts going in the other
10 direction. It would be difficult to move beyond this
11 being null, inconclusive. Just a few words to change it.
12 Do you see why people are null? Do you see why people are
13 getting a little confused by the tone of that sentence?

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think
15 so.

16 PANEL MEMBER BLANC: So I think you could tweak
17 it with just a few words.

18 CHAIRPERSON FROINES: But let's work out the --
19 words right now, because I don't want -- this is a
20 fundamental issue and that we should not have this --
21 after we voted, we shouldn't have this come back to us.
22 Because if somebody doesn't like it, it then says we do
23 need another meeting to resolve the issue. So I think we
24 should come up with the language right now, so that we're
25 all happy with how it's phrased.

1 PANEL MEMBER HAMMOND: May I take 3 steps
2 backwards in that case since we're going to do this.

3 I think that I'm just going to naive question.
4 And that would be given your review of the literature, do
5 you believe we have a good understanding of the
6 relationship between ETS and postmenopausal breast cancer?

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: I would
8 say no.

9 PANEL MEMBER HAMMOND: So if that's true, then
10 I'm just taking this global view, then that says to me
11 more research is needed. Is that a. --

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes. I
13 don't know if you want an explanation or why I'm saying
14 no.

15 PANEL MEMBER HAMMOND: What?

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: I don't
17 know if you want an explanation on what I said.

18 PANEL MEMBER HAMMOND: So then I just want to do
19 it in steps. So my thought would be that -- I think this
20 is in the nature of what we did last meeting, when we
21 started moving and separating them, and then look at how
22 strong this evidence was.

23 What we perhaps haven't done as carefully is
24 looked at the limitations of the evidence in the post and
25 articulate them. I think you have done it in your head

1 and you understand it. But maybe it needs to be
2 articulated. And I don't want to draw this out, but I'm
3 just thinking that if --

4 CHAIRPERSON FROINES: Be careful because you're
5 heading in that direction. You're heading --

6 PANEL MEMBER HAMMOND: I just realized that.

7 CHAIRPERSON FROINES: You're heading in a
8 direction that's going to require another meeting.

9 PANEL MEMBER HAMMOND: Let me just ask if the
10 limitations that you see in the postmenopausal breast
11 cancer are such that you could actually kind of list them
12 quickly or is that something that would take some going
13 over the literature to do?

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think it
15 would take a little more than me to try to do it off the
16 top of my head or off the cuff.

17 PANEL MEMBER HAMMOND: All right. It has struck
18 me that the weight of the whole approach has been to look
19 at the sound science is and not to articulate that. But I
20 actually feel -- to me it's important just to have that
21 sense of the -- because I know you know this literature
22 inside out and your paper is so much better -- that the --
23 if the feeling is the inconclusive results are due, not to
24 the fact that they're truly null and includes those that
25 are null, but rather the limitations of the studies. I

1 think we could just say that. The studies have
2 limitations, many of which are reflected in the general
3 limitations we talked about previously, and the
4 epidemiology, such as exposure misclassification and
5 things like that.

6 If we were to put that in. -- because what I
7 would like to see coming out of this in terms of public
8 health is if the distinction made right now between we
9 have a lot of -- and that study is done and an analysis of
10 that tells us there's nothing more to look at
11 postmenopausal or the research world has to continue to
12 look at that. I think that's what needs to be done.

13 PANEL MEMBER GLANTZ: I have some suggested
14 words. Okay, what I would do on page 141 --

15 CHAIRPERSON FROINES: I just want to say one
16 thing about what Kathy said and then you can go ahead.

17 I think that the evidence that we have before us
18 on the postmenopausal women, recognizing the difficulties
19 within the studies, are null. And so that if we are going
20 to start doing an internal evaluation of the complexities
21 of the study, that opens Pandora's Box.

22 PANEL MEMBER GLANTZ: I don't think we have to do
23 that.

24 CHAIRPERSON FROINES: And I think that we don't
25 want to do that frankly, but I think we want to respect

1 the fact that based on the evidence before us, the studies
2 do appear to be null.

3 PANEL MEMBER GLANTZ: Well, let me make the
4 following suggestion. And, in fact, they do what you just
5 said if you read the whole paragraph on page 153, but what
6 I would suggest is on page 141, to change the thing at the
7 end to say, "In contrast to the findings in younger women,
8 in studies which reported statistics for women diagnosed
9 with breast cancer after menopause, cluster around a null
10 association."

11 So the better -- you know, you could word it more
12 artfully. But to simply say, there where you're
13 describing the Epi studies just to say they cluster around
14 null.

15 And then on page 153, you have to -- I mean, the
16 paragraph we're talking about says sort of what you're
17 saying, John. It says, "The evidence of an association
18 between ETS exposure and elevated breast cancer is more
19 persuasive for those diagnosed" -- in fact, I would take
20 the word "more" out. I would say "...are persuasive for
21 those diagnosed at younger ages..." "There were 9 studies
22 from which we could extract breast cancer risks for
23 postmenopausal women. Except for 2 statistically
24 significant elevated risk estimates, these studies showed
25 either slightly elevated, but non-significant or null

1 results for overall postmenopausal strata. There are,
2 however, elevated risks estimates in some studies for
3 postmenopausal women either overall or in specific strata.
4 In addition, it should be noted that there are many
5 studies that show statistically significant elevated risks
6 for breast cancer in postmenopausal active smokers."

7 So that's paragraph. Then I would change the
8 last sentence to read something like, "Because the results
9 cluster around the null, however, at this time, we
10 conclude that the evidence associating ETS with breast
11 cancer in postmenopausal women is inconclusive."

12 CHAIRPERSON FROINES: I would argue, Stan, I
13 think that there's simple way to do this. And I think
14 that the sentence that's underlined on page 153 is fine.
15 I would simply move the last sentence on 141 to be the
16 last sentence on 153, and I think that deals with the
17 whole issue.

18 PANEL MEMBER GLANTZ: Well, you could do that
19 too.

20 PANEL MEMBER BYUS: I agree.

21 PANEL MEMBER GLANTZ: That's a good way to do it.
22 It just repeats --

23 CHAIRPERSON FROINES: So it's said twice, that's
24 fine.

25 PANEL MEMBER GLANTZ: Yeah, that's fine. I'm

1 happy with that too.

2 PANEL MEMBER HAMMOND: So you'd have both
3 sentences, John?

4 CHAIRPERSON FROINES: Yeah. One says
5 inconclusive, which means Paul's question about Chapter 1.
6 And the second draws the somewhat harder conclusion that
7 the studies are null. So it's the whole -- we are
8 internally consistent with that.

9 And I think that makes it very simple, because
10 it's just moving literally 1 sentence from one --

11 PANEL MEMBER BLANC: Or repeating it.

12 CHAIRPERSON FROINES: Repeating it.

13 PANEL MEMBER GLANTZ: I would repeat it. I
14 wouldn't move it.

15 PANEL MEMBER FRIEDMAN: Is that consistent in the
16 Executive Summary too?

17 CHAIRPERSON FROINES: Well, they'll have to make
18 sure that that is consistent.

19 PANEL MEMBER BLANC: That's a simple solution.

20 PANEL MEMBER HAMMOND: In the end, will there be
21 2 Executive Summaries as there are now or just one? I
22 mean, since Part A actually becomes Chapter 2 in this
23 document, is there just one Executive Summary then for the
24 entire document? Because I was unclear which Executive
25 Summary we're supposed to have.

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: We have an
2 Executive Summary for Part B, and then there's an overall
3 Executive Summary for A and B.

4 PANEL MEMBER HAMMOND: But what will the final
5 document have? They won't be those 2 Executive Summaries
6 I hope?

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: There will
8 be and they are -- there's an ARB --

9 PANEL MEMBER GLANTZ: That's always the way it's
10 been. There's an Executive Summary for Part A. There's
11 an Executive Summary for Part B. And there's an overall
12 Executive Summary.

13 PANEL MEMBER HAMMOND: Forgive me.

14 CHAIRPERSON FROINES: Joe.

15 PANEL MEMBER LANDOLPH: Melanie, underneath that
16 postmenopausal issue, are you guys worried about the fact
17 that there might be lurking a small fact that just it's
18 too difficult to measure with precision?

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes. And
20 the reason we're worried about that, a couple of the
21 studies showed they didn't separate out by menopausal
22 strata. They showed that women exposed to ETS from
23 spousal smoking greater than 27 years, greater than 30
24 years, a couple of different studies, had elevated risk
25 estimates. Unless those women got married when they were

1 10, they're very likely postmenopausal.

2 PANEL MEMBER LANDOLPH: And the word
3 "inconclusive" in there leaves it open and you can go
4 ahead.

5 CHAIRPERSON FROINES: And a couple positive
6 studies does not make a positive finding.

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: Exactly.

8 PANEL MEMBER FRIEDMAN: Because you don't mention
9 there's a couple negative studies too.

10 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

11 CHAIRPERSON FROINES: So I think that, unless I'm
12 mistaken, my copying that sentence and putting it there
13 will resolve the issue. And unless there's some
14 opposition, I think we should move ahead.

15 PANEL MEMBER FRIEDMAN: Okay.

16 CHAIRPERSON FROINES: So where are we at in terms
17 of the rest of the document?

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay,
19 there's --

20 CHAIRPERSON FROINES: It's 12:16 --

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: -- Chapter
22 4 and Chapter 5 we have not presented the overview to the
23 Panel. I note we haven't got -- we have gotten no public
24 comment on Chapter 5 and we have gotten no comments from
25 the Panel on chapter 5. And we got a public commenter on

1 Chapter 4, mostly related to the issue of whether or not
2 ETS is associated with SIDS.

3 Chapter 4 was perinatal manifestations. It
4 focused primarily on SIDS. We have a conclusive finding
5 in the '97 report on SIDS. We have a conclusive
6 strengthened finding in this report on SIDS. And we have
7 a suggestive finding of possible cognitive and
8 neurobehavioral effects in this document, based on 2
9 studies.

10 CHAIRPERSON FROINES: And do you want to present
11 slides to that effect or do you --

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: I could do
13 that very quickly.

14 CHAIRPERSON FROINES: What's the choice of the
15 Panel? I mean we can except it without the presentation
16 or we can have a presentation.

17 I think for completeness sake, I think it would
18 be -- and the record, I think it would useful to have a
19 presentation. Is that all right with everybody?

20 PANEL MEMBER BLANC: And then after we conclude a
21 discussion for this, what is the overall schedule?

22 CHAIRPERSON FROINES: My sense is after we have
23 this discussion, we'll break and eat, then we'll make any
24 final conclusions or discussion we want to have. And if
25 we then vote on this document with the changes that we'll

1 hear in the future, we'll then spend some time talking
2 about the Findings.

3 Are you comfortable with that?

4 PANEL MEMBER BLANC: (Nods head.)

5 CHAIRPERSON FROINES: Melanie, you're on.

6 --o0o--

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: Chapter 4
8 dealt with Developmental Toxicity to be a particular
9 postnatal manifestations.

10 This summary table indicates that there are
11 conclusive Findings for SIDS -- an association between ETS
12 and SIDS was strengthened with the update. There are
13 still suggestive findings of cognition and behavior. And
14 everything else was either inconclusive or some indication
15 of potential CNS changes based on the animal model that
16 was not human data.

17 --o0o--

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: There are
19 a number of studies that looked at SIDS. This slide just
20 shows some evidence of dose response by cigarettes per
21 day, smoked by the mother or by the father or by others in
22 a number of studies. And indicates that smoking plus bed
23 sharing results in a very large risk, at least in
24 Carpenter 2004.

25 So the upshot is there is evidence of dose

1 response, and that is postnatal ETS exposure on top of the
2 prenatal ETS exposure, so there's a distinct effect.

3 --o0o--

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: Anderson
5 and Cook conducted a meta-analysis, and they, in 1997,
6 published this and find an OR for SIDS of 1.94, noting
7 that after controlling for prenatal smoke exposure you
8 still have elevated SIDS risk and you also have elevated
9 SIDS risks when only the father smoked, which indicates an
10 effect of postnatal ETS.

11 It also can be noted that nicotine or cotinine
12 was elevated in the pericardial fluid of SIDS victims
13 relative to babies dying of other causes. That was noted
14 in 3 studies.

15 --o0o--

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: And there
17 were 3 studies that looked -- new studies that looked at
18 affects on cognition of behavior. One looked at
19 significant -- found significant inverse correlation
20 between scores on reading, math, and block design and
21 serum cotinine levels. That was published this year.

22 Another found an elevated odds ratio for conduct
23 problems in children of smoking mothers. And that the
24 risk went up a little bit with persistent maternal
25 smoking. In other words, they looked at 5 years olds and

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: No, not
2 this study. I have more complex slides if you want to get
3 into that.

4 PANEL MEMBER BLANC: No, but it is a problem as
5 opposed to -- well, actually it is an issue, when --
6 you're calling this a developmental toxicity health
7 effect.

8 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

9 PANEL MEMBER BLANC: So you're including
10 perinatal development?

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah,
12 right. We would not just -- development toxicity could
13 happen in at adolescence. It just means that during any
14 stage of development you could see a toxic effect.

15 PANEL MEMBER BLANC: So why isn't your whole
16 childhood asthma thing a developmental toxicity?

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, you
18 could consider that development toxicity.

19 PANEL MEMBER BLANC: Is this a standard
20 definition of developmental toxicology?

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: There
22 are -- yes, it actually --

23 PANEL MEMBER BLANC: I know we have it, but
24 refresh my memory.

25 PANEL MEMBER BYUS: I had this exact

1 discussion --

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, it
3 actually is. And Dr. Plopper could probably chime in her,
4 but you can look at -- you look at prenatal development
5 and you look at the postnatal development separately, and
6 lots of people do. But it's really a continuum all the
7 way until maturity.

8 PANEL MEMBER BYUS: If not at the way through
9 geriatrics, if you care to continue that way, which I
10 think we should be focusing on considerably.

11 (Laughter.)

12 OEHHA SUPERVISING TOXICOLOGIST MARTY:
13 Considering how old we're getting.

14 PANEL MEMBER BYUS: Yes.

15 (Laughter.)

16 PANEL MEMBER BLANC: And because this -- I mean
17 this is harder to track because it doesn't have -- because
18 we didn't discuss it last time, so there aren't underlying
19 things that are revisions from the previous versions, this
20 is essentially the version that we received did not
21 discuss directly in the last meeting, which is probably
22 I'm going back to what we've already discussed.

23 But would it help to either have one sentence
24 that said, "We continue to use the same definition of
25 developmental that we used in the '97 document for

1 consistency, to wit, this subsumes both prenatal
2 development and perinatal development and childhood
3 development."

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: We
5 actually have the first page of Chapter 4 discusses
6 essentially that.

7 OEHHA DEPUTY DIRECTOR ALEXEEFF: I have a
8 comment. George Alexeeff.

9 Paul, we generally divide developmental toxicity
10 in kind of 2 components, since we have different programs,
11 but there is -- which is why we had these chapters written
12 the way they were. There's one on prenatal exposure and
13 then any effects that occur from that prenatal exposure
14 whenever they're expressed are considered developmental
15 toxicity, because it's thought that the insult occurred,
16 you know, to the fetus.

17 Then the U.S. EPA has a definition that basically
18 covers the second part, which is that developmental
19 toxicity is any toxicity that occurs up through
20 adolescence, and that's what this is actually covering
21 here, up through adolescence.

22 PANEL MEMBER BLANC: Well, where is the previous
23 chapter?

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: Chapter 3
25 covered birth weight, low birth weight pre-term delivery,

1 inter-uterine growth, retardation.

2 PANEL MEMBER BLANC: So it's actually postnatal
3 exposures not manifestations.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

5 OEHHA DEPUTY DIRECTOR ALEXEEFF: Chapter 3 is
6 prenatal exposure.

7 PANEL MEMBER BLANC: Right, but Chapter 4 which
8 has got the subheading 2 postnatal manifestations. These
9 are postnatal exposures not manifestations.

10 OEHHA DEPUTY DIRECTOR ALEXEEFF: Yes.

11 PANEL MEMBER BLANC: Yes.

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think
13 part of the issue was that for SIDS, there is definitely
14 an effect of prenatal exposure and there's a separate
15 effect of postnatal exposure. People have been separating
16 it out.

17 PANEL MEMBER HAMMOND: So does Chapter 4 actually
18 include both prenatal exposure with postnatal
19 manifestations and postnatal exposure and postnatal
20 manifestations?

