

1 On regarding the NIOSH exposure regression model,
2 OEHHA's considerations were based on the many exposure
3 measurements made, as well as the evaluation of the model
4 performance that Dr. Woods alluded to earlier.

5 And for the earlier years in the study when the
6 exposure measurements were not available, there was
7 information on other important exposure factors that were
8 available and used to estimate exposure. So OEHHA
9 considered these strengths of the exposure modeling in its
10 consideration of the NIOSH study as the key study for this
11 assessment.

12 [SLIDE CHANGE]

13 DR. KRISHNAN: Now, onto the third topic area.
14 Of the dose response modeling based on this critical
15 study, there were many comments covering three general
16 areas, the model development, model selection, and model
17 evaluation.

18 [SLIDE CHANGE]

19 DR. KRISHNAN: As indicated earlier, OEHHA
20 concluded that U.S. EPA's two-piece linear spline model
21 provides the most appropriate and best fitting model for
22 assessing the cancer risks of ethylene oxide.

23 Issues were raised in public comments that
24 focused on: individual NIOSH study data not being
25 available to conduct an independent evaluation; the use of

1 categorical data to assess the model fit; and the
2 two-piece spline model in terms of minor differences in
3 calculating variance leading to small changes in p-values.

4 [SLIDE CHANGE]

5 DR. KRISHNAN: Although OEHHA did not have the
6 individual study data, key information was available to
7 evaluate the quality of the cohort study and the
8 dose-response relationship. OEHHA was able to evaluate a
9 number of exposure-response models using the publicly
10 available categorical data provided in either Steenland et
11 al. or the U.S. EPA documents.

12 Further, OEHHA considers that the categorical
13 data or results were calculated using long-standing and
14 widely accepted methods. As such, they've been considered
15 to be valid both by U.S. EPA and OEHHA.

16 [SLIDE CHANGE]

17 DR. KRISHNAN: On the topic of model selection,
18 OEHHA considered that the statistical approach used was by
19 the authors was based on widely accepted and appropriate
20 methods. And the model selection was based on several
21 considerations: evaluations of bias and causal inference;
22 parsimony; biological plausibility; differences between
23 higher and lower dose effects; p-value as well as other
24 statistical considerations. Thus, OEHHA and U.S. EPA
25 considered a number of factors in addition to p-value in

1 model selection.

2 [SLIDE CHANGE]

3 DR. KRISHNAN: As referred to in the public
4 review draft and early by Dr. Woods, the Texas Commission
5 on Environmental Quality, TCEQ, also conducted dose
6 response modeling for ethylene oxide. The cancer slope
7 they generated is about 2,000 times lower than that of the
8 U.S. EPA value and our proposed IUR. This point was
9 raised in the public comments.

10 And as you hear earlier, TCEQ chose a different
11 model, the Cox Proportional Hazards Model. And this model
12 is inconsistent with the underlying epidemiological does
13 response data, as shown in slide 19 of Dr. Woods
14 presentation. Furthermore, the reality checks by TCEQ did
15 not account for healthy worker effect and related effects.

16 [SLIDE CHANGE]

17 DR. KRISHNAN: The next set of issues raised on
18 dose response modeling relate to a reality check based on
19 background levels using the IUR and using hemoglobin
20 adducts for conducting and communicating the risk
21 assessment for ethylene oxide.

22 [SLIDE CHANGE]

23 DR. KRISHNAN: As noted earlier, the derivation
24 of the IUR for ethylene oxide is based on extra risk, risk
25 level adjusted for background incidence. So it is for

1 estimating the extra risk resulting from exposure to
2 facility emissions over and above the background.

3 OEHHA did not use the IUR based extra risk to
4 calculate the background risk to do a reality check,
5 especially for endogenous levels of ethylene oxide because
6 of large uncertainty in such an application.

7 So I intended this figure to show that, you know,
8 the IUR is based on extra risk. And to do -- doing a
9 reality check, you know, based on the IUR based on the
10 extra risk to interpret endogenous levels of ethylene
11 oxide is something that OEHHA did not do because of large
12 uncertainty in such an application. So I intended to say
13 while I kept changing the slides back and forth. Sorry
14 about it.

15 I touched the wrong button.

16 [SLIDE CHANGE]

17 DR. KRISHNAN: So on this topic, OEHHA considers
18 that it is unreasonable to use endogenous levels for
19 reality check because of the unknown contribution of
20 endogenous levels of EtO and other factors to the baseline
21 risk. And the IUR is for calculating cancer risk above
22 the baseline and for EtO exposures above the background.

23 And for the issue on hemoglobin adducts. While
24 the hemoglobin adducts, specifically the
25 hydroxyethylvaline adduct, or HEV, are useful as

1 biomarkers of ethylene oxide exposure and they integrate
2 exposure from all sources of ethylene oxide in all --
3 including endogenous and exogenous exposures. But due to
4 the paucity of data on the relationship with the relevant
5 internal dose metric for carcinogenicity makes them a
6 limiting factor for use in dose response assessment and
7 risk assessment.

8 [SLIDE CHANGE]

9 DR. KRISHNAN: The next set of issues raised in
10 comments on dose response relate to mechanistic
11 considerations. So you see two here.

12 An issue raised in the public comments is that
13 the steep initial dose -- initial slope of the two-piece
14 linear spline model is not justified by evidence from
15 animal cancer bioassays on genotoxicity data. And despite
16 the clear evidence that ethylene oxide is genotoxic and
17 carcinogenic issue has been raised that it does not
18 necessarily mean that ethylene oxide actually is a
19 genotoxic mode of action for its carcinogenicity. So it's
20 a mode of action question on carcinogenicity in relation
21 to the model used in this assessment.

22 [SLIDE CHANGE]

23 DR. KRISHNAN: Regarding the justification of the
24 two-piece linear spline model, as mentioned earlier, OEHHA
25 evaluated several exposure-response models using the

1 publicly available categorical data provided in Steenland
2 et al. and the U.S. EPA documents. And overall, OEHHA
3 found that none of the models it evaluated fit the
4 underlying NIOSH study data as well as the two-piece
5 linear spline model. This model is also consistent with
6 the low dose linearity assumption that is the default
7 assumption used in dose-response modeling. That
8 assumption contained in the Hot Spots guidelines reviewed
9 and approved by the SRP.

