

1           SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS  
2                           AIR RESOURCES BOARD  
3                           STATE OF CALIFORNIA  
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6                           PUBLIC MEETING  
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12                          TRANSCRIPT OF PROCEEDINGS  
13                          Friday, July 26, 2002  
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APPEARANCES

SCIENTIFIC REVIEW PANEL

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Dr. David W. Rice, Staff Toxicologist  
Dr. Andrew G. Salmon, Chief, Air Toxicology and Risk  
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1 EL MONTE, CALIFORNIA; FRIDAY, JULY 26, 2002

2 10:15 A.M.

3

4 PROCEEDINGS

5 CHAIRMAN FROINES: So I think we have a quorum  
6 and can open the meeting of July 26 of the Scientific  
7 Review Panel. And the first topic for discussion is  
8 the Air Toxics Hot Spots Program Risk Assessment  
9 Guidelines. So Melanie, Andy.

10 DR. MARTY: Okay. We were going to go through  
11 the chronic reference exposure levels that -- there's  
12 three that we've asked the panel to review that will  
13 be additional to all of the other ones that the panel  
14 has approved.

15 And these reference exposure levels --  
16 the panel has already had some discussion at the  
17 March and November meetings of last year. And now  
18 we're taking them back up. There were a few comments  
19 from the panel that we addressed in the latest  
20 versions.

21 I'm going to let Andy give the  
22 presentation.

23 DR. SALMON: Okay. Well, is this -- that's  
24 working. As the first line here shows, we're working  
25 on the chronic reference exposure levels. And the

1 panel's done a lot of work on this in the past. So I  
2 thought I'd begin by just summarizing what's happened  
3 to date. The main thing was -- the first thing was  
4 the guidance documents, which explain the  
5 methodology. And we're attempting to follow the  
6 methodology laid out in that document.

7                   And I think, as will come out later,  
8 there is a health approach to the methodology  
9 involved a little bit. There were -- there was an  
10 initial group with 22 chronic RELs.

11                   And since then -- if I can have the  
12 next slide, Jim; thank you -- we have added a number  
13 of additional ones. So we actually now have a total  
14 of, well, 76, actually, if you include the carbon  
15 disulfide which was adopted very recently.

16                   So what we now have -- could I have  
17 the next slide, please? Can I have the next slide,  
18 please, Jim? Today, we've got three chemicals which  
19 we are presenting today. Carbon disulfide, which we  
20 did deal with at the last meeting. So what we have  
21 today is fluorides and hydrogen fluoride, phosphine,  
22 and triethylamine. Can I have the next slide,  
23 please. Thank you.

24                   The fluoride one -- at this point, I'm  
25 going to have to explain that we have a revision,

1 which is a late response to comments and discussion  
2 which occurred actually right up to the last few  
3 days. And I have a revised toxicity summary, which  
4 Peter has -- which he's going to hand out to you now.

5                   What happened here was that there were  
6 two changes that we made. The first thing was that,  
7 in response to earlier discussion, it was agreed that  
8 we should develop an oral REL so that, in situations  
9 where the material was appearing as a particulate,  
10 this could be considered as a multimedia problem in  
11 the risk assessments.

12                   And so we needed an oral REL. So the  
13 first change, which was in the version which, I  
14 think, you saw and which went out for the public  
15 notice, that we developed an oral REL using basically  
16 the similar methodology to what was used for the  
17 public health goal for fluoride, which the drinking  
18 water developed recently. So could I have the next  
19 slide, please, Jim.

20                   Now, this is the oral REL. This is  
21 the basis -- essentially it's using the large  
22 population-based studies on fluoride in drinking  
23 water and examining, on the one hand -- the studies  
24 were examining the incidence of dental fluorosis at  
25 high levels of fluoride but also, of course, the

1 beneficial effects in preventing and reducing  
2 incidence of dental caries in people who have higher  
3 levels of fluoride relative to those who were  
4 relatively deficient in fluoride.

5                   And because this is not a standard  
6 adverse-effect-response type of relationship, we  
7 couldn't very well use any of the benchmark dose  
8 methodology, which we have been trying to move  
9 towards here. So basically this is a NOEL type of  
10 calculation. If I could have the next slide, please.

11                   The final conclusion of this was that  
12 this is a population-based study, which includes a  
13 large number of people, including children and  
14 including probably the most sensitive sufferers.  
15 Therefore, we didn't apply any additional uncertainty  
16 factors.

17                   And we came up with a chronic oral REL  
18 of 0.04 milligrams per kilogram day. So as I say,  
19 this is basically in line with the derivation used  
20 for developing the public health goals of the  
21 drinking-water program. If I could have the next  
22 slide.

23                   The other thing which we've been  
24 working on is a revision to the method of calculation  
25 for the inhalation chronic REL. When we first

1 presented this derivation, we were using the LOEL-  
2 NOEL method, based on an epidemiological study of  
3 fluoride-exposed workers.

4                   And it was following discussion at  
5 previous meetings with the panel that we decided that  
6 it was appropriate, rather than using a LOEL-NOEL  
7 kind of approach, that it would be better for us to  
8 use a benchmark concentration analysis in our first  
9 attempt to do this and use the same stratification as  
10 the data in effect in five separate dose groups,  
11 although the data in the study is actually presented  
12 with individual estimated exposure levels and the  
13 outcome.

14                   So the first analysis used stratified  
15 data. However, we have been continuing to discuss  
16 this approach with Dr. Glantz and with various other  
17 people who advise us on these matters.

18                   And one of the points which was made  
19 to us was that, using this stratified approach, in  
20 fact, from a statistical point of view, it's  
21 desirable in treating the data on an individual  
22 basis. And we initially didn't do this because we  
23 hadn't quite figured out how to make the software  
24 package that we were using do that. We were using  
25 group data.

1                   But recently, very recently, we were  
2 successful in running the bit using the individual  
3 data. And as was predicted by Dr. Glantz in his  
4 discussions with us, this did, in fact, improve the  
5 quality of the fit, lower the uncertainty.

6                   It also goes to -- or gave us the  
7 opportunity to correct a mistake which we had made in  
8 the first version of the derivation which we sent you  
9 earlier.

10                  So in order to present all these  
11 issues to you, I've prepared a revised version of the  
12 summary which is what you have before you now. In  
13 fact -- could I have the next slide, please, Jim.  
14 Thank you.

15                  The fit, as you see, is -- well,  
16 it's -- this slide basically shows the shape of the  
17 fitting curve. And the green dots, if you can see  
18 those, are, in fact, the individual response and  
19 nonresponse groups. And this is how the calculation  
20 goes in this mode. And if I could have the next  
21 slide, please, Jim.

22                  This is what happens with the  
23 derivation. We actually come up with a benchmark  
24 concentration value. This is the lower bound on the  
25 slide, in fact, of 0.37 milligrams of fluoride per

1 meter cubed. And then we apply the calculation in  
2 the usual way. In fact, if I could have the next  
3 slide, please.

4                   The final calculation includes an  
5 uncertainty factor of 10, which we left in, because  
6 this is an occupational group of certainly adult  
7 healthy males. We're not quite sure what their  
8 ethnic composition is.

9                   But in any event, it's fairly clear  
10 that this doesn't include children or, at least from  
11 what we can tell, any other obviously potentially  
12 susceptible subgroups. So we feel that it's  
13 appropriate to leave in the uncertainty factor of 10  
14 to represent diversity in the human population.

15                   And so our final recommendation is for  
16 a reference exposure level of 30 micrograms per meter  
17 cubed for fluoride or it's, in fact, 40 micrograms  
18 per meter cubed. I just noticed that somewhere on  
19 there it says, "40 milligrams." It should say, "40  
20 micrograms." I apologize for that typographic error.

21                   So 40 micrograms for hydrogen  
22 fluoride. It obviously just reflects the molecular  
23 weight. So that's our proposal.

24                   Then I think -- sorry -- if you can go  
25 back to that. I don't know whether the panel wants

1 to discuss this further at this point or if there's  
2 anything I can clarify additionally.

3 CHAIRMAN FROINES: How do you want to do it?  
4 Shall we talk about the chemical by chemical or when  
5 he's finished with three chemicals? Dr. Blanc?

6 DR. BLANC: Chemical by chemical.

7 CHAIRMAN FROINES: So why don't we take  
8 comments on the fluoride issue now?

9 DR. ATKINSON: On the first page, you have a  
10 typo, by the looks of it. Instead of 40 ppb, it  
11 should be 17.

12 DR. SALMON: Yes.

13 DR. MARTY: That's the -- I think that  
14 represents the older calculation. Oh, no.

15 DR. SALMON: That is the -- yes. That's  
16 right. We corrected the microgram value but forgot  
17 to change -- yes. I'm sorry. I apologize. The  
18 typography seems to be a little deficient here.

19 This, as you might have gathered, was done in  
20 something of a rush.

21 CHAIRMAN FROINES: Since Paul's the lead --  
22 but why don't we start with Stan because he has, as  
23 you say, been working with you.

24 DR. GLANTZ: Yeah. I'm happy. I mean there  
25 is a -- they did what I'd suggested. And I think

1 it's better.

2 CHAIRMAN FROINES: I thought the fact that you  
3 were sitting back and quite so relaxed meant that you  
4 were in that posture. So you have no comments?

5 DR. GLANTZ: No. I think it's fine.

6 CHAIRMAN FROINES: Paul?

7 DR. BLANC: Just to start with one small  
8 technical thing, most of the changes that happened  
9 with your estimated reference value was because you  
10 went from a .10 to a .05 --

11 DR. SALMON: Yes --

12 DR. BLANC: -- not because of --

13 DR. SALMON: -- that's correct.

14 DR. BLANC: Just out of curiosity, what would  
15 the old grouped-data method have yielded at .05?

16 DR. SALMON: We had a previous estimate of, I  
17 think, actually -- well, we quoted it as 20 at one  
18 point. But I think actually it's about 15.

19 DR. BLANC: So it's a very slight change.

20 DR. SALMON: Very slight. What happened with  
21 the change in the analysis is that it didn't, in  
22 fact, change the best estimate of the EDO 5 very much  
23 at all. There was a little shift but very slight.

24 The bigger change was the improved  
25 confidence level and slight tightening of the

1 uncertainty bounds, which is in line with what you'd  
2 expect.

3                   The other thing I ought to point out  
4 about the fit is that we still had to exclude what we  
5 classified as the "high-dose group" from the data  
6 set. We can't get a decent fit to any of the models  
7 if we include those high-dose values.

8                   We think that that means that there is  
9 something exceptional about those measurements. But  
10 that's independent of whether we do a categorized or  
11 individual data basis or also independent of what  
12 kind of mathematical model we try and fit to the  
13 data.

14                  DR. BLANC: Right. Now I wanted to ask some  
15 questions about the relationship between the  
16 inhalation and the oral issues, which we had talked  
17 about at previous meetings as well.

18                  DR. SALMON: Yes.

19                  DR. BLANC: I want to make sure I understand  
20 your rationale. The assumption would be that, of  
21 inhaled doses at an airborne concentration of chronic  
22 exposure of .013 milligrams per cubic meter, that a  
23 certain percentage of that would be absorbed?

24                  DR. SALMON: Yes.

25                  DR. BLANC: A fairly high percentage.

1 DR. SALMON: Yes. With a situation like that,  
2 we're basically assuming it would be 100 percent  
3 absorbed. We don't have any particular, you know --  
4 I mean, if it's deposited -- if it's a particle and  
5 it's deposited, you know, the chances are it's going  
6 to wind up in the system by one route or another.

7 DR. BLANC: Right. So can you tell me, at  
8 this chronic airborne concentration, what the  
9 equivalence -- and making certain assumptions about  
10 breathing rates -- what the milligrams-per-kilogram  
11 dose would be?

12 DR. SALMON: Yes. I think we have that  
13 calculation in the derivation. And where is that?  
14 It's in here somewhere.

15 DR. MARTY: It's at the end.

16 DR. SALMON: Yes. The equivalence -- what  
17 we're actually talking about is that breathing  
18 fluoride at the REL would probably provide about a  
19 10 percent increment in fluoride uptake to somebody  
20 who is getting the maximum fluoride allowed from  
21 drinking water, according to the oral intake value.

22 In other words, if somebody was in an  
23 area with fluoride supplementation to the maximum  
24 level or natural fluoride up to that maximum level  
25 that's recommended by our oral REL or by the PHG,

1 then breathing this much fluoride, in addition, would  
2 put them about 10 percent higher, which we considered  
3 to be reasonable because we wouldn't want them to  
4 see -- we wouldn't want to see them having a  
5 significant increment above that maximum oral intake  
6 because that's actually, you know, a zero on the  
7 safety factor value. It's the trough of a U-shaped  
8 response curve.

9                   So we feel, from this point of view,  
10 that the chronic REL is, you know, is a safe REL in  
11 that context. Obviously, in order -- if you were  
12 saying, "At what level would produce effects?" then,  
13 we're saying, "If you go tenfold higher than the REL,  
14 if you take out that tenfold safety factor that we  
15 have in there, then you do start to see effects,"  
16 which is what was observed in the study.

17                   There was a fair amount of variation  
18 in the study population. But basically that study  
19 population had a range of fluoride intakes which was  
20 reflective of what people would get from drinking  
21 water.

22                   DR. BLANC: So what you're saying is that, if  
23 a child were exposed at the proposed REL --

24                   DR. SALMON: I'm sorry?

25                   DR. BLANC: If a child were exposed at the

1 exposed -- or if there were airborne, chronic  
2 airborne, levels at the REL, the revised REL value of  
3 13 micrograms per meter --

4 DR. SALMON: Yes.

5 DR. BLANC: -- that child would have  
6 approximately, through the inhalation route, a  
7 hundred -- and if their drinking water were  
8 fluoridated to the standard --

9 DR. SALMON: Yeah.

10 DR. BLANC: -- they would have a hundred and  
11 ten percent of the standard.

12 DR. SALMON: Yes.

13 DR. BLANC: Plus another increment that would  
14 be related to the dust deposition from the airborne  
15 levels?

16 DR. SALMON: I'm assuming that any risk  
17 assessment that, you know, that considered how much  
18 they were getting would include all the routes of  
19 exposure. So we're not -- in calculating this  
20 airborne level, we're not putting in an increment  
21 for, you know, hand-to-mouth transfer from dust.

22 But if somebody were to do a  
23 multimedia risk assessment on a situation like that,  
24 then that's something that they should factor in as  
25 an additional route of exposure but --

1 DR. MARTY: They would -- in a site-specific  
2 risk assessment, they would have to add in the  
3 fluoride that they're getting by noninhalation routes  
4 in order to estimate the risk.

5 DR. SALMON: That's what we -- that's what the  
6 oral number is providing for, in fact.

7 DR. MARTY: Right. And that would be additive  
8 to the hazard index from inhalation. So it can't be  
9 ignored. It won't be ignored in the risk assessment  
10 process for the site-specific facilities.

11 DR. BLANC: And where in the text -- you said  
12 that this was in the text. Where in the text? What  
13 page is it on?

14 DR. SALMON: I'm looking at the bottom of  
15 Page 9. This is in the revised version, which was  
16 handed to you separately. It's presented in a  
17 slightly different form of words than what I just  
18 used, but that's basically --

19 DR. BLANC: I think it's very difficult, from  
20 that paragraph, to understand what you said, which is  
21 that the inhalation REL, not the oral REL, would  
22 result in approximately an equivalency of 10 percent  
23 of the -- see.

24 The difference that -- I think what  
25 this document has had trouble getting its arms

1 around -- and I don't know whether this matters  
2 hugely because I don't know whether we're going to  
3 encounter it in other situations -- is that the oral  
4 route is not theoretical since, you know, there are  
5 large numbers of persons in the general public who  
6 have fluoridated water.

7                   So you can assume that the oral --  
8 that there's an oral baseline --

9           DR. SALMON: Uh-huh.

10          DR. BLANC: -- exposure --

11          DR. SALMON: Yes.

12          DR. BLANC: -- to which you're adding.

13          DR. SALMON: Yes.

14          DR. BLANC: So in a sense, your REL has to  
15 subtract out an assumption -- I don't know if it "has  
16 to" -- but from a public health point of view, it's  
17 built upon an assumption that, for a significant  
18 subset of the population, that they already have  
19 received part of their dose intentionally.

20          DR. SALMON: Yes.

21          DR. BLANC: So it's quite different than, you  
22 know, other theoretical models. And I don't -- I  
23 don't think we've actually -- maybe when you had your  
24 lead discussions, I guess, you had to deal with this.  
25 But other than that, I'm trying to think of some

1 other examples.

2                   And there, it wasn't because people  
3 were, you know, intentionally being supplemented with  
4 the material. And it's all the more important  
5 because your endpoint, as your most sensitive  
6 endpoint here, is extent and effect of absorption.

7                   It would be different, I think, if you  
8 were dealing with inhalational endpoints where we  
9 were talking about two different organ systems and  
10 two different, you know, physiologic processes. But  
11 all of the effects of the fluoride that you're  
12 concerned with here is what would happen if this  
13 inhaled fluoride were absorbed systemically and added  
14 to the burden of fluoride that one has received from  
15 other sources.

16                  DR. SALMON: Yeah. Well, I think we attempted  
17 to address that point here. But I think it sounds as  
18 if we need to follow your advice in rewording this  
19 thing to make the point a little more clearly.

20                  DR. BLANC: I guess I wouldn't put it in the  
21 oral section. I guess I would put something in the  
22 inhalation section that told the reader --

23                               And then maybe there needs to be  
24 something which says what you said -- Melanie, what  
25 you said about and what you said, Andy, about what a

1 risk assessor would have to do, depending on what the  
2 local water situation was.

3 DR. SALMON: I think I agree. We should  
4 clarify that and put it in the appropriate place.

5 DR. BLANC: So that's my main point. Now let  
6 me just go through some other things.

7 CHAIRMAN FROINES: Can I make one comment?

8 DR. BLANC: Yes.

9 CHAIRMAN FROINES: The issue of fluoride,  
10 hydrogen fluoride, is extremely controversial, as you  
11 know, in Southern California. There are suits  
12 underway right now because of the refineries' use of  
13 hydrogen fluoride.

14 And so given that, that in a sense,  
15 the use of hydrogen fluoride in the petroleum  
16 refineries represents kind of a hot spot, the  
17 question I would have in relation to what Paul's  
18 asking is "Do you have a sense of what the hot spot  
19 air concentrations are with hydrogen fluoride and  
20 what implications that has for fluoridated water in  
21 those surrounding areas?"

22 DR. MARTY: When any of the facilities subject  
23 to the program are releasing HF, they have to do air-  
24 dispersion modelling and report the concentrations in  
25 their risk assessments. That is what gets

1 compared -- they have to do two things: The one-hour  
2 maximum concentration and then the annualized  
3 average.

4                   Those are what get compared in the  
5 hazard-index approach with the inhalation reference  
6 exposure level. In addition, they have to do  
7 deposition modelling and run it through our exposure  
8 algorithm to come up with an estimated dose by  
9 noninhalation route.

10                   And that gets compared to our oral  
11 chronic REL. And then the hazard indices get added  
12 together because it's a systemic effect.

13                   The one thing I'm thinking about,  
14 though, in all of this discussion, is that we're  
15 really only talking about the contribution of the  
16 facility. There's nothing in the program that  
17 requires them to look at contributions from other  
18 sources, which would be, in this case, the major  
19 source -- drinking water.

20                   So I'm rethinking that maybe what we  
21 need to do is assume that people are, in their  
22 drinking water, getting what is the public health  
23 goal and back off a little bit on our inhalation REL.

24                   DR. BLANC: If you subtract this REL --

25                   DR. MARTY: Right. Exactly. Which is what

1 you were getting at earlier. The one thing I need to  
2 check is most of the public health goals make an  
3 assumption about exposure from other routes. I  
4 honestly don't know if they do that for fluoride.

5 DR. SALMON: There's another source.

6 DR. MARTY: Right.

7 DR. BLANC: So I think what you need to --

8 DR. MARTY: So I need to figure that out.

9 DR. BLANC: I think you need to see whether  
10 their assumptions were appropriate. That is to say,  
11 did they assume a very trivial source from airborne  
12 levels when they did that --

13 DR. SALMON: Yes.

14 DR. BLANC: -- or not? Because, if they  
15 assumed a level that is an order or magnitude higher  
16 than what you're doing here, then it would be very  
17 conservative. On the other hand, if they assumed an  
18 order of magnitude lower or level lower --

19 DR. COLLINS: The PHG assumed a hundred  
20 percent for fluoride for PHG.

21 DR. MARTY: Oh, thank you --

22 DR. BLANC: So they didn't --

23 DR. MARTY: -- Jim.

24 DR. BLANC: -- assume there would be any --

25 DR. SALMON: They didn't assume any

1 inhalation.

2 DR. MARTY: Right. So that tells me we need  
3 to ratchet down our allowable by other routes in  
4 order to compensate for that.

5 DR. SALMON: Basically what we said if -- I  
6 mean if it's given that what we're proposing for  
7 inhalation is approximately what would be the best,  
8 we would need to see the allowable amount by that  
9 route if we reduced it to perhaps 90 percent or --

10 DR. MARTY: Right. So why don't we go back  
11 and look at that, make the adjustment, and then --

12 DR. BLANC: Resubmit.

13 DR. MARTY: Right.

14 DR. BLANC: But can I make my other comments  
15 now?

16 DR. GLANTZ: Please.

17 DR. BLANC: That was going to be my suggestion  
18 anyway. Given the amount of change, even without  
19 that, that probably would make sense. I know that  
20 this has been a particularly challenging  
21 minidocument. But I think it's because it's very  
22 unusual in its complicated public health nature.

23 So let me make some other comments.  
24 The first comment is directly germane to this whole  
25 issue, and it has to do with a sentence. I'm going

1 to be referring to the one you distributed so -- and  
2 I'm assuming there weren't other big edits other than  
3 the ones you've highlighted.

4                   On the very first page, there's a  
5 sentence I'm going to read to you in the next-to-last  
6 part of that paragraph: "A commonly recommended dose  
7 of one milligram fluoride ingested per day was  
8 reported to reduce dental caries and to be associated  
9 with a greatly increased rate of tooth mottling."

10                   Now, I'm not sure what you're trying  
11 to say there. Are you saying that a commonly but  
12 mis -- previously commonly but now revealed to be  
13 misguided and no longer valid recommended dose? What  
14 does the "commonly recommended" mean in that  
15 sentence?

16           DR. SALMON: I think -- well --

17           DR. BLANC: I think you --

18           DR. MARTY: I think we need to see -- let's go  
19 back and look --

20           DR. SALMON: We need to see exactly what the  
21 original reference was -- meant by the words  
22 "commonly recommended."

23           DR. BLANC: Anyway, I would rewrite that  
24 sentence --

25           DR. SALMON: Yes.

1 DR. BLANC: -- because it's not clear what  
2 you're trying to get at.

3 DR. SALMON: It's not clear. The whole  
4 argument --

5 DR. BLANC: And it muddles the whole thing.  
6 So if you read it and say, "So you're saying that the  
7 current standard gives you tooth modelling already?"  
8 I mean -- and it's a little bit more confusing too  
9 because 1 milligram is not 1 part per million. But  
10 it could easily be confused by a reader 'cause it's a  
11 "1."

12 DR. MARTY: Right.

13 DR. SALMON: Huh.

14 DR. BLANC: In your "Major Uses and Sources,"  
15 I think that it's really odd for a California  
16 document on fluoride not to specifically say how  
17 important hydrogen fluoride is in chip manufacturing,  
18 microelectronics. So I think that definitely has to  
19 be added.

20 I also think that, since you're going  
21 through some detail about industries, clearly an  
22 important industrial source is a by-product of  
23 phosphate fertilizer manufacturing. And that's why  
24 the cohort that you use to derive all your stuff is  
25 in the phosphates.

1                                Now, that's not a big industry in  
2 California; but since you're going through already  
3 and listing industries --

4                DR. SALMON: Yes. Yeah. It's obviously  
5 important on a larger scale.

6                DR. BLANC: Right. And, finally, I would  
7 like -- and we've come to this in other substances --  
8 I think that you need to mention that hydrofluoric  
9 acid is widely available as an over-the-counter  
10 consumer rust-removal agent. I mean walk into any  
11 Ace hardware store.

12               DR. SALMON: Well, would I --

13               DR. BLANC: It's also -- I mean people use it  
14 as a laundry product, even.

15               DR. SALMON: Yeah. We -- well, I think --  
16 yes. I mean obviously we will --

17               DR. BLANC: I think you can't be an  
18 encyclopedia. But, on the other hand, if you list so  
19 many other specific things and then leave out so many  
20 other things that are probably more important --

21               DR. SALMON: Yeah. We mention the electronic  
22 industry --

23               DR. BLANC: Yeah. But I don't think, for  
24 California --

25               DR. SALMON: -- but we need to be more

1 specific than that --

2 DR. BLANC: I mean you're talking about  
3 California --

4 DR. SALMON: -- specifically, the chip-making  
5 subset of the electronic industry, and given that  
6 that's a high-profile activity in California, as you  
7 say, it deserves special mention.

8 DR. BLANC: Now, I want to come back to --

9 CHAIRMAN FROINES: I think that the words  
10 "petroleum refinery," because it's such a hot issue  
11 in Southern California, should be set aside, as well.

12 DR. SALMON: Sorry?

13 DR. MARTY: Describe -- we could describe why  
14 it's used in petroleum refining, for example.

15 DR. BLANC: Of course. Is it used as a  
16 catalyst?

17 DR. SALMON: It's a catalyst in the tracking  
18 processes. I believe we could clarify that.

19 CHAIRMAN FROINES: It's on its way out. But  
20 it's still, I think, used in some refineries.

21 DR. SALMON: Anecdotally, I heard that there  
22 was one refinery in Southern California still using  
23 it.

24 DR. BLANC: Now I would also say that  
25 hydrofluoric acid is a rather important combustion

1 by-product whenever either -- when fluorocarbons  
2 across the board are burned. So that would include  
3 propellants but also includes, you know, all of the  
4 fluorocarbons --

5 DR. FUCALORO: Right. Hydrogen fluoride.

6 Yeah.

7 DR. BLANC: I think that's pretty important.

8 DR. SALMON: Yeah. Yes. It can be a  
9 significant occupational problem when you get --

10 DR. BLANC: That's more of an acute issue but  
11 still --

12 CHAIRMAN FROINES: But it doesn't mean that --  
13 it's an interesting issue because it means that  
14 there's more fluoride around than most people think  
15 there is. And so that it could be -- I think these  
16 point us back to the first issue.

17 DR. BLANC: Yeah. It means also that the air  
18 toxic hot spots, you know, says that there are, you  
19 know, X-amount of hydrogen fluoride used but nobody's  
20 talking about from structural fires, you know, how  
21 much is released.

22 DR. MARTY: Right. This data comes from the  
23 reporting of specific facilities that are subject to  
24 the Act rather than all the other stuff.