21 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, it
22 does. That's what I was getting at. Because, you know,
23 when a mother is smoking during pregnancy and then she
24 continues to smoke afterwards, it gets difficult to
25 separate that out, unless you have specific cases where it

1 was --

2 PANEL MEMBER HAMMOND: The epidemiology is the
3 way most things work. It's much more common to have
4 people -- women quit smoking during pregnancy and then
5 resume smoking afterwards, than to smoke through pregnancy
6 and quit after the birth. That's a rare event. Rare
7 enough that it's hard to believe you could do an
8 epidemiology study on.

9 OEHHA DEPUTY DIRECTOR ALEXEEFF: George Alexeeff
10 again. Because of our other programs, particularly
11 referring to Proposition 65 programs, which particularly
12 we've defined or counsel's defined it as exposures prior
13 to birth. Okay, so we had to separate those out in this
14 document.

15 So in those cases where the exposure covers both
16 areas, both prenatal and postnatal, we've pretty much put
17 those in the postnatal chapter, because you can't separate
18 them, and it's not clear, although the exposure
19 occurred -- well, the exposure occurred prenatally to the
20 exposure and postnatally, we're not sure if the effect is
21 due to either one or the other or both.

22 PANEL MEMBER HAMMOND: Of course. So maybe what
23 we need to do is for clarification is call this Roman
24 Numeral II, would be postnatal manifestation and prenatal
25 and postnatal exposures; is that correct?

1 PANEL MEMBER BLANC: Yes, that sounds like what
2 they're doing.

3 OEHHA DEPUTY DIRECTOR ALEXEEFF: Right. We've
4 teased it out when -- the authors have teased it out, but
5 we've been teasing it out.

6 PANEL MEMBER HAMMOND: Right. The chapter can
7 tease it. But as a heading we can say it's a prenatal and
8 postnatal exposures. So in the chapter you tease it out,
9 you could, right. But the title is not clear, is
10 postnatal manifestations, but it's not --

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: The
12 postnatal manifestations of ETS exposure, which could be
13 pre or post. So we could just put postnatal
14 manifestations of ETS exposure. And then it's discussed
15 within all of the studies for that section.

16 PANEL MEMBER BLANC: I actually prefer Kathy's
17 suggestive wording, which is postnatal exposures of pre or
18 postnatal -- postnatal manifestations of pre or postnatal
19 exposures. Because I think you're assuming too much of
20 the casual reader in terms of the nuance of the regulatory
21 and other nuances of what developmental is in the top
22 heading. This really makes it clear that you're -- that
23 the exposure need not include prenatal for you to think
24 that it's a developmental issue.

25 OEHHA DEPUTY DIRECTOR ALEXEEFF: Just another

1 point as for clarification, because there was a comment
2 made with regard to the mother stopping smoking during
3 pregnancy. Active smoking is not considered in the
4 prenatal exposure. It's all -- we're all talking ETS
5 exposure, not active smoking.

6 CHAIRPERSON FROINES: I think, George, that your
7 counsel is wrong, and you should take a case and pursue
8 it. If you could sue, maybe you can get a decision, but
9 you're letting lawyers define science. And that science
10 that they're defining isn't correct.

11 OEHHA DEPUTY DIRECTOR ALEXEEFF: No comment.

12 CHAIRPERSON FROINES: I think it's a serious
13 issue, because the issue of pre and postnatal exposures is
14 a major area for research, as far as I'm concerned. And
15 to the degree that we start to simplify the science for
16 what is obviously a legal decision is really unfortunate.

17 OEHHA DEPUTY DIRECTOR ALEXEEFF: Well, it's
18 not -- yeah, what I stated is basically the interpretation
19 of the statute that was a proposition that was adopted by
20 the citizens.

21 CHAIRPERSON FROINES: You shouldn't comment. You
22 should stay with your no comment. Let me comment, because
23 I can say it, and you don't have to get yourself in
24 trouble.

25 Go ahead, Melanie.

1 --o0o--

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: We did get
3 a few public comments on this chapter primarily on SIDS.
4 One is that prenatal maternal smoking is a major
5 confounder.

6 And our responses include that the effects are
7 seen after confounder control. The effects are seen with
8 paternal or other only smoking in the household. And also
9 after controlling for maternal smoking. That pericardial
10 nicotine and cotinine is associated significantly with
11 SIDS' death. That there is dose dependent increases in
12 SIDS risk with increased ETS exposure in a number of
13 studies. And that higher risks were noted in at least 2
14 studies when the baby is in the same room as the smoker.

15 CHAIRPERSON FROINES: Melanie, I have just one
16 question and it reflects the fact that I haven't read
17 carefully what's in the Executive Summary. I think this
18 new SIDS evidence, especially that associated with dose
19 response, is an important new finding. And hopefully,
20 you've got that in the Executive Summary emphasizing it,
21 to some degree, as well as having it in the main document.

22 This is an nice table or figure, and I think it
23 deserves some -- to make sure -- this will come up when he
24 get to our Findings, which I think are deficient. There
25 is new evidence that we need to make sure that where it's

1 particularly relevant it needs to have some emphasis in
2 the Executive Summary, as well as the full document, so it
3 doesn't get lost.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

5 PANEL MEMBER HAMMOND: Can this figure be put in
6 the chapter.

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, isn't
8 that in the chapter?

9 PANEL MEMBER HAMMOND: I was trying to find it
10 and I didn't see it.

11 PANEL MEMBER BLANC: Can I bring up a point that
12 jumps off from John's comment. And it has to do with the
13 methodology that you used and the methodology that you
14 used in 1997. The observation that none of the findings
15 that you found to be conclusive in the 1997 report have
16 needed to be downgraded to suggestive on the accumulation
17 of another decade of data. And that, in fact, in many
18 cases the further evidence for those things which were
19 already conclusive are even more convincing, if anything.

20 That observation I think tends to strengthen the
21 entire process and document, and therefore, is relevant.
22 There is really no place to say it except in the Executive
23 Summary. And it's certainly relevant to the SIDS' story.
24 And I would say another example would be childhood onset
25 of otitis media and asthma where before there were 30

1 studies and now there are 60 or whatever it is.

2 So that might be worth saying succinctly in the
3 Executive Summary. It's inherent, but it's kind of --
4 unless you look at it that way, it's not.

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay. We
6 can look at it.

7 PANEL MEMBER BLANC: Because if you'd been doing
8 something wrong methodologically the last time around,
9 this time it would have shown up, right, if you were too
10 cavalier, and you'd have to reverse yourself on something.

11 CHAIRPERSON FROINES: That's very important, I
12 think, to have as a major conclusory restatement in the
13 Executive Summary.

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

15 CHAIRPERSON FROINES: To have given examples in
16 the Executive Summary that illustrate it.

17 PANEL MEMBER GLANTZ: Yeah, we should probably
18 include in the Findings too.

19 CHAIRPERSON FROINES: Yeah.

20 PANEL MEMBER BLANC: Yeah. Good point.

21 CHAIRPERSON FROINES: Yeah. Let's not get to the
22 Findings.

23 --o0o--

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

25 Another comment came in that Anderson and Cook the

1 meta-analysis which found a significant effect can't
2 control for confounding, and that there's a high
3 correlation of maternal pre and postnatal smoking. And
4 Anderson and Cook actually did take a subset analysis of
5 studies where prenatal smoking was absent or at least
6 controlled for. And they still get elevated risk
7 estimates of this. Just another example.

8 --o0o--

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: And,
10 again, another comment that other confounding factors may
11 actually account for SIDS risks in ETS exposed babies.
12 But we know that the consistency of the association across
13 several different studies after adjustment for multiple
14 confounders reduces greatly the plausibility that the SIDS
15 ETS association is wholly explainable by confounding.

16 --o0o--

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: And that's
18 it.

19 PANEL MEMBER BYUS: I have one quick question.

20 CHAIRPERSON FROINES: Craig.

21 PANEL MEMBER BYUS: I'm sure they did, but did
22 they control for whether the baby was laid on its back or
23 face down, because this is the big thing now. When I
24 raised my children you were thought to be ignorant if you
25 placed you baby face down. And now they're telling

1 recently -- not so recently, but, in fact, that is exactly
2 the opposite thing to do. You're supposed to place your
3 baby on the back.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: The newer
5 studies did control for that. The older studies of course
6 didn't, because they didn't realize that was an effect.

7 PANEL MEMBER BLANC: In terms of this chapter and
8 the one that precedes it, there's a statement in the
9 Executive Summary related to the requirements for
10 childhood -- children being a sensitive subpopulation,
11 where you say, you know, we -- I forget where it's at in
12 the executive summary.

13 Now, I understand why having been so close to
14 this that it's sort of like a no-brainer for you. But, in
15 fact, you don't say why that's the case.

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, you
17 have some --

18 PANEL MEMBER BLANC: In the Executive Summary.

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: Oh, in the
20 Executive Summary we don't say that. We could add that.

21 PANEL MEMBER BLANC: So clearly since adults
22 don't get SIDS, and SIDS is only a phenomenon found in
23 young children, if you had no other health outcome but
24 that, that would meet the criteria for -- the legislative
25 criterion for children being named a sensitive

1 subpopulation. Is that a reasonable statement?

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah,
3 that's right.

4 PANEL MEMBER BLANC: You can't do it very easily
5 on the basis of cancer risk, because you don't really
6 have, you know, conclusive data for that. The asthma, I
7 supposed you could make the argument, because the relative
8 risks for asthma with ETS are generally higher in children
9 than the estimated relative risks in adults, but you
10 haven't made that argument explicitly in the text either.

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, we
12 did have some statements regarding that children are the
13 targets for developmental toxicity, not adults. So that's
14 kind of --

15 PANEL MEMBER BLANC: But all of your
16 developmental things except SIDS are suggestive not
17 conclusive, right?

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: I think
19 it's --

20 PANEL MEMBER BLANC: Except SIDS?

21 DR. MILLER: There's a number of the prenatal
22 ones are also --

23 PANEL MEMBER BLANC: You should use a couple of
24 examples of that. I mean, this is sort of closing the
25 loop, I think.

1 CHAIRPERSON FROINES: Melanie, does this mean
2 that when you finish this document that you will then move
3 ahead and move this on to be one of the substances under
4 SB 25?

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

6 CHAIRPERSON FROINES: Because you can make --
7 you'll develop a document for that, and that will be a
8 good place for a very focused discussion of some of these
9 issues.

10 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well,
11 actually we make that statement in this document. So this
12 is the document that will serve that purpose.

13 CHAIRPERSON FROINES: Okay. And Paul's point --

14 PANEL MEMBER GLANTZ: In fact, if you think back
15 into the very distant past, it was the fact that we
16 couldn't include ETS on the SB 25 list that I think Gary
17 pointed out at the meeting, that we needed to reopen.
18 Remember that?

19 PANEL MEMBER FRIEDMAN: I asked about it, because
20 I didn't understand why we -- why it wasn't considered a
21 toxic air contaminant before.

22 PANEL MEMBER GLANTZ: Back in the dark ages.

23 CHAIRPERSON FROINES: This point is that that
24 makes Paul's point more important, in essence.

25 PANEL MEMBER GLANTZ: Yeah.

1 that was statistically significant relative to nonsmokers
2 or non-ETS exposed.

3 And then there was not significant change in age
4 at menopause in Cooper et al., but that same investigator
5 found elevated FSH levels in passive smokers. And FSH
6 levels go up shortly before menopause and are involved in
7 driving towards menopause.

8 --o0o--

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: In terms
10 of male reproductive effect, there weren't any studies
11 that were new.

12 PANEL MEMBER BLANC: There weren't any studies
13 that what?

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: That were
15 new.

16 PANEL MEMBER BLANC: You have one new additional
17 study listed in your table. Can you go back to the table?

18 PANEL MEMBER BLANC: You had no studies.

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: It should
20 not be no new data.

21 PANEL MEMBER BLANC: So should the one that --
22 should the one -- the zero be reversed on that table on
23 page 5-1?

24 ARB ASSOCIATE TOXICOLOGIST WINDER: The one study
25 that's mentioned there in the table refers to a study that

1 was actually done, with respect to reproductive effects.
2 This is reporting that in males who's mothers were exposed
3 during pregnancy, subsequently developed male reproductive
4 effects. But this was not a study of male infants exposed
5 directly to ETS. So there's the reason for 1 is that
6 there's an apparent effect on male reproduction, but not
7 during child exposure.

8 PANEL MEMBER BLANC: So there is a new study. So
9 that's correct. And then --

10 OEHHA SUPERVISING TOXICOLOGIST MARTY: It's
11 maternal smoking, an effect of maternal smoking.

12 PANEL MEMBER BLANC: But it's still an effect of
13 male reproductive dysfunction is what you're talking
14 about?

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes, but
16 we're stuck in this thing --

17 PANEL MEMBER BLANC: Do you want to put an
18 asterisk and put something below the table and tell us
19 what is you're talking about?

20 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah, we
21 can do that.

22 PANEL MEMBER BLANC: You have here that there
23 were 3 studies on menstrual cycle disorders. You
24 summarized 2 of them here that were positive. Your
25 finding was that it was suggestive. That to me would

1 indicate that the third study wasn't negative, because
2 that would, consistent with your guidelines, put something
3 as more inconclusive if you only have 3 studies and 2 are
4 negative and one positive. I don't think that that would
5 work by your standards. So what was that third study. I
6 think, a lot hangs on that.

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: I'm
8 looking.

9 PANEL MEMBER BLANC: Is it the Chen study from
10 2000?

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: Chen is
12 dysmenorrhea.

13 PANEL MEMBER BLANC: Is that one of the ones that
14 you went back --

15 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's one
16 that we already had.

17 PANEL MEMBER BLANC: I know it's not -- you have
18 Hornsby --

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: And Chen
20 and Hull. Hull is fertility.

21 PANEL MEMBER BLANC: I'm looking at the -- so if
22 dysmenorrhea and duration of bleeding are both the same
23 study, and then you have Chen, so that's Chen and Hornsby.
24 So then we need one more, right?

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Looks to

1 me like the table is wrong. That should be 2 and not 3,
2 because we only have 2 described.

3 PANEL MEMBER BLANC: You're not thinking that --
4 or are you talking about the follicle stimulating hormone
5 study? I wouldn't call that dysmenorrhea, although that
6 could lead to dysmenorrhea.

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: No. No.
8 I just think the table is wrong.

9 CHAIRPERSON FROINES: I think unless there's --
10 this is going to lead into something substantive --

11 PANEL MEMBER BLANC: Well, it does have to do
12 with suggestive that's why I'm harping on it a little bit.

13 CHAIRPERSON FROINES: I understand that.

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: It should
15 say 2 not 3. That's the whole problem. This is wrong
16 There's only 2 described in the text, Hornsby et al.,
17 1998, and Chen et al., 2000.

18 PANEL MEMBER BLANC: I would respectfully suggest
19 then that it might be more conservative to call that
20 inconclusive, if you've got 2 studies and that's all there
21 is in the literature.

22 CHAIRPERSON FROINES: Well, how are you treating
23 the Cooper study? Is that the one that made up 3?

24 PANEL MEMBER BLANC: She says no.

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's a

1 separate category.

2 PANEL MEMBER HAMMOND: That's a separate
3 category.

4 CHAIRPERSON FROINES: No, I understand it's a
5 separate category, but it seems like --

6 PANEL MEMBER BLANC: It maybe one of the
7 fertility related studies.

8 CHAIRPERSON FROINES: Yeah.

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: Cooper
10 looked at age at menopause.

11 PANEL MEMBER BLANC: I think though that was
12 the --

13 CHAIRPERSON FROINES: I mean is the --

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: Cooper et
15 al., '95 which looked --

16 CHAIRPERSON FROINES: Is the duration of bleeding
17 a menstrual cycle disorder?

18 PANEL MEMBER BLANC: Yeah.

19 CHAIRPERSON FROINES: So that would be the third
20 study?

21 PANEL MEMBER BLANC: No, no, no. That's already
22 up there.

23 CHAIRPERSON FROINES: No, I don't think --

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's
25 Hornsby '98. That's Hornsby and Chen too.

1 CHAIRPERSON FROINES: Melanie, I think that if we
2 could agree that if there are 2 studies it becomes
3 inconclusive. If there are 3 studies, it can lead to
4 suggestive, and we should not just -- because it's 12:50
5 at this point.

6 PANEL MEMBER HAMMOND: But doesn't it depend on
7 how strong the studies are? If you have 2 --

8 PANEL MEMBER GLANTZ: Why don't we do this. What
9 don't we do this. Why don't we break and get some lunch
10 and then since -- you know, Melanie doesn't need lunch.
11 She can figure this out while we're having our sandwich.
12 Is that okay, Melanie?

13 (Laughter.)

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: Oh, sure.

15 (Laughter.)

