SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS

AIR RESOURCES BOARD

STATE OF CALIFORNIA

PUBLIC MEETING

TRANSCRIPT OF PROCEEDINGS

Friday, July 26, 2002
10:15 A.M.

Air Resources Board
Annex Number 4, Auditorium
9530 Telstar Avenue
El Monte, California

NEALY KENDRICK, CSR NO. 11265

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APPEARANCES

SCIENTIFIC REVIEW PANEL

Dr. John Froines, Chairman
Dr. Roger Atkinson
Dr. Paul D. Blanc
Dr. Craig V. Byus
Dr. Gary D. Friedman
Dr. Anthony Fucaloro
Dr. Stanton A. Glantz

Representing The California Air Resources Board:

Mr. Jim Behrmann, Liaison, Scientific Review Panel
Mr. Peter Mathews

Jim Aguila, Manager, Substance Evaluation Section

Representing The Department of Pesticide Regulation:

Randall Segawa, Senior Environmental Research Scientist (Supervisor)

Representing The Office of Environmental Health Hazard Assessment:

Dr. Robert J. Blaisdell, Chief, Exposure Modeling Unit
Dr. James F. Collins, Staff Toxicologist
Dr. Melanie A. Marty, Supervising Toxicologist
Dr. David W. Rice, Staff Toxicologist
Dr. Andrew G. Salmon, Chief, Air Toxicology and Risk Assessment Unit

I N D E X

EL MONTE, CALIFORNIA; FRIDAY, JULY 26, 2002

10:15 A.M.

PROCEEDINGS

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

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

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

I'm going to let Andy give the presentation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. BLANC: Chemical by chemical.

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

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

DR. SALMON: Yes.

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

DR. SALMON: That is the -- yes. That's right. We corrected the microgram value but forgot to change -- yes. I'm sorry. I apologize. The typography seems to be a little deficient here. This, as you might have gathered, was done in something of a rush.

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

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

it's better.

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

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

CHAIRMAN FROINES: Paul?

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

DR. SALMON: Yes --

DR. BLANC: -- not because of --

DR. SALMON: -- that's correct.

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

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

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

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

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

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

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

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

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

DR. SALMON: Yes.

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

DR. SALMON: Yes.

DR. BLANC: A fairly high percentage.

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

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

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

DR. MARTY: It's at the end.

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

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

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

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

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

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

DR. SALMON: I'm sorry?

DR. BLANC: If a child were exposed at the

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

DR. SALMON: Yes.

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

DR. SALMON: Yeah.

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

DR. SALMON: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

DR. SALMON: Uh-huh.

DR. BLANC: -- exposure --

DR. SALMON: Yes.

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

DR. SALMON: Yes.

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

DR. SALMON: Yes.

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

other examples.

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

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

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

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

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

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

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

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

CHAIRMAN FROINES: Can I make one comment?

DR. BLANC: Yes.

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

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

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

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

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

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

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

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

DR. BLANC: If you subtract this REL --

DR. MARTY: Right. Exactly. Which is what

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

DR. SALMON: There's another source.

DR. MARTY: Right.

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

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

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

DR. SALMON: Yes.

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

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

DR. MARTY: Oh, thank you --

DR. BLANC: So they didn't --

DR. MARTY: -- Jim.

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

DR. SALMON: They didn't assume any

inhalation.

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

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

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

DR. BLANC: Resubmit.

DR. MARTY: Right.

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

DR. GLANTZ: Please.

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

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

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

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

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

DR. SALMON: I think -- well --

DR. BLANC: I think you --

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

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

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

DR. SALMON: Yes.

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

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

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

DR. MARTY: Right.

DR. SALMON: Huh.

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

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

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

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

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

DR. SALMON: Well, would I --

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

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

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

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

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

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

specific than that --

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

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

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

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

DR. SALMON: Sorry?

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

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

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

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

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

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

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

DR. FUCALORO: Right. Hydrogen fluoride. Yeah.

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

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

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

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

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

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

DR. BLANC: Right. Right.

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

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

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

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

CHAIRMAN FROINES: Do you remember?

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

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

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

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

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

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

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

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

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

DR. SALMON: I can't --

DR. MARTY: What --

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

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

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

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

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

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

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

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

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

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

DR. MARTY: Right.

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

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

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

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

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

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

DR. MARTY: Right.

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

DR. SALMON: Yeah.

DR. GLANTZ: Yeah.

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

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

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

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

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

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

DR. BLANC: Because?

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

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

DR. MARTY: Bone density changes with age.

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

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

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

DR. SALMON: Well, we could --

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

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

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

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

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

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

DR. MARTY: Yeah. Presumably.

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

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

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

CHAIRMAN FROINES: No. I'm okay.

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

DR. SALMON: Yeah.

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

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

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

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

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

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

DR. MARTY: Okay.

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

DR. MARTY: Okay. We can do that.

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

DR. MARTY: Okay.

DR. BLANC: Because you're --

What's that?

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

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

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

DR. SALMON: Yes.

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

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

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

DR. BLANC: Okay.

DR. SALMON: Most of the inhalation --

DR. BLANC: Anyway, those are my comments.

CHAIRMAN FROINES: Thanks, Paul.

Roger?

DR. ATKINSON: No. I have no comments.

CHAIRMAN FROINES: Craig?

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

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

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

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

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

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

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

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

CHAIRMAN FROINES: Tony.

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

DR. SALMON: Uh-huh.

DR. FUCALORO: Which is the same --

DR. SALMON: Yes.

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

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

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

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

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

DR. SALMON: The fluoride will be ionized --

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

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

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

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

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

DR. MARTY: You may get some atomized --

DR. FUCALORO: Oh, atomizing is something else.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. MARTY: Okay.

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

DR. MARTY: Right.

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

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

DR. MARTY: No. That --

DR. BLANC: Is that what you would --

DR. MARTY: Right.

DR. BLANC: If that's what --

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

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

know. Just be consistent.

DR. MARTY: Right.

DR. FUCALORO: You know I read that as hydrofluoride is a colorless gas but you can get fluorides in particulates, assuming salts. I think that's what you meant. I took note of that. I didn't write something down. But I think that's what you meant.

DR. MARTY: Oh, okay. Right. In that -- under 2 -- "Physical and Chemical Properties" -- right? --

DR. FUCALORO: Yeah.

DR. MARTY: -- for fluoride as particulates?

DR. FUCALORO: Yeah. Yeah. Yeah. That's what I thought you meant.

DR. BLANC: Yeah. Thanks.

CHAIRMAN FROINES: Tony, are you finished?

DR. FUCALORO: Done.

CHAIRMAN FROINES: Gary?

DR. FRIEDMAN: Until I talk to my dentist, I have nothing to add.

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

CHAIRMAN FROINES: This discussion's been nothing less than anecdotal. That's for sure.

Okay. Melanie, I had just a couple of

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

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

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

DR. BLANC: Are relevant.

DR. MARTY: Right.

DR. BLANC: Yeah.

DR. MARTY: So effectively, we are --

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

CHAIRMAN FROINES: "Sayshus" (phonetic).

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

But if there's a decent one --

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

DR. BLANC: Which is fine.

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

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

In other words, I don't get a feeling

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. BLANC: Fluoridated water over the dam.

CHAIRMAN FROINES: What?

DR. BLANC: Fluoridated water over the dam.

DR. FRIEDMAN: Dental dam.

DR. FUCALORO: Dental dam.

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

Why don't we go on to phosphine?

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

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

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

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

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

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

proposed REL would be protective of the developmental effects.

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

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

DR. GLANTZ: I'm sorry.

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

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

DR. SALMON: The uncertainty factor --

CHAIRMAN FROINES: Roger?

DR. ATKINSON: I was --

DR. GLANTZ: What was the issue with it?

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

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

DR. GLANTZ: Oh, I see --

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

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

CHAIRMAN FROINES: Not that I know of.

DR. MARTY: I don't think so.

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

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

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

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

DR. MARTY: Yeah. We have not done that

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

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

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

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

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

NOAEL, which is 1 ppm.

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

DR. MARTY: As opposed to 10?

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

DR. COLLINS: 6.

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

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

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

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

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

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

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

DR. SALMON: Uh-huh.

DR. MARTY: Okay.

DR. GLANTZ: Yeah. I agree with that.

DR. SALMON: Okay.

CHAIRMAN FROINES: Craig?

DR. BYUS: That's fine.

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

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

reading that wrong?

DR. SALMON: Yes. Reduction of. Yeah.

DR. MARTY: Yeah.

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

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

DR. SALMON: Yeah.

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

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

But let me then ask this question:

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

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

DR. SALMON: I think it's computational.

DR. FUCALORO: Of course, it is.

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

DR. FUCALORO: Exactly.

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

But I imagine you could obtain that as a --

DR. FUCALORO: You can --

DR. SALMON: Yeah.

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

DR. SALMON: Absolutely.

DR. FUCALORO: -- very slightly.

DR. SALMON: Well --

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

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

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

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

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

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

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

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

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

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

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

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

DR. COLLINS: Uh-huh.

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

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

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

And you say it doesn't act ideally.

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

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

DR. MARTY: Yeah. I see your point.

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

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

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

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

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

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

DR. FUCALORO: And that's it.

CHAIRMAN FROINES: Gary.

DR. FRIEDMAN: No. I have nothing.

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

other comments.

CHAIRMAN FROINES: Oh, pardon me. Go ahead.

DR. BLANC: Thanks.

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

Then you present a slide with bronchiectasis.

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

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

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

DR. MARTY: Correct.

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

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

DR. SALMON: Yeah.

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

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

DR. MARTY: Sounds like we took a slide and

took it out and --

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

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

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

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

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

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

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

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

DR. MARTY: -- phosphine --

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

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

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

DR. SALMON: I'm not sure --

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

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

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

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

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

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

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

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

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

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

DR. MARTY: Yes. Exactly. Right.

DR. BLANC: Okay.

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

But we aren't --

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

DR. MARTY: It was only for methyl bromide.

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

DR. MARTY: That's right.

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

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

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

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

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

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

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

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

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

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

CHAIRMAN FROINES: They do?

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

DR. FUCALORO: Water.

DR. MARTY: That's why they work as

rodenticides.

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

DR. FUCALORO: "Freight-train jumper."

CHAIRMAN FROINES: Go ahead.

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

DR. FUCALORO: A hobo by any other name.

