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1 SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS
2 AIR RESOURCES BOARD
3 STATE OF CALIFORNIA

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PUBLIC MEETING

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TRANSCRIPT OF PROCEEDINGS

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Friday, April 26, 2002

10:07 A.M.

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Los Angeles Airport
6101 West Century Boulevard
Los Angeles, California

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24 NEALY KENDRICK, CSR NO. 11265

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JOB NO.: 02-23357

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APPEARANCES

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SCIENTIFIC REVIEW PANEL

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Dr. John Froines, Chairman

Dr. Roger Atkinson

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Dr. Paul D. Blanc

Dr. Craig V. Byus

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Dr. Gary D. Friedman

Dr. Anthony Fucaloro

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Dr. Stanton A. Glantz

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Dr. Elinor Fanning, UCLA School of Public Health

Technical Liaison to the Scientific Review Panel

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Representing The California Air Resources Board:

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Mr. Jim Behrmann, Liaison, Scientific Review Panel

Mr. Peter Mathews

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Representing The Department of Pesticide Regulation:

13

Dr. Andrew Rubin, Staff Toxicologist

Dr. Randall Segawa, Senior Environmental Research

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Scientist (Supervisor)

Ms. Tobi L. Jones, Assistant Director of Division of

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Registration Health Evaluation

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Representing The Office of Environmental Health

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Hazard Assessment:

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Dr. Melanie Marty, Senior Toxicologist

Dr. Andrew Salmon, Chief, Air Toxicology and Risk

14 follow-up to the exposure discussion we had in
15 January.

16 So we can -- we will take it up -- I
17 got the letter yesterday at 3:00 o'clock. And so
18 there wasn't any chance for us to put it on the
19 agenda ahead of time. So we'll take it up next time.
20 And the letter is extremely important because of the
21 close attention to the issue of exposure assessment
22 and monitoring that the panel has focussed on with
23 respect to pesticides. And so we'll want to take it
24 up at the next meeting.

25 We're changing the agenda. We're
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1 going to take up methyl isothiocyanate as the first
2 agenda item because we really want to try to get
3 through MITC and we want to be able to discuss the
4 prioritization document. And so if something had to
5 drop off at the end, it would have to be Melanie's
6 noncancer chronic -- her chronic RELs.

7 And but we definitely want to get to
8 carbon disulfide. And, finally -- I'm forgetting
9 something. But why don't we go ahead? So Tobi,
10 Andy -- who's going to be the lead? Welcome.

11 DR. RUBIN: Is this one working? Hello?
12 Okay. Okay. I'd like to bring the panel up to date
13 on the status of the MITC 1807 health assessment. As
14 we're all aware, completion of the SRP proceedings on
15 MITC hinges on consideration of a revised draft of
16 MITC 1807 document.

17 A number of changes have been inserted
18 into the document since it was last considered and
19 accepted by the panel back in May of 2000. I've
20 detailed those changes in a memo dated January 29. I
21 believe the panel got copies of this memo. But if
22 not, there are some available here out on the table.

23 For your reorientation -- next
24 slide -- I've summarized the changes in the first
25 overhead. I'll just read through this very quickly.

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1 I intend to concentrate today only on Number 1. But
2 just -- and then, if there are any questions on any
3 of the other changes, you can ask me afterward or
4 even now.

5 First of all, subchronic risk is now
6 estimated using the newly submitted 4-week rat
7 inhalation toxicity study of Klimisch as opposed to
8 the 13-week rat inhalation study of Roskamp.

9 2. There's a more detailed account
10 of the critical human eye irritation study of Russell
11 and Rush, which underlies our acute evaluation. And
12 this account emphasizes, in particular, the
13 robustness of the results at the LOEL value -- at the
14 LOEL dose.

15 3. There's greater methodologic
16 detail regarding the calculation of ambient and
17 application site exposures. And they've been added
18 as footnotes to Tables 9 through 12.

19 4. 1- and 8-hour acute air
20 concentration estimates and the resultant risk
21 calculations have been provided to accompany the
22 24-hour data that appeared in earlier drafts of the
23 report.

24 5. Application site studies that
25 would not currently be legal under recent technical
0007 information bulletins and product labels are
1 explicitly recognized in the document.

2 6. First, the uncertainties inherent
3 in after-the-fact modelling of MITC air
4 concentrations after the July, 1991, Sacramento river
5 spill are emphasized. And the results of modelling
6 calculations done by DPR, OEHHA, and the metam sodium
7 task force are presented in the document.

8 Second part of 6: The results of the
9 Kreutzer et al. epidemiologic study on the spill are
10 presented. This didn't add any appreciable new
11 information but filled in some detail.

12 7. There's a complete description of
13 the Earlimart MITC exposure incident of November 13,
14 1999.

15 8. The CDPR illness surveillance data
16 have been updated to 1999.

17 And, 9, in some issues that have come
18 up only in the last two to three weeks -- and these
19 are not yet in the document -- there is now going to
20 appear a treatment of benchmark dose modelling of the
21 subchronic rat inhalation toxicity study as well as
22 some emendations relating to the statistical power of
23 the study.

24 These arose out of discussions that
25
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1 occurred between DPR, OEHHA, and members of the
2 Scientific Review Panel.

3 Finally, there is a correction or a
4 flushing out of some data on an acute study that
5 doesn't really affect any of the NOELs or LOELs in
6 the study, but I just wanted to bring you -- bring
7 that to your notice.

8 CHAIRMAN FROINES: Andy, I have a procedural
9 question.

10 DR. RUBIN: Okay.

11 CHAIRMAN FROINES: Elinor, this is important.
12 Has the panel been given Andy's emendations? Or is
13 it only Paul, Stan, and myself who have seen those
14 proposed changes?

15 DR. FANNING: I think everybody received it in
16 Jim Behrmann's e-mail of this Monday.

17 PANEL MEMBER FUCALORO: Yes. Downloaded it.
18 Yes.

19 CHAIRMAN FROINES: Well, the reason I ask the
20 question is we obviously can't approve our own
21 findings if there is something of substance to be
22 added. As long as the panel has seen the proposed --
23 the proposed changes that are going to go into the

24 document and approves the document with an
25 understanding that those changes will be
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1 incorporated, then we're okay as a procedural matter.
2 And I think we are okay.

3 Okay. Go ahead.

4 DR. RUBIN: I've also brought --

5 PANEL MEMBER BYUS: I don't mean to interrupt
6 you. I have one brief question. I've got the
7 January 31st document. And you just handed out a
8 January 29th document. I'm just trying to read them
9 to determine which -- what's the difference?

10 DR. RUBIN: Oh. Is that the --

11 PANEL MEMBER BYUS: Should we be going by the
12 31st or the 29th?

13 DR. RUBIN: Is that the changes?

14 PANEL MEMBER BYUS: The changes. They look
15 like they're similar documents. But there is a later
16 one than the 29th.

17 DR. RUBIN: I wrote -- I may have gotten --
18 it's probably my fault. I wrote -- it's exactly the
19 same document, except I think the later one has the
20 exact pages --

21 PANEL MEMBER BYUS: No. It's somewhat -- it
22 has some differences. I just wondered what they are.
23 That's all I'm asking.

24 DR. RUBIN: I don't think there are any
25 differences --

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1 PANEL MEMBER BYUS: Okay.

2 DR. RUBIN: -- of any substance.

3 PANEL MEMBER BYUS: Okay.

4 DR. RUBIN: And the benchmark dose and the
5 statistical power emendations, I've also brought
6 copies of here, in case anyone doesn't have them.
7 And they're out on the table.

8 The issue that's commanded most of my
9 attention has been the subchronic endpoint in
10 regulatory NOEL determination. In previous drafts of
11 the MITC 1807 Health Evaluation, the critical
12 subchronic NOEL was based on the 13-week rat
13 inhalation study of Rosskamp, which we've already
14 discussed at some length in these proceedings.

15 However, as Rosskamp was extremely
16 problematic on technical, reportorial, and study-
17 design grounds, we were pleased to have the
18 opportunity to examine another inhalation study, this
19 one a 4-week study by Klimisch et al.

20 While the Klimisch study was not
21 perfect by any means, as if there is such a standard,
22 it was notably superior to the Rosskamp study in its
23 ability to supply a supportable regulatory NOEL.

24 I've got on this overhead just a brief
25 review of the study design. And I'm going to go

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1 through this as quickly as possible. This was a
2 study conducted in Wistar rats by animals per sex,

per dose -- 3 doses along with the control -- 1.7, 6.8, and 34 ppm.

It was a 4-week study, 5 days per week, 6 hours per day. These were whole-body exposures. MITC aerosol was generated by a gentle thermostatic heating of liquid MITC. Analytic determinations were done by adsorbing the MITC in 2-propanol, measuring by gas chromatography. There were 6 samples done per group per day.

The analytic aspects of this experiment were under very well -- very good control, particularly when you compare it to the Rosskamp study. The observations -- fairly standard toxicologic observations. Body weights done on a weekly basis. Clinical signs done daily; serum chemistry and hematology, just before sacrifice; and histopathology, following sacrifice.

Next overhead.

Just to give you a sense that, at the high dose, these animals, particularly the males, were adversely affected. You can see, even by Day 7, in the males, that the animals are losing weight. None of the other dose groups were differentiable

from controls. The weight loss -- this, by the way, is a slide of body weight gain, not absolute body weight.

So throughout the 28-day period, the high-dose animals were unable to even get back to their starting weights.

Females, interestingly enough, did not show statistically significant difference at the high dose. There certainly was a tendency there. In fact, 3 females did lose weight in the first week.

However, 1 of the 5 females steadfastly refused to lose any weight. And she was the one who made sure that this was not a statistically significant effect, but the tendency is there. And, again, there is no strong tendency at any -- at either the low or the mid-dose for weight loss.

The conclusion we draw from this is that the high-dose males -- less so the females -- are not well at the high dose, while the animals appear unaffected at the low and mid-doses.

Next overhead.

Clinical Signs. High-dose animals full of clinical signs. Mucous membrane and respiratory tract irritation evidenced by reddish

nasal discharge, salivation, and eye discharge resulting in a changed breathing pattern and whooping respiration, intensified cleaning behavior, stretched posture, eyelid closure, somnolence, ruffled fur.

Certain of these signs, the ruffled fur and the respiratory sounds, eventually became irreversible. In other words, at the beginning of

8 the experiment, at the high dose, the animals would
9 exhibit these signs at the -- for the duration of the
10 exposure but would soon recover. After a few days,
11 they didn't recover anymore.

12 At the mid-dose, we saw eyelid
13 closure, somnolence, and ruffled fur. These types of
14 signs are difficult to interpret. The only
15 conclusion that I draw from this is evidence of
16 failure to thrive. No other strong conclusions
17 possible. But the animals certainly affected at the
18 mid-dose. And no clinical signs at the low dose.

19 Next overhead.

20 Hematology Results. Hematology did
21 evidence some response, particularly in the males at
22 both the mid and the high doses. This is a table of
23 neutrophilic polymorphonuclear granulocytes.

24 PMNs are considered primary
25 nonspecific respondents to infection. In this case

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1 the response may be to some sort of tissue damage.
2 This effect was considered evidence by the contract
3 lab itself of lung inflammation, though it must be
4 regarded as inferential, as the measurements were
5 from the general circulation, not from the lung
6 itself.

7 Nonetheless, we do see a statistically
8 significant effect in males at the mid-dose.
9 Granted, it's only about maybe a 30, 40 percent
10 effect. It goes up to more than a tripling at the
11 high dose. Females -- the statistically significant
12 effect is only present at the high dose.

13 Next overhead.

14 Now we get into the area that's caused
15 a lot of discussion, shall I say, between
16 ourselves -- among ourselves in the medical
17 toxicology branch, between DPR and OEHHA, and
18 ultimately with the panel as well.

19 The histopathology results on the lung
20 and on the whole respiratory tree. At the high dose,
21 rhinitis, which is a nasal mucous membrane
22 inflammation; metaplasia of the nasal epithelium;
23 tracheal epithelial proliferation and single-cell
24 necrosis; bronchopneumonia; bronchial and bronchiolar
25 epithelial proliferation; emphysema; and nasal

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1 epithelial atrophy.

2 These animals are highly affected in
3 the lung at the high dose.

4 At 6.8 and 1.7 ppm, I'm going to give
5 you evidence that nasal epithelial atrophy was
6 increased at these two -- at the mid- and the low
7 doses. It is not overwhelming evidence. And our
8 conclusions require a lot of -- required a lot of
9 thought, a lot of discussion. And I'll try and show
10 you the evidence now.

11 Number -- next overhead.

12 CHAIRMAN FROINES: I would stick to the

13 objective evidence and leave out some of the
14 subjective talk about the evidence.
15 DR. RUBIN: Okay. Okay.
16 What the study did was to take
17 histopathologic -- four histopathologic sections from
18 each animal, numbered S1 through S4. If you -- the
19 first thing you notice, when you look at these, at
20 the incidence data, is that there was no nasal
21 epithelial atrophy in Section Plane 1 for some reason
22 never explained in the study.

23 The only conclusion that I could come
24 to was that, for whatever reason, S1 was not
25 influenced in this particular effect. Either the

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1 proper -- the appropriate cell types were not there,
2 there was something about how the MITC was entering
3 into the nasal cavity -- we just don't know.
4 If you look at S2, you'll see we have
5 it divided up as focal and nonfocal nasal epithelial
6 atrophy. In males, the very top line there --
7 I don't have a pointer here. Is there
8 a pointer here? Okay.
9 -- you see an increase -- from 1
10 animal of 5, to 2 animals of 5 -- between the control
11 and the low dose, no further increase at the
12 mid-dose, and going to zero at the high dose.

13 Same with females -- from 1 to 3, to 1
14 to zero. If that were the only incidence that we
15 were looking at, I would have said right away that
16 nothing happened in this experiment with respect to
17 nasal epithelial atrophy.

18 However, if you look at nonfocal
19 atrophy, which we are interpreting as a somewhat
20 more serious level of atrophy -- in other words, the
21 focal islands of atrophy, if you will --

22 Have it now? Oh, thank you.

23 Let's see here. We're looking at the
24 Row 2 here. The focal islands of atrophy have now
25 spread and become indistinguishable from each other,

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1 if you will. That's an interpretation on our part.
2 You'll see that in males, it goes 1 in 5, 1 in 5 --
3 whoops. I'm highlighting the water in here -- to 2
4 of 5, to 5 of 5.

5 So, by the high dose, all the animals
6 are experiencing nonfocal nasal epithelial atrophy
7 and the same with the females. What we're interested
8 in here is that, since the focal atrophy is going
9 down and the nonfocal atrophy is going up, we are
10 persuaded that there is an increase in severity
11 between the low dose and the mid-dose and that, in
12 fact, between the control and the low dose, there's
13 an increase in nonfocal atrophy, which eventually, as
14 you go up in dose, becomes nonfocal.

15 In neither of the remaining two
16 section planes do you see a strong effect in this
17 direction. You do see some evidence in males at

18 the -- in S3 for an increase in focal. No evidence
19 in females. And absolutely no evidence in Section
20 Plane 4.

21 My interpretation of this was that
22 Section Plane 2 was the farthest out toward the air
23 and may have received a larger effect of MITC dose.
24 I fully recognize that we're dealing with very low
25 numbers here. So I want to make sure that you're
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1 aware of this.

2 If you look at the data on a per-rat
3 basis -- next overhead -- in other words --

4 PANEL MEMBER FUCALORO: Excuse me. You had
5 some uncertainties about interpretation of the paper,
6 I mean, that you mentioned.

7 DR. RUBIN: Yeah.

8 PANEL MEMBER FUCALORO: Was there any attempt
9 to contact the authors?

10 DR. RUBIN: No. I never -- this was a study
11 done in 19 --

12 PANEL MEMBER FUCALORO: 86.

13 DR. RUBIN: -- 86? Yeah. Well, put out --

14 PANEL MEMBER FUCALORO: Well, published in
15 '87.

16 DR. RUBIN: Well, put out in '87.

17 PANEL MEMBER FUCALORO: Sure.

18 DR. RUBIN: It was done in Germany.

19 PANEL MEMBER FUCALORO: Ich spreche Deutsch.

20 DR. RUBIN: Yiddish.

21 PANEL MEMBER FUCALORO: And that too. I'm
22 from Brooklyn.

23 DR. RUBIN: Yes. So -- no. The answer is no.

24 PANEL MEMBER FUCALORO: Okay.

25 DR. RUBIN: However, I will say that the study

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1 authors never even mention nasal epithelial atrophy
2 as an effect. This came out of the toxicological
3 analysis of the study done by DPR, in particular
4 Dr. Tom Moore, who did the initial analysis of this
5 study. It was concurred upon by OEHHA, as well.

6 The next slide -- overhead --

7 Number 8.

8 PANEL MEMBER FUCALORO: Let me just follow up.
9 I mean, what you're getting at -- I mean, rather than
10 just, you know, we're getting this line of
11 reasoning -- you're getting at how you chose a
12 LOEL --

13 DR. RUBIN: Yes.

14 PANEL MEMBER FUCALORO: Isn't that basically
15 where you're going?

16 DR. RUBIN: Yeah.

17 PANEL MEMBER FUCALORO: And you're opting for
18 the lower concentration, I can gather from -- infer
19 from your comments.

20 DR. RUBIN: Yeah.

21 PANEL MEMBER FUCALORO: Okay.

22 DR. RUBIN: This slide is the last data slide.

23 Instead of looking at the data with respect to
24 section plane incidence, you combine the incidence
25 from each section plane and express, instead, on
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1 per-rat basis. You see the same pattern,
2 particularly if you look at the total. In other
3 words, you combine males and females. It goes from 3
4 of 10, to 5 of 10.
5 And then, as we now expect, the focal
6 starts to go down a little bit and then goes
7 seriously down by the high dose; whereas, the
8 nonfocal atrophy goes up all the way through the
9 experiment until all the animals are experiencing
10 this at the high dose.
11 Now, if you combine both focal and
12 nonfocal atrophy -- which, I believe, is valid
13 because I believe them to be part and parcel of the
14 same process -- you'll see that it goes from 3 of 10,
15 to 6 of 10, stays at 6 of 10, and goes to 10 of 10.
16 This is not a statistical -- at the low dose or the
17 mid-dose is not a statistically significant effect.
18 I've now, at the urging of the panel,
19 put in a back calculation, if you will, of the
20 Fischer exact calculations -- what would it -- how
21 many animals would it have taken to generate a
22 statistically significant effect at the low dose?
23 And by my calculation, it would have
24 taken anywhere from 18 to 22 animals to get a
25 statistically significant effect.

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1 If, instead of looking at the data on
2 a per-animal basis, you look -- you just count up all
3 the sensitive or the susceptible section planes, you
4 see that it goes from 6 out of 30 total section
5 planes, to 11 out of 30, stays at 11, and then goes
6 to 30. In other words, all the section planes showed
7 nasal epithelial atrophy.
8 Next slide. Conclusion: The
9 incidence of nasal epithelial atrophy rose at the low
10 dose of 1.7 ppm.
11 Next slide. Here, I just tried to
12 summarize the strengths and weaknesses.
13 I'll start with the weaknesses. For
14 the most part, statistical significance was not
15 achieved until the high dose. 2 of the 3 section
16 planes showed little or no evidence of response at
17 the low and mid-doses. And there was only
18 inferential evidence of increased severity, but it's
19 one that I support strongly.
20 In other words, that focal-to-nonfocal
21 progression that occurred between the low and
22 mid-doses in Section Plane 2 was evidence of the
23 increased severity.
24 The strengths of pointing out low
25 doses as the LOEL -- first, that such an effect was
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1 plausible in view of the known irritant properties of

2 the compound and, I would add, in view of what
3 happened to the animals at the high dose, which is
4 severe irritation.
5 2. The most clearly affected section
6 was Section Plane 2, which was the closest to the
7 outside air and thus likely received the higher
8 effective MITC dose.
9 3. Females showed a statistically
10 significant -- I forgot to show you this with the
11 section planes. Females showed a statistically
12 significant increase in total atrophy at the low dose
13 when incidence was expressed as the fraction of all
14 the section planes exhibiting this character.
15 4. Focal and nonfocal atrophy
16 represented a progression in the severity of a single
17 pathologic process. Thus it was legitimate to
18 consider their incidence rates together as
19 representative of total atrophy. Thus we can accept
20 that there was an increase in severity when going
21 from the low to the mid-dose.
22 And, 5, total atrophy when expressed
23 on a per-rat-incidence basis was increased in both
24 sexes at the low dose.
25 Next slide.

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1 PANEL MEMBER FRIEDMAN: Can I interrupt? I
2 have a question regarding Number 2. I thought I
3 heard you say before that you surmised that the
4 Section 2 was closest to the outside. Did the
5 authors actually state that it was?
6 DR. RUBIN: The authors never state this. It
7 was a deduction that I did based on the appearance of
8 the data. There's a fair amount of inference in this
9 data. I would not even attempt to hide it.
10 The fact that we saw an effect in
11 Section Plane 2 and not in section plane -- and less
12 so in 3 and less so, again, in 4 was some evidence.
13 I would add that metaplasia of the
14 nasal epithelium, which is something that was only
15 seen at the high dose, only occurred in Section Plane
16 1. So that also was some evidence that Section Plane
17 1 was closest to the outer edge.
18 I practically memorized this study
19 looking for some evidence of -- some statement of the
20 direction of these cuts but --
21 PANEL MEMBER BLANC: But there's no inference
22 that it's directional? You're just not sure which
23 direction it is, but there's clearly directionality?
24 DR. RUBIN: Yeah. That's correct.
25 PANEL MEMBER BLANC: So that's not a

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1 presumption?
2 DR. RUBIN: That's correct.
3 PANEL MEMBER BLANC: So that's important and
4 consistent with a biological mechanism.
5 PANEL MEMBER FRIEDMAN: What do you mean
6 "directionality"?

7 PANEL MEMBER BLANC: Sequence. Either it's
8 the closest in or the farthest away. And either of
9 one of them, you could invoke the biological
10 mechanisms. That would make sense.

11 What wouldn't make sense is if it was
12 some random pattern where it was 2 and then not 3 and
13 then 4. That would be far more difficult. But there
14 are various hype- -- biologically consistent
15 mechanisms why something that's closest or farthest
16 may be the most affected.

17 PANEL MEMBER FRIEDMAN: But we don't know
18 whether it's --

19 PANEL MEMBER BLANC: But I'm saying it doesn't
20 matter. What matters is that there's directionality.

21 PANEL MEMBER FRIEDMAN: I think we didn't know
22 where those cuts were made.

23 PANEL MEMBER BLANC: Well, I think -- I think
24 that any scientific -- I think it's rational that, if
25 their order -- if they're in some direction, that the
0025 ordering isn't random of the planes. You may not be
1 able to say, directionally, which plane was -- with
2 complete certainty, which plane was closest to the
3 outside air.

4 But there's no reason -- it would be
5 illogical to approach the data that the sections --
6 if they're numbered 1, 2, 3, 4, 5 -- are in random
7 sequence.

8 PANEL MEMBER FRIEDMAN: Then why isn't Number
9 1 closest to the outside or farthest in? Why is it
10 Number 2?

11 PANEL MEMBER BLANC: Oh, I don't -- he's not
12 saying that Number -- he is saying that Number 1
13 precedes Number 2.

14 Is that your statement?

15 DR. RUBIN: Yes.

16 CHAIRMAN FROINES: Quite frankly --

17 PANEL MEMBER FUCALORO: There's nothing there.

18 CHAIRMAN FROINES: -- that I think we should
19 stop talking about what is closest because we haven't
20 the slightest idea which is closest.

21 PANEL MEMBER BLANC: No. But I'm saying it
22 doesn't matter.

23 CHAIRMAN FROINES: I agree with you. I don't
24 think that's an issue. But I think we -- well, I
0026 want to get away -- I want to stay away from
1 speculation. I want to stay with what we know rather
2 than speculate what may be and draw conclusions based
3 on what we know rather than --

4 PANEL MEMBER BLANC: And all I'm saying is
5 that we don't need to invoke a discussion of what's
6 closest and what's farthest as long as there's a
7 systematic effect.

8 And I would also say that I actually
9 disagree with Number 1 under the "Weakness" column as
10 a relevant point because the data, in the same way
11

12 that there's directionality, in fact, there's a dose
13 response.

14 And what surprises me in all of the
15 discussion that you present, although it's inherent
16 in the benchmark approach, is that, in fact, these
17 data are statistically significant in chi square test
18 for trend.

19 And that's true if you separate them
20 by gender or if you do summary chi square stratified
21 by gender with a summary statistic. And, in fact,
22 it's less likely to be chance when you look at it as
23 a test for trend than if you look at the highest
24 versus the lowest and the middle versus the control
25 and the lowest versus the control.

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1 So to me it doesn't matter that, in
2 isolation, the lowest exposure dose is not, in and of
3 itself, statistically significant because I don't
4 think that would be the correct statistical analytic
5 approach in any event. And I would appreciate Stan's
6 comment in that regard.

7 PANEL MEMBER GLANTZ: Yeah. I totally agree
8 with that. And that's why I was encouraging you to
9 use the benchmark dose approach because that allows
10 for a dose-response relationship.

11 So I mean -- in the other thing, I
12 mean I think that the point that you've already made
13 about there being low power in the study is another
14 important point.

15 I mean I did a similar kind of
16 calculation to what you did. Just asked, you know,
17 "If we had the same pattern and the results, how
18 big -- how big would the study have had to be?"

19 And I came up with about the same. I
20 came up with, I think, 15 rats. But really it's
21 about the same as what you did -- 15 or 20.

22 PANEL MEMBER BLANC: By my calculation, the
23 "Keisware" test for trend with a strat -- adding the
24 stratification male-female -- P-value of .004.

25 DR. RUBIN: That's pretty -- fairly

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1 significant.

2 PANEL MEMBER BLANC: And if you a priori
3 combined the males and females into a single 2-by-4
4 "Keisware" test for trend, it has a P-value
5 associated with it of .003. So but -- so there
6 isn't even a need to do the a priori combination of
7 the males and females in order to choose statistical
8 significance.

9 PANEL MEMBER GLANTZ: Yeah. I think that
10 ought to be added. I hadn't thought of doing a test
11 for trend. But I think that would be worth it -- the
12 points that Paul just made ought to be added to the
13 report.

14 DR. RUBIN: Okay. Point taken.

15 Can I move on? Just a couple more
16 slides. Since we are interested in ambient--

17 CHAIRMAN FROINES: I think that, at some
18 point, we should have a larger discussion about this
19 notion of statistical significance. I come from
20 UCLA, where we have people like Sander Greenland,
21 who never would accept a statement about statistical
22 significance.

23 And certainly Paul and Stan, I think,
24 are in the same camp. And so this notion of tying
25 decision-makings in public health context to a simple

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1 P-value, I think is -- we should try and avoid that
2 simplicity.