16 PANEL MEMBER GLANTZ: I'll bring you a sandwich.

17 CHAIRPERSON FROINES: I'm trying to speed it
18 through, but I think Stan's suggestion is actually more
19 substantive.

20 PANEL MEMBER BLANC: Food is always more
21 substantive.

22 (Laughter.)

23 PANEL MEMBER BYUS: Quick lunch.

24 CHAIRPERSON FROINES: So how long do you want to
25 take for lunch. Where is the lunch, Peter?

1 MR. MATHEWS: It's right in here.

2 PANEL MEMBER FRIEDMAN: Can we do it in a half
3 hour?

4 CHAIRPERSON FROINES: Sure. Well, it's here. So
5 is everybody okay with a half an hour?

6 PANEL MEMBER GLANTZ: So we'll reconvene at 20
7 after?

8 CHAIRPERSON FROINES: We're reconvene at 20
9 after.

10 PANEL MEMBER GLANTZ: Okay.

11 (Thereupon a lunch break was taken.)

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1 characterized by the average number of cigarettes smoked
2 per day by regular household members while the subject was
3 present. So they did a fairly reasonable job of trying to
4 look at -- in more detail exposure than in a lot of
5 studies.

6 Occupational exposure to ETS though was recorded
7 as yes/no, so they did less of a thorough job on
8 occupational exposure. They did find some evidence of
9 dose response which is interesting. They had tertiles of
10 ETS exposure, and they got increased dysmenorrhea going up
11 by the tertiles.

12 And I guess it should be noted that the ORS for
13 low, medium and high were 1.1, 2.5 and 3.1. And the high
14 tertile was the only one that was statistically
15 significant. So that was Chen et al., and was the primary
16 reason for saying hey, there's a suggestion of an effect
17 here.

18 There's another study, Hornsby --

19 PANEL MEMBER HAMMOND: Melanie, the one thing is
20 that their definition of high is pretty low. I mean, the
21 middle range capped at 2.5 cigarettes a day.

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

23 PANEL MEMBER HAMMOND: So that, I think, has
24 less -- seems less significant than there were negative
25 findings in the low and medium, because medium is what we

1 would normally consider low.

2 OEHHA SUPERVISING TOXICOLOGIST MARTY: We do note
3 that actually, that their range of exposure is relatively
4 low.

5 In the Hornsby study there was a larger sample
6 size, but it was older women. So there were -- there
7 might be some issues there in terms of confounders. And a
8 less homogenous group to study in terms of reproductive
9 factors. They did have a larger sample size and they did
10 capture smoking information, and they categorized it as
11 Non, passive, and that's just living or sharing a
12 workplace with a smoker. So they didn't look at intensity
13 or duration actually. And then they had light smokers and
14 moderate to heavy smokers.

15 So the wringer in this study that bothers me is
16 that these women were part of a study of women whose
17 mothers had taken DES during the pregnancy. So how that
18 influences reproduction is an open question. Nonetheless,
19 they did find an effect of ETS exposure, in terms of
20 duration of dysmenorrhea and amount of daily bleeding,
21 both of which were statistically significant.

22 PANEL MEMBER HAMMOND: Is this a study of -- did
23 the study of DES daughters include daughters of mothers
24 who did not take DES, because they would have been, in
25 effect, DES.

1 OEHHA SUPERVISING TOXICOLOGIST MARTY: You know,
2 I don't have the paper here. They do say that DES
3 exposure was equally distributed in their smokers and
4 their nonsmokers within the study.

5 PANEL MEMBER BLANC: Okay. So I have a
6 suggestion perhaps for a way to address the issue that
7 there were just 2 studies here, that there's some
8 issues -- potential issues of interpretation with one of
9 those 2 studies.

10 I would suggest that if you look at table 5.0 on
11 page 5-1, you already put in one footnote to that table,
12 which was explaining what the male reproductive study was
13 with about, right?

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

15 PANEL MEMBER BLANC: I'd suggest that at the top
16 row where it says fertility or fecundability, and you have
17 5 new studies, you cross out 5 and you make that 7. You
18 put a footnote and you say this does include 2 studies
19 which focused on dysmenorrhea, which certainly could be a
20 marker of, you know, risk for and abnormal fertility and
21 fecundability, and you delete the row altogether that has
22 menstrual cycle disorders.

23 It doesn't change your conclusion. The top one
24 is still suggestive. It just doesn't attempt to deal with
25 menstrual cycle disorders as an entirely separate outcome,

1 and it acknowledges that, you know, you maybe having a
2 fairly broad definition, but since for -- you know, for
3 these purposes you really look at something which was a
4 suggestive area. Clearly you need more studies, which
5 will then allow you to tease these things out.

6 PANEL MEMBER BYUS: I don't think dysmenorrhea --
7 correct me if I'm wrong, but I don't think dysmenorrhea
8 has any effect on fertility or fecundability or whatever
9 the other one --

10 PANEL MEMBER BLANC: Sure it does. It's a marker
11 of people with dysmenorrhea can be more at risk of --

12 PANEL MEMBER BYUS: Less.

13 PANEL MEMBER BLANC: More at risk for
14 reproductive outcomes. I mean, you're throwing a broad
15 net. But for the purposes of this kind of screening, I
16 mean, this is just showing where there's something going
17 on. We don't know what it is. There's a suggestive
18 relationship, because your only other choice, I think,
19 given what you're saying is to keep the 2 things there and
20 downgrade that. I couldn't live with either solution. I
21 don't think that either approach is a terribly substantive
22 change to the document.

23 CHAIRPERSON FROINES: Do you think, Paul, my
24 guess is that that would require some changes within the
25 chapter because this only reflects the summary, but

1 there's probably some formatting to these changes, so
2 you'd have to put it in a new category. So it's --

3 PANEL MEMBER BLANC: You just have to eliminate a
4 category and put it within the other one. I actually
5 don't feel strongly either way, but I'm just giving you my
6 alternative. What I don't think is an alternative is
7 leaving it the way it is.

8 CHAIRPERSON FROINES: I think suggestive is
9 not --

10 OEHHA SUPERVISING TOXICOLOGIST MARTY: We could
11 combine them. We would definitely want to a footnote,
12 because fertility and fecundability studies are definitely
13 distinct from a study of dysmenorrhea and that endpoint
14 measure is pretty --

15 PANEL MEMBER BLANC: And say you have some
16 limitation but say, you know, this early stage of data, it
17 was, you know, made more sensitive to put it there and
18 consider it as a completely separate category.

19 CHAIRPERSON FROINES: The worst thing that could
20 happen is somebody will be reading it, if anybody reads
21 the whole document, and will say, "Gee, I would have put
22 this into a separate category." And then they'll go on
23 with the rest of their lives.

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: That's
25 true. Okay, that's fine with us.

1 CHAIRPERSON FROINES: I don't think it's going to
2 have any real consequence.

3 PANEL MEMBER HAMMOND: You know, this is an aside
4 on this. But there will probably be a lot more
5 information on this in the next few years as some of these
6 women with health issues studies come out. And so I think
7 that this -- we should just see -- you might even sort of
8 put it in that frame -- relatively little research has
9 been done in this area. It's just really in the beginning
10 stages, and so inconclusive reflects the lack of study.
11 But stay tuned.

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah, stay
13 tuned.

14 CHAIRPERSON FROINES: It's raises an interesting
15 question -- Kathy is raising an interesting question. For
16 example, we have never given, and it's been 7 years since
17 we were in this room with diesel, and we've never had a
18 meeting in which we asked OEHHA to update us on any TAC.
19 And that might be fun, as long as it wasn't the reason for
20 a meeting. But if it was part of a meeting, that if you
21 had some striking results that you thought the Panel
22 should be aware of, it's worth it and not out of the
23 question to do that.

24 PANEL MEMBER BLANC: Just another very small
25 point, which may be generalized to certain other things.

1 I haven't looked systematically and looked where you have
2 the male reproductive dysfunction, which now is going to
3 have the footnote You had 0 studies last time and now have
4 a single study in this category.

5 Did you -- you actually didn't have findings in
6 the 1997, which you categorized in any way, either
7 conclusive or anything else. So wouldn't it be not
8 applicable?

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: It should
10 have been not assessed, which is what we did in other
11 chapters, was not assessed.

12 PANEL MEMBER BLANC: Okay. That would have been
13 true for menstrual cycle disorders if you kept it in here.
14 But if you do the other thing, it's a moot point.

15 CHAIRPERSON FROINES: Does that raise a question
16 about whether -- is this study sufficiently interesting
17 that you want to include it? Do you want to have that
18 category?

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: You mean
20 in terms of organization of the chapter?

21 PANEL MEMBER BLANC: A single male one, are you
22 talking about?

23 CHAIRPERSON FROINES: Yes.

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: Oh, the
25 single male one.

1 PANEL MEMBER GLANTZ: I think yeah, sure, for
2 completeness.

3 PANEL MEMBER HAMMOND: It says that you looked at
4 the literature for that. I think that's very important.
5 Even if you can't find anything, it's important.

6 CHAIRPERSON FROINES: Well, it depends a little
7 bit on the quality of the study.

8 PANEL MEMBER HAMMOND: No, no. I'm just thinking
9 that this -- it highlights what is -- or is out there.

10 CHAIRPERSON FROINES: That's fine.

11 PANEL MEMBER GLANTZ: So are we done now?

12 CHAIRPERSON FROINES: I'm waiting to hear from
13 Melanie.

14 OEHHA SUPERVISING TOXICOLOGIST MARTY: We're done
15 now. At least, I'm done now.

16 (Laughter.)

17 CHAIRPERSON FROINES: So at this --

18 PANEL MEMBER BYUS: You think you're done. Well,
19 maybe we can fix that.

20 (Laughter.)

21 CHAIRPERSON FROINES: If you think you're done
22 now --

23 (Laughter.)

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: Young
25 lady, if you think you're done now, you better rethink

1 that.

2 (Laughter.)

3 CHAIRPERSON FROINES: Okay. So let's go around
4 the room and see if there are questions and comments.

5 We're still dealing with the overall document, its
6 adequacy and how we want to proceed.

7 So I'll start with Stan who was one of the leads
8 on the document and then we'll go to Roger, who was also a
9 lead, and then go to the rest of the Panel.

10 So Stan.

11 PANEL MEMBER GLANTZ: I think I'm happy. I don't
12 have anything else to say. I think it's a really nicely
13 done document. I mean, as I said, I have a few
14 grammatical little things, but I'll just give it to them.

15 CHAIRPERSON FROINES: Roger.

16 PANEL MEMBER ATKINSON: No comments, no
17 questions. Fine by me.

18 CHAIRPERSON FROINES: Joe.

19 PANEL MEMBER LANDOLPH: I think you put a
20 tremendous amount of effort in and addressed the many
21 comments and criticisms. The document reads well. I'm
22 satisfied.

23 CHAIRPERSON FROINES: Well, remember, everybody,
24 this -- pardon me for stopping you, but all 3 comments
25 kind of spoke to Melanie and the staff. This discussion

1 is between ourselves about our views of the document and
2 our decisions of -- in other words, you should say you
3 think the document is adequate and --

4 PANEL MEMBER GLANTZ: Oh, okay. Well, I
5 misunderstood.

6 CHAIRPERSON FROINES: This is not to Melanie.
7 This is our discussion.

8 PANEL MEMBER GLANTZ: I'll make a motion. And I
9 move that the Panel accept the document, subject -- well,
10 wait. We can always discuss the motion. I'd like to move
11 that the Panel accept the document, subject to the changes
12 that have been discussed at this meeting with us
13 delegating to the Chair the authority to do one final
14 review after OEHHA and ARB have agreed to the corrections.

15 CHAIRPERSON FROINES: Well, I had hoped to sort
16 of go around the room before we go to that.

17 PANEL MEMBER GLANTZ: Oh, okay. Well, then I
18 won't make it. I don't have anything more to say.

19 PANEL MEMBER BLANC: Well, Melanie had alluded
20 to, before she went to the developmental things of
21 respiratory chapter, which we did not discuss at the last
22 meeting, but we did discuss at the meeting before that.
23 And there were a number of substantive changes that were
24 requested.

25 Now, we've never reviewed systematically the

1 changes that were made. I have no idea whether you have
2 summary slides that do that or you want to walk through
3 it, but I do think that the record should reflect some
4 follow-up discussion on the respiratory, because it's a
5 rather big section. And it did have substantive step up
6 in strength of association for the adult respiratory
7 findings.

8 I think the pediatric respiratory finding
9 conclusions were unchanged. They were only strengthened;
10 is that correct?

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes. The
12 biggest jump was for asthma, exacerbation and induction in
13 adults, which actually included adolescents. The
14 structure of the chapter changed. We took all of the
15 information on kids and put it first, and then separated
16 out the information on adolescents and adults. So that
17 was one which resulted in a lot of cutting and pasting,
18 but that was one change that was made.

19 Some other -- a few other studies popped up that
20 we put those in. There were no changes made in any of the
21 findings for this update.

22 I think Paul had brought up the issue that we
23 were inconsistent in talking about adolescents. In one
24 place they were kids in another place there were adults,
25 and part of that was the way the studies were done. Some

1 of them looked at kids and adolescents and some of them
2 looked at adolescents and adults. So we tried to be
3 careful about how we talked about that. And the section
4 on asthma in adults is now asthma in adolescents and
5 adults.

6 Mark is reminding me there is one study that we
7 meant to add, and I thought was in here, and is not. So
8 that's another study by Lam on adult respiratory symptoms
9 and in police officers in Hong Kong. So that's something
10 that we still have to do.

11 PANEL MEMBER BLANC: That means that's not on the
12 table on page 6-1?

13 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah,
14 we're going to add a study.

15 PANEL MEMBER BLANC: So the column of additional
16 studies for the next to last row respiratory symptoms and
17 other effects will go from 5 to 6?

18 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes.

19 PANEL MEMBER BLANC: And then because the
20 terminology in the tables of -- correct me if I'm wrong,
21 but the terminology suggestive parentheses strengthened,
22 is not consistently used in the document or is it
23 described as an option in Chapter 1.

24 What I would suggest is doing that by footnote,
25 where you footnote those 2 and say, "Although these remain

1 suggestive, they are strengthened."

2 PANEL MEMBER GLANTZ: I like having it in the
3 table. I mean, I think you're being overly legalistic.
4 And to me -- I mean, I find these first tables very
5 helpful in looking at the document. And I think the fact
6 that you're still saying it's suggestive, but the evidence
7 is stronger is a nice thing to have in the table.

8 PANEL MEMBER BLANC: But the implication is
9 everywhere else in the document where it says suggestive
10 and doesn't say strengthened means that it's not.

11 PANEL MEMBER GLANTZ: Then that means that
12 they're saying it's still suggestive.

13 PANEL MEMBER BLANC: And has gotten no more
14 stronger than the last time.

15 PANEL MEMBER GLANTZ: Well, that's how I read it.

16 PANEL MEMBER BLANC: Well, is that your
17 implication everywhere else in the document? That's
18 really my point. So it is somewhat legalistic but the
19 implication when I see this, if they want to use that
20 terminology, is that where they don't use that terminology
21 the implication is that the suggestive associations are no
22 stronger no than they were before.

23 PANEL MEMBER GLANTZ: Melanie, is that --

24 OEHHA SUPERVISING TOXICOLOGIST MARTY: In most
25 places we did do suggestive strengthened. And on that it

1 should have been there also for the Cognition and
2 Behavioral Chapter 4, because we had 3 more studies that
3 provided additional suggestive --

4 PANEL MEMBER BLANC: Just be consistent.

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah.

6 CHAIRPERSON FROINES: Well, it seems to me --

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: We could
8 do it either way, I don't care.

9 PANEL MEMBER GLANTZ: Well, I like it. I mean, I
10 thought the strength in places that you had, because I
11 noticed it throughout the report. I thought that was
12 useful information.

13 CHAIRPERSON FROINES: Well, it seems to me that
14 have 2 choices. One is to put a footnote if you like it,
15 and everybody agrees -- and they may or may not -- then
16 there needs to be a footnote that explains strengthened or
17 you need to add the term to Chapter 1 and explain it, but
18 it can't go by -- it cannot stay the way it is.

19 PANEL MEMBER BLANC: Well, just one sentence in
20 that first little bullet in Chapter 1, where you say what
21 suggestive is. You could say "A suggestive association
22 could be further strengthened if additional studies have
23 emerged, yet not sufficient enough in quality or findings
24 to move something to..." you know?

25 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay.

1 That's easy.

2 PANEL MEMBER GLANTZ: I think that's fine with
3 me.

4 CHAIRPERSON FROINES: I think unfortunately again
5 given that we are going into the trial on Tuesday, we have
6 to be somewhat legalistic in our approach.