25 DR. BLANC: Right. Right.

1 DR. SALMON: Most of these are incidental  
2 sources and that I think you know it's clear that we  
3 know little to nothing about. And I don't suppose  
4 that the quantities are huge. But they're there.  
5 And they could be large in response to a specific  
6 incident, I'm sure.

7 DR. BLANC: Yeah. What I don't know and would  
8 be actually interesting whether -- does the Air  
9 Resources Board ever do sampling in response to large  
10 structural fires? Did they do sampling in the  
11 Oakland fire?

12 DR. MARTY: I think it actually it was the Bay  
13 Area Quality Management District that did the  
14 sampling. They have also done sampling from a couple  
15 of industrial fires. I don't know if they would have  
16 looked for HF or not. But we can try to get the  
17 data.

18 DR. BLANC: That would be interesting, I  
19 think.

20 CHAIRMAN FROINES: Do you remember?

21 DR. MARTY: No. Did not look at fluoride.

22 DR. SALMON: Basically, haven't found much.

23 DR. BLANC: Okay. Now, I thought your -- now,  
24 your arguments, I think, are convincing that,  
25 particularly because of the public health issues,

1 that the endpoint of fluorosis makes sense and not a  
2 respiratory endpoint. So I don't want to -- I'm not  
3 going to -- my comment here is not to revisit that.

4 But I do want to call to your  
5 attention to the "Effects of Human Exposure," first  
6 paragraph, last compound sentence there.

7 DR. FUCALORO: Where is that? I'm sorry.

8 DR. BLANC: Page 2. "A significant --  
9 p-less-than-.05 -- increase in the incidence of  
10 historical acute respiratory disease was observed in  
11 fluoride-exposed individuals -- semicolon -- however,  
12 radiographic examination revealed a difference of  
13 lesser significance -- in p-less-than-.10 -- for  
14 pulmonary changes."

15 Now, that's not a convincing sentence.  
16 If you were talking about -- you're not talking about  
17 a huge number of workers. And you're talking about  
18 measurement of an endpoint which is radiographic,  
19 which I think would be extremely insensitive to the  
20 lung-function changes.

21 So -- and .10 -- it would depend on  
22 the numbers. So I guess what I'd like to see is the  
23 numbers in that sentence --

24 DR. SALMON: I can't --

25 DR. MARTY: What --

1 DR. BLANC: -- what the radiographic endpoint  
2 was.

3 DR. MARTY: Uh-huh. As of the --

4 DR. BLANC: Add a comment that, you know, "We  
5 recognize that this did not measure pulmonary  
6 function."

7 DR. MARTY: It's a very gross measure of  
8 effect.

9 DR. BLANC: And then the very last sentence of  
10 the whole section, which is on Page 6, which says,  
11 "No studies regarding the chronic irritant or  
12 respiratory effects of HF exposure in humans or  
13 animals were available."

14 What you mean is that there were no  
15 studies -- no human studies of pure HF exposure, not  
16 that there are no studies of HF involving HF  
17 exposure. And it's really referring to the paragraph  
18 several paragraphs above where you're talking about  
19 the recent data in aluminum smelter workers.

20 Now, first of all, the Seixas study is  
21 not the only study of aluminum smelter workers in  
22 hydrogen fluoride. And I don't know if you're going  
23 to do a whole literature review, but I wondered if  
24 there isn't a review article on pot room asthma that  
25 you could refer to. But there are, you know, quite a

1 number of international studies on pot room workers  
2 and their respiratory health that document that  
3 hydrofluoric acid aerosols are important in that  
4 industry.

5                   Now, if you want to conclude that  
6 paragraph with a sentence saying that there's -- I  
7 have to say though, you know, that the reason why you  
8 can use the phosphate study is not because they  
9 weren't co-exposed but because we know biologically  
10 that fluoride is the active substance related to it.

11                   So the argument itself that you can't  
12 use the pot room because they're exposed to multiple  
13 things -- that's not the issue. The issue is that  
14 they're exposed to multiple respiratory irritants --

15                   DR. MARTY: Right.

16                   DR. BLANC: -- where you should be closest.  
17 And also I don't think, since this is a section on  
18 human exposure studies -- the point that you don't  
19 have other animal studies should be said under the  
20 section about animal studies if that's you what mean  
21 to say. So I thought that whole thing was misplaced.

22                   And then the -- I want to ask another  
23 question about the analysis of -- there was a whole  
24 discussion here about why years of exposure wasn't  
25 related and, you know, in your modelling, which, you

1 know, it's fine if you want to include it. I wasn't,  
2 you know -- it really wasn't that important to me as  
3 a reader.

4 But what I was confused by is why you  
5 didn't look at fluoride years of exposure. Yeah.  
6 Obviously years of exposure is not going to be a  
7 strong predictor if some people are exposed to very  
8 light airborne levels and some people are exposed to  
9 higher levels.

10 And you couldn't include years of  
11 exposure and years -- and fluoride years of exposure  
12 in the same model because they would be collinear.  
13 But if you modelled fluoride years of exposure,  
14 wouldn't that be a -- I'm assuming that that would be  
15 a strong predictor because, if that wasn't, it would  
16 argue against the fluoride relationship.

17 Same way people used, you know, fiber  
18 years of exposure in asbestos, I mean --

19 DR. MARTY: Right.

20 DR. BLANC: Stan, do you understand what I'm  
21 asking?

22 DR. SALMON: Yeah.

23 DR. GLANTZ: Yeah.

24 DR. BLANC: I know why you shouldn't -- I mean  
25 there's a good argument why you shouldn't use age in

1 that kind of model because in that model it's sort of  
2 a surrogate for exposure and not a surrogate for age.  
3 But the other thing, I didn't really understand --

4 DR. SALMON: I think we're, to some extent,  
5 depending on the authors' analysis of the study.

6 DR. BLANC: I thought you were the ones who  
7 did the logistic progression. I thought that was  
8 all --

9 DR. SALMON: Oh, yes. It was. Yeah.

10 DR. MARTY: I'm sorry. I think we didn't want  
11 to include years in the dose metric, which you would  
12 be doing if you did fluoride years, milligrams-  
13 cubic-meter years.

14 DR. BLANC: Because?

15 DR. MARTY: Because it would confound the dose  
16 response. It's information that you don't really  
17 need that you're throwing in. And it's going to make  
18 your dose response, I think, more uncertain,  
19 especially since we're talking about a bone-density  
20 measure.

21 DR. BLANC: You're saying that it would  
22 confound it because you would get a stronger  
23 relationship because there's some change with age?

24 DR. MARTY: Bone density changes with age.

25 DR. BLANC: Yeah. But you've already shown

1 that age itself as a cohort isn't -- by itself is not  
2 a very strong predictor. I'm not suggesting that you  
3 have a multivaried model that you include both dose  
4 and age or both dose and years worked as two separate  
5 predictors.

6 But it would be reasonable to look at  
7 separately as a model where the predictor, instead of  
8 being your airborne fluoride level at one point in  
9 time, would be the airborne level that was measured  
10 times the years that you were exposed, assuming that  
11 you've been always exposed in a high-exposure job.  
12 Or else maybe drop the whole discussion.

13 DR. SALMON: Well, we could --

14 DR. BLANC: I mean, just from an  
15 epidemiological -- maybe you other guys have the same  
16 take on it because it didn't --

17 DR. MARTY: Let me run it by our  
18 epidemiologists. They might say, "Why do you have  
19 that in here?"

20 DR. BLANC: And I will make a public health  
21 pitch for why it might matter, I suppose, if your  
22 effect -- if the age effect of exposure was really  
23 mediated by environmental factors, one of which is  
24 fluoride. I mean why do people's bones get denser  
25 over time?

1                   We know there's a lot of environmental  
2 fluoride. Maybe the whole reason is not age as a  
3 phenomenon. Maybe it's age interacting with  
4 environmental exposure of which this, maybe, is the  
5 key exposure. So maybe it does --

6           DR. MARTY: Also after 40, you get -- your  
7 bones get less dense. So if -- you know, that  
8 actually complicates it even further.

9           DR. BLANC: But these are all working-age  
10 people. So they're not 70-year-olds.

11          DR. MARTY: Yeah. Presumably.

12          DR. BLANC: So most of them are on the up --

13          DR. SALMON: We could certainly -- we could  
14 examine that and see whether it produces anything  
15 interesting.

16          DR. BLANC: I'm almost at the end of my  
17 comments. I'm sorry. You're looking a little --

18          CHAIRMAN FROINES: No. I'm okay.

19          DR. BLANC: The part about the National  
20 testing -- the rats on Page 7.

21          DR. SALMON: Yeah.

22          DR. BLANC: And you talk about the end -- the  
23 tooth endpoint and the dysplasia of the dentine. The  
24 previous section -- since you're talking about, in  
25 this very much older study, the 1949 study, a bunch

1 of different sort of fairly crude endpoints, were  
2 there no other endpoints looked at in the NTP study  
3 other than its not being a carcinogen or whatever it  
4 was being studied for?

5 DR. COLLINS: No. It was -- they did look at  
6 cancer. And I think it was found to be a carcinogen.  
7 So I think that got a lot of display in the study.

8 DR. BLANC: And were there other endpoints  
9 they looked at?

10 DR. COLLINS: I'm sure there were a lot of  
11 things. Yeah. I think we just picked the things  
12 that were relevant to --

13 DR. BLANC: I mean I think that it would be  
14 worth having a sentence like "Although other  
15 endpoints were looked at" --

16 DR. MARTY: Okay.

17 DR. BLANC: -- "there was no consistent  
18 pattern." Or --

19 DR. MARTY: Okay. We can do that.

20 DR. BLANC: And I think that that's where I  
21 would say, "They looked at respiratory endpoints, and  
22 they found no pulmonary findings whatsoever," because  
23 that's the implication from the earlier statement.

24 DR. MARTY: Okay.

25 DR. BLANC: Because you're --

1                   What's that?

2                   But actually your other comment, by  
3 the way, about how there's no animal study showing  
4 lung effects, since your other study shows pulmonary  
5 hemorrhage in animals, which is a lung effect -- I  
6 guess that's not a great chronic study to --

7           DR. SALMON: It's not a full chronic study.

8           DR. BLANC: It's a subacute study. But it is  
9 a little confusing.

10          DR. SALMON: Yes.

11          DR. BLANC: And so there really ever hasn't  
12 been a decent inhalation study in animals --

13          DR. SALMON: Not a chronic one. I mean the  
14 point is that this stuff is nasty enough that people  
15 generally don't like to handle it for extended  
16 periods of time. They do short-term studies, you  
17 know, given that the acute exposure to a higher dose  
18 creates all kinds of mayhem.

19                   I think they content themselves with  
20 looking at that rather than trying to do, you know, a  
21 long-term study with all the logistic problems of  
22 doing a long-term study with material like that.

23          DR. BLANC: Okay.

24          DR. SALMON: Most of the inhalation --

25          DR. BLANC: Anyway, those are my comments.

1           CHAIRMAN FROINES: Thanks, Paul.

2                           Roger?

3           DR. ATKINSON: No. I have no comments.

4           CHAIRMAN FROINES: Craig?

5           DR. BYUS: Yeah. I have the same comments  
6 about it's confusing about being in the water and  
7 being -- I mean I would put that right up in the  
8 front of exposure that it's in the drinking water at  
9 this level in many places in California. It's added,  
10 or it's in the water naturally and that it has a  
11 desirable --

12                           I mean I think I've looked for the  
13 word "enamel," "tooth enamel" in there. And I  
14 haven't -- there's nothing. You don't ever say that  
15 anywhere. And my understanding, from my dentist, is  
16 that the fluoride is desirable to harden the tooth  
17 enamel.

18                           And that occurs mainly during  
19 development and that it doesn't work too well after  
20 you're an adult. And so that's why you want it in  
21 the water when you're a child, when children are  
22 drinking it.

23                           I mean you need to sort of say that in  
24 terms of the desirable aspects of why it's there  
25 although I guess it is -- my other dentist, my

1 endodontist recommended that I do apply topical  
2 fluoride. Even in an adult, topically applied  
3 fluoride will strengthen the enamel below your  
4 gumline as your gums recede. Just a little aside.

5                   But, anyway, it is confusing. And so  
6 then the response is --

7           DR. FUCALORO: You're making me feel old.

8           DR. BYUS: -- the desirability of it versus  
9 the toxicity. I mean it's not, you know -- it's  
10 desirable in a dose, certainly, during development.  
11 And then it's undesirable in a toxic above that. I  
12 think you just need to lay that out just clearly.

13           CHAIRMAN FROINES: Tony.

14           DR. FUCALORO: I don't really have a comment.  
15 I have a question though. 1 part per million is the  
16 goal -- correct? -- of fluoride? I assume that's  
17 fluoride, not sodium fluoride, because that's the  
18 weight. So I'm looking on Page 9.

19           DR. SALMON: Uh-huh.

20           DR. FUCALORO: Which is the same --

21           DR. SALMON: Yes.

22           DR. FUCALORO: -- as that milligram per liter.  
23 And that comes to about 5-times-10-to-the-8 moles  
24 fluoride there, approximately speaking. My question  
25 is that has no -- you don't expect much evaporation

1 of fluoride or vaporization of fluoride from that low  
2 concentration; is that correct?

3 I mean you don't expect to have an  
4 exposure problem from just water hanging around.

5 DR. MARTY: You mean from taking a shower --

6 DR. FUCALORO: Yeah. You're taking a shower.  
7 Right. You don't drink most of the water that flows  
8 through your house, you know.

9 DR. SALMON: The fluoride will be ionized --

10 DR. FUCALORO: Well, yeah. But, you know,  
11 fluoride is not a strong acid. Hydrofluoric is a  
12 weak acid.

13 DR. SALMON: But at that level pH of regular  
14 water, there's not going to be --

15 DR. FUCALORO: Well, the pH of regular water,  
16 if there's not too many dissolved minerals in it, is  
17 very low because it has dissolved carbon dioxide. So  
18 it's acidic, which would promote the formation of HF  
19 from fluoride. And I don't know to the extent -- you  
20 don't think it will happen much --

21 DR. ATKINSON: It's not going to volatilize  
22 out of water.

23 DR. FUCALORO: No. It's not going to  
24 volatilize. But it's going to have a very low end --

25 DR. MARTY: You may get some atomized --

1 DR. FUCALORO: Oh, atomizing is something  
2 else.

3 DR. MARTY: -- while you're taking a shower.  
4 It's a common problem in assessing risks of stuff in  
5 water to try to estimate the dose that you get that  
6 way. For volatiles, there's a model. For  
7 nonvolatiles, to date, there really isn't a good  
8 model.

9 DR. FUCALORO: But that would have been my  
10 guess, I mean, that it pretty much stayed in the  
11 water. It's not a problem. But people have  
12 obviously thought about it.

13 DR. SALMON: I think the people who were  
14 working on the PHG considered a lot of those things;  
15 but the general consensus, as Melanie says, is that  
16 there isn't a particularly good model to describe  
17 what other incidental exposure you might have besides  
18 drinking water.

19 DR. FUCALORO: Because I was taking a shower  
20 this morning. And I smelled. And I said, "What the  
21 hell's in this stuff?"

22 DR. SALMON: You probably don't want to know.

23 DR. FUCALORO: I don't want to know.

24 CHAIRMAN FROINES: Well, I think this goes  
25 back to Paul's first point, though, because, given

1 that there is an oral dose from fluoridated water, it  
2 seems to me that having some sense of what is the  
3 total exposure is a very reasonable question.

4 DR. MARTY: We did add in a paragraph at the  
5 very -- it's the very last paragraph. Because of  
6 this issue, you know, the fluoride in water is going  
7 to vary a lot. Some of it's higher than what you  
8 would want, naturally.

9 And so we wanted to make a statement  
10 that, even if you're lower than our inhalation  
11 reference exposure level that, you know, you have to  
12 be cautious, depending upon the population you're  
13 evaluating, as to what their exposures are from  
14 water. And the only data we had about variability  
15 came from a German study which we quoted in here.

16 So we do say that "Consideration  
17 should therefore be given to populations with  
18 exceptionally high fluoride intake due to locally  
19 elevated concentrations in the drinking water."

20 Do you have a real good way to handle  
21 that point quantitatively in a program like this  
22 where the risk assessments are site specific and it  
23 just depends on where you are?

24 DR. BLANC: But what you do have to do -- and  
25 I don't think you have to do your REL, assuming that

1 someone would get overexposed by water through some  
2 problem -- but you have to take your REL-making  
3 assumption about what people will routinely be  
4 exposed to.

5 DR. MARTY: Okay.

6 DR. BLANC: And that's what you have to do.

7 DR. MARTY: Right.

8 DR. BLANC: Then I asked a question about  
9 terminology that you used throughout the document and  
10 whether you're being consistent. You're describing  
11 hydrofluoric -- hydrogen fluoride as a colorless gas  
12 or as particulates.

13 Is that the term that you'd normally  
14 use when you're talking about things that might exist  
15 as a -- perhaps as a fumigant temporarily but would  
16 become an aerosol?

17 DR. MARTY: No. That --

18 DR. BLANC: Is that what you would --

19 DR. MARTY: Right.

20 DR. BLANC: If that's what --

21 DR. MARTY: We should use "aerosol" in that  
22 case.

23 DR. BLANC: I mean or is that how you  
24 describe -- what term would you use to describe  
25 hydrochloric or HCL -- what did you call it? I don't

1 know. Just be consistent.

2 DR. MARTY: Right.

3 DR. FUCALORO: You know I read that as

4 hydrofluoride is a colorless gas but you can get

5 fluorides in particulates, assuming salts. I think

6 that's what you meant. I took note of that. I

7 didn't write something down. But I think that's what

8 you meant.

9 DR. MARTY: Oh, okay. Right. In that --

10 under 2 -- "Physical and Chemical Properties" --

11 right? --

12 DR. FUCALORO: Yeah.

13 DR. MARTY: -- for fluoride as particulates?

14 DR. FUCALORO: Yeah. Yeah. Yeah. That's

15 what I thought you meant.

16 DR. BLANC: Yeah. Thanks.

17 CHAIRMAN FROINES: Tony, are you finished?

18 DR. FUCALORO: Done.

19 CHAIRMAN FROINES: Gary?

20 DR. FRIEDMAN: Until I talk to my dentist, I

21 have nothing to add.

22 DR. FUCALORO: We'll be getting an e-mail.

23 CHAIRMAN FROINES: This discussion's been

24 nothing less than anecdotal. That's for sure.

25 Okay. Melanie, I had just a couple of

1 questions. First, did the people preparing this  
2 document -- did they review the references that were  
3 cited in the ATSDR document? Because your references  
4 in here and the ATSDR document are quite different.  
5 And there are a lot more references that are not  
6 cited here.

7                   And so one's first impression -- I  
8 didn't go back and look at all the references -- but  
9 one's first impression is that there are a lot of  
10 studies that are missing from this discussion.

11               DR. MARTY: We did look at the ATSDR,  
12 including the new one that's out as a draft. It  
13 comes back to that same problem with the chronic REL  
14 summaries is that we're trying to do brief summaries.  
15 And so we're really only plucking descriptions of  
16 studies that --

17               DR. BLANC: Are relevant.

18               DR. MARTY: Right.

19               DR. BLANC: Yeah.

20               DR. MARTY: So effectively, we are --

21               DR. BLANC: The way I would suggest handling  
22 that is -- for example, what I suggested about the  
23 aluminum industry -- which is that you correctly  
24 cited probably the most recent reference that was  
25 relevant -- the Seixas study --

1           CHAIRMAN FROINES: "Sayshus" (phonetic).

2           DR. BLANC: -- "Sayshus" study -- "Noah" --  
3 "Noah" study -- but citing one review article, if  
4 there is a decent one, is a way to solve that because  
5 then anybody who is -- who would be, you know,  
6 tracking back, would get others. And I don't think  
7 you need to cite, you know, 15 studies of the  
8 aluminum smelting industry.

9                         But if there's a decent one --

10          DR. SALMON: Yes. I think -- I mean a lot of  
11 the work which ATSDR was doing concentrated on the  
12 oral RELs anyway. And we are primarily relying on  
13 citing PHG review as our source for --

14          DR. BLANC: Which is fine.

15          DR. SALMON: But I think that's, you know,  
16 clearly something we can --

17          CHAIRMAN FROINES: Well, I still have some  
18 discontent, I guess, with the way you handle the  
19 aluminum smelter issue. It's sort of like you wave  
20 it away as being too difficult to deal with. But  
21 there is a very -- a fairly extensive literature on  
22 pot room asthma and health-related effects. And  
23 this -- just this sentence seemed a bit glib to me  
24 about what is not an inconsequential issue.

25                         In other words, I don't get a feeling

1 that somebody has said, "Well, what's the weight of  
2 the evidence look like in terms of these respiratory  
3 effects?" But -- so I'll leave it at that.

4           The other thing I was going to say is  
5 I have eight papers here on -- that are not cited  
6 that relate to fluorosis that come from Mexico that  
7 you undoubtedly haven't seen yet. And they're  
8 certainly not quoted either in the ATSDR document or  
9 in this document.

10           And, in fact, they have -- the one  
11 that's most interesting is that one entitled  
12 "Fluoride-Induced Disruption of Reproductive Hormones  
13 in Males." And this has been submitted to  
14 "Environmental Research." And it has some rather  
15 striking results.

16           And also there is some new data out of  
17 Mexico showing quite striking neurologic effects.  
18 And so, since you are going to be going back and  
19 looking at some of this, I'll give you these. And  
20 you can see if, in terms of your analysis, they are  
21 relevant.

22           This particular paper, clearly, is not  
23 peer reviewed at this point. But you might -- we can  
24 follow up and see if it's accepted. Because if it is  
25 accepted, then it would actually affect the risk

1 assessment -- I mean this document -- because it is  
2 at relatively -- it seems to me relatively low levels  
3 with rather striking results.

4                   So I'll give you this. And you can  
5 take a look at this. But there are a whole series of  
6 other papers. There is a journal called "Fluoride."  
7 And, not surprisingly, there's a lot of papers about  
8 fluorine in it. So that's all.

9                   DR. COLLINS: Some of these studies, like the  
10 TEA study used by ATSDR -- we mentioned it in  
11 passing. But it was an oral study where they looked  
12 at 66 women. And we -- in our study, we have  
13 inhalation with 77 men.

14                   And then our oral number was based on  
15 hundreds of people, not just --

16                   CHAIRMAN FROINES: Yeah. I think the point  
17 you're making is well taken. I'm not suggesting that  
18 things are missing. I'm suggesting that, when I went  
19 through the ATSDR document, I just noticed vast  
20 differences. And I just don't know what the source  
21 of it is. I'm not asking you to go back and put them  
22 in. I'm just saying --

23                   DR. SALMON: So I think one of the issues is  
24 that quite a lot of the ATSDR was related to possible  
25 sources of information about oral, inhalation and

1 oral, intake; whereas we were concentrating on the  
2 inhalation --

3 DR. COLLINS: And they're also looking at  
4 acute. We've already handled acute.

5 CHAIRMAN FROINES: No. I didn't mean --

6 DR. MARTY: It does bring up an issue, though,  
7 that we wanted to discuss a little more with the  
8 panel. And that is expanding our chronic toxicity  
9 summaries more because this issue comes up every  
10 meeting that, you know, you guys see papers that  
11 aren't in here and "Why aren't they in here?"

12 So we, at OEHHA management, have been  
13 having discussions about going slower and having more  
14 per chemical. So having said that, you may expect to  
15 see a little bit bigger documents in the future.

16 CHAIRMAN FROINES: Well, the problem with  
17 these compounds, as opposed to diesel exhaust or to  
18 lead, is that you don't spend a lot of time in  
19 feedback with the lead person. So you and Paul  
20 didn't spend hours talking about fluoride.

21 It turns out, with fluoride, its being  
22 so important, we probably should have. But that's  
23 water over the dam.

24 DR. BLANC: Fluoridated water over the dam.

25 CHAIRMAN FROINES: What?

1 DR. BLANC: Fluoridated water over the dam.

2 DR. FRIEDMAN: Dental dam.

3 DR. FUCALORO: Dental dam.

4 CHAIRMAN FROINES: We're going to move ahead  
5 now. So I wouldn't necessarily think that you need  
6 to necessarily expand, but it does seem to me that  
7 we -- on some of these compounds, discussions with  
8 the leads can -- because the lead should be the  
9 person who knows the literature, rather than somebody  
10 else. And so, hopefully, we can -- don't put more  
11 burden on you.

12 Why don't we go on to phosphine?

13 DR. SALMON: Okay. Well, phosphine -- this  
14 one, we've had to revisit primarily because the  
15 problem's been a lot of inconsistencies among the  
16 animal studies. And we've had to basically do the  
17 best we can with a rather confused and confusing data  
18 set here.

19 We added an additional uncertainty  
20 factor because of the severity of the endpoint  
21 observed in some of the studies and the relative  
22 closeness of the effect levels for some of those  
23 severe effects in certain studies to the -- what  
24 other studies would present as a NOEL or a relatively  
25 safe level.

1                   So we've modified the analysis to  
2 reflect the uncertainty, basically, there. And we've  
3 also added some information on the uses of phosphine.  
4 Next slide, please.

5                   This is the derivation that we're  
6 proposing here. It's a mouse study, respiratory  
7 effects being the critical effects. The data are not  
8 really suitable for a benchmark dose analysis. So  
9 we're using a LOEL-NOEL approach. And we derived a  
10 NOEL -- in fact, if I could have the next slide,  
11 please.

12                   We've included the usual uncertainty  
13 factors as we usually do but also, as I mentioned  
14 earlier, this additional uncertainty factor of 3,  
15 reflecting the severity of some of the effects  
16 observed in the overall quality and uncertainty of  
17 the data base as a whole. And we have a  
18 recommendation here of chronic REL of 0.8 micrograms  
19 per meters cubed.

20                   So -- okay. Thank you. The  
21 problem -- as usual, we would like to be able to  
22 assess the differential impact on children's health,  
23 in terms of developmental studies and the data that  
24 we have, which is not huge. But there is a  
25 developmental study, and the implication is that a

1 proposed REL would be protective of the developmental  
2 effects.

3                   We don't have any information, really,  
4 to quantify any differential effects in terms of the  
5 impact on respiratory systems. We can't make any  
6 specific predictions. We have to rely on the  
7 included tenfold safety factor to, in turn, give a  
8 variation in human population to provide a safety  
9 margin to protect children.

10           CHAIRMAN FROINES: Thank you. The lead just  
11 came back in the room.

12           DR. GLANTZ: I'm sorry.

13           CHAIRMAN FROINES: Stan -- Dr. Glantz is the  
14 phosphine lead.

15           DR. GLANTZ: Oh, well, I read this. And it  
16 all seemed reasonable to me. I didn't realize I was  
17 the lead. But I didn't have anything to say about  
18 it. I read through it, and it seemed pretty  
19 straightforward.