3 DR. RUBIN: Right. I mean I totally agree
4 with that. And I think this analysis is evidence of
5 my opinion on that. You -- we are interested in, for
6 the 1807 process, in ambient and in application site
7 air.

8 When we get a study -- when we get an
9 inhalation study, it's an intermittent exposure --
10 this one being 6 hours per day, 5 days per week --
11 and we feel it necessary to make some kind of
12 transformation of the data to estimate what would be
13 the equivalent toxicologic effect were the animals
14 exposed or were people, as it were, exposed all of
15 the time -- in other words, 24 hours a day, 7 days
16 per week.

17 We use a Haber's law extrapolation to
18 do this. In other words, we basically make a
19 proportionality going from 5 days a week to 7 days a
20 week and from 6 hours a day to 24 hours a day. And
21 that cuts the LOEL from 1.7 ppm to 300 ppb.

22 This is not -- I actually called Peter
23 Witschi on this point. Not everyone would agree
24 wholeheartedly with invoking Haber's law in a
25 situation where you have an irritant, but it is a

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1 default that we are using so that we can estimate an
2 effect level for people that are constantly exposed.

3 Due to the considerable uncertainties
4 inherent both in establishing an effect at the low
5 dose and in the applicability of Haber's law in the
6 case of a subchronic irritational response, an
7 uncertainty factor of 3, instead of 10, was used to
8 estimate the critical subchronic NOEL of a
9 hundred ppb.

10 Next slide. Okay. This slide grew
11 out of all the --

12 PANEL MEMBER FRIEDMAN: I'm sorry to interrupt
13 again. If there's greater uncertainty, why would you
14 use a smaller uncertainty factor? Because of this
15 great uncertainty, instead of using a factor of 10,
16 you use a factor of 3. I don't quite understand that
17 reasoning.

18 DR. RUBIN: Well, I -- my view of a straight
19 Haber's law extrapolation is that this would be -- in
20 my view, anyway, this is probably -- possibly an
21 overestimate of the effect.

22 PANEL MEMBER FRIEDMAN: I see. So you're
23 worried about uncertainty in that direction, not in
24 either direction?
25 DR. RUBIN: Right.

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1 CHAIRMAN FROINES: I don't understand what --
2 PANEL MEMBER BLANC: I think -- let me see if
3 I understand what you're saying. What you're
4 saying -- and I think it's not unreasonable.
5 What you're saying is that, because
6 you're dealing with an irritant response, which is
7 likely to be more potent with a high -- with a high
8 dose and not linear in its response in that way, that
9 smoothing it out using Haber's law is extremely
10 conservative --
11 DR. RUBIN: Yes.
12 PANEL MEMBER BLANC: -- because it's -- with
13 an irritant response, one might presume that it's far
14 more important to have a short-term, high-level
15 exposure than a longer-term, low-level exposure. And
16 since that, in itself, is quite conservative, that
17 further multiplying that by a factor of 10 would be
18 less appropriate than using a factor of 3. Is that
19 a --
20 DR. RUBIN: That's a fair statement.
21 PANEL MEMBER FUCALORO: Yes.
22 PANEL MEMBER GLANTZ: Yes. I actually thought
23 about that too. And I agree with that too, although
24 I did have to think about it a little bit. It might
25 help the document to just take the -- use what Paul

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1 just put forth and just add a sentence in the
2 document in the appropriate place 'cause it did --
3 when I first read it, I had exactly the same reaction
4 Gary did.
5 DR. RUBIN: I'll have to go back and read what
6 I actually said there.
7 PANEL MEMBER GLANTZ: Yeah.
8 DR. RUBIN: Okay. On benchmark dose
9 modelling, the benchmark dose approach offers an
10 alternative to the conventional NOEL-LOEL approach to
11 determining regulatory doses or concentrations.
12 The benchmark dose is -- I'm quoting
13 from a US-EPA document. Crump was the first author
14 on this document. "Benchmark dose is a statistical
15 lower confidence limit on the dose, producing a
16 predetermined level of change in adverse response
17 compared with the response in untreated animals."
18 A major advantage -- or it's possible
19 that it could be a disadvantage in some cases --
20 benchmark dose values are established by modelling
21 the dose-response relationship using the entire data
22 set from a toxicologic study as opposed to using the
23 single determining LOEL dose relied upon in the
24 conventional approach.
25 Now, that means, of course, that

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1 what's happening at the high dose is influencing the
2 slope of the curve at the low dose where we're
3 interested in establishing regulatory NOEL values.
4 I'm not sure at all that that's biologically
5 justifiable, but it may be. We just don't know.
6 In the current case, using the per-rat
7 nasal epithelial atrophy incidence data -- the 3 in
8 10, 6 in 10, 6 in 10, 10 of 10 -- and using Haber
9 converted air concentrations -- in other words,
10 instead of converting the final effect, we just
11 convert the concentrations that they were exposed
12 to -- we found that they -- that these data were best
13 approximated by a probit curve model.

14 This was also pointed out to us by
15 OEHHA in their critique of our document. Using this
16 model, the 5 percent lower bound effect level was 75
17 parts per billion, and the 10 percent lower effect
18 level was 148 parts per billion. These values
19 effectively bracketed and supported the
20 conventionally derived NOEL of a hundred ppb.

21 So we feel that's fairly strong
22 support. In other words, if you invoke the entire
23 incidence curve, you get a number pretty close to the
24 LOEL value that we calculated. There are
25 uncertainties in both approaches, but they support

0034 each other, in my opinion and in the opinion of
1 Dr. Glantz, if I may say.

2 PANEL MEMBER GLANTZ: Yeah. Yeah. I think
3 this really strengthens and complements the previous
4 discussion. And also I think -- the one thing which
5 I told Andy I won't, like, hammer on -- but I really
6 think it would be helpful to put the graph in the
7 document to illustrate that it is, in fact --

8 PANEL MEMBER FUCALORO: I think so.

9 PANEL MEMBER GLANTZ: I mean there's very
10 limited data here. So it's not dazzling. But I
11 think putting that, the graph showing the fit in,
12 would be a nice thing to add. I won't, like, insist
13 on it. But I would like to see it in there.

14 And I don't know what other people
15 think or thought about it. Okay. I guess you don't
16 have to put the graph in there. No one else is
17 jumping up and down. But it would make me very
18 happy.

19 CHAIRMAN FROINES: It seems to me that there's
20 an interesting policy dilemma that you have. Your
21 standard -- what do you call it? -- your
22 conventionally derived value is the methodology that
23 was established by the Food and Drug Administration
24 in 1957.

0035 1 DR. RUBIN: Uh-huh.
2 CHAIRMAN FROINES: And then we have the

3 benchmark approach that Kenny Crump first described
4 in 1983.

5 DR. RUBIN: Uh-huh.

6 CHAIRMAN FROINES: And here we are in 2002.
7 And we're using the conventional approach, which is
8 now 45 years old, as the method of operation.
9 And it seems to me that, when we have
10 data that -- we've spent so much time talking about
11 the benchmark approach with Melanie because, in some
12 cases, they have data and can use the benchmark
13 approach and, in some cases, they don't have the data
14 to use the benchmark approach.

15 But where they have the data, they
16 consider it the better approach to developing risk
17 assessment for noncancer endpoints.

18 And so it seems to me that it would be
19 valuable for DPR to move to at least 1983 on this
20 issue rather than sticking with the Food and Drug
21 Administration, who originally designed this approach
22 to define how much filth should be allowed in food.

23 And it seems to me it's time to move
24 past that because you -- because at some level, OEHHA
25 and -- both you, using the benchmark approach, come

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1 up with a value of around 75.

2 DR. RUBIN: Yeah.

3 CHAIRMAN FROINES: You then -- what you call
4 the 6.7 percent effect level in your document -- but
5 the .05 level -- the 5 percent level -- is the 75
6 percent level.

7 So, in essence, you're make a policy
8 decision to accept a less -- a greater effect, if you
9 will, greater percentage effect than the 5 percent
10 level. So you are not taking the same level of
11 methodologic conservatism that the benchmark approach
12 gives you at the 5 percent level.

13 And it seems to me that one should
14 say, "Okay. Now, why is 6.7 percent an acceptable
15 value when by, in general, people would accept 5
16 percent?"

17 So that there's a contradiction, it
18 seems to me. And to say, "We're going to stick with
19 the 6.7 percent effect level because that's the way
20 we've been doing it from time immemorial," probably
21 is not the best answer to the question.

22 So it's not something that we need to
23 resolve today, but it is certainly something we need
24 to resolve over a period of time because clearly the
25 benchmark approach, where there is adequate data,

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1 seems to be the better approach.

2 Tobi?

3 ASSISTANT DIRECTOR JONES: Could I speak to
4 the panel? And for those of you who have forgotten
5 who I am, I am Tobi Jones, Assistant Director of
6 Division of Registration Health Evaluation.

7 And I think what Andy can tell you in
8 a lot more detail than I, as the generalist manager
9 of the division, is we're in the process of
10 evaluating, using benchmark dose as a methodological

11 tool, working very closely at -- OEHHA uses it.

12 I think the discussion that Andy has
13 had with members of the panel on this particular
14 study has been very useful to him in seeing how it's
15 applied.

16 I don't think we're quite ready to
17 make that entire conversion. And I think, if -- you
18 know, if you would like further discussion here on
19 where we are in that deliberation, Andy is probably
20 perhaps the better one to discuss that. So, yes, I
21 think we take your comments to heart, John. But
22 we're not quite there in making that wholesale
23 conversion. Okay?

24 PANEL MEMBER GLANTZ: Well, if I could just --
25 I think, as a practical matter and as Andy just

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1 pointed out, you get about the same number either
2 way. And given the uncertainties that are implicit
3 in all these calculations, I don't think it's worth
4 having a huge fight about. So I think you've moved a
5 little bit by even agreeing to put it in the report.

6 But I really strongly agree with John.

7 I think that the benchmark dose
8 approach, when you have the data to do it, is a much,
9 much more dependable way to approach these issues
10 because it makes use of all the data at once, because
11 it's based on a more plausible sort of model --
12 mathematical model of what's going on, and because it
13 doesn't have the problem that you always have when
14 you do these NOEL-LOEL calculations where the results
15 are a strong function of what dose you happen to
16 study. And so --

17 PANEL MEMBER FUCALORO: That's right.

18 PANEL MEMBER GLANTZ: -- you know, if the
19 Klimisch group had picked different doses for their
20 study, you'd have come up with different numbers.
21 And that's -- I think it's a real problem.

22 Whereas, when you use the benchmark
23 approach, as long as you're assuming a reasonable
24 mathematical function for the dose-response
25 relationship, the results are going to be much less

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1 dependent on which specific doses you study.

2 CHAIRMAN FROINES: And one can look at
3 different mathematical formulations for that dose
4 response.

5 PANEL MEMBER GLANTZ: Yes.

6 CHAIRMAN FROINES: One doesn't only have to
7 use the probit model.

8 PANEL MEMBER GLANTZ: Well, that's true too.
9 And, you know, it's always nice if you do that and
10 you find the results are not too -- not relatively
11 insensitive to that assumption.

12 So, you know, I think in the context
13 of this report, you know, I don't think we gain
14 anything by hammering on this, at this point,
15 especially since the department does seem to be

16 thinking about moving into the 80's on this issue.
17 But I really think it would be much
18 better if that was the -- I mean, if I had my
19 druthers, that's how you'd do it.

20 PANEL MEMBER FUCALORO: Yeah.

21 PANEL MEMBER GLANTZ: And, in fact, just for
22 the record, since we may not get to Melanie's REL
23 document, there's one place in there where she
24 actually did it your way. And I heard her saying,
25 "No. No. Go back to your benchmark model."

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1 CHAIRMAN FROINES: I'm not arguing that you
2 make changes, but I just wanted to make the point
3 that --

4 ASSISTANT DIRECTOR JONES: I wanted --

5 PANEL MEMBER GLANTZ: I guess what we're
6 saying -- it would be nice, when the next document
7 comes, if you could do it.

8 ASSISTANT DIRECTOR JONES: Yeah. But I think
9 one thing to keep in mind is we work very closely
10 with US EPA. They do not wholesale use the benchmark
11 test approach.

12 PANEL MEMBER FUCALORO: What? I can't hear
13 you.

14 ASSISTANT DIRECTOR JONES: They do not use
15 wholesale on anything --

16 PANEL MEMBER BLANC: Well, it is lucky -- it's
17 lucky for federal EPA, then, that they don't have to
18 come to this panel. But you do. And I would take
19 very seriously what John Froines --

20 PANEL MEMBER FUCALORO: You're tough guys,
21 Mike.

22 PANEL MEMBER BLANC: -- said because we will
23 not be generous if a document comes to --

24 ASSISTANT DIRECTOR JONES: My point being,
25 though, that because we work closely with them, in

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1 doing risk assessments on pesticides --

2 PANEL MEMBER GLANTZ: Right. Right.

3 ASSISTANT DIRECTOR JONES: -- of course, we're
4 very interested in using the most applicable
5 methodology. But at the same time, you know,
6 completely ignoring what EPA's doing all the time
7 doesn't maintain a good dialogue.

8 PANEL MEMBER FUCALORO: May I ask a question?
9 Let me say is there any controversy that, when the
10 benchmark approach is applicable, it is superior to
11 the other? Is there any controversy in that
12 statement?

13 If there's none, it seems to me that
14 the benchmark approach would be the one you should be
15 moving toward. I mean that's that --

16 DR. RUBIN: I'm not sure that there's --

17 PANEL MEMBER FUCALORO: Or, in fact, if
18 there's even a superior one -- you said the 80's. Is
19 there something even better yet? I'm not a
20 statistician. But if, in fact, there were -- it

21 seems to me that what's being said here, I agree
22 with. If you can use the benchmark approach because
23 it is a superior approach, it gives us better values,
24 by all means.

25 I think that's what you're saying,

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1 though. I understand. I understand that you have --

2 ASSISTANT DIRECTOR JONES: I'm not --

3 PANEL MEMBER FUCALORO: I understand that you
4 also have to converse with EPA --

5 ASSISTANT DIRECTOR JONES: I'm not a -- I
6 would leave the question of superiority of a
7 technique like that to Andy to comment on. I would
8 say, from Andy's supervisor -- Dr. Pfeifer -- I don't
9 think we're quite there yet in assuming in all cases
10 that it is the superior approach. But Andy's the
11 toxicologist.

12 CHAIRMAN FROINES: Why don't we leave it to --
13 well, I mean I'm at fault for raising a general issue
14 but --

15 PANEL MEMBER GLANTZ: Well, I actually just
16 want to pound on this slightly more.

17 PANEL MEMBER FUCALORO: Keep going.

18 PANEL MEMBER GLANTZ: No. I think this is an
19 important point. I mean the -- we're not saying that
20 you should always use it mindlessly. But I think, in
21 this case, it would have been better. And when you
22 can, you should.

23 As for the EPA, the federal EPA -- and
24 some of my best -- I have lots of friends at the
25 federal EPA. But, you know, this panel has a long

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1 history of considering what the federal EPA says and
2 thinks but not being the least bit bound by it. And
3 we like to think often we do a better job than they
4 do --

5 CHAIRMAN FROINES: I think that the --

6 PANEL MEMBER GLANTZ: -- or California does a
7 better job than they do.

8 CHAIRMAN FROINES: There is -- there are --
9 since Stan went a little bit ahead, I'll go a little
10 ahead too.

11 PANEL MEMBER GLANTZ: He and I are, like, a
12 really bad influence on each other.

13 PANEL MEMBER FUCALORO: Let's not go over the
14 top here.

15 CHAIRMAN FROINES: But I'll make -- I just
16 want to make one comment. And that is that obviously
17 one of the limitations of the benchmark dose is the
18 quality of the dose data. If you have poor exposure
19 information, you have a hard time using it.

20 Oftentimes we have very bad or very
21 weak exposure assessment data. And that comes from
22 the fact that the studies that we have to work with
23 did not do an effective job, either in toxicology or
24 in epidemiology, to do adequate exposure assessment.

25 Then what happens is people come in

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1 and comment and say, "The exposure assessment data
2 wasn't very good; so therefore you can't take this
3 study very seriously."

4 So we start to reward poor exposure
5 assessment. And that's obviously contradictory. It
6 seems to me that we have to do what we can to get as
7 good exposure data so we can use the more advanced
8 models.

9 The more -- this is not -- I mean this
10 is a probit model looking at dose response. This
11 isn't the beeswax you, you know. I mean this is a
12 fairly simple-minded innovation when you think about
13 it.

14 So that but it does depend upon the
15 exposure information, which does take us back to the
16 larger issue of "How adequate are the studies that we
17 have to work with?" And that's a topic for another
18 discussion, I think.

19 PANEL MEMBER BLANC: Can I ask a procedural
20 question?

21 CHAIRMAN FROINES: Sure.

22 PANEL MEMBER BLANC: Andy, in terms of the
23 other points that, in your first overhead --

24 DR. RUBIN: The 9 points?

25 PANEL MEMBER BLANC: Yeah.

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1 -- at what point would you like us to
2 engage you on those?

3 DR. RUBIN: I'm -- at any time you wish. I
4 realize we're -- there's a time factor here and
5 whether we can get through the other presentations,
6 but I'm, you know -- I'm prepared to answer any
7 questions.

8 PANEL MEMBER BLANC: Well, will you clarify
9 how the other presentations will deal with this
10 document? Or are the other presentations on another
11 topic?

12 DR. RUBIN: The other presentations today on
13 another topic.

14 PANEL MEMBER BLANC: So you're the only
15 presenter?

16 DR. RUBIN: This is it on MITC.

17 PANEL MEMBER BLANC: You finished your
18 presentation? Okay. So then I have a rather
19 substantive area of discussion related to your
20 presentation.

21 DR. RUBIN: Yeah.

22 PANEL MEMBER BLANC: And it would help me for
23 you to clarify, because it's been a while since the
24 last presentation, to what extent does the current
25 health assessment revision in terms of including this

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1 critical data from the Earlimart incident differ from
2 the last document? It's not formatted in a way that
3 I can actually see what's a text change. Was that
4 included at all previously or --

5 DR. RUBIN: No. No. It's a totally new
6 section.
7 PANEL MEMBER BLANC: Can I, then, that being
8 said --
9 DR. RUBIN: Yeah.
10 PANEL MEMBER BLANC: What didn't -- what I
11 could not grasp easily in the document -- and let me
12 walk you through this.
13 So -- I want to make sure I understood
14 the data -- based on mathematical modelling of the
15 exposure in this real-world incident, it was felt
16 that most of the people who were symptomatic had
17 experienced acute exposures of between .5 and 1 part
18 per million --
19 DR. RUBIN: That's right.
20 PANEL MEMBER BLANC: -- is that correct?
21 So in other words, at 500 to a
22 thousand parts per billion but certainly as at low --
23 at as low a level as 500 parts per billion, 80
24 percent of the people seemed to be symptomatic or
25 some number like that.
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1 DR. RUBIN: Yes. In other words, several days
2 after the incident, a DPR team went in there and
3 interviewed people in the neighborhood.
4 PANEL MEMBER BLANC: Right. Right.
5 DR. RUBIN: It's not -- they didn't attempt to
6 cover the entire neighborhood. But they
7 interviewed -- I don't know -- a hundred and seventy
8 people or something like that and found that a very
9 high proportion of those people experienced
10 irritation-type symptoms and other symptoms --
11 dizziness and things like that.
12 PANEL MEMBER BLANC: Right. Right. Just
13 talking about the irritation, let's take that which
14 is the most straightforward in those kinds of
15 incidents. And yet the NOEL upon you which you base
16 your acute exposure value was 220 parts per billion,
17 based on a laboratory experiment with fairly pure --
18 DR. RUBIN: Yes.
19 PANEL MEMBER BLANC: -- MITC.
20 I felt very uncomfortable with 220
21 parts per billion being the NOEL if, at 500 parts
22 per billion, 80 percent of those exposed were having
23 acute irritant symptoms.
24 DR. RUBIN: I looked at this -- it's funny
25 because I looked at those data as being quite
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1 supportive of that, of the LOEL and NOEL. In other
2 words, those people were exposed at the very lowest
3 concentration that the people in the lab were
4 exposed -- now, that was a human study, if you
5 remember -- and experienced similar symptoms.
6 In my book, that was supportive of the
7 LOEL determination.
8 PANEL MEMBER BLANC: Well, perhaps you should
9 walk us through exactly what the NOEL and LOEL were

10 in the laboratories. The reason why it's critical is
11 because, in the real world, of course, when you have
12 a metam sodium release, people are not only exposed
13 to MITC, they're exposed to hydrogen sulfide and MIC.
14 And all three of those are clearly mucous membrane
15 irritants.

16 DR. RUBIN: Right. Well, the human eye
17 irritation experiment was done using MITC under
18 highly controlled conditions -- humans. U.C. Davis
19 Medical Center established a LOEL dose of a 800 ppb
20 based on subjective eye irritation -- in other words,
21 "My eyes feel irritated."

22 And they had a statistical method for
23 determining how, you know, whether --

24 PANEL MEMBER BLANC: Right.

25 DR. RUBIN: -- it was something there or not.

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1 PANEL MEMBER BLANC: And what was the dose
2 below 800?

3 DR. RUBIN: 220.

4 PANEL MEMBER BLANC: Was the next low dose at
5 which they had --

6 DR. RUBIN: The next lowest dose --

7 PANEL MEMBER BLANC: But wouldn't your data
8 from Earlimart suggest that 500 parts per billion,
9 not very conservatively, is the lowest effect level
10 if you're saying your modelling was absolutely
11 correct and that there was not anything like the
12 linear response? There was some kind of threshold.

13 But doesn't that suggest that the
14 lowest effect level was not 800 but 500 parts per
15 billion? And certainly you don't have a
16 500-parts-per-billion exposure level in the
17 experimental study.

18 DR. RUBIN: Yeah.

19 CHAIRMAN FROINES: How many people were in the
20 experiment?

21 DR. RUBIN: There were 9 to 16 people per
22 dose. So it was one of the -- and it's mentioned in
23 the assessment that that's one of the weaknesses,
24 that this is a rather low number and that, even at
25 220, where we couldn't make any statistical

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1 statements about different -- being different from
2 controls, it is possible that the level of response
3 may have strayed -- may have gone above control
4 levels.

5 But we could not make any --

6 PANEL MEMBER BLANC: Well, what was the --

7 Wait. Wait. Now let me follow up.

8 What was the level of the prevalence
9 of irritant symptoms in the 220-parts-per-billion
10 exposure group?

11 DR. RUBIN: There was no irritation.

12 PANEL MEMBER BLANC: None? Zero?

13 DR. RUBIN: Yeah. But at 800, all of the
14 participants in the experiment experienced

15 irritation.
16 PANEL MEMBER BLANC: And not a single person
17 in the 200 --
18 DR. RUBIN: And not a single person -- if you
19 go back and look at the traces, you might think that
20 "Oh, possibly this person may have experienced
21 something," but based on the noise factor, even among
22 the controls, we couldn't make a distinction there.
23 We're looking at eye-blink responses --
24 PANEL MEMBER BLANC: I see. I see.
25 DR. RUBIN: -- and subjective responses and so

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1 forth.
2 PANEL MEMBER BLANC: But they also had a
3 subjective questionnaire or a score?
4 DR. RUBIN: What they did wasn't a
5 questionnaire. They were presented with a line in
6 front of them.
7 PANEL MEMBER BLANC: Right. A visual analog
8 scale?
9 DR. RUBIN: Well, it's called a Lykert scale.
10 You probably know more --
11 PANEL MEMBER BLANC: Well, a Lykert scale
12 isn't a line. It's actually -- a Lykert scale is an
13 ordinal -- "very strongly agree," "sort of agree" --
14 it's numeric. An analog scale is a line where you
15 mark between 1 and 10.
16 DR. RUBIN: Yeah. Well --
17 PANEL MEMBER BLANC: So it's not exactly a
18 Lykert. But anyway --
19 DR. RUBIN: That's what they did. They put a
20 mark on a line based on how serious it was. And
21 then --
22 PANEL MEMBER FUCALORO: What you're saying is
23 that there was no distinction between no dose and the
24 220 -- and the people who responded to 220?
25 DR. RUBIN: Right.

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1 PANEL MEMBER BLANC: No statistical
2 difference? Or were they mathematically the same?
3 DR. RUBIN: They were not differentiable.
4 PANEL MEMBER BLANC: Did they present the
5 numbers in the paper? I mean I haven't seen the
6 paper.
7 DR. RUBIN: Oh, yeah. They're all there.
8 PANEL MEMBER BLANC: So they presented it as a
9 mean with a standard deviation?
10 DR. RUBIN: Yeah.
11 PANEL MEMBER BLANC: A mean score? I mean
12 this is kind of critical because you've got a group
13 of people exposed and you model that it was between
14 500 and a thousand parts per billion. So certainly
15 500 was the -- and at that, 80 percent of the people
16 had symptoms, not 10 percent of the people.
17 PANEL MEMBER ATKINSON: But surely one of the
18 problems is that the 500-to-a-thousand ppb is a mere
19 estimate. I mean there were no actual measurements

20 apparently taken.

21 PANEL MEMBER BLANC: Well, okay. But we're
22 supposed to be public health conservative. It's a
23 little hard -- do you see the contradiction between
24 these two data sets? I don't think it's supportive
25 of the -- you took it as supportive of the 200

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1 NOEL --

2 DR. RUBIN: Yes, I did.

3 PANEL MEMBER BLANC: -- and I take it as
4 making me very uncomfortable. It's much too close to
5 this level at which --

6 CHAIRMAN FROINES: Tobi?

7 ASSISTANT DIRECTOR JONES: Paul, could I --
8 again, with my generalist hat on -- I think Roger's
9 comment is very salient.

10 I think you're -- I think you're
11 placing an accuracy on our modelling efforts and
12 because there weren't monitoring data to go along
13 with that, the 500-to-a-thousand parts per million,
14 or ppm range, may not, in fact, reflect what
15 occurred.

16 We use -- and Randy is a better
17 modelling expert than I here. But I think that one
18 shouldn't consider the results of our modelling as an
19 absolute against which we compare a human subject
20 study.

21 CHAIRMAN FROINES: Yes. But Paul's right. We
22 are -- in general, have a tendency -- tend to want to
23 make public health decisions that are protective.

24 And so Roger's absolutely correct.
25 Your modelling may have uncertainty on both sides and

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1 that, in fact, the distribution of exposures may be
2 log -- it's probably logged normally. It may be
3 logged "normally distributed." And so who knows
4 where the -- what the best central sense of the
5 central tendency is.

6 But if there's uncertainty on both
7 sides of the value, then to make an a priori
8 assumption that 500 may not be correct, with the
9 implication that there's only one side of that
10 uncertainty distribution, I think, is a mistake.