10 And regarding the mode of action issue, both
11 OEHHA and U.S. EPA agree that there is sufficient weight
12 of evidence to support a mutagenic mode of action. That
13 being said, the draft IUR was derived using human cancer
14 epidemiological data. And knowing the mechanism is not a
15 prerequisite for using the human data to drive an IUR.

16 [SLIDE CHANGE]

17 DR. KRISHNAN: I would pause here to take any
18 questions or any initial comments about the selection of
19 the study and model selection before going to the final
20 topic.

21 [SLIDE CHANGE]

22 DR. KRISHNAN: The fourth and final topic covered
23 by the public comments as represented here relate to IUR
24 development and application.

25 [SLIDE CHANGE]

1 DR. KRISHNAN: OEHHA received comments regarding
2 the selection of the IUR value after the dose-response
3 modeling conducted by EPA. EPA's analysis provided two
4 values, an initial value of 3.3, 10 to the minus three per
5 microgram per meter cubed based on consideration of
6 age-independence of relative risks in the analysis. And
7 that was used in OEHHA's public review draft.

8 And then there was a recalculated value of three
9 10 to the minus three in EPA's document, which is 10
10 percent lower. It's a recalculated value, which is
11 compatible with the application of age-specific factors.

12 While the first one assumed risk being
13 independent of age, the second one accounted early life
14 susceptibility. And we now believe that the final EPA
15 number of three, 10 to the minus three micrograms per
16 meter cubed is the appropriate value to use. This is
17 because this number can be used directly with the Air
18 Resources Board's HARP, the Hot Spots Analysis Software
19 Program, within which age-specific -- the age sensitivity
20 factors are integrated for conducting facility health risk
21 assessments.

22 [SLIDE CHANGE]

23 DR. KRISHNAN: An issue raised during the public
24 comments under this area is there's a difference in the
25 cancer risk estimates using the hot spots methodology

1 versus EPA's risk estimates for ethylene oxide. But this
2 is not an ethylene oxide-specific issue as we looked into
3 it. And it really related to the calculation methodology,
4 one being based on air concentration and the other being
5 based on inhaled dose. The inhaled dose calculation takes
6 into account not only the exposure concentration, but also
7 the age-specific inhalation rate and body weight has done
8 under the hot spots methodology. And this methodology has
9 previously been reviewed by the SRP.

10 And as I mentioned, you know, the outcome based
11 on -- calculation based on directly the concentration are
12 the one based on dose accounting for inhalation and body
13 weight is not specific to ethylene oxide.

14 So with that, we look forward to the Panel
15 discussion and input on the initial -- on the public
16 review draft and these four issues or topic areas that I
17 presented and any additional thoughts including thoughts
18 about further clarification of the use of IUR under the
19 Hot Spots Program in this document on ethylene oxide. And
20 before I turn it over to you Chairman Anastasio, I briefly
21 want to go over the next steps, if you would permit me to
22 do so.

23 CHAIRPERSON ANASTASIO: Yes, please go ahead.

24 [SLIDE CHANGE]

25 DR. KRISHNAN: So after the meeting today, OEHHA

1 will continue to consider and develop written responses to
2 public comments received so far and at this meeting.
3 We'll revise the draft in consideration of these public
4 comments, and the SRP's input at this meeting, and then
5 OEHHA will bring the revised draft SRP for review at a
6 future meeting.

7 Thank you.

8 CHAIRPERSON ANASTASIO: Great. Than you, Dr.
9 Krishnan. Thank you, Dr. Woods.

10 Let's start with our lead reviewers. Beate,
11 would you like to go first?

12 PANEL MEMBER RITZ: Yes. So I reviewed this
13 document and I specifically emphasized, of course, the
14 epidemiology, because I'm an epidemiologist, but I
15 reviewed everything. I thought it was really well written
16 in general. However, I have a lot of wording issues with
17 the epidemiology parts, so I will -- I will give you all
18 of these wording issues, and, you know, we can discuss why
19 I think you should possibly consider rewording certain
20 sentences, because they're not up to date anymore with how
21 epidemiologists talk about studies.

22 I don't think I need to give you my list right
23 now of these kind of wording changes. For example, one
24 was sensitivity. You call studies more sensitive. That's
25 not -- sensitivity in epidemiology has a very special

1 meeting. You probably want to reword that slightly.

2 Generally, I think the epidemiology is actually
3 quite strong in the sense that this NIOSH study was
4 extremely valuable and a strong study. So I went back to
5 the original study, read it in detail, and came up with my
6 own evaluation. And I, as an occupational and
7 environmental epidemiologist, I have to say I've rarely
8 ever seen such a great piece of work in a human study,
9 especially when it comes to the exposure assessment with
10 so many measurements, the regression analysis they used in
11 order to determine individual level exposures for all of
12 these workers, but also the analysis that tried a lot of
13 different lagging methods.

14 And, in general, the way how critical and
15 self-critical the writers of this study actually were in
16 terms of trying to go down every road to find out whether
17 there's bias. So I think the NIOSH study is really the
18 strongest study of the bunch, but it's also, in general,
19 really a strong study. And I completely agree with using
20 that study for the IUR development.

21 In terms of the -- in terms of the slope that was
22 used, the spline models, spline models are very common in
23 epidemiology. Every time my students come with a dose
24 response, we start with categories. And then I say, well,
25 why don't you try a spline model, because they are, you

1 know, quite strong in identifying these difference slopes
2 at different levels of exposure. And this is not unusual
3 that you're not just using one parameter when you don't
4 have enough data for completely nonparametric estimation,
5 that you're using a spline model and that you're getting
6 results like this. Actually, I've done radiation studies
7 before and there's a very good example where
8 carcinogenicity of upper radiation has a very steep slope
9 in the beginning and then cell killing starts.

10 And, you know -- and so the slope basically
11 flattens out. So that's a biologic example of another
12 type of exposure where we see a lot stronger risk for
13 cancer in the lower end of the exposure curve. And then
14 at the higher end, and I mean everybody knows they are
15 using radiation to treat cancers, right, because it's cell
16 killing at the higher end of the radiation exposure you
17 see this flat line or even the risk going down eventually.
18 So that didn't surprise me at all and I think what we've
19 seen about all of these slope factors was quite convincing
20 here.