7 PANEL MEMBER GLANTZ: Okay.

8 CHAIRPERSON FROINES: Melanie.

9 OEHHA SUPERVISING TOXICOLOGIST MARTY: That was
10 really the gist of what happened in Chapter 6.

11 PANEL MEMBER BLANC: And the questions that -- I
12 think there were 1 or 2 places where I had a question
13 about studying where it was cited. I think the Eisner
14 study, which you use as a support for asthma, bartenders,
15 that got moved appropriately?

16 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yes. And
17 your study also got moved to other.

18 PANEL MEMBER BLANC: Good. Okay.

19 OEHHA SUPERVISING TOXICOLOGIST MARTY: As I
20 recall, we did virtually everything that you had
21 suggested.

22 PANEL MEMBER BLANC: Great.

23 CHAIRPERSON FROINES: Melanie, I thought you said
24 that there's someplace where you have adult and
25 adolescence, but I'm looking at table 6.00 and I don't see

1 that.

2 PANEL MEMBER BLANC: Well, her point was, I think
3 if I understood it, is that in the adolescence, which had
4 sometimes been included in with adults and sometimes
5 included with children are now included with adults. So
6 they're subsumed in the adult section. Is that correct?

7 OEHHA SUPERVISING TOXICOLOGIST MARTY: Yeah.
8 Exactly. I put little footnote in the table, Footnote C,
9 it says "Some studies include adolescents as adults,"
10 where I put asthma, because we want it -- it was hard
11 putting adults and adolescents. It made the table look
12 funny, so we just footnoted it.

13 CHAIRPERSON FROINES: Well, don't you have to add
14 a clause that says that that occurred, but we recognize
15 that adolescents' lung function is still undergoing
16 growing. I adolescents are different than adults.

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: We could
18 add that clause in the section description.

19 CHAIRPERSON FROINES: I mean, the question is
20 does -- are the studies impacted by the fact that these
21 are adolescents?

22 OEHHA SUPERVISING TOXICOLOGIST MARTY: Well, it's
23 hard to know, because, you know, not every study did
24 exactly the same thing and then didn't use the same age
25 participants.

1 PANEL MEMBER BLANC: And they were responsive to
2 the critique from --

3 CHAIRPERSON FROINES: No, I understand. I
4 understand that it's not trivial. I don't want to
5 nitpick, but depending upon the study if you are looking
6 at adolescents, it does have implications. So my point is
7 just simply recognize -- put a clause in there that
8 recognizes that adults and adolescents are different.

9 PANEL MEMBER BLANC: Could be.

10 CHAIRPERSON FROINES: Could be different.

11 I think we're waiting on you.

12 OEHHA SUPERVISING TOXICOLOGIST MARTY: Okay. I
13 will put the clause in that adolescents are still
14 developing lung function.

15 CHAIRPERSON FROINES: So we're still on Chapter
16 6.

17 OEHHA SUPERVISING TOXICOLOGIST MARTY: Right.

18 CHAIRPERSON FROINES: We're still, I guess, with
19 Paul.

20 PANEL MEMBER BLANC: I think that's sufficient
21 discussion. I just wanted the record to reflect that even
22 though we hadn't discussed it last time, that changes from
23 the previous discussion were addressed and clarified. And
24 I think you've put on the record that there was one other
25 study added to the other health effects, and that there

1 was for -- I think the other thing that you did was to go
2 back and make sure that you weren't missing studies that
3 occurred in the interval.

4 OEHHA SUPERVISING TOXICOLOGIST MARTY: Exactly.

5 PANEL MEMBER BLANC: So aside from the study that
6 you mentioned that's not yet in the table, does that table
7 include some studies that weren't in previous versions? I
8 mean, have some already gotten in there or is this exactly
9 the same number of studies, albeit a couple of them were
10 moved around or were there already --

11 OEHHA SUPERVISING TOXICOLOGIST MARTY: There
12 actually are a couple more studies in there.

13 PANEL MEMBER BLANC: I thought there were, so you
14 just want to make that clear too, okay.

15 I'm done.

16 CHAIRPERSON FROINES: I think we have gone
17 through the first 3, and we were at Kathy.

18 PANEL MEMBER HAMMOND: Is it too late to ask a
19 question?

20 CHAIRPERSON FROINES: No.

21 PANEL MEMBER HAMMOND: This is about Part A. And
22 it just says -- I was going through things and I missed
23 something and I have a question about the exposure
24 assessment. I'm so sorry.

25 This is going through the finding, and I'm trying

1 to put it together. And I apologize for not catching this
2 sooner. And the question has to do with the in-transit
3 vehicle exposures. In the children's scenario you make a
4 use a higher concentration than you do in the business
5 traveler. And basically what you did is in the children's
6 scenario, you start with the value of 693 grams per cubic
7 meter or particles. And then you proportion that to
8 nicotine.

9 In the business traveler you take the average of
10 that 693 and the -- another number to come with 392 and
11 then you take that. Was there a reason you took the
12 average? I missed this when I read it. I was looking to
13 see it. And it was only when I went back and looked at
14 did I realize that there were 2 different in-transit
15 numbers used.

16 One combines windows up and windows closed and
17 there other just has windows always closed. So this is
18 the scenario C4 versus T2. So on pages V49 and V54 and
19 the explanations for each of those are in preceding pages.

20 ARB SUBSTANCE EVALUATION MANAGER AGUILA: Dr.
21 Hammond, we have Peggy Jenkins who could probably shed a
22 lot more light. But my understanding is that C4 scenario
23 was intended to represent a maximum case. So we took the
24 upper range of the in-vehicle study for that number.

25 PANEL MEMBER HAMMOND: Right. But I think the --

1 this is something that I thought was also a high exposure
2 area.

3 ARB SUBSTANCE EVALUATION MANAGER AGUILA: Well,
4 it's not really a maximum based, it's more of a high-end,
5 more of a realistic scenario, if you will.

6 ARB INDOOR EXPOSURE ASSESSMENT SECTION MANAGER
7 JENKINS: Peggy Jenkins. The business high traveler
8 matches the children's high traveler or high exposure, so
9 we kept that, but we went -- we used the highest number
10 for the maximal.

11 PANEL MEMBER HAMMOND: I got it.

12 CHAIRPERSON FROINES: What page are you on?

13 PANEL MEMBER HAMMOND: I was on V49 versus V54.
14 What Peggy is pointing out -- or Dr. Jenkins is pointing
15 out is that V47 matches the V54 the in-transit estimate.

16 Thank you. It was something I was looking at and
17 -- okay, right. I think I did catch that. I was reading
18 through it and I forgot it.

19 ARB INDOOR EXPOSURE ASSESSMENT SECTION MANAGER

20 JENKINS: Yes.

21 PANEL MEMBER HAMMOND: Going back to the finding
22 and putting it together. Okay, thank you. I apologize
23 for it.

24 So now back to the Committee about the report. I
25 think we have been provided a really excellent report and

1 summary. And I'm very pleased that we have a scientific
2 basis in which to make some findings. That's basically
3 what you want.

4 CHAIRPERSON FROINES: It's up to you.

5 PANEL MEMBER HAMMOND: Then that's the kind of
6 information you want from us, right?

7 CHAIRPERSON FROINES: (Nods head.)

8 PANEL MEMBER HAMMOND: I don't have reservations
9 at this point. I think we are now provided with the
10 necessary information to go forward.

11 CHAIRPERSON FROINES: Charles.

12 PANEL MEMBER PLOPPER: I think the report IS
13 complete and insightful. I think it's going to be useful.
14 I support IT.

15 CHAIRPERSON FROINES: Gary.

16 PANEL MEMBER FRIEDMAN: Are we talking about our
17 findings yet or just about the report?

18 CHAIRPERSON FROINES: The report.

19 PANEL MEMBER FRIEDMAN: I think it's a fine
20 report, a very good piece of work.

21 CHAIRPERSON FROINES: Basically, what we're doing
22 here, I think, is, in a sense, we are individually stating
23 conclusions that will fulfill our obligation under the law
24 that says we need to determine whether the report is
25 scientifically valid. I don't know the exact language

1 anymore, but you know what I'm saying.

2 It's the 24th.

3 PANEL MEMBER BLANC: My question is to Stan,
4 which is to in parallel to the brief follow up on the
5 respiratory chapter, the cardiovascular health effects
6 chapter has only really one substantive change, which is a
7 brief added section on oxidative stress. And I think that
8 reflects the discussion. I don't remember whether that
9 reflects the discussion last time or the time before.
10 There were some substantive discussions about redividing
11 things. I think those have occurred. Has everything
12 else --

13 PANEL MEMBER GLANTZ: Yes.

14 PANEL MEMBER BLANC: -- occurred with the
15 cardiovascular chapter and your review of that
16 meta-analysis?

17 PANEL MEMBER GLANTZ: Yeah. The one
18 suggestion -- this was in the list of things that I was
19 going to just give them, but I think that we just
20 published a big paper, which I had given Melanie the
21 manuscript for, Joaquin Barnoya and I, in circulation on
22 mechanisms, which I think ought to be worked in somewhere
23 into Chapter 8 just so that it gets in the reference list.

24 But the material that we published is all pretty
25 much covered in the chapter. So I read through Chapter 8

1 quite carefully and I'm happy with it. Other than adding
2 that one reference just for completeness.

3 CHAIRPERSON FROINES: Where is the section
4 oxidative stress.

5 PANEL MEMBER GLANTZ: It's near the end, as I
6 recall.

7 PANEL MEMBER BLANC: Yes. It's on 8-42 and 8-43,
8 oxidative effects.

9 PANEL MEMBER GLANTZ: I thought the chapter -- I
10 thought they integrated everything we've suggested.

11 PANEL MEMBER BLANC: That being said, I think
12 that the -- and presuming that the specific changes that
13 have been discussed here today, none of which, in my
14 opinion, rise to the level of a major or crucially
15 substantive change, I think that I'm very satisfied with
16 the document. I think it's been quite responsive to the
17 feedback, that you've been given.

18 CHAIRPERSON FROINES: Craig.

19 PANEL MEMBER BYUS: I concur. I really think
20 this document was very well put together. I'm actually
21 struck by what a health hazard environmental tobacco smoke
22 is. After reading this -- I mean, I read the last
23 document in considerable detail. And now after reading
24 this one, the case against environmental tobacco smoke is
25 even stronger and more pervasive in terms of organs and

1 diseases that are correlated with it in terms of
2 causality.

3 And the quality with which the document presents
4 all the data, which is -- and it is very complex, very
5 difficult. It is quite good.

6 So I'm very pleased with it. I'm pleased with
7 the way it was done. I'm pleased with the results. I'm
8 pleased with the way it was written, the quality.

9 CHAIRPERSON FROINES: Melanie, I'm going to say
10 one thing and then move ahead. I think that the section
11 on oxidative stress could have been much more fully
12 developed. I think it's not really as fully developed as
13 it should be. The word inflammation is not used once in
14 that section. The word glutathione is not mentioned once
15 in that section.

16 It really looks like what was put together to
17 meet a request, but it isn't as fully developed as I would
18 prefer. But I think it basically -- you know, I mean -- I
19 think it's like a primer on the topic. And so for
20 purposes of this document, I think it's sufficient. I
21 personally don't think it's complete, but I don't want to
22 raise hackles.

23 So as far as I'm concerned, we can move ahead. I
24 do think this could have been better developed to be
25 perfectly honest. But I don't want to open Pandora's Box

1 either, because it's not relating to the specific studies.
2 It's really relating to the topic in general, so it
3 doesn't -- I don't think it impacts the overall view that
4 everybody has for the report.

5 But if you want to make any changes in this
6 appendix, then I certainly would be open to it.

7 PANEL MEMBER GLANTZ: Well, you know, the paper I
8 mentioned that Joaquin and I did they reviewed has a lot
9 of discussion -- there's a lot of new research. The
10 reason I didn't push this is the point you made, this
11 isn't going to change the substance of the report.

12 But when you're finalizing it, if you'd look at
13 that paper, I think you could flesh this out some with the
14 references that are in there.

15 CHAIRPERSON FROINES: You know, the problem is
16 that when -- since I work on oxidative stress all the
17 time, you become acutely aware of all that's missing. So
18 that you hold it to a higher standard. But I think it
19 doesn't impact what this report is attempting to achieve.
20 And so it's -- the report is never intended to be an
21 encyclopedia. It's intended to deal with ETS, and I think
22 we should let it go at that.

23 So I agree with Stan. So at this point, Stan, I
24 think that we can have a motion.

25 PANEL MEMBER GLANTZ: Okay. Well, I'd like to

1 move that we accept the report subject to the revisions
2 that have been discussed at this meeting and that the
3 Panel delegate the authority to the Chair to review the
4 final edited version and accept it on behalf of the Panel.

5 PANEL MEMBER LANDOLPH: Second.

6 CHAIRPERSON FROINES: Discussion.

7 PANEL MEMBER FRIEDMAN: I think it's -- I would
8 really like to take a look at what you add about the
9 association of alcohol and ETS, if you don't mind that
10 little addition.

11 CHAIRPERSON FROINES: No. He just said that it's
12 up to the Chair to read the changes, which doesn't mean
13 the Chair isn't going to circulate the changes, so other
14 people can read them, because --

15 PANEL MEMBER GLANTZ: The Chair, I think, would
16 do that.

17 CHAIRPERSON FROINES: I operate strategically.

18 PANEL MEMBER BLANC: I would just like to offer a
19 friendly amendment, which is before the word "edits" in
20 that motion that the word "minor" be inserted, because I
21 do believe there are minor edits.

22 PANEL MEMBER GLANTZ: I accept your friendly
23 amendment.

24 CHAIRPERSON FROINES: Okay. Any further
25 discussion?

1 This is a landmark vote, because we've been
2 battling ETS since when, Stan?

3 PANEL MEMBER GLANTZ: Since the first -- when did
4 the first report start moving, 1993?

5 OEHHA SUPERVISING TOXICOLOGIST MARTY: Three or
6 four.

7 CHAIRPERSON FROINES: It's another. It's been
8 more than a decade.

9 PANEL MEMBER BLANC: I'll call for the question.

10 CHAIRPERSON FROINES: Sorry.

11 All those in favor raise your hands?

12 (Hands raised.)

13 CHAIRPERSON FROINES: It's a unanimous vote.

14 Okay.

15 PANEL MEMBER GLANTZ: Melanie, is probably very
16 disappointed that she'll get to move on to something else.

17 (Laughter.)

18 CHAIRPERSON FROINES: Well, we want to have a
19 workshop, at some point soon, to talk about what compounds
20 should be coming forward. And I think Janette will see
21 that as a help to her efforts rather than an hindrance.

22 I'm very anxious to talk about what TACs should
23 this committee be taking up, at some point, because it's
24 been 5 years -- well, 7 years, and we don't want to wait 7
25 years again, I think.

1 PANEL MEMBER GLANTZ: We should do the Findings.

2 CHAIRPERSON FROINES: We're going to do the
3 Findings right now.

4 Okay. Everybody has a copy of the Findings. And
5 I should jut say for the record that the Panel has just
6 voted that the report is based on sound scientific
7 knowledge, methods and practices and represents a complete
8 and balanced assessment of our current scientific
9 understanding. The panel was unanimous in meeting that
10 legislative language.

11 So we are now at the issue of the Findings which
12 people have read. And I guess the floor is open for
13 comment.

14 Gary.

15 PANEL MEMBER HAMMOND: Are you going to go one by
16 one on the Findings?

17 CHAIRPERSON FROINES: Whatever, however.

18 PANEL MEMBER BLANC: Well, actually --

19 PANEL MEMBER FRIEDMAN: I have one on number 5
20 and 6.

21 PANEL MEMBER BLANC: Actually I have a process
22 question. Is it your goal at this sitting now through our
23 comments to edit the existing text such that you have a
24 final text right now at this meeting. Is that what your
25 purpose of this discussion is?

1 CHAIRPERSON FROINES: No, my intent at this
2 meeting is to have comments from the Panel about how
3 these -- well, if everybody agrees that these Findings are
4 fine, we can take a vote, and we'll be done. I don't
5 think that's going to happen. And therefore, I think what
6 we're doing is we are in the process of discussing the
7 Findings as they exist and making recommendations for
8 subsequent changes.

9 PANEL MEMBER BLANC: And then come back to us
10 or --

11 CHAIRPERSON FROINES: Which will come back --
12 which we will then take -- we'll take the transcript on
13 the comments and then we'll develop a new set of Findings
14 and we'll circulate that, and then we will -- how do we
15 deal with a vote on that, Jim, if we're not going to have
16 a meeting?