20           DR. SALMON: The uncertainty factor --

21           CHAIRMAN FROINES: Roger?

22           DR. ATKINSON: I was --

23           DR. GLANTZ: What was the issue with it?

24           DR. SALMON: One of the issues was our use of  
25 the additional uncertainty factor to reflect the

1 inconsistency of the data base and the severity of  
2 the effect seen in some studies in doses which were  
3 not that different --

4 DR. GLANTZ: Oh, I see --

5 DR. SALMON: -- from the allegedly safe level  
6 derived in other studies. So that's the point of  
7 contention, you know. Everything else is, you know,  
8 within the constraints of the data, pretty much, you  
9 know, as the guidelines would tell us to do it.

10 DR. GLANTZ: So actually I had missed that --  
11 I have to admit that -- when I read this because I  
12 read it -- have we ever done that before?

13 CHAIRMAN FROINES: Not that I know of.

14 DR. MARTY: I don't think so.

15 DR. SALMON: Not for the chronic RELs. No. I  
16 think --

17 Jim, have we used a severity factor  
18 for any of the acutes?

19 DR. COLLINS: Not really. Because we had  
20 various levels of acute RELs -- so that would have  
21 kicked it into effect.

22 DR. SALMON: So we, in effect, have done  
23 similar things with acute RELs. It hasn't had quite  
24 this effect.

25 DR. MARTY: Yeah. We have not done that

1 before. And the reason we did it is that the data  
2 base on phosphine is a little strange. If you look  
3 at studies. even conducted within the same laboratory  
4 in the same strain -- and in Newton's lab, there in a  
5 subchronic study, they found transient toxicity that  
6 they don't find in their chronic study.

7                   And also the limited data on lethality  
8 endpoints -- it appears that there's a very steep  
9 dose-response curve for phosphine. So -- and when  
10 part of this might be related to the "PMB" used to  
11 study looking at pregnant female rats, they actually  
12 had lethality effects at 7 ppm.

13                   Yet, in their chronic study at 3 ppm,  
14 they find no toxic effects. So that's -- I don't  
15 know if it's related to pregnancy or it's just a  
16 reflection of the very steep dose response for  
17 phosphine.

18                   But it makes you a little bit anxious  
19 about using these data to develop a chronic REL. So  
20 we wanted to throw in an additional threefold  
21 uncertainty factor just for data base -- I don't know  
22 want to call it "discrepancies" -- but really lack of  
23 good dose response information.

24                   So it cranks up our cumulative  
25 uncertainty factor to 300. And that's below the

1 NOAEL, which is 1 ppm.

2 DR. GLANTZ: And why did you pick 3 as opposed  
3 to --

4 DR. MARTY: As opposed to 10?

5 DR. GLANTZ: -- 10 or pi or anything else?

6 DR. COLLINS: 6.

7 DR. BLANC: For which? For the  
8 interspecies --

9 DR. GLANTZ: No. The interspecies and all  
10 that is pretty standard.

11 DR. BLANC: Isn't there a choice, though?  
12 Aren't there times where you can use an interspecies  
13 factor of 10 and have an interspecies factor of 10?

14 DR. SALMON: The usual choice is either an  
15 unmodified interspecies factor of 10 or a use of the  
16 RGDR calculation, which is -- yeah -- the  
17 calculation, the human equivalent calculation  
18 concentration in this case assumes a -- well, uses an  
19 RGDR calculation.

20 So the default in that case would be  
21 to use the RGDR calculation plus an uncertainty  
22 factor for interspecies of 3. So the assumption  
23 being that the RGDR calculation, in effect, is  
24 functioning as a sort of crude kinetic model which is  
25 allowing a portion of the interspecies variation.

1 DR. BLANC: I think what I would argue, in  
2 this case, is that, given the uncertainties involved  
3 and given the challenges of the data base and the  
4 sort of protoplasmic toxicity of the chemical  
5 involved in the steep dose response curve, that  
6 rather than getting to this sort of odd circumstance  
7 of putting in the uncertainty factor, I would be  
8 conservative and simply not go the human equivalency  
9 concentration route and use the factor of 10.

10 It will get you to the same place  
11 without having to sort of develop a whole new  
12 sort-of-side-door way of getting in the uncertainty  
13 that you obviously feel in the data base.

14 DR. SALMON: Uh-huh.

15 DR. MARTY: Okay.

16 DR. GLANTZ: Yeah. I agree with that.

17 DR. SALMON: Okay.

18 CHAIRMAN FROINES: Craig?

19 DR. BYUS: That's fine.

20 DR. FUCALORO: On Page 3, second sentence on  
21 the Roman 5, it says, "Noncancer toxicity endpoints  
22 included weight gain and relative organ weights of  
23 kidneys, lungs, liver, heart, brain, and spleen."

24 Do you mean noncancer toxicity  
25 endpoints included reduction in weight gain? Am I

1 reading that wrong?

2 DR. SALMON: Yes. Reduction of. Yeah.

3 DR. MARTY: Yeah.

4 DR. FUCALORO: And at the -- towards the end  
5 of that paragraph, you have a sentence which begins  
6 "This group also." I'll give you a second to find  
7 that.

8 "This group also conducted a  
9 short-term, repeated-dose experiment" -- period.  
10 Then it has, in my copy, after the period, a comma --  
11 "e-d" -- and then capital "S" for 6. So obviously  
12 some sort of typo there, I'd just point out.

13 DR. SALMON: Yeah.

14 DR. FUCALORO: Now, I have one other comment  
15 that's more of a general comment. And I'm not sure  
16 that this is the appropriate time to bring it up.  
17 But perhaps it's just specific with me. In looking  
18 on Page 1 under "Chemical Properties Summaries," you  
19 don't have the density at 25 degrees Celsius.

20 If I asked you, "What is the density  
21 of phosphine at 25 degrees Celsius?" what would you  
22 tell me? Do you have that data, those data?  
23 Anywhere? All right. You don't have 'em here. All  
24 right.

25 But let me then ask this question:

1 Where it has, at the bottom, "Conversion Factor:  
2 1.39 micrograms per cubic meter per part per  
3 billion," which, of course, I would mention is the  
4 same as 1.39 milligrams per cubic meter per one part  
5 per million -- I would say that all your documents  
6 should be consistent.

7 I mean sometimes you're using  
8 micrograms and sometimes using -- where did you get  
9 that factor? Is that in the literature? Or is it  
10 purely computational?

11 DR. SALMON: I think it's computational.

12 DR. FUCALORO: Of course, it is.

13 DR. SALMON: I think it's based upon the  
14 assumption that it functions as an ideal gas --

15 DR. FUCALORO: Exactly.

16 DR. SALMON: -- as it should probably, where  
17 it's a dilute mixture in air. But as to your  
18 question -- "What is the vapor density at 20  
19 degrees?" -- which is obviously a material question  
20 in terms of its safety and how it behaves, I don't  
21 know.

22 But I imagine you could obtain that as  
23 a --

24 DR. FUCALORO: You can --

25 DR. SALMON: Yeah.

1 DR. FUCALORO: Well, and it would vary, I  
2 suppose, from the ideal gas equation --

3 DR. SALMON: Absolutely.

4 DR. FUCALORO: -- very slightly.

5 DR. SALMON: Well --

6 DR. FUCALORO: And so what I'm suggesting is  
7 that those numbers remain the same. I mean, that is  
8 to say, that the density of the vapor at 25 degrees  
9 is probably 1.39 grams per liter.

10 DR. ATKINSON: That would be one atmosphere of  
11 phosphine.

12 DR. FUCALORO: Maybe with factors of ten  
13 introduced. Yeah. I mean, you know, by a factor  
14 of --

15 DR. ATKINSON: You mean it would be just  
16 straight computational --

17 DR. FUCALORO: I'm doing straight ideal --

18 DR. ATKINSON: You're assuming it's an ideal  
19 gas.

20 DR. FUCALORO: Right. Right. Right. Right.  
21 An ideal gas at one atmosphere.

22 DR. ATKINSON: I wouldn't have thought one  
23 atmosphere of phosphine would be an ideal gas.

24 DR. FUCALORO: That's the difference. So  
25 that's why there would have to be a reference.

1 DR. BLANC: If you were from Jupiter, it would  
2 be an ideal gas.

3 DR. COLLINS: It might be an ideal poison,  
4 now.

5 DR. FUCALORO: But if you notice, for example,  
6 in the fluorides -- hydrogen fluorides -- that's  
7 exactly what they report.

8 DR. COLLINS: Uh-huh.

9 DR. FUCALORO: So -- right? -- at one  
10 atmosphere, that's what they report. The density is  
11 point eight -- .83 grams per liter. That's what I'm  
12 referring to. So the question is -- I don't -- I  
13 don't know what that means. But the -- it seems to  
14 me that the density reported at 25 degrees Celsius is  
15 for one atmosphere pressure.

16 DR. ATKINSON: Well, in fact, it looks as  
17 though it's just calculated from the --

18 DR. FUCALORO: Well, that's my point exactly  
19 is that most of this is computational. And it makes  
20 it seem like it's empirical, you see. And that's the  
21 point I wanted to make.

22 And you say it doesn't act ideally.

23 Well, I suspect, if phosphine doesn't  
24 act ideally, neither does hydrogen fluoride,  
25 especially with hydrogen bonding and all of that. So

1 I just wonder if you should remove that density and  
2 put only the conversion factor, indicating it's  
3 purely computational. Do you see my point?

4 DR. MARTY: Yeah. I see your point.

5 DR. FUCALORO: It's a general comment for all  
6 these things. Yeah.

7 DR. SALMON: So ostensibly we could attempt to  
8 find measured values from the data base --

9 DR. MARTY: Well, what we could do is --

10 DR. FUCALORO: You can measure -- I mean the  
11 density can be measured by --

12 CHAIRMAN FROINES: In the spirit of time, this  
13 is not the most crucial issue that we're facing in  
14 terms of finding approval on this. Why don't we have  
15 Tony work with you to work out the best language in  
16 general rather than taking much more time on this  
17 issue?

18 Because I think it's something that  
19 can be resolved -- it's not a major health-related  
20 issue; I mean it has health implications -- but it  
21 could be resolved out of the discussion.

22 DR. FUCALORO: And that's it.

23 CHAIRMAN FROINES: Gary.

24 DR. FRIEDMAN: No. I have nothing.

25 DR. BLANC: Going around, I wasn't -- I had

1 other comments.

2 CHAIRMAN FROINES: Oh, pardon me. Go ahead.

3 DR. BLANC: Thanks.

4 What you presented on your slide is a  
5 different endpoint than what you have in the  
6 document. So is that a revision? In the document,  
7 the critical effect is decrease in body weight gain,  
8 increase in relative organ weights.

9 Then you present a slide with  
10 bronchiectasis.

11 DR. SALMON: That appears to me that, if --

12 DR. BLANC: The numbers were the same but --

13 DR. SALMON: It sounds like there might have  
14 been -- the document is correct.

15 DR. MARTY: Correct.

16 DR. SALMON: If sounds as if we omitted the  
17 revision in the slide. And I didn't spot that. I'm  
18 sorry. But the document is correct. And the slide  
19 was incorrect.

20 DR. BLANC: But it's the same values.

21 DR. SALMON: Yeah.

22 DR. BLANC: So you must have, at some point,  
23 chosen a different endpoint?

24 DR. COLLINS: I think at one point, we --

25 DR. MARTY: Sounds like we took a slide and

1 took it out and --

2 DR. COLLINS: At one point, we were using the  
3 two-year study. And I think that's where, after we  
4 found some inconsistencies, we went back to the 90  
5 days studying mice.

6 DR. BLANC: I think I need to look at that  
7 slide again because I think it was the Barbosa. But  
8 you're saying it was just a composition error in the  
9 slide?

10 DR. SALMON: Yeah. It was just a composition  
11 error in the slide. I'm sorry. I think that the  
12 slide was --

13 DR. BLANC: What study were you using, then?  
14 Because you only talk about two studies -- the  
15 Barbosa and then a study which found no effect  
16 whatsoever.

17 DR. GLANTZ: This isn't the slide you want.  
18 That's the wrong slide.

19 DR. BLANC: That's even the wrong chemical.

20 DR. MARTY: Jim, can you go back to the slide  
21 where --

22 DR. SALMON: Can you go back to the slide --

23 DR. MARTY: -- phosphine --

24 DR. SALMON: That must have been one of the  
25 other phosphine studies that isn't used now which

1 is -- it's a compositional error in the slide because  
2 the document --

3 DR. BLANC: Well, can you remember what that  
4 study was? Because wouldn't that make it -- wouldn't  
5 that be the study that would make sense as your  
6 supportive study rather than the study that -- which  
7 I agree you have to talk about the Newton, 1999,  
8 study because it shows the inconsistency in the data  
9 bases but --

10 DR. SALMON: I'm not sure --

11 DR. BLANC: Or you do you think this was taken  
12 from some other chemical?

13 DR. SALMON: It might have been taken from  
14 some other chemical. It's clearly an error, which --

15 DR. BLANC: Okay. So there is no other study.

16 Although I would normally say or I  
17 would normally be fairly uncomfortable with this sort  
18 of body-weight-gain endpoint because it's so nebulous  
19 in your support, I would say that, because of the  
20 systemic toxicity of phosphine, which is very  
21 difficult to pin down, even mechanistically, I don't  
22 think that, in this particular case, an unreasonable  
23 endpoint.

24 We're not talking about an -- you  
25 know, an irritant. We're talking about a sort of

1 cytoplasmic toxin with a myriad of effects. So from  
2 that point of view, you know, it doesn't bother me  
3 that that's what you did.

4                   Now I have another question. The  
5 reason that you're doing this chemical at all is  
6 because the regulatory -- you have regulatory  
7 permission to do fumigants; is that right?

8                   DR. MARTY: Well, it's not -- the reason we're  
9 looking at this chemical is because we have -- it's  
10 one of the air toxic hot spots chemicals we're  
11 required to develop reference exposure levels for.

12                   It's coming later, rather than sooner,  
13 because there are, in the hot spots data base -- and  
14 this is just the facilities that have to report --  
15 there were 3,300 pounds emitted in the data base.

16                   DR. BLANC: So it's not one of these things  
17 that, because it's a structural fumigant or a  
18 fumigant, you're allowed to do it as opposed to a lot  
19 of the pesticides you can't do?

20                   DR. MARTY: Yes. Exactly. Right.

21                   DR. BLANC: Okay.

22                   DR. MARTY: Obviously the agricultural-slash-  
23 fumigation uses of the phosphides result in a lot  
24 more phosphine going into the air than any of the  
25 emissions that are coming from stationary sources.

1 But we aren't --

2 DR. BLANC: But you -- but, in fact, don't you  
3 have some allowance where you can look at structural  
4 fumigants or something? Isn't there --

5 DR. MARTY: It was only for methyl bromide.

6 DR. BLANC: Oh, okay. So that was an  
7 exception?

8 DR. MARTY: That's right.

9 DR. BLANC: This is a question that the Chair  
10 may have to address; but given what we went through  
11 with MITC and metam sodium, should this document be a  
12 document of phosphine or of phosphine and zinc  
13 phosphide and aluminum phosphide in its breakdown  
14 products?

15 DR. MARTY: You know, we're a little bit --

16 DR. BLANC: Or what are the implications of  
17 that?

18 DR. MARTY: Yeah. We're a little bit  
19 constrained just talking about the chemicals that  
20 actually are on the air toxics hot spots list. I  
21 don't think that the phosphides are on there. But I  
22 will double-check.

23 DR. BLANC: Do you feel that there is -- and I  
24 mean you mentioned, in the first paragraph, that you  
25 think that the issue is that, anytime you have zinc

1 phosphide or aluminum phosphide, it is going to be to  
2 released -- this substance -- in the presence of any  
3 atmospheric moisture whatsoever.

4 DR. MARTY: Well, maybe we should take what  
5 you just said and put that in here because you have  
6 to know that to understand those sentences -- to  
7 understand the implications of those sentences.

8 CHAIRMAN FROINES: I was out in the hall for a  
9 second; so I missed -- I think I missed something.  
10 But I -- interestingly enough, I can't make the  
11 decision that Paul just said I should because I had  
12 the same question that I hadn't repeated since it  
13 hadn't gotten to me yet.

14 So my question is: "Does the  
15 phosphine, under atmospheric conditions, go to  
16 phosphides or vice versa?" I mean what are we  
17 talking about?

18 DR. BLANC: No. You're talking about aluminum  
19 phosphide and zinc phosphide always break down to  
20 give you phosphine.

21 CHAIRMAN FROINES: They do?

22 DR. BLANC: In the presence of any -- any --  
23 any moisture whatsoever.

24 DR. FUCALORO: Water.

25 DR. MARTY: That's why they work as

1 rodenticides.

2 DR. BLANC: The --- you know, often the -- and  
3 it's a grain pesticide. So the route of exposure,  
4 the source of exposure is either in fixed silos or in  
5 freight trains carrying grain. And some of the more  
6 dramatic case reports have been of -- what's the  
7 politically correct word for "somebody who jumps  
8 freight trains" now?

9 DR. FUCALORO: "Freight-train jumper."

10 CHAIRMAN FROINES: Go ahead.

11 DR. BLANC: Anyway, you know, they'll settle  
12 into a car --

13 DR. FUCALORO: A hobo by any other name.

14 DR. BLANC: -- that was recently fumigated and  
15 still get poisoned. So that's where some of the  
16 case-report literature comes from.

17 CHAIRMAN FROINES: So --

18 DR. MARTY: Why don't we say that somewhere?  
19 We could say that.

20 DR. BLANC: Actually, this is one case where  
21 what might make sense would be to look at the annual  
22 report of the American Association of Poison Control  
23 Centers and say how many cases of phosphine poisoning  
24 there are reported or phosphine poisonings reported  
25 per year because they really are sporadic.

1                   Although I mean again, as you say,  
2   appropriately, it's not that -- what is the relevance  
3   to the chronic exposure process? It's really more an  
4   acute exposure. But if you want to get some sense  
5   that it's out there --

6           DR. SALMON: I think that's an important issue  
7   to get that statistic in.

8           DR. MARTY: That's fine.

9                   (Brief interruption.)

10          CHAIRMAN FROINES: Go on to triethylamine. I  
11   think that there are some unresolved questions about  
12   this vis-a-vis the pesticide issue, but let's leave  
13   it for now because we can finalize this document and  
14   think about the aluminum-phosphide-to-phosphine issue  
15   subsequently. Go ahead.

16          DR. GLANTZ: When you say, "finalize this  
17   document," do you mean the phosphine document we just  
18   finished talking about or the next one?

19          CHAIRMAN FROINES: The phosphine document.

20          DR. GLANTZ: Okay.

21          CHAIRMAN FROINES: We're not going to take a  
22   vote on the --

23          DR. GLANTZ: Fluoride.

24          CHAIRMAN FROINES: -- fluoride. But we can  
25   vote on the phosphine, I think, because the changes

1 are relatively minor and then triethylamine.

2 DR. SALMON: Well, I want make sure I've got  
3 the right information this time.

4 DR. BLANC: Aren't you glad people were  
5 looking at the slides?

6 CHAIRMAN FROINES: It's like Melanie saying  
7 that the panels keeps bringing up studies that -- and  
8 asking about them. That's a good sign, not a bad  
9 sign.

10 DR. GLANTZ: Well, it all depends on your  
11 perspective.

12 CHAIRMAN FROINES: I understand that.

13 DR. FUCALORO: Everybody has a perspective.

14 DR. SALMON: Triethylamine -- the issue here  
15 is basically irritation, especially eye irritation,  
16 which is something that is consistent chemically with  
17 the structure of triethylamine.

18 We have a study in which there's a  
19 NOEL report. And the finding is a little curious in  
20 that they say, on the one hand, they didn't observe  
21 any lesions but, on the other hand, they describe  
22 symptoms which are pretty clearly associated with  
23 severe irritation. So we've chosen to interpret the  
24 study as providing a LOEL at 247 parts per million  
25 and a NOEL at 25 parts per million. Can I have the

1 next slide, please.

2 DR. GLANTZ: Wait.

3 DR. SALMON: I'm sorry?

4 DR. GLANTZ: Can you go back to the previous  
5 slide? When you're saying there were no gross  
6 lesions at the exposure -- with the exposure of 25 or  
7 247?

8 DR. SALMON: That was what the authors said.  
9 But we read their narrative, and basically they do  
10 report behavioral changes which are associated with  
11 severe irritation.

12 DR. GLANTZ: At 25 or 247?

13 DR. SALMON: At 247 but not at 25. So we're  
14 saying --

15 DR. GLANTZ: Okay. That's sort of -- your  
16 slide isn't very clear.

17 DR. SALMON: Yeah. There would be --

18 DR. GLANTZ: So there were no --

19 DR. SALMON: The issue is that the authors  
20 asserted that there were no changes in either dose  
21 level. But their subsequent narrative identified  
22 evidence that, in fact, there were quite severe  
23 irritant responses to the high dose level.

24 DR. GLANTZ: Oh, okay.

25 DR. COLLINS: We don't just read the

1 abstracts.

2 DR. SALMON: Sometimes --

3 CHAIRMAN FROINES: Andy, I had -- I think  
4 there's a separate issue which is, as you look at --  
5 you define the 25 as a NOEL and the 247 as a LOEL;  
6 but the study also was a study of 30, 60, and 120  
7 days.

8 And so my question is: "What did they  
9 see at 30 days?" In other words, are we talking here  
10 about an acute effect? Or are we talking about a  
11 chronic effect? They may have done a 120-day study;  
12 but if they're finding the same effect at 30 days,  
13 then it seems to me that they're finding -- you're  
14 finding a consistent acute response rather than a  
15 chronic response.

16 I mean, if that's your chronic  
17 response, the question is: "What do you find over  
18 short periods of time? And is it appropriate, then,  
19 to consider that a chronic response?"

20 DR. SALMON: Yeah. I think we have a  
21 general -- I mean, as far as the different necropsy  
22 times are concerned, the authors basically report no  
23 findings at any of the time slots. They're not  
24 specific about the time of onset or the durability of  
25 the irritant response.

1                   But this is a general problem that,  
2   you know, how -- when the critical effect is  
3   basically an irritant response and we're looking at a  
4   desirability of setting a chronic reference exposure  
5   level with that as a critical effect, we basically  
6   had to take it that, you know, that their continuing  
7   response, which is noticeable at the end of a  
8   long-term study or a longer-term study, is something  
9   which is appropriate to use as a basis for a chronic  
10  reference exposure level.

11                   I think we don't necessarily have all  
12  the information as to what the time-response  
13  relationship of that response is. It's certainly  
14  something which we've been looking at independently.  
15  It's a question of whether, for instance, it's  
16  appropriate to apply Haber's law to irritant  
17  responses.

18                   And we don't have any data, really,  
19  for the extrapolation of longer periods. But we're  
20  looking at that in terms of shorter, you know, and  
21  more acute types of exposure independently.

22                   DR. MARTY: You know, this is the same  
23  discussion we've had before with other irritants, you  
24  know. Are we talking about repeated acute effects  
25  that then go away when they aren't being exposed, in

1 this case? And in other cases, where we ended up  
2 using irritation as the endpoint for chronic RELs, it  
3 was really because that is the most sensitive  
4 endpoint of toxicity for those chemicals.

5                   But it's a valid point. And we still  
6 haven't resolved whether, you know, it makes any  
7 sense to do a chronic REL for something like this  
8 that clearly the -- well, according to the available  
9 studies, the endpoint that is consistently seen is  
10 irritation.

11                  DR. SALMON: I think also -- sorry. Excuse  
12 me -- on that point, looking at the other studies  
13 which we describe, we're seeing -- in those other  
14 studies, we are seeing, if you like, progressive  
15 appearance of histopathological lesions which are  
16 consistent with a general irritant chemical type of  
17 exposure.

18                   And so I think our belief is that  
19 there is an ongoing and progressive phenomenon of  
20 irritation and at higher doses.

21                  DR. COLLINS: These same authors did a study  
22 at a thousand ppm for 10 days. 2 of them of 5 males  
23 and 1 of the 5 females died. So the information they  
24 looked at is metaplasia, first. And so 2.7's not a  
25 bad guess for a LOEL.

1 DR. BLANC: Probably the more relevant support  
2 study is the one that you cite -- the rabbit study.

3 DR. SALMON: Yeah. Absolutely.

4 DR. BLANC: Now, when you -- but you don't do  
5 a section, a broken-out section, where you do the  
6 calculations based on the supportive study. Is that  
7 because it's only 6 weeks?

8 DR. SALMON: It's very qualitative.

9 DR. COLLINS: I've got that study, if you want  
10 to look at it. It's very qualitative.

11 DR. BLANC: The rabbit study?

12 DR. COLLINS: Reger -- Brieger and Hodes,  
13 1951.

14 DR. BLANC: No. I'm talking -- oh, yeah.  
15 Right.

16 DR. SALMON: So it's just too --

17 DR. COLLINS: It's very qualitative. I can  
18 show it to you if you want. It's not enough to make  
19 this a good -- oh, I'm sorry.

20 It's a very qualitative study. So it  
21 would be hard to figure out whether it's all the  
22 animals or a fraction of the animals. Just that I  
23 saw this at 50, but it was once at a hundred. So  
24 it's just its consistence --

25 DR. BLANC: So it's not enough for you to spin

1 out the whole thing but --

2 DR. COLLINS: It also shows that 50 ppm -- 48  
3 ppm looks like a LOEL.

4 DR. BLANC: Right. What happens when you  
5 do -- would you remind me, again, when you -- you're  
6 ideally looking for a chronic for at least 3 months  
7 or more, not 6 weeks? Chronic --

8 DR. MARTY: It depends on the species. I  
9 think rodents, it's generally defined --

10 DR. COLLINS: 6 months.

11 DR. BLANC: 6 months.

12 DR. COLLINS: If we had 3 months, we'd use a  
13 subchronic REL.

14 DR. BLANC: So for 6 months, you say it's  
15 chronic? So if you spun out this 48 parts per  
16 million as a low effect level, even though you don't  
17 have well defined what the effect was, you would  
18 look --

19 DR. COLLINS: The equivalent of 16 ppm for a  
20 chronic study if you divided by 3, which would then  
21 be somewhat below this NOEL --

22 DR. MARTY: I'm sorry. I'm going to jump in  
23 here and just correct one thing. And that is, in our  
24 chronic REL documents for rodents, we cut chronic off  
25 at 13 weeks.

1 DR. COLLINS: That would be a -- that would  
2 get a subchronic of 3 rather than 10.

3 DR. SALMON: Yeah. The Lynch study, being 28,  
4 counts as a full chronic; whereas, the Brieger and  
5 Hodes, being 6 weeks, would definitely be a, you  
6 know --

7 CHAIRMAN FROINES: Andy, I want to, in a  
8 sense, follow up on what Paul said and go back to  
9 where I started. The rabbit study -- one finds --

10 I understand, Melanie, that ongoing  
11 issue about irritation and that. That's not -- I'm  
12 not really raising that. I mean we're doing research  
13 on capsaicin receptors right now in terms of acute  
14 and irritative effects. And we argue that there are  
15 chronic effects that derive from it.