21 What else?

22 There was one other study I think that could be
23 considered a little bit more in support of the low
24 exposure risk for breast cancer at least. That was the
25 Swedish study where the authors looked at only one company

1 that used a sterilization method with EtO and had a lot
2 less workers and a lot less well done exposure assessment,
3 but otherwise a pretty strong data set, because the Swedes
4 have cancer registries. And that study actually suggested
5 a very strong risk for breast cancer in the lower end of
6 the exposures, but basically didn't have any higher
7 exposures to play with, so they can't really tell you
8 what's happening at higher exposure levels. But maybe
9 that could be emphasized a little bit more that there is
10 another study actually in support of that higher risk at
11 lower ends.

12 I also agree that studies that have been
13 published recently that use the Toxics Release Inventory
14 or some EPA NATA models for population risk are really not
15 useful. They are conforming, but possibly confirming the
16 hazard, but they're not really useful for this IUR
17 development. So they're possibly just in support of what
18 we've seen here, usable in that way.

19 The issue of above -- excess risk above
20 background, I mean, that's what epidemiology does. That's
21 our bread and butter. There's no question that that's the
22 right way to do it. We are always comparing additional
23 exposure above the background risk, so that's nothing new.

24 Was there another question that we were asked to
25 answer that I forgot?

1 CHAIRPERSON ANASTASIO: Dr. Krishnan, maybe you
2 could share your last slide again that had the issues you
3 wanted to discuss.

4 DR. KRISHNAN: Yes. Hold on.

5 CHAIRPERSON ANASTASIO: Great. Thank you.

6 PANEL MEMBER RITZ: Oh, yeah. So -- oops. Now,
7 I can't see it anymore.

8 Ah, it's coming.

9 Yeah, so adopting EPA's final value I think it's
10 a good idea, because leukemia, not breast cancer, but
11 leukemia definitely and lymphoma are childhood cancers or
12 seen in childhood as well, and they might be susceptible
13 age groups, so I agree with that.

14 And the last point, I don't have anything new.

15 CHAIRPERSON ANASTASIO: Beate --

16 PANEL MEMBER RITZ: And as I said, I have -- I
17 have editorials on the way that the epidemiology is
18 described, but I'll hand that in.

19 CHAIRPERSON ANASTASIO: Yeah. That's great.
20 Thank you for your comments. I had a follow-up question
21 for you, Beate. You talked about having read the NIOSH
22 study. Can you talk about this issue of the modeled
23 exposures pre-1978? Did you form an opinion about that?

24 PANEL MEMBER RITZ: Yeah, I actually really liked
25 that, because I developed similar kind of models with my

1 colleagues at UCLA that we use -- that we are using in air
2 pollution epidemiology. They're called land use
3 regression models. And they're basically the same of what
4 these offers here have done. What you do is you use
5 everything you know about features in the workplace or in
6 the environment that contribute to exposures. So in the
7 case of, for example, air pollution, that would be how
8 many cars go down a road, what the land use is of that
9 part of the area that you're trying to evaluate air
10 pollution in what -- you know, how -- what the fleet
11 composition is, whether they are trees, et cetera, et
12 cetera.

13 And then you are measuring air pollution at one
14 point or multiple points across an area and you're trying
15 to use everything -- every source of exposure that you
16 know is a source of exposure to predict the actual
17 measured value. And that's what we call a land use
18 regression and generally an R square of -- above 0.8 is
19 considered exceptionally good. And what these authors did
20 here is basically the same thing. They knew about the job
21 titles. They knew about equipment. They knew about how
22 this equipment was used and other engineering controls.

23 And then they had 2,700 measurements, which is a
24 lot. And they tried to use all of what they knew about
25 the workplace to predict the actual measured level in the

1 workplace. And they got an R square of more than 0.8.
2 And that's -- and with that, you now can use this
3 regression model to actually predict every worker's
4 individual exposure if you know where you worked, because
5 you have all of these variables that predict -- that
6 predict the level of exposure and you can regress that
7 value on every worker.

8 And I think that's a very strong way to do it.
9 And they try to do the same thing by asking industrial
10 hygienists to actually predict these kind of exposures and
11 their regression model outperformed the predictions of
12 these very knowledgeable exposure assessors in the
13 workplace. And I'm actually not surprised that they did.

14 CHAIRPERSON ANASTASIO: That's great. Thank you.
15 Yeah, thanks very much for your comments.

16 I'd like to turn it over now to Dr. Messer our
17 expert statistician.

18 PANEL MEMBER MESSER: Thank you, Cort.

19 Yeah, so I think what will be most useful is if I
20 can provide some written discussion of some of these
21 technical issues. I think that might be most helpful to
22 clarifying some of these points.

23 In general, I agree with the comments of Beate
24 that I think she gave a very nice summary of the
25 methodological strengths of the underlying paper and of

1 the appropriateness of the general approach of a linear
2 spline model, especially when trying to assess exposure
3 risk -- the exposure risk relation in a particular region,
4 in a low-dose region, so above the background. So you're
5 looking at additional exposures, but within a plausible
6 range of exposures, not at very, very high exposures, such
7 as might not be experienced in the -- in this setting.
8 It's appropriate to use a model that uses the data in that
9 region that you're interested in to infer the slope. And
10 that's what align a linear spline model does.

11 So it's like -- it mimics a regression just over
12 the region of interest and it allows the higher values to
13 have some influence on this area that you're interested
14 in, but it limits the inference specifically to the area
15 that you're interested in in your model. So it's a very
16 appropriate methodology and I find the graphs generally
17 quite convincing, especially for ruling out the Cox
18 proportional hazards model. I'd like to read that model a
19 little more carefully to make sure I understand what it's
20 doing and then I'll give some technical comments on why I
21 think the fit is so poor of the Cox proportional hazard
22 model.