11 I think one has to assume that you may
12 be off by a factor of 10 or a hundred or what have
13 you on both sides. And then you have to make a
14 decision about how protective that you think you need
15 to be. And in some respects, that would argue for
16 taking a lower estimate of exposure as your -- as
17 your LOEL rather than a higher one.

18 PANEL MEMBER GLANTZ: Uh-huh.

19 CHAIRMAN FROINES: Isn't that -- am I --

20 PANEL MEMBER GLANTZ: I have a question. This
21 is a point I completely missed, I have to admit, when
22 I read the report.

23 But let's say that the only
24 information you had was the results from that spill

25 and you knew that, at your best estimate of 500 parts
0055

1 per billion, 80 percent of the people had a response.
2 If you then applied your usual kinds of uncertainty
3 factors, what would you come up with as your NOEL?

4 DR. RUBIN: Basically if we had a LOEL of
5 500 ppb is what you're saying --

6 PANEL MEMBER GLANTZ: Yeah. Yeah. Where you
7 had an 80 percent response.

8 PANEL MEMBER FUCALORO: 500 to a thousand.
9 Yeah.

10 DR. RUBIN: Yeah. So we would take the lower
11 part. We would take 500 and divide it by 10 --

12 PANEL MEMBER GLANTZ: Yeah.

13 DR. RUBIN: -- to generate a NOEL.

14 PANEL MEMBER GLANTZ: Yeah.

15 PANEL MEMBER FUCALORO: I think that's Paul's
16 point.

17 PANEL MEMBER GLANTZ: Which gets you to 50.

18 ASSISTANT DIRECTOR JONES: One other
19 consideration about the analysis of the Earlimart
20 exposure is it most likely was not pure MITC, as the
21 human study was, because it was the result of metam
22 sodium application. And others here -- Randy and
23 folks from the Air Board -- can speak to the possible
24 contributions of H2S and MIC.

25 PANEL MEMBER BLANC: Well, that's why I think
0056

1 it's more applicable.

2 PANEL MEMBER FUCALORO: That's what he said --

3 ASSISTANT DIRECTOR JONES: But it also -- that
4 trying to draw conclusions about an on-the-ground
5 incidence relative to MIC becomes difficult because
6 you have more complicated factors than you do for the
7 laboratory study.

8 CHAIRMAN FROINES: But the basic flaw --

9 PANEL MEMBER GLANTZ: The way to look at it is
10 it's much more relevant to the real world though --

11 CHAIRMAN FROINES: Well, it's not only more
12 relevant --

13 PANEL MEMBER GLANTZ: -- because complicating
14 factors exist in the real world.

15 CHAIRMAN FROINES: The problem with the
16 regulatory approach to science, it seems to me, is
17 that we do this chemical by chemical at a time.
18 Nobody's exposed simply to MITC. People are exposed
19 to H2S.

20 In fact, if you look at your document
21 in terms of breakdown of metam sodium, it breaks down
22 to H2S and MITC. So, in fact, what we should be
23 dealing with here is a document that assesses the
24 risk from the breakdown products that are MITC, MIC,
25 H2S, even carbon disulfide.

0057

1 And the fact that we're only
2 addressing a single chemical leads to underestimating
3 risk rather than overestimating risk.

4 DR. RUBIN: I agree with that.
5 CHAIRMAN FROINES: I mean, in fact, we should
6 have a document that says, "Here's what people are
7 exposed to. And here's the risk associated with
8 that."
9 So the single chemical-by-chemical
10 approach is fine in the abstract, but it's not the
11 real world.
12 PANEL MEMBER GLANTZ: Well, so, Paul, what do
13 you think should be done?
14 PANEL MEMBER BLANC: So, Andy, can we walk
15 this through? So, then, if you took 500 parts per
16 billion as the LOEL and assumed you had no NOEL --
17 DR. RUBIN: Yeah.
18 PANEL MEMBER BLANC: -- then you would divide
19 that by a hundred?
20 DR. RUBIN: 10.
21 PANEL MEMBER BLANC: Divide it by 10? And
22 then what --
23 DR. RUBIN: Because it's a human study,
24 there's no extrapolation from animals to humans,
25 assuming that there's a tenfold difference in
0058 sensitivity in the human population.
2 PANEL MEMBER BLANC: And then? Is that what
3 your --
4 DR. RUBIN: That would be a NOEL -- 50 ppb.
5 PANEL MEMBER BLANC: And then if the NOEL were
6 50 ppb, the REL would be?
7 DR. RUBIN: Would be 5 ppb.
8 PANEL MEMBER BLANC: Instead of 22.
9 DR. RUBIN: Right.
10 PANEL MEMBER BLANC: Don't you think that
11 would be more conservative?
12 DR. RUBIN: Well, anytime you go lower, you're
13 more conservative.
14 PANEL MEMBER BYUS: Is it more accurate?
15 DR. RUBIN: I'm very reluctant myself to use
16 the after-the-fact modelling for regulatory values.
17 I -- just so many uncertainties there -- what the
18 flux rate and the wind direction and all the kinds of
19 things that had to be done in order to estimate those
20 numbers.
21 And I fully recognize that, in the
22 real world, you are exposed to more than MITC.
23 However, I have held in this document that we have
24 analytically established values in a human
25 experiment. To me that was a very, very -- that's a
0059 very strong argument for using that experiment to --
2 PANEL MEMBER BLANC: Except that there's a
3 problem with that experiment, which is that you have
4 one dose with nothing and one dose with a hundred
5 percent effect. And, in fact, actually, I'm not sure
6 that it's nothing because I haven't seen the data.
7 So there is a critical point as to
8 whether or not it comes -- it's exactly parallel to

9 this discussion of the test for trend if, in fact,
10 the mean symptom score was 5 compared to 3 but was
11 not statistically significant and there was a big
12 standard deviation.

13 That's quite a bit different than if
14 the mean symptom score was 5 and 5 compared to
15 nothing. So --

16 DR. RUBIN: Yeah. Well, I did look at that
17 data pretty hard. And I mean I admit it's been a
18 while.

19 PANEL MEMBER BLANC: Right.

20 DR. RUBIN: So I -- the controls show a splay
21 of response, if you will -- the ones that had goggles
22 on and just air passing through the goggles --

23 PANEL MEMBER BLANC: Right.

24 DR. RUBIN: -- some people, when they put the
25 goggles on, marked some level of irritation to begin

0060

1 with --

2 PANEL MEMBER BLANC: I understand that. But
3 I'm asking what the mean score was, not what the
4 standard deviation. You're addressing the
5 variability.

6 DR. RUBIN: Yeah. Yeah. It -- I think that's
7 in the document.

8 PANEL MEMBER GLANTZ: You can look in your
9 report, if you want.

10 PANEL MEMBER FUCALORO: You can stop and look
11 it up if you want.

12 DR. RUBIN: Yeah. Let's just take a look at
13 the document.

14 PANEL MEMBER GLANTZ: We don't expect that you
15 have memorized the entire document.

16 DR. RUBIN: I thought I had it memorized.
17 Yeah. Let's see.

18 Okay. So what I have here in the
19 document as far as the subjective, the Lykert
20 scale -- mean responses at those times, at 1 and 2
21 hours, expressed as the percentage of the full Lykert
22 scale indicated by the subject were 25 percent, plus
23 or minus 14 percent, and 26 percent, plus or minus 14
24 percent. That's at 1 and 2 hours.

25 1- and 2-hour, air-only controls

0061

1 exhibited responses of 6 percent, plus or minus 9
2 percent, and 5 percent, plus or minus 8 percent.

3 PANEL MEMBER BLANC: So you're saying -- okay.
4 So what you're saying is that, in fact, there was a
5 response. It just wasn't statistically significant.
6 In fact, you're saying there was a fourfold increase
7 in the --

8 PANEL MEMBER FUCALORO: It seemed like a big
9 response.

10 DR. RUBIN: No. That's at the LOEL, at the
11 LOEL dose compared to air-only controls.

12 PANEL MEMBER BLANC: Oh, at 800.

13 DR. RUBIN: Yeah.

14 PANEL MEMBER BLANC: I'm sorry. And what was
15 it at the NOEL?
16 DR. RUBIN: 800 was at, say, 25 or 26 percent.
17 PANEL MEMBER BLANC: So it wasn't a hundred
18 percent of the people had symptoms.
19 DR. RUBIN: This is -- that is not -- that's
20 not an incidence. That's a percentage of the full
21 Lykert scale.
22 PANEL MEMBER BLANC: Okay. Okay. Okay.
23 Okay. And what was the percentage at the NOEL?
24 DR. RUBIN: And at the NOEL -- at the -- no.
25 These are the controls --

0062

1 PANEL MEMBER BLANC: What page are you reading
2 from?
3 PANEL MEMBER FUCALORO: What page? Yeah.
4 DR. RUBIN: Page 19.
5 PANEL MEMBER BLANC: Oh, "Health Effects"?
6 PANEL MEMBER GLANTZ: Part C.
7 DR. RUBIN: I'm looking to see if there's any
8 220 in here. Page 19 about 6, 7 lines down. Let's
9 see. At the bottom of Page 18 -- "In a 4- and 8-hour
10 test, subjects exposed to point -- to 220 ppb MITC
11 did not amount to statistically significant
12 irritation response to the test material."
13 I actually don't have the --
14 PANEL MEMBER FUCALORO: Boy, a table would
15 have been helpful.
16 CHAIRMAN FROINES: What page? I --
17 PANEL MEMBER GLANTZ: Bottom of Page 18 up to
18 19.
19 CHAIRMAN FROINES: 18?
20 PANEL MEMBER GLANTZ: Part C, the very bottom
21 of Page 18.
22 DR. RUBIN: I did not put in there the numbers
23 for the 220. I just said that they not did not
24 exhibit a statistically significant response. I can
25 put them in there, if you'd like.

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1 PANEL MEMBER BLANC: Well, I think I'm
2 suggesting more than putting them in there. I'm
3 suggesting that, if, in fact, there was a difference,
4 albeit not statistically significant in and of
5 itself, that perhaps you should be using a benchmark
6 approach and calculating a dose response.
7 DR. RUBIN: My recollection of the data is
8 that there was no difference, statistically --
9 PANEL MEMBER BLANC: Not --
10 DR. RUBIN: -- statistically and biologically.
11 In other words, looking at the data, I could
12 differentiate 220 from controls. I mean obviously
13 I'm going to go back and look at that to verify it.
14 PANEL MEMBER BLANC: Well, I mean, absent --
15 absent other data, I would say, Andy, that I'm going
16 to strongly urge that the panel reject an acute REL
17 of 22 and suggest that the data support a REL of 5.
18 PANEL MEMBER GLANTZ: Well, given that you

19 have expressed that very strong feeling, do you think
20 it's worth, maybe, to get whatever else we can out of
21 the way and then table this discussion and maybe you
22 can get somebody up in Sacramento to fax down the
23 paper so we can get the numbers rather than just
24 speculating?

25 I don't think it's fair to Andy to
0064

1 expect him to memorize it.

2 PANEL MEMBER BLANC: No. No. I'm just --

3 PANEL MEMBER GLANTZ: But I think then we
4 could have a -- we could kind of conclude the
5 discussion based on the actual numbers because it
6 would be nice to bring this to closure today but to
7 give them a chance to get the stuff, rather than to
8 just speculate. Does that seem reasonable?

9 CHAIRMAN FROINES: What do you think, Andy?

10 DR. RUBIN: I'm willing to go back and dig the
11 numbers out and fax them out to you, if you'd like.

12 PANEL MEMBER GLANTZ: No. What I was
13 suggesting is that somebody back in your office that
14 you could get on the phone with and tell them how to
15 rummage through your desk and find it and fax it down
16 here today.

17 DR. RUBIN: Oh, today. Oy.

18 PANEL MEMBER GLANTZ: If we sort of finish --
19 if we tabled this specific discussion for now, deal
20 with any other issues, and then go on to another
21 agenda item while you have someone rifle through your
22 office and --

23 DR. RUBIN: What they would have to do is
24 actually go through the study itself --

25 PANEL MEMBER GLANTZ: Yeah.

0065

1 DR. RUBIN: -- which is on my desk.

2 PANEL MEMBER GLANTZ: Okay. Well, you would
3 could talk them through it.

4 DR. RUBIN: But they would have to -- it
5 actually takes some doing because you have to go back
6 into these traces and so forth. I'm not confident
7 that that's going to be possible today.

8 PANEL MEMBER BLANC: So, Andy, isn't there a
9 published paper, though?

10 DR. RUBIN: No.

11 PANEL MEMBER BLANC: No?

12 DR. RUBIN: This is a contract study.

13 PANEL MEMBER BLANC: I see.

14 PANEL MEMBER FUCALORO: Can I --

15 PANEL MEMBER GLANTZ: Well, maybe. But I
16 think -- I think that maybe to try -- maybe we can't
17 get it today, but it is an important point and if you
18 could get at least try to get somebody to fax down
19 the relevant pages, then maybe we could have a more
20 informed discussion.

21 CHAIRMAN FROINES: Is that -- I mean given
22 that we're going to close here at 2:30, quarter to
23 3:00, what makes sense?

24 PANEL MEMBER FUCALORO: I can't leave at
25 quarter to 3:00.
0066

1 DR. RUBIN: I'm not of --
2 CHAIRMAN FROINES: Before we assume, I think
3 we need more input from the panel on Paul's comment
4 because the panel needs to decide how it wants to
5 proceed as a whole.
6 PANEL MEMBER FUCALORO: Andy -- this is
7 another issue -- is the data presented -- can you
8 present the data in tabular form for easy -- you
9 wrote it up here --
10 DR. RUBIN: Yeah.
11 PANEL MEMBER FUCALORO: -- in the report. I
12 read it. In tabular form -- "This many -- this
13 concentration. This many hours. This percentage
14 along the line" and so on and so forth -- can that be
15 presented in tabular form for ready evaluation?
16 And I think what Paul's suggesting is
17 that, regardless of statistical studies, we should be
18 able to see a difference or we might see a difference
19 between 226 or whatever that number was -- 220 -- and
20 another -- and no dose, for example, you know, either
21 yes or no.
22 And that would show up in some tabular
23 form that you could present. Does that seem --
24 DR. RUBIN: No. That's not unreasonable.
25 PANEL MEMBER FUCALORO: Okay. Now, what
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1 you're suggesting, though, it might not be possible
2 to do today, as Stan suggested, because one would
3 have to --
4 PANEL MEMBER GLANTZ: Well, I'm just
5 suggesting he try. If they can't --
6 PANEL MEMBER BLANC: Well, let me -- maybe
7 there's another way of approaching this that would be
8 helpful. You know, I could be an outlier here and --
9 PANEL MEMBER FUCALORO: Not you.
10 PANEL MEMBER BLANC: -- and -- what?
11 PANEL MEMBER FUCALORO: Not you.
12 PANEL MEMBER BLANC: Yeah. And if I am, then,
13 although it would be nice to have this other data,
14 it's not that important fundamentally. You would
15 stay with the 220 value, which then yields a value
16 of --
17 PANEL MEMBER FUCALORO: 22.
18 PANEL MEMBER BLANC: -- 22. If there is a
19 strong feeling on the panel beyond my own view that
20 it actually wouldn't matter and even if there were no
21 biological or statistical difference in the
22 laboratory control study of 220 parts per billion
23 compared to 800 parts per billion in eye irritation,
24 the epidemiologic data with mathematical modelling is
25 more compelling and the 500 value should be used as a
0068

1 low effect level, then there is no need to get the
2 other data.

3 It would be nice to see everything
4 running, you know, together. So I think that it's
5 important -- it's important for me to hear what other
6 people are thinking.

7 CHAIRMAN FROINES: Well, let me summarize --
8 Would you like to make a comment?

9 PANEL MEMBER FRIEDMAN: I just feel, now that
10 the issue has been brought up, that I would like to
11 see those data too.

12 CHAIRMAN FROINES: Okay. Let me --

13 PANEL MEMBER FUCALORO: I'm sorry. Gary, what
14 did you say? I didn't hear you.

15 PANEL MEMBER FRIEDMAN: I said I would like to
16 see the data, too, now that the issue has been
17 brought up. I think it's now sort of on public
18 record; and now that we're all facing that question,
19 we should see the data.

20 PANEL MEMBER FUCALORO: We should see the
21 data.

22 PANEL MEMBER GLANTZ: Why don't we go on to
23 the next item?

24 CHAIRMAN FROINES: Let me summarize, if I can.
25 The issue that drove this discussion was, in fact,

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1 the Earlimart episode where the modelling seemed to
2 indicate that the exposure levels may have ranged
3 from 500 parts per billion to 1 part per million.

4 And but the agency's position is that
5 there are significant or some uncertainties within
6 the modelling. And one would be they would be
7 hesitant to draw conclusions and set a REL and a NOEL
8 based on those modelling data.

9 And then that, too, goes back to the
10 basis of the data which was the human study and that
11 the precise question is the lower dose level in that
12 human study.

13 And so the panel is saying that they
14 would like to see that study in order to look at the
15 low-dose data in relationship to control and high
16 dose to see if, in fact, there's any kind of
17 relationship that needs to be taken seriously that
18 would, in a sense, support the Earlimart conclusions
19 that there is a lower NOEL -- LOEL than 800 parts per
20 billion.

21 And so it seems to me that the panel
22 is saying they would like to see that and, based on
23 that analysis, then decide to stay with -- more or
24 less stay with what we have or consider a change.

25 DR. RUBIN: So my question now -- what format,

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1 if you will, would you like to see that data? Would
2 you like to actually see the study itself? Or would
3 you like me to go through it and give you the results
4 at the -- here I just said there was no statistical
5 effect at the low dose.

6 You want to see what the low dose -- I
7 mean I should have put those numbers in the -- and I

8 can see now that they should be in there. Is that
9 what you want to see or --

10 CHAIRMAN FROINES: Well, I think the panel is
11 also concerned with what came up earlier, which is
12 that the trend test was significant and that the
13 simple statistical significant test wasn't and so
14 that the statistical approach -- that the panel had
15 questions about that.

16 So I think, it seems to me that I
17 think it's up to the panel what they want. But I
18 would argue that the panel probably wants to see the
19 data as well as see your interpretation.

20 PANEL MEMBER GLANTZ: Yeah. What I would
21 suggest, as a practical matter, is that the -- what
22 I'd like to see today is what you can get us in an
23 hour. And then we can decide if that's enough or if
24 we want to carry this over, you know.

25 But I would hope, based on my

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1 understanding of your description of what you have, I
2 think, hopefully, there are a couple of pages out of
3 this report or a few graphs that you could show us
4 that would answer the questions.

5 And then we can we could decide
6 either -- as John said, we either go with the things
7 the way they are or we say, "This is compelling
8 enough that we recommend a change." Or if it's not
9 obvious, we to have would have to come -- bring it
10 back to the next meeting.

11 But what I'd, again, propose is that
12 we either go on -- that we go on to any other issues
13 about this report and then start to work on something
14 else to give you a chance to get that or just stop
15 the discussion now and give you a chance to go get
16 it.

17 CHAIRMAN FROINES: Okay. What's -- unless
18 there's other comments, my question to you is what's
19 practical from your standpoint?

20 DR. RUBIN: I'm not confident that we can do
21 that because I know that study. It's page after page
22 of data -- various different concentrations all in
23 the back. It would mean that somebody up there in
24 Sacramento -- probably Keith Pfeifer -- would have to
25 go to my desk; pick up the volume; figure out which

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1 volume it is, first of all; go back there and figure
2 out what it is that Andy's asking him for.

3 And I'm not confident that can be
4 done -- it might take him an hour just to -- or two
5 hours, even -- just to figure out what it is that
6 they want.

7 PANEL MEMBER FUCALORO: So what's the
8 alternative approach?

9 CHAIRMAN FROINES: Well, I would prefer -- I
10 would prefer, since this thing has been going on for
11 such a long period of time, that we bring it to
12 closure. And I think Stan feels the same.

13 DR. RUBIN: Yeah.
14 CHAIRMAN FROINES: My sense is that what I
15 would suggest is that we proceed on the assumption
16 that -- proceed on the assumption that we're going to
17 stay with the values that we have, pending a review
18 of the document and if, in between now and the next
19 meeting, if it appears as though Paul's point is
20 correct, then we will bring it up at the next
21 meeting.

22 Otherwise, we will approve the
23 document or approve our finding at this meeting,
24 pending that review.

25 PANEL MEMBER FUCALORO: I agree.

0073

1 PANEL MEMBER ATKINSON: I'd like to comment
2 that I would be very uncomfortable using the
3 Earlimart study as anything to hang any quantitative
4 data on, given the modelling.

5 CHAIRMAN FROINES: I don't think -- that's not
6 being proposed. What's -- I mean I think that the
7 Earlimart started us off. But at this point we're
8 talking about the actual laboratory --

9 DR. RUBIN: Yeah.

10 CHAIRMAN FROINES: Paul, what's your --

11 PANEL MEMBER BLANC: What's that?

12 CHAIRMAN FROINES: Well, what's your -- I'm
13 proposing an approach.

14 PANEL MEMBER GLANTZ: Are you happy with what
15 he's proposing?

16 PANEL MEMBER BLANC: I think you answered my
17 question.

18 CHAIRMAN FROINES: Gary?

19 PANEL MEMBER FRIEDMAN: That sounds good.

20 CHAIRMAN FROINES: Craig?

21 PANEL MEMBER BYUS: (No audible response.)

22 PANEL MEMBER FUCALORO: What day is it?

23 PANEL MEMBER BYUS: I -- yeah. I mean the
24 train load and the dumping in the river is not what
25 I'd call "real world," by any stretch of the

0074

1 imagination.

2 DR. RUBIN: This is Earlimart. This was an
3 agricultural application.

4 PANEL MEMBER BYUS: And just reading this
5 over, it would be nice to see this data presented.

6 DR. RUBIN: The eye irritation data?

7 PANEL MEMBER BYUS: I realize there's time
8 limitations but --

9 CHAIRMAN FROINES: Let's proceed on the
10 assumption that we will review the -- you will review
11 and we will review this study and if there are -- if
12 there are differences of opinion about its showing
13 low dose -- lower-dose effects, we'll take it up at
14 the next meeting, but otherwise we'll continue on
15 pace today.

16 DR. RUBIN: Okay.

17 CHAIRMAN FROINES: And so I'll go back to Paul

18 because we're -- in essence now, we're in the stage
19 of the panel discussion on this issue.
20 (Brief interruption.)
21 (Off-the-record discussion.)
22 CHAIRMAN FROINES: Elinor --
23 We haven't asked Elinor for her -- any
24 views --
25 PANEL MEMBER GLANTZ: Let him show his last
0075
1 slide.
2 CHAIRMAN FROINES: What?
3 PANEL MEMBER GLANTZ: Let him show his last
4 slide.
5 DR. RUBIN: One last conclusion slide. Back
6 to the seasonal, the subchronic, the REL for the
7 seasonal effects was set at 1 ppb, in other words,
8 the NOEL of a hundred ppb just divided by an
9 uncertainty factor of a hundred.
10 Ambient MOEs. These are margins of
11 exposure, range between 28 and 166,667 with 3 of 14
12 studies falling below the -- quote -- "health-
13 protective benchmark of 103 additional studies
14 falling right around a hundred." This is a concern
15 for us for seasonal exposure.
16 Application site MOEs ranged between 1
17 and 50, in other words, not 1 application site
18 monitoring was not a concern. In other words, they
19 were all a concern, all under a hundred.
20 As I understand it, toxic air
21 contaminant listing occurs when MOEs are below a
22 thousand. I recommend that MITC be listed as a toxic
23 air contaminant both on acute and subchronic -- on
24 the base of acute and subchronic analysis.
25 CHAIRMAN FROINES: Okay. Thank you very much.
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1 PANEL MEMBER BLANC: That's all -- I'm not
2 done yet. I have some other questions that aren't
3 quite as substantive --
4 DR. RUBIN: Okay.
5 PANEL MEMBER BLANC: -- just need
6 clarification. In terms of the immuno -- potential
7 immunotoxicity of metam sodium in its breakdown
8 products --
9 DR. RUBIN: Yeah.
10 PANEL MEMBER BLANC: -- there was a recent
11 article in the "Journal of Toxicology and
12 Environmental Health," which is a review article, not
13 a primary data article and, in fact, refers to some
14 extent to California data, Health Department data.
15 But one of the things that I was --
16 that's particularly relevant from the article is that
17 the two authors -- their particular area of interest
18 is immunotoxicology --
19 DR. RUBIN: Yeah. Pruett --
20 PANEL MEMBER BLANC: Pruett and Keil and some
21 of their relevant citations, particularly Pruett,
22 aren't cited in the health effects document. The

23 Keil article is, but the Pruett articles aren't.
24 And I just want to ask you to go back
25 through, just to double-check. I just want to make
0077

1 sure we didn't --

2 DR. RUBIN: I think the reason for that is
3 that Pruett -- I think he's the head of that lab. I
4 think it's at Louisiana state.

5 PANEL MEMBER BLANC: Uh-huh.

6 DR. RUBIN: And he's not the first author. So
7 there's Keil -- I mean I discuss Pruett's data in
8 this assessment. Generally he exposed animals at
9 much higher levels to get immunologic effects. I
10 can't remember what his other --

11 PANEL MEMBER BLANC: Well, the reason why I
12 bring it up is because, although his exposures are --
13 they're oral studies and they're to metam sodium --
14 in the discussion in this review article, since
15 they're discussing their own data, they emphasize
16 that this is -- that these are probably important
17 MITC effects.

18 And they specifically say it wouldn't
19 matter whether it was by oral exposure or by
20 inhalation. You would probably see the same effects.
21 So it's a -- if it were just a review article, I
22 would -- it would be, perhaps, less relevant.

23 But since it's a review article where
24 they're reviewing a lot of their own data, it carries
25 a little bit more weight, I think.

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1 DR. RUBIN: Yes.

2 PANEL MEMBER BLANC: And Pruett is the first
3 author on at least one of the articles that they cite
4 heavily in the review.

5 DR. RUBIN: Yeah. That's actually in the
6 metam sodium risk assessment. In other words, I've
7 got an entirely separate risk assessment. We
8 actually submitted a version of this a couple of
9 years ago to the panel. But it's evolved quite a bit
10 from there.

11 PANEL MEMBER BLANC: I mean maybe it could
12 be --

13 CHAIRMAN FROINES: Wait. I'm -- what are you
14 talking about? A metam sodium risk assessment?

15 DR. RUBIN: Yeah. We have developed two
16 separate risk assessments, one on MITC and one on the
17 parent compound metam sodium. MITC is the one that's
18 being considered in front of the panel, obviously.