17 PANEL MEMBER GLANTZ: Well, I'd like to -- I
18 mean, I'd like to see -- I had actually thought we would
19 finalize the vote on them today and be done, because I
20 think that they're fairly straightforward. So I think
21 that ought to be the goal. But if we don't -- if that
22 doesn't work out, we have another meeting scheduled on
23 July 8th, and we can take the final vote at that meeting.

24 But I personally thought we would get, since I
25 don't think there's anything controversial here, I mean

1 there's a few things that, based on this discussion would
2 be reworded. But I would hope that we could actually
3 finish today. I think that should be the goal, not that
4 we will accomplish it or not.

5 CHAIRPERSON FROINES: Well, Stan, I think
6 speaking from my point of view, I think that in some
7 respects there's a lot of good material in these Findings.
8 I think the problem is what's missing from the Findings,
9 in part.

10 PANEL MEMBER GLANTZ: Well, why don't we just go
11 through this and see how far we get.

12 PANEL MEMBER BLANC: I'm sorry. I didn't want to
13 derail it, I was just hoping to get a sense of what the
14 parameters were. And I understand the parameters. Let's
15 start having the discussion, but we're not hooked into a
16 discussion which has to be at the level of completing the
17 document, if it's not going in that direction.

18 CHAIRPERSON FROINES: We have the option of
19 completing the document, but we have the other option of
20 voting on July 8th for the final document.

21 Gary had comments.

22 PANEL MEMBER FRIEDMAN: I have things on 5 and 6,
23 but if you wanted to go through it one by one, I could
24 wait. How do you want to do this, do you want to just...

25 CHAIRPERSON FROINES: I think that -- However.

1 It's up to you.

2 PANEL MEMBER FRIEDMAN: I'll just go ahead.

3 Following Stan's comment that we should be
4 critical and not rubber stamp, and Craig's concern that,
5 you know, the relationship between estrogen and breast
6 cancer is really not that well understood, I still feel
7 that the similarity between active and passive smoking in
8 terms of risk of breast cancer is sort of the elephant in
9 the room, that we have to comment -- at least comment on.
10 And I have a suggested sentence to go at the end of number
11 5.

12 I would say, "Given that active smoking also
13 involves passive smoking, the reasons for the similarity
14 of active and passive smoking risks elevation for breast
15 cancer are not well understood." I just would like to add
16 that, so that we're not saying everything is beautiful.
17 And so I just would like to say that we have some concerns
18 that we don't really understand that.

19 CHAIRPERSON FROINES: Anybody have a problem with
20 that?

21 Paul.

22 PANEL MEMBER BLANC: I actually don't have a
23 problem with that sentence. I would be willing -- it
24 depends -- I would prefer to have a bit more global
25 comment that we should add is directly related.

1 Katharine, I hope it's okay if I say it, because I know
2 your next in line.

3 I think that the fundamental problem with the
4 Findings as they're written is that there's a very drastic
5 imbalance with very long commentary on breast cancer, for
6 example, and very short summary statements on other
7 Findings. And I find that that implies something which
8 may not be intended.

9 I think the breast cancer section should be cut
10 considerably or you're going to be forced to have that
11 length of discussion with every item. Our Findings, after
12 all -- I like the tone of Gary's statement. In fact, I
13 could live with that, you know, 2 sentences plus that, but
14 not half a page on that.

15 PANEL MEMBER GLANTZ: Yeah, I agree with that.
16 And what I was going to suggest is that in terms of number
17 5 that we keep the first couple sentences. But then where
18 it says, "More than a dozen studies,..." I would delete
19 everything down to where it says, "...stratified by age or
20 menopausal status.", which would make -- because I had
21 exactly the same reaction you did, Paul.

22 So number 5 would then read, "There has been
23 substantial new research published on ETS breast cancer
24 since the 1997 report. Epidemiological studies, supported
25 by toxicology of tobacco smoke constituents, provide

1 evidence consistent with a causal association between ETS
2 and breast cancer in younger primarily premenopausal
3 women."

4 Actually, you could even delete the last, and
5 that would be what I would say. And then I think Gary's
6 sentence I would actually put it maybe as a separate
7 statement.

8 CHAIRPERSON FROINES: Kathy.

9 PANEL MEMBER HAMMOND: I had a similar reaction
10 to number 5. I felt one got lost in the details, so I
11 agreed with Stan's suggestion.

12 What I had been planning to suggest is people
13 reading this would get lost. It's an important message.
14 It's an important message and important finding is along
15 the lines of -- and I was going to put it the end, but
16 delete a lot of this. We don't need to do it, but I'll
17 put this on the record.

18 The last sentence should be something that is
19 clear. Like, "Thus, there is now conclusive evidence that
20 ETS is causally associated with breast cancer in younger
21 primarily premenopausal women. That statement has to be a
22 clear statement.

23 PANEL MEMBER GLANTZ: But if you delete --

24 PANEL MEMBER HAMMOND: No, no. I'm saying --

25 PANEL MEMBER GLANTZ: But it would do exactly

1 what you're saying.

2 PANEL MEMBER HAMMOND: I understand that. That's
3 what I said, Stan. I just want to put that on the record
4 that it's important -- it's supporting what you're
5 saying -- it's important that we be very clear what the
6 Finding is. And that is the Finding. And I don't think
7 all the -- I think it's better to delete all the extra
8 words, all the caveats, all the other things. If we are
9 going to have them, it may be has to be in a different
10 kind of context, and maybe there's another number that's
11 defined, you know, maybe number 5. If you want to have
12 all that detail -- you may want to have all the detail,
13 but then there's a simple statement, like the statement in
14 number 6, a simple statement, that says that there this is
15 causal evidence. But it needs to be clear and right now
16 it's not.

17 PANEL MEMBER GLANTZ: Well, is there anybody
18 against deleting the material beginning with, "More than a
19 dozen studies..." through the rest of there.

20 PANEL MEMBER FRIEDMAN: I thought you were
21 leaving something in at the end.

22 PANEL MEMBER GLANTZ: No, I actually changed. We
23 don't need it, because it's redundant.

24 So basically number 5 would be the first 2
25 sentences.

1 PANEL MEMBER HAMMOND: I think that's fine.

2 PANEL MEMBER BLANC: Plus what Gary added.

3 PANEL MEMBER FRIEDMAN: Well, if you're going to
4 add my thing, I sort of would like to leave in the
5 carcinogenicity -- the last sentence there, too, so to
6 give it some -- you know, I would sort of like to leave
7 that in.

8 PANEL MEMBER GLANTZ: Okay. Well, then fine.
9 That was actually the one I was going to leave. So let's
10 keep that.

11 CHAIRPERSON FROINES: So but you want the first 2
12 sentences, and the last sentence, plus Gary's.

13 PANEL MEMBER HAMMOND: Gary is on the --

14 PANEL MEMBER FRIEDMAN: No, no. I just was
15 saying that there's still -- we don't understand why
16 there's similar risks between active and passive.

17 PANEL MEMBER HAMMOND: I just lost it, right.

18 PANEL MEMBER FRIEDMAN: Because people are going
19 to jump on that and we have to recognize that this is an
20 issue.

21 PANEL MEMBER GLANTZ: I would suggest --

22 PANEL MEMBER HAMMOND: The only problem I have,
23 as soon as we do that -- I mean, I think you're right. We
24 should have that in there. But now we're going to have 4
25 sentences. We have 2 sentences here. We have the one at

1 the end and the sentence you're going down, which is a
2 good one. We have 4 sentences. Again, I'm afraid the
3 meaning -- the thrust of the finding will be lost.

4 So I guess I would suggest that the second
5 sentence may become the last sentence, so at least it ends
6 with a clear statement as to what the Findings -- what the
7 Finding is that there's epidemiologic studies supported by
8 toxicology.

9 CHAIRPERSON FROINES: Well, the sentence that
10 stays in here, "The carcinogenicity data on tobacco
11 smoke..." could be sentence number 2 at the top, which
12 then is followed by epidemiologic studies and that gives
13 you a. -- it actually flows.

14 PANEL MEMBER HAMMOND: But then -- I don't want
15 the last sentence to be the one about what the apparent
16 inconsistency of active smoking. That's an equivocal
17 statement. I think the equivocal statement ought to be
18 earlier up in the plan.

19 PANEL MEMBER BLANC: Kathy's point is well taken.
20 And it will also make sense with Point number 6 that
21 follows.

22 PANEL MEMBER FRIEDMAN: So, in other words, put
23 this last sentence plus mine is the second and third and
24 then finish with what's there as the second.

25 PANEL MEMBER HAMMOND: Yes.

1 PANEL MEMBER FRIEDMAN: That sounds good. You
2 may, after you see it, you may want to --

3 PANEL MEMBER HAMMOND: Yeah, he may want to
4 word-smith it, but it should end with that strong
5 statement.

6 CHAIRPERSON FROINES: Yeah, that would be fine.
7 So we're saying that the sentence that Gary adds
8 becomes sentence number 2?

9 PANEL MEMBER FRIEDMAN: No. It's number 3, and
10 the last sentence becomes number 2.

11 CHAIRPERSON FROINES: I got it.

12 PANEL MEMBER GLANTZ: But I would just -- just
13 for completeness, I would also suggest slightly rewording
14 what is the current last sentence to say something like,
15 "The carcinogenicity data to tobacco smoke constituents
16 continues to strongly support the conclusion that breast
17 cancer is causally associated with ETS exposure." That
18 would be --

19 PANEL MEMBER FRIEDMAN: I like the plausible
20 statement.

21 PANEL MEMBER BYUS: I like it, too.

22 PANEL MEMBER GLANTZ: Okay, I rescind my
23 suggestion.

24 PANEL MEMBER FRIEDMAN: I would even take out the
25 word "strongly".

1 PANEL MEMBER BYUS: I would too. I would take
2 the word out "strongly".

3 CHAIRPERSON FROINES: If you will allow the Chair
4 to make one comment. What's happening is people are
5 talking over each other. And Kathy is still trying to get
6 through what her comments were to be. So if we can try
7 and not jump in when people aren't finished.

8 PANEL MEMBER HAMMOND: Well, I think it's more
9 important to finish Item 5 and have all our discussion on
10 that before we go. But I do want to -- I have another
11 comment on 6. But let's finish -- are we done with 5?

12 PANEL MEMBER FRIEDMAN: May we do 6 with that
13 too, because I have one suggestion.

14 CHAIRPERSON FROINES: Sure go ahead.

15 PANEL MEMBER FRIEDMAN: Instead of saying -- I
16 would just insert, "If any". "There is little, if any,
17 evidence of an increase in breast cancer risk..."

18 CHAIRPERSON FROINES: I get a yes from Paul, yes
19 from Roger, yes from Joe, yes from Craig, yes from Kathy,
20 silence from Stan, yes from Charles.

21 PANEL MEMBER GLANTZ: The only reason I'm being
22 silent is just I'm thinking back to what it says in the
23 report, and it did say there might be some subgroups, but
24 I'm not going to -- I think that's okay.

25 PANEL MEMBER FRIEDMAN: There might be some what?

1 PANEL MEMBER GLANTZ: Well, it said like there
2 might be some sensitive subgroups.

3 PANEL MEMBER FRIEDMAN: Yeah, but that's so weak
4 and the strongest studies --

5 PANEL MEMBER GLANTZ: No, I'm not arguing with
6 you. I'm just -- that was what I was thinking, that's why
7 I was quite, but I can accept that.

8 CHAIRPERSON FROINES: I think we also need to
9 think about the impact of the report, in a sense. We're
10 doing the science not the policy. But we want to make
11 sure that the points are clearly enunciated that we want
12 everybody to read, and the degree to which -- so I agree
13 with you in that sense.

14 PANEL MEMBER GLANTZ: No, I can accept. No, no.
15 I was just -- the reason I was quiet was I was just
16 thinking about it. I can accept your suggestion without a
17 problem. So we have unanimity.

18 CHAIRPERSON FROINES: I was going on everybody
19 going like this and --

20 PANEL MEMBER GLANTZ: Well, I was thinking. I
21 was quiet. I'm sorry. I won't do it again.

22 PANEL MEMBER FRIEDMAN: What I said was going to
23 take away from your conclusion that it was a toxic air
24 contaminant --

25 PANEL MEMBER GLANTZ: No, no. I agree. I agree.

1 I just was thinking. I'm sorry.

2 CHAIRPERSON FROINES: Are you done with 6?

3 PANEL MEMBER FRIEDMAN: Yes, I'm done.

4 CHAIRPERSON FROINES: We'll go back to -- I'm not
5 sure you're totally done.

6 PANEL MEMBER HAMMOND: Okay. I'm now moving to
7 exposure, moving back to the exposure. This is number 3.

8 If we're going to accept a scenario-based
9 exposure approach, the Findings here are inconsistent with
10 the report. So if you turn to B-55, this is the summary
11 of the scenario-based approaches. And, in fact, the
12 scenario-based approaches leads to much higher levels of
13 24-hour average exposures than are in our Findings.

14 So I actually have 2 points here. One is we have
15 not mentioned here, although it's strongly in the report,
16 that children are particularly vulnerable to these
17 exposures. And I think given the concern about children,
18 we probably should highlight that as one of our Findings
19 about children, both that they are likely to have -- be
20 among the more highly exposed people and that they don't
21 have the ability to escape as easily as adults do or to
22 remove themselves from ETS.

23 So that's one type of finding.

24 But the other is in terms of the levels. So in
25 the Findings, it says that they can range up to 3

1 micrograms per cubic meter and yet in the table you say it
2 goes up to 20 micrograms per cubic meter. That's quite a
3 significant difference.

4 In fact, the children -- the high exposure is 7
5 and the maximally exposed was almost 20. And I do believe
6 that 20 is an appropriate number if we're talking about
7 the range. I'm not saying it's typical or average, but if
8 we're talking about range, then we should be using the
9 same numbers.

10 PANEL MEMBER BLANC: Is what happened -- what
11 they mine is that the time weighted 24-hour exposure is a
12 mean estimate. They don't really mean range in the
13 mathematical sense. They mean that if you look at the
14 range of means -- the 20 value was the mean value, right?
15 The 20 was a range of a scenario that the mean value for
16 that series of scenarios was 3 or something? Is that what
17 where that difference comes from?

18 CHAIRPERSON FROINES: Jim, are we talking about a
19 mean or a max?

20 ARB SUBSTANCE EVALUATION MANAGER AGUILA: The 19
21 is a max.

22 CHAIRPERSON FROINES: The what?

23 ARB SUBSTANCE EVALUATION MANAGER AGUILA: The
24 19.4 in the formula is a maximum.

25 CHAIRPERSON FROINES: So the point is -- their

1 time weighted 24-hour estimate can range up to, and so
2 that's the mean value, as opposed to the maximum value.

3 PANEL MEMBER HAMMOND: But it's not. I mean, if
4 you're basing this on the scenarios that are given, every
5 scenario that has an in-vehicle exposure, you know, the
6 low one is 7, right. So that's higher, since in-vehicle
7 is listed.

8 Now, if you took in-vehicle out -- there are
9 different ways to approach it to deal with this. But I
10 think finding as it stands is incorrect or inconsistent
11 with the report. So it could be for those living in homes
12 with indoor smokers, their time weighted 24-hour average
13 estimate can -- I would -- you know, can be -- I wouldn't
14 say range up to. We actually do have measurements over 3,
15 but let's just say can be about 3 micrograms per cubic
16 meter, but the in-vehicle immediately raises it to
17 something higher.

18 PANEL MEMBER BYUS: We should say what that
19 number is?

20 PANEL MEMBER HAMMOND: Right. I think what I'm
21 saying is either -- you know, then there might be a
22 sentence of saying in-vehicle exposures can lead to much
23 higher 24-hour average and reach levels of 10 to 20 or 5
24 to 20.

25 PANEL MEMBER GLANTZ: Can I ask the ARB people,

1 if -- I agree with Kathy that we should put that in there.
2 Can you tell us how this should be edited to accomplish
3 what Kathy is asking for?

4 CHAIRPERSON FROINES: Can I follow up on what
5 Stan is saying, because I'm still operating on the
6 assumption that there's a possibility we can finish and
7 there's a possibility we can't. And if we can get
8 specific language as we move along like we did with 5,
9 then we'll be closer to the goal of finishing.

10 PANEL MEMBER HAMMOND: That's why I was proposing
11 that.

12 CHAIRPERSON FROINES: So what's the number that
13 we are --

14 PANEL MEMBER BLANC: Well, maybe what I'm going
15 to say will solve that problem, which is unless there's a
16 legal requirement I think this would get the point across
17 it would be more readable without including all of the
18 numbers and base it on language such as Kathy is
19 suggesting using, you know, a much higher, order of
20 magnitude higher without going through all the numbers,
21 unless there's some legal requirement. Because once again
22 having this level of detail, I can go to the Executive
23 Summary if I want to see all the numbers.