16 But here you have an endpoint which is  
17 that the rats kept their eyes closed. That's your  
18 definition of a chronic effect. It's not eye  
19 irritation. It's that the rats kept their eyes  
20 closed. That -- I find it a little difficult to hang  
21 my hat on a sentence like that because I think that's  
22 the sentence that you're using.

23 In the rabbit study, one -- and I  
24 think that's why Paul is bringing it up -- one finds  
25 concentration-dependent pathology, according to your

1 document. That seems to me to be -- have a better  
2 evidentiary feel to it, than that sentence, in terms  
3 of defining a chronic effect.

4 DR. BLANC: Well, no. I think there's a  
5 linguistic solution to it. Basically, you have a  
6 25-part-per-million no-effect level that you feel  
7 confident with because there were no pathologic  
8 findings and the animals were exposed.

9 The reason why you disregard,  
10 appropriately, the 247 parts per million and say,  
11 "That's not a no-effect level," is because the  
12 animals didn't have reliable exposure because they  
13 kept their eyes closed and their faces buried in  
14 their -- their nose buried in their fur.

15 Sort of like what we do in academic  
16 life, day to day; right? So --

17 DR. MARTY: But, no. Because even that is a  
18 behavioral response to irritation.

19 DR. BLANC: I understand that's a sort of  
20 secondary issue. But the real reason why you're not  
21 saying, "247 is a no-effect level" -- there's two  
22 reasons.

23 One is that they weren't really  
24 exposed -- no idea what their exposure was because  
25 they closed their eyes. So how are you going to

1 measure, you know, what their eye exposure was if  
2 their eyes were closed? So I mean that's a more  
3 potent argument.

4                   Whereas, it is fairly believable that  
5 25 parts per million was a no-effect level since they  
6 seem to have been exposed reliably and there weren't  
7 any effects. So you can solve this problem about  
8 whether keeping your eyes closed is or is not an  
9 effect. I mean it certainly suggests that something  
10 was going on.

11                   But the main thing is that the 25 is a  
12 reliable no-effect level. And the rabbit study  
13 suggests, certainly, that it wouldn't be reasonable  
14 to make an argument that "Well, maybe, the no-effect  
15 level was a hundred parts per million" because you  
16 have something that suggests that, if anything, 25  
17 parts per million isn't overly conservative.

18                   I think the only other question has to  
19 do with, since rabbits are so commonly used as an  
20 animal model for irritant effects and particularly  
21 ocular effects, I think you should make your argument  
22 explicitly that you do use the 10, factor of 10,  
23 interspecies because the -- that we know that --  
24 well, we have reason to believe that, you know, rats  
25 aren't really necessarily a preferred species for

1 ocular effects.

2                   Another way of doing it would be, if  
3 you used the rabbit data, if you used the 48 as a  
4 low-effect level and you used an interspecies factor  
5 of 3, rather than 10, because we know the rabbits are  
6 a good model for eye irritation, you probably come  
7 out to a very similar number because instead of doing  
8 a factor of a hundred, it would be a factor of 30,  
9 based on a no-effect level of 4.8.

10                   I mean I haven't done the arithmetic,  
11 but it would probably come out pretty close, wouldn't  
12 it?

13                   DR. SALMON: Well, basically, if we were using  
14 that analysis on the rabbit study, we would then  
15 reduce the interspecies factor from 10 to 3 but we  
16 would increase the subchronic uncertainty factor from  
17 1 to 3 because of the shorter study.

18                   DR. BLANC: Oh, so it would all come out the  
19 same. All right. Anyway --

20                   CHAIRMAN FROINES: Can I? I don't agree with  
21 Paul on this one. And I don't agree with Melanie,  
22 when she says this is a behavioral change. I'm  
23 concerned about the strength of the evidence.

24                   And I suspect that the paper -- did  
25 the paper say that there -- that the animals did not

1 close their eyes at all during the 25-part-per-  
2 million study and keep their heads buried? And is  
3 this paper sufficient in terms of its detail that one  
4 can really draw that conclusion?

5 DR. SALMON: Jim, can you comment on that?

6 CHAIRMAN FROINES: I mean do you --

7 DR. COLLINS: Well, I don't know whether I can  
8 quote it or not. Just a second. Okay. "Rats of  
9 both sexes tolerated exposure at" -- sorry.

10 "Rats of both sexes tolerated the  
11 exposure at 25 ppm without exhibiting overt signs of  
12 toxicity. At 247 ppm TEA, the rats kept their eyes  
13 closed and noses buried in their fur during the  
14 entire exposure period."

15 DR. FUCALORO: Just that the chemical made  
16 them shy. Psychological effect.

17 DR. COLLINS: They realized they were naked.

18 I'd also like to point out that the  
19 human study that we used as a comparative gave  
20 approximately the same answer, and that was based on  
21 eye irritation. However, they were exposed to other  
22 things. It was a relatively small number of people.  
23 But at least it was consistent with the number we got  
24 in rats, for whatever that's worth.

25 CHAIRMAN FROINES: Well, I think that we need

1 to -- I would suggest that the path you take is to  
2 take the two studies and write some language that  
3 links them intellectually so that where there is  
4 actually pathology being recognized and that the  
5 calculations be carried out the way we've just talked  
6 about so that at least we have some strength to the  
7 argument.

8                   Otherwise, I must admit I find it less  
9 convincing as a endpoint for a chronic finding.

10                   What?

11           DR. FUCALORO: It's an acute finding, isn't  
12 it?

13           DR. BLANC: Can I bring up now a completely  
14 different kettle of fish for this chemical? You're  
15 not going to be happy about this, I know. But maybe  
16 there is a simple answer.

17                   Haven't there been case reports of  
18 asthmatic sensitization from triethylamine? There's  
19 been a growing body of literature about polyamines as  
20 occupational asthmogens.

21           DR. SALMON: Well, we don't --

22           DR. MARTY: We didn't find anything when we  
23 looked for it. I know there's other amines --  
24 triethylamine, I'm pretty sure, has been linked.

25           DR. BLANC: How recently and how hard did you

1 look? I mean this is a kind of a critical issue, not  
2 because you can develop the REL or change the REL  
3 maybe, but I think it would certainly -- to be  
4 consistent, you'd have to restructure your last  
5 section on children --

6 DR. MARTY: Uh-huh.

7 DR. BLANC: -- given the approach that you  
8 took -- tried to take consistently with asthma in  
9 childhood and things that cause asthma.

10 DR. MARTY: Yeah. Let's --

11 DR. BLANC: Or if, at least in that paragraph,  
12 if you can't find anything, well, I think I would  
13 say, you know, "We did not identify any case reports.  
14 There are case reports of related polyamines. This  
15 is theoretical at this point" -- something --

16 DR. MARTY: Yes. I actually wrote a note to  
17 myself to put something just like that in there --  
18 that other amines are associated with occupational  
19 asthma. So we can -- what we'll do is look and make  
20 sure and, if we can't find anything on triethylamine  
21 or if we could and then, if we can, we'll put -- you  
22 know, add that in.

23 If we can't, we'll make a statement  
24 that there is a concern.

25 DR. FUCALORO: Well, ammonia would do the

1 same --

2 DR. BLANC: No. No. There's something  
3 peculiar about these amines --

4 DR. FUCALORO: -- is that right?

5 DR. BLANC: -- that they act as haptens or --

6 DR. COLLINS: The main thing we found are the  
7 blurring of vision and, to some extent, headaches.  
8 Somebody's also looked at blood pressure. But I  
9 haven't seen anything on asthma yet.

10 CHAIRMAN FROINES: Yes, there is -- I have the  
11 same sense, the way Paul said it, that there is some  
12 literature that I have a feeling exists, but I don't  
13 know it.

14 There obviously is a problem of, in  
15 some cases, compounding exposure with isocyanate,  
16 because obviously the same amines are used in  
17 isocyanate. And that has asthma properties there.  
18 That's pretty well known.

19 DR. BLANC: There's a review article on  
20 polyamines and asthma. And I would look at that  
21 carefully. It's about -- I don't know the title or  
22 the author off the top of my head. But it's within  
23 the last 5 years.

24 CHAIRMAN FROINES: I'd also look in Peter  
25 Spencer's book on neurotoxicology. There might be

1 something in there.

2 DR. COLLINS: Peter who?

3 CHAIRMAN FROINES: Peter Spencer.

4 DR. BLANC: Where I would look is -- and I'll  
5 do it when I get back -- is the appendix to the  
6 second edition of Moira Chan-Yeung and Jean-Luc  
7 Malo's book where it has the table, you know, with  
8 350 chemicals with case reports, because it's going  
9 to be in the case report literature. It's not going  
10 to be --

11 And then can I ask a Tony question?  
12 Physical properties. I get that this is a liquid  
13 that vaporizes pretty easily. But since it boils at  
14 89 degrees, it's not really a gas, is it, on the  
15 surface of the earth, I mean?

16 DR. GLANTZ: Unless it's hot.

17 DR. ATKINSON: A fair amount of it -- I mean a  
18 certain amount of it would be present as a gas, in  
19 the gas phase.

20 DR. BLANC: Right. But I mean --

21 DR. ATKINSON: But it's a colorless gas.

22 DR. BLANC: What?

23 DR. ATKINSON: But it's colorless when it's --

24 DR. BLANC: I know. But I mean you're not  
25 being consistent is all I'm saying. Everywhere else

1 it could be described as a liquid. And you could  
2 make clear that it's -- you could make clear in your  
3 text somewhere that it vaporizes very easily.

4 DR. SALMON: Should we describe it as a  
5 volatile --

6 DR. BLANC: Volatile. But it's a colorless  
7 liquid, isn't it, in its physical properties?

8 DR. FUCALORO: Look at its vapor pressure.  
9 It's very high. It's pretty high.

10 CHAIRMAN FROINES: So can we -- are you  
11 finished?

12 DR. BLANC: Yes.

13 CHAIRMAN FROINES: This was supposed to be one  
14 of the quick-and-dirty parts of this meeting. And it  
15 never does end up being that.

16 DR. ATKINSON: I have one further comment.

17 CHAIRMAN FROINES: Sorry.

18 DR. ATKINSON: Triethylamine is presumably  
19 emitted from cattle feedlots.

20 DR. BLANC: Yeah.

21 DR. ATKINSON: There's a bunch of amines that  
22 are emitted from cattle feedlots. And I've brought a  
23 reference along for you. I mean they're something  
24 like a few percent of the ammonia emissions. So Mira  
25 Loma should be --

1           CHAIRMAN FROINES:  So there should be  
2 triethylamine in here --

3           DR. SALMON:  We would do well to --

4           DR. ATKINSON:  And the other thing about them  
5 is they react with gas -- gaseous nitric acid to form  
6 salts, which would end up the in particle phase.

7           DR. FUCALORO:  Nitrates.

8           DR. ATKINSON:  Yeah.  Amine nitrates.

9           DR. FUCALORO:  Sure.

10          DR. MARTY:  We will add that.

11          DR. ATKINSON:  I'll give you the reference  
12 when we --

13          CHAIRMAN FROINES:  How does the panel want to  
14 do this?  We actually have requested changes on all  
15 three chemicals.

16          DR. BLANC:  I think, though, you were right.  
17 I think that the one we have to see again is the  
18 fluoride.  I think the other two -- the changes are  
19 not so substantive because, even if you find a case  
20 report of occupational asthma, I wasn't suggesting  
21 that you change all of your calculations.

22          CHAIRMAN FROINES:  Well, then, I would -- if  
23 you agree with that, then I would say that we vote to  
24 approve the phosphine and triethylamine documents,  
25 recognizing that small changes are going to occur.

1                   And you can send them to us before the  
2 next meeting. We can take a look and see if there  
3 are any major problems. But basically we can approve  
4 them. And then the fluoride will come back at the  
5 next meeting.

6                   So I need a motion to approve the  
7 documents on the two chemicals.

8           DR. FUCALORO: Moved.

9           CHAIRMAN FROINES: Second?

10          DR. GLANTZ: Second.

11          CHAIRMAN FROINES: All those -- discussion.

12                   (No audible response.)

13          CHAIRMAN FROINES: All those in favor.

14                   (Each panel member raises his hand.)

15          CHAIRMAN FROINES: Unanimous. The vote was  
16 unanimous. And we'll see the fluoride document at  
17 the next meeting. It's 5 minutes after 12:00. We  
18 can go on to the next item on the agenda, or we can  
19 break for lunch. Lunch is in the cafeteria, which is  
20 next door. What are people's pleasures?

21          DR. FUCALORO: What's the anticipated amount  
22 of time we have left?

23          CHAIRMAN FROINES: I would bet three hours.

24          DR. FUCALORO: Three hours?

25          CHAIRMAN FROINES: It's hard to say. It's

1 hard to judge because I would have guessed this would  
2 have been an hour at most. And so if you ask me and  
3 I say, "Three hours," I think -- I would guess people  
4 are going to tire out. So things tend to speed up.  
5 So why don't we say two hours just to cover the rest  
6 of this?

7 DR. BLANC: I'll just make the following  
8 suggestion that we -- if people would be amenable,  
9 that we begin the discussion, assuming we're going  
10 in the same order, on the air toxics hot spots  
11 program guidance manual and see if we can wrap that  
12 up in half an hour.

13 But if we're there -- if it's 12:30  
14 and we're still going on that, we then break in the  
15 midst of that discussion because I think there would  
16 be some symmetry to finishing Item 2 and then coming  
17 back for what I think will be a fairly difficult  
18 discussion of Item 3.

19 CHAIRMAN FROINES: I don't think the next --  
20 the discussion on the methodology is necessarily  
21 going to be that short. But I'm willing to do that.

22 DR. GLANTZ: Let's try.

23 CHAIRMAN FROINES: Stan, you're the lead on  
24 the next topic so --

25 DR. GLANTZ: Yeah.

1           CHAIRMAN FROINES:  -- so if you think this  
2 discussion's going to go --  
3           DR. GLANTZ:  Yeah, I do.  
4           CHAIRMAN FROINES:  -- at length --  
5           DR. GLANTZ:  I think it will be pretty quick,  
6 unless I missed something.  
7           DR. FUCALORO:  Not you.  
8           CHAIRMAN FROINES:  Does everybody -- so we'll  
9 go to about 12:30 and then decide how it looks.  
10                         How long is your presentation,  
11 Melanie, going to be?  
12           DR. MARTY:  There's about 25 slides, total,  
13 including slides on the comments which sometimes the  
14 panel wants and sometimes they don't, depending on if  
15 they have issues with our responses.  
16           CHAIRMAN FROINES:  Well, then, I would suggest  
17 that we go through the slides and then break for  
18 lunch.  
19           DR. GLANTZ:  Okay.  
20           CHAIRMAN FROINES:  I don't see --  
21           DR. GLANTZ:  Should we bring lunch back here  
22 and --  
23           DR. BLANC:  No.  
24           DR. GLANTZ:  No?  Okay.  
25           DR. BLANC:  Let's start.

1 DR. FRIEDMAN: Short lunch.

2 DR. MARTY: Just as an introductory, we're now  
3 talking about the risk assessment guidance manual for  
4 the air toxic hot spots program, which is a  
5 condensation of the four technical support documents  
6 that the panel has already approved.

7 DR. BLAISDELL: Okay. We've had four  
8 technical support documents that you have already  
9 reviewed. These describe the methods for developing  
10 acute and chronic reference exposure levels, cancer  
11 potency factors, and exposure assessment.

12 These documents have undergone public  
13 review. They've been peer reviewed by the Scientific  
14 Review Panel. They're adopted for use by the OEHHA  
15 director. Okay. These form the basis of the  
16 guidance manual. Next slide, please.

17 The Part I Technical Support Document  
18 for the determination of acute reference exposure  
19 levels for airborne toxicants was approved in March  
20 of 1999 and includes the methodology for the  
21 development of acute reference exposure levels.

22 The Part II Technical Support Document  
23 for describing available cancer potency factors was  
24 adopted in April of 1999. There are about a hundred  
25 and twenty cancer potency factors that are used to

1 assess cancer risk in that program.

2                   Then, the Part III Technical Support  
3 Document for the determination of noncancer chronic  
4 reference exposure levels was adopted in April of  
5 2000. And it presents a methodology for development  
6 of chronic RELs, and about 72 chronic RELs have been  
7 adopted to date.

8                   The Part IV Technical Support Document  
9 for exposure assessment and stochastic analysis was  
10 approved in September of 2000. It developed point  
11 estimates and distributions for exposure variates as  
12 well as algorithms for fate and transport and  
13 exposure analysis. Next slide.

14                   The guidance manual for the  
15 preparation of health risk assessments -- the  
16 document that we're considering today -- is a  
17 compilation of the four technical support documents  
18 previously approved by the panel and adopted by the  
19 OEHHA director.

20                   The information includes that which  
21 was needed to perform a hot spots risk assessment.  
22 There is some limited additional information on the  
23 risk assessment model that was not covered in the  
24 Part IV Technical Support Document.

25                   This new material includes variates

1 for workers' exposure, KOC and KOW values for organic  
2 chemicals needed for root uptake pathway for produce  
3 exposure. And also we have dropped the oral cancer  
4 potency factor for hexavalent chromium. Next slide.

5                   The variates for worker exposure.  
6 OEHHA is recommending a point-estimate approach only  
7 for workers' exposure because the distributions are  
8 not available. We have changed from a 46-year  
9 working life to a 40-year working life to conform  
10 with the Prop. 65 value, which probably represents a  
11 high-end value.

12                   We're proposing a breathing rate of  
13 142 liters per kilogram body weight per day, which  
14 corresponds to 10 cubic meters per day with a  
15 70-kilogram body weight. And this is the value  
16 proposed in the US EPA's exposure factors handbook of  
17 1989 for workers. Next slide.

18                   And we're proposing a soil-ingestion  
19 rate of 1.4 milligrams per kilogram body weight per  
20 day, which corresponds to the hundred milligrams per  
21 day that we identified as the appropriate value for  
22 adults. We're proposing 3 weeks off per year for the  
23 workers instead of 2 weeks. The dermal-exposure  
24 variates are high end to cover outdoor workers.

25                   Soil loading of 1 milligram per cubic

1   centimeter squared -- I'm sorry.  It's exposure  
2   frequency of every day at work and body surface area  
3   exposed to 5,800 square centimeters, which is on the  
4   high side.  The dermal pathway actually represents a  
5   very small fraction of the risk relative to  
6   inhalation and soil ingestion.  Next slide.

7                   OEHHA has developed a tiered approach  
8   to this assessment, as we've discussed in the Part IV  
9   Technical Support Document.  Tier 1 is a point-  
10  estimate approach using OEHHA-specified exposure  
11  parameters.  All facilities performing risk  
12  assessments start with this approach.

13                   Tier 2 would be a point-estimate  
14  approach using site-specific exposure parameters  
15  where scientifically defensible.  Next slide.

16                   Tier 3 is a stochastic approach using  
17  OEHHA-developed-or-endorsed exposure parameter  
18  distributions.

19                   And Tier 4 would be a stochastic  
20  approach using site-specific distributions on data  
21  for parameters instead of the OEHHA distributions  
22  where scientifically defensible.  Next slide.

23                   The Air Resources Board has developed  
24  a computer program for the hot spots program.  The  
25  hot spots analysis and reporting program is user

1 friendly and should make risk assessments much easier  
2 to perform. It has the exposure algorithms, point  
3 estimates, distributions, cancer potency factors, and  
4 RELs developed in the Technical Support Documents I  
5 through IV.

6                   And the software includes an  
7 air-modelling component and will also perform  
8 stochastic risk assessment. Next slide.

9                   In summary, again, the hot spots risk  
10 assessment guidance manual is a compilation of the  
11 four previously approved technical support documents.  
12 The information necessary to perform hot spots risk  
13 assessment is presented. And there is a very limited  
14 amount of new material. Thank you.

15                  DR. MARTY: I do have additional slides that  
16 describe some key comments that came in during the  
17 public comment period. We could go over those now or  
18 not.

19                  DR. BLANC: I think you've summarized them in  
20 the written --

21                  DR. MARTY: Right.

22                  DR. BLANC: I mean you gave them to us.

23                  DR. MARTY: Everything -- right. We responded  
24 to comments.

25                  DR. BLANC: And if you want to characterize

1 what you've done, if there were certain of these  
2 comments that you felt it was reasonable to elaborate  
3 the text to better explain the position -- but none  
4 of these comments led to a significant reversal of  
5 your regulatory recommendations.

6 DR. MARTY: Correct.

7 DR. BLANC: So I don't think we need to see  
8 the wording that was used.

9 CHAIRMAN FROINES: I have a question, Melanie.  
10 In the comments from the Western States Petroleum  
11 Association, in the document that we received by  
12 e-mail from you, you delete a sentence that says, "In  
13 our judgment, use of the 75th percentile breathing-  
14 rate distribution to estimate 70-year dose and risk  
15 to very small zones of impact may be inadequate to  
16 protect public health."

17 Has that deletion been made available  
18 to the public for comment?

19 DR. MARTY: Actually --

20 CHAIRMAN FROINES: Because you -- because  
21 there -- because you, at some level, acknowledge the  
22 comments by WSPA as having validity. But then, by  
23 removing this 75th percentile, you take out an actual  
24 approach to the issue.

25 DR. MARTY: Okay. Let me give you the

1 chronology of the response to comments. They  
2 actually aren't out to the public. What we do is we  
3 provide the panel what are essentially draft  
4 responses to comments.

5                   If there are issues that involve  
6 significant changes to the document, then all of that  
7 goes back out for public review. But the responses  
8 to comments don't get posted on our web page until  
9 the final document is posted. So in other words, if  
10 people want to see them, they can. And we actually  
11 had one person ask for them, and he did see them.  
12 But he saw the comments after this revision was made.

13                   So there hasn't been discussion in the  
14 public about trying to do something different than  
15 what is already in the Part IV Technical Support  
16 Document.

17                   And this comment -- when we were  
18 developing the response, we had lots of discussions  
19 with ARB and internally within OEHHA and initially  
20 had decided to make this concrete suggestion as to an  
21 alternative. But in further discussion with ARB  
22 managers and OEHHA and legal staff, it became clear  
23 that we can't really just do this without reopening  
24 Part IV.

25                   DR. GLANTZ: Now, when you say, "do this" --

1 because this was the one thing I kind of zeroed in on  
2 too -- but before we get on to this, I read through  
3 all the -- through the documents pretty carefully.  
4 And I read through all the comments. And I didn't  
5 have any problem.

6 I think they responded -- as you said,  
7 Paul -- reasonably to the comments. And the document  
8 itself is, other than these few things that were  
9 mentioned today, just a recapitulation of stuff we've  
10 already seen. And it's actually, I thought, quite a  
11 good summary. And it put all this stuff into a  
12 context.

13 But that -- this question about this  
14 sentence -- it sort of bothered me because I think  
15 the point that WSPA made that by consistent -- and  
16 generally, I support the use of the 95 percent,  
17 95 percentile point as a consistent health-protective  
18 rule.

19 But they did make pretty vigorous  
20 argument that, in this one case, it might be -- it  
21 might be being overly conservative or overly  
22 cautious. But then when I -- so I presume in the --  
23 so many iterations of this sort of flew by at the  
24 end -- this 75 -- 75th percentile is in the document  
25 that went out for comment; right?

1 DR. MARTY: No, it is not.

2 DR. GLANTZ: No? So you added it?

3 DR. MARTY: It is not added anywhere. It  
4 was --

5 DR. GLANTZ: Oh, this is -- well, wait. So --

6 DR. MARTY: This is only in the response to  
7 comments.

8 DR. GLANTZ: So what you were saying is you  
9 are suggesting, in response to the comments, to add  
10 the 75th percentile --

11 DR. MARTY: Right.

12 DR. GLANTZ: -- and then you decided not to do  
13 it?

14 DR. MARTY: Exactly.

15 DR. GLANTZ: Okay. Well, the thing that -- I  
16 have two problems with this, as it is. And I did  
17 talk briefly to Melanie about this before the  
18 meeting.

19 One is I don't see what the  
20 justification for this using the 75th percentile is  
21 other than that it's less than the 95th percentile.  
22 So that might have been one of the things that  
23 bothers you guys. I don't know.

24 And then, if you leave it the way it  
25 was, which was to just say the statement you had in

1 here before, was to just say, "Well, based on the  
2 arguments that WSPA made, the 95th percentile may be  
3 overly conservative for facilities with a very small  
4 zone of impact," which you say, which I think is not  
5 an incorrect statement.

6                   But it kind of leaves me hanging. If  
7 this is something which is supposed to be a document  
8 to give guidance to people in preparing risk  
9 assessments to sort of -- well, if you're saying,  
10 "Well, 95th percentile is, in this case, probably  
11 overly conservative," well, then, what should they  
12 do?

13           DR. MARTY: Well, that's actually --

14           DR. GLANTZ: So this -- it's sort of a  
15 conundrum but --

16           DR. MARTY: It is a conundrum. But we had  
17 some more discussion --

18           DR. GLANTZ: After we talked?

19           DR. MARTY: -- after I talked with you, with  
20 our management. And they came back and said, "Well,  
21 Melanie, you have a tiered approach in the risk-  
22 assessment paradigm where you state that you can use  
23 site-specific information in lieu of either point  
24 estimates or the point-estimate approach or  
25 distributions that you are recommending such that a

1 person who is writing the risk assessment for a  
2 facility that has this very small zone of impact can  
3 alternatively -- can provide an alternative  
4 analysis."

5                   So what we want to do is take this  
6 suggestion of language and add that and remind people  
7 that this tiered approach allows them to do that.

8           DR. GLANTZ: Well, that might be the solution,  
9 then, is to make that -- okay. That, I think, is a  
10 very sensible answer.

11                   And I think that might be the solution  
12 to the problem -- instead of that 75th-percentile  
13 sentence that you put in and then took out that  
14 bothered everybody, is to simply say what you just  
15 said that, in these cases, using one of these  
16 higher-tier approaches, where you're doing more  
17 detailed modelling, would probably be more sensible  
18 than the point -- than just basing it on upper-bound  
19 point estimates.

20                   That -- I would be happy with that. I  
21 think that's a good solution.

22           CHAIRMAN FROINES: Paul?

23           DR. BLANC: Well, and I think the way -- I  
24 think that one possible approach to having that  
25 solution and I think what makes the paragraph

1 somewhat imbalanced is that, when you deleted the  
2 potential 75th-percentile sentence, you should simply  
3 have also deleted the sentence that precedes it.

4           If you delete the sentence before it,  
5 you're basically reiterating that there's the option  
6 for looking because it isn't possible in all  
7 situations because what happens, when you keep the  
8 one sentence and delete the other, is you're saying,  
9 "Okay. So the 95th doesn't work." And then you  
10 should say, "Well, what does work?"

11           DR. FUCALORO: Yeah.

12           DR. MARTY: Oh, okay.

13           DR. BLANC: And that's why you would put in  
14 the sentence in the first place -- the 75th  
15 percentile. But if you delete both sentences, I  
16 think you solve the problem.