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

CHAIRMAN FROINES: So --

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

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

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

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

DR. MARTY: That's fine.

(Brief interruption.)

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

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

CHAIRMAN FROINES: The phosphine document.

DR. GLANTZ: Okay.

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

DR. GLANTZ: Fluoride.

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

are relatively minor and then triethylamine.

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

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

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

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

CHAIRMAN FROINES: I understand that.

DR. FUCALORO: Everybody has a perspective.

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

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

next slide, please.

DR. GLANTZ: Wait.

DR. SALMON: I'm sorry?

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

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

DR. GLANTZ: At 25 or 247?

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

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

DR. SALMON: Yeah. There would be --

DR. GLANTZ: So there were no --

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

DR. GLANTZ: Oh, okay.

DR. COLLINS: We don't just read the

abstracts.

DR. SALMON: Sometimes --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. SALMON: Yeah. Absolutely.

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

DR. SALMON: It's very qualitative.

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

DR. BLANC: The rabbit study?

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

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

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

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

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

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

out the whole thing but --

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

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

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

DR. COLLINS: 6 months.

DR. BLANC: 6 months.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ocular effects.

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

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

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

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

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

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

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

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

CHAIRMAN FROINES: I mean do you --

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

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

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

DR. COLLINS: They realized they were naked.

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

CHAIRMAN FROINES: Well, I think that we need

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

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

What?

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

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

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

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

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

DR. BLANC: How recently and how hard did you

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

DR. MARTY: Uh-huh.

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

DR. MARTY: Yeah. Let's --

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

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

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

DR. FUCALORO: Well, ammonia would do the

same --

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

DR. FUCALORO: -- is that right?

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

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

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

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

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

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

something in there.

DR. COLLINS: Peter who?

CHAIRMAN FROINES: Peter Spencer.

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

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

DR. GLANTZ: Unless it's hot.

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

DR. BLANC: Right. But I mean --

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

DR. BLANC: What?

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

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

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

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

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

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

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

DR. BLANC: Yes.

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

DR. ATKINSON: I have one further comment.

CHAIRMAN FROINES: Sorry.

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

DR. BLANC: Yeah.

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

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

DR. SALMON: We would do well to --

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

DR. FUCALORO: Nitrates.

DR. ATKINSON: Yeah. Amine nitrates.

DR. FUCALORO: Sure.

DR. MARTY: We will add that.

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

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

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

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

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

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

DR. FUCALORO: Moved.

CHAIRMAN FROINES: Second?

DR. GLANTZ: Second.

CHAIRMAN FROINES: All those -- discussion.

(No audible response.)

CHAIRMAN FROINES: All those in favor.

(Each panel member raises his hand.)

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

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

CHAIRMAN FROINES: I would bet three hours.

DR. FUCALORO: Three hours?

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

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

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

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

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

DR. GLANTZ: Let's try.

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

DR. GLANTZ: Yeah.

CHAIRMAN FROINES: -- so if you think this discussion's going to go --

DR. GLANTZ: Yeah, I do.

CHAIRMAN FROINES: -- at length --

DR. GLANTZ: I think it will be pretty quick, unless I missed something.

DR. FUCALORO: Not you.

CHAIRMAN FROINES: Does everybody -- so we'll go to about 12:30 and then decide how it looks.

How long is your presentation, Melanie, going to be?

DR. MARTY: There's about 25 slides, total, including slides on the comments which sometimes the panel wants and sometimes they don't, depending on if they have issues with our responses.

CHAIRMAN FROINES: Well, then, I would suggest that we go through the slides and then break for lunch.

DR. GLANTZ: Okay.

CHAIRMAN FROINES: I don't see --

DR. GLANTZ: Should we bring lunch back here and --

DR. BLANC: No.

DR. GLANTZ: No? Okay.

DR. BLANC: Let's start.

DR. FRIEDMAN: Short lunch.

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

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

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

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

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

assess cancer risk in that program.

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

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

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

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

This new material includes variates

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

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

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

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

Soil loading of 1 milligram per cubic

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

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

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

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

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

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

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

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

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

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

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

DR. MARTY: Right.

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

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

DR. BLANC: And if you want to characterize

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

DR. MARTY: Correct.

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

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

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

DR. MARTY: Actually --

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

DR. MARTY: Okay. Let me give you the

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

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

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

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

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

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

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

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

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

DR. MARTY: No, it is not.

DR. GLANTZ: No? So you added it?

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

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

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

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

DR. MARTY: Right.

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

DR. MARTY: Exactly.

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

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

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

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

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

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

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

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

DR. GLANTZ: After we talked?

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

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

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

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

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

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

CHAIRMAN FROINES: Paul?

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

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

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

DR. FUCALORO: Yeah.

DR. MARTY: Oh, okay.

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

DR. FUCALORO: Yeah.

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

DR. BLANC: Yeah.

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

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

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

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

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

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

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

CHAIRMAN FROINES: But this needs to be --

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

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

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

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

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

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

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

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

But I think if you take both sentences

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

CHAIRMAN FROINES: Uh-huh.

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

CHAIRMAN FROINES: I think that's fine.

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

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

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

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

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

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

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

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

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

was something you could hand somebody who is reasonably knowledgeable.

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

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

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

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

CHAIRMAN FROINES: Gary.

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

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

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

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

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

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

to get the probability of cancer.

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

DR. MARTY: Right.

DR. FUCALORO: -- mathematically equivalent.

DR. MARTY: Right.

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

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

DR. FRIEDMAN: I know. But --

DR. GLANTZ: -- per kilogram --

DR. MARTY: Time.

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

DR. FUCALORO: Just divide 'em.

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

DR. GLANTZ: Yeah.

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

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

clear on.

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

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

DR. MARTY: Right. Right. Right.

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

DR. MARTY: Right.

CHAIRMAN FROINES: Tony?

DR. FUCALORO: No.

CHAIRMAN FROINES: Craig?

DR. BYUS: Fine.

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

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

DR. ATKINSON: Yeah.

DR. GLANTZ: Yeah.

DR. BLAISDELL: Yeah. Okay.

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

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

DR. BLAISDELL: Yeah. Yeah.

DR. FUCALORO: Is this the second problem?

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

DR. FUCALORO: "Log."

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

DR. FUCALORO: Well, or minus.

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

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

DR. ATKINSON: Yeah.

CHAIRMAN FROINES: Is that it?

DR. ATKINSON: That's it.

CHAIRMAN FROINES: Paul?

DR. BLANC: No.

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

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

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

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

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

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

to the maximum-exposed person?"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. GLANTZ: You know, one thing --

CHAIRMAN FROINES: So I think the answer to my

question is "Yes" --

DR. GLANTZ: Yes.

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

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

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

DR. GLANTZ: Oh, okay.

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

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

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

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

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

DR. FUCALORO: Second.

CHAIRMAN FROINES: Discussion?

(No audible response.)

CHAIRMAN FROINES: All in favor.

(Each panel member raises his hand.)

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

(The lunch recess was taken at 12:44 P.M.)

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EL MONTE, CALIFORNIA; FRIDAY, JULY 26, 2002

AFTERNOON SESSION

(1:29 P.M.)

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

DR. RICE: Hi.

CHAIRMAN FROINES: Hi.

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

DR. SALMON: Hi, Keith.

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

DR. FUCALORO: I could never see that guy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Cumulative Risk Assessment of Organophosphates."

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

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

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

Okay. Next one.

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

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

those recommendations to the work group.

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

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

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

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

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

DR. FUCALORO: The --

DR. RICE: Yeah.

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

DR. RICE: Uh-huh.

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

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

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

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

long time.

DR. RICE: I hadn't anticipated that question. No. That was a joke. That was something Tobi was going to address. But I'll certainly take a stab at -- I can talk about it from a technical level -- well, work group level.

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

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

CHAIRMAN FROINES: And that's what?

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

CHAIRMAN FROINES: All of the issue papers?

DR. RICE: -- finished.

Yes. Finished, pulled together with an introductory chapter.

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

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

DR. RICE: Those are background papers.

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

DR. RICE: Sure.

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN FROINES: Paul, he's with OEHHA.

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

DR. GLANTZ: Friends.

DR. BLANC: -- at --

DR. GLANTZ: -- DPR.

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

DR. FUCALORO: Telephone.

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

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

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

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

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

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

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

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

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

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

DR. RICE: True.

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

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

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

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

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

And you're going to have to come to some conclusions from these questions.

DR. RICE: Right. Right. That's the purpose of these.

DR. BYUS: So I think that -- you know, I think that is a good thing as well. How long it's taken is another question. And I mean I do agree with you it seems to taken considerably longer time than it should have.

But if the product is good at the end, I think it's well -- it will have been well worth the time, if the product turns out to be good, because there are 40-plus organophosphate pesticides, maybe more, with related activity.

These are all the sort of seminal questions and all the risk assessments -- these are questions that have been not answered appropriately, in my opinion, for many years by EPA, by everyone.

And so hopefully, if DPR comes to the

right conclusions -- the "right" -- well, I mean that's the point. If you come to the correct conclusions, it will be a good thing. So --

DR. RICE: Thank you.

DR. BYUS: -- I guess that's the bottom line, in my opinion -- what the conclusion -- how you answer these questions and how you defend your answer, how you respond to how it would end -- and when we read this document, when you read these documents, this document, you will -- the science is laid out there in a reasonably, well, good form.

DR. BLANC: Well, then, why structure it as two separate documents? Why not --

DR. BYUS: I know.

DR. BLANC: Why -- well, no. Because it cuts right to the point you're raising. If you believe that the working document -- working group document provides all the scientific documentation that will be required to answer the policy questions, then why not write the executive summary of the background documents in the form of the questions that you're posing and answer them citing chapter and verse from your background documents?

DR. RICE: Right. Right.

DR. BLANC: "As shown on Page 25, the

correlation between RBC cholinesterase and brain cholinesterases, you know, averages between .7 and .9; and, therefore, RBC cholinesterase is an excellent surrogate."

DR. BYUS: Or, in reality, what they should have done --

DR. BLANC: All I --

DR. BYUS: -- which is what you wanted them to do, is write the questions first --

DR. BLANC: I wanted these --

DR. BYUS: I know. I know --

DR. BLANC: I deliberately didn't --

DR. BYUS: And then write --

DR. BLANC: I deliberately didn't say that --

DR. BYUS: Oh, okay.