24 PANEL MEMBER HAMMOND: I mean, the simplest
25 answer I could see, to make the least number of changes,

1 is just to change the 3 micrograms to 20 micrograms per
2 cubic meter.

3 PANEL MEMBER ATKINSON: I thought it was 19.

4 PANEL MEMBER HAMMOND: Yeah. Well, I'll just say
5 20, because I don't think -- that implies a certain amount
6 of precision I don't believe exists. So one of the
7 simplest suggestions with the minimum changes would be 20,
8 but I would ask if you think that would be misleading?

9 CHAIRPERSON FROINES: But I want to go back to
10 what Paul said, Kathy, and see -- because this is our
11 Findings. This is not simply a recitation of what's in
12 the rest of the document. So the degree to which we, in a
13 sense, have Findings that look like the Executive Summary,
14 that may be just fine. But I think we always have to
15 answer the question what do we intend our Findings to
16 convey?

17 And if it's a series of numbers, that's fine.
18 But if there is a statement that draws a conclusion from
19 us, then we should think about that. And so the question
20 is what's our intent?

21 PANEL MEMBER HAMMOND: I mean, I could certainly
22 reword this as I would say it myself, if that's what you'd
23 like. I mean, I would -- you know, I would certainly feel
24 comfortable saying that, "Those living in homes with
25 smokers experiencing..." -- you know, I would say, "Those

1 living in homes with indoor smokers have much higher
2 levels of exposures and those who experienced in-vehicle
3 exposures, those levels can go even an order of magnitude
4 higher than that." And I would then conclude with a
5 sentence about, "Children are particularly vulnerable to
6 these exposures and" --

7 PANEL MEMBER BLANC: No.

8 PANEL MEMBER HAMMOND: -- "are particularly
9 likely to experience those higher exposures if their
10 parents smoke."

11 PANEL MEMBER GLANTZ: Why don't you, while we
12 continue the discussion, take your pencil out and write
13 the specific language, and then we can talk about it
14 afterwards.

15 CHAIRPERSON FROINES: She is going to write it.

16 PANEL MEMBER BLANC: Kathy, I also think that the
17 sentence in our Findings about that a scenario-based
18 exposure method uses the blah, blah, blah, blah, blah,
19 blah, blah. I don't think that's necessary. It's enough
20 to say they use a scenario-based approach. I think the
21 rest of the paragraph can be deleted. We just say
22 exposures range by more than an order of magnitude higher.

23 PANEL MEMBER HAMMOND: I'm happy with that too.

24 CHAIRPERSON FROINES: So again, I want to
25 reemphasize that these Findings should say what we want

1 them to say and not just be recitations of facts.

2 PANEL MEMBER BYUS: That's what I was going to
3 say. You think, Kathy, a scenario-based method is
4 appropriate, that this was a good way of doing it
5 accurately, reflecting the best methodology, or -- do you
6 want to say something like that? I mean, you know, this
7 field. And so I mean --

8 PANEL MEMBER HAMMOND: Well, I mean, I actually
9 think the scenario-based approach is informative. I think
10 that's the better way to look at it. As I think you can
11 combine scenario-based information with measurement data
12 with all of these things together we can come to these
13 kind of findings. So maybe that's the way you want to
14 look at. I think the scenario-based approach was very
15 informative.

16 PANEL MEMBER BYUS: It was very informative,
17 coupled with the actual measurement data.

18 PANEL MEMBER GLANTZ: The only change I would
19 suggest, Kathy, that you had is I think the statement
20 about kids' exposures, we should have that as a separate
21 finding --

22 PANEL MEMBER HAMMOND: I was wondering about that
23 too.

24 PANEL MEMBER GLANTZ: -- to fit in with the SB 25
25 stuff. So I was going -- so I would edit 3 and then

1 create a new finding to follow it dealing with kids.

2 ARB INDOOR EXPOSURE ASSESSMENT SECTION MANAGER

3 JENKINS: Excuse me, could I offer one point of
4 clarification. I'm not sure this comes through in the
5 report, but for the scenario C-4, the children's maximally
6 exposed scenario, we do, what we call, sort of a realistic
7 maximally exposed. So this doesn't refer to the most
8 exposed child. It would be a group of children and some
9 of whom would have higher levels. So, in that sense, I
10 think it's appropriate.

11 PANEL MEMBER HAMMOND: Well, I mean, you know, to
12 be perfectly honest, just based on my own measurements,
13 I'm pretty sure that there are infants out there that are
14 exposed without even being in a car, in their homes to 20
15 micrograms per cubic meter.

16 ARB INDOOR EXPOSURE ASSESSMENT SECTION MANAGER

17 JENKINS: Right.

18 CHAIRPERSON FROINES: I think that statement
19 number 1 is exactly what we want to say. How do people
20 feel about statement number 2?

21 PANEL MEMBER BLANC: I think on the same basis of
22 statement number 2 was overly long. And I think the
23 second sentence, which says, "The study gathered two
24 8-hour samples and six 1-hour samples per site tested.",
25 should be deleted. I think it's not relevant to what we

1 have to say.

2 And I think that you can say, if you need to have
3 numbers, I'd say the results showed a range of ambient
4 nicotine concentrations from .013 to 4.6. And I don't
5 think, for our purposes, we need to differentiate between
6 them.

7 CHAIRPERSON FROINES: Did you say the ambient
8 nicotine concentrations which showed a range, is that what
9 you're saying?

10 PANEL MEMBER BLANC: "Results showed a range of
11 ambient nicotine concentrations from .013 to the 4.6
12 micrograms period, you know, per meter. I don't think the
13 stuff about the 8-hour and the 1-hour and the this and the
14 that. For our purposes, it's not --

15 CHAIRPERSON FROINES: Well, it's actually -- you
16 can't go .013 to 4.6, because you have different times.

17 PANEL MEMBER BLANC: Why?

18 CHAIRPERSON FROINES: Well one is 8 hours and
19 one's 1-hour.

20 PANEL MEMBER ATKINSON: You can do 0.01 to 5 or
21 to 4. It's all the same. 0.01 to 4 that essentially
22 covers both.

23 CHAIRPERSON FROINES: To 5.

24 PANEL MEMBER ATKINSON: Or 5.

25 PANEL MEMBER BYUS: They're so similar.

1 CHAIRPERSON FROINES: That's fine. Kathy is
2 going to give us number 3.

3 PANEL MEMBER BLANC: And a new number 4.

4 CHAIRPERSON FROINES: And a new number 4.

5 PANEL MEMBER HAMMOND: Say 3A and 3B for now.

6 CHAIRPERSON FROINES: And 1 is okay, but we're
7 now over to 4.

8 PANEL MEMBER BLANC: I have substantive problems
9 with number 4. I understand the goal of number 4. The
10 goal of number 4 is to try to summarize everything that
11 was said in the 1997 report as being causally related.
12 But I don't find that helpful as a single bullet, partly
13 for the reasons that have already been alluded to about
14 the need for us to be careful about separating out the
15 children versus the non-children's effects.

16 So I think if there was one bullet perhaps that
17 said, you know, "The 1997 report had already established
18 that ETS was causally related to the following health
19 effects relevant to developmental toxicity or other
20 effects in children.", you know, and then list those.

21 And then there should be a statement that says,
22 "none of these..." -- "All of these continue to be
23 inclusive in this document."

24 And then a separate bullet which says, "If you
25 wish that the 1997 report found the following conclusive

1 associations among adults...", you know, colon blah, blah,
2 blah. "And all of these continue to be conclusively
3 associated within this document."

4 CHAIRPERSON FROINES: I want to add too -- I want
5 to take what you said, and that's fine we can take the
6 transcript and work with that. What I'd like to do,
7 though, Paul, is to have a table that's attached to the
8 Findings that, in a sense, summarizes what was 97 and what
9 is the present, so any reader can actually look at the
10 document and look at the table and basically it's right
11 there in front of them.

12 But we should say it as you've just said it. But
13 I think having a 1-page table that summarizes everything
14 would be very useful. At least for me, looking at a table
15 is always helpful. So unless somebody has a strong
16 disagreement with it.

17 So the language --

18 PANEL MEMBER GLANTZ: I mean, basically -- I'm
19 sorry.

20 CHAIRPERSON FROINES: All I was going to say is
21 we can take the transcript -- Jim, when do we get the
22 transcript?

23 MR. BEHRMANN: Two weeks.

24 CHAIRPERSON FROINES: We'll not make the July
25 11th meeting?

1 MR. BEHRMANN: July 8th, no.

2 CHAIRPERSON FROINES: Well, then can we vote on
3 stuff on something that we're going to do?

4 PANEL MEMBER GLANTZ: Can I suggest the same
5 thing I suggested. This is not a big deal. Why don't you
6 just sort of write -- you know, everyone agrees with what
7 you're suggesting. Just mark one of these up and then you
8 can you read this exactly the wording you want. We don't
9 need -- I mean, it's pretty simple.

10 PANEL MEMBER BLANC: All right. But I have to
11 say that my impression of this discussion is that there's
12 enough various changes -- as much as we would love to have
13 something, I think there is going to have to be something
14 that's circulated. I think it's stretching the
15 feasibility, as much as one would want to.

16 I don't think that you need to have the
17 transcript of this discussion in order to do these
18 changes. I think if you're given good enough notes,
19 you'll be able to circulate for everybody on the 8th the
20 version that you need. I don't think you need to have the
21 transcript to do that. But I don't think we're going to
22 be able to do it.

23 PANEL MEMBER GLANTZ: Well, anyway. But why
24 don't you just to -- basically, all you have to do is
25 break the list into 2 pieces because it's the same wording

1 we have here. It's just 2 separate Findings.

2 CHAIRPERSON FROINES: Okay. Paul, to the degree
3 that you aren't able to get that done today, you can just
4 send it to us and we'll incorporate it. I agree, I don't
5 know if we're going to be quite so efficient to get
6 everything done.

7 Go ahead.

8 PANEL MEMBER HAMMOND: This is just an attempt at
9 the 2 sections I was going to try to rewrite.

10 The first statement would be, "Exposure to ETS
11 varies widely among individuals and depends on the
12 individual circumstances. Thus, Californians who live in
13 nonsmoking homes have only brief encounters with ETS are
14 likely to be exposed to less than 0.1 micrograms per cubic
15 meter 24-hour time weighted average nicotine air
16 concentrations. While those who live with smokers are
17 exposed only in their homes may be exposed to 10 to 100
18 times as much ETS. Exposure to ETS in vehicles may be
19 much higher and lead to even higher 24-hour average
20 exposures."

21 PANEL MEMBER FRIEDMAN: Good. No numbers.
22 That's great.

23 PANEL MEMBER HAMMOND: Well, there's one number
24 to get started, then everything builds from there.

25 And then the second statement about children.

1 "Children who live with smokers may be exposed to high
2 levels of ETS in their homes and even higher levels in
3 vehicles. Children have much less ability to avoid these
4 ETS exposures than adults."

5 Is that what we're trying to say?

6 PANEL MEMBER FRIEDMAN: What's the reason for the
7 last sentence?

8 PANEL MEMBER GLANTZ: Yeah, I think you should
9 leave the last sentence out.

10 PANEL MEMBER HAMMOND: Just leave it out?

11 Okay, that's fine. I guess --

12 PANEL MEMBER GLANTZ: That's not supported by the
13 document. It's true, but not supported by the document.

14 CHAIRPERSON FROINES: So Paul is working --

15 PANEL MEMBER BYUS: Just one question about your
16 statement, which I think is very good. Do we want to say
17 why we're measuring nicotine? We use the word -- we keep
18 going back and forth between nicotine and ETS. I know
19 nicotine is a semi-surrogate. It's a semi-surrogate. It'
20 not a total surrogate, because nicotine actually itself
21 might do something. But it's a surrogate for all the
22 other bad things that are in there. I mean, do we want to
23 make that statement or not?

24 PANEL MEMBER FRIEDMAN: There's an index.

25 PANEL MEMBER BYUS: There's an index. Do you

1 follow me? Do you want to make that statement or not?

2 PANEL MEMBER GLANTZ: I think that's a very good
3 point. I think you should say nicotine as a surrogate
4 for --

5 PANEL MEMBER BYUS: Exactly.

6 PANEL MEMBER HAMMOND: No, no. I'm thinking.
7 I'm thinking of how to do it. I'm not opposing it. I'm
8 trying to think how to fold it in without it -- in a flow.
9 That's all. I'm not opposed to it. I'm trying to think
10 of how to fit it in.

11 PANEL MEMBER GLANTZ: Well, it may be -- maybe
12 you should leave out the one number that's there.

13 PANEL MEMBER HAMMOND: Well, the trouble is I
14 think it's important. I think it's important to have a
15 base, a place from which to discuss it.

16 Well, actually that's true. We could do that.

17 So then it would be, "Thus, Californians who live
18 in nonsmoking homes have only brief encounters with ETS
19 are likely to be exposed to extremely low levels of ETS.
20 While those who live with smokers and are exposed only in
21 their homes may be exposed to 10 to 100 times as much."

22 PANEL MEMBER BYUS: That's good.

23 PANEL MEMBER GLANTZ: I wouldn't just mention
24 homes though, because people can be exposed in other
25 places.

1 PANEL MEMBER HAMMOND: I'm focusing on where,
2 again, I think what's been here. Actually, I'll tell you
3 what the problem is, I just realized -- one problem with
4 what I've written is -- is going back to the idea of what
5 a toxic air contaminant is about. It's supposed to be
6 focused on outdoor air. And I haven't, in this finding,
7 said a thing about the outdoor air levels. I probably
8 should say something.

9 PANEL MEMBER GLANTZ: That's in number 2.

10 PANEL MEMBER HAMMOND: Is it? Actually, that's
11 where these -- these things were actually nicotine
12 measurements, but they weren't called out as such. Oh,
13 yes it says ambient nicotine, yeah, right.

14 Well, I mean given that we kept 2 in here, in
15 thinking about it, is that because 2 has numbers putting
16 the number in the homes of nonsmokers is a useful thing.

17 PANEL MEMBER ATKINSON: Yeah, just leave the
18 number in.

19 PANEL MEMBER HAMMOND: The way I had it
20 originally.

21 PANEL MEMBER ATKINSON: Yeah, the way you had it
22 originally.

23 PANEL MEMBER HAMMOND: Because I think it flows
24 from 2 very well.

25 PANEL MEMBER ATKINSON: Two covers nicotine.

1 PANEL MEMBER HAMMOND: Right.

2 PANEL MEMBER GLANTZ: But I think, at some point,
3 in number 1 and number 2, you should just have a
4 parenthetical statement saying one surrogate marker for
5 ETS is nicotine.

6 PANEL MEMBER HAMMOND: I mean --

7 PANEL MEMBER GLANTZ: Just a parenthetical
8 statement.

9 PANEL MEMBER HAMMOND: -- it wouldn't matter what
10 marker you used, because the point is to have that they
11 all had a ratio.

12 PANEL MEMBER GLANTZ: Right. But just to make
13 the point that that is a surrogate marker.

14 PANEL MEMBER BYUS: A valid surrogate marker,
15 accurate, representative.

16 PANEL MEMBER HAMMOND: Okay. I suggest that
17 number 2 be modified as follows. And it now says,
18 "Results showed a range of ambient nicotine", "(a commonly
19 accepted surrogate for ETS." Concentrations from, and
20 then we're set.

21 PANEL MEMBER BYUS: Good.

22 PANEL MEMBER FRIEDMAN: Could you use the word
23 extremely low. Could I suggest very low. I mean, it just
24 sounds so --

25 PANEL MEMBER HAMMOND: No. We're going to leave

1 the number in there. It's not going to be left -- because
2 we've got numbers in 2. Now, I'm going to put the home
3 numbers in there.

4 PANEL MEMBER GLANTZ: The other thing is I think
5 that number 3 shouldn't just talk about home exposures.
6 There are still some people who are exposed in workplaces,
7 for example. Not very many. But you don't want to leave
8 The impression that the home is the only place.

9 PANEL MEMBER HAMMOND: Okay. There's --

10 PANEL MEMBER GLANTZ: The report talks about
11 that.

12 PANEL MEMBER HAMMOND: All right. So what we
13 could say is --

14 PANEL MEMBER GLANTZ: Just say --

15 PANEL MEMBER HAMMOND: Give me a second here. I
16 just talked about home and vehicles. And what if I say
17 "...workplaces where smoking is still allowed can also
18 lead to higher exposures."