23 I'll provide some comments on the way the model
24 comparison was done. And again, I may have some technical
25 comments there, but I think generally, it's quite

1 appropriate. And generally there's a clear lack of fit of
2 many of those models, but I may have some suggestions for
3 how to conduct that kind of model comparison assessment.
4 I agree with the main approaches assessing bias
5 considerations of causal inference, biological
6 plausibility, parsimony. Those are all valid and then the
7 basic assessment of fit to the data.

8 I'd like to read the public -- the technical
9 public comments. I understand there were comments on how
10 the variance was calculated and other technical comments.
11 So I'll read those comments and provide a technical
12 response to them. But generally, this looks like a high
13 quality -- a high quality approach based on -- as Beate
14 pointed out, based on high quality data.

15 CHAIRPERSON ANASTASIO: Thank you, Karen. I know
16 you want to get into more detail in your written comments,
17 but can you give us a summary of why the Cox proportional
18 hazard model isn't a good fit.

19 PANEL MEMBER MESSER: My guess is because they
20 didn't -- because the underlying hazard is modeled as a
21 completely linear hazard. My guess is that's what they
22 did. You can use a two-piece linear spline model to model
23 the hazard in a Cox regression, and likely that would have
24 been more appropriate and likely that's not what was done.
25 So that's what I'd like to just double check.

1 You know, I think a Cox proportional hazards
2 model, I have to see the specifics of how they applied it,
3 but that model itself might be quite appropriate. It's
4 just they didn't model the risk appropriately. They
5 probably used just a linear regression, which as we've
6 seen from the other -- the other models presented doesn't
7 fit the data very well. So I think that's what's going
8 on.

9 CHAIRPERSON ANASTASIO: Okay.

10 Thank you. Any other comments?

11 PANEL MEMBER MESSER: No. I think -- I think
12 that's it. I agree with the main points of the
13 presentation, that -- especially the idea that the spline
14 model is an empiric -- an empiric fit to the risk data.
15 That's what's required of a model like this. So the
16 comments that there's not a mechanistic support for that
17 particular kink, I don't think that's necessary. It's an
18 empirical fit to the risk that's important here.

19 And just another comment about this idea of back
20 extrapolating from the spline model into the area of
21 endogenous exposure. I agree with the comments by OEHHA
22 that that would not be an appropriate use of this model
23 that was developed exclusively on the excess risk data.

24 CHAIRPERSON ANASTASIO: Okay. Great. Thank you
25 very much for your comments.

1 I'm going to now -- we'll go through other
2 panelists and I'll ask each person individually to tell us
3 if they have additional comments. I'm just going to go in
4 order on my Zoom screen. So Pam, you're first.

5 PANEL MEMBER LEIN: Thank you, Cort. I really
6 don't have anything to add to what both Karen and Beate
7 have already indicated.

8 I agree, I think that the approach used by OEHHA
9 is appropriate. I think the conclusions they reached are
10 well substantiated by the information provided in the
11 report. Yeah. I don't have much to add on the
12 clarification of the use of the IUR under Hot Spots
13 Program. I'm -- I have to become more familiar with the
14 Hot Spots Program, but conceptually it makes sense to me.

15 So overall, I support the basic premise
16 underlying the approach used by OEHHA and support the
17 conclusions that they've reached.

18 CHAIRPERSON ANASTASIO: Okay. Thank you.

19 Ahmad, comments.

20 PANEL MEMBER BESARATINIA: Yes. I think going
21 through the draft, I found it quite interesting. And I
22 must say that equally interesting was the public comment
23 section, which was quite extensive. This was one of the,
24 I must say, the longest public comments draft that we -- I
25 have seen. There are many valid points in these public

1 health comments. And I think Dr. Krishnan kind of
2 highlighted them in his presentation. There were at least
3 three or four points that need to be addressed in the
4 revised version. Obviously, just a point-by-point reply,
5 where these comments can be addressed.

6 I think the three or four main points were the
7 selection of this NIOSH study. Reading through the draft,
8 it appears as if this is a gold standard study and the
9 other two studies have been kind of set aside. I think
10 there needs to be a little bit more information as to why
11 this study was selected. There is very brief -- very
12 brief description in the tables, if I can get that Table
13 7, I guess -- somewhere in the comment section of Table 7,
14 they are indicating why the other two study, including
15 Union Carbide Corps and the Swedish study was not
16 selected. But perhaps that type of clarification should
17 come in the text.

18 There was another issue with the selection of
19 models. That is obviously something that needs to be
20 elaborated in the main document.

21 The other point was the endogenous exposure, the
22 endogenous sources as well as ambient exposure from other
23 sources. So that needs to be, I think, expanded a bit,
24 particularly as we know the tobacco smoke is the single
25 most source of ethylene oxide. So it needs -- I would

1 like -- I would have liked to see more information on that
2 regard.

3 There was the issue of healthy worker bias that
4 was raised by multiple commenters on the public comment
5 section. So the use of internal comparison group versus
6 the general population to drive the SMR and SIR. So those
7 are things that would be helpful if the authors put it up
8 front, so it makes it -- it makes it more comprehensive,
9 the draft itself, as well as somehow even-handed. The way
10 that it is -- it reads right now, it leaves the impression
11 that it's a done deal. NIOSH study is the gold standard
12 model is the one that needs to be used, because if EPA
13 used it.

14 So I would -- I would have liked to have a bit
15 more discussion on that in the draft itself. But other
16 than that, I agree with both Beate and Karen, the main
17 points are highlighted in the draft. I agree with them.
18 It's just some clarification and expansion of the draft
19 itself.

20 Thank you.

21 CHAIRPERSON ANASTASIO: Thank you, Ahmad.

22 Kathy, comments.

23 PANEL MEMBER HAMMOND: Yes, thank you. I have no
24 further comments. I think it was very good job and I
25 Thank the presenters, and also the -- my fellow SRP

1 members for their excellent comments.

2 CHAIRPERSON ANASTASIO: Thank you, Kathy.

3 Joe, do you?

4 PANEL MEMBER LANDOLPH: Yeah.

5 I've gone over it a number of times. I want to
6 put some more time into finalizing my opinions. There was
7 a comment I think it was by the public that even though
8 ethylene oxide is a mutagen, that doesn't mean how it
9 causes carcinogenesis via mutagenesis.