17           DR. FUCALORO: Yeah.

18           CHAIRMAN FROINES: No. I don't think they  
19 have, have they?

20           DR. BLANC: Yeah.

21           CHAIRMAN FROINES: Well, because they're  
22 saying that they are willing to consider other  
23 approaches --

24           DR. BLANC: Which is what they're saying here.

25           DR. GLANTZ: This is what they're adding here.

1           CHAIRMAN FROINES: We're talking about this  
2 document. We're talking about what should be  
3 contained as guidance in this document. This is --  
4 you see. The key thing is that theoretically -- if I  
5 understand this document correctly, this is the  
6 document that everybody's going to use.

7                         We'll come to this because -- because  
8 I had some problems with this as the document they're  
9 going to use. But that's another subject for a few  
10 minutes from now.

11                        But the point is that, if you're going  
12 to have -- if you are going to allow other approaches  
13 than the 95th percentile, that needs to be explicitly  
14 stated, not in some other document about the tiers,  
15 but in the document that people are actually going to  
16 use.

17           DR. GLANTZ: No. But this document talks  
18 about the four tiers. This document goes through and  
19 discusses --

20           CHAIRMAN FROINES: But this needs to be --

21           DR. GLANTZ: -- all the different ways to use  
22 them.

23           CHAIRMAN FROINES: But this needs to be made  
24 specific in this document.

25           DR. GLANTZ: Well, no. Well, I don't disagree

1 with that. This is something that would go in this  
2 document. And the document doesn't just talk about  
3 point estimates. It talks about the use of the  
4 stochastic models and these other things too.

5                   So I think the document -- I think  
6 that the statement Melanie's making, written  
7 properly, is completely consistent with the rest of  
8 the document.

9                   CHAIRMAN FROINES: I'm not objecting. I'm  
10 just saying it really does need to be explicitly  
11 stated in the document.

12                   DR. GLANTZ: Well, no. No. I agree with  
13 that. I think with the point that, I think, Paul  
14 made -- and this was one of the things that sort of  
15 bothered me too -- is, well, if you delete the  
16 sentence -- the problem with the 75th-percentile  
17 number is it's also -- it's just pulled out of the  
18 air, basically.

19                   And my concern, which was -- which  
20 Paul had articulated -- was that, if you take that  
21 out, then the previous sentence sort of doesn't make  
22 a lot of sense because it says, "Well, the 95th  
23 percentile may be too conservative." But then so  
24 what?

25                   But I think if you take both sentences

1 out and instead insert something along the line of  
2 what Melanie said that, "In this specific case,  
3 you're probably better off using a more detailed  
4 model -- the stochastic model, basically," then, that  
5 solves the problem.

6 CHAIRMAN FROINES: Uh-huh.

7 DR. GLANTZ: You know, basically, they could  
8 either use the 95th percentile, if they just want to  
9 use the point estimates, recognizing that that's  
10 likely to be very conservative or, if they want a  
11 more realistic model, this is a place where it's  
12 worth, it's definitely worth the trouble to do a  
13 stochastic model.

14 CHAIRMAN FROINES: I think that's fine.

15 DR. GLANTZ: Okay. And I think that fixes the  
16 problem.

17 CHAIRMAN FROINES: I just want to make one  
18 comment that -- Craig and Roger know -- I testified  
19 before a planning commission on an environmental  
20 impact report on Wednesday in Riverside about a  
21 facility that's going to be constructed in Mira  
22 Loma -- our source of ammonia.

23 And one of the things that's  
24 interesting is, when you go from the world of risk  
25 assessment into the world of people actually

1 preparing environmental impact reports -- and they're  
2 done by environmental engineers, not by  
3 toxicologists -- you realize that their level of  
4 understanding is very different than ours is.

5                   And how they, then, apply what we do  
6 and what OEHHA does is sometimes problematic.

7                   And I think one needs to be sensitive  
8 that we lay out, with as much clarity as possible,  
9 what the level of expectation really is because I  
10 think that it's difficult to interpret some of the  
11 things that the toxicologists in OEHHA or in SRP like  
12 this actually adopt when you're in a very different  
13 kind of world.

14                   And so the level of specificity has to  
15 be greater and the clarity has to be greater if we're  
16 really going to have people who can apply what we do  
17 effectively.

18                   DR. GLANTZ: Well, I agree with that. And I  
19 think that -- but I think we fixed this problem. And  
20 I mean I don't think this report is going to be put  
21 up for any Pulitzer prizes.

22                   But I actually thought it was  
23 pretty -- I mean maybe it's 'cause I've plowed  
24 through the other four reports before we got to this;  
25 but I thought it was pretty clear. And I thought it

1 was something you could hand somebody who is  
2 reasonably knowledgeable.

3                   And it does sort of say, "Do" -- you  
4 know, it's a kind of a step-by-step cookbook for how  
5 to do this. I mean it was a little bit redundant in  
6 places. But, you know, I thought it was a good  
7 summary of all that stuff we've already gone through.

8                   Obviously, you find some things that I  
9 missed but --

10                  DR. MARTY: Also, if I may add, that the risk  
11 assessments that are produced using this document  
12 have to undergo review at the air district level and  
13 also by OEHHA. So we, you know -- it's an iterative  
14 thing. We come back and say, "Well, we may have  
15 misunderstood this," or whatever.

16                  And the districts -- at the district  
17 level, especially in the South Coast -- they have  
18 pretty good expertise at doing these kinds of things.

19                  CHAIRMAN FROINES: Gary.

20                  DR. FRIEDMAN: There's something that, you  
21 know, you may have covered in previous reviews that  
22 wasn't clear to me as someone who's done some  
23 epidemiology of cancer. You talk about cancer risk  
24 as being in kilogram days per milligram. That's  
25 something I have never encountered before. I just

1 wondered, could you -- is it kilograms of people's  
2 weight?

3 DR. MARTY: It's the -- right. Right.  
4 It's -- the slope factors are expressed in units of  
5 inverse dose. So the curve -- milligrams of  
6 carcinogen per kilogram body weight. And that  
7 represents slope of the dose-response curve at the  
8 low end of exposure. It's extrapolated to the low  
9 end.

10 So there was a confusion on the part  
11 of one of the people reviewing the manual. They  
12 didn't understand the units of inverse dose. And  
13 then, when you take your dose in milligrams-per-  
14 kilogram day and you multiply it by the slope of the  
15 dose-response curve, which is the unit risk factor or  
16 cancer potency factor, then you get a unitless  
17 estimate of the probability of tumor formation.

18 DR. FRIEDMAN: I could see that those  
19 cancelled out; but I couldn't quite understand, in  
20 English, what that meant -- the cancer risk being  
21 kilogram time per -- per milligram of substance.

22 DR. MARTY: The risk is actually a unitless  
23 probability. The slope factor is where people were  
24 confused. And that is expressed in units of inverse  
25 dose. That's what you multiply by the estimated dose

1 to get the probability of cancer.

2 DR. FUCALORO: Or to take the dose that was  
3 inverted and divide. Divide. So it's about the --  
4 it's just --

5 DR. MARTY: Right.

6 DR. FUCALORO: -- mathematically equivalent.

7 DR. MARTY: Right.

8 DR. FRIEDMAN: So it's kilograms of human  
9 being and times the --

10 DR. GLANTZ: No. It's milligrams. It's  
11 milligrams of dose --

12 DR. FRIEDMAN: I know. But --

13 DR. GLANTZ: -- per kilogram --

14 DR. MARTY: Time.

15 DR. GLANTZ: -- time. But then there are  
16 factors the inverse of that so --

17 DR. FUCALORO: Just divide 'em.

18 DR. FRIEDMAN: So I mean, the more time, the  
19 more cases. Is that what you're saying?

20 DR. GLANTZ: Yeah.

21 DR. MARTY: Well, the doses are expressed in  
22 units of milligrams per kilogram day -- per kilogram  
23 per day.

24 DR. FRIEDMAN: I can understand the dose. But  
25 it's the cancer-risk part of it that I'm not really

1 clear on.

2 DR. MARTY: Okay. You have to look at it as  
3 the slope of a line between tumor incidence and dose.  
4 So that slope is expressed as per dose, incidence per  
5 dose.

6 DR. FRIEDMAN: I see. It's the slope rather  
7 than a specific rate.

8 DR. MARTY: Right. Right. Right.

9 DR. FRIEDMAN: I always think of rate,  
10 incidence rate. But it's a slope. Okay. Thank you.

11 DR. MARTY: Right.

12 CHAIRMAN FROINES: Tony?

13 DR. FUCALORO: No.

14 CHAIRMAN FROINES: Craig?

15 DR. BYUS: Fine.

16 DR. ATKINSON: I had a question. On Table 53,  
17 on Page 5 -- what would be 14 -- you have a list of  
18 values of K octanol/water. Are those really the  
19 right units? Or should those be log KOW's? I always  
20 thought that --

21 DR. MARTY: It's logs. It needs to be logs.

22 DR. ATKINSON: Yeah.

23 DR. GLANTZ: Yeah.

24 DR. BLAISDELL: Yeah. Okay.

25 DR. ATKINSON: And then you've got the same

1 problem, then, on Table 5-5 on Page 526, which is  
2 where they're listed as KOW instead of a log KOW. It  
3 makes a slight difference.

4 DR. BLAISDELL: Yeah. Yeah.

5 DR. FUCALORO: Is this the second problem?

6 DR. ATKINSON: It's just on the table that  
7 explains where those numbers came from. And it just  
8 gives them as KOWs. Maybe you just need to say --

9 DR. FUCALORO: "Log."

10 DR. ATKINSON: Well, it's got KOW equals 6.10  
11 for dioxin. And it's obviously log KOW.

12 DR. FUCALORO: Well, or minus.

13 DR. ATKINSON: No. It's 10 to the 6th.

14 DR. FUCALORO: It's 10 to the 6th?

15 DR. ATKINSON: Yeah.

16 CHAIRMAN FROINES: Is that it?

17 DR. ATKINSON: That's it.

18 CHAIRMAN FROINES: Paul?

19 DR. BLANC: No.

20 CHAIRMAN FROINES: Okay. Melanie, I had a  
21 couple of points -- nothing of any major consequence.  
22 In the, for SRP review, "Possible Additions to the  
23 Guidance Manual," you talk about "OEHHA has  
24 presented, in this document, exposure variates for  
25 estimating 9-, 30-, and 70-year exposures."

1                   I may have missed it in here, but I  
2 thought that was in the Part IV document, not in this  
3 document. At least, I couldn't find it. If I  
4 didn't, it's my fault.

5                   But I had -- but to the degree that  
6 I'm interested in people's use of this document,  
7 is -- in your response to comments, you, at length,  
8 talk about the 70-year lifetime, although  
9 acknowledging that people don't necessarily live in  
10 houses for 70 years and all that.

11                   And so my question is, as a policy  
12 matter, on the one hand, you argue, I think,  
13 effectively and vigorously, for the 70-year-lifetime  
14 exposure as a criteria. But then you have, as you  
15 say -- you presented methods for estimating 9 and 30  
16 years.

17                   And my question is: "How would one --  
18 in what context would one use that for a population-  
19 based risk assessment?"

20                   DR. MARTY: You wouldn't use it for the  
21 population-based risk assessment. I think what we  
22 tried to do when we were developing Part IV is  
23 respond to concerns expressed, by people who do risk  
24 assessments for these facilities, that the risk  
25 management is generally based on "What is the risk

1 to the maximum-exposed person?"

2                   And we have always assumed a 70-year-  
3 exposure duration, in part, because the district set  
4 acceptable cancer risks. And they sort of modelled  
5 it after Prop. 65. And those are supposed to be  
6 lifetime cancer risks.

7                   But it's true that people don't  
8 necessarily live and stay within the zone of impact  
9 of a facility for their entire lives. And, to that  
10 person, the individual risk would be less. You  
11 can't -- so what we tried to do is say, "Okay. Let's  
12 take what EPA has done for their 'haz'-waste sites."

13                   And they use a 9-year to represent  
14 kind of an average length of time that somebody lived  
15 at one address. And 30 years was their estimate of a  
16 high end, although it's not really based on much  
17 data.

18                   And you say -- oh, they can also  
19 present what the risk looks like for an individual  
20 who's lived there an average length of time and EPA's  
21 estimate of a higher end as well as the 70-year risk.  
22 But that really focusses just on individual risk.

23                   And from a public health perspective,  
24 that facility is still there, whether or not the  
25 individual person is still there. There's still a

1 burden on the population. It may be distributed  
2 across more people as people move in and out of the  
3 area. But we think it's important, from a public  
4 health perspective, to focus on lifetime risks and  
5 lifetime burden on the population.

6                   So that's why we really want to see  
7 that 70-year-risk estimate. Every facility is  
8 required to do a 70-year. If they want to do these  
9 other exposure durations, they can.

10                  CHAIRMAN FROINES: Well, I, again, given what  
11 I just did on Wednesday, where I actually had to  
12 comment on this environmental impact report where the  
13 report talks at great length about the fact that  
14 people don't live someplace for 70 years -- in my  
15 view, the EIR misunderstands the science of why we do  
16 the 70-year and its implications for risk management.

17                   And I think the danger is that, if  
18 it's not made clear, that people will misunderstand  
19 and want to go around calculating 9-year lifetimes  
20 and saying, "See. This is what it is. So we don't  
21 really need to do any risk management or to control  
22 exposures because people aren't living there for 70  
23 years."

24                   I think that the danger is that,  
25 again, that people can read something in which you

1 say, "Yes. You can go do this for 9 and 30," and  
2 then they may want to use that as a justification for  
3 a lack of action where it may be necessary.

4                   And I'm not impugning anybody's  
5 integrity. I'm simply saying that there may be a  
6 misunderstanding. So it seems to me to be useful to  
7 add a sentence or two into your document that really  
8 did clarify the issue so that nobody is confused by  
9 what the implications of the 70-year lifetime and how  
10 it's going to be used are.

11                   I don't think it's more than two  
12 sentences -- one, two, three at most. But I think it  
13 will help. And I literally have seen this  
14 misinterpretation two days ago.

15                   And so the danger is that -- and if I  
16 hadn't testified, who knows whether that becomes a  
17 precedent and then starts to be used in other places  
18 throughout the State. So there is a concern about  
19 how effectively people can apply some of the  
20 documents.

21                   The only other question I was going to  
22 raise was: "Is the computer program" -- unlike Stan,  
23 I found that the document not to be a cookbook as  
24 much as I would have hoped. I would have preferred a  
25 real cook -- a simple-minded cookbook where somebody

1 just goes boom, boom, boom, boom, boom through it and  
2 comes out with the numbers they need.

3                   And I don't think this really does  
4 that. I think it --

5           DR. GLANTZ: Well, I think it was more --  
6 actually, to be more precise, it was like the manual  
7 for the computer program.

8           CHAIRMAN FROINES: The cookbook? So what I'm  
9 asking is "Is the computer program the cookbook in  
10 essence?" Is that --

11           DR. MARTY: Well, the computer program does  
12 everything for the entire facility, starting with  
13 their emissions estimates, runs through the  
14 dispersion and deposition modelling, runs it through  
15 all the exposure algorithms that are presented in the  
16 manual in Part IV, and comes up with the risk.

17                   There are toggles in the program. You  
18 can turn on the stochastic or turn it off, if you  
19 don't want to do a stochastic, like, all of this  
20 70-year cancer risk, et cetera, end up coming up at  
21 the end. And all of the parameters that were  
22 reviewed in the Parts I through IV are in that  
23 computer program.

24           DR. GLANTZ: You know, one thing --

25           CHAIRMAN FROINES: So I think the answer to my

1 question is "Yes" --

2 DR. GLANTZ: Yes.

3 CHAIRMAN FROINES: -- it is the computer" --

4 DR. GLANTZ: You know, one thing -- one thing  
5 I was just thinking about that might make the  
6 document a little bit more useful would be if you  
7 were to include -- make up a hypothetical example and  
8 just say -- and include it. You know, "Here are the  
9 parameters you pick. Here's why. Here's the inputs  
10 that you put into the program. And here's the output  
11 and how you interpret it."

12 DR. BLAISDELL: We were actually planning on  
13 doing that as a stand-alone document. The problem  
14 with the risk assessment is that it was pretty  
15 voluminous. It would have made this thing maybe  
16 twice or three times as big.

17 DR. GLANTZ: Oh, okay.

18 DR. BLAISDELL: So we're definitely planning  
19 on doing it. We're actually in the process of  
20 producing that with the hard printouts and  
21 everything.

22 DR. MARTY: We're working with ARB and the  
23 districts to produce that example. We'll have a real  
24 simple example. And then the districts wanted a more  
25 complex analysis to have a sample of that.

1           CHAIRMAN FROINES: I think that would be  
2 useful. So basically given the fact that the -- it  
3 sounds like the computer program is exactly what I  
4 think people need in terms of a step-by-step  
5 procedure. I think that meets my concerns about this  
6 document.

7                         And Stan's suggestion, I think you  
8 already are going to pursue. So I don't have any  
9 further questions either.

10           DR. BLANC: I'd like to move that we accept  
11 this draft document with the minor changes indicated.

12           DR. FUCALORO: Second.

13           CHAIRMAN FROINES: Discussion?

14                         (No audible response.)

15           CHAIRMAN FROINES: All in favor.

16                         (Each panel member raises his hand.)

17           CHAIRMAN FROINES: The vote is unanimous. So  
18 we'll take lunch.

19                         (The lunch recess was taken at

20                                 12:44 P.M.)

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1 EL MONTE, CALIFORNIA; FRIDAY, JULY 26, 2002

2 AFTERNOON SESSION

3 (1:29 P.M.)

4

5 CHAIRMAN FROINES: The next item on the agenda  
6 is the "Update on Risk Assessment of  
7 Cholinesterase-Inhibiting Compounds."

8 DR. RICE: Hi.

9 CHAIRMAN FROINES: Hi.

10 DR. RICE: I'm Dave Rice. I'm a staff  
11 toxicologist with OEHHA. And this is Keith Feifer.

12 DR. SALMON: Hi, Keith.

13 DR. RICE: Keith has lost a lot of weight  
14 lately.

15 DR. FUCALORO: I could never see that guy.

16 DR. RICE: Keith couldn't make it due to a  
17 scheduling conflict. Tobi Jones was going to sit in,  
18 in his place. And apparently she had a family  
19 emergency at the last minute. And so I'm it.

20 What I'd like to do is just take a  
21 couple of minutes to go through this update. And I  
22 hope this is one of the short and sweet presentations  
23 for the day. But we'll see.

24 In my first overhead that was just up  
25 there, what I wanted to point out was just a brief

1 update of the work group activities. And I wanted to  
2 especially point out, particularly point out, is that  
3 this is a collaborative project between -- what was  
4 on the prior overhead -- collaborative project  
5 between OEHHA and DPR, which is noteworthy in its own  
6 right.

7                   Okay. In this overhead -- this is  
8 just a general overview of the activities of the work  
9 group, most of which we presented at the last update.  
10 And I'm really presenting this to kind of refresh  
11 your memories of the last update we gave.

12                   The first item of business was we  
13 identified topics for discussion papers and made  
14 assignments to the appropriate staff. We ended up  
15 with 28 individual papers. We are complete with 23  
16 of them. 3 are, in a large way, complete. They're  
17 under revision. And 2 are yet to be presented.

18                   As you can tell, most of the papers  
19 have been presented to the work group. They've been  
20 revised and presented to the work group again if  
21 major revisions were necessary.

22                   From those papers, we identified  
23 specific topic areas based on the questions raised in  
24 those papers and from the discussions of the work  
25 group. And basically those topic areas are just a

1 reiteration of the topics of the papers themselves,  
2 framed in a risk-assessment context. And we  
3 developed a list of key issue topics and issue  
4 questions of this paper.

5                   And the last two bullets, just ignore  
6 for now. I'll come back to them and discuss them a  
7 little more or elaborate on them in a couple of  
8 minutes.

9                   The next overhead is just a summary of  
10 what members of the panel were provided within the  
11 last day or two. And that is the --

12                   Oh, thanks, Mel. That's just the  
13 categories for cholinesterase-issue questions. And  
14 you can see that we came up -- if you don't have  
15 those copies with you and you would like a copy, I  
16 have some extras. Okay?

17                   We have five general areas, issue  
18 areas, and with subareas under the five. The first  
19 area is the "Relevance of Cholinesterase Inhibition  
20 to Risk Assessment," under which we consider plasma,  
21 RBC, brain, and peripheral cholinesterase.

22                   The "Use of Human Cholinesterase  
23 Data," "Quantitative Factors for Establishing  
24 LOAEL-NOAEL," and the "Relationship of Cholinesterase  
25 Inhibition to Other Endpoints." And the last area is

1 "Cumulative Risk Assessment of Organophosphates."

2                   Now can you put that back up, again,  
3 John? Put that one back up, please. I didn't  
4 provide in this overhead any of the actual questions  
5 themselves. They are on the handout that was  
6 provided to you -- I think it was yesterday.

7                   And an example of the questions would  
8 be something like, under "Plasma Cholinesterase," the  
9 very first question we came up with was: "Is the  
10 evidence for a physiological function for  
11 butyrylcholinesterase sufficient to consider the  
12 inhibition of plasma cholinesterase in laboratory  
13 animals or humans as biologically significant?"

14                   That was the type of questions we're  
15 developing and providing recommended answers to.

16                   Okay. Next one.

17                   The process that we're following to  
18 deal with these issues questions are -- like I  
19 mentioned, we consolidated the discussion papers into  
20 specific issue questions and issue question areas.

21                   The lead staff for each area or each  
22 subarea develops recommendations to the -- fine-tunes  
23 the questions, develops recommendations to those  
24 questions, writes it up, and presents their  
25 recommendations and the scientific justifications for

1 those recommendations to the work group.

2                   The paper is discussed at the work  
3 group. The recommendations are revised, if  
4 necessary. And the discussion is documented. We  
5 attempt to reach a consensus. And there's an issue  
6 paper prepared from that discussion.

7                   And it includes that consensus  
8 opinion, if we're able to reach it. It also includes  
9 the majority and minority views, if there were any.  
10 The idea is to take all those issue papers and that  
11 those will serve as the basis for our recommended  
12 guidelines -- the answers to those questions.

13                   And our ultimate goal is to take the  
14 issue-question papers, combine them, write an  
15 introductory chapter that summarizes them, detail the  
16 recommended guidelines, and have that as a  
17 stand-alone document.

18                   We will take the discussion papers  
19 that we prepare at the beginning of the project and  
20 put them all together in a group as a technical  
21 support document, if you will. And that's pretty  
22 much where we are and what we're doing.

23                   If you have any questions about that  
24 or comments, suggestions, whatever, I would be happy  
25 to try to answer them.

1 DR. FUCALORO: The --

2 DR. RICE: Yeah.

3 DR. FUCALORO: -- information on the  
4 cholinesterase work group came to us yesterday. Some  
5 people may have not even accessed their e-mail --

6 DR. RICE: Uh-huh.

7 DR. FUCALORO: -- in order to get copies of  
8 it. I happened to. So it's hard. I didn't have  
9 time to look at it. So there are many questions  
10 here, and I'm sure there are some here who have not  
11 read them. I actually haven't read them, even though  
12 I was able to access them, because I didn't have  
13 time.

14 So I guess what I'm asking is, the  
15 next time around, if you could maybe provide it  
16 sooner so we could look at it to comment on it  
17 knowledgeably.

18 DR. RICE: Certainly. Certainly. Yeah. And  
19 I'm sorry about getting them out to you at such a  
20 late date. It was more just for an informational  
21 purpose than a discussion purpose. But I'll  
22 certainly try to get them out earlier to you next  
23 time.

24 DR. GLANTZ: I guess my question is: When is  
25 this going to be done? This has been going on for a

1 long time.

2 DR. RICE: I hadn't anticipated that question.

3 No. That was a joke. That was something Tobi was  
4 going to address. But I'll certainly take a stab  
5 at -- I can talk about it from a technical level --  
6 well, work group level.

7 We, so far -- can you go back to the  
8 prior slide, John -- on the issue questions, we have  
9 developed the questions and had the discussions and  
10 prepared the issue -- or issue documents for all of  
11 Topic A, Topic C1, all of Topic D, and -- yeah.  
12 Those are what we've done so far. We have the  
13 remainder to do, obviously.

14 We anticipate finishing those and  
15 pulling them together in a chapter and writing the  
16 introductory chapter by the end of this year or, at  
17 the very latest, early next year. Hopefully, this  
18 year.

19 CHAIRMAN FROINES: And that's what?

20 DR. RICE: That's actually having these issues  
21 papers --

22 CHAIRMAN FROINES: All of the issue papers?

23 DR. RICE: -- finished.

24 Yes. Finished, pulled together with  
25 an introductory chapter.

1           CHAIRMAN FROINES: All? 'Cause you said --  
2 you listed the ones that are partially finished.

3           DR. BLANC: Those aren't the issue papers.  
4 Those --

5           DR. RICE: Those are background papers.

6           DR. BLANC: Can I see if I can understand  
7 the --

8           DR. RICE: Sure.

9           DR. BLANC: -- structure that you're  
10 describing?

11                         Having taken approximately two years  
12 to write a series of background papers, not all of  
13 which are finalized, you're then going to use those  
14 background papers to generate a series of policy-  
15 related questions, interpretive questions, which are  
16 then going to generate a series of written answers,  
17 as a sort of written Socratic dialogue, which will be  
18 also, in and of itself, a long document.

19                         And both documents would then at some  
20 point come to this committee? So you've -- it's a  
21 3-tiered process -- 4-tiered process, let's say --  
22 where initially there was the workshop that this  
23 group did together.

24                         Then you went back. And, then,  
25 working jointly with OEHHA, you wrote those

1 background pieces, which then have generated  
2 questions, which then will lead to writing another  
3 set of documents; is that right? I mean that's what  
4 you described.

5 DR. RICE: Well, that's pretty much what I  
6 described. It's almost right. I kind of misspoke,  
7 inasmuch as the background documents serve as the  
8 basis for the answers to those questions.

9 The questions are questions that we  
10 had pretty much all along. But they certainly have  
11 come up during the discussion of those documents.  
12 But the papers needed to be written to provide the  
13 scientific background to justify our recommendations.

14 DR. BLANC: Well, because if I had to describe  
15 a process which would be, in its conception, likely  
16 to drag itself out and sort of wear out the  
17 opposition, this would be the kind of passive-  
18 aggressive management strategy I would have devised  
19 myself. And I think it's very clever in that regard.

20 And then I would -- then I would  
21 accompany that by very long periods between reporting  
22 and then providing people updates which they couldn't  
23 possibly cope with, like a long list of questions  
24 that you receive by e-mail 12 hours before a meeting.