19 PANEL MEMBER GLANTZ: Yes.

20 PANEL MEMBER HAMMOND: How is that?

21 PANEL MEMBER FRIEDMAN: Is it allowed or just go
22 on.

23 PANEL MEMBER HAMMOND: Workplaces where smoking
24 is allowed, and that can include bars.

25 CHAIRPERSON FROINES: While we're waiting for

1 Paul and Kathy to do their writing, can people look at
2 points -- just to get started again -- 7, 8 and 9. Now,
3 my assumption is that these points, in being written, were
4 based on the goals that Gary enunciated some time ago to
5 make our Findings as frugal and as efficient as possible.

6 So that, as you can see, what the -- really all
7 the way down to 11 -- 7, 8 -- 7, 8, 9, 10, 11 are really
8 very summary statements. And the question is, is
9 everybody comfortable with the frugal nature of the
10 statement? And there's nothing behind what I just said.

11 PANEL MEMBER BLANC: Say that again. Where are
12 you I was working.

13 CHAIRPERSON FROINES: I'm just asking for
14 people's comments on 7 through 11, since they are broad
15 summary statements.

16 PANEL MEMBER BLANC: Well, I think that number 7
17 has to say explicitly, at the end of it, "...adding an
18 additional conclusive adverse health effect among
19 children."

20 And I think that point number 10 needs to
21 similarly be broken out into childhood versus nonchildhood
22 into 10A and 10B.

23 And I don't understand why 11 is where it is in
24 the order of where it is. Oh, now, I do. Now I do.
25 Never mind.

1 In number 10 -- okay, I see where -- so let's go
2 to number 11.

3 Number 11 is new endpoints that didn't exist at
4 all. It's trying to make -- first of all, "menstrual
5 cycle disorders" will not drop out of that. But, in fact,
6 there were data the last time around -- why does it say
7 "causal association" actually?

8 PANEL MEMBER GLANTZ: "...suggestive evidence of
9 a causal association..." That's the language that's used
10 throughout.

11 PANEL MEMBER BLANC: Oh, I see, okay. So this is
12 trying to differentiate between -- Okay, I got you.

13 PANEL MEMBER GLANTZ: I mean, I actually wrote
14 the original draft. Well, I took -- what happened, the
15 origin of these -- just so it's clear how they're
16 organized this way. The original draft Findings that were
17 drafted by the staff before the last meeting were very
18 long. And cognizant of Gary's desire to have them
19 succinct, I tried to compress them and divide them up
20 between things that were causal before and stayed causal,
21 things that were raised, and things that were -- and then
22 suggestive that were unchanged, and then the ones that
23 were raised to suggestive. So that was the logic, and
24 then they got rewritten a few times after that, but that
25 was the logical intent.

1 PANEL MEMBER BLANC: So I think that 10 and 11
2 should be reparsed out so that one of them is things that
3 have -- are newly suggestive for children's effects,
4 regardless of whether that category of effect was even
5 considered in '97, but that's not so important to us.

6 So the fact that they didn't have -- that stroke
7 was not a category in 1997, I don't need it to appear in a
8 separate one. What makes more sense is to parse out the
9 adult and the child and have one point about things which
10 are -- have risen to be suggestive among children, and
11 another group that have risen to be suggestive among
12 adults.

13 PANEL MEMBER GLANTZ: I think that's sensible.

14 PANEL MEMBER BLANC: And the nasopharyngeal
15 cancers that's opposed to sinus? Nasal sinus cancer?
16 These were dealt with separately -- just to refresh my
17 memory -- because in the previous point number -- the old
18 point number 4, lung cancer and nasal sinus cancer are
19 listed. So they were able to -- so they truly do mean
20 separately, nasopharyngeal cancer and cancer of the nasal
21 sinus are separate?

22 PANEL MEMBER LANDOLPH: (Nods head.)

23 PANEL MEMBER BLANC: You've read the cancer
24 chapter?

25 PANEL MEMBER LANDOLPH: Yeah, because up in the

1 front in the summary, they list lung and nasal sinus
2 cancers as ETS causal of them, and the nasopharyngeal was
3 down, I think, it's suggestive.

4 PANEL MEMBER BLANC: Okay.

5 And as Kathy was suggesting, I think there needs
6 to be a bullet written that is a separate bullet, which
7 says altogether, because of the convincing evidence of
8 childhood exposure to ETS, which, in fact, may be higher
9 under certain scenarios, and because of the conclusive
10 evidence of an association with illnesses, which are
11 either exclusively an issue for children or are more
12 common among children, either causally or suggestively,
13 that this certainly is an air contaminant which meets a
14 criteria, you know, achieves the criteria under the
15 children's. I mean, we need to have that as a bullet.
16 And I think that --

17 PANEL MEMBER GLANTZ: I thought that was there.

18 PANEL MEMBER BLANC: No. It's in the Executive
19 Summary of the document, but we haven't explicitly said
20 that separately, have we?

21 PANEL MEMBER GLANTZ: Yeah, it is. It's, "The
22 Panel Recommends that the ARB as a toxic..." "The Panel
23 further recommends..." "...once listed, be added to the
24 list of toxic air contaminants that may disproportionately
25 impact..." --

1 PANEL MEMBER BLANC: But it doesn't what our
2 rationale is for that. I think that we have to -- I would
3 prefer to see in addition to that a separate bullet which
4 goes from A to B that then that should go from B to C,
5 because I think it's an important regulatory requirement.

6 And then I think that the bullet we talked about
7 in our earlier discussion that the fact that all of the
8 conclusions that were -- all of the associations that were
9 felt to be conclusive in the last document none of those
10 have been reversed, that there have been many that were
11 suggestive in the previous document that have risen to
12 conclusive, and others where they've been strengthened.
13 And none of the subjective ones have been substantively
14 weakened. It supports the systematic methodology used or
15 something to that effect. I don't know exactly how that
16 should be worded.

17 How important is it to have point number 12?
18 We've got a lot of detail, what is it trying to tell me?
19 Is it choosing certain inconclusive associations for more
20 attention than other inconsistent inconclusive
21 associations?

22 PANEL MEMBER LANDOLPH: I think the topic is
23 okay, but I think it needs to be truncated significantly.

24 CHAIRPERSON FROINES: But, for example, "However,
25 the effect of smoking on the father's sperm cannot be

1 ruled out..." I don't know -- I don't think we had
2 evidence on the father's sperm.

3 PANEL MEMBER GLANTZ: Yeah. I mean, again, when
4 I tried to draft this up, I was taking this much longer
5 thing a trying to kind of smush it. I mean, my preference
6 would actually be to delete 12, because the rest of the --
7 because this is sort of a catch-all sort of interesting
8 things that may be ought to be thought about some more.

9 PANEL MEMBER BLANC: Well, how about a statement
10 that we recognize that there were many associations which
11 were ultimately found to be inconclusive. It remains to
12 be seen, you know, what further research will show. The
13 mere fact that something was inconclusive, doesn't mean
14 that it shouldn't be studied further.

15 So, you know, something like that.

16 PANEL MEMBER GLANTZ: That would be okay. I
17 think that would be better than what's here.

18 PANEL MEMBER BLANC: Because if we choose one
19 thing down, we have to go through every single thing in
20 the document, or else we're trying to say something that
21 some things are less inconclusive than others.

22 PANEL MEMBER BYUS: Why didn't we pick this --

23 PANEL MEMBER GLANTZ: I mean I actually -- I kind
24 of think, though, that's obviously. I mean my preference
25 would be to just delete number 12. You know, so then all

1 of the Findings are based on things where there's at least
2 suggestive evidence. And then everything else that there
3 isn't, then that's -- they can go read the report.

4 And then the other thing is if we include the
5 table that John was talking about, with all of those
6 things listed in the table.

7 John, is that okay with you?

8 CHAIRPERSON FROINES: What?

9 PANEL MEMBER BYUS: Nod your head, John.

10 (Laughter.)

11 PANEL MEMBER GLANTZ: Well, what I'm suggesting
12 is that we just delete number 12.

13 CHAIRPERSON FROINES: But I think that sentence
14 is okay to put in. I don't think that's a problem.

15 PANEL MEMBER GLANTZ: Well do you think it's
16 really necessary, Paul?

17 PANEL MEMBER BLANC: I could live with it either
18 way. I was actually trying to be responsive to Joe's
19 comment that he thought it would be helpful to say
20 something about it, but I'm not strongly wedded. I think
21 that one approach could be for John to try to tinker with
22 something, if he feels that he comes up with a line that
23 makes sense and that he supports. I would sort of defer
24 to his editorial judgment on that.

25 PANEL MEMBER LANDOLPH: Yeah. I would suggest --

1 I'd like to make a suggestion for truncation. I mean, you
2 can cut this down dramatically, the size of 12.

3 PANEL MEMBER BLANC: The reason I even brought it
4 up at all is because I got the sense at times when we were
5 talking about things which were inconclusive was that, you
6 know, one wouldn't want to overly interpret inconclusive
7 as putting a kibosh on any possibility. I guess that's
8 probably how this point -- where this point was coming
9 from.

10 So without singling out examples, I think we
11 could say that, even though for you and me it's kind of an
12 obvious statement, just because the data are insufficient
13 now or contradictory.

14 PANEL MEMBER GLANTZ: Well, how about the
15 following, because we're going to add this table, you
16 know, which John had talked about. Why don't we just
17 change number 12 to refer to the table, and to say, "The
18 attached table lists all the endpoints that were
19 examined." And then say, "For those areas which are
20 inconclusive that there may be a need for further
21 research.", or something like that.

22 PANEL MEMBER FRIEDMAN: There's always a need for
23 more epidemiology.

24 (Laughter.)

25 PANEL MEMBER GLANTZ: We could discuss that.

1 PANEL MEMBER BYUS: Always.

2 PANEL MEMBER GLANTZ: You know, maybe that would
3 be a way to do it.

4 PANEL MEMBER BLANC: Were you going to put in
5 inconclusive and conclusive? Was that going to be in your
6 table or were you taking a step up?

7 PANEL MEMBER BYUS: The only thing that's
8 conclusive --

9 CHAIRPERSON FROINES: My view of the table was,
10 and I think I've seen one before, the endpoints --

11 PANEL MEMBER BLANC: All the endpoints. So even
12 the inconclusive and the conclusive would be there?

13 CHAIRPERSON FROINES: Yes.

14 PANEL MEMBER GLANTZ: I think that's the way to
15 pull all of this in is through the tables. So number 12
16 would refer to the table, and say, "Those areas which are
17 inconclusive did not necessarily mean it's a negative
18 conclusion, but rather that there may be a need for Gary
19 to do further research with high levels of funding.",
20 which was a joke.

21 (Laughter.)

22 PANEL MEMBER FRIEDMAN: How about just saying
23 "Other areas of interest with inconclusive results are
24 shown on Table 12."

25 PANEL MEMBER BYUS: Period.

1 PANEL MEMBER FRIEDMAN: I've got enough money
2 right now.

3 (Laughter.)

4 PANEL MEMBER GLANTZ: So are we all --

5 PANEL MEMBER HAMMOND: Okay. Let me just try
6 again on some lists. I changed my mind when I looked over
7 number 2 where that little clause should be.

8 So number 2, if you go to the end of the first
9 sentence, which concludes, "... ,the ARB monitored nicotine
10 concentrations at several outdoor smoking areas in
11 California." ";Nicotine is a commonly used surrogate for
12 ETS." That fits.

13 And then number 3A, and they all be numbered
14 differently later, is slightly changed. "Exposure to ETS
15 varies among individuals and depends on their individual
16 circumstances. Thus, Californians who live in nonsmoking
17 homes and have only brief encounters with ETS are likely
18 to be exposed to less than 0.1 micrograms per cubic meter
19 (24-hour time weighted average nicotine to air
20 concentrations). While those who live with smokers and
21 are exposed only in their homes may be exposed to 10 to
22 100 times as much ETS. Exposure to ETS in vehicles may be
23 much higher and lead to even higher 24-hour average
24 exposures. Workplaces and bars where smoking still occurs
25 have high ETS concentrations."

1 And then the other item is -- it now reads,
2 "Children who live with smokers may be exposed to high
3 levels of ETS in their homes and even higher levels in
4 vehicles. Although each ETS exposures in California
5 adults have declined substantially in the past decade, the
6 exposures of children who live with smokers have not been
7 reduced nearly as much."

8 That last was new, but I just -- it was discussed
9 substantially in the report. And I think that there's a
10 lot of evidence that that's true.

11 PANEL MEMBER FRIEDMAN: Do we know that, you
12 know, because people are concerned that they live with a
13 smoker, and the smoker doesn't go outside to smoke or to
14 purposely avoid exposing the kid.

15 PANEL MEMBER HAMMOND: Well, I happen to know
16 that, from some of my research, however in the grand
17 scheme of things, much data -- the data that are available
18 in general tell us that adult exposures have declined much
19 more substantially than children's exposures.

20 PANEL MEMBER FRIEDMAN: There are data that
21 support that?

22 PANEL MEMBER HAMMOND: Yeah, and that's in the
23 report.

24 PANEL MEMBER BLANC: But the point is in terms of
25 if air exposure is non-indoor air exposure, would be that

1 the increment of non-indoor air exposure that a kid
2 gets --

3 PANEL MEMBER HAMMOND: You mean outdoor air
4 exposure?

5 PANEL MEMBER BLANC: -- the outdoor air exposure
6 would be put on top of their higher baseline. I'm just
7 trying to tie it in to what you said earlier about our,
8 you know, focus in a sense.

9 PANEL MEMBER HAMMOND: By the way, where does
10 in-vehicle count in that regard?

11 To answer your question, I really don't know how
12 to put that.

13 PANEL MEMBER GLANTZ: I have 2 suggestions and
14 slight -- I would add casinos to the list, but that's --

15 PANEL MEMBER HAMMOND: Oh. So we're going to say
16 workplaces, casinos and bars.

17 PANEL MEMBER GLANTZ: Yeah. And then the other
18 thing that I just in listening to was thinking, that I
19 think would be worth adding to the Findings, would be
20 those estimates of the total emissions in tons that are in
21 part A, because people -- I found that people are quite
22 amazed by those numbers. So I would like to suggest
23 adding as a number, either between 1 and 2 or 2 and 3 just
24 those numbers.

25 PANEL MEMBER HAMMOND: I'd just add it to the

1 tend of number 1.

2 CHAIRPERSON FROINES: Would you be responsible to
3 do that.

4 PANEL MEMBER HAMMOND: Approximately X number of
5 tons of ETS particles are emitted.

6 CHAIRPERSON FROINES: Katharine, would you be
7 responsible for doing that.

8 We just talked about the legal requirements. And
9 we can vote to approve the Findings with the anticipated
10 changes and subject to further review by the Panelists,
11 when they're completed. Do you understand what I'm
12 saying?

13 PANEL MEMBER GLANTZ: Yeah. So if that's the
14 case, would it be appropriate --

15 CHAIRPERSON FROINES: Kirk, is that a fair
16 rendition of what you and I talked about?

17 ARB SENIOR STAFF COUNSEL OLIVER: Yeah, that's
18 correct, Chairman Froines.

19 PANEL MEMBER GLANTZ: So would it be appropriate
20 for there to be a motion?

21 CHAIRPERSON FROINES: Let me just make sure.
22 We're saying that we can vote to approve the Findings
23 recognizing that there are anticipated changes that will
24 be incorporated and subject to review by the Panel 3
25 points.

1 PANEL MEMBER GLANTZ: Okay well, so when you
2 say --

3 CHAIRPERSON FROINES: Let me just make sure that
4 I'm on point.

5 ARB SENIOR STAFF COUNSEL OLIVER: Yeah. For the
6 record, this is Kirk Oliver Senior Staff Counsel for the
7 Air Resources Board.

8 Yes, you're correct, Chairman Froines, the
9 process would be a motion would be made to adopt the
10 Findings consistent with the agreed changes based on the
11 agreements that you made in your discussion here. The
12 Findings would be accordingly changed, and then
13 individually sent to each member for their assent that the
14 changes were accurate and that they reflected the
15 agreements that were made today.

16 PANEL MEMBER FRIEDMAN: And if we see that
17 there's some additional editing or minor changes that we
18 think are necessary, then what happens?

19 ARB SENIOR STAFF COUNSEL OLIVER: If they're just
20 minor editing changes, then they could -- you would relay
21 those back to Chairman Froines and those could be made
22 without the further assent of the other panel members.

23 However, if there were anything substantive, then
24 they'd have to go back to the other panel members for
25 their review.

1 PANEL MEMBER GLANTZ: So how about this for a
2 process. We could have such a motion --

3 CHAIRPERSON FROINES: Before, is everybody
4 comfortable with what I said and what Kirk said?

5 PANEL MEMBER BLANC: Yes, Chairman Froines.

6 PANEL MEMBER GLANTZ: Chairman Froines?

7 CHAIRPERSON FROINES: This opens up so many
8 jokes.

9 (Laughter.)