10 I would kind of take the opposite opinion on it.
11 It's a hell of a mutagen. It's been demonstrated in many
12 systems. That doesn't mean that conclusively settles this
13 by any means, but I'd like to see more data, you know, see
14 actually some data that it could act by a non-mutagenic
15 mechanism before I could accept the way that was written.
16 So I think that should be changed a little bit. I would
17 say maybe the presumption right now, the hypothesis that
18 ethylene oxide is a known, strong mutagen, and that this
19 might be the way or one of the ways that it causes
20 carcinogenesis. I kind of take a tack like that.

21 I agree with all the comments that everybody made
22 so far, particularly tobacco smoke is a strong source of
23 ethylene oxide. That should be stressed. That ethylene
24 oxide is very mutagenic.

25 And let's see, what else? I like the dose

1 response modeling. That was very illustrative with the
2 spline curves and all, and I agree with all that.

3 And the data on breast cancer is very important.
4 I'd like to see a table maybe at the end when you finish
5 this what's going to be a pretty huge document of the IURs
6 for -- you know, for breast cancer, the leukemias,
7 anything else that is thought to be carcinogenic for and a
8 summary at the end of the document. And I was very
9 impressed by these line spline models too and their
10 ability to predict -- explain the data.

11 I want to go over the draft document with a
12 fine-tooth chrome and finish my comments and give them to
13 you. And I agree with Ahmad, I think this first draft is
14 very, very interesting. So I like the writing in general.
15 I'm sure it can be spiffed up a little bit, but it's
16 pretty clear. I have no trouble reading this document and
17 understanding it. It's a very well written document, very
18 thighs document, very clear.

19 CHAIRPERSON ANASTASIO: Thank you, Joe.

20 So I have some comments, but we're scheduled for
21 a break at 11. And I think it's going to take more than
22 10 minutes for my comments, so I'd like to take our break
23 now. We'll take a 10-minute break from 10:52 to 11:02.
24 And then we will reassemble, and I'll have my comments,
25 and then we'll get response from OEHHA.

1 All right. So we'll see you in 10 minutes.

2 (Off record: 10:52 a.m.)

3 (Thereupon a recess was taken.)

4 (On record: 11:02 a.m.)

5 CHAIRPERSON ANASTASIO: Okay. We're going to
6 restart everybody.

7 Excuse me. I'm going to wait for Joe and Karen
8 to return.

9 Excellent. Okay. So I wanted to express my
10 comments. The first one was that, you know, we talked
11 about this model of leveraging information from other
12 agencies like EPA and the development of health guidance
13 values with the hope that it would save time. And I'm
14 just wondering for Dr. Woods and Dr. Krishnan, did it save
15 significant amounts of time?

16 DR. KRISHNAN: I think the intent was not to
17 directly adopt without any evaluation or going through.

18 CHAIRPERSON ANASTASIO: Oh, sure, right. No.
19 No. I wasn't suggesting that, but you know it wasn't as
20 time-consuming I imagine as a typical IUR would be. And
21 is that true? Did this -- did this new process save time?

22 DR. KRISHNAN: In this particular case and for
23 this chemical from my limited experience, yes, OEHHA, I
24 would say, you know, no, it didn't -- it did?

25 DR. WOODS: Yeah.

1 DR. KRISHNAN: Because I think normally, it had
2 taken even longer or could I ask --

3 DR. STEINMAUS: I mean, for me, who was involved
4 in selecting this study, it was just such a high quality
5 study that I didn't -- and the evaluations were so -- and
6 not just in the papers themselves, but in the 2016 update
7 by Kyle Steenland. It was just such a high quality,
8 intense, comprehensive evaluation, that it was easy to go
9 with that study and that data.

10 CHAIRPERSON ANASTASIO: I see. So a confounding
11 factor in understanding the impact of the process versus
12 this very good study. Okay. Thank you.

13 My second comment is about this question of
14 whether EtO concentrations are elevated near sterilization
15 and other point sources. And some of the public comments
16 were suggesting that they were not, which would seem odd,
17 but it really depends on the lifetime of EtO in the
18 atmosphere. So I thought it would be helpful if you could
19 add just a sentence or two about the lifetime of EtO,
20 which from my reading is on the order of days, which would
21 suggest that you should see a pretty strong gradient of
22 significantly higher concentrations in your sources.

23 My second comment was about Figure 6. Can -- Dr.
24 Woods or Dr. Krishnan, can you show -- can you share your
25 screen with the Figure 6 with all the different fits on

1 it? I think you had two versions.

2 DR. WOODS: Sure. Let me get that pulled up for
3 you. Give me just a second.

4 CHAIRPERSON ANASTASIO: Yeah. And actually the
5 next one. Let's look at the super busy one. Yeah.

6 So first comment is, this is categorical data.
7 The individual data you mentioned is not available. I
8 understand it's thousands of data points, but that's not
9 available?

10 DR. STEINMAUS: Well, we probably could have
11 asked for it. Steenland makes a comment in his 2016
12 evaluation that he no longer had access to it, because he
13 wasn't at NIOSH any more. So I suspect it would have been
14 very difficult, if not impossible, to get, but the bottom
15 line is we didn't feel like we needed the individual data,
16 since the evaluations that Steenland had done for U.S.
17 were so comprehensive.

18 CHAIRPERSON ANASTASIO: I see. I'm not familiar
19 with using categorical data. I'm not a statistician, but
20 is there generally no expression of variability on
21 categorical data? Like I would -- if my group was showing
22 me data, I would expect error bars.

23 DR. STEINMAUS: Well, most -- the lines are
24 actually continuous data, not categorical. And then the
25 dots are the categorical data. So you're absolutely

1 right, this is from U.S. EPA and they certainly could have
2 put in the 95 percent confidence intervals. And maybe
3 they should have on the -- on the categorical data, the
4 dots, but I think that would have just made this slide way
5 too busy. They did present those 95 percent confidence
6 intervals in their -- in their report.

7 CHAIRPERSON ANASTASIO: I remember seeing that.

8 DR. STEINMAUS: So I got a note that I should
9 introduce myself. So I'm Craig Steinmaus. I'm an
10 epidemiologist and physician at OEHHA.