25 So I'd like to go on the record as --

1 I thought Tony was very generous in his comments. I  
2 mean I would like you to transmit to your  
3 superiors --

4 CHAIRMAN FROINES: Paul, he's with OEHHA.

5 DR. BLANC: -- well, to your colleagues --

6 DR. GLANTZ: Friends.

7 DR. BLANC: -- at --

8 DR. GLANTZ: -- DPR.

9 DR. BLANC: -- DPR -- I would like you to  
10 transmit, through whatever channels are most  
11 appropriate, the official --

12 DR. FUCALORO: Telephone.

13 DR. BLANC: -- displeasure of this -- of me,  
14 as a member of this committee. I don't know how  
15 others feel at this process and how it's playing out,  
16 both in form and in substance.

17 DR. RICE: Well, I'll certainly take that into  
18 account for myself, being part of the committee of  
19 the work group. And also I will transmit that to the  
20 other members of the work group verbally.

21 DR. BYUS: Let me -- since I am the remaining  
22 lead person on this process, I have received the  
23 various drafts of the working -- the document -- the  
24 scientific document, if you will -- which has all the  
25 chapters dealing with the various topics.

1                   And while I haven't read it, I've read  
2 a lot of -- some of it in detail. I haven't read it  
3 all. But I have looked it all over. And it is --  
4 from my own point of view, it's -- the scientific  
5 discussions are all there. And they're laid out in a  
6 reasonably comprehensive way.

7                   So I think that document, in and of  
8 itself, is a good one. I mean not -- I'm not  
9 speaking editorially. It's not editorially how I  
10 would necessarily have done it. And you know, I'm  
11 not -- but the topics are laid out. They're reviewed  
12 well.

13                   And I view that as a valuable thing  
14 for DPR and OEHHA to have done because I think that  
15 the issues are somewhat complex. There's a lot of  
16 historical reasons where various opinions have been  
17 held. And they -- the tenor of the document is a  
18 good one. And it's objective. It attempts to lay  
19 out factually what the facts are without really  
20 getting at these questions.

21                   So I think that was a good thing that  
22 they did that because it provides them, their  
23 scientists, and everyone, both in DPR and OEHHA, with  
24 sort of the up-to-date scientific consensus for these  
25 various topics. So I think that has been very good.

1                   But I would recommend, though, that  
2   you, as part of the procedure, that you might,  
3   instead of waiting for all of this, you might  
4   actually send everyone -- send us that document --  
5   finish that document and get it out and not  
6   necessarily wait for the entire process to be  
7   completed.

8                   Now, we've always wanted them to focus  
9   on these questions -- on the questions. And I just  
10  got this too. I actually got this a couple days  
11  before everyone else. So I had some few extra time  
12  to read these questions.

13                  And I think it's a reasonable  
14  approach. And I think the questions -- I think  
15  you've asked the questions three or four or five  
16  times -- the same question. I mean there's really --  
17  you keep asking them over and over again --

18                  DR. RICE: True.

19                  DR. BYUS: -- which is better than not asking  
20  them at all.

21                  But I think this will be good. These  
22  are a lot of the seminal questions that they need to  
23  answer and need to come to grips with.

24                  And then they can use the science in  
25  that document and their communal, now, knowledge from

1 writing that, I think, which is the main thing, to  
2 address these documents -- these questions with some  
3 degree of, I hope, with some degree of validity that  
4 they'll be able to back up.

5                   And when we question them, the science  
6 should be there.

7                   And you're going to have to come to  
8 some conclusions from these questions.

9           DR. RICE: Right. Right. That's the purpose  
10 of these.

11           DR. BYUS: So I think that -- you know, I  
12 think that is a good thing as well. How long it's  
13 taken is another question. And I mean I do agree  
14 with you it seems to taken considerably longer time  
15 than it should have.

16                   But if the product is good at the end,  
17 I think it's well -- it will have been well worth the  
18 time, if the product turns out to be good, because  
19 there are 40-plus organophosphate pesticides, maybe  
20 more, with related activity.

21                   These are all the sort of seminal  
22 questions and all the risk assessments -- these are  
23 questions that have been not answered appropriately,  
24 in my opinion, for many years by EPA, by everyone.

25                   And so hopefully, if DPR comes to the

1 right conclusions -- the "right" -- well, I mean  
2 that's the point. If you come to the correct  
3 conclusions, it will be a good thing. So --

4 DR. RICE: Thank you.

5 DR. BYUS: -- I guess that's the bottom line,  
6 in my opinion -- what the conclusion -- how you  
7 answer these questions and how you defend your  
8 answer, how you respond to how it would end -- and  
9 when we read this document, when you read these  
10 documents, this document, you will -- the science is  
11 laid out there in a reasonably, well, good form.

12 DR. BLANC: Well, then, why structure it as  
13 two separate documents? Why not --

14 DR. BYUS: I know.

15 DR. BLANC: Why -- well, no. Because it cuts  
16 right to the point you're raising. If you believe  
17 that the working document -- working group document  
18 provides all the scientific documentation that will  
19 be required to answer the policy questions, then why  
20 not write the executive summary of the background  
21 documents in the form of the questions that you're  
22 posing and answer them citing chapter and verse from  
23 your background documents?

24 DR. RICE: Right. Right.

25 DR. BLANC: "As shown on Page 25, the

1 correlation between RBC cholinesterase and brain  
2 cholinesterases, you know, averages between .7 and  
3 .9; and, therefore, RBC cholinesterase is an  
4 excellent surrogate."

5 DR. BYUS: Or, in reality, what they should  
6 have done --

7 DR. BLANC: All I --

8 DR. BYUS: -- which is what you wanted them to  
9 do, is write the questions first --

10 DR. BLANC: I wanted these --

11 DR. BYUS: I know. I know --

12 DR. BLANC: I deliberately didn't --

13 DR. BYUS: And then write --

14 DR. BLANC: I deliberately didn't say that --

15 DR. BYUS: Oh, okay.

16 DR. BLANC: -- because that is what you did;  
17 so that is what you did.

18 But I don't really understand the  
19 rationale for the two-year process it will take to  
20 write another -- write and review another document,  
21 even though you say you're going to have something by  
22 December. I don't think that is realistic. That's a  
23 whole separate document --

24 DR. RICE: It's putting together the pieces  
25 that we're generating right now -- the issue-

1 question discussions. It's a separate document in,  
2 you know, physical form only. It's basically a  
3 summary of the discussion we're having in coming up  
4 with guidance or coming up with the answers to the  
5 questions that we've posed. And they're very short.

6 We're -- our thinking is to have a  
7 small guidance document posing the questions; giving  
8 the answers; providing the discussion; referring to  
9 the technical document, which will be very long.

10 I mean it could be in one document.  
11 It really doesn't matter to me. But, again, our  
12 thinking was to have a short guidance document and a  
13 more substantial scientific support document. That's  
14 all. The amount of work required to do them as  
15 separate documents is not much more.

16 DR. BLANC: So what you're saying is that you  
17 have a six-month time line to write an executive  
18 summary, essentially an executive summary, of the  
19 document you've already written?

20 DR. RICE: No. We have -- we have not --  
21 we've written 28, almost 28 individual documents.  
22 We're now going through and -- based on what we've  
23 uncovered, discussed in those original documents --  
24 answering the issue questions we posed.

25 CHAIRMAN FROINES: But my understanding was

1 that -- which of the categories where there is --  
2 where the documents have not been written?

3 DR. RICE: Okay. Right now, there is one  
4 document -- there is only -- what? -- 3 documents  
5 that have not been written. One of them is in the  
6 use of cholinesterase data. It would have been  
7 written except the lead person writing it had a  
8 skiing accident and was out for 3 months.

9 We have -- 2 other documents are in  
10 the cumulative risk assessment for organophosphates.  
11 These just haven't been written 'cause the staff  
12 doing those documents hasn't had the time to do that.  
13 They've been very busy with other documents.

14 DR. BYUS: That's the one I requested.

15 DR. FUCALORO: Yeah. That's the one that --

16 DR. GLANTZ: Yeah. That's the most important  
17 one.

18 DR. BYUS: Well, I'm not -- no. I wouldn't  
19 say it's the most important. But many of these --  
20 the questions, as they're posed are, to me -- again,  
21 I am not an expert in cholinesterase. But I'm a  
22 biochemist-pharmacologist; so I do understand this  
23 well.

24 These are many -- for the -- they're  
25 not all appropriate questions. There are certainly

1 most of them, in my view. So I'm being optimistic,  
2 but the answers are what we're looking for. The  
3 answers are the key thing, obviously -- how you --  
4 what conclusions you come to. And I think it will be  
5 helpful for the panel when they do, do this to have  
6 the scientific document there to read --

7 DR. RICE: Sure.

8 DR. BYUS: -- for these topics. And so then  
9 it will be very clear whether or not they're  
10 answering them correctly. I mean I think we won't  
11 have much trouble at all coming to that level of  
12 conclusion.

13 DR. RICE: Right.

14 DR. BYUS: Right.

15 CHAIRMAN FROINES: I think we don't need to  
16 prolong this because he represents OEHHA.

17 Randy, I assume that you don't have  
18 anything to say on this topic.

19 MR. SEGAWA: I'm sorry. No.

20 CHAIRMAN FROINES: And my view is that this  
21 process was problematic from its outset. I've never  
22 varied in that view. If -- being the fact that I'm  
23 from a university, I would never ever have  
24 approached this issue by having people in  
25 regulatory agencies have the primary responsibility

1 for developing what is essentially an academic  
2 document.

3 I would have gone out on contract and  
4 gotten academic researchers who are used to preparing  
5 documents, especially within reasonable time frames;  
6 and I would have had them do it. I don't know of any  
7 contract that I'm aware of where an agency like OEHHA  
8 or DPR has ever given a three- or four-year contract  
9 to a university to prepare a document on a topic.

10 You don't do that. It's six months,  
11 or it's a year and so on and so forth. This process  
12 seems to me to be very akin to the rock of Sisyphus.  
13 It may never emerge at the current rate that it's  
14 going.

15 And I have to be quite candid and say  
16 that I think it's, to some extent, insulting to this  
17 panel to not have a representative from DPR to be  
18 here to talk about this agenda item. We made this  
19 agenda a month ago. Somebody should have been here  
20 to talk about it.

21 We shouldn't put the burden on you.  
22 So that the message -- this panel has to send a  
23 message via the transcript to DPR. I don't think  
24 that you're the appropriate person, and you shouldn't  
25 be burdened with our beating up on you because of the

1 time it took to get this or the process or what have  
2 you.

3 But I do think we should say  
4 something -- we should say something about the  
5 process because it does seem to be a never-ending  
6 process.

7 And it does bother me, to some extent,  
8 to have you say in the overhead that "If we can't  
9 reach agreement, we'll have minority reports." Well,  
10 the State has to have a policy on cholinesterase. We  
11 don't -- this is not a debating society. It's a  
12 regulatory policy judgment that's being made.

13 You don't -- we don't get to have  
14 multiple documents with multiple points of view in  
15 them. We -- this panel wants to review a policy  
16 document with the associated science.

17 And it seems to me that Winston  
18 Hickox, as the head of Cal EPA, needs to make sure  
19 that OEHHA and DPR can come to some agreement about  
20 the policy of organophosphate regulation in the  
21 State.

22 DR. RICE: Well, I didn't mean to imply that  
23 we would have majority and minority opinions --

24 CHAIRMAN FROINES: You said it.

25 DR. RICE: -- on the issue recommendations

1 themselves. It will just be in the discussion behind  
2 that recommendation. We are very clear in coming out  
3 with recommendations to our questions that are  
4 directed to the points, like, "Yes," "No," "Cannot be  
5 determined." And there's not a minority-majority  
6 recommendation.

7 DR. BLANC: I'm going to come back to what I  
8 said before.

9 Actually I don't think that it's an  
10 inconsequential matter whether or not the structure  
11 of these policy recommendations is a separate  
12 document or the executive summary of the 28  
13 scientific background documents that will be united  
14 by it -- an introduction -- because, just from the  
15 review point of view as well as the logistics of it,  
16 it will be very hard, I think, to -- it will be much  
17 harder to assess the strength and validity of the  
18 various answers to the questions, if that's how it's  
19 structured -- as questions and answers -- unless the  
20 answers, which as brief as they are, say, "As shown  
21 on Page 128-X and as documented on Page 425-Y;  
22 therefore, the following:"

23 DR. RICE: I understand.

24 DR. BLANC: And it -- and I think it will  
25 force -- I think it will force that executive summary

1 to be even heftier but will also make it more  
2 effective because essentially it's a document which  
3 is using, as its support material, another document  
4 but could also be invoking things which aren't in the  
5 other document, as far as that goes.

6 I mean it just has to stand on its own  
7 as even a brief document. For example, things  
8 like -- how are you going to deal with things that  
9 have been published in the interim? Are you going to  
10 start suddenly referring to them in this other  
11 document but they won't be in the master document?

12 CHAIRMAN FROINES: Gary?

13 DR. FRIEDMAN: John, I just wanted to ask if  
14 you really think that the transcript is going to be  
15 an effective means of communication of our concerns  
16 because that's the way it's going to have to go. I  
17 wonder if an additional letter would be appropriate,  
18 because I wonder: Would the people even read the  
19 transcript?

20 CHAIRMAN FROINES: Well, I think --

21 DR. FUCALORO: Can anyone read those  
22 transcripts?

23 CHAIRMAN FROINES: I think it would be highly  
24 appropriate for me to send a letter on behalf of the  
25 panel to Paul Helliher with DPR and express concerns

1 about the process, if you think that makes sense.

2 DR. FRIEDMAN: I think the transcript would  
3 not be, necessarily, an effective way to communicate.

4 DR. FUCALORO: Will we see any of these 28  
5 documents soon? These background scientific data?

6 DR. RICE: Well, again, we have been providing  
7 virtually all the documents to the SRP leads.

8 DR. FUCALORO: To the what?

9 DR. RICE: To the SRP leads.

10 DR. FUCALORO: In my experience --

11 DR. RICE: Dr. Byus has them.

12 DR. BYUS: I might recommend that you send  
13 that document to the panel within a month. I mean  
14 just --

15 DR. FUCALORO: We have nothing else to do. We  
16 enjoy reading those things.

17 DR. BYUS: I mean I really -- that would be a  
18 recommendation. Send that to -- complete that  
19 document, which you should be able to do -- complete  
20 it and, except for that cumulative, which you haven't  
21 even started, which I don't want to get into but I --

22 DR. RICE: You know who's working on it.

23 DR. BYUS: I know. I know.

24 DR. BLANC: I'd like to get some feedback,  
25 though, from the group. I mean I have my opinion,

1 but if I'm way off base and nobody else takes the  
2 point of view that --

3 DR. GLANTZ: No. I agree with you. I mean  
4 this is --

5 DR. FUCALORO: You mean getting the document  
6 sooner? In other words --

7 DR. GLANTZ: Oh, that's a given.

8 DR. BLANC: Yeah. That's a given. But  
9 abandoning this plan to have a whole second-tier  
10 document and --

11 DR. BYUS: Oh, I see what you're saying.

12 DR. BLANC: -- and writing an executive  
13 summary of the documents that they have almost  
14 complete in the form, if they wish, of the policy  
15 questions but that it's actually an executive summary  
16 of the documents that, in its answers to these policy  
17 questions, refers specifically to pages or sections  
18 that are relevant.

19 DR. FUCALORO: You know, I think, listening to  
20 you, it sounds good to me. However, we haven't  
21 really deliberated on that. So I wonder about making  
22 a motion, for example, and including it here and  
23 setting -- changing the course of this, whether or  
24 not we should at least think about it a little  
25 longer. I think this is prudence speaking rather

1 than --

2 DR. GLANTZ: Than Tony.

3 DR. FUCALORO: I'm saying, at first blush, it  
4 sounds good. I'm just not sure that it would stand  
5 muster.

6 DR. GLANTZ: I was just going to say, I mean,  
7 "Why couldn't you do what Paul's suggesting?"  
8 Leaving aside the ones that haven't been drafted yet,  
9 I mean why couldn't you just take -- you'll have your  
10 summary of the science. You've got your questions  
11 articulated. Why can't you just go from one to the  
12 other and bring back --

13 DR. RICE: There's no -- I'm sorry.

14 DR. GLANTZ: What?

15 DR. RICE: There's no reason we couldn't  
16 physically put them together.

17 DR. GLANTZ: Okay. That leaves out a huge  
18 amount of work and another step. So I think Paul's  
19 suggestion is a good idea.

20 DR. BLANC: I don't -- that wasn't -- your  
21 answer wasn't exactly what I -- what you said is  
22 "There's no reason we can't put them together."

23 But what I'm suggesting is --

24 DR. RICE: Make them one document.

25 DR. BLANC: Okay. Because what I'm suggesting

1 is a change, a conceptual change, in how you  
2 presented this second document.

3 DR. RICE: Second document? As I understand  
4 what you're saying is: They take the background  
5 papers we've already developed, write an executive  
6 summary that basically will be the second -- or  
7 basically takes --

8 DR. BLANC: Yes.

9 DR. RICE: -- the place of the second  
10 document --

11 DR. BLANC: Yeah.

12 DR. RICE: -- that I've been talking about --

13 DR. BLANC: Right.

14 DR. RICE: -- in whatever form we see fit --

15 DR. BLANC: Right.

16 DR. RICE: -- be it questions --

17 DR. BLANC: Yes.

18 DR. RICE: -- statements, what have you,  
19 referring to the --

20 DR. BLANC: Yes.

21 DR. RICE: -- scientific articles that are in  
22 the background documents.

23 DR. BLANC: Yes. Yes. Exactly. Do you  
24 understand that?

25 DR. RICE: I understand that. Yeah.

1 DR. BLANC: Okay.

2 DR. RICE: And that's fine with me. I'm not  
3 the only one to make that decision.

4 DR. BLANC: No. I understand.

5 DR. GLANTZ: Well, but I think -- I mean I  
6 also didn't get these questions till just now. But I  
7 mean they are well-articulated questions. And I mean  
8 I could just see just simply going through and  
9 answering them and --

10 DR. BYUS: I could answer them right now.

11 DR. GLANTZ: You could?

12 DR. BYUS: I mean, you know, many of them,  
13 myself.

14 DR. RICE: I could too.

15 DR. BYUS: I know you could. And I'm not --  
16 and that's even without the entire reading in detail  
17 the entire document that they've prepared. I mean  
18 you don't have to have all that information to answer  
19 these questions. Some of it -- a lot of it, you  
20 need. You don't need all of this.

21 So I mean I could do it. And so I'm  
22 sure, if I could do it, you guys can do it. It's the  
23 policy aspect of it that, I think, is the problem.  
24 It requires -- it's my impression that it requires --  
25 that it's the policy aspects of it.

1 DR. GLANTZ: But, you know, it's a little bit  
2 like students coming in with a final, you know. The  
3 more time people have, especially given the history  
4 on this, the longer it's going to take. And I think  
5 it would be much better if we could -- I mean I'm,  
6 again, agreeing with Paul, if we could see something  
7 sooner rather than later.

8 CHAIRMAN FROINES: I think that these  
9 discussions have an air of unreality about them --

10 DR. GLANTZ: Yeah.

11 CHAIRMAN FROINES: -- because we spent --  
12 OEHHA's developed the four documents; and we, today,  
13 talked about the fifth document. And there's  
14 enormous detail in there about how one approaches  
15 risk assessment. And there's no question that  
16 there's a lot of information.

17 But that's different than defining the  
18 basic policy questions that need to be addressed to,  
19 then, develop all that information. I mean it seems  
20 to me that one could or should be able to prepare  
21 today, a week from now, a 3-page document that  
22 defines the broad policy-based questions that need to  
23 be addressed.

24 I don't think it's rocket science,  
25 frankly. I think it is relatively straightforward,

1 and I think it could have been done three years ago,  
2 two years ago -- that the basic questions -- I think  
3 we understand what they are. So the degree to which  
4 we keep complicating -- the science is complicated.  
5 But some of the larger questions are relatively more  
6 straightforward.

7 I think that document, which is what  
8 Paul's talking about as the overlying executive  
9 summary, is a relatively -- is a document that  
10 shouldn't be a major undertaking -- not at this  
11 point, not after all the work that's gone into it  
12 or -- and if I'm wrong, somebody needs to tell me why  
13 that's wrong.

14 DR. RICE: No. It's not a major undertaking,  
15 in and unto itself. But it just takes time to  
16 prepare because there's approximately 15 people  
17 working on it at any given time. And we're trying to  
18 reach, build a consensus on each of the issue  
19 questions as we go along. There's a lot of questions  
20 and a lot of data to consider in support of each  
21 question.

22 And it's not -- while it's an  
23 important part of our workload, I mean it's not our  
24 only project. So we can't devote our entire time on  
25 it. So all those things considered contributes to

1 the length of time it's taking to get this finished.

2 CHAIRMAN FROINES: I think that -- I  
3 understand that. That doesn't answer my question  
4 because my question is: "Couldn't somebody sit down,  
5 person-to-person, and over a short period of time, in  
6 a 3-page document, define the broad-based policy  
7 issues that are going to be addressed?"

8 It seems to me that that isn't, I  
9 mean, a -- and I'll tell you that, in fact, the EPA  
10 science advisory panel has been doing just that. So  
11 you could actually go to the EPA's review -- it's  
12 been going on for the last year -- and derive, from  
13 what they've done, the questions.

14 Ruby Reed sits on that document --  
15 sits on that committee and it seems to me that that  
16 committee's attempting to deal with the same kinds of  
17 questions.

18 DR. RICE: Right.

19 CHAIRMAN FROINES: And so it seems to me that  
20 there's an entire advisory committee, an entire  
21 agency effort going on that could be applied within  
22 the context of the State's activity. And that  
23 doesn't seem to be happening.

24 DR. BLANC: Well, John, if a consensus were to  
25 emerge from this committee it is that the -- is that

1 it would be our strong recommendation that the  
2 approach to finalizing the document would be to take  
3 the document that they have; circulate it rather  
4 rapidly; and then soon after its circulation, create  
5 an executive summary, which would incorporate --  
6 which, if they wished, could incorporate it in a  
7 question-and-answer form.

8 I think that that should be part of  
9 your letter to the pesticide people because they  
10 won't do it unless -- they won't do it simply because  
11 you said, "That's an option." If you say, "That's an  
12 option," I don't think it will happen.

13 DR. BYUS: That would be my recommendation.  
14 Because I think the scientific document that they  
15 prepared could be wrapped up quickly. I mean it's  
16 going to take -- they haven't finished -- but it  
17 could be wrapped up very quickly.

18 And I think they should put their  
19 effort into getting something completed. And that  
20 would be completed -- you should be able to complete  
21 it quickly. And then -- say, by our next meeting --  
22 give it to us so we can -- before our next meeting,  
23 so we can review it.

24 And then by our next meeting, whenever  
25 that would be, circulate the executive summary

1 questions for us to review.

2 CHAIRMAN FROINES: Well, I think it's a little  
3 more complicated than that because, if we had a  
4 meeting in September and you want them to get the  
5 documents to us by then and we review it, look at it  
6 by then, the time is kind of tight. I mean it can  
7 happen presumably, but spell out for me -- spell out  
8 for the record -- and I'll use it in the letter that  
9 I write to Paul Helliher -- what you would like to  
10 see happen, with some specificity.

11 DR. BYUS: I'm just trying to remember which  
12 chapters haven't been written yet.

13 I think you could finish that document  
14 in a month. Can you finish that document in a month?

15 DR. RICE: I don't think so. I really do  
16 think it will take us, given, you know --

17 DR. BYUS: Scientific document now -- just the  
18 science part.

19 DR. RICE: You mean just putting together the  
20 chapters?

21 DR. BYUS: Yeah.

22 DR. RICE: That's all it is.

23 DR. BYUS: Right. That's why I'm asking you.

24 DR. RICE: I don't know --

25 DR. BYUS: Except for the cumulative

1 organophosphate data, isn't it pretty well  
2 finished -- the chapters?

3 DR. RICE: With that exception. And the "Use  
4 of Human Cholinesterase Data" is not finished.

5 DR. FUCALORO: I can't hear you.

6 DR. RICE: The "Use of Human Cholinesterase  
7 Data" chapter is not finished either.

8 DR. BYUS: Couldn't you finish that in one  
9 month and get it to us in a month?

10 DR. RICE: You know, I hate -- it seems  
11 reasonable that it could be. I can't speak for the  
12 person writing the paper.

13 DR. BYUS: So it seems --

14 DR. RICE: Again, I'm not sure how our  
15 management and DPR's management feels about sending  
16 out a document that's incomplete that way, in terms  
17 of not having all the chapters.

18 DR. GLANTZ: Well, except what we're trying to  
19 say is that we want them encouraged to just get it  
20 done.

21 DR. RICE: I understand. And I can assure you  
22 that --

23 DR. BYUS: This is a way to do that.

24 DR. RICE: Yeah.

25 DR. GLANTZ: And the longer -- and you know,

1 because I think some of the -- and, again, we're not  
2 beating you up personally -- but given the sort of  
3 history of this, I think, left to their own devices,  
4 you know, it will be a very long time before we see  
5 anything.

6                   And so I think, since it sounds like  
7 what you have is pretty close, the -- you know, if  
8 we're going to meet in September, it would be nice if  
9 we had the scientific document by a couple of weeks  
10 before the meeting to at least at look at it and  
11 discuss, if it wasn't as an information item.

12                   And then -- and maybe the executive  
13 summary document and the policy document or executive  
14 summary-slash-policy document that John and Paul are  
15 talking about, maybe, for the following meeting.

16           DR. FUCALORO: "Following meeting"?

17           DR. GLANTZ: The following meeting, which  
18 would be October, November, or something. And we  
19 wouldn't -- actually I wouldn't anticipate taking any  
20 formal action on the document that we would discuss  
21 in September.

22                   But we could discuss it and give you  
23 some feedback, which could then be used, you know --  
24 you could take that and take it into account in  
25 preparing this more policy-oriented document, which

1 would come back at the next meeting.

2                   What do you think about that as a  
3 plan?

4           CHAIRMAN FROINES: I think that's what the two  
5 of you are saying.

6           DR. GLANTZ: Yeah.

7           CHAIRMAN FROINES: My concern is as follows:

8                   First is, this has been a major  
9 undertaking. I mean obviously they've assigned 16  
10 people to work on it. It's not a trivial approach.  
11 It's a major effort. And I can see why they would be  
12 somewhat hesitant to release something that they  
13 consider only partially finished.

14                   However, it seems to me that that --

15           DR. GLANTZ: Could encourage them to finish  
16 it.

17           CHAIRMAN FROINES: This would encourage them  
18 to finish it.

19                   So the second point is I think that  
20 the schedule you've proposed is a little tight to be  
21 able to -- I think that --

22           DR. GLANTZ: How about slipping the whole  
23 thing one meeting?

24           CHAIRMAN FROINES: Well, I think that the  
25 problem is going to be the adequacy of our review

1 because we don't want a superficial review process  
2 for ourselves. And this is going to be a fairly  
3 lengthy document with a lot of science in it.

4                   And it's going to take a while. And  
5 we have to understand our own limitations in terms of  
6 how fast and how effectively we can review a very  
7 major document.