19 But there is -- and I actually
20 submitted this to the panel a couple of times ago --
21 the document as it existed then. The toxicology of
22 metam sodium is notably different than that of MITC.
23 But I haven't brought it to the panel because it's
24 not --

25 PANEL MEMBER BLANC: But the authors here, you
0079

1 know, make the explicit point that, in terms of the

2 immunologic effects they're talking about, it's
3 probably contributed equally by the parent compound
4 and MITC.
5 DR. RUBIN: Yeah.
6 PANEL MEMBER BLANC: So therefore it becomes
7 relevant for MITC by virtue of what they're saying
8 here --
9 DR. RUBIN: Right.
10 PANEL MEMBER BLANC: -- and then citing their
11 own work.
12 DR. RUBIN: Yeah.
13 PANEL MEMBER BLANC: So I think it needs to be
14 addressed -- it should be addressed explicitly, maybe
15 in 2 sentences. I don't know. It may be very brief.
16 But I'm just a little bit uncomfortable with --
17 DR. RUBIN: I could bring over another, you
18 know -- whatever references you're talking about. I
19 think they're in the metam document. But I do have
20 at least the one reference here that was, in my
21 opinion, was --
22 PANEL MEMBER BLANC: More relevant.
23 DR. RUBIN: -- more relevant --
24 PANEL MEMBER BLANC: The Keil -- the Keil
25 references.
0080
1 DR. RUBIN: -- more relevant to MITC. Yeah
2 exactly.
3 PANEL MEMBER BLANC: So that that's -- I don't
4 think it's a major issue. It's a -- but I'm always
5 nervous when I, you know, if I see someone making a
6 big deal over particular, you know, body of work
7 that, then, isn't appearing in our document. So
8 that's why I bring it up.
9 And the other point is very, very
10 minor but may have other applicability in other
11 reviews that you do. And that is you do cite the
12 Kreutzer reference that was on your --
13 DR. RUBIN: Yeah.
14 PANEL MEMBER BLANC: -- summary -- the 1994 --
15 DR. RUBIN: Yeah.
16 PANEL MEMBER BLANC: -- reference which is, I
17 assume, an article within a monograph?
18 DR. RUBIN: Yes.
19 PANEL MEMBER BLANC: And there was a later
20 publication by Kreutzer which was in a peer review
21 journal with some of the same co-authors but other
22 co-authors -- the community-based epidemiologic study
23 of health effects from a metam sodium spill on
24 California's Sacramento river from 1996.
25 DR. RUBIN: Who's the first author?
0081
1 PANEL MEMBER BLANC: Kreutzer. And --
2 DR. RUBIN: That, I'm not -- I'm not aware of.
3 PANEL MEMBER BLANC: Yeah. And I would just
4 say that, in general -- and I'll provide you with
5 that reference. But I would say, in general --
6 DR. RUBIN: Yeah. Usually peer review --

7 PANEL MEMBER BLANC: It's probably overlapping
8 reports. But I think, in general, a citation from
9 the peer review literature is preferable to a
10 citation from a monograph, if, let's say, that it's
11 equivalent data information.

12 DR. RUBIN: Okay.

13 PANEL MEMBER BLANC: I'll give you this, if
14 you don't -- do you have this, this review article by
15 Pruett?

16 DR. RUBIN: Yes, I do. In fact, he cites us
17 in there, I believe.

18 PANEL MEMBER BLANC: Yeah, he does.

19 DR. RUBIN: I've got -- you know, I've got all
20 the papers, all those papers.

21 PANEL MEMBER BLANC: Well, it's pretty recent.
22 That's why I asked.

23 DR. RUBIN: Yeah.

24 PANEL MEMBER BLANC: I'm done.

25 CHAIRMAN FROINES: Gary?

0082

1 PANEL MEMBER FRIEDMAN: (No audible response.)

2 CHAIRMAN FROINES: Craig?

3 PANEL MEMBER BYUS: Nothing.

4 CHAIRMAN FROINES: Stan?

5 PANEL MEMBER GLANTZ: I'm okay.

6 PANEL MEMBER ATKINSON: I have 2 or 3 minor
7 comments, which I'll -- they're misstatements, but
8 they're very minor.

9 CHAIRMAN FROINES: Okay.

10 DR. RUBIN: That you'll give me in writing
11 or --

12 PANEL MEMBER ATKINSON: I'll give you them.

13 DR. RUBIN: Oh, okay.

14 CHAIRMAN FROINES: Does everybody have the
15 proposed findings?

16 Elinor, do you want to take Andy's
17 place?

18 DR. FANNING: Sure.

19 PANEL MEMBER BLANC: I'd like to have a
20 10-minute break.

21 CHAIRMAN FROINES: I think we'll take a break
22 right now to give the reporter a chance to --

23 (Break.)

24 CHAIRMAN FROINES: We are now going to take up
25 the panel's findings.

0083

1 Elinor, do you want to comment? Would
2 you comment on -- the panel has two copies of the
3 findings, one of which is -- shows the changes that
4 occurred this week, and one is a clean copy of that.

5 And then we have made some additional
6 changes, and Elinor's going to tell you what that
7 is -- what those are.

8 DR. FANNING: Okay. The version that was sent
9 to the panel, which is the strikeout version in front
10 of you -- these findings have actually been
11 significantly modified from the version that you

12 approved in May of 2000. This -- yeah.

13 PANEL MEMBER BYUS: It's fine.

14 DR. FANNING: Amazing that it's been so long.
15 So a number -- because of the nine or so items that
16 you see from Andy that have changed in the document,
17 we've got gone back and tried to make your findings
18 reflect those.

19 There were some additional kind of
20 cleanup points that came out of the May, 2000,
21 meeting, where you had given -- panel members had
22 recommended changes at that time. Those changes have
23 all been made, and the changes from that meeting do
24 not show in strikeout.

25 So, just to simplify things, the only

0084

1 changes that show on strikeout are the ones that
2 pertain to the new document version. Okay? Now --

3 CHAIRMAN FROINES: Is that clear?

4 DR. FANNING: Yeah. Did I confuse you? Or
5 did that make sense? Part and part. Okay.

6 I think also, as I was listening to
7 your discussion this morning, it's quite clear that
8 we're going to need to make some further
9 modifications to this document.

10 First of all, one of the main areas
11 would be that this findings document version does not
12 reflect the benchmark dose modelling that has been --
13 that was discussed this morning 'cause we didn't have
14 that yet.

15 So the addendum on benchmark dose and
16 the comments that were made by panel members on the
17 trend, the statistical trend in the Klimisch data --
18 those are not reflected in Finding Number 36. So we
19 may wish, when we get to 36, to discuss the language
20 there in detail.

21 I think the second major area coming
22 from this morning's talks for this document's going
23 to need further work pertains to Finding Number 21 on
24 the acute effects of MITC. You may wish to add
25 language there and also to -- there are some

0085

1 conclusions that we make in Findings 46 and 47 about
2 the mixed exposure that results from metam sodium
3 application.

4 Those are just some that I can see
5 right away that we will probably want to change as we
6 go through this document.

7 How do you want to proceed? Should we
8 go through and look at each of the findings that has
9 changed since your last version?

10 CHAIRMAN FROINES: No. I think that -- I
11 think we have to assume that the panel's read the
12 document and will take comments --

13 DR. FANNING: Okay.

14 CHAIRMAN FROINES: -- from the panel rather
15 than spending an hour to walk them through it, unless
16 somebody wants to walk through it. Gary?

17 PANEL MEMBER FRIEDMAN: No. I have comments.
18 I don't want to walk through it.
19 CHAIRMAN FROINES: So continuing, Paul, you're
20 the first.
21 PANEL MEMBER BLANC: First?
22 CHAIRMAN FROINES: You're the first person
23 that I come to, to my left.
24 PANEL MEMBER BLANC: Oh, okay. Going in a --
25 CHAIRMAN FROINES: Clockwise.

0086

1 PANEL MEMBER BLANC: -- clockwise direction,
2 shall we say.
3 Question for you: One of the things
4 that struck me where you talk about dates of use, in
5 terms of usage, is with the revisions of the
6 documents coming from DPR, is 1998's the most recent
7 year, then, for which there's usage data that they
8 cite?
9 DR. FANNING: I know more recent data exists.
10 I believe the current document cites up to '98. And
11 I think it used to cite to '97. So there was --
12 there was a change on that. And I didn't put it in
13 strikeout 'cause I considered it minor. I will
14 verify that.
15 PANEL MEMBER BLANC: I mean I don't think our
16 findings should be ahead of what's in the document.
17 So if the document doesn't go beyond '98, I don't
18 think we should. I think I would like to be
19 reassured that there hasn't been a fivefold increase
20 since 1998.
21 DR. FANNING: Right.
22 PANEL MEMBER BLANC: I mean is the difference
23 between 1998 and 1999 and 2000 -- is it sort of --
24 DR. FANNING: I think, in fact, it may have
25 decreased. I think --

0087

1 We're talking about the pesticide-use
2 data.
3 And I think -- I did -- I actually
4 looked it up and went to the pesticide-use reports.
5 Yeah. The current document cites up to 1998. And I
6 did go look at the '99 data. And I'm afraid I didn't
7 write it down. But this reflects accurately what's
8 in the document.
9 PANEL MEMBER BLANC: Right. I don't -- you
10 know, again, I don't think we can cite things that
11 aren't there. But I'd --
12 DR. FANNING: Yeah. That's what I thought.
13 PANEL MEMBER BLANC: What's that?
14 DR. FANNING: Use seems to have a slight
15 declining trend.
16 PANEL MEMBER BLANC: Okay. So it's not a huge
17 increase in the --
18 DR. FANNING: Right.
19 PANEL MEMBER BLANC: Okay. That's fine.
20 Should I just go in order, John? Is that what you
21 want me to do?

22 CHAIRMAN FROINES: Uh-huh.
23 PANEL MEMBER BLANC: These are, you know --
24 mostly these are minor points unless it's something
25 that I've already brought up in the other discussion.

0088

1 On Point Number 5, where the last line, where it
2 says, "In practice, degradation to MITC, MIC, and
3 hydrogen sulfide is favored" -- the implication there
4 is not that there's degradation to MIC that doesn't
5 go through MITC, is it?

6 DR. FANNING: No. What the sentence -- that
7 sentence was actually modified by panel feedback at
8 the May, 2000, meeting. "Favored" means -- there,
9 means "soil conditions and pH" and so on, so that
10 it's meant to say that the pathway producing MITC,
11 MIC, and H₂S is somewhat dominant over that pathway
12 that produces --

13 PANEL MEMBER BLANC: I didn't have a
14 problem --

15 DR. FANNING: -- carbon disulfide and
16 methyl --

17 PANEL MEMBER BLANC: -- with the "favored."
18 I had a just -- the only part about that that's
19 confusing is I think that, if the MIC were in
20 parentheses and if it said, "In practice, degradation
21 to MITC -- parentheses -- and then to MIC -- end of
22 parentheses -- and hydrogen sulfide is favored" --
23 because the metabolism or the breakdown to hydrogen
24 sulfide is independent of the MITC but the MIC only
25 comes from the MITC; correct?

0089

1 DR. FANNING: Yes.

2 PANEL MEMBER BLANC: And so I wasn't clear if
3 you were applying something --

4 CHAIRMAN FROINES: We'll fix it.

5 DR. FANNING: Yeah.

6 PANEL MEMBER BLANC: Next point. Number --
7 newly Number 6, the very last phrase -- "metam sodium
8 is the dominant source of MITC and MIC in California
9 air." Yeah. It's the dominant agricultural source.

10 DR. FANNING: Okay.

11 PANEL MEMBER BLANC: And I think it's really
12 the dominant source altogether, but the issue there
13 is that it's the dominant agricultural source. Yes?

14 DR. FANNING: Okay.

15 PANEL MEMBER BLANC: Because theoretically
16 somebody could be releasing MIC if they have a big,
17 you know, chemical manufacturing --

18 CHAIRMAN FROINES: Well, there is a pesticide
19 plant in Southern California. I don't know if they
20 make MITC.

21 PANEL MEMBER BLANC: I don't think this is --
22 again, none of these are going to be make major
23 things, but I'm just going to go through it if that's
24 what you want. Number 17.

25 CHAIRMAN FROINES: We don't want to ever

0090

1 repeat the lead Stan Glantz event which took a whole
2 day of -- but I think it's probably --
3 PANEL MEMBER GLANTZ: Hey, that was important.
4 PANEL MEMBER BYUS: That was good.
5 PANEL MEMBER BLANC: This is new wording that
6 you have on Point Number 17. The whole point may be
7 new, for all I know. The next-to-last sentence --
8 "Air-dispersion modelling by DPR estimated that air
9 concentrations of MITC were mostly between .5 and 1
10 part per million."

11 "Mostly"? What does "mostly" mean to
12 you in there?

13 DR. FANNING: Well, I did take that language
14 from the summary of Earlimart incident that was
15 prepared for the document, for the new version. And
16 I think "mostly" is actually their word.

17 I believe -- and DPR staff can correct
18 me if I'm wrong -- that this reflects different
19 modelling scenarios that were used, different
20 distances from the field, different times so that
21 there was an estimate of 3 ppm exposure very near the
22 field but the majority of people evaluated would have
23 experienced, by their model, the concentrations
24 between 500 ppb and 1 ppm.

25 "Mostly," maybe, is not the best word.

0091

1 PANEL MEMBER BLANC: I mean should the word
2 "mostly" be dropped? I'm assuming that the models
3 didn't suggest that the range was really, you know,
4 that, for 75 percent of the people, the range was .5
5 to 1 but that a lot of -- but actually the range was
6 even broader than that.

7 And that would, coming back to our
8 earlier discussion, would be rather unnerving. So
9 I'm assuming that the word "mostly" just should be
10 dropped.

11 PANEL MEMBER ATKINSON: You could replace it
12 by "to which people were exposed."

13 DR. FANNING: It looks -- the text from the
14 document says that "MITC concentrations in the
15 populated area of Zone A" -- so within a certain
16 distance; and, by the way, 80 percent of those
17 exposed were exposed in Zone A -- "Zone A
18 concentrations were estimated to fall, for the most
19 part, between .5 and 1 ppm." Okay?

20 So then there are other zones, other
21 neighborhoods that were more distant. And then there
22 was the near field edge. So I don't know what the
23 broader range -- say, for Zone A, for that
24 neighborhood -- would be.

25 PANEL MEMBER BLANC: John, do you understand

0092

1 my confusion here?

2 DR. FANNING: Yeah.

3 PANEL MEMBER BLANC: Andy, can you help us
4 with this?

5 DR. RUBIN: Yeah, I know. I'm not sure I can

6 help you, but DPR generated a map, a plume-dispersion
7 map.

8 PANEL MEMBER BLANC: Right.

9 DR. RUBIN: So you have the neighborhoods.
10 You have the fields. And then you have the
11 neighborhoods of varying distances from the fields.

12 PANEL MEMBER BLANC: Yeah.

13 DR. RUBIN: And you get -- it sort of looks
14 like weather map, in a way. You get a, you know,
15 like, a bubble --

16 PANEL MEMBER BLANC: Right.

17 DR. RUBIN: -- that says, "In this area, based
18 on these wind conditions and so forth that we assume
19 occurred, the modelling concentrations are .1 --.5 to
20 1 ppm."

21 But there may have been areas of
22 Zone A that weren't covered by that bubble. That's
23 probably why I used that language -- that they may
24 actually have been exposed to lower concentrations.

25 PANEL MEMBER BLANC: But the Point 10 in your

0093

1 summary --

2 DR. RUBIN: Point 10?

3 PANEL MEMBER BLANC: Oh, he has -- I'm sorry.

4 "Following an incident of agricultural
5 drift over populated areas, residents of Earlimart,
6 California, were exposed to levels of MITC estimated
7 to be in the range of .5 to 1 part per million. Odor
8 complaints were received" -- blah, blah, blah.

9 "Of 171 exposed individuals, nearly 80
10 percent experienced symptoms of eye or upper
11 respiratory irritation."

12 The 171 exposed individuals -- were
13 they all in Zone A, then?

14 DR. RUBIN: I have the numbers here.

15 DR. FANNING: No. 136 --

16 DR. RUBIN: 136.

17 DR. FANNING: -- in Zone A.

18 PANEL MEMBER BLANC: And, then, where were the
19 other people from?

20 DR. RUBIN: Further out. Zone B, C, D.

21 PANEL MEMBER BLANC: And --

22 DR. RUBIN: In other words, enough -- I'm
23 interrupting you. Sorry.

24 PANEL MEMBER BLANC: No. So what's the
25 denominator, then? The 171 is people who had any

0094

1 complaints at all? Or were they just people who were
2 surveyed?

3 DR. RUBIN: These are people who were
4 surveyed.

5 PANEL MEMBER BLANC: Regardless of whether
6 they had complaints or not? They weren't --

7 DR. RUBIN: Right. Right.

8 PANEL MEMBER BLANC: Okay. So there were --
9 so as they got farther out of Zone A into B and C,
10 there was still an incidence of respiratory and

11 mucous membrane irritation. And in those areas, the
12 modelling was that the exposure level was lower than
13 .5 to 1?

14 DR. FANNING: No concentrations are given in
15 this document for those other zones, the other
16 neighborhoods.

17 CHAIRMAN FROINES: But were there -- the
18 obvious -- this is Pandora's box being opened up
19 because what it seems -- what you seem to be saying
20 is that there were affected people in other zones
21 where the concentrations -- where you were further
22 away and therefore the concentrations would be
23 expected to be lower. Is that the case? Because if
24 that's the case, then we have a problem.

25 PANEL MEMBER BLANC: Melanie, maybe you could
0095

1 help because I'm reading from your memo.

2 DR. MARTY: We had the same problem. We don't
3 have concentrations. We have -- we have the exact
4 same question that John has.

5 CHAIRMAN FROINES: So what did we do? We just
6 forgot those people who were symptomatic in those
7 areas? What's going on?

8 DR. RUBIN: I'll have to get -- I'll have to
9 check back on that data. I'm --

10 CHAIRMAN FROINES: You realize that this is a
11 fundamental issue because you're suggesting that
12 there may be people exposed to lower concentrations
13 who were symptomatic. And so if you thought that the
14 .5-part-million question was an issue, wait till we
15 get to this one.

16 Am I correct, Paul?

17 PANEL MEMBER BLANC: Yeah. Yeah.

18 DR. FANNING: Yeah.

19 CHAIRMAN FROINES: But it's their data. We
20 have to use their data. We can't say, "Yes. these
21 models tend to be incorrect." We don't know that.
22 But if they put it forward, then they have to live by
23 it.

24 DR. FANNING: Yeah. The way -- the only, you
25 know -- since I just had this document to go on, the

0096

1 way that I -- the language I suggested for your
2 finding has a sentence that says, "Exposure levels
3 are unknown," and then goes on to describe what I
4 could glean of the modelling results here.

5 But it does seem that you may need to
6 see the complete modelling results to complete your
7 finding on this.

8 PANEL MEMBER BLANC: Well, Andy, can we go
9 back? I have three versions, then, of summaries of
10 the data. One is Elinor's various modifications of
11 draft findings. Another is the Health Department's
12 response to the DPR.

13 DR. RUBIN: OEHHA's.

14 PANEL MEMBER BLANC: OEHHA's -- I'm sorry --
15 response to DPR. And the other is DPR's draft. And

16 somehow what we did this morning was, Andy, we heard
17 your presentation on your document, which responded
18 in part to DPR's input or the memo that we were sent
19 that Melanie was a co-author of.

20 But we actually haven't heard from
21 OEHHA in terms of their outstanding questions. And
22 so maybe we should take a step back and just give a
23 OEHHA a chance to speak. Maybe they have nothing to
24 say.

25 But this -- for example, I would have
0097

1 thought OEHHA would have been more proactive if they
2 had the same question about the Earlimart data. I
3 hope there aren't other areas that OEHHA's anxious
4 about but not voicing their concerns.

5 DR. MARTY: Melanie Marty from OEHHA. There
6 are little differences that we had in terms of the
7 approach for the benchmark concentration.

8 PANEL MEMBER BLANC: Right. That was
9 addressed.

10 DR. MARTY: Yeah. And that was already
11 addressed. And this particular issue -- this is the
12 first time, actually, that I have -- that this has
13 been brought to my attention -- this issue of "Were
14 all those 171 people within the modelled isopleth
15 from the air-dispersion modelling?"

16 And I don't know the answer to that.
17 The pesticide group, represented by Michael
18 DiBartolomeis here, also doesn't know the answer to
19 that, as he just indicated to me. So I think it --
20 we need to figure out where these people were; what
21 was, you know, what was modelled.

22 At the same time, I have some
23 heartburn using modelled concentrations to indicate
24 personal exposure of these individuals because,
25 within those isopleths, the concentration could, you

0098
1 know, be really squirrely and some people may have
2 gotten considerably more than the range of .5 to 1
3 and some people considerably less.

4 So it's really hard to go back and
5 say, "This guy was right here, and therefore his
6 concentration was X." so I have a little bit of
7 heartburn over doing that.

8 CHAIRMAN FROINES: I think that's fair. And I
9 think the panel would agree with you. But I think
10 it's also true that that --

11 DR. MARTY: Okay. On Page 25 of the document.

12 PANEL MEMBER BLANC: Which section?

13 DR. MARTY: Oh, let's see. On Page 25 of the
14 document, is it --

15 DR. FANNING: It's Part C.

16 DR. MARTY: Part C.

17 DR. FANNING: Page 25 at the top.

18 DR. MARTY: Page 25, describing the Earlimart
19 incident. Yeah. That's what you guys just looked at
20 that. We don't have what the concentrations were for

21 these other zones. So that's what -- that's what's
22 missing.

23 And also my guess is -- and I haven't
24 seen this -- but that the zones -- they're not going
25 to correspond neatly to an isopleth map of

0099

1 concentrations.

2 DR. RUBIN: No. That's the point I just made.

3 DR. MARTY: I don't know if ARB has any
4 comment on the modelling either. OEHHA -- we
5 don't -- we're not modelers. So I'm sorry. I can't
6 help.

7 CHAIRMAN FROINES: I don't think anybody is
8 suggesting that we define the REL or the NOEL based
9 on the modelling. But as a matter of public health
10 conservatism, if you find sick people further away,
11 that's something that should be addressed. It can't
12 be just ignored. That's the problem.

13 DR. MARTY: Yeah.

14 PANEL MEMBER ATKINSON: On Page 24, it states
15 that the 0.5-to-1-ppm-concentration range extended
16 into Zone B and possibly into C. So it's not just
17 those --

18 DR. RUBIN: Yeah. That's true.

19 CHAIRMAN FROINES: Well, look --

20 PANEL MEMBER BLANC: -- but not into.

21 CHAIRMAN FROINES: The role of this panel is
22 to function as a kind of quality-assurance,
23 quality-control effort on the science. All we're
24 trying to do is to get clarity on the science.
25 That's what we're trying to do. We're not trying to

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1 make science here.

2 But we're certainly trying to
3 understand what you are talking about. And so we
4 need to know the answer to these kinds of questions.
5 And you need to know the answers to your questions.
6 What modelling -- when you do the modelling, what
7 were the concentrations in the area that's you found
8 people with symptoms? It's a very simple question.

9 PANEL MEMBER BLANC: Well, or another thing
10 that might make the data more interpretable or would
11 lend it to health effects interpretation would be,
12 instead of having solely incidence data presented by
13 Zones A, B, C, and D, which are geographically
14 defined, why not give us incidence data by the
15 isopleth model of concentrations? We need that --

16 DR. MARTY: Overlaying where the individuals
17 were --

18 PANEL MEMBER BLANC: Yes.

19 DR. MARTY: -- with the map that was generated
20 by the dispersion modelling.

21 CHAIRMAN FROINES: Michael, do you have a
22 comment?

23 DR. DIBARTOLOMEIS: No. I'm standing here
24 just in case.

25 DR. MARTY: That presupposes you know where

0101

1 the individuals were. And, you know, I don't know if
2 you can get that from -- I don't know how the survey
3 was done --

4 PANEL MEMBER BLANC: Yeah. But you see the
5 unfortunate thing about the way the data are
6 presented in the document is that it is very easy to,
7 especially in the summarized part of it -- but it's
8 very easy to misunderstand it.

9 What is being said is not what's being
10 said. What is being said was my original
11 understanding that if, in a population which was --
12 which had a modelled exposure of .5 to 1, with all
13 the limitations of that modelling, here's what the
14 incidence was.

15 But that turns out not to be the case.
16 There was a certain incidence within the modelled
17 exposure -- .5 to 1. And then there was an incidence
18 at a lower modelled exposure concentration, although
19 I don't know what that exposure modelling was and I
20 don't know what the incidence was. But it wasn't
21 zero in either -- in either axis.

22 Shall I go on, then, or --

23 DR. FANNING: I'm sorry. Could I just get a
24 little bit of summary on that point, then? Do you
25 want to see the document changed with more

0102

1 concentrations? Or do you want to take the data as
2 presented in the document and create a finding for
3 the panel that is accurate given what is there?

4 In other words, we could say, "In
5 people whose exposure was estimated to be between .5
6 and 1 ppm, the incidence rates were as follows:"

7 PANEL MEMBER BLANC: We can't say that, based
8 on the data that's provided. What we could say is
9 that "There was a high incidence of symptoms and the
10 highest incidence of symptoms appear to be consistent
11 with an isopleth of .5 to 1. There clearly were
12 people symptomatic at lower levels of exposure, based
13 on available data."

14 We cannot say what the modelling was
15 and what the incidence was or -- I mean if -- that's
16 if you want to have findings based on what we have
17 currently.

18 If there was other data presented, I
19 want to make other findings. But I think the finding
20 would have to be that "We cannot determine from the
21 data available what the modelling would suggest was
22 the lower -- was the lower -- lowest effect level."

23 CHAIRMAN FROINES: I think -- so that I think
24 that we've just added another item for the interim
25 period, which is to get some greater clarity to what

0103

1 was indeed found. And then we can write a finding
2 that will be consistent with that, if that's okay.

3 DR. FANNING: Okay.

4 CHAIRMAN FROINES: Is that okay, panel? And I

5 think -- and Roger has been very articulate about the
6 uncertainty in this modelling. And any finding
7 should reflect that, I think.

8 PANEL MEMBER ATKINSON: Okay.

9 PANEL MEMBER BLANC: I also think that,
10 whatever else is said, I think that the final
11 sentence which says -- of Point 17, which says,
12 "Exposure to other breakdown products of metam sodium
13 was neither measured nor modelled" -- the point is
14 that it wasn't modelled.

15 Metam sodium wasn't measured either,
16 nor was MITC. It implies that something was actually
17 measured for anything.

18 DR. FANNING: Okay.

19 PANEL MEMBER BLANC: So it's just that it
20 wasn't modelled --

21 DR. FANNING: Sure.

22 PANEL MEMBER BLANC: -- I mean. So those were
23 my comments.

24 CHAIRMAN FROINES: Gary?

25 PANEL MEMBER FRIEDMAN: I have a more general

0104

1 comment. And I'm not suggesting that major work
2 should be done on this, but I have never seen our
3 findings in such great detail. It seems to me we
4 have a couple of pages with the major points, the
5 major data, and our conclusions that it's a toxic air
6 contaminant or here it should be listed.