DR. BLANC: -- because that is what you did; so that is what you did.

But I don't really understand the rationale for the two-year process it will take to write another -- write and review another document, even though you say you're going to have something by December. I don't think that is realistic. That's a whole separate document --

DR. RICE: It's putting together the pieces that we're generating right now -- the issue-

question discussions. It's a separate document in, you know, physical form only. It's basically a summary of the discussion we're having in coming up with guidance or coming up with the answers to the questions that we've posed. And they're very short.

We're -- our thinking is to have a small guidance document posing the questions; giving the answers; providing the discussion; referring to the technical document, which will be very long.

I mean it could be in one document. It really doesn't matter to me. But, again, our thinking was to have a short guidance document and a more substantial scientific support document. That's all. The amount of work required to do them as separate documents is not much more.

DR. BLANC: So what you're saying is that you have a six-month time line to write an executive summary, essentially an executive summary, of the document you've already written?

DR. RICE: No. We have -- we have not -- we've written 28, almost 28 individual documents. We're now going through and -- based on what we've uncovered, discussed in those original documents -- answering the issue questions we posed.

CHAIRMAN FROINES: But my understanding was

that -- which of the categories where there is -- where the documents have not been written?

DR. RICE: Okay. Right now, there is one document -- there is only -- what? -- 3 documents that have not been written. One of them is in the use of cholinesterase data. It would have been written except the lead person writing it had a skiing accident and was out for 3 months.

We have -- 2 other documents are in the cumulative risk assessment for organophosphates. These just haven't been written 'cause the staff doing those documents hasn't had the time to do that. They've been very busy with other documents.

DR. BYUS: That's the one I requested.

DR. FUCALORO: Yeah. That's the one that --

DR. GLANTZ: Yeah. That's the most important one.

DR. BYUS: Well, I'm not -- no. I wouldn't say it's the most important. But many of these -- the questions, as they're posed are, to me -- again, I am not an expert in cholinesterase. But I'm a biochemist-pharmacologist; so I do understand this well.

These are many -- for the -- they're not all appropriate questions. There are certainly

most of them, in my view. So I'm being optimistic, but the answers are what we're looking for. The answers are the key thing, obviously -- how you -- what conclusions you come to. And I think it will be helpful for the panel when they do, do this to have the scientific document there to read --

DR. RICE: Sure.

DR. BYUS: -- for these topics. And so then it will be very clear whether or not they're answering them correctly. I mean I think we won't have much trouble at all coming to that level of conclusion.

DR. RICE: Right.

DR. BYUS: Right.

CHAIRMAN FROINES: I think we don't need to prolong this because he represents OEHHA.

Randy, I assume that you don't have anything to say on this topic.

MR. SEGAWA: I'm sorry. No.

CHAIRMAN FROINES: And my view is that this process was problematic from its outset. I've never varied in that view. If -- being the fact that I'm from a university, I would never ever have approached this issue by having people in regulatory agencies have the primary responsibility

for developing what is essentially an academic document.

I would have gone out on contract and gotten academic researchers who are used to preparing documents, especially within reasonable time frames; and I would have had them do it. I don't know of any contract that I'm aware of where an agency like OEHHA or DPR has ever given a three- or four-year contract to a university to prepare a document on a topic.

You don't do that. It's six months, or it's a year and so on and so forth. This process seems to me to be very akin to the rock of Sisyphus. It may never emerge at the current rate that it's going.

And I have to be quite candid and say that I think it's, to some extent, insulting to this panel to not have a representative from DPR to be here to talk about this agenda item. We made this agenda a month ago. Somebody should have been here to talk about it.

We shouldn't put the burden on you. So that the message -- this panel has to send a message via the transcript to DPR. I don't think that you're the appropriate person, and you shouldn't be burdened with our beating up on you because of the

time it took to get this or the process or what have you.

But I do think we should say something -- we should say something about the process because it does seem to be a never-ending process.

And it does bother me, to some extent, to have you say in the overhead that "If we can't reach agreement, we'll have minority reports." Well, the State has to have a policy on cholinesterase. We don't -- this is not a debating society. It's a regulatory policy judgment that's being made.

You don't -- we don't get to have multiple documents with multiple points of view in them. We -- this panel wants to review a policy document with the associated science.

And it seems to me that Winston Hickox, as the head of Cal EPA, needs to make sure that OEHHA and DPR can come to some agreement about the policy of organophosphate regulation in the State.

DR. RICE: Well, I didn't mean to imply that we would have majority and minority opinions --

CHAIRMAN FROINES: You said it.

DR. RICE: -- on the issue recommendations

themselves. It will just be in the discussion behind that recommendation. We are very clear in coming out with recommendations to our questions that are directed to the points, like, "Yes," "No," "Cannot be determined." And there's not a minority-majority recommendation.

DR. BLANC: I'm going to come back to what I said before.

Actually I don't think that it's an inconsequential matter whether or not the structure of these policy recommendations is a separate document or the executive summary of the 28 scientific background documents that will be united by it -- an introduction -- because, just from the review point of view as well as the logistics of it, it will be very hard, I think, to -- it will be much harder to assess the strength and validity of the various answers to the questions, if that's how it's structured -- as questions and answers -- unless the answers, which as brief as they are, say, "As shown on Page 128-X and as documented on Page 425-Y; therefore, the following:"

DR. RICE: I understand.

DR. BLANC: And it -- and I think it will force -- I think it will force that executive summary

to be even heftier but will also make it more effective because essentially it's a document which is using, as its support material, another document but could also be invoking things which aren't in the other document, as far as that goes.

I mean it just has to stand on its own as even a brief document. For example, things like -- how are you going to deal with things that have been published in the interim? Are you going to start suddenly referring to them in this other document but they won't be in the master document?

CHAIRMAN FROINES: Gary?

DR. FRIEDMAN: John, I just wanted to ask if you really think that the transcript is going to be an effective means of communication of our concerns because that's the way it's going to have to go. I wonder if an additional letter would be appropriate, because I wonder: Would the people even read the transcript?

CHAIRMAN FROINES: Well, I think --

DR. FUCALORO: Can anyone read those transcripts?

CHAIRMAN FROINES: I think it would be highly appropriate for me to send a letter on behalf of the panel to Paul Helliker with DPR and express concerns

about the process, if you think that makes sense.

DR. FRIEDMAN: I think the transcript would not be, necessarily, an effective way to communicate.

DR. FUCALORO: Will we see any of these 28 documents soon? These background scientific data?

DR. RICE: Well, again, we have been providing virtually all the documents to the SRP leads.

DR. FUCALORO: To the what?

DR. RICE: To the SRP leads.

DR. FUCALORO: In my experience --

DR. RICE: Dr. Byus has them.

DR. BYUS: I might recommend that you send that document to the panel within a month. I mean just --

DR. FUCALORO: We have nothing else to do. We enjoy reading those things.

DR. BYUS: I mean I really -- that would be a recommendation. Send that to -- complete that document, which you should be able to do -- complete it and, except for that cumulative, which you haven't even started, which I don't want to get into but I --

DR. RICE: You know who's working on it.

DR. BYUS: I know. I know.

DR. BLANC: I'd like to get some feedback, though, from the group. I mean I have my opinion,

but if I'm way off base and nobody else takes the point of view that --

DR. GLANTZ: No. I agree with you. I mean this is --

DR. FUCALORO: You mean getting the document sooner? In other words --

DR. GLANTZ: Oh, that's a given.

DR. BLANC: Yeah. That's a given. But abandoning this plan to have a whole second-tier document and --

DR. BYUS: Oh, I see what you're saying.

DR. BLANC: -- and writing an executive summary of the documents that they have almost complete in the form, if they wish, of the policy questions but that it's actually an executive summary of the documents that, in its answers to these policy questions, refers specifically to pages or sections that are relevant.

DR. FUCALORO: You know, I think, listening to you, it sounds good to me. However, we haven't really deliberated on that. So I wonder about making a motion, for example, and including it here and setting -- changing the course of this, whether or not we should at least think about it a little longer. I think this is prudence speaking rather

than --

DR. GLANTZ: Than Tony.

DR. FUCALORO: I'm saying, at first blush, it sounds good. I'm just not sure that it would stand muster.

DR. GLANTZ: I was just going to say, I mean, "Why couldn't you do what Paul's suggesting?" Leaving aside the ones that haven't been drafted yet, I mean why couldn't you just take -- you'll have your summary of the science. You've got your questions articulated. Why can't you just go from one to the other and bring back --

DR. RICE: There's no -- I'm sorry.

DR. GLANTZ: What?

DR. RICE: There's no reason we couldn't physically put them together.

DR. GLANTZ: Okay. That leaves out a huge amount of work and another step. So I think Paul's suggestion is a good idea.

DR. BLANC: I don't -- that wasn't -- your answer wasn't exactly what I -- what you said is "There's no reason we can't put them together."

But what I'm suggesting is --

DR. RICE: Make them one document.

DR. BLANC: Okay. Because what I'm suggesting

is a change, a conceptual change, in how you presented this second document.

DR. RICE: Second document? As I understand what you're saying is: They take the background papers we've already developed, write an executive summary that basically will be the second -- or basically takes --

DR. BLANC: Yes.

DR. RICE: -- the place of the second document --

DR. BLANC: Yeah.

DR. RICE: -- that I've been talking about --

DR. BLANC: Right.

DR. RICE: -- in whatever form we see fit --

DR. BLANC: Right.

DR. RICE: -- be it questions --

DR. BLANC: Yes.

DR. RICE: -- statements, what have you, referring to the --

DR. BLANC: Yes.

DR. RICE: -- scientific articles that are in the background documents.

DR. BLANC: Yes. Yes. Exactly. Do you understand that?

DR. RICE: I understand that. Yeah.

DR. BLANC: Okay.

DR. RICE: And that's fine with me. I'm not the only one to make that decision.

DR. BLANC: No. I understand.

DR. GLANTZ: Well, but I think -- I mean I also didn't get these questions till just now. But I mean they are well-articulated questions. And I mean I could just see just simply going through and answering them and --

DR. BYUS: I could answer them right now.

DR. GLANTZ: You could?

DR. BYUS: I mean, you know, many of them, myself.

DR. RICE: I could too.