8                   So I would argue that we should ask  
9 for the document -- I would put it maybe three months  
10 down the line. But I would include a 2- or 3-page  
11 document that lays out the policy issues because I  
12 think that should -- somebody should be able to sit  
13 down and write that out today in an hour.

14           DR. RICE: Well --

15           CHAIRMAN FROINES: And I think, simply think,  
16 that those issues are not such that they could not be  
17 defined.

18           DR. RICE: That's what these questions are.

19           CHAIRMAN FROINES: I understand. No. These  
20 questions -- these are not the questions. These are  
21 the questions -- these are the scientific questions.  
22 These aren't the policy questions.

23           DR. RICE: Well, our group is working on  
24 guidelines. We're not -- we don't do policy. We're  
25 working strictly on the science and the guidelines --

1 the science behind the guidelines.

2 CHAIRMAN FROINES: So I think -- but I think,  
3 when we talk about the policy, we are talking about  
4 the guidelines; right?

5 DR. BLANC: Just a comment about -- I don't  
6 think you were looking for a lot of feedback on these  
7 questions, you know, in terms of content.

8 DR. RICE: No.

9 DR. BLANC: But I would make a comment that  
10 might be relevant, which is each -- that the working  
11 group that's doing that question of format should  
12 strive very carefully to have them be symmetric.

13 It will make it easier for us and  
14 easier for the all other responders and reviewers.  
15 And I think they are structured with that in mind,  
16 but there are places where they're not symmetric.  
17 And I would pay very close attention to that.

18 DR. RICE: For example?

19 DR. BLANC: For example, with Question  
20 Number 2, you talk about butyrylcholinesterase, and  
21 you take butyrylcholinesterase inhibition in the  
22 neuromuscular junction of adults.

23 But then, later on -- the next, very  
24 next, question is: "Butyrylcholinesterase inhibition  
25 in the neural and extraneural tissues in developing

1 organisms," which means that you don't care anything  
2 about butyrylcholinesterase inhibition in extraneural  
3 tissue of adults because you've limited one in this  
4 very particular way and not the other.

5 DR. RICE: Right.

6 DR. BLANC: And so it's not very symmetric.  
7 That's an example of --

8 DR. RICE: Well, we did that deliberately.

9 DR. BLANC: So even if there were any issue of  
10 butyrylcholinesterase inhibition in extraneural  
11 tissues of adults, it's not something that should  
12 ever be considered anyway.

13 DR. RICE: I understand your concern on the  
14 question but --

15 DR. BLANC: I mean is that what that is? Is  
16 that --

17 DR. RICE: Exactly -- well, I don't know that  
18 I would draw that conclusion.

19 DR. BLANC: But if you're going to structure  
20 something as a questions-and-answers sort of -- as a  
21 sort of Socratic questions and answers and if it's  
22 going to tie into the document, you can't assume  
23 that, because I haven't asked -- you know that you're  
24 not asking the question because you believe that the  
25 document demonstrates why there's no issue there; is

1 that correct?

2 DR. RICE: Uh-huh.

3 DR. BLANC: But you need to ask the question  
4 so that the answer is -- as the document shows, that  
5 it is not an issue in anything other than the  
6 neuromuscular junction of adults, if this is how  
7 you're going to do this.

8 DR. RICE: Okay.

9 DR. BLANC: Because you're doing it with  
10 things for which you know that the obvious answer is  
11 "Yes"; right? Like, the brain  
12 acetylcholinesterase -- "Is acetylcholinesterase  
13 inhibition in the brain an adverse effect?" Right?

14 Well, that's a no-brainer; right?

15 DR. BYUS: So to speak.

16 DR. RICE: Yes. It is a no-brainer.

17 DR. BLANC: But you put it there because you  
18 know, if you didn't ask the question --

19 DR. RICE: Right.

20 DR. BLANC: -- you would not have a chance to  
21 address the data that you have that shows, that,  
22 obviously, it is an adverse effect.

23 DR. RICE: Right.

24 DR. BLANC: So be cautious.

25 DR. RICE: Okay.

1 DR. BLANC: And the other thing I would be  
2 cautious about, when you phrase these questions, if  
3 they're compound questions or multiple things in the  
4 same question, if you perceive that one piece of the  
5 question is far more controversial than all the other  
6 pieces of the question, then I would break that out  
7 as a separate question.

8 DR. RICE: Okay.

9 DR. BLANC: For example, you have a couple of  
10 questions where -- I'll give you an example.

11 A.2, Question 2: "Should RBC  
12 acetylcholinesterase activity be used as a surrogate  
13 for brain or peripheral acetylcholinesterase activity  
14 or neurobehavioral observations?" And then you  
15 conclude the question.

16 But the one question is the sort of  
17 straightforward question. And you have its parallel  
18 in another part where you ask the same thing.

19 But the thing that would be very  
20 controversial would be if you were to say, "Yes. I  
21 have data that shows RBC cholinesterase inhibition;  
22 but when I did an observational study, I didn't see  
23 anything wrong with the animals. And, therefore, we  
24 should discount the RBC cholinesterase data," for  
25 example.

1                   But that's an entirely different kind  
2 of question than the question about "I saw the RBC  
3 was down. But the acetylcholinesterase -- but the  
4 other cholinesterase wasn't affected. And since I  
5 know that that's a better marker, I'm going to  
6 discount it."

7           DR. RICE: I -- I understand.

8           DR. BLANC: So I would break out questions  
9 like that if you think that there's quite a different  
10 policy implication.

11          DR. RICE: Okay.

12          DR. BYUS: Guidelines; right? Guidelines.  
13 Guidelines.

14                   I have one other possible suggestion  
15 or question -- just an idea. You could bring the  
16 science document to us as a draft document which was  
17 just for our feedback and same with the questions  
18 so that you wouldn't have to worry about being quite  
19 so --

20          DR. GLANTZ: You know, that's actually what I  
21 meant --

22          DR. BYUS: Right.

23          DR. GLANTZ: -- to have it come to us as a  
24 draft rather than --

25          DR. BYUS: As a draft. There is some validity

1 to that approach in that we could help guide them,  
2 provide additional feedback to them, prior to the  
3 fact that they answer these questions.

4 CHAIRMAN FROINES: Well, I --

5 DR. BYUS: I mean --

6 CHAIRMAN FROINES: -- just want to caution  
7 you.

8 DR. BYUS: I know. I know. I --

9 CHAIRMAN FROINES: This is an advisory panel.

10 DR. BYUS: Right.

11 CHAIRMAN FROINES: -- that is paid \$100 to  
12 meet periodically to address these issues. We're not  
13 employees of DPR and OEHHHA. And we have to be  
14 careful not to promise more than we can deliver.  
15 It's been my assumption that this panel would seek  
16 outside assistance, when we got this document, in  
17 terms of peer review by people who are active in this  
18 field.

19 There's nobody on this panel who's an  
20 active researcher in this field. So when we ask for  
21 them to send us a document by September or October, I  
22 think we have to be realistic about what we're going  
23 to do with that document. How effectively are we  
24 going to review it? Are we going to seek outside  
25 input at that point?

1                   In other words, we're -- once  
2   you've -- once you've pushed the agencies to deliver  
3   a document, you are making some commitment about how  
4   you're going to follow up with it. And I think we  
5   need to be clear on what that's going to be.

6                   I don't think it's just a question of  
7   this panel getting this enormous document and  
8   skimming it and giving some suggestions and calling  
9   that quits. I don't think it's adequate. And I  
10   don't think it would be fair to the agencies.

11                  So that, if we're going to request the  
12   document, we ought to be relatively clear on what  
13   we're going to do with it, who's going to review it,  
14   and what the time frame is for that review. And I  
15   think that, otherwise, it's not fair to these folks  
16   to push them to deliver.

17                  DR. BLANC: Well, I think that's -- I don't  
18   think it's -- I don't think that -- I think we're all  
19   saying the same thing in different ways.

20                  And I think that's why people are  
21   trying to suggest some kind of incremental process  
22   that will give us something to begin working with  
23   because I also do not want to -- that's why I don't  
24   like this whole other idea because I don't -- of  
25   "We're going to do this. We're going to do that.

1 And everything's going to be finished. And then on  
2 February 1, 2004, we're going to plop 1,000 pages  
3 down on your desk."

4 And then, at that point, we would  
5 really be --

6 CHAIRMAN FROINES: Right.

7 DR. BLANC: -- under some kind of, you know,  
8 moral obligation to do something rather quickly. I  
9 would be very happy to see the first 6 books or  
10 whatever they are -- the first 6 parts.

11 Since they were all written  
12 independently, they should all be able to be read  
13 independently. I'd be willing to look at 6 of them  
14 at each meeting over the next year, you know, of the  
15 24.

16 DR. BYUS: Right.

17 DR. FUCALORO: You're under danger of having  
18 just one final document, without any information  
19 provided in between the final document and now, of  
20 coming up with something which we may find  
21 unacceptable.

22 DR. BLANC: Within their own -- within their  
23 own reports, aren't each of these 24 chapters at  
24 least as stand-alone as one of the chronic RELs  
25 discussions? And we get those in little batches and

1 look at them and give feedback.

2 DR. RICE: I don't know. I'm not familiar  
3 with the chronic RELs. They are pretty stand-alone,  
4 each paper is --

5 DR. BYUS: Starting the sequence with the  
6 beginning. You start in the beginning of the  
7 documents. And if you just -- you can't pull them  
8 randomly out.

9 DR. RICE: Some refer to other papers.

10 DR. BYUS: Some, you can. But if you start at  
11 the beginning and read the first 4 chapters and then  
12 you read the next 4, they make their -- they're stand  
13 alone in that regard, in my estimation.

14 DR. BLANC: So I would say, you know, let us  
15 start seeing some of them, just so we get a sense of  
16 even where it's going. We're not seeing them to  
17 approve them. We're seeing them informationally and  
18 then having -- you know, putting half an hour, an  
19 hour in the agenda for the discussion of those  
20 chapters.

21 CHAIRMAN FROINES: Can I make a suggestion?

22 DR. RICE: Certainly.

23 CHAIRMAN FROINES: It seems to me that  
24 Category A, the "Relevance of Cholinesterase  
25 Inhibition in Risk Assessment," I think we would all

1 agree, is a fundamental issue in this whole question.  
2 And then you said that C is finished -- "Quantitative  
3 Factors in the Selection of LOAEL- NOAEL" is also  
4 finished.

5 DR. RICE: No. Just C1. "Analytical  
6 Variability."

7 CHAIRMAN FROINES: Oh, never mind. I think  
8 that what should happen, if I can suggest, I think  
9 that the document, Category A document, should be  
10 made available to the panel.

11 DR. BYUS: Which chapters would that be?

12 DR. RICE: Principally --

13 DR. BYUS: Not all the documents would be, but  
14 the first 4 or 5 --

15 DR. RICE: Oh, gosh, I don't have a list with  
16 me either. The first 4 or 5?

17 DR. BYUS: Right.

18 DR. FUCALORO: That's just what --

19 DR. RICE: Principally --

20 DR. FUCALORO: This requires no special  
21 effort; right? They're already prepared. All it  
22 requires is --

23 DR. RICE: The chapters have been prepared.  
24 Correct. And the issue questions have been  
25 developed, discussed, answered, and written up. Yes.

1 DR. FUCALORO: Okay.

2 DR. BYUS: Sort of a Catch-22, John, in that  
3 we're going to have to -- we either wait, encourage  
4 them for the complete thing or we try to do it all  
5 along. I don't know what the answer is. The best  
6 way --

7 CHAIRMAN FROINES: I hear everybody -- there's  
8 nobody on this panel who has said that they would not  
9 like to see a draft document. So I take that as a  
10 given at this point. Is that fair?

11 DR. FRIEDMAN: Right.

12 CHAIRMAN FROINES: Okay?

13 DR. FRIEDMAN: And it doesn't have to be the  
14 whole thing, just a part.

15 CHAIRMAN FROINES: That's why I'm saying, "A,"  
16 because I think the "Relevance of Cholinesterase  
17 Inhibition" is clearly one -- is probably the  
18 fundamental issue that we're going to be concerned  
19 about -- is a fundamental issue.

20 DR. BYUS: Is a fundamental issue.

21 CHAIRMAN FROINES: Is a fundamental issue.  
22 And there's clearly a -- but that's a fundamental  
23 issue. And that's where the debate has been at EPA  
24 and beyond. So if you make that available, the panel  
25 can review it.

1                   Now my question to the panel is:  
2   "Okay. We have the document. Who's going to review  
3   it?"

4                   Do you want to review -- is this a  
5   group that wants to review it? Or do you want to  
6   seek outside input? What's the approach?

7           DR. BLANC: I think what we should do is have  
8   them get those 4 chapters to us. Let us discuss them  
9   as a committee as a whole. Craig has already been  
10  the lead. He can lead us through the discussion.

11                   Let us have one of the goals of that  
12  discussion, based on this preliminary phase of the  
13  document, be a decision as to whether or not we need  
14  to seek outside expertise and, if so, in what format  
15  and what time?

16           DR. BYUS: That's what I think.

17           DR. BLANC: And let another goal of that  
18  review be to give feedback, generic feedback, to the  
19  two agencies as to whether or not we think we  
20  still -- whether we still think it makes sense to  
21  have an executive summary in a question-and-answer  
22  form or whether we think there needs to be a more  
23  traditional executive summary because otherwise it's  
24  a morass or whether we think there should be some  
25  other format in which the scientific background needs

1 to be distilled.

2 I think that's all the arguments for  
3 doing it early. If we do it too late in the process,  
4 it will be completely unfair, I think, to the  
5 agencies if we suddenly change the rules of the game.

6 DR. RICE: Again, I can't decide whether to  
7 submit this to the committee or not. But I can  
8 certainly take it back and --

9 CHAIRMAN FROINES: Does everybody on the panel  
10 agree with that statement?

11 DR. FUCALORO: They'd only be providing just 4  
12 chapters on --

13 DR. BYUS: I'll just say 4 to 6 chapters.

14 DR. RICE: Well, the supporting chapters,  
15 whatever they may be.

16 DR. BYUS: Supporting chapters?

17 DR. RICE: Whatever they may be.

18 So what I'm hearing is that, A, you  
19 would like to see the issue questions and the  
20 subsequent discussion and our recommendations of  
21 those questions and the supporting chapters of --  
22 that we used for those discussions and our answers  
23 provided the committee when?

24 DR. BLANC: At our next meeting.

25 DR. RICE: Well, prior to the next meeting?

1 DR. BLANC: For our -- so that we can discuss  
2 it at our next meeting.

3 CHAIRMAN FROINES: In that respect, the panel  
4 is, at some level, agreeing to function as a kind of  
5 lead person, collective lead person, on this round of  
6 the process.

7 DR. BLANC: With a very focussed agenda, which  
8 is to say, "Is this the direction to go, both in  
9 terms of format and is this -- and what kind of  
10 expertise do we need to bring in and how, in order to  
11 review it?"

12 DR. RICE: How much lead time?

13 DR. GLANTZ: For the panel?

14 DR. RICE: Before the meeting for the panel.

15 DR. GLANTZ: At least a couple weeks.

16 CHAIRMAN FROINES: Well, I think you should  
17 get back to us -- oh, the lead time for the panel?

18 DR. RICE: To give to the panel before the  
19 next meeting. Two weeks?

20 CHAIRMAN FROINES: No.

21 DR. RICE: Two weeks?

22 CHAIRMAN FROINES: No. No.

23 DR. RICE: No?

24 CHAIRMAN FROINES: I don't think so. I  
25 think -- we want to avoid silliness in all this whole

1 process. And everybody is charging up the mountain.  
2 But I think we've got to be realistic about it. This  
3 panel should really have three to four weeks with  
4 these documents before they can get --

5 DR. GLANTZ: Well, that would be better.

6 CHAIRMAN FROINES: What?

7 DR. BLANC: You really faded out on that  
8 too -- three to four weeks. I think three weeks is  
9 okay because it is functionally -- in all of our  
10 lives, as I say, if it came four weeks before, we  
11 would --

12 DR. BYUS: We would hold it for a week.

13 DR. BLANC: Yeah.

14 DR. GLANTZ: Three weeks is the commonly --

15 DR. MARTY: Can I raise a couple issues? You  
16 know --

17 DR. FUCALORO: No.

18 DR. MARTY: I am going to take back the issue  
19 that -- it was not fair to have just Dave here to try  
20 and answer these kinds of questions. And you know  
21 I'm actually not involved in this process. But I'm  
22 trying to -- you know, you get inoculated enough  
23 times by doing dumb things and getting hit over the  
24 head by management, that I don't want to put Dave in  
25 the position of promising to deliver anything.

1 DR. GLANTZ: And we'll do --

2 DR. MARTY: So, you know, you have sent a very  
3 strong message. I can take that message back.

4 DR. GLANTZ: Well, why don't we -- let me  
5 suggest this, Melanie, because I agree. We don't  
6 want Dave to be sent back and never be seen again.

7 DR. RICE: That may have already happened.

8 DR. GLANTZ: Yeah. I think this is something  
9 for the Chair to deal with. I think -- I think that  
10 there's a clear sense of the panel. I think we don't  
11 need to sit here, in a committee as a whole,  
12 negotiating schedules. I think there's a sense of  
13 what we want. I think you can go back and  
14 communicate it to the management.

15 You can communicate that what's  
16 happened in the past with this committee has made it  
17 become this restless. And I think we should leave it  
18 to the Chair to negotiate with the agency management  
19 and to come back with a firm schedule which is  
20 reasonable from everyone's point of view or from our  
21 point of view.

22 CHAIRMAN FROINES: I want to say one thing in  
23 that respect. That's fine. But I think, Melanie,  
24 your just joining the discussion is good. It's my  
25 view that the decision of when a document comes to

1 this panel is the decision of the agency.

2                   It is not the decision of the panel.  
3 We can request it. And we can be restless, and we  
4 can be emphatic. But we are an advisory committee.  
5 And it is the decision of the agency when to bring  
6 the document to us. I think that's -- the point must  
7 be said. We're not -- we're not demanding this  
8 document. We're asking for it in order to facilitate  
9 the process.

10           DR. FUCALORO: Exactly.

11           CHAIRMAN FROINES: That's what we're doing.

12           DR. FUCALORO: Right.

13           CHAIRMAN FROINES: And so we would like to  
14 have this document come before us so we can help the  
15 process be more effective and more efficient and what  
16 have you. But it is ultimately the decision of the  
17 agency if they want to agree or disagree with that.  
18 If they disagree, we'd like to hear from them about  
19 their views.

20                   But it seems to me that I don't want  
21 us to act beyond the scope of our role. Our role  
22 ultimately is to define whether or not something is  
23 scientifically adequate and when it comes to this.  
24 And in this case, we think that the process would be  
25 helped by it coming for an earlier review.

1                                   And so that's where I think we're at.

2    Is that fair?

3                   DR. BYUS:   That's good.

4                   DR. BLANC:   And then our part of the bargain  
5    of not placing some odious review feedback is that,  
6    the later that they wait and the more finalized the  
7    structure of the document is, particularly if it's  
8    finalized in an unusual format for which you don't  
9    have buy-in from this group, the more likely that it  
10   is that there will be resistance to its approval.

11                                 Now, again, you're not from the lead  
12   agency, which has had the most evidence of feet  
13   dragging.

14                                 So if I were in that agency and if my  
15   ultimate goal were, in fact, to delay the whole  
16   process and perhaps never see anything come out of it  
17   at all, I would actually take exactly the tack of  
18   sending us an inflammatory document, very well  
19   developed, which we would reject or demand such heavy  
20   revision that, you know, that two more years would go  
21   by.

22                                 And I don't think that's what anybody  
23   wants.

24                   DR. GLANTZ:   Oh, well --

25                   DR. MARTY:   There's one other little issue

1 that I don't know the answer to but I just have heard  
2 through the grapevine. And that is that there was a  
3 statute passed some years ago now that requires  
4 anything coming out of Cal EPA that impacts risk-  
5 assessment policy or guidance to undergo public  
6 comment.

7 I asked Dave if he knew the answer to  
8 how they were going to deal with that in terms of  
9 this document.

10 And he doesn't know the answer.

11 And neither do I. And just --

12 DR. GLANTZ: Yeah. But you know -- well, I  
13 mean obviously, Melanie, we want to obey the law.  
14 But there's no reason that we couldn't be discussing  
15 something as a draft, even before it went out to  
16 public comment.

17 DR. MARTY: Oh, I agree with that.

18 DR. GLANTZ: If it was a final action item --

19 DR. MARTY: Yeah. No. I didn't mean to imply  
20 that --

21 DR. GLANTZ: -- then, if the law requires  
22 public comment, which it probably does, then there  
23 should be an appropriate public comment. But I don't  
24 think -- getting back to what Paul said, what we're  
25 trying to do is get something that we can comment on

1 before it gets locked down to that point.

2 DR. MARTY: Yeah. I didn't mean to imply that  
3 we shouldn't, therefore, give it to you. I just  
4 wanted to let you know that that process might have  
5 to take place.

6 CHAIRMAN FROINES: What?

7 DR. MARTY: That the public comment process  
8 might have to take place, depending on how the  
9 lawyers read it.

10 DR. GLANTZ: Well, didn't we --

11 DR. FUCALORO: Just let me say that's the  
12 reason someone suggested that they get in contact  
13 with you -- to keep the pulse on it, keep your hand  
14 on the pulse.

15 DR. GLANTZ: I'd like -- I think we've now  
16 pounded this into the mud. And I'd like to suggest  
17 that we move on with an agreement that the Chair will  
18 work this out with the agencies in the spirit of this  
19 discussion.

20 CHAIRMAN FROINES: Anything else?

21 DR. FUCALORO: That's it.

22 DR. FRIEDMAN: One thing: Since the Chair --  
23 I don't think we really clarified, you know -- you  
24 had said, within an hour, they should write the  
25 policy. Are you going to withdraw that in terms of

1 your recommendation?

2 CHAIRMAN FROINES: Oh, I meant that  
3 rhetorically.

4 DR. FRIEDMAN: No. But I mean you meant  
5 within a month or -- well, you wanted it soon. And I  
6 just wasn't clear in my mind. And I was going to  
7 request an example of what you mean by a "policy  
8 issue that wasn't covered by the questions" --

9 CHAIRMAN FROINES: Okay.

10 DR. FRIEDMAN: -- so that it's all clear in  
11 our minds because I think --

12 CHAIRMAN FROINES: Well, I think, let's leave  
13 it to -- I think we should leave it to the documents  
14 that currently are prepared and not ask them to write  
15 additionally --

16 DR. FRIEDMAN: Good.

17 DR. FUCALORO: Minimal. Minimal.

18 CHAIRMAN FROINES: -- because I think that the  
19 questions we have here can be translated into policy  
20 statements because they really do represent the  
21 policy decisions in some respects. But let's not try  
22 and ask them to, in a sense, take this and rewrite  
23 the guidelines.

24 DR. FRIEDMAN: Good. That makes sense.

25 CHAIRMAN FROINES: No. I meant that really as

1 a rhetorical issue -- that some of the stuff -- that  
2 some of the material that was going to be written in  
3 this third document that Paul was talking about and  
4 that you mentioned earlier -- some of that should  
5 already be, in a sense, before -- before the people  
6 developing the document as the questions that they  
7 ultimately have to answer, I think. So that --

8 DR. GLANTZ: Next.

9 DR. FRIEDMAN: Are we aiming to leave at 3:00  
10 or shortly after? Because I'm told that the traffic  
11 is terrible on the freeway. So we'll have to  
12 leave --

13 CHAIRMAN FROINES: Randy, are you here to  
14 discuss the air monitoring of pesticides?

15 MR. SEGAWA: I could answer questions, but I  
16 have no formal presentation.

17 DR. BLANC: Are you doing any?

18 MR. SEGAWA: Yes. I'm Randy Segawa with the  
19 Department of Pesticide Regulation. I'm sorry.  
20 Could you repeat the question?

21 DR. BLANC: Are you doing any?

22 MR. SEGAWA: Are we doing any what?

23 DR. BLANC: Any pesticide monitoring  
24 currently?

25 MR. SEGAWA: Yes. We are doing pesticide

1 monitoring. We -- actually I should say the Air  
2 Resources Board is doing air monitoring at the  
3 request of the DPR.

4 DR. BLANC: And what are you requesting them  
5 to do currently?

6 MR. SEGAWA: Currently, Air Resources Board is  
7 monitoring for the pesticides chlorothalonil, for  
8 acephate, and methamidophos.

9 DR. BLANC: And in addition to those three  
10 pesticides that are being monitored -- well, first of  
11 all, how many sites are they being monitored at for  
12 you by the ARB?

13 MR. SEGAWA: For the ambient air monitoring,  
14 where we sample in towns and regions where high use  
15 occurs, I believe we are monitoring either four or  
16 five sites for each of those pesticides.

17 DR. BLANC: And how many other pesticides have  
18 you monitored in the six months -- asked ARB to  
19 monitor for you in the six months previous to that?

20 MR. SEGAWA: Air Resources Board conducts  
21 annual monitoring. Let me back up and explain a  
22 little bit about the process. Toward the beginning  
23 of each calendar year, DPR sends a request to the Air  
24 Resources Board for the specific pesticides we'd like  
25 them to monitor the following year.

1                   So, for example, here in 2002, we  
2 recently sent them a request for monitoring in 2003.  
3 So last year, we requested monitoring for this year.

4                   They conduct the monitoring during the  
5 periods and areas of high use. And so for the  
6 monitoring last year, they monitored the fumigants  
7 methyl bromide; 1,3-dichloropropene; chloropicrin;  
8 and the breakdown process of metam sodium to MITC as  
9 well -- methyl isothiocyanate.

10                  DR. BLANC: You're saying that, in this  
11 calendar year 2002, to date, those were the five in  
12 addition to the three that you mentioned?

13                  MR. SEGAWA: Those four fumigants or the five  
14 pesticides, they monitored last fall.

15                  DR. BLANC: In the fall of 2001?

16                  MR. SEGAWA: Correct.

17                  DR. BLANC: Are those aeration or ambient?

18                  MR. SEGAWA: Ambient.

19                  DR. BLANC: And then three additional ones in  
20 calendar year 2002. And those were the only three  
21 that you requested?

22                  MR. SEGAWA: That's what they're currently  
23 doing if their budget holds up. We did request  
24 monitoring for sulfuryl fluoride and chloropicrin  
25 when they are used in structural fumigation.

1 DR. BLANC: Right. And then, in terms of the  
2 list that you're gathering for 2003, how many  
3 different pesticides will appear on that list?

4 MR. SEGAWA: We're in negotiations with Air  
5 Resources Board at this point. Their monitoring  
6 division has taken some major budget cuts. And so  
7 we're uncertain as to where it stands right now for  
8 2003.