7 And I'm just wondering whether --
8 how -- we're sort of regurgitating the whole report.
9 And I'm not sure that that's our function or that
10 that's -- we're really doing a service by doing that.

11 And I would suggest that, in the
12 future, we try to narrow down the thing to the major
13 conclusion as we've done in all previous examples
14 that I can remember.

15 PANEL MEMBER GLANTZ: Yeah. I agree totally.

16 DR. FANNING: Yeah.

17 PANEL MEMBER FUCALORO: And I can give you my
18 comment now because it follows up what you said. I'm
19 just curious. Findings 18 through 20 regarding
20 exposure of experimental animals to metam sodium in
21 drinking water -- I'm not sure how that relates to
22 anything we should be doing. And so I -- my comments
23 are yours. So we can kill two birds with one stone.

24 PANEL MEMBER GLANTZ: Three birds.

25 CHAIRMAN FROINES: Elinor and I talked at

0105

1 great length about this issue because I had the same
2 problems. And we took out -- and you haven't seen
3 what we've taken out yet.

4 PANEL MEMBER GLANTZ: Good.

5 DR. FANNING: Well --

6 CHAIRMAN FROINES: There are two paragraphs --
7 there are two paragraphs we've taken out. So we --
8 as you've noticed, if you've -- that what we did was
9 to shorten the document that was originally drafted.

10 The origin of this, of course, is what
11 everybody's forgotten is that this encyclopedia began
12 with diesel. And we've been writing very long
13 documents ever since.

14 And this is in a good point to say,
15 "Halt. We don't want to do that." I think what we
16 should do, in fact, is to define what are the
17 important scientific issues. And that's what our
18 findings should reflect.

19 PANEL MEMBER FUCALORO: In other words, what
20 we base -- what anyone can base their recommendation
21 to designate something a TAC, I mean, based upon, you
22 know, the exposure level -- well, the exposure level
23 and the toxicity -- I mean the major toxicity
24 findings.

25 CHAIRMAN FROINES: Well, we will certainly --
0106

1 we've put a lot of time into this already, as you
2 might expect. And so what I'd like is that, if
3 people will feel that there are sections that should
4 be shortened, we'll be happy to do that. I'm not
5 going to go back and redo it myself. It has to come
6 from them.

7 PANEL MEMBER FUCALORO: No. I think Gary's
8 idea was that it would be in the future.

9 PANEL MEMBER GLANTZ: He's saying it's in the
10 future.

11 PANEL MEMBER FRIEDMAN: Given the time that's
12 elapsed with this and how much work has gone into it,
13 I don't think we should rewrite it from scratch. But
14 I just question this format for our report.

15 CHAIRMAN FROINES: Yes. I think that's what
16 we're saying. So we should not go redo this, but in
17 the future it should be -- the number of findings
18 should be less than a substantial --

19 PANEL MEMBER FRIEDMAN: This is actually
20 longer than the executive summary of the original
21 report.

22 DR. FANNING: Yes. I'll say that it was a
23 great temptation, in taking this up again after a
24 year, to begin over again and make a very simple,
25 streamlined document that highlighted the important
0107

1 issues. It did seem, though, perhaps more expedient
2 to just build on what you had already approved at
3 this point and just try to make the relevant changes,
4 move on from here.

5 And the reason this document was so
6 complex in the beginning had to do with the -- there
7 were a lot of issues that came up around this
8 particular chemical. And there was some feeling a
9 couple, two years back, that some of the detail might
10 be important.

11 PANEL MEMBER BLANC: I think that the points,
12 your points are very well taken, both in terms of
13 process and in terms of the history of it.

14 DR. FANNING: Yeah.

15 PANEL MEMBER BLANC: And I think that one of
16 the questions I would have for the chair is whether
17 or not you wish to enter into an explicit discussion
18 of the panel's consensus that the document and our
19 finding about the document -- it is important that it
20 encompass metam sodium and its breakdown products.

21 And I think we effectively do that by
22 having the level of detail that we have here. And
23 that's one of the reasons why it is as detailed as it
24 is. But on the other hand, there was no point where
25 we sort of take the bull by the horns except in Point

0108

1 53 where --

2 CHAIRMAN FROINES: Where?

3 PANEL MEMBER BLANC: The very next -- the very
4 last point is really getting at that. And I guess my
5 question -- should that be even more explicit than it
6 is? Or is it good enough as is?

7 CHAIRMAN FROINES: Well, I -- from my
8 standpoint, it seemed -- that seemed to be a
9 reasonable statement. I think that, to enlarge upon
10 it, it's going to, again, create more discussion and
11 greater time will be lost or gained, however you want
12 to look at it.

13 But the -- I would like to leave it
14 pretty much as it is unless there's a consensus which
15 can --

16 PANEL MEMBER GLANTZ: And I don't think Gary
17 is proposing that you not leave this one as it is. I
18 think he's talking about the next one.

19 CHAIRMAN FROINES: No. No. No. Paul's
20 asking a specific question. Paul's asking -- look at
21 53. Paul's asking a very precise question.

22 PANEL MEMBER GLANTZ: Which is?

23 CHAIRMAN FROINES: Paul's asking is the -- in
24 53, there's a sentence that says, "In addition,
25 because MITC air levels derive overwhelmingly from

0109

1 applications of metam sodium with a smaller part
2 contributed by dazomet, we recommend that these two
3 pesticides also be listed, along with MIC, as toxic
4 air contaminants."

5 Paul's asking the question "Do we want
6 to -- do we want to discuss that issue further?"

7 And I'm saying I thought that was
8 sufficient.

9 PANEL MEMBER FUCALORO: No. I thought -- I
10 thought we had hammered that out and we had decided,
11 once you apply metam sodium, you're getting MITC that
12 attaches --

13 PANEL MEMBER BLANC: I didn't mean to discuss
14 it. I meant is that explicit enough? Is that enough
15 text? Not that we need to discuss it, but does this
16 text --

17 PANEL MEMBER GLANTZ: I think it's pretty
18 clear.

19 PANEL MEMBER BLANC: Okay. And as a sort of a

20 part of that, the very -- the last part of which was
21 that MIC is automatically -- which is attached due
22 its status as a hazardous air pollutant -- where does
23 that leave hydrogen sulfide and carbon disulfide?
24 Are they already listed elsewhere?

25 PANEL MEMBER FUCALORO: I don't know.

0110

1 CHAIRMAN FROINES: They're HAPs.

2 PANEL MEMBER FUCALORO: I would guess that
3 they would be.

4 CHAIRMAN FROINES: So they probably should be
5 included in there.

6 PANEL MEMBER BLANC: Shouldn't there be a
7 sentence there that says --

8 DR. FANNING: I know carbon disulfide is, but
9 hydrogen --

10 DR. MARTY: I'm pretty sure that hydrogen
11 sulfide is not a HAP. I'm pretty sure that George
12 Bush, Sr., blue-pencilled it.

13 CHAIRMAN FROINES: Who?

14 DR. MARTY: George Bush, Sr., had it removed.

15 CHAIRMAN FROINES: Really?

16 PANEL MEMBER FUCALORO: Why?

17 DR. MARTY: I'm almost a hundred percent
18 certain of that. We've got the list. It's not on
19 there; correct?

20 CHAIRMAN FROINES: It's not on there?

21 UNIDENTIFIED AUDIENCE MEMBER: He took it off.

22 CHAIRMAN FROINES: Well, that's a very
23 significant --

24 PANEL MEMBER FUCALORO: It's interesting.

25 CHAIRMAN FROINES: -- issue especially because

0111

1 H₂S is a primary breakdown product and one could
2 argue that, given that it's in -- in the chemical
3 context, it's in the same category as MITC, that one
4 should have dealt with both of them simultaneously.

5 PANEL MEMBER FUCALORO: Yeah. I can't --

6 CHAIRMAN FROINES: So we should have a
7 sentence in there that says, "H₂S is a product -- it
8 is not a HAP -- and needs to be considered in the
9 future."

10 PANEL MEMBER GLANTZ: Well, H₂S being a
11 breakdown product -- that's in Paragraph 5.

12 CHAIRMAN FROINES: But in the conclusion about
13 what's going to be listed and what's not listed.

14 PANEL MEMBER BLANC: What about carbon
15 disulfide? I'm sorry.

16 DR. FANNING: Carbon disulfide is listed via
17 the federal list.

18 PANEL MEMBER BLANC: It is?

19 DR. FANNING: It's a HAP.

20 PANEL MEMBER BLANC: So that we should
21 explicitly say that too in that paragraph.

22 DR. FANNING: Since we're on this, the new
23 version of the document also has identified metam
24 potassium as a new source of MITC.

25 PANEL MEMBER FUCALORO: Sure.

0112

1 DR. FANNING: Does the panel want to add metam
2 potassium --

3 PANEL MEMBER BLANC: Yes.

4 DR. FANNING: -- as well? Right now, you have
5 dazomet.

6 PANEL MEMBER BLANC: I would say the wording
7 should be "For applications of metam sodium and metam
8 potassium -- comma --" with dazomet --

9 DR. FANNING: And so we recommend that
10 these --

11 CHAIRMAN FROINES: Where are you at?

12 DR. FANNING: -- these three pesticides,
13 then --

14 PANEL MEMBER BLANC: Well, these three
15 pesticides --

16 PANEL MEMBER FUCALORO: Let me ask a question,
17 a hypothetical question. What if a manufacturer gets
18 mischievous and decides to put -- I don't know --
19 metam lithium or something, changing the "cation" ion
20 and still producing MITC? I guess he would still --
21 that manufacturer would still fall under this,
22 wouldn't he?

23 PANEL MEMBER BYUS: It would help --

24 CHAIRMAN FROINES: Would he have any market?

25 PANEL MEMBER FUCALORO: He -- you're saying,
0113

1 if the wording is strong enough. I'm suggesting --
2 originally said, "Yes, I think it is."

3 But now I'm thinking that perhaps you
4 might want to put some words which say, "All
5 products -- all products which lead -- which primary
6 goal, the consequence of application is to lead to
7 MITC" or something like that, I think, might be what
8 we wish.

9 CHAIRMAN FROINES: Okay.

10 PANEL MEMBER FUCALORO: I'm not --

11 CHAIRMAN FROINES: I don't think lithium is
12 about to emerge on the market.

13 PANEL MEMBER FUCALORO: I know. I was trying
14 to think of a cheap one. I was thinking of cesium,
15 but that's very expensive.

16 PANEL MEMBER BLANC: Maybe the pesticide
17 people could comment on this, but isn't there also a
18 formulation which is metam disodium? Does such a
19 thing exist? Because this came up in Poison Control
20 Center case presentation where there were two CAS
21 numbers for metam sodium. And we were confused, and
22 somebody tracked it down. And one was technically
23 the CAS number for metam disodium or something like
24 that.

25 PANEL MEMBER GLANTZ: Aren't we getting kind
0114

1 of faraway from the report?

2 PANEL MEMBER BLANC: Yeah. Just asking.

3 That's relevant to your question.

4 DR. FANNING: So maybe a little more on
5 this -- do you want to say something to the effect
6 that of, you know, "All pesticides which produce MITC
7 as the active fumigant should be listed"? Or do you
8 want to specifically identify metam sodium, metam
9 potassium, and dazomet?

10 CHAIRMAN FROINES: Well, we want to -- I think
11 there was a general agreement on including metam
12 potassium. So we can go with that.

13 DR. FANNING: Okay.

14 CHAIRMAN FROINES: And then what Tony is
15 saying is that we may want to add a sentence --

16 PANEL MEMBER FUCALORO: Right.

17 CHAIRMAN FROINES: -- that, if other
18 pesticides are identified that break down to MITC,
19 they should be included.

20 PANEL MEMBER BYUS: Right.

21 CHAIRMAN FROINES: I think -- is that what
22 you -- I think --

23 PANEL MEMBER FUCALORO: Yeah. Yeah. That
24 would be my suggestion.

25 DR. FANNING: Okay.

0115

1 PANEL MEMBER FUCALORO: But H2S is still
2 something that we need to discuss, I would think.

3 CHAIRMAN FROINES: And I think that the other
4 thing for the record is that there is a consensus on
5 this panel that we need briefer, to-the-point
6 findings that identify precise issues and address
7 them. And I think that's Gary's recommendation, but
8 I think everybody agreed with it.

9 DR. FANNING: Uh-huh.

10 CHAIRMAN FROINES: Craig?

11 PANEL MEMBER BYUS: Yeah. I just have a --
12 Number 36.

13 CHAIRMAN FROINES: Did you have any more
14 comments, Gary?

15 PANEL MEMBER FRIEDMAN: No.

16 PANEL MEMBER BYUS: Number 36. I assume this
17 is the Klimisch study we talked about this morning?

18 DR. FANNING: Yes.

19 PANEL MEMBER BYUS: Okay. Well, it says here,
20 "A NOEL was not identified. In pairwise comparison
21 to control animals, the increase in nasal atrophy
22 reaches statistical significance only at the highest
23 exposure of 34 parts per million. Nonetheless, the
24 panel considers the finding of 1.7 parts per million
25 toxicologically relevant."

0116

1 Maybe we should put in here about the
2 chi square test for --

3 CHAIRMAN FROINES: We are.

4 PANEL MEMBER BYUS: -- trend. Okay.

5 CHAIRMAN FROINES: I think Paul's talked about
6 that.

7 PANEL MEMBER BYUS: Did he say that in --

8 DR. FANNING: Paul didn't actually specify

9 that. I asked you that at the beginning, saying, "I
10 suspect we need to modify 36 based on that."

11 PANEL MEMBER BYUS: It makes it sound like
12 we're --

13 PANEL MEMBER FUCALORO: Arbitrary.

14 PANEL MEMBER BYUS: "Even though it's not
15 statistically significant, we do think it's
16 significant." I mean I just think, the way it reads,
17 it's like we just decided to do it arbitrarily.

18 CHAIRMAN FROINES: We need to develop new
19 language.

20 PANEL MEMBER GLANTZ: Yeah. I mean I think
21 for that what I would -- this is a place where -- and
22 a great example of words -- there's too much
23 information --

24 PANEL MEMBER BYUS: Too much information.
25 Yes.

0117

1 PANEL MEMBER GLANTZ: -- as my daughter says
2 to me. I think you can just say, "A LOEL of 1.7 was
3 identified from a 4-week inhalation study in rats,
4 based on atrophy of the nasal" --

5 PANEL MEMBER BYUS: There you go.

6 PANEL MEMBER GLANTZ: -- "epithelium" --

7 PANEL MEMBER BYUS: And leave it at that.

8 PANEL MEMBER GLANTZ: -- period.

9 PANEL MEMBER BYUS: Leave it at that.

10 CHAIRMAN FROINES: Do you want to --

11 PANEL MEMBER GLANTZ: And then I'd like on
12 that one to add in a sentence saying that "A
13 benchmark dose approach to the same experiment yields
14 similar results."

15 PANEL MEMBER BYUS: Very good.

16 PANEL MEMBER GLANTZ: You need to keep the
17 last -- you need to keep the last sentence, then.

18 "The subchronic NOEL of 100 parts per billion" --

19 CHAIRMAN FROINES: Do you want to include --
20 do you want to do what Elinor was suggesting, that a
21 sentence -- sentences be added that talk about the
22 dose-response statistics?

23 PANEL MEMBER BLANC: No. What he's suggesting
24 is the opposite. From the -- after -- from the --
25 that you strike everything in there beginning with "A

0118

1 NOEL was not identified. In the pairwise
2 comparison -- at the highest concentrations --
3 nonetheless" --

4 PANEL MEMBER GLANTZ: Well, I would even
5 strike it before that. I would say, if you go up to
6 the line before that, it says, "A LOAEL of 1.7 ppm
7 MITC was identified from a 4-week inhalation study in
8 rats, based on increased atrophy of the nasal
9 epithelium" -- period.

10 And I would delete everything down to
11 the last -- and then I would -- the whole rest of
12 that item except for the last sentence.

13 CHAIRMAN FROINES: So --

14 PANEL MEMBER GLANTZ: And then I would add a
15 sentence saying, "One reaches similar conclusions
16 based on a benchmark dose analysis of the dose
17 response -- of a dose-response relationship."
18 CHAIRMAN FROINES: So you don't want to add
19 any discussion of the statistics associated with
20 the --
21 PANEL MEMBER GLANTZ: No. They can go read
22 the report for that.
23 CHAIRMAN FROINES: Well, it's not in there.
24 PANEL MEMBER GLANTZ: Well, it will be. Paul
25 wrote that up. And he circulated -- or not "Paul" --
0119
1 Andy, I presume -- where's Andy? Is he still --
2 CHAIRMAN FROINES: No.
3 PANEL MEMBER GLANTZ: No. But the point is
4 that Paul --
5 PANEL MEMBER BLANC: Well, Andy said he would
6 modify it.
7 CHAIRMAN FROINES: Well, Paul Blanc gave the
8 trend --
9 PANEL MEMBER GLANTZ: But that'll go in the
10 report.
11 CHAIRMAN FROINES: -- the numbers from the
12 trend test. And so Andy will then incorporate that.
13 PANEL MEMBER GLANTZ: Into the report.
14 CHAIRMAN FROINES: And we won't incorporate
15 that into our document.
16 PANEL MEMBER BLANC: No.
17 CHAIRMAN FROINES: I mean Andy's making notes
18 now. So it means it wasn't clear to him that he was
19 going to do that.
20 PANEL MEMBER GLANTZ: Well, my understanding,
21 just to be doubly clear, was that the changes that
22 were circulated that talked about the power issues
23 and the benchmark dose issues that were circulated to
24 the panel a few days ago or a week ago -- that's
25 going to be added to the report.
0120
1 CHAIRMAN FROINES: Right.
2 PANEL MEMBER GLANTZ: And then the material
3 that Paul talked about will also be added to the
4 report. And I think that deals with that. I don't
5 think we need to --
6 CHAIRMAN FROINES: Is everybody in agreement
7 with that?
8 PANEL MEMBER BYUS: Totally.
9 CHAIRMAN FROINES: Okay. Still with you.
10 PANEL MEMBER BYUS: I just had one other
11 question on Number 42. You say, "A lesser factor" --
12 you're cutting out "A lesser factor might be
13 appropriate for extrapolation of systemic effects
14 observed in the subchronic study. However, a factor
15 of 10 was retained to provide additional protection
16 against the possibility that MITC may be onconic."
17 You just don't need the --
18 DR. FANNING: First of all, the endpoint on

19 which the current NOEL is based is not -- is no
20 longer systemic effects.

21 PANEL MEMBER BYUS: Okay.

22 DR. FANNING: So that part wasn't appropriate.

23 PANEL MEMBER BYUS: Okay.

24 DR. FANNING: And the sort of -- the sort
25 of -- the thinking behind that on so many factors
0121

1 changed a little bit with the new basis of it. So my
2 sense was that that was no longer necessary.

3 PANEL MEMBER BYUS: Okay. That's fine. I'm
4 done.

5 CHAIRMAN FROINES: Tony.

6 PANEL MEMBER FUCALORO: Well, I had the same
7 comment as Gary did. But I would just point -- in
8 Number 44, to get out this hydrogen sulfide issue
9 again, I still am somewhat surprised that hydrogen
10 sulfide is not a toxic air contaminant.

11 And I'm wondering -- probably it's not
12 the right time to talk about it -- I'm wondering
13 whether or not we should at some point discuss this
14 or maybe someone can explain to us why it's not.

15 DR. MARTY: It is a criteria air pollutant.

16 PANEL MEMBER FUCALORO: And that would --
17 yeah.

18 DR. MARTY: But it's an ambient air quality
19 standard. It's based on odor and not health effects.
20 So I think that needs to be noted.

21 PANEL MEMBER FUCALORO: I see. Okay. All
22 right. Then, that's all.

23 CHAIRMAN FROINES: There's a national ambient
24 air quality standard for hydrogen sulfide? What?
25

0122

1 DR. FANNING: State. It's a state value.

2 CHAIRMAN FROINES: Yeah. I'm glad to hear
3 that because I thought I knew. And it's based on
4 odor?

5 DR. MARTY: Yes.

6 PANEL MEMBER BLANC: Well, it has a pretty low
7 odor threshold.

8 PANEL MEMBER FUCALORO: It does. I can smell
9 it anywhere.

10 CHAIRMAN FROINES: But there's some
11 interesting neurologic data about its effects at low
12 dose. So it's an interesting compound.

13 PANEL MEMBER FUCALORO: Yeah. When the
14 concentration gets too high, you can't smell -- you
15 cannot smell it. And that's, of course, deadly.
16 Then you really can't smell it. You can't smell
17 anything.

18 CHAIRMAN FROINES: Tony?

19 PANEL MEMBER FUCALORO: I'm finished.

20 CHAIRMAN FROINES: You don't want us to put
21 that statement in the record. So -- but are you
22 finished?

23 PANEL MEMBER FUCALORO: I want everything I

24 said erased.

25 CHAIRMAN FROINES: Melanie?

0123

1 DR. MARTY: I'd just like to remind the panel
2 we do have a chronic reference exposure level for
3 hydrogen sulfide because it's not on the Air Toxics
4 Hot Spots list. So we have looked at that. And
5 it's based on health effects, but it's pretty
6 consistent with the odor threshold because it's
7 really stinky stuff.

8 DR. FANNING: And you don't have an acute REL;
9 is that correct?

10 DR. MARTY: I think we do. And it's based on
11 the -- yeah. It's the -- yeah. We do have an acute
12 REL for it also. But that's mostly based on the odor
13 and the path of physiologic reaction to odor.

14 CHAIRMAN FROINES: Well, let's not get into it
15 because that will start raising questions about the
16 relevance of your RELs to the EPR process. So we'll
17 leave that one aside for the moment.

18 Stan.

19 PANEL MEMBER GLANTZ: I'm -- I don't have
20 anything else to say. I mean I could tinker with
21 this, but I think we're done. I don't -- I don't
22 have any other points. I would delete a bunch of
23 stuff.

24 CHAIRMAN FROINES: You can delete it.

25 PANEL MEMBER GLANTZ: No. It's not worth it.

0124

1 Well, can I delete something? I'll delete something.
2 If you go to 41 -- and this is an example of too much
3 information -- where it says, "Reference exposure
4 levels for acute, seasonal, and chronic exposures
5 developed by DPR in Table 1" -- I would delete the
6 rest of the findings. But you don't have to.

7 DR. FANNING: So take out the --

8 PANEL MEMBER GLANTZ: Yeah. I would just say,
9 "Here they are."

10 DR. FANNING: -- uncertainty factor --

11 PANEL MEMBER GLANTZ: That's in the report.
12 People can go read the report. I mean there are
13 several points. The only reason I'm not making a big
14 deal out of it is I mean there's a whole bunch of
15 things in here where you go through all these
16 dividing by 10, divided by a hundred. I think that
17 stuff's all in the report.

18 And so I would -- and I mean going
19 through this, I think, in 42, 44, or is it 44 or 42?

20 CHAIRMAN FROINES: Well, I think it's
21 reasonable --

22 PANEL MEMBER GLANTZ: But if you want to leave
23 it --

24 CHAIRMAN FROINES: -- if the panel agrees
25 that, if you want to submit deletions, that they will

0125

1 basically trust you and we'll certainly make them.

2 PANEL MEMBER GLANTZ: Okay. I mean, just in

3 the -- going along with what Gary said, I mean I
4 think that, the longer these things get, the more
5 useful -- the less useful they are.
6 And I think going into all of these
7 computational details -- that's all in the report.
8 So I would take that out. And --
9 PANEL MEMBER FRIEDMAN: I'd support that. I'd
10 be willing to sort of go through and cross out things
11 if you're open to receiving that. I don't, you
12 know --
13 CHAIRMAN FROINES: We could have violent
14 disagreements, but we'll --
15 PANEL MEMBER FUCALORO: You'd need another
16 meeting.
17 PANEL MEMBER GLANTZ: Yeah. That's the thing.
18 I don't want to delay this anymore is the problem.
19 Well, here, just looking at it, I mean I already gave
20 you the one on 41. Let's see. 42 -- "Because
21 toxicological data on chronic inhalation are
22 lacking" -- "study in rats." Then in the next --
23 CHAIRMAN FROINES: Take out 42.
24 PANEL MEMBER GLANTZ: Huh?
25 CHAIRMAN FROINES: Take out 42.