DR. BYUS: I know you could. And I'm not -- and that's even without the entire reading in detail the entire document that they've prepared. I mean you don't have to have all that information to answer these questions. Some of it -- a lot of it, you need. You don't need all of this.

So I mean I could do it. And so I'm sure, if I could do it, you guys can do it. It's the policy aspect of it that, I think, is the problem. It requires -- it's my impression that it requires -- that it's the policy aspects of it.

DR. GLANTZ: But, you know, it's a little bit like students coming in with a final, you know. The more time people have, especially given the history on this, the longer it's going to take. And I think it would be much better if we could -- I mean I'm, again, agreeing with Paul, if we could see something sooner rather than later.

CHAIRMAN FROINES: I think that these discussions have an air of unreality about them --

DR. GLANTZ: Yeah.

CHAIRMAN FROINES: -- because we spent -- OEHHA's developed the four documents; and we, today, talked about the fifth document. And there's enormous detail in there about how one approaches risk assessment. And there's no question that there's a lot of information.

But that's different than defining the basic policy questions that need to be addressed to, then, develop all that information. I mean it seems to me that one could or should be able to prepare today, a week from now, a 3-page document that defines the broad policy-based questions that need to be addressed.

I don't think it's rocket science, frankly. I think it is relatively straightforward,

and I think it could have been done three years ago, two years ago -- that the basic questions -- I think we understand what they are. So the degree to which we keep complicating -- the science is complicated. But some of the larger questions are relatively more straightforward.

I think that document, which is what Paul's talking about as the overlying executive summary, is a relatively -- is a document that shouldn't be a major undertaking -- not at this point, not after all the work that's gone into it or -- and if I'm wrong, somebody needs to tell me why that's wrong.

DR. RICE: No. It's not a major undertaking, in and unto itself. But it just takes time to prepare because there's approximately 15 people working on it at any given time. And we're trying to reach, build a consensus on each of the issue questions as we go along. There's a lot of questions and a lot of data to consider in support of each question.

And it's not -- while it's an important part of our workload, I mean it's not our only project. So we can't devote our entire time on it. So all those things considered contributes to

the length of time it's taking to get this finished.

CHAIRMAN FROINES: I think that -- I understand that. That doesn't answer my question because my question is: "Couldn't somebody sit down, person-to-person, and over a short period of time, in a 3-page document, define the broad-based policy issues that are going to be addressed?"

It seems to me that that isn't, I mean, a -- and I'll tell you that, in fact, the EPA science advisory panel has been doing just that. So you could actually go to the EPA's review -- it's been going on for the last year -- and derive, from what they've done, the questions.

Ruby Reed sits on that document -- sits on that committee and it seems to me that that committee's attempting to deal with the same kinds of questions.

DR. RICE: Right.

CHAIRMAN FROINES: And so it seems to me that there's an entire advisory committee, an entire agency effort going on that could be applied within the context of the State's activity. And that doesn't seem to be happening.

DR. BLANC: Well, John, if a consensus were to emerge from this committee it is that the -- is that

it would be our strong recommendation that the approach to finalizing the document would be to take the document that they have; circulate it rather rapidly; and then soon after its circulation, create an executive summary, which would incorporate -- which, if they wished, could incorporate it in a question-and-answer form.

I think that that should be part of your letter to the pesticide people because they won't do it unless -- they won't do it simply because you said, "That's an option." If you say, "That's an option," I don't think it will happen.

DR. BYUS: That would be my recommendation. Because I think the scientific document that they prepared could be wrapped up quickly. I mean it's going to take -- they haven't finished -- but it could be wrapped up very quickly.

And I think they should put their effort into getting something completed. And that would be completed -- you should be able to complete it quickly. And then -- say, by our next meeting -- give it to us so we can -- before our next meeting, so we can review it.

And then by our next meeting, whenever that would be, circulate the executive summary

questions for us to review.

CHAIRMAN FROINES: Well, I think it's a little more complicated than that because, if we had a meeting in September and you want them to get the documents to us by then and we review it, look at it by then, the time is kind of tight. I mean it can happen presumably, but spell out for me -- spell out for the record -- and I'll use it in the letter that I write to Paul Helliker -- what you would like to see happen, with some specificity.

DR. BYUS: I'm just trying to remember which chapters haven't been written yet.

I think you could finish that document in a month. Can you finish that document in a month?

DR. RICE: I don't think so. I really do think it will take us, given, you know --

DR. BYUS: Scientific document now -- just the science part.

DR. RICE: You mean just putting together the chapters?

DR. BYUS: Yeah.

DR. RICE: That's all it is.

DR. BYUS: Right. That's why I'm asking you.

DR. RICE: I don't know --

DR. BYUS: Except for the cumulative

organophosphate data, isn't it pretty well finished -- the chapters?

DR. RICE: With that exception. And the "Use of Human Cholinesterase Data" is not finished.

DR. FUCALORO: I can't hear you.

DR. RICE: The "Use of Human Cholinesterase Data" chapter is not finished either.

DR. BYUS: Couldn't you finish that in one month and get it to us in a month?

DR. RICE: You know, I hate -- it seems reasonable that it could be. I can't speak for the person writing the paper.

DR. BYUS: So it seems --

DR. RICE: Again, I'm not sure how our management and DPR's management feels about sending out a document that's incomplete that way, in terms of not having all the chapters.

DR. GLANTZ: Well, except what we're trying to say is that we want them encouraged to just get it done.

DR. RICE: I understand. And I can assure you that --

DR. BYUS: This is a way to do that.

DR. RICE: Yeah.

DR. GLANTZ: And the longer -- and you know,

because I think some of the -- and, again, we're not beating you up personally -- but given the sort of history of this, I think, left to their own devices, you know, it will be a very long time before we see anything.

And so I think, since it sounds like what you have is pretty close, the -- you know, if we're going to meet in September, it would be nice if we had the scientific document by a couple of weeks before the meeting to at least at look at it and discuss, if it wasn't as an information item.

And then -- and maybe the executive summary document and the policy document or executive summary-slash-policy document that John and Paul are talking about, maybe, for the following meeting.

DR. FUCALORO: "Following meeting"?

DR. GLANTZ: The following meeting, which would be October, November, or something. And we wouldn't -- actually I wouldn't anticipate taking any formal action on the document that we would discuss in September.

But we could discuss it and give you some feedback, which could then be used, you know -- you could take that and take it into account in preparing this more policy-oriented document, which

would come back at the next meeting.

What do you think about that as a plan?

CHAIRMAN FROINES: I think that's what the two of you are saying.

DR. GLANTZ: Yeah.

CHAIRMAN FROINES: My concern is as follows:

First is, this has been a major undertaking. I mean obviously they've assigned 16 people to work on it. It's not a trivial approach. It's a major effort. And I can see why they would be somewhat hesitant to release something that they consider only partially finished.

However, it seems to me that that --

DR. GLANTZ: Could encourage them to finish it.

CHAIRMAN FROINES: This would encourage them to finish it.

So the second point is I think that the schedule you've proposed is a little tight to be able to -- I think that --

DR. GLANTZ: How about slipping the whole thing one meeting?

CHAIRMAN FROINES: Well, I think that the problem is going to be the adequacy of our review

because we don't want a superficial review process for ourselves. And this is going to be a fairly lengthy document with a lot of science in it.

And it's going to take a while. And we have to understand our own limitations in terms of how fast and how effectively we can review a very major document.

So I would argue that we should ask for the document -- I would put it maybe three months down the line. But I would include a 2- or 3-page document that lays out the policy issues because I think that should -- somebody should be able to sit down and write that out today in an hour.

DR. RICE: Well --

CHAIRMAN FROINES: And I think, simply think, that those issues are not such that they could not be defined.

DR. RICE: That's what these questions are.

CHAIRMAN FROINES: I understand. No. These questions -- these are not the questions. These are the questions -- these are the scientific questions. These aren't the policy questions.

DR. RICE: Well, our group is working on guidelines. We're not -- we don't do policy. We're working strictly on the science and the guidelines --

the science behind the guidelines.

CHAIRMAN FROINES: So I think -- but I think, when we talk about the policy, we are talking about the guidelines; right?

DR. BLANC: Just a comment about -- I don't think you were looking for a lot of feedback on these questions, you know, in terms of content.

DR. RICE: No.

DR. BLANC: But I would make a comment that might be relevant, which is each -- that the working group that's doing that question of format should strive very carefully to have them be symmetric.

It will make it easier for us and easier for the all other responders and reviewers. And I think they are structured with that in mind, but there are places where they're not symmetric. And I would pay very close attention to that.

DR. RICE: For example?

DR. BLANC: For example, with Question Number 2, you talk about butyrylcholinesterase, and you take butyrylcholinesterase inhibition in the neuromuscular junction of adults.

But then, later on -- the next, very next, question is: "Butyrylcholinesterase inhibition in the neural and extraneural tissues in developing

organisms," which means that you don't care anything about butyrylcholinesterase inhibition in extraneural tissue of adults because you've limited one in this very particular way and not the other.

DR. RICE: Right.

DR. BLANC: And so it's not very symmetric. That's an example of --

DR. RICE: Well, we did that deliberately.

DR. BLANC: So even if there were any issue of butyrylcholinesterase inhibition in extraneural tissues of adults, it's not something that should ever be considered anyway.

DR. RICE: I understand your concern on the question but --

DR. BLANC: I mean is that what that is? Is that --

DR. RICE: Exactly -- well, I don't know that I would draw that conclusion.

DR. BLANC: But if you're going to structure something as a questions-and-answers sort of -- as a sort of Socratic questions and answers and if it's going to tie into the document, you can't assume that, because I haven't asked -- you know that you're not asking the question because you believe that the document demonstrates why there's no issue there; is

that correct?

DR. RICE: Uh-huh.

DR. BLANC: But you need to ask the question so that the answer is -- as the document shows, that it is not an issue in anything other than the neuromuscular junction of adults, if this is how you're going to do this.

DR. RICE: Okay.

DR. BLANC: Because you're doing it with things for which you know that the obvious answer is "Yes"; right? Like, the brain acetylcholinesterase -- "Is acetylcholinesterase inhibition in the brain an adverse effect?" Right?

Well, that's a no-brainer; right?

DR. BYUS: So to speak.

DR. RICE: Yes. It is a no-brainer.

DR. BLANC: But you put it there because you know, if you didn't ask the question --

DR. RICE: Right.