9 DR. BLANC: Is it -- is the range of the  
10 number of pesticides between three and six, did you  
11 say?

12 MR. SEGAWA: It has been in the past years.

13 DR. BLANC: So is there any relationship  
14 between the discussions in terms that we've had  
15 previously with this panel about priority pesticides  
16 for ARB to monitor for your unit that has played  
17 itself out in what you've actually requested and what  
18 has been actually been monitored? Is there a  
19 correlation between your -- the prioritizations we've  
20 talked about and what's actually being monitored?

21 MR. SEGAWA: I hope so. That is our intent.

22 DR. BLANC: Has that played itself out in this  
23 year? Can you give us a rationale for the three  
24 pesticides -- acephate -- I'm sorry. I didn't get  
25 the breakdown.

1           MR. SEGAWA: Right. If you recall our  
2 previous meeting, we did discuss the prioritization  
3 document. You had a number of comments. We're still  
4 working through that and revising that document. But  
5 we did request those three -- actually five  
6 pesticides for 2002, based on that draft document  
7 that you saw last meeting.

8                         And those chemicals were basically  
9 next up in priority. Most of those that were on the  
10 list have been previously monitored by Air Resources  
11 Board.

12           CHAIRMAN FROINES: Randy -- I'm sorry -- what  
13 are the three you're doing in 2002?

14           MR. SEGAWA: Those are chlorothalonil,  
15 acephate, and methamidophos. I should say that  
16 acephate actually occurs lower in the priority.  
17 However, acephate breaks down into methamidophos.  
18 And so we want to look at them concurrently.

19           CHAIRMAN FROINES: And what happened to  
20 chloropicrin?

21           MR. SEGAWA: Chloropicrin, Air Resources  
22 monitored last year. And then, again, we've  
23 requested monitoring later this year for chloropicrin  
24 as it's used as a structural fumigant.

25           DR. BLANC: But no more field data from

1 strawberries than what you already did?

2 MR. SEGAWA: Air Resources Board has done  
3 previous monitoring. And in addition, we've  
4 requested additional monitoring data from the  
5 registrants for that particular --

6 CHAIRMAN FROINES: Of those compounds -- of  
7 those four compounds -- acephate, chlorothalonil,  
8 methamidophos, and chloropicrin -- how many of those  
9 were application monitored?

10 MR. SEGAWA: They all were. All five  
11 chemicals, we've asked for application monitoring.  
12 For the chlorothalonil, acephate, and methamidophos,  
13 we've also asked for ambient monitoring.

14 CHAIRMAN FROINES: So in the fiscal year 2002  
15 that ends --

16 MR. SEGAWA: Calendar year.

17 CHAIRMAN FROINES: Calendar year. So these  
18 five compounds -- four compounds, as I read it --

19 MR. SEGAWA: And sulfuryl fluoride.

20 CHAIRMAN FROINES: -- they will all be done by  
21 the close of 2002 with application monitoring?

22 MR. SEGAWA: That was our request. Whether  
23 ARB still has the resources to complete all that, I  
24 do not know for sure.

25 CHAIRMAN FROINES: So but last year you did

1 the metam sodium, telone -- and I forget the other  
2 ones you said -- but by -- for ambient monitoring?

3 MR. SEGAWA: Correct.

4 CHAIRMAN FROINES: Okay.

5 DR. BLANC: What about that presentation we  
6 had about the technology that would allow multiple  
7 pesticides to be monitored simultaneously, something  
8 like, you know, 20 of them or 15?

9 John, can you remember what I'm  
10 talking about?

11 DR. BYUS: Yeah. I remember. It was good.

12 MR. SEGAWA: Yeah. We do it by analysis for  
13 multiple pesticides whenever we can. For example,  
14 when we requested the 4 fumigants for last year, we  
15 requested that, of course, in 2000. And at that  
16 time, we had hoped that ARB would actually be able to  
17 monitor for all 4 using a single method.

18 That didn't turn out to be the case.  
19 But as we can, we do request monitoring for several  
20 chemicals simultaneously.

21 DR. BLANC: No. I'm asking something a bit  
22 more specific. We had a presentation to this panel  
23 about technology that would allow quite a bit more  
24 simultaneous monitoring. Does that sound familiar to  
25 you?

1 MR. SEGAWA: It does not, unfortunately.

2 DR. ATKINSON: Well, it depends on the  
3 compounds and the compound classes they're doing.

4 DR. BLANC: Right.

5 MR. SEGAWA: So in some cases, we might be  
6 able to do it; in other cases, maybe not.

7 DR. FUCALORO: Some sort of chromatography?

8 DR. ATKINSON: No. I mean you can do,  
9 presumably do, a whole bunch of organophosphorus  
10 compounds at once. But if you're looking for  
11 something which isn't an organophosphorus compound,  
12 you may not.

13 CHAIRMAN FROINES: Paul's asking about the --  
14 when we had the session when Bob Spear spoke and the  
15 fellow -- I forget where he was from.

16 DR. ATKINSON: Yeah. From USGS.

17 MR. SEGAWA: Oh, yes. Thanks for jogging my  
18 memory. I do recall the discussion now. And that  
19 person was Mike Majewski with the US Geological  
20 Survey. And, yes, he has monitored for a number of  
21 chemicals simultaneously.

22 We've done so on occasion for specific  
23 problem areas. For example, the Department's been  
24 working in the City of Lompoc because that's an area  
25 where people have been complaining about pesticide

1 use in that area. We had to do some air monitoring  
2 for some 25 or 30 pesticides simultaneously, all used  
3 within that particular area.

4                   So where we're monitoring on a  
5 geographic basis, we employ that technique. For most  
6 of this program, though, we're focussing on  
7 individual chemicals. So it doesn't lend itself to  
8 multiple analysis as readily.

9                   DR. BLANC: It's not exactly clear to me why  
10 that would be because if ARB -- I understand why that  
11 would be true for the use monitoring. But for all of  
12 these, you said there was general airborne monitoring  
13 happening as well.

14                   So if you have a site where you're  
15 collecting samples, it would make sense to not only  
16 collect one sample for the specific chemical that  
17 you're interested in but also to use a sampling  
18 device to collect a bulk sample and use this other  
19 methodology if it's available to you.

20                   MR. SEGAWA: Yes. To some extent. But if you  
21 recall, both for the ambient monitoring as well as  
22 the application-site monitoring, we try to target the  
23 monitoring in areas and time periods of high use.  
24 And a lot of cases -- that doesn't occur with several  
25 chemicals at one time.

1                   For example, malathion may be used in  
2 Fresno County; whereas, diazinon is used in Kern  
3 County. And so the monitoring is more focussed to  
4 try and get the highest concentrations for each  
5 individual pesticide.

6           DR. BLANC: Well, I don't want to belabor the  
7 point. But I think we were impressed, the last time  
8 we had air-monitoring data presented to us, at how  
9 fragmentary and limited it was.

10                   And it has considerable support from  
11 this committee to take a more global approach to at  
12 least gather some broad-based sampling data that  
13 would simultaneously monitor a number of pesticides,  
14 similar to what I assume you're describing in Lompoc,  
15 and that those be done, even in the absence of being  
16 clear that you would have the technical signal, so  
17 that we get some sense of what the sort of ambient  
18 background was on some of these pesticides.

19                   I think it would be helpful for this  
20 group, at some point in the next year, to have a  
21 presentation that would be done jointly by you and  
22 someone from the ARB technical side so that we could  
23 get a better sense because I can only come away from  
24 your presentation thinking that, sometime in the next  
25 75 years, we may've been able to have five sampling

1 data points each for, you know, the hundred  
2 pesticides that are used in California.

3 I mean it seems like an extremely  
4 limited data set.

5 MR. SEGAWA: You're correct. And if you  
6 recall that, that workshop where we did discuss this  
7 topic, one of the things we did focus on was trying  
8 to supplement the monitoring data with modelling or  
9 estimates of what air concentrations might be in  
10 other periods, other time periods and other places.  
11 And we are moving forward with those efforts as well.

12 CHAIRMAN FROINES: Yeah. Paul, let me say  
13 that I had a conversation with Paul Goslin as a  
14 result of his letter to me on this issue. And I  
15 don't have anything really to report as a result of  
16 that conversation. What he said in the letter -- I  
17 didn't mean that negatively.

18 What he said -- what Paul said in the  
19 letter was essentially what he talked about on the  
20 telephone. And his -- he said that they were moving  
21 forward, as Randy just said, to develop a new  
22 methodology and new approaches to the monitoring.

23 And so but I think that the -- there  
24 are a range of issues that need to be discussed on  
25 the exposure-assessment question that relate not only

1 to the actual monitoring that goes on but to the  
2 nature of the determination of the -- pardon me -- to  
3 the use of the information.

4                   The law -- the regulations state that  
5 the MOE needs to be calculated, and there are  
6 different factors that need to be applied.

7                   I'm trying to do this hurriedly. So  
8 I'm not very articulate. But there are a range of  
9 issues. And I think what we should do is to thank  
10 Randy for his brief presentation.

11                   And then Elinor and I will develop a  
12 list of very specific topics on the exposure issue.  
13 And we'll present them at the next meeting for  
14 discussion, if that's -- if you're willing because I  
15 made a whole list of issues and we're not going to --  
16 Gary and Elinor are not going to be able to get out  
17 and make planes if we take it up.

18                   And so what I'll do is to lay out, in  
19 a 1-page or 2-page document, a series of issues that  
20 we need to discuss on the exposure question.

21                   And part of it will be, Randy, to ask  
22 Paul for a sense of the timetable and the process for  
23 the new developments that you're working on so that  
24 the panel has a sense not simply of the promise that  
25 those approaches are being followed but, you know,

1 what's the -- how's it going to stage out?

2                   And so we'll make that -- Elinor and I  
3 will prepare that for the next meeting. We can  
4 discuss it in more detail because it really goes not  
5 simply to the notion of monitoring but goes to how  
6 monitoring data is then used to calculate an MOE.  
7 And there are issues that we need to talk about, if  
8 that's all right with you.

9           MR. SEGAWA: That's fine.

10          CHAIRMAN FROINES: Thanks, Randy.

11                   Formaldehyde. I'm told that we have a  
12 four-slide presentation.

13          MR. AGUILA: It's down to two now.

14          CHAIRMAN FROINES: Four would have been okay.

15          MR. AGUILA: Well, good afternoon to the panel.

16          DR. GLANTZ: That's one slide.

17          MR. AGUILA: My name is Jim Aguila. I'm with  
18 the California Air Resources Board. And I'm here  
19 today to give a very brief presentation on a recent  
20 petition that Air Resources Board had received.

21                   This petition was received from an  
22 industry brief -- industry group known as the  
23 "Formaldehyde Epidemiology, Toxicology, and  
24 Environmental Group" who have submitted an  
25 application requesting that the ARB take a look at

1 the original risk assessment for formaldehyde.

2                   And basically what I wanted to do is  
3 just kind of jump into a process that was developed  
4 by the Scientific Review Panel back in 1989, which  
5 basically established some guidelines for taking a  
6 look at these kinds of requests.

7           CHAIRMAN FROINES: I think Gary Friedman was  
8 the first user of this process.

9           MR. AGUILA: Is that right? I went back and  
10 took a look myself. And I believe we don't have any  
11 chemicals that actually have made it through the  
12 entire process yet.

13                   Anyhow, what I'd like to do is maybe  
14 walk you through it very briefly so you can get a  
15 sense for the flow. Essentially, we did receive the  
16 application in April. And the first step is  
17 basically for us to share the information with the  
18 Office of Environmental Health Hazard Assessment,  
19 which we have done.

20                   The procedure basically stipulates  
21 that there is an initial step where OEHHA would take  
22 a look at the quality of the submittal to see if it  
23 meets certain screening criteria, which is defined in  
24 one of the handouts that's been provided to you.

25                   Again, OEHHA would also take a look at

1 the evidence to see if there is a need to reopen the  
2 original risk assessment. Basically that finding is  
3 summarized and transmitted to the Air Resources Board  
4 for evaluation. And next slide, please.

5                   Subsequently the Air Resources Board  
6 would take a look at the OEHHA findings and  
7 recommendations and basically transmit that  
8 information to the SRP Chairman, who would be  
9 requested to review not only OEHHA's recommendation  
10 but also the newly submitted information as well.

11                   And at this point, the process does  
12 have some flexibility. The SRP Chairman could  
13 choose, at that point, if he feels it's warranted,  
14 could assign the lead person to take a deeper look  
15 into the recommendation and the submittal itself.

16                   Assuming that there is a lead person  
17 that's assigned, the lead person would work directly  
18 with OEHHA and other agencies, as required, to do  
19 basically an independent evaluation. And those  
20 findings would be transmitted back to the SRP  
21 Chairman, and the findings would also be discussed at  
22 an SRP panel meeting.

23                   And essentially the purpose of this  
24 review process is, Number 1, to save the SRP some  
25 time but also to make a determination whether or not

1 the newly submitted information would warrant a  
2 reopening of the original risk assessment. And  
3 basically that's the process for the initial review.

4 And if the finding, after the process  
5 has gone through, is to recommend the reopening of  
6 the original risk assessment, then the Air Resources  
7 Board would make that request formally to OEHHA to  
8 basically initiate that process. So any questions?

9 CHAIRMAN FROINES: We -- previously we got, I  
10 think, to this place; and it was on benzene. And  
11 Dr. Friedman recommended that the information did not  
12 require a reopening of the record, I think.

13 DR. FRIEDMAN: It's been a long time, but that  
14 sounds right.

15 DR. GLANTZ: Yeah.

16 CHAIRMAN FROINES: And then it went to -- then  
17 that recommendation would go to the ARB chairman.  
18 And then, as far as I remember, that's where it ended  
19 up.

20 DR. FRIEDMAN: It was either Kendrick or  
21 Aldrich was the chairperson at that time. I think  
22 they then transmitted it back to the ARB. I don't  
23 think it was discussed very much at this meeting.

24 MR. AGUILA: Yeah. As I indicated, there is  
25 some flexibility in the process that -- that would

1 basically constitute a basis for the Air Resources  
2 Board to reject that petition in the case you cite.

3 CHAIRMAN FROINES: So what's the time frame on  
4 formaldehyde? Where -- it's with Melanie, presumably  
5 at this point.

6 DR. MARTY: Yeah. It's with OEHHA. And we  
7 have the same person who did the initial quantitative  
8 risk assessment wading through the material now. And  
9 we hope to have something move forward to the panel  
10 in the fall. It's one of the many things on this  
11 person's plate. So it's in line.

12 CHAIRMAN FROINES: It's okay. The panel  
13 doesn't have much to do either.

14 DR. GLANTZ: So is there anything we need to  
15 do at this point or just wait till --

16 DR. FUCALORO: This is just information.

17 DR. GLANTZ: Wait until Melanie has something  
18 for someone?

19 CHAIRMAN FROINES: It goes from Melanie to the  
20 Chairperson of the ARB. The Chairperson, then, will  
21 send it to me. And then we'll assign a person or  
22 persons to review it.

23 DR. GLANTZ: Okay.

24 CHAIRMAN FROINES: So we think it will  
25 probably be in to us sometime this fall, presumably.

1 DR. MARTY: Yes.

2 DR. FUCALORO: Are we adjourned?

3 CHAIRMAN FROINES: No.

4 DR. FUCALORO: Sorry.

5 CHAIRMAN FROINES: Stan wants to raise some --

6 DR. GLANTZ: I want to raise -- I realize the  
7 State has a budget crisis, and I also have no  
8 problems with the digs, but I think we need to meet  
9 near airports. This -- if you look on a map of L.A.,  
10 this is the maximum distance from all airports. And  
11 it really makes travelling a pain.

12 And I'm not saying we -- I'm not  
13 objecting to coming to Southern California because  
14 you guys get dragged to Northern California. But  
15 I -- and we don't have to meet at the Taj Mahal or  
16 the Owani.

17 But I think that the traditional  
18 practice of this committee of trying to hold the  
19 meetings close to airports where people can get in  
20 and get out without very long trips needs to be  
21 maintained, you know.

22 DR. COLLINS: How about the break room of the  
23 highway patrol substation at the airport?

24 DR. GLANTZ: That would be okay with me. But,  
25 no. I mean I'm serious. I mean Gary's having to

1 leave now because -- to get to an airport. The  
2 travel arrangements I ended up with were Byzantine.  
3 And it's just not an efficient use of people's time.

4 DR. FUCALORO: Unfortunately, Ontario, which  
5 serves three people in this panel --

6 DR. GLANTZ: Yeah.

7 DR. FUCALORO: -- and San Francisco are no  
8 longer directly linked.

9 DR. GLANTZ: Even if we were meeting, you  
10 know -- I don't mind the time we had to go to Oakland  
11 to fly to Ontario. That was okay. But we are about  
12 as far from the airport in the L.A. Basin --

13 DR. FUCALORO: Then I move that all subsequent  
14 meetings be done at Ontario International Airport.

15 DR. GLANTZ: All right. I'll second that.  
16 Well -- all right.

17 DR. FUCALORO: Well, no. I mean I agree. I  
18 mean Ontario's very convenient for us -- very  
19 convenient.

20 DR. GLANTZ: Well, no. I mean I think we  
21 should -- I mean we have tried, in all the years I've  
22 been on the panel, to schedule these meetings in  
23 ways that were reasonably equitable to the panel  
24 members and where everybody got to do a reasonable  
25 amount of flying all over the place.

1                   But I just think that we need -- that  
2 what we have here is -- I don't know how this is,  
3 vis-a-vis you guys driving to get here; but in terms  
4 of flying in and out, this is about as far from any  
5 place as you could get.

6                   CHAIRMAN FROINES: Well, let me ask you a  
7 question. As far as I'm --

8                   Jim, you may want to join in.

9                   As far as I'm concerned, when we have  
10 them in San Francisco, it's -- the situation is okay  
11 because we use that convention center. I don't know  
12 how expensive that convention center is or whether  
13 UCSF is cheaper or what. But it seems to me that  
14 there's no significant San Francisco problem.

15                  DR. ATKINSON: We can't get there.

16                  CHAIRMAN FROINES: Except that the people from  
17 Riverside can't get there.

18                  DR. GLANTZ: Well, who cares? That's  
19 neither --

20                  CHAIRMAN FROINES: Well, we can meet --

21                  DR. BYUS: Oakland. If we can meet in  
22 Oakland --

23                  DR. GLANTZ: I'm perfectly happy to go over to  
24 Oakland.

25                  DR. FUCALORO: Meet in Oakland.

1 DR. BYUS: Meet in Oakland.

2 CHAIRMAN FROINES: Now, the other alternative  
3 is to --

4 Jim, it seems me that the other  
5 alternative for Riverside-Ontario is to hold the  
6 meetings at AQMD, which should be free. And that's a  
7 piece of cake for these three folks 'cause they're  
8 right there. That's even closer for them. And that  
9 means that Paul and Stan would have to fly into  
10 Ontario.

11 DR. GLANTZ: And Gary.

12 CHAIRMAN FROINES: And Gary's in Oakland. So  
13 he's not --

14 DR. FRIEDMAN: I'm equidistant from either San  
15 Francisco or Oakland. So I like flying out of  
16 Oakland on Southwest. It works very well.

17 CHAIRMAN FROINES: Paul?

18 DR. BLANC: You know, I can work around -- it  
19 really, for me, has not been an issue where it is in  
20 Southern California. You know, it's just, if my  
21 schedule allows me to get to Southern California,  
22 I've got a way of doing it.

23 It's a little -- it's not quite as --  
24 I don't have quite -- for me, this wasn't that  
25 inconvenient because, you know, I tend not to do the

1 same-day flight into L.A. just 'cause it's -- even if  
2 it's somewhat convenient, it's too iffy. But --

3 CHAIRMAN FROINES: The problem -- I, of  
4 course, like the idea of coming into LAX. And LAX is  
5 a good place for people from the Bay Area. However,  
6 it forces these three people to travel for a very  
7 long distance; and that seems to me to argue in  
8 favor --

9 DR. GLANTZ: Well, I'm not arguing for a  
10 specific airport. I'm just saying that I would like  
11 the meetings near whatever airport it is we fly into.  
12 And, you know, that's all.

13 CHAIRMAN FROINES: Roger, how long did it take  
14 to you drive over to John Peter's place at USC?

15 DR. ATKINSON: It depends on the --

16 CHAIRMAN FROINES: Traffic.

17 DR. ATKINSON: -- on the traffic. But I would  
18 say an hour and a half probably, depending on the  
19 time of day. I could probably make it in an hour --

20 DR. GLANTZ: At midnight.

21 DR. BYUS: At 2:00 in the morning.

22 CHAIRMAN FROINES: I took two-and-a-half hours  
23 to get to Riverside the other day from my house in  
24 Santa Monica. So it's --

25 DR. ATKINSON: Yes. It can easily be that.

1           CHAIRMAN FROINES:  So it seems to me, that  
2   having, exploring the AQMD site as being a bit more  
3   convenient for airport -- it's very -- it's  
4   relatively close to Ontario.  But that means you're  
5   going to have to drive.

6           DR. GLANTZ:  Whatever.  Okay.  Well, I made my  
7   point.  I mean I just think that putting the meeting  
8   in a place which is so faraway is, in a way, penny  
9   wise and pound foolish because it leads to, at least  
10  for me and Gary, quite dysfunctional travel -- for me  
11  personally, quite dysfunctional travel arrangements.

12                        I end up spending a lot of money on  
13  cabs and getting no sleep, and then the meeting gets  
14  cuts short.

15           CHAIRMAN FROINES:  We -- can I raise another  
16  question?  'Cause I'm worried about the time.

17           DR. GLANTZ:  Yeah.  Well, I'm done.

18           CHAIRMAN FROINES:  The other question -- I  
19  would prefer that we set a day on, every two  
20  months -- like a Monday at 10:00 o'clock every two  
21  months.  And then that will be our schedule for the  
22  following year.  In the past, people have opposed  
23  that scheduling.

24                        But obviously it makes a lot of sense  
25  and benefits Peter if we do that.  Do people still

1 oppose that or --

2 DR. FUCALORO: I don't oppose it; but I'm just  
3 letting you know, this coming fall, for whatever  
4 reason, I have at least four days a week during class  
5 session that I'll be unavailable the whole day.

6 In other words, if I were to meet --  
7 it could be in the morning or in the afternoon -- it  
8 would almost have to be in Southern California.  
9 Fifth day, I'm trying to keep free just for that sort  
10 of thing. And that fifth day -- I can tell you what  
11 it is. It's Friday.

12 CHAIRMAN FROINES: Let's forget what I just  
13 said because, this fall, it's not going to work.

14 DR. BYUS: I think it's a good idea. I do  
15 think it's a good idea.

16 CHAIRMAN FROINES: Peter, we'll explore it for  
17 next year. But this fall, I know, won't work. So  
18 we'll take a --

19 Go ahead, Jim.

20 MR. BEHRMANN: Jim Behrmann. Let me just say  
21 that I appreciate the panel's willingness to work  
22 with us, especially during the time when the budget  
23 is really tight. And I do expect that, in the coming  
24 meetings, we'll work as diligently as we can to meet  
25 in a facility that's relatively close to an airport.

1                   Oakland -- we have the benefit of  
2    OEHHA's facility being nearby.  Unfortunately, most  
3    of the other airports' facilities cost us quite a  
4    bit.  And our direction has been to seek facilities  
5    where we can obtain them at minimal cost.

6           DR. GLANTZ:  Right.  But I think -- what I'm  
7    saying to you, Jim, is that, as John said, we're  
8    effectively volunteers.

9           MR. BEHRMANN:  Yes.

10          DR. GLANTZ:  And I think that you need to try  
11    and schedule these meetings to make effective use of  
12    our time too --

13          MR. BEHRMANN:  Certainly.  And --

14          DR. GLANTZ:  -- realizing we're strewn all  
15    over the state because you know -- well, I'll just --  
16    I think you need to just take that into account.  And  
17    I think it needs to go back to your management that  
18    they get a lot of work out of this committee and, if  
19    they had to pay us to do this work, it would cost  
20    more than renting a room somewhere.

21          MR. BEHRMANN:  Exactly.  And that was my  
22    reason for opening by saying that I really do  
23    appreciate the panel's willingness to work with us  
24    and your time.

25          CHAIRMAN FROINES:  It's clear that the -- it

1 seems to me that, given there are State facilities in  
2 Oakland, Oakland is a great place.

3 MR. BEHRMANN: Yes.

4 CHAIRMAN FROINES: It means Paul and Stan have  
5 to drive across the bridge or take the subway. But  
6 that one works very well. And it's a question of,  
7 when we're here in Southern California, where do we  
8 do it? And we want to balance between the two  
9 places.

10 And so we'll just -- it seems to me  
11 that having some place around the Ontario airport  
12 probably makes the most sense for the three people  
13 who have to commute -- the longest commute. Now, I  
14 don't know --

15 DR. FUCALORO: Now, which Brown is the mayor  
16 of Oakland?

17 CHAIRMAN FROINES: Paul just asked if we could  
18 come up with suggestions for the September meeting.  
19 But I'm not convinced that this is ever possible to  
20 do it. But shall we say the third Monday in  
21 September?

22 MR. BEHRMANN: John, I would look at both  
23 September and October.

24 DR. BLANC: I would suggest Friday, October 4,  
25 actually.

1 DR. FUCALORO: Friday is my best bet. If it  
2 were on a Monday, it would almost have to be in the  
3 morning.

4 CHAIRMAN FROINES: Peter, why don't you try  
5 and poll people on Friday, October 4?

6 DR. FUCALORO: I may actually have to resign,  
7 seriously, because it turns out that, for at least  
8 the next year, I'm going to have a pretty -- at least  
9 for the fall, I mean -- I have a pretty stiff  
10 schedule.

11 DR. BLANC: We'll see about Friday the 4th.

12 CHAIRMAN FROINES: Let's discuss that -- we  
13 can do that off the record in private.

14 A motion?

15 DR. FUCALORO: Let's adjourn.

16 DR. BYUS: Adjourn.

17 DR. ATKINSON: Adjourn.

18 CHAIRMAN FROINES: Second?

19 DR. GLANTZ: Yeah. Second.

20 CHAIRMAN FROINES: All in favor?

21 ALL PANEL MEMBERS: Aye.

22 DR. BYUS: What about discussion?

23 CHAIRMAN FROINES: And before Paul says  
24 anything, it was unanimous.

25 (Proceedings concluded at 3:11 P.M.)

1 STATE OF CALIFORNIA )  
 ) ss.  
2 COUNTY OF LOS ANGELES )

3

4 I, NEALY KENDRICK, CSR No. 11265, do hereby  
5 certify:

6 That the foregoing transcript of proceedings  
7 was taken before me at the time and place therein set  
8 forth and thereafter transcribed by computer under my  
9 direction and supervision, and I hereby certify the  
10 foregoing transcript of proceedings is a full, true,  
11 and correct transcript of the proceedings.

12 I further certify that I am neither counsel  
13 for nor related to any party to said action nor in  
14 anywise interested in the outcome thereof.

15 IN WITNESS WHEREOF, I have hereunto subscribed  
16 my name this 7th day of August, 2002.

17

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\_\_\_\_\_  
NEALY KENDRICK, CSR NO. 11265

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