11 CHAIRPERSON ANASTASIO: Great. Thank you for
12 introducing yourself and thank you for your responses.

13 Okay. Right. I'm remembering now. The
14 categorical confidence intervals are in the table. Okay.

15 I'd like to try to understand better this
16 2,000-fold difference in the OEHHA IUR, in the Texas CEQ
17 IUR. Was this the slide that has the TCEQ fit is one of
18 those blue lines at the bottom?

19 DR. STEINMAUS: Yeah, that's correct. It's the
20 lowest line was the same model that TCEQ used.

21 CHAIRPERSON ANASTASIO: Okay. Well, I would not
22 call that a good fit to the data. So can you describe to
23 me kind of qualitatively why it is then at very low
24 cumulative exposures there's such a big difference between
25 the spline fit and this Cox proportional hazard fit?

1 DR. STEINMAUS: Yeah. U.S. -- it's complicated
2 and it would take a long time to explain all of it, but
3 let me -- U.S. EPA had a very good explanation for that in
4 their response to public comments. And we referenced that
5 explanation and gave a brief overview.

6 The bottom line is that that lower line, the log
7 relative risk Cox proportional hazard model, actually over
8 the entire course of the exposure range is sublinear,
9 which means that it's flat at the bottom at the lower
10 exposures. And then in order to meet -- to come close to
11 the exposures in the higher exposure range, it has to --
12 it has to curve way up.

13 So that curve, that sublinear curve, makes it low
14 in the lower exposure ranges, which are what we're seeing
15 here in this figure. So that's why that blue line is so
16 low and it's much different than the categorical data
17 points and much different than the spline model. It's
18 because of that eventual superlinear aspect. Again, you
19 can't see it here, but at the higher exposure doses, it
20 starts curving. It has to curve way up to meet these
21 higher exposure doses.

22 CHAIRPERSON ANASTASIO: I see. Is it -- so this
23 is EPA data. You don't have access to this data?

24 DR. STEINMAUS: We don't have access to the
25 individual data, you know, the data points on every single

1 individual in this study. And, you know, it's not just
2 that, you know, NIOSH might not want to give it to us.
3 It's also, you know, privacy concerns. You know, I've
4 done a number of studies and U.S. EPA has asked for my
5 data. And it has taken me a year or two to get our ethics
6 board at UC Berkeley to approve it, so -- because of, you
7 know, personal confidentiality issues.

8 So, you know, there's difficulties in getting
9 individual data. But again, like I said before, we didn't
10 feel like we needed it.

11 CHAIRPERSON ANASTASIO: No. Sorry. I wasn't
12 talking about the individual data here. I was talking
13 about the parameters for these regression fits.

14 DR. STEINMAUS: Yeah. Yeah. We have the
15 regression coefficients and the 95 -- or 90 -- 90 to 95
16 percent confidence intervals on all of these. Yeah, it's
17 all in the U.S. EPA document.

18 CHAIRPERSON ANASTASIO: Let me suggest that it
19 might be helpful to show the data either with a blowup of
20 the very low cumulative exposure range, so you can see the
21 difference between the Cox proportional hazard fit, which
22 sounds quite poor in that relevant range, or to show the
23 data -- not -- the data and the fit primarily on a log
24 scale. Just something to show the difference in the
25 cumulative exposure range that actually matters for

1 environmental exposures, right, because those are way
2 close to the origin, right?

3 DR. STEINMAUS: Yeah. That would be correct,
4 yep.

5 CHAIRPERSON ANASTASIO: So being able to -- at
6 least for me, being able to understand why this 2,000-fold
7 difference in the IURs really hinges on what's happening
8 close to the origin, or at least very low cumulative
9 exposure levels.

10 DR. STEINMAUS: Yeah. And, you know, you can't
11 see it on this graph, because, you know, the blue line
12 obviously at the lower exposure range is below 5,000
13 obviously is much less steep --

14 CHAIRPERSON ANASTASIO: Right.

15 DR. STEINMAUS: -- than that dotted red line.
16 So -- but you make a pretty good point. Maybe we could
17 focus more on that lower exposure region to really show
18 the difference.

19 CHAIRPERSON ANASTASIO: Right. And, you know,
20 you've got a factor of 2,000 difference, so you almost
21 have to use a log scale to really have that come out.

22 Other comment related to this figure, you know,
23 in the document, there's some -- oh, wait. Kathy, do you
24 have a follow-up comment on this issue?

25 PANEL MEMBER HAMMOND: Yeah. I was just going

1 to -- I like the idea and I was going to suggest you could
2 have another graph that's just showing that lower
3 concentration, and then it could be. And that -- and I
4 think that would be particularly useful. I think that was
5 a good idea, Cort, to have it in the range where we're
6 talking about environmental levels are, you know, and what
7 we're -- you know, so the box could -- it would be
8 informative in the area that's most important and
9 relevant.

10 DR. STEINMAUS: Yeah. So just expand that lower
11 left section of this graph. Just expand that.

12 PANEL MEMBER HAMMOND: Well, I guess -- yeah.
13 What I'm suggesting is a second graph that just uses that
14 small area.

15 DR. STEINMAUS: Right. Yeah. Okay. Yeah,
16 that's a good idea.

17 CHAIRPERSON ANASTASIO: So on a related note in
18 the document, you discuss that -- why the difference
19 between a TCEQ and the OEHHA IUR. And the first point is,
20 well, TCEQ didn't consider breast cancer, which I agree is
21 an important point, but it's a pretty small factor
22 compared to this factor of 2,000, right. Since breast
23 cancer was responsible for less than half of the incidents
24 of cancer, that's, you know, going to be no more than a
25 factor of two on the IUR I think.

1 So you had another reason why -- I think it was
2 fit was another reason. My suggestion is put the reasons
3 for the difference between TCEQ and OEHHA in rough order
4 of their importance in terms of explaining this factor of
5 2,000. And it seems like the fit is the biggest issue.
6 And so I think that needs to go first and I think it needs
7 more discussion. And so this new figure of blowing up the
8 low cumulative exposure data range would help in that
9 description.