10 PANEL MEMBER GLANTZ: There's a red book right
11 next to it.

12 CHAIRPERSON FROINES: If you only knew what was
13 in that.

14 (Laughter.)

15 PANEL MEMBER GLANTZ: Well, I think that's fine.
16 And if there was a problem, we could presumably rediscuss
17 this at the meeting on the 8th if there's a need for any
18 substantive additional discussion, couldn't we?

19 ARB SENIOR STAFF COUNSEL OLIVER: Yes, Dr.
20 Glantz. In fact, what I would recommend is that the
21 notice for the meeting on the 8th have an agenda item that
22 would allow that kind of discussion to take place if it
23 were necessary.

24 CHAIRPERSON FROINES: Thanks, Kirk.

25 PANEL MEMBER BLANC: I'd like to make a motion.

1 PANEL MEMBER HAMMOND: I have the admission
2 statement, if you'd like to hear it, just -- I think the
3 more we get done this meeting, the less likely -- the end
4 of number 1 add the following: "...for example, annual ETS
5 emissions in California are estimated to include
6 approximately 40 tons of nicotine 365 tons of suspended
7 particles, and 1,900 tons of carbon monoxide.

8 PANEL MEMBER GLANTZ: I would also suggest since
9 ever this report, the 1997 of this report became a major
10 document that's been used all over the world. I think it
11 would be worth including a parenthetical statement with
12 the national numbers also, which are in the report.

13 CHAIRPERSON FROINES: I think that we could.

14 PANEL MEMBER HAMMOND: It's in the -- most people
15 will read the report not our Findings.

16 PANEL MEMBER GLANTZ: That's true. Never mind.
17 I rescind my suggestion.

18 CHAIRPERSON FROINES: The hyperbole is over the
19 top, I thought.

20 PANEL MEMBER FRIEDMAN: Well, just a
21 clarification. You won't see the minutes until after the
22 July 8th meeting; is that right?

23 CHAIRPERSON FROINES: Yeah.

24 PANEL MEMBER FRIEDMAN: So you probably need a
25 copy of the sentence that I said, because it's only in the

1 minutes.

2 CHAIRPERSON FROINES: I'm expecting to get that
3 from you, to get from Paul what he's written, to get Kathy
4 what she's written. I have notes. Jim has notes, and we
5 think we can put this together.

6 PANEL MEMBER HAMMOND: We send this to you?

7 CHAIRPERSON FROINES: Yes.

8 PANEL MEMBER FRIEDMAN: Can we see, because I
9 will be gone the week -- it ends on July 8 and will not be
10 able to come to the meeting, would it possible to see the
11 revised Findings before -- get them next week some time?

12 CHAIRPERSON FROINES: Well, I have to be in New
13 York until Thursday, so it's going to be tight, but I'll
14 try.

15 PANEL MEMBER FRIEDMAN: Other wise, I may not be
16 able to respond.

17 CHAIRPERSON FROINES: Well, I think the answer is
18 yes, but it could be a little tight. So I need a --

19 So I need a motion.

20 PANEL MEMBER BLANC: I'd like to make a motion
21 that the Findings, as proposed, subject to editing
22 consistent with the discussion we have just had, and
23 subject to review and ascent of the Panel members be
24 accepted.

25 PANEL MEMBER BYUS: I'll second the motion.

1 CHAIRPERSON FROINES: Is there further
2 discussion?

3 All in favor?

4 (Hands raised.)

5 CHAIRPERSON FROINES: The vote is unanimous.

6 This is when Paul usually makes a motion to
7 close, but we're not going to do that quite yet. The
8 administrative -- consideration of administrative issues.
9 I just wanted to raise a couple of questions, a couple of
10 points.

11 First, as everybody here knows we're taking up
12 sulfuryl fluoride as a pesticide at the July meeting. And
13 Craig has been the lead and Roger has been the lead on the
14 compound, and they have put in a lot of time and effort on
15 it. And so the one thing I wanted to say about that is
16 this is the first time we've taken up a TAC with the new
17 director of DPR, Mary-Ann Warmerdam.

18 So please, everybody, I know it's only 2 weeks
19 away and Paul's not going to be there. Gary is not going
20 to be there. So the burden is going to fall on a smaller
21 number of people. So please, please, please work at
22 reviewing the document beforehand. Clearly, we want to
23 establish a strong positive relationship with the new
24 director to the degree that we're able to. And so that's
25 one thing.

1 The second thing is I wanted to raise a question
2 about what would the Panel want to do with respect to how
3 soon before a meeting do you want to receive the document
4 for review. For example, you had less than a month
5 slightly less than a month for the sulfuryl fluoride
6 document. And so Jim and I spent a fair amount of time
7 talking about the issue of how much advanced notice should
8 the Panel have on various documents. It's your call.

9 PANEL MEMBER BLANC: I thought it was sufficient.
10 I think that if you got it 2 months in advance, what would
11 happen is people would wait till some time closer to the
12 event. I don't want to say how close to the event.

13 PANEL MEMBER LANDOLPH: Or worse, they'd lose it
14 in the piles of paper.

15 PANEL MEMBER BLANC: I thought, you know, what
16 was done this time was appropriate.

17 CHAIRPERSON FROINES: So the policy for the Panel
18 would be a 1-month lead time.

19 PANEL MEMBER BLANC: It would be preferable. It
20 doesn't need to be longer. And there may be situations in
21 which it's less, but I don't want it to be -- I think the
22 Chair should use some discretion.

23 CHAIRPERSON FROINES: I think that what's
24 happened is that DPR anticipates bringing a certain number
25 of documents to us, so our workload is going to increase

1 presumably with a question mark.

2 PANEL MEMBER BLANC: Well, let's just see if that
3 happens, and we can comment on it. That should be our
4 only problem.

5 CHAIRPERSON FROINES: And the third item, an
6 administrative item, is that we want -- we have been all
7 sent a priority list of the 10 highest priority chemicals
8 that DPR expects to take up. And so we're going to
9 have -- at one meeting in the future, we're going to be
10 discussing those priority chemicals. Now, I'm assuming
11 that everybody has that list of 10 priorities, right?

12 PANEL MEMBER ATKINSON: I may have it, but I
13 haven't noticed it.

14 PANEL MEMBER BLANC: I think that would have to
15 be re-sent where we get -- you're not saying it's going to
16 be discussed at the next meeting?

17 CHAIRPERSON FROINES: No. It's definitely not
18 going to be discussed at the next meeting.

19 PANEL MEMBER BLANC: So I would say that one
20 month prior to the meeting in which you think that's going
21 to be discussed you should re-send it.

22 CHAIRPERSON FROINES: Okay. Jim, you got that?

23 MR. BEHRMANN: Yes.

24 CHAIRPERSON FROINES: We'll re-send it. And
25 we'll also send, I think, the 1996 document on

1 prioritization for you to look at in comparison to what
2 has been spent now, because what we've got now is
3 dramatically different than what we've had in the past.

4 And the other thing that the Panel should know,
5 in contrast to the relationship with OEHHA and ARB, the
6 prioritization approach and the prioritization of
7 chemicals are not being sent to us for us to review as a
8 panel with a subsequent approval. They're basically sent
9 to the Panel, and each panel member is theoretically to
10 respond as an individual.

11 And as far as I'm concerned, that's completely at
12 odds with our approach with ARB and with OEHHA in the
13 past. And it's actually at odds with what's happened with
14 DPR in the past, and that -- so that's an issue for
15 discussion at some future meeting.

16 Stan.

17 PANEL MEMBER GLANTZ: Well, you know, that's very
18 interesting to note, because when I got that letter, I
19 couldn't quite figure out why it was being sent to me,
20 since it wasn't an agenda item before the Panel. And I
21 actually think that you should communicate to DPR that
22 it's just not appropriate for them to be polling the Panel
23 as individuals.

24 I mean, there's a lot that comes out of the
25 discussions at the meetings. And I think if they would

1 like our input on prioritization, which I think they
2 should want, that should be brought before the Panel as an
3 agenda item, and the Panel should respond as the Panel not
4 individual members respond.

5 CHAIRPERSON FROINES: Well, as you may remember,
6 when Paul Helliker said "Hello" "Goodbye" to us some time
7 ago, we sent a letter that actually stated that in that
8 letter. And I asked Mary-Ann if she would review the
9 letter to Helliker so she'd be aware of some of the
10 issues. So actually she's on notice that that is an
11 issue, and we can follow-up with another communication to
12 say, the panel considers it inappropriate that we don't
13 take it up as a. --

14 PANEL MEMBER BLANC: Well, can I ask legal
15 counsel to comment on whether it's not only inappropriate
16 but if it's legal?

17 CHAIRPERSON FROINES: The counsel is not here.

18 PANEL MEMBER BLANC: Yes, he is.

19 PANEL MEMBER BYUS: He just moved. He's hiding.

20 PANEL MEMBER BLANC: He's with ARB, so he
21 can't -- so do we have counsel that's --

22 CHAIRPERSON FROINES: I can answer the question.
23 There is no legal requirement that they do so.

24 PANEL MEMBER BLANC: No legal requirement that
25 they consult with the Board as a whole, but is it illegal

1 for them to try to consult with us one on one?

2 PANEL MEMBER HAMMOND: Who are we one on one? Do
3 we exist one on one? I mean, we exist as a panel.

4 PANEL MEMBER BLANC: But they're writing to us as
5 members of the Panel ex officio to comment in our role as
6 members of the Panel individually.

7 PANEL MEMBER GLANTZ: I don't think that's
8 appropriate.

9 PANEL MEMBER HAMMOND: I don't think that the
10 Panel is more than the sum of its parts.

11 PANEL MEMBER BLANC: I'm not disagreeing with any
12 of that. I'm not disagreeing it's inappropriate. My
13 question is not only is it inappropriate but in fact is it
14 illegal?

15 PANEL MEMBER GLANTZ: I don't think it's illegal.
16 I mean, they have a right to ask anybody they want.

17 CHAIRPERSON FROINES: Kirk, do you know the
18 answer to that question?

19 ARB SENIOR STAFF COUNSEL OLIVER: I don't believe
20 I'm familiar enough with the situation to be able to
21 comment on that.

22 CHAIRPERSON FROINES: Well, I can tell you what I
23 know, which is that OEHHA is required under the 2588
24 legislation to have us approve their documents as they
25 develop them. DPR does not have that requirement, and so

1 therefore they're not required to bring the prioritization
2 issues to us as a panel. Now, we can argue that the law
3 says that they are to take a public health approach to
4 developing documents, and that it would appear appropriate
5 for them to do so, but there's no legal requirement that
6 they have to.

7 PANEL MEMBER BLANC: I understand that part.

8 CHAIRPERSON FROINES: I understand.

9 PANEL MEMBER FRIEDMAN: Well, there are 2 points.
10 First of all, when OEHHA presents their document they
11 often consult with us individually if we have expertise in
12 the area. And if that's all that DPR is doing, I don't
13 see a problem with that, if they eventually want to then
14 bring, after receiving some comments, bring it to the
15 Panel.

16 On the other hand, I do feel whether it's legal
17 or not that we should tell them that we really want to
18 react to this officially as a panel that we don't want to
19 do it as individuals.

20 CHAIRPERSON FROINES: Joe.

21 PANEL MEMBER LANDOLPH: Yeah, I agree with Gary
22 completely. But I don't want to alienate them either. We
23 want to encourage them to come to us, but tell them just
24 that the members feel that we would prefer to be
25 approached simultaneously as a panel.

1 CHAIRPERSON FROINES: Do you remember that what's
2 happened is we were working with them on guidelines for
3 Acetylcholinesterase Inhibitors. We are working with them
4 on exposure assessment methodologies. Craig proposed some
5 modeling approaches at one point for example. We are
6 working with them on risk assessment methodologies, so
7 we -- and we were working with them on prioritization.

8 And when Helliker pulled back, he pulled back on
9 all 4 of those. All of those are at this moment dead.
10 And so there has been a tremendous seat change, if you
11 will, in terms of the number of items we are working with
12 them collaboratively on in the current situation.

13 PANEL MEMBER BLANC: Can I ask a technical
14 question. If the legal counsel for the ARB is not the
15 counsel to whom one would go for advice on our legal
16 relationship with the DPR who is the legal counsel to
17 which we would go for opinion? Is there a higher counsel
18 in CalEPA as a whole?

19 CHAIRPERSON FROINES: I assume that we could go
20 to Alan Lloyd, the Secretary for CalEPA and his legal
21 counsel would advise.

22 PANEL MEMBER BLANC: And has that legal counsel
23 up to date advised us in terms of our global relations
24 with DPR?

25 CHAIRPERSON FROINES: No.

1 PANEL MEMBER BLANC: Well, I would certainly like
2 to offer you the option within your discretion as Chair,
3 should you wish to do so, to seek that counsel without
4 requiring you to do so.

5 CHAIRPERSON FROINES: Does everybody agree with
6 that?

7 PANEL MEMBER FRIEDMAN: Well, I just -- whether
8 it's legal, I still think that we could still request
9 that -- I'm not really worried whether -- why is it so
10 important whether it's legal or not, I mean?

11 PANEL MEMBER BLANC: Well, first of all, I don't
12 want to break the law even if I -- you know, whatever my
13 opinion might be about it being appropriate, not
14 appropriate, good policy, not good policy. So that's one
15 thing.

16 Secondly, if, in fact, the EPA counsel not only
17 says yes, they can't come to you one by one and that my
18 review of the statute is that they do have to come to you
19 as a group, which is not your understanding currently, but
20 not based on legal discussions currently with counsel for
21 EPA, that would certainly change things. And I'm not -- I
22 think I'm not overly concerned on how -- I'm not worried
23 that doing that would somehow, you know, poison the well.
24 I think that only by being rigorous and business like can
25 we really move forward effectively in the current climate.

1 CHAIRPERSON FROINES: There's one piece of
2 information that you don't know that is worth mentioning.
3 And that is that I volunteered to meet with the DPR
4 Director after she was appointed so we could talk about
5 these issues. And then I talked to Alan Lloyd, the
6 Secretary of CalEPA, and said what would be a good idea
7 would be for you to join that discussion. So we agreed
8 that Mary-Ann and I would have an hour discussion just the
9 2 of us on these issues, and then Alan would come in and
10 we would have a subsequent discussion on where we were, so
11 that he could ameliorate differences and be helpful and
12 what have you.

13 So at this point, it's my expectation that some
14 time in July, Alan and Mary-Ann and I are going to meet to
15 talk specifically about these particular issues of
16 collaboration, and the future of the process.

17 PANEL MEMBER BLANC: But they're not going to
18 consult, which is all the more important, on that before
19 that time you have a sense of what the legal is.

20 CHAIRPERSON FROINES: But we do anticipate -- in
21 the letter from Tobi Jones she did say that we should
22 anticipate 2 more pesticides this year, chloropicrin and I
23 forget the other one.

24 MR. BEHRMANN: Methidathion.

25 CHAIRPERSON FROINES: Now, you know, she had to

1 go through Senate confirmation, and we'll see what happens
2 once we're back to normal. But our anticipation is that
3 we have 2 DPR pesticides coming down the road some time
4 this year. And chloropicrin is going to be a big ticket
5 item. I don't know the other ones.

6 So are we finished?

7 PANEL MEMBER HAMMOND: I'm move to adjourn.

8 CHAIRPERSON FROINES: Do we have a second?

9 PANEL MEMBER ATKINSON: Second.

10 CHAIRPERSON FROINES: We're gone.

11 That's adjourned for the transcript.

12 All in favor?

13 (Ayes.)

14 CHAIRPERSON FROINES: We are adjourned.

15 (Thereupon the California Air Resources
16 Board, Scientific Review Panel meeting
17 adjourned at 3:30 p.m.)

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1 CERTIFICATE OF REPORTER

2 I, JAMES F. PETERS, a Certified Shorthand
3 Reporter of the State of California, and Registered
4 Professional Reporter, do hereby certify:

5 That I am a disinterested person herein; that the
6 foregoing California Air Resources Board, Scientific
7 Review Panel meeting was reported in shorthand by me,
8 James F. Peters, a Certified Shorthand Reporter of the
9 State of California, and thereafter transcribed into
10 typewriting.

11 I further certify that I am not of counsel or
12 attorney for any of the parties to said meeting nor in any
13 way interested in the outcome of said meeting.

14 IN WITNESS WHEREOF, I have hereunto set my hand
15 this 12th day of July, 2005.

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JAMES F. PETERS, CSR, RPR

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