DR. BLANC: -- you would not have a chance to address the data that you have that shows, that, obviously, it is an adverse effect.

DR. RICE: Right.

DR. BLANC: So be cautious.

DR. RICE: Okay.

DR. BLANC: And the other thing I would be cautious about, when you phrase these questions, if they're compound questions or multiple things in the same question, if you perceive that one piece of the question is far more controversial than all the other pieces of the question, then I would break that out as a separate question.

DR. RICE: Okay.

DR. BLANC: For example, you have a couple of questions where -- I'll give you an example.

A.2, Question 2: "Should RBC acetylcholinesterase activity be used as a surrogate for brain or peripheral acetylcholinesterase activity or neurobehavioral observations?" And then you conclude the question.

But the one question is the sort of straightforward question. And you have its parallel in another part where you ask the same thing.

But the thing that would be very controversial would be if you were to say, "Yes. I have data that shows RBC cholinesterase inhibition; but when I did an observational study, I didn't see anything wrong with the animals. And, therefore, we should discount the RBC cholinesterase data," for example.

But that's an entirely different kind of question than the question about "I saw the RBC was down. But the acetylcholinesterase -- but the other cholinesterase wasn't affected. And since I know that that's a better marker, I'm going to discount it."

DR. RICE: I -- I understand.

DR. BLANC: So I would break out questions like that if you think that there's quite a different policy implication.

DR. RICE: Okay.

DR. BYUS: Guidelines; right? Guidelines. Guidelines.

I have one other possible suggestion or question -- just an idea. You could bring the science document to us as a draft document which was just for our feedback and same with the questions so that you wouldn't have to worry about being quite so --

DR. GLANTZ: You know, that's actually what I meant --

DR. BYUS: Right.

DR. GLANTZ: -- to have it come to us as a draft rather than --

DR. BYUS: As a draft. There is some validity

to that approach in that we could help guide them, provide additional feedback to them, prior to the fact that they answer these questions.

CHAIRMAN FROINES: Well, I --

DR. BYUS: I mean --

CHAIRMAN FROINES: -- just want to caution you.

DR. BYUS: I know. I know. I --

CHAIRMAN FROINES: This is an advisory panel.

DR. BYUS: Right.

CHAIRMAN FROINES: -- that is paid $100 to meet periodically to address these issues. We're not employees of DPR and OEHHA. And we have to be careful not to promise more than we can deliver. It's been my assumption that this panel would seek outside assistance, when we got this document, in terms of peer review by people who are active in this field.

There's nobody on this panel who's an active researcher in this field. So when we ask for them to send us a document by September or October, I think we have to be realistic about what we're going to do with that document. How effectively are we going to review it? Are we going to seek outside input at that point?

In other words, we're -- once you've -- once you've pushed the agencies to deliver a document, you are making some commitment about how you're going to follow up with it. And I think we need to be clear on what that's going to be.

I don't think it's just a question of this panel getting this enormous document and skimming it and giving some suggestions and calling that quits. I don't think it's adequate. And I don't think it would be fair to the agencies.

So that, if we're going to request the document, we ought to be relatively clear on what we're going to do with it, who's going to review it, and what the time frame is for that review. And I think that, otherwise, it's not fair to these folks to push them to deliver.

DR. BLANC: Well, I think that's -- I don't think it's -- I don't think that -- I think we're all saying the same thing in different ways.

And I think that's why people are trying to suggest some kind of incremental process that will give us something to begin working with because I also do not want to -- that's why I don't like this whole other idea because I don't -- of "We're going to do this. We're going to do that.

And everything's going to be finished. And then on February 1, 2004, we're going to plop 1,000 pages down on your desk."

And then, at that point, we would really be --

CHAIRMAN FROINES: Right.

DR. BLANC: -- under some kind of, you know, moral obligation to do something rather quickly. I would be very happy to see the first 6 books or whatever they are -- the first 6 parts.

Since they were all written independently, they should all be able to be read independently. I'd be willing to look at 6 of them at each meeting over the next year, you know, of the 24.

DR. BYUS: Right.

DR. FUCALORO: You're under danger of having just one final document, without any information provided in between the final document and now, of coming up with something which we may find unacceptable.

DR. BLANC: Within their own -- within their own reports, aren't each of these 24 chapters at least as stand-alone as one of the chronic RELs discussions? And we get those in little batches and

look at them and give feedback.

DR. RICE: I don't know. I'm not familiar with the chronic RELs. They are pretty stand-alone, each paper is --

DR. BYUS: Starting the sequence with the beginning. You start in the beginning of the documents. And if you just -- you can't pull them randomly out.

DR. RICE: Some refer to other papers.

DR. BYUS: Some, you can. But if you start at the beginning and read the first 4 chapters and then you read the next 4, they make their -- they're stand alone in that regard, in my estimation.

DR. BLANC: So I would say, you know, let us start seeing some of them, just so we get a sense of even where it's going. We're not seeing them to approve them. We're seeing them informationally and then having -- you know, putting half an hour, an hour in the agenda for the discussion of those chapters.

CHAIRMAN FROINES: Can I make a suggestion?

DR. RICE: Certainly.

CHAIRMAN FROINES: It seems to me that Category A, the "Relevance of Cholinesterase Inhibition in Risk Assessment," I think we would all

agree, is a fundamental issue in this whole question. And then you said that C is finished -- "Quantitative Factors in the Selection of LOAEL- NOAEL" is also finished.

DR. RICE: No. Just C1. "Analytical Variability."

CHAIRMAN FROINES: Oh, never mind. I think that what should happen, if I can suggest, I think that the document, Category A document, should be made available to the panel.

DR. BYUS: Which chapters would that be?

DR. RICE: Principally --

DR. BYUS: Not all the documents would be, but the first 4 or 5 --

DR. RICE: Oh, gosh, I don't have a list with me either. The first 4 or 5?

DR. BYUS: Right.

DR. FUCALORO: That's just what --

DR. RICE: Principally --

DR. FUCALORO: This requires no special effort; right? They're already prepared. All it requires is --

DR. RICE: The chapters have been prepared. Correct. And the issue questions have been developed, discussed, answered, and written up. Yes.

DR. FUCALORO: Okay.

DR. BYUS: Sort of a Catch-22, John, in that we're going to have to -- we either wait, encourage them for the complete thing or we try to do it all along. I don't know what the answer is. The best way --

CHAIRMAN FROINES: I hear everybody -- there's nobody on this panel who has said that they would not like to see a draft document. So I take that as a given at this point. Is that fair?

DR. FRIEDMAN: Right.

CHAIRMAN FROINES: Okay?

DR. FRIEDMAN: And it doesn't have to be the whole thing, just a part.

CHAIRMAN FROINES: That's why I'm saying, "A," because I think the "Relevance of Cholinesterase Inhibition" is clearly one -- is probably the fundamental issue that we're going to be concerned about -- is a fundamental issue.

DR. BYUS: Is a fundamental issue.

CHAIRMAN FROINES: Is a fundamental issue. And there's clearly a -- but that's a fundamental issue. And that's where the debate has been at EPA and beyond. So if you make that available, the panel can review it.

Now my question to the panel is: "Okay. We have the document. Who's going to review it?"

Do you want to review -- is this a group that wants to review it? Or do you want to seek outside input? What's the approach?

DR. BLANC: I think what we should do is have them get those 4 chapters to us. Let us discuss them as a committee as a whole. Craig has already been the lead. He can lead us through the discussion.

Let us have one of the goals of that discussion, based on this preliminary phase of the document, be a decision as to whether or not we need to seek outside expertise and, if so, in what format and what time?

DR. BYUS: That's what I think.

DR. BLANC: And let another goal of that review be to give feedback, generic feedback, to the two agencies as to whether or not we think we still -- whether we still think it makes sense to have an executive summary in a question-and-answer form or whether we think there needs to be a more traditional executive summary because otherwise it's a morass or whether we think there should be some other format in which the scientific background needs

to be distilled.

I think that's all the arguments for doing it early. If we do it too late in the process, it will be completely unfair, I think, to the agencies if we suddenly change the rules of the game.

DR. RICE: Again, I can't decide whether to submit this to the committee or not. But I can certainly take it back and --

CHAIRMAN FROINES: Does everybody on the panel agree with that statement?

DR. FUCALORO: They'd only be providing just 4 chapters on --

DR. BYUS: I'll just say 4 to 6 chapters.

DR. RICE: Well, the supporting chapters, whatever they may be.

DR. BYUS: Supporting chapters?

DR. RICE: Whatever they may be.

So what I'm hearing is that, A, you would like to see the issue questions and the subsequent discussion and our recommendations of those questions and the supporting chapters of -- that we used for those discussions and our answers provided the committee when?

DR. BLANC: At our next meeting.

DR. RICE: Well, prior to the next meeting?

DR. BLANC: For our -- so that we can discuss it at our next meeting.

CHAIRMAN FROINES: In that respect, the panel is, at some level, agreeing to function as a kind of lead person, collective lead person, on this round of the process.

DR. BLANC: With a very focussed agenda, which is to say, "Is this the direction to go, both in terms of format and is this -- and what kind of expertise do we need to bring in and how, in order to review it?"

DR. RICE: How much lead time?

DR. GLANTZ: For the panel?

DR. RICE: Before the meeting for the panel.

DR. GLANTZ: At least a couple weeks.

CHAIRMAN FROINES: Well, I think you should get back to us -- oh, the lead time for the panel?

DR. RICE: To give to the panel before the next meeting. Two weeks?

CHAIRMAN FROINES: No.

DR. RICE: Two weeks?

CHAIRMAN FROINES: No. No.

DR. RICE: No?

CHAIRMAN FROINES: I don't think so. I think -- we want to avoid silliness in all this whole

process. And everybody is charging up the mountain. But I think we've got to be realistic about it. This panel should really have three to four weeks with these documents before they can get --

DR. GLANTZ: Well, that would be better.

CHAIRMAN FROINES: What?

DR. BLANC: You really faded out on that too -- three to four weeks. I think three weeks is okay because it is functionally -- in all of our lives, as I say, if it came four weeks before, we would --

DR. BYUS: We would hold it for a week.

DR. BLANC: Yeah.

DR. GLANTZ: Three weeks is the commonly --

DR. MARTY: Can I raise a couple issues? You know --

DR. FUCALORO: No.