0126

1 PANEL MEMBER GLANTZ: You could delete the
2 whole thing, you think?
3 CHAIRMAN FROINES: Sure.
4 PANEL MEMBER GLANTZ: And, then 40 -- well,
5 there is --
6 PANEL MEMBER BLANC: You know what I think?
7 You're going down it too quickly.
8 PANEL MEMBER FUCALORO: I think he's right. I
9 think this requires some deliberation. I mean you --
10 PANEL MEMBER GLANTZ: I think, rather than me
11 doing it, I'd rather get the thing accepted. And we
12 will become -- we will, like, have something that we
13 don't have. But the point is you don't need, as I
14 think Gary or somebody said -- this is longer than
15 the executive summary.
16 CHAIRMAN FROINES: We all agree. We've talked
17 about it.
18 PANEL MEMBER FUCALORO: No. No. Gary made
19 his point.
20 CHAIRMAN FROINES: We've talked about it --
21 PANEL MEMBER GLANTZ: So don't delete --
22 CHAIRMAN FROINES: Elinor and I talked about
23 it this week. We agreed. Everybody has said it.
24 Let's not discuss every issue more than three times.
25 PANEL MEMBER BLANC: But, I do have a process

0127

1 question. It sounds like -- well, Roger, you make
2 your comments first. Mine's more global.
3 PANEL MEMBER ATKINSON: I don't have any.
4 PANEL MEMBER BLANC: All right. Then here's
5 my process question: It seems as if -- okay -- we
6 have a sentence here, a word there. You've got notes
7 of this. You're going to go back to the word

8 processor and make those changes.
9 And within, you know, three days, that
10 could be circulated; and it will be, you know, on
11 that -- at least on that level. And, you know, it
12 will be one of those things where, unless somebody
13 strongly disagrees, this is the minor modifications
14 of the findings that we've approved.
15 But there's this big hole in the
16 findings that we're discussing. And it has to do
17 with what the acute REL is.
18 CHAIRMAN FROINES: We already agreed to
19 approve these findings with these minor, minor
20 changes.
21 PANEL MEMBER BLANC: Right.
22 CHAIRMAN FROINES: And then during the
23 course -- over the next, say, month, if there is new
24 evidence that suggests we need to change our findings
25 and recommend changes to DPR, then we will then take
0128 that up at another meeting. But otherwise we'll go
2 with these existing findings.
3 PANEL MEMBER BLANC: Well, that's what I'm
4 just trying to clarify. So what is the -- so the
5 process would be that we would move to reopen -- I
6 mean that's what it would be? And it would be
7 something that would come from you as chair?
8 PANEL MEMBER FUCALORO: And we're getting
9 additional information -- right? -- from Andy on
10 the -- on those -- on that study.
11 CHAIRMAN FROINES: I would send a letter to
12 everyone on the panel saying, "Given the new
13 information, we think it's prudent to reopen the
14 discussion."
15 PANEL MEMBER GLANTZ: I'd like to propose an
16 alternative procedural thing, which is sort of along
17 the lines of things we've done before.
18 I'd like to move that we approve the
19 report and the findings subject to this discussion
20 today or tentatively approve them; that the -- well,
21 no -- and that subject to -- the Chair will circulate
22 the final edited cleaned-up findings for everyone to
23 look at, and that before the -- and that, in the
24 meantime, the Chair and Paul will work with DPR on
25 this issue that Paul has raised about -- and then if,
0129 in those discussions, there does not appear to be any
2 issue that's worthy of further discussion by the
3 panel, John would simply sign the findings and submit
4 them.
5 If it appears, between now and the
6 next meeting, that there are substantive issues that
7 would result in a change to the findings, then do not
8 sign them and submit them; and we will complete the
9 work at the next meeting. That's what I move we do.
10 CHAIRMAN FROINES: I think that's what I said
11 but --
12 PANEL MEMBER GLANTZ: Yeah. But that's a

13 motion.
14 PANEL MEMBER FUCALORO: Who can second
15 something that long?
16 PANEL MEMBER GLANTZ: We have a
17 court reporter. Go ahead and do it -- second that.
18 PANEL MEMBER FUCALORO: I second it.
19 CHAIRMAN FROINES: The court reporter did not
20 second the motion.
21 PANEL MEMBER FUCALORO: No, not -- I
22 understand the gist of what you're saying. And I
23 think that's what everyone understands. And I think
24 that's fine.
25 CHAIRMAN FROINES: Is there discussion? Paul,
0130

1 you're okay with that?
2 PANEL MEMBER BLANC: Yes. That's fine.
3 You're the one that has to be the most comfortable.
4 DR. FANNING: I have one question, John. And
5 that's -- sorry to go back to the details -- but you
6 had suggested two deletions to me that the panel has
7 not yet seen. And would you like to identify those?
8 Shall I identify those and ask about them?
9 CHAIRMAN FROINES: Yeah. I don't have the --
10 I don't know -- I don't remember what they are.
11 DR. FANNING: I know what they are.
12 CHAIRMAN FROINES: Okay.
13 DR. FANNING: Additionally, Dr. Froines
14 recommended that Findings Number 38 and 40 be
15 entirely deleted. These two findings address the
16 margins of exposure that were reported for the
17 ambient air studies as opposed to the application
18 site studies.
19 So he considered those to be somewhat
20 superfluous, given the MOEs that resulted from
21 application site air.
22 CHAIRMAN FROINES: It's also consistent with
23 our recommendations to DPR on the importance of
24 application-site monitoring.
25 DR. FANNING: Yeah.

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1 CHAIRMAN FROINES: They have -- there's lots
2 of ambient monitoring discussion in the report. But
3 what I'm interested in, in the long run, is that our
4 findings reflect the basis for decisions.
5 In other words, you could have 20
6 studies that you could report, but you used one to
7 make a decision, and that's the one we should comment
8 on. And so it's that kind of thinking that I think
9 is important.
10 PANEL MEMBER FUCALORO: Right.
11 PANEL MEMBER BLANC: Well, then, I would
12 propose a friendly amendment to Stan's motion that
13 would take into account these two further deletions
14 of Points 39 and 40.
15 PANEL MEMBER GLANTZ: 38 and 40.
16 DR. FANNING: 38 and 40.
17 PANEL MEMBER BLANC: 38 and 40. I'm sorry.

18 38 and 40.
19 PANEL MEMBER FUCALORO: That's not enough,
20 Stan. The person who seconds it also has to accept
21 the friendly --
22 PANEL MEMBER GLANTZ: All right. Do you
23 accept it?
24 PANEL MEMBER FUCALORO: All right.
25 DR. FANNING: And I'm afraid there's one more
0132

1 that's pertinent to what the Chair said about that
2 the finding should reflect the basis for the
3 decision, the fundamental point that was used.
4 Finding Number 51 -- currently it
5 says -- the last sentence reads, "Such is the case
6 for MITC" -- referring to margins of exposure that
7 are within a level indicating risk. "Such is the
8 case for MITC, based on MOEs for acute exposure."
9 In our current Finding 39, MOEs for
10 seasonal exposures at application sites are also
11 within a range that indicate risk. So we may want to
12 modify this finding to say, "acute and moderate
13 term," or "acute and seasonal exposures" as sort of
14 your basis for your recommendation.
15 CHAIRMAN FROINES: Okay.
16 PANEL MEMBER FUCALORO: In the last sentence,
17 you would say, "Such is the case for MITC based on
18 MOEs for acute and seasonal exposure"? That's what
19 you're suggesting? Well, if that's what it says, of
20 course, it should -- we should say what we mean.
21 DR. FANNING: Yeah. And one final question
22 for the panel would be -- I just want to note that
23 the way the title of your findings currently reads --
24 first of all, the italicized language that's
25 highlighted obviously would be removed. That's just
0133

1 a comment. That's not part of your title for the
2 record.

3 So the title, as we have it currently,
4 would read "Scientific Panel Review Findings on the
5 Department of Pesticide Regulation's Toxic Air
6 Contaminant Document for Metam Sodium and other
7 pesticidal sources of MITC."

8 PANEL MEMBER FUCALORO: Yeah. And that gets
9 to what we were discussing in the last one,
10 obviously -- the pesticidal sources of MITC. Does
11 this disadvantage a company that produces metam
12 sodium?

13 Or should we be more neutral and say,
14 "Toxic air contaminants for pesticidal sources of
15 MITC and MITC itself" or something like that? Does
16 that disadvantage the company that makes metam
17 sodium?

18 PANEL MEMBER GLANTZ: That is the main source
19 of MITC.

20 PANEL MEMBER BLANC: Yeah.

21 PANEL MEMBER FUCALORO: I just asked the
22 question. I don't feel really strongly either way.

23 PANEL MEMBER BLANC: I don't understand your
24 question or your comment.
25 DR. FANNING: I just wanted to verify that the
0134
1 title reads as you want it.
2 PANEL MEMBER BLANC: But there must be a
3 reason why you want to verify it. What is the
4 implication that we should be aware of?
5 DR. FANNING: Well, the document that DPR has
6 brought to you is titled "Evaluation of MITC." So I
7 just --
8 PANEL MEMBER BLANC: Well, then, what I would
9 suggest is that, if the title of our finding was
10 worded as it is up until the very end where it says,
11 you know, "and other pesticidal sources of methyl
12 isothiocyanate -- MITC" -- and then there should be a
13 parentheses -- "the document, which is entitled by
14 DPR as" -- quote -- "'Evaluation of Methyl
15 Isothiocyanate as a Toxic Air Contaminant, Parts A
16 through C'" -- whatever it is, because obviously
17 there could be confusion at a later date.
18 One could say, based on your findings,
19 there's no corresponding document with the title that
20 corresponds to it.
21 DR. FANNING: Right. Right.
22 PANEL MEMBER BLANC: I don't want to back off
23 from what it is that we're doing our findings over.
24 In fact, the question would be whether the title of
25 this should say, "other pesticidal sources of Methyl
0135
1 Isothiocyanate and related breakdown products." But
2 I don't think that that has to be in the title.
3 So that would be my suggestion would
4 be that there be a parentheses saying, "the document
5 entitled by DPR as."
6 DR. FANNING: Okay. I think that improves the
7 accuracy of the title.
8 CHAIRMAN FROINES: Hearing no --
9 PANEL MEMBER BLANC: And I suggest that as a
10 friendly amendment to Stan's previous --
11 PANEL MEMBER GLANTZ: In fact, I would
12 actually go a bit further.
13 Given the history of this, I would
14 say, "Scientific Review Panel Findings on the
15 Department of Pesticide Regulation's Toxic Air
16 Contaminant Document" -- quote -- "'Evaluation of
17 Methyl Isothiocyanate as a Toxic Air Contaminant'" --
18 comma -- close quote -- "which is produced by the use
19 of metam sodium and other pesticidal sources" or
20 something like that to make it clear that the primary
21 commenting is on the document on MITC but, in the
22 title, to note where it comes from so there can be no
23 question raised by any pesky people that we're
24 commenting on this document.
25 PANEL MEMBER BLANC: Elinor, could you follow
0136
1 that? It's just a slight -- it's just a reordering.

2 DR. FANNING: Yeah. Reordering, essentially,
3 the language that you gave. Yeah. I got that. And
4 I'll get the details from the transcript if I wrote
5 it down wrong.

6 Sorry. There's one more small one.

7 PANEL MEMBER GLANTZ: Oh, there's yet another
8 one? Okay.

9 DR. FANNING: It's small.

10 PANEL MEMBER BLANC: Is this the last?

11 DR. FANNING: This would be the last of my
12 questions for you.

13 PANEL MEMBER BLANC: Okay. Okay.

14 DR. FANNING: That would be in Finding 47.
15 First of all, the current language -- "may exceed
16 benchmark risk levels."

17 Dr. Froines recommended changing that
18 to "regulatory exposure levels" for clarity. So that
19 was a small wording change.

20 But the other question on that is the
21 sentence -- "The combined risk of exposure to the
22 mixture of irritants is the most relevant benchmark
23 by which risk management strategies for metam sodium
24 should be measured."

25 And the question is, given the
0137 discussions today, would you say that, "combined
2 risks of exposure to mixtures is the most relevant
3 benchmark by which risk management strategies for
4 metam sodium and other pesticidal sources of MITC"?
5 PANEL MEMBER GLANTZ: Yes.

6 PANEL MEMBER FUCALORO: That's consistent
7 language.

8 DR. FANNING: Okay. That's -- it's a small
9 thing. But that's my last question for you.

10 PANEL MEMBER GLANTZ: So you have to second or
11 you have to agree to that all that.

12 PANEL MEMBER FUCALORO: I certainly do. My
13 cooperation has never wavered.

14 CHAIRMAN FROINES: This is undoubtedly the
15 longest motion in the history of this panel.

16 PANEL MEMBER FUCALORO: I hate to have my
17 name --

18 PANEL MEMBER GLANTZ: I think actually my
19 whole lead thing was longer than that.

20 PANEL MEMBER FUCALORO: I hate to have my name
21 associated with this, but --

22 PANEL MEMBER BLANC: The reason why Item
23 Number 47 is important, by the way, is that it
24 provides our Chair with a rationale by which he can
25 do this follow-up on the data from Earlimart since
0138 clearly it would be a contradiction to, on the one
2 hand, have a finding such as Number 47 and at the
3 same time downplay the actual data set which
4 addresses this issue.

5 DR. FANNING: Yeah. I think it's clear that
6 your Finding 47 was designed to address situations

7 exactly like what you see in the Earlimart data.
8 CHAIRMAN FROINES: So we should proceed.
9 PANEL MEMBER BLANC: So do you want to call
10 the motion?
11 CHAIRMAN FROINES: Yes. All in favor of the
12 motion, which we will not try and restate. We will
13 generate it from the transcript.
14 (Panel members raise their hands.)
15 CHAIRMAN FROINES: The vote -- those opposed?
16 The vote carries unanimously for
17 approval of the findings.
18 PANEL MEMBER GLANTZ: And the report.
19 CHAIRMAN FROINES: And the report.
20 PANEL MEMBER GLANTZ: Subject to the motion.
21 PANEL MEMBER BLANC: As per the motion.
22 PANEL MEMBER GLANTZ: Or as per the motion.
23 Yeah. No jokes.
24 CHAIRMAN FROINES: Okay. We have about an
25 hour -- 1:15, 2:15 -- an hour and a half. Let's take
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1 a 5-minute break. And then let's go to the
2 prioritization document. But before the
3 prioritization document, Melanie, can we do carbon
4 disulfide?
5 DR. MARTY: Yes.
6 CHAIRMAN FROINES: No. We're going to take a
7 break. Then we'll do carbon disulfide. Then we'll
8 do the prioritization document.
9 (Break.)
10 CHAIRMAN FROINES: Melanie, I think all we
11 need to do is raise the issue because we've
12 already -- on carbon disulfide, we have already had a
13 discussion, and we did not take a vote on it. So we
14 are simply -- this is almost an administrative matter
15 rather than a technical one.
16 DR. MARTY: Right. The panel reviewed carbon
17 disulfide and came to agreement with what we had done
18 for developing the chronic REL.
19 But the problem was procedural. It
20 had not been properly noticed before the last meeting
21 that we were going to discuss carbon disulfide. So
22 legally we couldn't vote -- you guys couldn't vote to
23 approve the REL.
24 So now that we've properly noticed --
25 PANEL MEMBER FUCALORO: Oh, I see.
0140
1 DR. MARTY: -- it, you can take your
2 discussion and move forward to approve or disapprove
3 the REL.
4 CHAIRMAN FROINES: Well, do you want to make a
5 brief showing of an overhead?
6 DR. MARTY: We can -- we have two slides which
7 basically will remind you of what we did to generate
8 the REL.
9 CHAIRMAN FROINES: Yeah. I hate to vote
10 without 'cause there has been a gap and --
11 DR. MARTY: Okay.

12 DR. SALMON: Do you want to see those slides?
13 DR. MARTY: Yeah.
14 CHAIRMAN FROINES: Go ahead.
15 DR. MARTY: Yeah.
16 DR. SALMON: Okay. Coming up.
17 PANEL MEMBER GLANTZ: And Dr. Blanc will find
18 something to reject.
19 DR. MARTY: Basically we looked at -- we
20 looked at people exposed in the viscose rayon
21 industry and looked at nerve conduction velocity as
22 the critical effect. The NOAEL was not observed in
23 this study.
24 We did a benchmark concentration
25 calculation and adjusted for exposure continuity from
0141
1 the occupational exposures to equivalent residential
2 24-hour exposure. And the exposure duration was --
3 PANEL MEMBER FUCALORO: Can you go back? I'm
4 sorry. Go on.
5 DR. MARTY: Sure. It was a chronic -- these
6 folks were exposed chronically.
7 PANEL MEMBER FUCALORO: Thank you.
8 DR. SALMON: Okay.
9 DR. MARTY: Okay. So the human equivalent
10 concentration turns out to be 2 1/2 ppm for the
11 benchmark concentration at 5 percent response rate.
12 We didn't feel that we needed a subchronic
13 uncertainty factor because there was a duration of
14 exposure.
15 And, of course, there's no
16 interspecies extrapolation. We applied an
17 intraspecies uncertainty factor of 10. So the total
18 cumulative uncertainty factor is 10. This results in
19 a chronic REL of basically 800 micrograms per cubic
20 meter or 300 ppb.
21 We also, if you'll recall, had added
22 in a paragraph about potential for differential
23 impacts on children's health. And we looked at,
24 basically, animal studies on developmental toxicity.
25 And the data are messy.
0142
1 Some studies show effects. Some
2 studies, using higher concentrations, show no
3 effects. So we conclude that the two studies that
4 did show effects, which were Russian studies, were
5 not very consistent with the data base as a whole.
6 And further research might clarify some of these
7 potential behavioral "tox" impacts.
8 But no adverse effects were reported
9 at concentrations below the proposed REL. And that
10 summarizes what we had discussed previously.
11 PANEL MEMBER FUCALORO: So what is our
12 require -- what is required of us? That we approve
13 this REL --
14 CHAIRMAN FROINES: Yes.
15 PANEL MEMBER FUCALORO: -- for CS2?
16 DR. MARTY: Right.

17 CHAIRMAN FROINES: No. We approve the
18 methodology and the analysis that led to the
19 development of this REL.
20 PANEL MEMBER FUCALORO: So is there a motion
21 to that effect that --
22 CHAIRMAN FROINES: Somebody should make --
23 PANEL MEMBER FUCALORO: I'll make a motion to
24 that effect.
25 CHAIRMAN FROINES: Do we have a second?
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1 PANEL MEMBER FUCALORO: I think Stan should do
2 that.
3 PANEL MEMBER GLANTZ: Well, actually this was
4 discussed at the last meeting, which I missed. So
5 I --
6 PANEL MEMBER BLANC: I'll second it.
7 CHAIRMAN FROINES: Does that mean that you are
8 refusing to second it because --
9 PANEL MEMBER GLANTZ: I think I should abstain
10 since I didn't hear the discussion.
11 CHAIRMAN FROINES: Oh, okay.
12 PANEL MEMBER GLANTZ: That's a problem.
13 CHAIRMAN FROINES: Okay. Is there further
14 discussion on this matter? No?
15 Hearing none, shall we -- all those in
16 favor of approval?
17 ("Ayes.")
18 CHAIRMAN FROINES: Opposed?
19 (No audible response.)
20 CHAIRMAN FROINES: Abstentions?
21 (No audible response.)
22 CHAIRMAN FROINES: One abstention. So the
23 vote carries. 1, 2, 3, 4, 5, 6 --
24 PANEL MEMBER GLANTZ: Just for the record, the
25 abstention is only because I missed the last meeting
0144
1 and did not hear the discussion. It is not a
2 statement about the --
3 CHAIRMAN FROINES: So the vote is 6 in favor
4 and 1 abstention.
5 Thanks, Melanie. Thanks, Andy.
6 Paul Blanc gave a great seminar on
7 carbon disulfide yesterday. So some of us are really
8 well prepared for this discussion. Hearing Paul, we
9 think the REL should be about 1 part per billion.
10 That wasn't said seriously.
11 CHAIRMAN FROINES: Randy, do you want to
12 introduce yourself for the --
13 DR. SEGAWA: Sure. I'm Randy Segawa,
14 Environmental Scientist with the Department of
15 Pesticide Regulation. And I'll be talking about
16 DPR's updated prioritization for monitoring as well
17 as risk evaluation of toxic air contaminants.
18 The draft prioritization that was sent
19 to you earlier is an update of DPR's 1996 report. To
20 give you a little bit of background, within
21 California, there's approximately 900 different

22 pesticides currently registered for use in the state.
23 Approximately 40 of those are currently listed as
24 toxic air contaminants, which leave, of course, a
25 balance of approximately 860 that we need to evaluate

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1 as potential candidates.

2 The prioritization that we're looking
3 at now applies both to monitoring for candidate toxic
4 air contaminants as well as their risk evaluation.
5 If you recall, the previous prioritization -- 1996 --
6 was focussed mainly on monitoring. This update now
7 deals both with monitoring as well as risk
8 evaluation.

9 900 pesticides, of course, or 860
10 pesticides are quite a bit to evaluate. So we
11 whittled that group down. And the current
12 prioritization includes two groups of pesticides.

13 The first 200 pesticides that DPR's
14 looking at under the Birth Defect Prevention Act,
15 SB 950, as well as all pesticides listed under
16 Proposition 65.

17 To do this prioritization, we set up a
18 number of criteria to rank the pesticides. These
19 criteria fall into three main categories -- toxicity,
20 volatility, and use or sales.

21 Specifically in "toxicity," we're
22 ranked according to acute toxicity, whether it's
23 listed as a carcinogen under Prop 65, whether it's
24 listed as a reproductive toxin under Prop 65, and the
25 no-observed-effect level for chronic and subchronic

0146

1 exposure.

2 PANEL MEMBER FUCALORO: Just a second. Can I
3 interrupt you?

4 DR. SEGAWA: Yes.

5 PANEL MEMBER FUCALORO: The criteria for
6 prioritization -- you have Toxicity, Vapor Pressure,
7 and Uses and Sale. Now, I can understand -- Use and
8 Sale. Is "vapor pressure" a surrogate for
9 "exposure"? It's not. What is exposure -- where is
10 "exposure" in this?

11 DR. SEGAWA: In this case, it is a surrogate
12 for "exposure." Yes.

13 PANEL MEMBER ATKINSON: Is it a very good
14 surrogate? I mean, in reality, the partitioning
15 between air and water, for example, is really the
16 vapor pressure divided by the aqueous solubility or
17 the Henry's law constant.

18 And if you're talking about air to
19 soil or sediment, then it would be the Henry's law
20 constant divided by the octanol/water partition
21 coefficient. So it looks to me as though vapor
22 pressure alone is a little bit too simplistic.

23 I mean, for something which is highly
24 water soluble, it's not the only thing that's going
25 to affect things getting into the atmosphere.

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1 DR. SEGAWA: You're absolutely correct. By
2 incorporating other physical or chemical processes,
3 though, we do make the criteria much more complex and
4 more difficult to score.

5 For example, not all pesticides are
6 applied or mixed with water. Not all are applied to
7 soil. There are -- a great many pesticides are
8 applied to foliage, for example. And so --

9 PANEL MEMBER ATKINSON: Yeah. But if it's
10 foliage, it would presumably be either onto water
11 layers that are present on foliage or to the leaf
12 itself, which would be octanol/water, again.

13 I mean there's plenty of stuff in
14 equilibrium or in multimedia modelling that would
15 allow you to go one step beyond just the vapor
16 pressure.

17 DR. SEGAWA: Yes.

18 PANEL MEMBER ATKINSON: And it's either going
19 to be either Henry's law constant or octanol/water or
20 a mixture of those two.

21 DR. SEGAWA: So do you have a specific
22 suggestion or recommendation, then?

23 PANEL MEMBER ATKINSON: I think -- no. That's
24 the problem.

25 DR. SEGAWA: Yeah.

0148

1 PANEL MEMBER ATKINSON: I mean it --

2 PANEL MEMBER FUCALORO: Yeah.

3 PANEL MEMBER ATKINSON: -- depends whether it
4 goes onto soil or onto water.

5 PANEL MEMBER FUCALORO: And it also depends on
6 what's known of the particular compound.

7 PANEL MEMBER ATKINSON: Yeah. That's right.

8 PANEL MEMBER FUCALORO: That's one of the
9 problems.

10 DR. SEGAWA: Okay.

11 PANEL MEMBER ATKINSON: I mean I would have
12 thought that the Henry's law constant would have
13 probably been a bit better than just vapor pressure
14 alone.

15 PANEL MEMBER BLANC: When you use the vapor
16 pressure -- just to clarify -- it's broken down into
17 an ordinal scale -- sort of "not very much," "a lot,"
18 "a little." Or you're not using the absolute vapor
19 pressure as a number?

20 PANEL MEMBER ATKINSON: Yeah. It's used --

21 DR. SEGAWA: Yes. Actually --

22 PANEL MEMBER ATKINSON: -- 2 further on -- 2
23 or 3 further on.

24 DR. SEGAWA: Yeah. We'll get into more
25 details on each of these criteria. I'm just going to

0149

1 general characteristics right now.

2 PANEL MEMBER BLANC: Maybe we can come back to
3 this question --

4 DR. SEGAWA: Yes. Exactly. Yes.

5 PANEL MEMBER FUCALORO: It is ordinal, though.

6 It has to be ordinal, though. You'll see.
7 DR. SEGAWA: Okay. These criteria are changed
8 somewhat from the criteria we used in 1996. For
9 acute toxicity, that criteria is unchanged, both in
10 the criteria we use as well as the scoring.

11 The Prop 65 carcinogen criteria is an
12 addition. It replaces the EPA and NTP carcinogen
13 categories that we had used previously. The Prop 65
14 reproductive toxin category is added. We did not
15 have a category for a reproductive toxin previously.

16 The criteria for chronic and
17 subchronic NOEL -- that's unchanged from 1996.

18 For vapor pressure, we have changed
19 the scoring, which I'll get to in more detail on a
20 couple more slides. Same with use and sales. We've
21 changed the scoring on how that's ranked.

22 And as Dr. Atkinson pointed out
23 previously, we have included a Henry's law constant.
24 We're proposing to drop that at this point. But we
25 can discuss that further once we get to the

0150
1 volatility scoring.

2 The exact category in scoring for
3 acute toxicity -- again, this is unchanged from the
4 1996 prioritization. It's based on US EPA's toxicity
5 categories which, in turn, is based on a 4-hour
6 inhalation LC50.

7 Under the EPA's categorization, we
8 assigned 4 points if the LC50 is less than .05
9 milligrams per liter and 3 points if it's between .05
10 and .5. And you can see that it's one point decrease
11 for every tenfold factor -- or every increase in
12 tenfold factor from there.

13 CHAIRMAN FROINES: I have a question about
14 this.

15 DR. SEGAWA: Yes.

16 CHAIRMAN FROINES: But Melanie's gone, and
17 so's Andy. Oh, there's Andy. Sorry. Oh, I --
18 sorry. I just didn't see you.

19 PANEL MEMBER FUCALORO: What's in your glass?

20 PANEL MEMBER GLANTZ: Stand up, Melanie.
21 Melanie will stand up.

22 CHAIRMAN FROINES: I formally apologize. I
23 want it on the record. Okay. Melanie or Andy or
24 both -- of the acute RELs that the panel has
25 approved, how many pesticides would you say are

0151
1 included in that list?

2 DR. MARTY: Very few. I'm guessing it's less
3 than 5 -- 5 or less. The ones I can think of are
4 acrolein, methyl bromide, chlorine --

5 PANEL MEMBER BLANC: Chloropicrin.

6 DR. MARTY: -- chloropicrin --

7 DR. SALMON: Well, phosphine, if you count
8 that.

9 DR. MARTY: Phosphine. I don't think we have
10 an acute REL for phosphine.

11 CHAIRMAN FROINES: I'm asking the question, in
12 part, because it seems to me that a 4-hour inhalation
13 LC50 is a very, very simple estimate of acute
14 toxicity and that it seems to me to be an inadequate
15 estimate of acute toxicity.

16 Given the -- given what we did, for
17 example, in the acute RELs, which is a very -- was a
18 relatively complex process, the question is: Is this
19 the best we can do in terms of acute toxicity?

20 And I think it's an important issue
21 because, for example, MITC acute toxicity is after --
22 at the end, what was the basis for the
23 recommendations. And so the question is, by using an
24 LC50 as the only way of evaluating acute toxicity,
25 are we getting the best bang for the buck, so to

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1 speak?

2 PANEL MEMBER BLANC: In a relative phasing --

3 ASSISTANT DIRECTOR JONES: John, Randy can
4 correct me if I'm wrong, but I believe -- and I don't
5 know formally if that was the same value that was
6 used -- but that is the most readily available data
7 that we have at DPR.

8 So I think, for purposes of
9 prioritization, trying to use readily available data
10 as one of several factors for attempting to rank
11 compounds, both for monitoring and for risk
12 assessment, was the effort here.

13 CHAIRMAN FROINES: Well, it's an important
14 question because an LC50 is such a simple endpoint.
15 And I don't know where, if one looked at MITC or any
16 of the other acute RELs, where, how --

17 In other words, if you take the RELs
18 that we have that Melanie's developed and you look at
19 the LC50s and then you take a look and see if -- what
20 you get when you compare them, that would be an
21 interesting exercise to see if, in fact, we're
22 getting a sufficiently complex evaluation of acute
23 toxicity.