10 DR. STEINMAUS: Yeah, you're a hundred percent
11 right. And I think we put a lot of that in the -- our
12 responses to public comments, but I don't know that we
13 have that much of that in the draft, so...

14 CHAIRPERSON ANASTASIO: Right. Yeah, there's not
15 much in the document itself. There is some, but --

16 DR. STEINMAUS: Yeah. Yeah, maybe we could
17 transfer some stuff over, yeah.

18 CHAIRPERSON ANASTASIO: Karen, do you have a
19 follow-up point on that?

20 PANEL MEMBER MESSER: Yeah. Just that I agree,
21 it's surprising that, you know, if this is an accurate
22 representation of how TECQ, T-E-C-Q, value was developed,
23 it's very surprising that a model that fit this poorly was
24 used, so -- in the Texas document. So I may go back and
25 look at that Texas document a little -- a little bit to

1 try to understand how they could have developed a model
2 that fit this poorly.

3 CHAIRPERSON ANASTASIO: Yeah. It would be --

4 DR. STEINMAUS: Yeah, I'm really interested in
5 your input. Yeah, I think it's just another of the many,
6 many, many examples of, you know, when you base things
7 solely on a p-value or an AIC score how you can -- it can
8 lead you to some major mistakes, but I'm very interested
9 in your opinion on that.

10 PANEL MEMBER MESSER: Yeah. And then just a word
11 of caution, you know, if we blowup that lower left-hand
12 corner. I like the idea of putting the Y axis perhaps on
13 a log scale here in this graph. If you concentrate on the
14 low exposure region of X axis, I wouldn't go so far as to
15 exclude those first three data points, because they're
16 driving the models.

17 CHAIRPERSON ANASTASIO: The first three non-zero
18 exposure.

19 PANEL MEMBER MESSER: Yeah, those first three
20 purple categorical data points.

21 CHAIRPERSON ANASTASIO: Yeah.

22 PANEL MEMBER MESSER: Got to --

23 PANEL MEMBER HAMMOND: The observed data.

24 PANEL MEMBER MESSER: Yes. The observed data,
25 not the modeled fits. But if you blow this up, it's still

1 helpful to include the observed data.

2 CHAIRPERSON ANASTASIO: Yeah.

3 DR. STEINMAUS: I probably shouldn't say this,
4 but I just got to -- thank you so much for saying that
5 "observed data," because that was another point that was
6 in the public comments. And I agree with you a hundred
7 percent, those are the observed data points.

8 CHAIRPERSON ANASTASIO: One final comment related
9 to this. So in one of the written public comments, there
10 were -- they used the regression fits to estimate, I
11 believe it was, the incidence of the lymphoid cancer. And
12 their point was that the TCEQ estimates, based on the TCEQ
13 fit, were closer to the observations in the study than
14 were the OEHHA -- if you took the OEHHA regression and
15 calculated the incidence. Can you address that point?

16 DR. STEINMAUS: Yeah. What TCEQ did in those
17 calculations was as their reference group, they used the
18 U.S. population as a whole. Steenland, and even TCEQ in
19 their final numbers, they used an internal comparison
20 group, which is much better. So the TCEQ that -- you're
21 referring to their reality check or their ground-truthing
22 exercise. It's most likely biased, because they use that
23 U.S. reference -- the U.S. population as their reference
24 group and not an internal comparison group, so it's
25 probably biased by the healthy worker effect, or the

1 healthy worker survivor effect, or related issues to that.
2 So that was our point is that that analysis was biased.

3 CHAIRPERSON ANASTASIO: Okay. And if -- okay.
4 All right. Thank you on that. And then my final comment
5 was -- oh, wait. I see hands. Very exciting here.

6 Beate, you want to go first.

7 PANEL MEMBER RITZ: Yeah. I just would like a
8 clarification. I heard something, and I may have been
9 wrong, that the leukemia -- in the presentation, that the
10 leukemias make up the bulk of the cancers. I'm a little
11 bit surprised by that, because it's a rarer disease. And
12 if you increase breast cancer risk by 50 percent or 90
13 percent, it's usually more cancers than if you would do
14 that same relative risk increase for leukemias, a lot more
15 in attributable numbers. So I just want to make sure that
16 I did not mishear and that that's also reported correctly.

17 DR. STEINMAUS: Yeah. I mean, obviously, you're
18 absolutely right. Breast cancer did have an important
19 contribution to our -- the overall number. So, you know,
20 certainly lymphoid cancers did too. You know, the
21 relative risks were pretty high. But yeah, they both
22 contributed, both cancers.

23 CHAIRPERSON ANASTASIO: Karen.

24 PANEL MEMBER MESSER: Yeah. I'll do this more
25 carefully when I can see the response to the review to the

1 public comments, but I just wanted a clarification, when
2 TECQ did their ground truthing, were they projecting to
3 U.S. population -- were they fitting to the U.S.
4 population lymphoma rates or to the rates in the exposure
5 study?

6 DR. STEINMAUS: They were trying to project to --
7 not the rates, but they were trying to project to the
8 numbers of cases that were seen in the Steenland study.
9 So that -- that was their ultimate goal to try to estimate
10 those numbers of cases and see if it matched what was
11 actually reported.

12 The problem was was that when they did that, they
13 did like SMR calculations, like we would normally do SMR
14 calculations, where we used the general U.S. population as
15 the reference group. So that was the issue, they used the
16 general U.S. population as opposed to using a group of
17 workers, a group of lesser exposed workers from the
18 Steenland cohort.

19 PANEL MEMBER MESSER: Okay. Thank you.

20 CHAIRPERSON ANASTASIO: Beate.

21 PANEL MEMBER RITZ: Yeah. So basically, they are
22 using the U.S. rates to derive the expected number of
23 cancers in the -- in the cohort.

24 DR. STEINMAUS: Yes, that's correct.

25 CHAIRPERSON ANASTASIO: Okay. And then my last

1 comment was about the modeled exposures in the NIOSH
2 study. So one of the public comments was suggesting that
3 the pre-1978 exposures that were modeled were lower than
4 subsequent exposures. And they talked about this issue of
5 the model apparently assumed a fixed calendar year, I
6 think, of 1978 for prior years. So can you talk about
7 exposure levels pre-1978 in terms of their magnitude
8 compared to post-1978 and why you think this is a good
9 approach.