DR. MARTY: I am going to take back the issue that -- it was not fair to have just Dave here to try and answer these kinds of questions. And you know I'm actually not involved in this process. But I'm trying to -- you know, you get inoculated enough times by doing dumb things and getting hit over the head by management, that I don't want to put Dave in the position of promising to deliver anything.

DR. GLANTZ: And we'll do --

DR. MARTY: So, you know, you have sent a very strong message. I can take that message back.

DR. GLANTZ: Well, why don't we -- let me suggest this, Melanie, because I agree. We don't want Dave to be sent back and never be seen again.

DR. RICE: That may have already happened.

DR. GLANTZ: Yeah. I think this is something for the Chair to deal with. I think -- I think that there's a clear sense of the panel. I think we don't need to sit here, in a committee as a whole, negotiating schedules. I think there's a sense of what we want. I think you can go back and communicate it to the management.

You can communicate that what's happened in the past with this committee has made it become this restless. And I think we should leave it to the Chair to negotiate with the agency management and to come back with a firm schedule which is reasonable from everyone's point of view or from our point of view.

CHAIRMAN FROINES: I want to say one thing in that respect. That's fine. But I think, Melanie, your just joining the discussion is good. It's my view that the decision of when a document comes to

this panel is the decision of the agency.

It is not the decision of the panel. We can request it. And we can be restless, and we can be emphatic. But we are an advisory committee. And it is the decision of the agency when to bring the document to us. I think that's -- the point must be said. We're not -- we're not demanding this document. We're asking for it in order to facilitate the process.

DR. FUCALORO: Exactly.

CHAIRMAN FROINES: That's what we're doing.

DR. FUCALORO: Right.

CHAIRMAN FROINES: And so we would like to have this document come before us so we can help the process be more effective and more efficient and what have you. But it is ultimately the decision of the agency if they want to agree or disagree with that. If they disagree, we'd like to hear from them about their views.

But it seems to me that I don't want us to act beyond the scope of our role. Our role ultimately is to define whether or not something is scientifically adequate and when it comes to this. And in this case, we think that the process would be helped by it coming for an earlier review.

And so that's where I think we're at. Is that fair?

DR. BYUS: That's good.

DR. BLANC: And then our part of the bargain of not placing some odious review feedback is that, the later that they wait and the more finalized the structure of the document is, particularly if it's finalized in an unusual format for which you don't have buy-in from this group, the more likely that it is that there will be resistance to its approval.

Now, again, you're not from the lead agency, which has had the most evidence of feet dragging.

So if I were in that agency and if my ultimate goal were, in fact, to delay the whole process and perhaps never see anything come out of it at all, I would actually take exactly the tack of sending us an inflammatory document, very well developed, which we would reject or demand such heavy revision that, you know, that two more years would go by.

And I don't think that's what anybody wants.

DR. GLANTZ: Oh, well --

DR. MARTY: There's one other little issue

that I don't know the answer to but I just have heard through the grapevine. And that is that there was a statute passed some years ago now that requires anything coming out of Cal EPA that impacts risk-assessment policy or guidance to undergo public comment.

I asked Dave if he knew the answer to how they were going to deal with that in terms of this document.

And he doesn't know the answer.

And neither do I. And just --

DR. GLANTZ: Yeah. But you know -- well, I mean obviously, Melanie, we want to obey the law. But there's no reason that we couldn't be discussing something as a draft, even before it went out to public comment.

DR. MARTY: Oh, I agree with that.

DR. GLANTZ: If it was a final action item --

DR. MARTY: Yeah. No. I didn't mean to imply that --

DR. GLANTZ: -- then, if the law requires public comment, which it probably does, then there should be an appropriate public comment. But I don't think -- getting back to what Paul said, what we're trying to do is get something that we can comment on

before it gets locked down to that point.

DR. MARTY: Yeah. I didn't mean to imply that we shouldn't, therefore, give it to you. I just wanted to let you know that that process might have to take place.

CHAIRMAN FROINES: What?

DR. MARTY: That the public comment process might have to take place, depending on how the lawyers read it.

DR. GLANTZ: Well, didn't we --

DR. FUCALORO: Just let me say that's the reason someone suggested that they get in contact with you -- to keep the pulse on it, keep your hand on the pulse.

DR. GLANTZ: I'd like -- I think we've now pounded this into the mud. And I'd like to suggest that we move on with an agreement that the Chair will work this out with the agencies in the spirit of this discussion.

CHAIRMAN FROINES: Anything else?

DR. FUCALORO: That's it.

DR. FRIEDMAN: One thing: Since the Chair -- I don't think we really clarified, you know -- you had said, within an hour, they should write the policy. Are you going to withdraw that in terms of

your recommendation?

CHAIRMAN FROINES: Oh, I meant that rhetorically.

DR. FRIEDMAN: No. But I mean you meant within a month or -- well, you wanted it soon. And I just wasn't clear in my mind. And I was going to request an example of what you mean by a "policy issue that wasn't covered by the questions" --

CHAIRMAN FROINES: Okay.

DR. FRIEDMAN: -- so that it's all clear in our minds because I think --

CHAIRMAN FROINES: Well, I think, let's leave it to -- I think we should leave it to the documents that currently are prepared and not ask them to write additionally --

DR. FRIEDMAN: Good.

DR. FUCALORO: Minimal. Minimal.

CHAIRMAN FROINES: -- because I think that the questions we have here can be translated into policy statements because they really do represent the policy decisions in some respects. But let's not try and ask them to, in a sense, take this and rewrite the guidelines.

DR. FRIEDMAN: Good. That makes sense.

CHAIRMAN FROINES: No. I meant that really as

a rhetorical issue -- that some of the stuff -- that some of the material that was going to be written in this third document that Paul was talking about and that you mentioned earlier -- some of that should already be, in a sense, before -- before the people developing the document as the questions that they ultimately have to answer, I think. So that --

DR. GLANTZ: Next.

DR. FRIEDMAN: Are we aiming to leave at 3:00 or shortly after? Because I'm told that the traffic is terrible on the freeway. So we'll have to leave --

CHAIRMAN FROINES: Randy, are you here to discuss the air monitoring of pesticides?

MR. SEGAWA: I could answer questions, but I have no formal presentation.

DR. BLANC: Are you doing any?

MR. SEGAWA: Yes. I'm Randy Segawa with the Department of Pesticide Regulation. I'm sorry. Could you repeat the question?

DR. BLANC: Are you doing any?

MR. SEGAWA: Are we doing any what?

DR. BLANC: Any pesticide monitoring currently?

MR. SEGAWA: Yes. We are doing pesticide

monitoring. We -- actually I should say the Air Resources Board is doing air monitoring at the request of the DPR.

DR. BLANC: And what are you requesting them to do currently?

MR. SEGAWA: Currently, Air Resources Board is monitoring for the pesticides chlorothalonil, for acephate, and methamidophos.

DR. BLANC: And in addition to those three pesticides that are being monitored -- well, first of all, how many sites are they being monitored at for you by the ARB?

MR. SEGAWA: For the ambient air monitoring, where we sample in towns and regions where high use occurs, I believe we are monitoring either four or five sites for each of those pesticides.

DR. BLANC: And how many other pesticides have you monitored in the six months -- asked ARB to monitor for you in the six months previous to that?

MR. SEGAWA: Air Resources Board conducts annual monitoring. Let me back up and explain a little bit about the process. Toward the beginning of each calendar year, DPR sends a request to the Air Resources Board for the specific pesticides we'd like them to monitor the following year.

So, for example, here in 2002, we recently sent them a request for monitoring in 2003. So last year, we requested monitoring for this year.

They conduct the monitoring during the periods and areas of high use. And so for the monitoring last year, they monitored the fumigants methyl bromide; 1,3-dichloropropene; chloropicrin; and the breakdown process of metam sodium to MITC as well -- methyl isothiocyanate.

DR. BLANC: You're saying that, in this calendar year 2002, to date, those were the five in addition to the three that you mentioned?

MR. SEGAWA: Those four fumigants or the five pesticides, they monitored last fall.

DR. BLANC: In the fall of 2001?

MR. SEGAWA: Correct.

DR. BLANC: Are those aeration or ambient?

MR. SEGAWA: Ambient.

DR. BLANC: And then three additional ones in calendar year 2002. And those were the only three that you requested?

MR. SEGAWA: That's what they're currently doing if their budget holds up. We did request monitoring for sulfuryl fluoride and chloropicrin when they are used in structural fumigation.

DR. BLANC: Right. And then, in terms of the list that you're gathering for 2003, how many different pesticides will appear on that list?

MR. SEGAWA: We're in negotiations with Air Resources Board at this point. Their monitoring division has taken some major budget cuts. And so we're uncertain as to where it stands right now for 2003.

DR. BLANC: Is it -- is the range of the number of pesticides between three and six, did you say?

MR. SEGAWA: It has been in the past years.

DR. BLANC: So is there any relationship between the discussions in terms that we've had previously with this panel about priority pesticides for ARB to monitor for your unit that has played itself out in what you've actually requested and what has been actually been monitored? Is there a correlation between your -- the prioritizations we've talked about and what's actually being monitored?

MR. SEGAWA: I hope so. That is our intent.

DR. BLANC: Has that played itself out in this year? Can you give us a rationale for the three pesticides -- acephate -- I'm sorry. I didn't get the breakdown.

MR. SEGAWA: Right. If you recall our previous meeting, we did discuss the prioritization document. You had a number of comments. We're still working through that and revising that document. But we did request those three -- actually five pesticides for 2002, based on that draft document that you saw last meeting.

And those chemicals were basically next up in priority. Most of those that were on the list have been previously monitored by Air Resources Board.

CHAIRMAN FROINES: Randy -- I'm sorry -- what are the three you're doing in 2002?

MR. SEGAWA: Those are chlorothalonil, acephate, and methamidophos. I should say that acephate actually occurs lower in the priority. However, acephate breaks down into methamidophos. And so we want to look at them concurrently.

CHAIRMAN FROINES: And what happened to chloropicrin?

MR. SEGAWA: Chloropicrin, Air Resources monitored last year. And then, again, we've requested monitoring later this year for chloropicrin as it's used as a structural fumigant.

DR. BLANC: But no more field data from

strawberries than what you already did?