24 ASSISTANT DIRECTOR JONES: I don't think the
25 effort of the exercise was to do an evaluation of the

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1 acute toxicity. It was to -- and I think, on the
2 advice of the panel -- try to simplify the array of
3 materials which we used to establish some kind of
4 prioritized list.

5 CHAIRMAN FROINES: I do not agree with you.
6 In your prioritization document, the notion of
7 simplification -- one has to be careful. The panel
8 really did not go through the prioritization
9 categories in detail at the January meeting.

10 And I think that you may have
11 misunderstood our intent. But we'll come to that as
12 we go through.

13 ASSISTANT DIRECTOR JONES: Okay. And I guess
14 we didn't get feedback to that effect.

15 CHAIRMAN FROINES: Go ahead.

16 PANEL MEMBER BLANC: Well, I was going to say
17 that, on a pragmatic basis, one of the things that
18 one would be looking for in any of these schemes
19 would be "Do you get a spread of results with it?"

20 PANEL MEMBER FUCALORO: That's what I was
21 going to ask. In other words --

22 PANEL MEMBER BLANC: So, at a certain point
23 after we go through this, is a sort of screening
24 question you would ask yourself: "If I categorize
25 these individual chemicals, based on this axis of the

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1 scoring system, does everybody come out as a 1? Or
2 does everybody come out as a 4?"

3 If there's a spread, where 25 percent
4 of them are 1 and 25 percent of them are 2 and 25
5 percent are 3 and 25 percent are 4, then I would say
6 you are getting a spread that's telling you something
7 relative. It seems to be differentiating in some
8 way.

9 You're asking a question about "Is
10 that the very best way to differentiate?" but,
11 typically, for this kind of crude scoring, if you've
12 got different domains that you're evaluating and it
13 doesn't -- on the face of it, it would be seem to be
14 serving its purpose.

15 And I think that's a practical way of
16 looking at that kind of single axis. So we really --
17 it will depend a bit on how it performs, I think.

18 PANEL MEMBER FUCALORO: Why don't you just ask
19 the question? I mean do you have the chemicals
20 listed? And you're looking for the -- you said a
21 spread, a distribution among these 4 categories. Did
22 you have a distribution?

23 DR. SEGAWA: Yes. If you look at the report,
24 the table near the back -- at least -- it lists all
25 the individual scores in the individual categories.

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1 PANEL MEMBER FUCALORO: Now, this is a report
2 dated when?

3 DR. SEGAWA: January, 2002.

4 PANEL MEMBER FUCALORO: Right.

5 CHAIRMAN FROINES: One may have a very
6 different dose-response slope or general relationship
7 between irritation or immunologic changes or any
8 other acute endpoint you might measure relative to
9 mortality. And so to use mortality as a measure of
10 acute toxicity is a little troubling, I think.
11 But --

12 PANEL MEMBER BYUS: How do you want to do
13 this, John? Do you want us to jump in at any
14 appropriate time? Or do you want us to --

15 CHAIRMAN FROINES: Well, I think that, as we
16 go through, I think that we should -- as Randy goes
17 through each of his categories, I think we should get
18 comments during that particular category. I don't
19 think we should then try and go back later. One,
20 we'll run out of time. And, then, secondly, it won't

21 be as focussed.

22 PANEL MEMBER BYUS: So I have a comment about
23 the LC50s as well. I mean I teach in pharmacology.
24 In addition to what you've just said about toxicity
25 versus lethality for drugs, it being much more

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1 important what the toxic dose -- 50 percent -- is
2 rather than the lethal dose 'cause it's the dose
3 limiting toxicity.

4 But also I teach that it's also much
5 more relevant to do something like the LC5 as opposed
6 to the LC50. I mean what you really don't want --
7 you really want to know what is happening on the
8 fringes of your population rather than the 50 percent
9 mark.

10 So if you were going to use a lethal
11 dose for comparative purposes, you wouldn't pick the
12 50 percent-point dose. You would pick the 5 percent
13 dose because that would affect the slopes, the
14 distribution much more. It would be much more
15 relevant.

16 DR. SEGAWA: Yes.

17 PANEL MEMBER BYUS: And I assume that that
18 information is available. If they've calculated LV
19 and LC50s, they've also calculated -- you'd need --
20 the 5 percent dosage --

21 DR. SEGAWA: Right.

22 PANEL MEMBER BYUS: -- calculation would be
23 there as well.

24 DR. SEGAWA: Right.

25 PANEL MEMBER BYUS: So I would suggest you

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1 might consider that.

2 DR. SEGAWA: And actually that was going to be
3 one point I was going to make. We are trying to
4 prioritize over 200 pesticides here. And whatever
5 criteria we choose, we have to be able to score it
6 for all 200-plus pesticides.

7 And, for instance, I don't know that
8 we have RELs for all 200 plus or so. And I -- same
9 with the LC5. We may or may not have them.

10 PANEL MEMBER BYUS: But if somebody's
11 calculated -- I can guarantee you, if someone has
12 calculated the LD50 or the LC50, they must have the
13 LC5 data. It is available. It's there in the curve.
14 I think you have to -- it would be there, by
15 definition.

16 DR. SEGAWA: Yeah.

17 PANEL MEMBER BYUS: And you could get it; and
18 it would be much better than using the 50 percent
19 point, I mean if you're going to use lethality.

20 DR. SEGAWA: Yes. Any other questions or
21 comments on the acute toxicity? Okay.

22 Then, moving on to the Prop 65
23 categories, we're using both the carcinogen listing
24 as well as the reproductive toxic listing. 2 points
25 if the pesticide is on the cancer list; zero points

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1 if it's not.

2 Same with the reproductive list -- 2
3 points if it's listed and zero points if it's not.

4 PANEL MEMBER BYUS: I have a question. Why is
5 it that it only gets 2 points if it's a carcinogen?
6 I mean it just seems to me what you're doing is
7 vastly -- given your -- we can come back to this at
8 the end if there's a global discussion of how you
9 decide how many points are in each category.

10 And this is a very important
11 consideration because it affects the overall
12 number --

13 DR. SEGAWA: Yes.

14 PANEL MEMBER BYUS: -- and the overall
15 priorities. But, in any case, giving -- only giving,
16 if it's a carcinogen, 2 points, I think vastly
17 underestimates the significance of the toxicity of a
18 carcinogen in this overall scheme.

19 DR. SEGAWA: Right. The scoring --

20 PANEL MEMBER BYUS: So it would be 2 points
21 out of how many total?

22 DR. SEGAWA: Out of 28 possible. Yeah. You
23 may very well be correct. The points assigned and
24 the way we scored it is definitely subjective.
25 There's really no objective way to determine the

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1 scoring, and so it is a subjective measure.

2 One of the things that we tried to
3 revise from the 1996 prioritization was your
4 recommendation that we want to try and balance the
5 weighting of the toxicity use and volatility.

6 And so, before, the toxicity
7 categories were highly weighted, in the previous
8 prioritization. And so now we're trying to weight
9 them less in comparison to the other two categories.
10 So that's what led to the lower scoring in this case.

11 PANEL MEMBER BYUS: Okay. I still don't -- I
12 mean I think we should come back to this --

13 DR. SEGAWA: Yes. I agree.

14 PANEL MEMBER BYUS: -- discussion at the end
15 relative -- how you -- how many points you -- whether
16 the categories you've come up with are correct and
17 then how many points you give each category --

18 DR. SEGAWA: Yeah. I agree. We should come
19 back to --

20 PANEL MEMBER BYUS: -- and how you weigh each
21 category.

22 DR. SEGAWA: Yeah. When we look at the
23 overall score and how that comes out.

24 PANEL MEMBER FUCALORO: Yeah. We've been
25 through this before.

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1 DR. SEGAWA: Yeah.

2 PANEL MEMBER BYUS: We did.

3 PANEL MEMBER FUCALORO: Okay. And I brought
4 up some issues. I guess I'll just mention them here.

5 First of all, there are two types of
6 categories here. One is exposure, availability in
7 the environment. The other is toxicity. It's not
8 clear whether you should be adding them all together
9 or not or multiplying one by the other, you know. I
10 don't know.

11 The other thing is I still think that
12 it's unwise mathematically to have these -- make sure
13 these add up to 4. You can do a 1-to-10 scale on
14 everything and then put coefficients in front of each
15 category, which you can then adjust to make -- to
16 say, "Well, I want to weight cancer, a
17 carcinogenicity, a little more." You turn up that
18 coefficient a little more, you know.

19 So that's my suggestion. I'll make
20 it. I'm not going to veto anything. I don't think I
21 have the authority to veto. But I'm not going to
22 vote against it if you don't. But I think you ought
23 to be thinking about those sorts of things.

24 I think there's probably some research
25 on how one makes priority lists. And I don't know if
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1 you're familiar with it. I'm not. But I can just
2 imagine, though, some of these issues coming up.
3 It's just common sense. That's all.

4 CHAIRMAN FROINES: I -- as a philosophical
5 construct, I agree with what Tony was saying. I
6 might have said it a little differently. I think
7 that the one subject area is human health. Is the
8 material toxic? That seems to me to be the primary
9 criteria that we're concerned with.

10 If there is exposure, is there a
11 potential for human beings to be adversely affected
12 by the pesticide? That's where -- that's it. That's
13 the centerpiece of everything we do. And that has to
14 have -- it seems to me -- has to be the primary
15 evaluation that we carry out.

16 Then we say, "Now, having said that,
17 having said that X chemical has significant toxicity
18 or potential toxicity, then are people exposed to
19 it?" And that becomes a weighting of the toxicity.

20 So the algorithm of using simply an
21 additive idea doesn't reflect the sort of underlying
22 objectives that one has to, I think, establish. To
23 me, the primary objective is to determine toxicity
24 and then to determine whether people are exposed to
25 it or not.

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1 PANEL MEMBER FUCALORO: Exactly.

2 CHAIRMAN FROINES: And that means that your
3 exposure rating could be multiplicative, for example.
4 It doesn't have to be additive because you end up
5 with propargite and sulfuryl fluoride having the same
6 numbers.

7 Those are very different compounds in
8 terms of toxicity. And so it -- in a sense, both of
9 them having 18 ends up meaning that one has made a

10 mistake. One's made a mistake in terms of
11 prioritization, I think.

12 And so it seems to me that, once you
13 say, "Toxicity is the centerpiece and the modifying
14 factor is the exposure," you've defined the way to
15 look at the problem. And so it seems to me that -- I
16 would argue that "zero to 2" is ridiculous. It's not
17 even in my window of discussion.

18 So we should come back to it. But I
19 think that this is certainly an inadequate estimation
20 of a major biological endpoint. And so I'll leave it
21 for the time being.

22 But I think that one has to think
23 about it in ways that are having -- one has to define
24 what are the objectives and what are the key
25 parameters that we want to be concerned with and then
0163 1 decide what the algorithm looks like.

2 DR. SEGAWA: Okay.

3 PANEL MEMBER GLANTZ: Well, you know, I mean
4 I think they tried to do -- first of all, whether you
5 score it the way they do or whether you score
6 everything on a zero-to-10 basis and then put a
7 weight on it, you get the same results. So that
8 doesn't really matter.

9 And the other problem that's inherent
10 in this whole process -- and there's absolutely
11 nothing you can do about it -- is, when you've got a
12 multidimensional system, which you have, there is no
13 unique order. I mean you can prove that in number
14 theory.

15 So I mean I think that they're doing
16 the best they can. And I think that one of the
17 changes between -- which we haven't gotten to yet --
18 but one of the changes they made from the last
19 prioritization document was to weight the amount of
20 the stuff that's used much more heavily than they did
21 before.

22 So I think that, effectively, they've
23 been trying to do exactly what you're saying. I
24 mean, if you wanted to change the scale so that you
25 took the toxicity score and multiplied it by the
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1 amount that's used or the exposure -- I mean that's
2 not a bad idea.

3 But I don't think that those kinds of
4 adjustments are going to get around the sort of
5 fundamental theoretical problem you have that you
6 can't uniquely rank a multidimensional system.

7 And, you know, if you look at the
8 prioritizations that we've done for the ARB TACs -- I
9 mean what was done then was that we came up with this
10 rough order, based on these kinds of scales, which
11 actually struck me as pretty reasonable, and then
12 looked at them and applied some judgment and moved
13 things around.

14 And I really think that will get you

15 further than, you know, tinkering with the scale.
16 I mean my concern about this was I
17 noticed the dates, you know. This law passed in --
18 what? -- 1983, which is not quite 20 years ago. And
19 how many pesticides have we made it through the
20 process? 3? Does that count MITC? So 3 and a half.
21 So that's an average of about 1 every
22 7 years or something. That's kind of -- that, to me,
23 is a much bigger problem. And if DPR could move
24 these things a little more expeditiously, the details
25 of exactly where you ended up in the list would be

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1 less important.
2 CHAIRMAN FROINES: Well --
3 PANEL MEMBER FUCALORO: I don't agree.
4 PANEL MEMBER GLANTZ: Well, that's okay.
5 PANEL MEMBER FUCALORO: I don't agree. I
6 think -- I think it's important to have a good
7 priority list. But I do agree with you. There's the
8 concern that the pesticides have not come before us
9 in very frequently -- at a high frequency rate. I
10 think I agree with that.

11 But I do believe that any priority
12 list should be broken down into two parts -- again,
13 the exposure potential and the toxicity. Just like
14 one has a slope factor, for example, in some sort of,
15 say, carcinogenicity and then the exposure. You put
16 them together in a multiplicative fashion.

17 You know what you're talking about.
18 You're talking about exposure. You're talking about
19 toxicity.

20 PANEL MEMBER GLANTZ: Oh, no. And I'm not
21 disagreeing that DPR wanted to adjust their
22 methodology. That's probably slightly better. But
23 my guess is it's not going to change the list
24 radically.

25 PANEL MEMBER BLANC: I think actually it could
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1 change it incredibly --

2 PANEL MEMBER GLANTZ: Oh, you do?

3 PANEL MEMBER BLANC: -- because of the
4 arithmetic --

5 PANEL MEMBER GLANTZ: Okay.

6 PANEL MEMBER BLANC: I mean, what you say is
7 true in principle. But I think that there are some
8 aspects of this which are so ill-founded in terms of,
9 on a practical basis, how your weights come out.

10 I mean I know you haven't finished
11 going through your slide by slide. But since we have
12 a handout, I'm going to speak, based on the handouts
13 since we've, you know --

14 PANEL MEMBER FUCALORO: Just let us know which
15 one.

16 PANEL MEMBER BLANC: Yeah. So, you know, you
17 have two slides on -- that are related to the axis
18 that Tony refers to of use. One is vapor pressure,
19 and one is use and sales.

20 Now, we can debate about whether or
21 not there should be something dealing with
22 nonvolatile, highly water-soluble materials that
23 would tend to, you know, be out there in droplets
24 very quickly.

25 But leaving that aside, even if you
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1 took this at face value, what one would get is 16
2 points with a volatile, widely used agricultural
3 chemical. And the most you could get from the very
4 most toxic chemical, based on your scoring system,
5 is -- I'd have to do the arithmetic, but I think
6 it's --

7 PANEL MEMBER FUCALORO: 12.

8 PANEL MEMBER BLANC: -- is it 12?

9 So there's something screwy about that
10 if you're using it, as you propose, as an additive
11 scale because what it means is that something with a
12 low toxicity of 1 that's, you know, volatile and
13 highly used is going to be your highest priority
14 material, which we would fundamentally and completely
15 disagree with.

16 So what happens is that -- Stan, I
17 think they've carried it to such an extreme, that it
18 doesn't mean that it can't -- once you come to sort
19 of fundamental decisions about "What are the domains
20 in which you think toxicity matters? And what are
21 the domains in which you think exposure matters?"
22 then it can very quickly -- you can tinker with the
23 scales so you're getting reasonable separation and
24 weight.

25 So I think that the first step is to
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1 make sure there's sort of consensus on what your
2 domains are. And I think you've gone -- what you've
3 done here has sort of conceptually muddled the
4 waters.

5 PANEL MEMBER FUCALORO: I mean a same way of
6 saying that is that -- I mean some of -- in the
7 category where the total is 16, water falls into that
8 category in this scale.

9 PANEL MEMBER BLANC: Yeah. The word and
10 chemical. So --

11 PANEL MEMBER FUCALORO: Its use is all over
12 the place and its vapor pressure is very high, I mean
13 but, you know, that's --

14 PANEL MEMBER FRIEDMAN: For the record, you
15 know, apparently in the 1996 categorization, you
16 spent a lot -- you devoted a lot more interest in
17 toxicity and since then have added some of these
18 exposure variables. And I was just wondering -- was
19 that in response to this panel's recommendation?

20 DR. SEGAWA: Correct.

21 CHAIRMAN FROINES: No.

22 PANEL MEMBER FRIEDMAN: So I think we should
23 make that --

24 CHAIRMAN FROINES: No.

25 PANEL MEMBER FRIEDMAN: You may have carried
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1 it to a greater extreme --
2 CHAIRMAN FROINES: We have read the transcript
3 from the January meeting. And there is nothing in
4 the transcript that reflects that statement. That's
5 not correct, and I won't accept it -- that this panel
6 said that there should be a lower weighting of
7 toxicity. This panel never said that.
8 PANEL MEMBER FRIEDMAN: No. But we suggested
9 that they add more exposure; is that correct?
10 CHAIRMAN FROINES: Yes.
11 PANEL MEMBER FRIEDMAN: So maybe they've
12 carried it to an extreme that we would not agree
13 with. But I think it's fair -- in all fairness, we
14 should recognize that they're trying to respond to
15 something that we suggested. Maybe we don't agree
16 with the way they've done it, but I think that
17 they're being responsive.
18 CHAIRMAN FROINES: I think -- having gone over
19 the January transcript, I think that that may be
20 true. But that was never the intent of this panel --
21 to create a situation that we now have here with this
22 document.
23 PANEL MEMBER BLANC: So I think there's a
24 couple of easy solutions, really quick fixes. And
25 they would just require a sort of a meeting of the
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1 minds.
2 One is that I couldn't support more
3 strongly Dr. Fucaloro's comments that the use
4 scoring, however it is determined mathematically,
5 should be used as a multiplicative factor and not as
6 an additive factor.
7 And that will generate two scores --
8 unweighted scores and use-weighted scores, which will
9 be important. And we'll need to see which chemicals
10 have moved because of the use-weighting.
11 The nuance of how you create the
12 use-weighting score and how big it is -- I would just
13 suggest it as a magnitude -- if you're using it as a
14 multiplicative factor, it doesn't need to be such a
15 huge numeric value.
16 But I think the point was very well
17 taken about water solubility and what that would mean
18 functionally for exposure. And that needs to be in
19 there somehow.
20 In terms of the toxicity score and how
21 the weightings are for toxicity, I think that it
22 would be the consensus, I would imagine, of this
23 group that carcinogenicity and reproductive toxicity
24 aren't are a kind of trade-off; that, if those are
25 domains in which toxicity are important, those
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1 domains need to be weighted as strongly as whatever
2 measure of acute toxicity -- generic or acute
3 toxicity you use.

4 And then you have a sort of a generic
5 measure of chronic toxicity which you're basing on
6 DPR or US EPA chronic and subchronic
7 no-observed-effect levels. That's your sort of
8 generic chronic toxicity.

9 Then you have a reproductive axis.
10 And then you have a carcinogenicity axis. And then
11 you have an acute toxicity domain. And I think what
12 the panel is telling you is those all need to be
13 weighted equally, at least.

14 Nobody's saying, "Make the
15 carcinogenicity the driving point." But it shouldn't
16 be underweighted, half underweighted, which is what
17 you're doing.

18 One question I would have, from a
19 technical nature, is since you seem to have NOELs for
20 chronic or subacute toxicity for every chemical,
21 since that was one of your pragmatic ways of choosing
22 a rubric, do you not also have NOELs for acute
23 toxicity that parallel? Or do those not exist?

24 DR. SEGAWA: I presume that we do, but I don't
25 know for sure.

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1 PANEL MEMBER BLANC: Well, wouldn't using the
2 acute toxicity NOELs as the acute toxicity marker,
3 rather than the LC50, address the comments that have
4 been made by the other panel members?

5 And wouldn't it also be more symmetric
6 or more parallel with your other toxicity measures,
7 assuming that they're available?

8 ASSISTANT DIRECTOR JONES: In all cases, we do
9 not have acute NOELs. Oftentimes for the kinds of
10 assessments -- and Andy can tell me if I'm wrong --
11 for the kind of assessments that you heard today or
12 have been discussing with MITC, the acute NOEL is
13 extracted out of another study.

14 And part of the reason that I said we
15 use the LC50 inhalation study is we receive a battery
16 of acute toxicity studies that don't look at NOELs.
17 They look at LC50, LD50, and that kind of thing.

18 And I think, as Dr. Byus indicated,
19 from some of these data, we may be able extract lower
20 values; but we don't -- we can't readily, you know,
21 sort of --

22 PANEL MEMBER BLANC: Whereas --

23 ASSISTANT DIRECTOR JONES: -- readily, readily
24 get the acute NOELs.

25 PANEL MEMBER BLANC: Whereas -- whereas for

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1 the chronic and subacute, the EPA has already
2 extracted or calculated the NOEL?

3 ASSISTANT DIRECTOR JONES: And we have too.
4 We have too. All I'm saying is those values come
5 more readily out of specific studies that are
6 designed to ask questions about chronic and
7 subchronic toxicity.

8 We don't -- there is not necessarily a

9 comparable parallel for acute toxicity where you can
10 get an explicit NOEL out of that. And we oftentimes
11 find ourselves extracting an acute NOEL out of a
12 reproto study, a carcinogenicity study.

13 PANEL MEMBER BLANC: Would you have an
14 estimate of the list of the agricultural chemicals in
15 question -- for how many of them, for some other
16 reason, you already have an acute NOEL for one reason
17 or another?

18 ASSISTANT DIRECTOR JONES: I'd have to go back
19 and look at the number of risk assessments we've
20 completed.

21 PANEL MEMBER BLANC: Because, you know, if
22 it's 60 or 70 percent already -- if you think it's
23 that high --

24 ASSISTANT DIRECTOR JONES: Oh --

25 PANEL MEMBER BLANC: -- then it would probably

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1 be worth doing the other 30 percent.

2 ASSISTANT DIRECTOR JONES: We probably don't.
3 We probably haven't done that -- and these are risk
4 assessments we've done under the Birth Defect
5 Prevention Act.

6 The numbers are probably not that high
7 because we, you know -- on an annual basis, we
8 probably complete probably six to eight active
9 ingredients per year.

10 PANEL MEMBER BLANC: In terms of NOELs, acute
11 NOELs?

12 ASSISTANT DIRECTOR JONES: No. In terms of
13 completed risk characterization documents that
14 parallel the documents that you look at under the
15 1807 act.

16 PANEL MEMBER BLANC: And the EPA doesn't do
17 that -- federal EPA doesn't do that either, on terms
18 of acute?

19 ASSISTANT DIRECTOR JONES: They're going
20 through their re-registration process. And under
21 their risk assessments contained in their
22 registration-eligibility documents, they may include
23 those data. But they do -- they basically are
24 looking at the same data set that we are. And so
25 they do not have explicit studies that are designed

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1 to determine an acute NOEL.

2 PANEL MEMBER BLANC: Well, one solution to
3 this problem in the domain of acute toxicity would
4 be, assuming you had a 4-point ordinal ranking, is
5 that -- in cases where you have acute data, you use
6 that and only in cases -- in cases where you have an
7 acute NOEL data already or it's very easily
8 obtainable, you use that.

9 And the default is that you use --
10 your fallback is the LC50, if you don't.

11 ASSISTANT DIRECTOR JONES: Okay.

12 PANEL MEMBER BLANC: 'Cause we obviously don't
13 want you to delay having a priority scheme for 20

14 years doing another series of studies. That's not
15 the point here. So I'm sensitive to the efficiency
16 of the data. But it seems to me you could have an
17 algorithm that would allow you to have your cake and
18 eat it too.

19 CHAIRMAN FROINES: Well, I think that, going
20 back to Stan's point, that up to now this panel has
21 approved -- what? -- 3 pesticides, 4 pesticides in 20
22 years. Dealing with the vast numbers of pesticides
23 isn't necessarily our problem.

24 I mean I think that, if you look at
25 the listing, if you have between 6 points and 8

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1 points, you go between 800,000 and greater than 12
2 million pounds, one could argue that below 800,000
3 doesn't mean that there aren't some important
4 pesticides.

5 But one could look at the Categories
6 6, 7, and 8 in terms of use in California -- that
7 would be ranging with for greater than 800,000
8 pounds -- and try and do a more -- look at acute
9 NOELs or look at carcinogenicity or look at
10 reproductive toxicity or the chronic, and it seems
11 like we might come up with a fairly interesting list
12 that -- for which there were potential, anyway, of
13 humans being affected in California, adversely.

14 And so it may be that, rather than
15 just say, "We need to use the LC50," that we may want
16 to slice and dice it a slightly different way to try
17 and get at -- quote -- "the problems" rather than --

18 The priority score is an attempt to
19 identify problems. And so that's what its endpoint
20 should be. And so, to the degree that we don't -- we
21 end up with systems that don't help us answer that
22 question or artificially answer it, then it seems to
23 me the prioritization doesn't -- isn't as effective
24 as one might hope.

25 PANEL MEMBER BLANC: Well, John, would you

0177

1 agree with Tony's fundamental suggestion --

2 CHAIRMAN FROINES: Absolutely. That's my
3 starting point.

4 PANEL MEMBER BLANC: Would the other panel
5 members agree with that?

6 So, in other words, whatever version
7 you come back to us should have two sets of scores --
8 use-unweighted and use-weighted. And I suggest that
9 the use-weighting be by a multiplicative process.

10 ASSISTANT DIRECTOR JONES: I think one
11 observation that we made, in taking a couple of
12 different scoring mechanisms and playing it through,
13 is that the pesticide active ingredients about which
14 we have most concern, which tend to be the fumigants,
15 show up at the top of the list.

16 And we have devoted considerable
17 effort to evaluating the risk of those, both in this
18 setting and independently. And so, from the

19 standpoint of how we are looking at human exposure,
20 our simplified prioritization scheme reflects the
21 kinds of concerns that we are dealing with.

22 PANEL MEMBER ATKINSON: I'd like to come back
23 to the volatility side of things. I mean I notice
24 that, in 1996, you were using both vapor pressure and
25 Henry's law constant. And that, to a certain extent,

0178 was really double-counting. So I agree with you
1 certainly going towards one measure of volatility.
2

3 And I can certainly see that vapor
4 pressure's the obvious, simple one. But I have do
5 have a couple of comments on, even if you used vapor
6 pressure, I really don't see that you need to split
7 it up into zero to 8 points because really, once
8 something's got any reasonable vapor pressure
9 greater than, say, 1 torr, it's going to presumably
10 partition somewhat into the atmosphere.

11 The other one is that if it's got
12 vapor pressure less than 10-to-the-minus-6 torr,
13 it's never going to exist in the gas phase in the
14 atmosphere.

15 Admittedly, you might use that, if
16 it's going to be sprayed and exist as a particle or
17 as an aerosol droplet -- lower volatility compounds.
18 But, otherwise, I think you could split it up into,
19 at the most, two or three categories.

20 And I would urge you to look into
21 using either Henry's law constant and the octanol/
22 water partition coefficient or vapor pressure divided
23 by the octanol/water partition coefficient for things
24 that are sprayed or end up in the soil and the
25 Henry's law constant for things that are -- that end

0179 up in the water.
1

2 I think you would get -- it would help
3 a little if the data's available and you can do it.

4 DR. SEGAWA: I was going to say, one of the
5 problems we had with Henry's constant was that we
6 didn't have reliable data for a lot of the chemicals.

7 PANEL MEMBER ATKINSON: For the -- I mean it's
8 essentially the vapor pressure divided by the aqueous
9 solubility. So --

10 DR. SEGAWA: Right. But in many cases, we
11 didn't have data that was done at the same
12 temperature. And so we had to make mathematical
13 adjustments and things like that. And, like I said,
14 we didn't have a whole lot of faith in some of the
15 data.

16 PANEL MEMBER FUCALORO: But it's -- well, I'd
17 guess you need to know the enthalpy.

18 PANEL MEMBER ATKINSON: I don't know. Just
19 the aqueous solubility -- I mean vapor pressure --
20 the one that really changes is the vapor pressure.
21 The aqueous solubility isn't going to change much,
22 not dramatically between 20 C and 30 C or whatever.

23 CHAIRMAN FROINES: I have a -- I want to

24 change the subject a little bit. I have one question
25 that is troubling a little bit. And that is that the
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1 problem -- there is problem, it seems to me, with the
2 notion of administrative listing, namely, that
3 there's a list of chemicals here for which there are
4 some highly toxic chemicals that are administratively
5 listed because they were HAPs, defined by the Clean
6 Air Act amendments in 1990.

7 But the HAPs -- because they become
8 administratively listed, what worries me about them
9 is that they fall into a black hole and are then not
10 addressed in the future because it seems to me that,
11 at some level, a compound that's identified
12 administratively still requires a risk assessment
13 because a HAPs doesn't give you a risk assessment and
14 that the risk assessment then becomes used in the
15 actual control process for risk management purposes.

16 And so one of the questions that I
17 have, in terms of priority, is the compounds that are
18 listed here as administratively designated -- where
19 do they fit in terms of this prioritization? Because
20 what worries me about lists of chemicals is that the
21 list becomes an end -- and it has the danger of
22 becoming an end in itself.

23 And but obviously we list things so
24 that then is there a subsequent process to control
25 it -- control public exposure.

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1 PANEL MEMBER FUCALORO: Mitigation.

2 CHAIRMAN FROINES: So the question then
3 becomes, of the compounds that are administratively
4 listed, when do we see the risk assessments for them
5 and control strategies developed accordingly?

6 PANEL MEMBER FUCALORO: You do have control
7 strategies for those listed. I mean that's --

8 DR. SEGAWA: For some, we do. But getting
9 back to your original question, this panel, at least
10 in the past, has only looked at candidate toxic air
11 contaminants, not pesticides that are already listed.

12 CHAIRMAN FROINES: No. That's not true. We
13 have spent months and months and months on Melanie's
14 chronic RELs and acute RELs. We've approved hundreds
15 of chemicals that were already identified as toxic
16 air contaminants. So it's not true that we've only
17 dealt with candidate compounds.

18 DR. SEGAWA: With DPR, that's the case.

19 PANEL MEMBER GLANTZ: Yeah. But we've only
20 done 3.

21 PANEL MEMBER FUCALORO: You can't cover too
22 many.

23 ASSISTANT DIRECTOR JONES: I guess, in answer
24 to another part of your question, methyl bromide is
25 an example of a HAP. We haven't brought that before

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1 the committee. That does not mean we haven't moved
2 ahead with a risk assessment and moved ahead with

3 risk-mitigation measures.
4 CHAIRMAN FROINES: The what?
5 ASSISTANT DIRECTOR JONES: That we haven't
6 moved ahead with risk-mitigation measures. So we
7 have used other authority than listing it as a TAC or
8 listing it as a TAC administratively, because it is a
9 HAP, to move ahead with mitigation.
10 CHAIRMAN FROINES: So you're suggesting that
11 you wouldn't bring those compounds before this panel
12 to review the risk assessment?
13 ASSISTANT DIRECTOR JONES: We wouldn't
14 necessarily. I mean I think that had been a
15 direction in the past. And I think that's what
16 Andy -- Randy is referring to.
17 So in the case of methyl bromide, we
18 had the National Academy of Science review our risk
19 assessment and -- but moved ahead with mitigation
20 based on that risk assessment.
21 CHAIRMAN FROINES: But I -- actually methyl
22 bromide is a case in point because this panel has the
23 intent of taking up methyl bromide, that Paul Goslin
24 and I discussed two years ago about our taking methyl
25 bromide -- bringing, after the National Academy

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1 review occurred -- was to bring it before the panel
2 for a review.
3 So that compound actually -- we have
4 an expectation of seeing it at some point.
5 ASSISTANT DIRECTOR JONES: Well, I guess he
6 didn't inform us of that. I mean I didn't think
7 going through another review with this panel would
8 necessarily serve the purpose because I mean we still
9 have three documents that we would like to move ahead
10 with on, with the panel.
11 CHAIRMAN FROINES: Well, okay. Let's put this
12 aside and -- but it's an issue of -- the issue of
13 administratively listed compounds is an issue, I
14 think, that deserves attention. So let's go back to
15 the prioritization issue.
16 PANEL MEMBER FUCALORO: Well, what are we to
17 do now? I mean are you going to go back and review
18 this document and your method? Or --
19 ASSISTANT DIRECTOR JONES: Well, you know, I
20 mean it's April of 2002. We've presented what kind
21 of areas we were working on, based on your comments
22 to us in January of 2001. We will take your comments
23 that you provided at this meeting and rerun it and
24 identify additional data that we conclude.

25 And I would say we will probably have

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1 continued discussions with the committee. And we'll
2 provide you drafts as we have done and would
3 appreciate your comments on how we take what you have
4 described to us today in transforming the data.
5 PANEL MEMBER GLANTZ: Yeah. I would hope,
6 given the very slow pace that this has gone and the
7 fact that you have most of the information you need

8 here -- and I'm sort of beaten into submission on the
9 multiplication. I agree now.

10 To generate another draft of this,
11 done along the lines that the panel's talking about,
12 should not be a huge undertaking. So I would hope
13 that you could bring back another draft before we
14 meet -- don't we have a meeting next month? So it's
15 in two months?

16 So I would hope that we could have a
17 draft of this come back then and that everyone would
18 sort of nod and say, "Oh, yes. This looks very
19 good," 'cause I think the panel's given you pretty
20 specific guidance.

21 And as they say, I think you have the
22 data you need. It's just a matter of kind of
23 recasting the calculations.

24 And, you know, the other thing that
25 you might want to do -- and I actually was, a long

0185
1 time ago, was the lead person with the ARB
2 prioritization.

3 You might try a couple of alternative
4 reasonable weighting schemes and just see how much
5 difference it makes too because, you know, if you get
6 results that are reasonably independent of the
7 specific numbers you pick for the weighting, that's
8 always encouraging.

9 And I think, if you take the
10 suggestions that have been made, that, in some sense,
11 collapses some of the categories. And then the other
12 thing is with the weighting by multiplying by
13 exposure -- that will probably simplify things some.

14 PANEL MEMBER FUCALORO: Yeah. And I think
15 that's a good idea to see that the list seems be to
16 relatively independent of the algorithm used to
17 develop the list is what he's suggesting.

18 But also there's a lot of experience
19 in your department. If someone looks at a list and
20 says, "This is cockamamy. This should not be so
21 high. This one should not be so low," that then you
22 know you have a problem with your algorithm and you
23 have to rethink it.

24 ASSISTANT DIRECTOR JONES: Well, I think that,
25 given the experts at the table and toxicologists that

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1 I work with to take your previous suggestions and
2 rework the list, the list came out kind of like we
3 thought it would, based on --

4 PANEL MEMBER FUCALORO: I didn't hear what you
5 said. I'm sorry.

6 ASSISTANT DIRECTOR JONES: Yeah. Because the
7 list came out --

8 PANEL MEMBER FUCALORO: "Because the list came
9 out"? I didn't hear you.

10 ASSISTANT DIRECTOR JONES: Because the list
11 came out like we would expect.

12 PANEL MEMBER FUCALORO: I see.

13 ASSISTANT DIRECTOR JONES: And it had, you
14 know, compounds that we have the most concern about
15 that have the highest use and --
16 PANEL MEMBER GLANTZ: Oh, maybe it's --
17 ASSISTANT DIRECTOR JONES: And I think, you
18 know, recalculating some of the numbers, based on
19 your suggestions, would be very instructive. But I
20 guess, Tony, we've sort of, you know -- the experts
21 looked at it --
22 PANEL MEMBER FUCALORO: Sure. Yeah.
23 ASSISTANT DIRECTOR JONES: -- and were not
24 dissatisfied with our simplified approach --
25 PANEL MEMBER FUCALORO: Right.

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1 ASSISTANT DIRECTOR JONES: -- in prioritizing
2 those compounds that we have concerns about.
3 PANEL MEMBER GLANTZ: Well, you know, and it
4 may be that, when you do it with a panel suggesting,
5 it won't change things wildly, although Paul seems to
6 think it will.
7 PANEL MEMBER BLANC: Well --
8 PANEL MEMBER GLANTZ: But that's something --
9 I mean that's an exercise that you can do that should
10 be pretty straightforward. And that's why I suggest
11 that we bring it back at the next meeting. My
12 concern, to just not bang a dead horse, though, is
13 that we're doing one every 7 years. And that, to me,
14 is the bigger problem that you've got this huge list
15 of chemicals.
16 And at the rate we're going, you know,
17 we're all going to be dead before you get down to
18 Number 10.
19 ASSISTANT DIRECTOR JONES: Well, we'd like to
20 get --
21 CHAIRMAN FROINES: Can I -- can I --
22 ASSISTANT DIRECTOR JONES: We'd like to get
23 3 --
24 PANEL MEMBER FUCALORO: Did you say you'd like
25 to see that happen?

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1 (Laughter.)
2 ASSISTANT DIRECTOR JONES: We would like to
3 see the 3 documents that we have prepared to come
4 before the panel deliberated on and move on.
5 CHAIRMAN FROINES: But what are those three
6 documents that are ready to --
7 ASSISTANT DIRECTOR JONES: Azinphos-methyl,
8 molinate. And chlorpyrifos has not yet had leads
9 assigned, but that's the third document.
10 CHAIRMAN FROINES: Which? Are they all 3
11 ready to come to the panel?
12 ASSISTANT DIRECTOR JONES: Azinphos -- we need
13 feedback from you and whoever the other lead is.
14 Molinate. Molinate is ready to come back to the
15 panel. And chlorpyrifos still needs leads assigned
16 to work with us and complete that. But all three
17 have had deliberations and public meetings.

18 CHAIRMAN FROINES: I think the azinphos-methyl
19 compound needs to be reviewed, in a sense, because I
20 don't want a compound coming before us that -- I
21 don't want compounds coming before us that we're not
22 going to recommend them as toxic air contaminants.

23 In other words, we don't want -- if
24 you have a compound that doesn't meet criteria for
25 coming as a TAC, I wouldn't bring it before the panel
0189

1 if we're going to then say, "We don't think this is a
2 TAC."

3 So azinphos-methyl is a problem
4 substance, I think, at this point, given the letter
5 that I got yesterday.

6 PANEL MEMBER BLANC: I wasn't sure. So the
7 answer was you thought it would be feasible to, at
8 our July meeting, to bring this modified document
9 back?

10 ASSISTANT DIRECTOR JONES: Yes.

11 PANEL MEMBER FUCALORO: I can see it.

12 ASSISTANT DIRECTOR JONES: And, John, I think,
13 given your interest in discussing Paul Goslin's
14 letter to you, Randy and I'll go back and talk to
15 Paul about your wanting to discuss that at the next
16 meeting because your question is salient. Randy and
17 I had a further discussion with Paul about that very
18 issue.

19 CHAIRMAN FROINES: About which issue? I'm
20 sorry.

21 ASSISTANT DIRECTOR JONES: About whether or
22 not we bring TACs before the panel that may not meet
23 the criteria of being listed under DPR's regulations.

24 And I think one of the things that
25 perhaps is not clear in Paul's letter but which he
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1 articulated us is that he greatly values the peer
2 review of this panel of RELs for pesticides because
3 those have utility outside of their being listed as a
4 toxic air contaminant. But I will tell Paul that --

5 CHAIRMAN FROINES: Well, no. I think that --

6 ASSISTANT DIRECTOR JONES: -- that in terms of
7 discussing his letter, I think that will be an
8 important --

9 CHAIRMAN FROINES: Don't misunderstand. Don't
10 misunderstand. This panel took up, reviewed MTBE for
11 the Air Resources Board. And so we have a history of
12 taking up things that are not necessarily in this --
13 you know. And that's fine. I think that's quite
14 reasonable.

15 My only concern is that, some years
16 ago, for example, we took up ethylene dibromide,
17 which was at that point not being used to -- not in
18 the from the DPR, but from the standpoint of as a TAC
19 with ARB.

20 And so there was -- the panel at that
21 time was -- got frustrated because they felt as
22 though they were spending a lot of time on something

23 for which there was virtually no human exposure and
24 there was a frustration about that. So it's those
25 kinds of considerations.

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1 I think it's -- in the end, it is your
2 decision which chemicals come to this panel. It is
3 not the panel's decision. It's your decision. So I
4 would say unequivocally that we would defer to your
5 judgment on those matters. It's not up to us to
6 define your priorities. It's up to you. And we'll
7 then -- we'll respond accordingly.

8 PANEL MEMBER GLANTZ: But, at the same time --
9 I mean the role we've played historically has been to
10 assist them and also ARB in coming up with a
11 scientifically defensible rational set of priorities.

12 Because I remember -- the whole thing
13 that got the priority -- I mean, again, I was the one
14 who started this longer ago than I want to admit --
15 and it was when, at one point, ARB was talking about
16 coke oven emissions to this panel. And there are no
17 coke ovens in California. Remember?

18 So we said, "Why are we bothering?"
19 It's, like, bad if you live next to a coke oven in
20 Pennsylvania.

21 ASSISTANT DIRECTOR JONES: No. And we would
22 agree. We would agree wholeheartedly. We would like
23 your review of pesticides that have concerns to the
24 State.

25 CHAIRMAN FROINES: I think that the -- at this
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1 point, just to summarize -- one point, of course,
2 that's been mentioned a number of times, which is
3 looking at a multiplicative approach. The second
4 comment was "Can we identify different approaches to
5 acute toxicity over the LC50?"

6 The third point is I think that the
7 panel would not be very happy about a priority scheme
8 that list -- that had reproductive and
9 carcinogenicity as a 0-to-2 ranking. That seems to
10 underestimate the importance of the ranking. And, in
11 fact, I think the panel would, in general, argue that
12 toxicity is a major -- should be a major defining
13 feature.

14 And so, clearly, carcinogenicity and
15 reproductive toxicity are elements of significance.
16 There is Roger Atkinson's point about the Henry's law
17 constant versus vapor pressure. And obviously the
18 issue of use is a key one in terms of looking at
19 compounds relative to whether or not there are large
20 amounts being used.

21 So I think those are the -- those are
22 the issues that are -- that we've talked about. Am I
23 missing something here?

24 DR. SEGAWA: Just to make sure I understand
25 the panel's wish is that you would like to see that

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1 the individual toxicity categories -- that is, acute,

2 NOEL, repro, and carcinogen -- all weighted equally;
3 is that correct?
4 And that use would be used as a
5 multiplicative factor to toxicity. It was unclear to
6 me whether the volatility, vapor pressure, or
7 whatever we choose is a multiplicative --
8 PANEL MEMBER BLANC: Exposure. Exposure --
9 PANEL MEMBER FUCALORO: Exposure.
10 DR. SEGAWA: Oh, exposure. Okay. I'm sorry.
11 PANEL MEMBER BLANC: -- which includes both
12 use and volatility.
13 DR. SEGAWA: Oh, I see.
14 CHAIRMAN FROINES: The toxicity is the
15 centerpiece, and the coefficient or multiplication is
16 the exposure.
17 PANEL MEMBER BLANC: And that there be two
18 sets of rankings -- exposure-unweighted and an
19 exposure-weighted ranking.
20 DR. SEGAWA: Okay.
21 PANEL MEMBER BYUS: And I would just like to
22 add -- I think, with the HAPs and about the other
23 compounds we have already listed as TACs -- you
24 should run all of them, or at least as many of them
25 as you can, through your prioritization scheme, as
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1 well, especially things we know a lot about because
2 at least we can see where they fall.
3 PANEL MEMBER FUCALORO: They'll be markers --
4 markers in the list.
5 PANEL MEMBER BYUS: They'll be markers. Or
6 any other ones that you --
7 DR. SEGAWA: We actually went through that
8 exercise. They just didn't appear since they weren't
9 candidates.
10 PANEL MEMBER BYUS: Okay.
11 DR. SEGAWA: That was one of the reasons why
12 we felt that the proposed prioritization was actually
13 pretty good because things like methyl bromide,
14 dichloropropene, formaldehyde -- they all came up
15 high in those rankings.
16 PANEL MEMBER BYUS: But I want to ask you
17 why --
18 CHAIRMAN FROINES: Well, there are some ones
19 back here that I sure as hell wouldn't put up high.
20 But I think you mean the ones that really we do know
21 are problems.
22 DR. SEGAWA: Right.
23 CHAIRMAN FROINES: Right. So I think that the
24 January meeting -- I think we may have given you a
25 false impression. And I apologize if that was the
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1 case. But I don't want to say that -- think that you
2 didn't follow our direction. But there clearly was
3 some level of misunderstanding. And to the degree
4 that we are part of that, we apologize.
5 But I think that is a clear
6 statement -- a clear statement of, I think, where we

7 are, would be at this point.
8 I don't think -- I agree with Stan. I
9 actually think that we are not far from coming to a
10 place where we need to come up -- where the final
11 document would be acceptable. I don't think it's a
12 major effort at this point. It's easy for me to say,
13 you know.

14 PANEL MEMBER GLANTZ: I agree.

15 CHAIRMAN FROINES: I think we're tinkering.

16 PANEL MEMBER BYUS: It remains to be seen how
17 much we're tinkering.

18 CHAIRMAN FROINES: No. I mean --

19 PANEL MEMBER BYUS: Well, we spent -- for
20 example, Dr. Fucaloro, Dr. Atkinson, and I spent --
21 what? -- 2 hours, 2-and-a-half hours with OEHHA on
22 their prioritization scheme. I mean it was a very
23 intense discussion. I think we made -- we basically
24 said the same things that were said here today. I
25 mean it's --

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1 PANEL MEMBER GLANTZ: Now, you might actually
2 want to take a look -- you know, we went through
3 this --

4 PANEL MEMBER BYUS: I remember the -- I
5 brought up Stan's old prioritization document and how
6 much time you had spent on it.

7 PANEL MEMBER GLANTZ: You know, you might want
8 to look at that. And the other one that we -- where
9 we just went through this about a year ago was the
10 thing on the -- I forget the bill, but the kids'
11 exposure where we had all these same problems and
12 ended up, I thought, with a pretty good document.

13 So you just might want to take a look
14 at that too. I'm sure Melanie will be happy to give
15 you a copy -- 50 copies.

16 CHAIRMAN FROINES: I think that the one point
17 I didn't mention in my review was the comment
18 somebody made about two 8's adding up to 16 gave too
19 much emphasis on exposure. But we've talked about
20 that much more terms in of the multiplicative point.
21 So I think it was, in a sense, covered under that.

22 So at this point I think we're going
23 to quit for the day.

24 PANEL MEMBER BLANC: Do you have any
25 discussion about the date, the July date, Peter?

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1 PANEL MEMBER FUCALORO: Do you have any
2 responses?

3 CHAIRMAN FROINES: July 22, 23, or 26.

4 PANEL MEMBER FUCALORO: Yes.

5 PANEL MEMBER GLANTZ: Let's decide.

6 CHAIRMAN FROINES: Riverside or Ontario.

7 PANEL MEMBER FUCALORO: I don't care.
8 Riverside.

9 CHAIRMAN FROINES: I don't think we should --

10 PANEL MEMBER GLANTZ: The only -- the only --
11 with all due respect to our colleagues in

12 Riverside --
13 PANEL MEMBER BYUS: Riverside in July is
14 delightful for the Air Resources Board.
15 PANEL MEMBER GLANTZ: I was just in Riverside
16 on Monday for a meeting. And the problem is there's
17 no flights out of San Francisco.
18 PANEL MEMBER BYUS: I know.
19 CHAIRMAN FROINES: You San Francisco people --
20 we have bent --
21 PANEL MEMBER GLANTZ: Okay. All right.
22 CHAIRMAN FROINES: -- over backwards so many
23 times to accommodate your --
24 PANEL MEMBER GLANTZ: All right. This is a
25 nice place. Don't you want to come to L.A.?

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1 PANEL MEMBER BYUS: No.
2 PANEL MEMBER FUCALORO: I really don't care.
3 I mean, if it's Southern California, any of those
4 dates are fine with me.
5 CHAIRMAN FROINES: Well, for people -- having
6 it a little west of Riverside obviously is a benefit
7 for those of us who come from this side of town
8 but --
9 PANEL MEMBER BYUS: So Ontario is better.
10 CHAIRMAN FROINES: So if we can have it near
11 the airport, that would seem --
12 PANEL MEMBER BYUS: In the airport.
13 PANEL MEMBER BLANC: What were the dates
14 again?
15 CHAIRMAN FROINES: July 23, 22, and 26.
16 PANEL MEMBER GLANTZ: How about Burbank?
17 PANEL MEMBER FUCALORO: The problem with
18 Ontario, I think, is that there are no direct flights
19 from San Francisco.
20 PANEL MEMBER BLANC: That is correct. No.
21 That is correct. There are none.
22 CHAIRMAN FROINES: Well, what about having it
23 near Burbank? But that's, again, we --
24 PANEL MEMBER BYUS: Burbank.
25 PANEL MEMBER GLANTZ: Is that the worst of all

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1 possible worlds?
2 PANEL MEMBER BLANC: No. Burbank is fine.
3 PANEL MEMBER GLANTZ: There are flights from
4 San Francisco.
5 PANEL MEMBER FUCALORO: I'd rather be out
6 here. You gotta be careful of Blanc because he has
7 friends. He likes to go and visit all these places.
8 PANEL MEMBER BLANC: I would say that Monday
9 or Fridays are, in general, you know, better than
10 the middle of the week, from my point of view.
11 CHAIRMAN FROINES: Peter, did you give me
12 this, expecting people were going to give a yea, nay
13 on the date?
14 PANEL MEMBER GLANTZ: Well, why don't we?
15 Let's do it. We're almost all here.
16 CHAIRMAN FROINES: Can we do it?

17 PANEL MEMBER FUCALORO: I have no preference
18 on that. I'm not going to vote.
19 CHAIRMAN FROINES: Can we do it?
20 PANEL MEMBER ATKINSON: Yeah.
21 CHAIRMAN FROINES: Gary?
22 PANEL MEMBER FRIEDMAN: (No audible response.)
23 PANEL MEMBER BYUS: I don't know. Any of the
24 dates are fine with me right now.
25 PANEL MEMBER FUCALORO: I don't work. I'm a
0200
1 professor.
2 CHAIRMAN FROINES: Paul?
3 PANEL MEMBER BYUS: You don't want that on the
4 record.
5 PANEL MEMBER BLANC: How about the 26th?
6 PANEL MEMBER GLANTZ: Is that Friday?
7 PANEL MEMBER BLANC: Yeah.
8 PANEL MEMBER GLANTZ: Okay. That's fine with
9 me.
10 CHAIRMAN FROINES: 26th is okay with you.
11 26th is okay with you. 26th is okay with you and
12 you.
13 PANEL MEMBER FUCALORO: 7-26? Where?
14 PANEL MEMBER BYUS: We don't know yet.
15 CHAIRMAN FROINES: We don't know yet.
16 PANEL MEMBER FUCALORO: Place to be
17 determined.
18 PANEL MEMBER GLANTZ: If you could make it
19 someplace that, you know, there are flights out of
20 San Francisco.
21 PANEL MEMBER BLANC: There are flights to Cabo
22 that are nonstop.
23 PANEL MEMBER GLANTZ: Huh?
24 PANEL MEMBER BLANC: There are flights to Cabo
25 that are nonstop.
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1 PANEL MEMBER GLANTZ: To where?
2 PANEL MEMBER BLANC: Cabo San Lucas.
3 PANEL MEMBER FUCALORO: Forget this guy.
4 PANEL MEMBER GLANTZ: How about the Owani
5 hotel? That would be good.
6 CHAIRMAN FROINES: I would like to have a
7 meeting in Monterey sometime.
8 PANEL MEMBER FUCALORO: And I would like to
9 have a meeting in Palermo. I mean who cares where
10 you'd like to have a meeting?
11 PANEL MEMBER BYUS: I always voted for Lake
12 Tahoe.
13 CHAIRMAN FROINES: Tahoe's good too.
14 PANEL MEMBER BYUS: In the winter.
15 PANEL MEMBER GLANTZ: Hawaii?
16 PANEL MEMBER BLANC: That would be --
17 CHAIRMAN FROINES: Can we -- sit down. May I
18 have a motion to adjourn?
19 PANEL MEMBER GLANTZ: So moved.
20 PANEL MEMBER BLANC: Second.
21 CHAIRMAN FROINES: All in favor?

22 ("Ayes.")
23 CHAIRMAN FROINES: It's unanimous.
24 (Proceedings concluded at 2:41 P.M.)
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0202

1 STATE OF CALIFORNIA)
) ss.
2 COUNTY OF LOS ANGELES)
3

4 I, NEALY KENDRICK, CSR No. 11265, do hereby
5 certify:

6 That the foregoing transcript of proceedings
7 was taken before me at the time and place therein set
8 forth and thereafter transcribed by computer under my
9 direction and supervision, and I hereby certify the
10 foregoing transcript of proceedings is a full, true,
11 and correct transcript of the proceedings.

12 I further certify that I am neither counsel
13 for nor related to any party to said action nor in
14 anywise interested in the outcome thereof.

15 IN WITNESS WHEREOF, I have hereunto subscribed
16 my name this 5th day of May, 2002.
17
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NEALY KENDRICK, CSR NO. 11265

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