MR. SEGAWA: Air Resources Board has done previous monitoring. And in addition, we've requested additional monitoring data from the registrants for that particular --

CHAIRMAN FROINES: Of those compounds -- of those four compounds -- acephate, chlorothalonil, methamidophos, and chloropicrin -- how many of those were application monitored?

MR. SEGAWA: They all were. All five chemicals, we've asked for application monitoring. For the chlorothalonil, acephate, and methamidophos, we've also asked for ambient monitoring.

CHAIRMAN FROINES: So in the fiscal year 2002 that ends --

MR. SEGAWA: Calendar year.

CHAIRMAN FROINES: Calendar year. So these five compounds -- four compounds, as I read it --

MR. SEGAWA: And sulfuryl fluoride.

CHAIRMAN FROINES: -- they will all be done by the close of 2002 with application monitoring?

MR. SEGAWA: That was our request. Whether ARB still has the resources to complete all that, I do not know for sure.

CHAIRMAN FROINES: So but last year you did

the metam sodium, telone -- and I forget the other ones you said -- but by -- for ambient monitoring?

MR. SEGAWA: Correct.

CHAIRMAN FROINES: Okay.

DR. BLANC: What about that presentation we had about the technology that would allow multiple pesticides to be monitored simultaneously, something like, you know, 20 of them or 15?

John, can you remember what I'm talking about?

DR. BYUS: Yeah. I remember. It was good.

MR. SEGAWA: Yeah. We do it by analysis for multiple pesticides whenever we can. For example, when we requested the 4 fumigants for last year, we requested that, of course, in 2000. And at that time, we had hoped that ARB would actually be able to monitor for all 4 using a single method.

That didn't turn out to be the case. But as we can, we do request monitoring for several chemicals simultaneously.

DR. BLANC: No. I'm asking something a bit more specific. We had a presentation to this panel about technology that would allow quite a bit more simultaneous monitoring. Does that sound familiar to you?

MR. SEGAWA: It does not, unfortunately.

DR. ATKINSON: Well, it depends on the compounds and the compound classes they're doing.

DR. BLANC: Right.

MR. SEGAWA: So in some cases, we might be able to do it; in other cases, maybe not.

DR. FUCALORO: Some sort of chromatography?

DR. ATKINSON: No. I mean you can do, presumably do, a whole bunch of organophosphorus compounds at once. But if you're looking for something which isn't an organophosphorus compound, you may not.

CHAIRMAN FROINES: Paul's asking about the -- when we had the session when Bob Spear spoke and the fellow -- I forget where he was from.

DR. ATKINSON: Yeah. From USGS.

MR. SEGAWA: Oh, yes. Thanks for jogging my memory. I do recall the discussion now. And that person was Mike Majewski with the US Geological Survey. And, yes, he has monitored for a number of chemicals simultaneously.

We've done so on occasion for specific problem areas. For example, the Department's been working in the City of Lompoc because that's an area where people have been complaining about pesticide

use in that area. We had to do some air monitoring for some 25 or 30 pesticides simultaneously, all used within that particular area.

So where we're monitoring on a geographic basis, we employ that technique. For most of this program, though, we're focussing on individual chemicals. So it doesn't lend itself to multiple analysis as readily.

DR. BLANC: It's not exactly clear to me why that would be because if ARB -- I understand why that would be true for the use monitoring. But for all of these, you said there was general airborne monitoring happening as well.

So if you have a site where you're collecting samples, it would make sense to not only collect one sample for the specific chemical that you're interested in but also to use a sampling device to collect a bulk sample and use this other methodology if it's available to you.

MR. SEGAWA: Yes. To some extent. But if you recall, both for the ambient monitoring as well as the application-site monitoring, we try to target the monitoring in areas and time periods of high use. And a lot of cases -- that doesn't occur with several chemicals at one time.

For example, malathion may be used in Fresno County; whereas, diazinon is used in Kern County. And so the monitoring is more focussed to try and get the highest concentrations for each individual pesticide.

DR. BLANC: Well, I don't want to belabor the point. But I think we were impressed, the last time we had air-monitoring data presented to us, at how fragmentary and limited it was.

And it has considerable support from this committee to take a more global approach to at least gather some broad-based sampling data that would simultaneously monitor a number of pesticides, similar to what I assume you're describing in Lompoc, and that those be done, even in the absence of being clear that you would have the technical signal, so that we get some sense of what the sort of ambient background was on some of these pesticides.

I think it would be helpful for this group, at some point in the next year, to have a presentation that would be done jointly by you and someone from the ARB technical side so that we could get a better sense because I can only come away from your presentation thinking that, sometime in the next 75 years, we may've been able to have five sampling

data points each for, you know, the hundred pesticides that are used in California.

I mean it seems like an extremely limited data set.

MR. SEGAWA: You're correct. And if you recall that, that workshop where we did discuss this topic, one of the things we did focus on was trying to supplement the monitoring data with modelling or estimates of what air concentrations might be in other periods, other time periods and other places. And we are moving forward with those efforts as well.

CHAIRMAN FROINES: Yeah. Paul, let me say that I had a conversation with Paul Goslin as a result of his letter to me on this issue. And I don't have anything really to report as a result of that conversation. What he said in the letter -- I didn't mean that negatively.

What he said -- what Paul said in the letter was essentially what he talked about on the telephone. And his -- he said that they were moving forward, as Randy just said, to develop a new methodology and new approaches to the monitoring.

And so but I think that the -- there are a range of issues that need to be discussed on the exposure-assessment question that relate not only

to the actual monitoring that goes on but to the nature of the determination of the -- pardon me -- to the use of the information.

The law -- the regulations state that the MOE needs to be calculated, and there are different factors that need to be applied.

I'm trying to do this hurriedly. So I'm not very articulate. But there are a range of issues. And I think what we should do is to thank Randy for his brief presentation.

And then Elinor and I will develop a list of very specific topics on the exposure issue. And we'll present them at the next meeting for discussion, if that's -- if you're willing because I made a whole list of issues and we're not going to -- Gary and Elinor are not going to be able to get out and make planes if we take it up.

And so what I'll do is to lay out, in a 1-page or 2-page document, a series of issues that we need to discuss on the exposure question.

And part of it will be, Randy, to ask Paul for a sense of the timetable and the process for the new developments that you're working on so that the panel has a sense not simply of the promise that those approaches are being followed but, you know,

what's the -- how's it going to stage out?

And so we'll make that -- Elinor and I will prepare that for the next meeting. We can discuss it in more detail because it really goes not simply to the notion of monitoring but goes to how monitoring data is then used to calculate an MOE. And there are issues that we need to talk about, if that's all right with you.

MR. SEGAWA: That's fine.

CHAIRMAN FROINES: Thanks, Randy.

Formaldehyde. I'm told that we have a four-slide presentation.

MR. AGUILA: It's down to two now.

CHAIRMAN FROINES: Four would have been okay.

MR. AGUILA: Well, good afternoon to the panel.

DR. GLANTZ: That's one slide.

MR. AGUILA: My name is Jim Aguila. I'm with the California Air Resources Board. And I'm here today to give a very brief presentation on a recent petition that Air Resources Board had received.

This petition was received from an industry brief -- industry group known as the "Formaldehyde Epidemiology, Toxicology, and Environmental Group" who have submitted an application requesting that the ARB take a look at

the original risk assessment for formaldehyde.

And basically what I wanted to do is just kind of jump into a process that was developed by the Scientific Review Panel back in 1989, which basically established some guidelines for taking a look at these kinds of requests.

CHAIRMAN FROINES: I think Gary Friedman was the first user of this process.

MR. AGUILA: Is that right? I went back and took a look myself. And I believe we don't have any chemicals that actually have made it through the entire process yet.

Anyhow, what I'd like to do is maybe walk you through it very briefly so you can get a sense for the flow. Essentially, we did receive the application in April. And the first step is basically for us to share the information with the Office of Environmental Health Hazard Assessment, which we have done.

The procedure basically stipulates that there is an initial step where OEHHA would take a look at the quality of the submittal to see if it meets certain screening criteria, which is defined in one of the handouts that's been provided to you.

Again, OEHHA would also take a look at

the evidence to see if there is a need to reopen the original risk assessment. Basically that finding is summarized and transmitted to the Air Resources Board for evaluation. And next slide, please.

Subsequently the Air Resources Board would take a look at the OEHHA findings and recommendations and basically transmit that information to the SRP Chairman, who would be requested to review not only OEHHA's recommendation but also the newly submitted information as well.

And at this point, the process does have some flexibility. The SRP Chairman could choose, at that point, if he feels it's warranted, could assign the lead person to take a deeper look into the recommendation and the submittal itself.

Assuming that there is a lead person that's assigned, the lead person would work directly with OEHHA and other agencies, as required, to do basically an independent evaluation. And those findings would be transmitted back to the SRP Chairman, and the findings would also be discussed at an SRP panel meeting.

And essentially the purpose of this review process is, Number 1, to save the SRP some time but also to make a determination whether or not

the newly submitted information would warrant a reopening of the original risk assessment. And basically that's the process for the initial review.

And if the finding, after the process has gone through, is to recommend the reopening of the original risk assessment, then the Air Resources Board would make that request formally to OEHHA to basically initiate that process. So any questions?

CHAIRMAN FROINES: We -- previously we got, I think, to this place; and it was on benzene. And Dr. Friedman recommended that the information did not require a reopening of the record, I think.

DR. FRIEDMAN: It's been a long time, but that sounds right.

DR. GLANTZ: Yeah.

CHAIRMAN FROINES: And then it went to -- then that recommendation would go to the ARB chairman. And then, as far as I remember, that's where it ended up.

DR. FRIEDMAN: It was either Kendrick or Aldrich was the chairperson at that time. I think they then transmitted it back to the ARB. I don't think it was discussed very much at this meeting.

MR. AGUILA: Yeah. As I indicated, there is some flexibility in the process that -- that would

basically constitute a basis for the Air Resources Board to reject that petition in the case you cite.

CHAIRMAN FROINES: So what's the time frame on formaldehyde? Where -- it's with Melanie, presumably at this point.

DR. MARTY: Yeah. It's with OEHHA. And we have the same person who did the initial quantitative risk assessment wading through the material now. And we hope to have something move forward to the panel in the fall. It's one of the many things on this person's plate. So it's in line.

CHAIRMAN FROINES: It's okay. The panel doesn't have much to do either.

DR. GLANTZ: So is there anything we need to do at this point or just wait till --

DR. FUCALORO: This is just information.

DR. GLANTZ: Wait until Melanie has something for someone?

CHAIRMAN FROINES: It goes from Melanie to the Chairperson of the ARB. The Chairperson, then, will send it to me. And then we'll assign a person or persons to review it.

DR. GLANTZ: Okay.

CHAIRMAN FROINES: So we think it will probably be in to us sometime this fall, presumably.

DR. MARTY: Yes.

DR. FUCALORO: Are we adjourned?

CHAIRMAN FROINES: No.

DR. FUCALORO: Sorry.

CHAIRMAN FROINES: Stan wants to raise some --

DR. GLANTZ: I want to raise -- I realize the State has a budget crisis, and I also have no problems with the digs, but I think we need to meet near airports. This -- if you look on a map of L.A., this is the maximum distance from all airports. And it really makes travelling a pain.

And I'm not saying we -- I'm not objecting to coming to Southern California because you guys get dragged to Northern California. But I -- and we don't have to meet at the Taj Mahal or the Owani.

But I think that the traditional practice of this committee of trying to hold the meetings close to airports where people can get in and get out without very long trips needs to be maintained, you know.

DR. COLLINS: How about the break room of the highway patrol substation at the airport?

DR. GLANTZ: That would be okay with me. But, no. I mean I'm serious. I mean Gary's having to

leave now because -- to get to an airport. The travel arrangements I ended up with were Byzantine. And it's just not an efficient use of people's time.

DR. FUCALORO: Unfortunately, Ontario, which serves three people in this panel --

DR. GLANTZ: Yeah.

DR. FUCALORO: -- and San Francisco are no longer directly linked.

DR. GLANTZ: Even if we were meeting, you know -- I don't mind the time we had to go to Oakland to fly to Ontario. That was okay. But we are about as far from the airport in the L.A. Basin --

DR. FUCALORO: Then I move that all subsequent meetings be done at Ontario International Airport.

DR. GLANTZ: All right. I'll second that. Well -- all right.

DR. FUCALORO: Well, no. I mean I agree. I mean Ontario's very convenient for us -- very convenient.

DR. GLANTZ: Well, no. I mean I think we should -- I mean we have tried, in all the years I've been on the panel, to schedule these meetings in ways that were reasonably equitable to the panel members and where everybody got to do a reasonable amount of flying all over the place.

But I just think that we need -- that what we have here is -- I don't know how this is, vis-a-vis you guys driving to get here; but in terms of flying in and out, this is about as far from any place as you could get.

CHAIRMAN FROINES: Well, let me ask you a question. As far as I'm --

Jim, you may want to join in.

As far as I'm concerned, when we have them in San Francisco, it's -- the situation is okay because we use that convention center. I don't know how expensive that convention center is or whether UCSF is cheaper or what. But it seems to me that there's no significant San Francisco problem.

DR. ATKINSON: We can't get there.

CHAIRMAN FROINES: Except that the people from Riverside can't get there.

DR. GLANTZ: Well, who cares? That's neither --

CHAIRMAN FROINES: Well, we can meet --

DR. BYUS: Oakland. If we can meet in Oakland --

DR. GLANTZ: I'm perfectly happy to go over to Oakland.

DR. FUCALORO: Meet in Oakland.

DR. BYUS: Meet in Oakland.

CHAIRMAN FROINES: Now, the other alternative is to --

Jim, it seems me that the other alternative for Riverside-Ontario is to hold the meetings at AQMD, which should be free. And that's a piece of cake for these three folks 'cause they're right there. That's even closer for them. And that means that Paul and Stan would have to fly into Ontario.

DR. GLANTZ: And Gary.

CHAIRMAN FROINES: And Gary's in Oakland. So he's not --

DR. FRIEDMAN: I'm equidistant from either San Francisco or Oakland. So I like flying out of Oakland on Southwest. It works very well.

CHAIRMAN FROINES: Paul?

DR. BLANC: You know, I can work around -- it really, for me, has not been an issue where it is in Southern California. You know, it's just, if my schedule allows me to get to Southern California, I've got a way of doing it.

It's a little -- it's not quite as -- I don't have quite -- for me, this wasn't that inconvenient because, you know, I tend not to do the

same-day flight into L.A. just 'cause it's -- even if it's somewhat convenient, it's too iffy. But --

CHAIRMAN FROINES: The problem -- I, of course, like the idea of coming into LAX. And LAX is a good place for people from the Bay Area. However, it forces these three people to travel for a very long distance; and that seems to me to argue in favor --

DR. GLANTZ: Well, I'm not arguing for a specific airport. I'm just saying that I would like the meetings near whatever airport it is we fly into. And, you know, that's all.

CHAIRMAN FROINES: Roger, how long did it take to you drive over to John Peter's place at USC?

DR. ATKINSON: It depends on the --

CHAIRMAN FROINES: Traffic.

DR. ATKINSON: -- on the traffic. But I would say an hour and a half probably, depending on the time of day. I could probably make it in an hour --

DR. GLANTZ: At midnight.

DR. BYUS: At 2:00 in the morning.

CHAIRMAN FROINES: I took two-and-a-half hours to get to Riverside the other day from my house in Santa Monica. So it's --

DR. ATKINSON: Yes. It can easily be that.

CHAIRMAN FROINES: So it seems to me, that having, exploring the AQMD site as being a bit more convenient for airport -- it's very -- it's relatively close to Ontario. But that means you're going to have to drive.

DR. GLANTZ: Whatever. Okay. Well, I made my point. I mean I just think that putting the meeting in a place which is so faraway is, in a way, penny wise and pound foolish because it leads to, at least for me and Gary, quite dysfunctional travel -- for me personally, quite dysfunctional travel arrangements.

I end up spending a lot of money on cabs and getting no sleep, and then the meeting gets cuts short.

CHAIRMAN FROINES: We -- can I raise another question? 'Cause I'm worried about the time.

DR. GLANTZ: Yeah. Well, I'm done.

CHAIRMAN FROINES: The other question -- I would prefer that we set a day on, every two months -- like a Monday at 10:00 o'clock every two months. And then that will be our schedule for the following year. In the past, people have opposed that scheduling.

But obviously it makes a lot of sense and benefits Peter if we do that. Do people still

oppose that or --

DR. FUCALORO: I don't oppose it; but I'm just letting you know, this coming fall, for whatever reason, I have at least four days a week during class session that I'll be unavailable the whole day.

In other words, if I were to meet -- it could be in the morning or in the afternoon -- it would almost have to be in Southern California. Fifth day, I'm trying to keep free just for that sort of thing. And that fifth day -- I can tell you what it is. It's Friday.

CHAIRMAN FROINES: Let's forget what I just said because, this fall, it's not going to work.

DR. BYUS: I think it's a good idea. I do think it's a good idea.

CHAIRMAN FROINES: Peter, we'll explore it for next year. But this fall, I know, won't work. So we'll take a --

Go ahead, Jim.

MR. BEHRMANN: Jim Behrmann. Let me just say that I appreciate the panel's willingness to work with us, especially during the time when the budget is really tight. And I do expect that, in the coming meetings, we'll work as diligently as we can to meet in a facility that's relatively close to an airport.

Oakland -- we have the benefit of OEHHA's facility being nearby. Unfortunately, most of the other airports' facilities cost us quite a bit. And our direction has been to seek facilities where we can obtain them at minimal cost.

DR. GLANTZ: Right. But I think -- what I'm saying to you, Jim, is that, as John said, we're effectively volunteers.

MR. BEHRMANN: Yes.

DR. GLANTZ: And I think that you need to try and schedule these meetings to make effective use of our time too --

MR. BEHRMANN: Certainly. And --

DR. GLANTZ: -- realizing we're strewn all over the state because you know -- well, I'll just -- I think you need to just take that into account. And I think it needs to go back to your management that they get a lot of work out of this committee and, if they had to pay us to do this work, it would cost more than renting a room somewhere.

MR. BEHRMANN: Exactly. And that was my reason for opening by saying that I really do appreciate the panel's willingness to work with us and your time.

CHAIRMAN FROINES: It's clear that the -- it

seems to me that, given there are State facilities in Oakland, Oakland is a great place.

MR. BEHRMANN: Yes.

CHAIRMAN FROINES: It means Paul and Stan have to drive across the bridge or take the subway. But that one works very well. And it's a question of, when we're here in Southern California, where do we do it? And we want to balance between the two places.

And so we'll just -- it seems to me that having some place around the Ontario airport probably makes the most sense for the three people who have to commute -- the longest commute. Now, I don't know --

DR. FUCALORO: Now, which Brown is the mayor of Oakland?

CHAIRMAN FROINES: Paul just asked if we could come up with suggestions for the September meeting. But I'm not convinced that this is ever possible to do it. But shall we say the third Monday in September?

MR. BEHRMANN: John, I would look at both September and October.

DR. BLANC: I would suggest Friday, October 4, actually.

DR. FUCALORO: Friday is my best bet. If it were on a Monday, it would almost have to be in the morning.

CHAIRMAN FROINES: Peter, why don't you try and poll people on Friday, October 4?

DR. FUCALORO: I may actually have to resign, seriously, because it turns out that, for at least the next year, I'm going to have a pretty -- at least for the fall, I mean -- I have a pretty stiff schedule.

DR. BLANC: We'll see about Friday the 4th.

CHAIRMAN FROINES: Let's discuss that -- we can do that off the record in private.

A motion?

DR. FUCALORO: Let's adjourn.

DR. BYUS: Adjourn.

DR. ATKINSON: Adjourn.

CHAIRMAN FROINES: Second?

DR. GLANTZ: Yeah. Second.

CHAIRMAN FROINES: All in favor?

ALL PANEL MEMBERS: Aye.

DR. BYUS: What about discussion?

CHAIRMAN FROINES: And before Paul says anything, it was unanimous.

(Proceedings concluded at 3:11 P.M.)

STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

I, NEALY KENDRICK, CSR No. 11265, do hereby certify:

That the foregoing transcript of proceedings was taken before me at the time and place therein set forth and thereafter transcribed by computer under my direction and supervision, and I hereby certify the foregoing transcript of proceedings is a full, true, and correct transcript of the proceedings.

I further certify that I am neither counsel for nor related to any party to said action nor in anywise interested in the outcome thereof.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 7th day of August, 2002.

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NEALY KENDRICK, CSR NO. 11265