10 DR. STEINMAUS: Yeah, exposure modeling isn't my
11 expertise, especially when Dr. Hammond is in the room. I
12 mean, I'll go back to the -- no exposure modeling is going
13 to be perfect. In occupational epidemiology it's
14 incredibly difficult to do exposure modeling. So, yes,
15 they didn't have exposure measurements before -- I think
16 it was actually 1976. They didn't have exposure
17 measurements, but they had all those other pieces of data
18 that were related -- that were directly related to
19 exposure levels. So we're pretty sure exposures were
20 higher before 1978 -- '76. We're pretty sure that's the
21 case.

22 And it also appears that those factors that they
23 used -- you know, again, Dr. Woods listed all of them, you
24 know, proximity to sterilization, what they were
25 sterilizing, you know, calendar year, all that stuff.

1 It's pretty clear that those factors were strongly
2 correlated to exposure levels. So that's why I think
3 we're pretty confident that the model was accurate.

4 Again, there's going to be some inaccuracies.
5 But the question is what's the degree of those
6 inaccuracies and what would be the impact on the relative
7 risk that we're reported. So I did a variety of different
8 analyses just to sort of assess. Okay, if the sensitivity
9 exists, or if the specificity exists, or the exposure
10 model, how would that impact the relative risks? And it
11 wasn't going to be all that great, right? It probably
12 wouldn't have made a huge difference to the relative risk.

13 So bottom line, to answer your question, yeah,
14 we're pretty sure the exposures were higher, but we're
15 also pretty sure that that was picked up in the Steenland
16 exposure model.

17 CHAIRPERSON ANASTASIO: I see. Am I remembering
18 wrong, that one of the public comments suggested that the
19 OEHHA treatment -- or, sorry, not the OEHHA treatment, but
20 the Steenland treatment this modeling of exposures was
21 resulting in lower exposures pre-1976?

22 DR. STEINMAUS: I think they were saying lower
23 than what other people might have predicted. Yeah. My
24 understanding was the exposures were higher pre-1976.

25 CHAIRPERSON ANASTASIO: Okay. Okay, thank you.

1 Kathy.

2 PANEL MEMBER HAMMOND: Sure. Yeah, it's been a
3 while since I've read some of those papers, but I did read
4 them at one time. And Dr. Steinmaus is exactly correct
5 that the -- what -- the effort was done on some of this
6 was done actually at Berkeley -- UC Berkeley. They took a
7 bunch of measurements in a lot of places. And in some
8 places like where they put like a exhaust in, they would
9 turn that off and do measurements. So they did
10 measurements with all the fact -- or many of the factors
11 that you would think would affect exposure and built a
12 model based on that, and then retrospectively in time said
13 when did local exhaust, for instance, come into play.

14 And so that's how they would develop the exposure
15 model with all the factors that they could identify and
16 find in the different measurements they made. So it's
17 measurement -- a model based on measurements and with
18 parameters that would impact exposure.

19 CHAIRPERSON ANASTASIO: Right. Thank you, Kathy.

20 Karen.

21 PANEL MEMBER MESSER: Yeah. Just a clarifying
22 question. We're talking -- if someone could direct me to
23 those comments in the public comments, that be would
24 helpful. I think there may be some clarification that
25 would be helpful whether we're talking about the actual

1 exposure being higher pre-1976 or whether the modeled
2 exposure being too low to predict the actual exposure. So
3 those are two different issues. If the model -- and I
4 don't know what the comment said. From this discussion,
5 it's hard to know what the comment -- the public comment
6 was.

7 If the modeled exposure is underpredicting the
8 actual exposure, then that would lead to bias in the
9 eventual estimates, so that would be the issue. So it's
10 unclear to me from this discussion whether the public
11 comment was directed at actual exposures or a bias in the
12 model.

13 CHAIRPERSON ANASTASIO: It was a bias --

14 DR. STEINMAUS: Yeah. Yeah.

15 CHAIRPERSON ANASTASIO: Yeah.

16 PANEL MEMBER MESSER: So do you think there is a
17 bias in the model or -- I mean, that's always hard to --

18 DR. STEINMAUS: Yeah. You know, we would have no
19 way of assessing that.

20 PANEL MEMBER MESSER: Right.

21 DR. STEINMAUS: Again, you know, we just go back
22 to, you know, the validation data that they did have was
23 excellent. And then, you know, they did have information
24 available on all those factors the Dr. Hammond talked
25 about.

1 PANEL MEMBER MESSER: Do their -- do their
2 modeled exposures turn out to be higher overall pre-1976?
3 Do you -- was there information on that?

4 DR. STEINMAUS: Higher than post-1976?

5 PANEL MEMBER MESSER: Yeah.

6 DR. STEINMAUS: Yeah, I'm going to have to go
7 back and look at that, but my recollection was, yes, they
8 were higher.

9 PANEL MEMBER MESSER: Okay. So that would --
10 that would, in a sense, be some sort of validation of the
11 model also. Okay.

12 CHAIRPERSON ANASTASIO: Thank you, Karen.

13 Ahmad.

14 Ahmad, you're muted.

15 PANEL MEMBER BESARATINIA: Sorry about that.
16 Yeah, just regarding Karen question, this was raised in
17 several places in the public comment. For instance, in
18 page 40, I think the second paragraph it was third in
19 NIOSH exposure model based on the conditioning of calendar
20 year predicted early sterilization and so on. So -- and
21 they were saying that these predictions were substantially
22 lower than workers in 1978 when exposure concentration
23 predictions were based on measurements, so that is one
24 thing

25 But the other thing, I also noticed that they are

1 saying that there was a loss of data -- electronic data
2 regarding exposure estimation prior to 1978. So how could
3 they verify this?

4 DR. STEINMAUS: Sorry, what's the question?

5 PANEL MEMBER BESARATINIA: Well --

6 DR. STEINMAUS: There was a loss of data.

7 PANEL MEMBER BESARATINIA: Yeah. They were
8 saying that the NIOSH exposure estimation prior to 1978,
9 the original data are lost. So how could one verify this
10 estimation if there is no data available?

11 DR. STEINMAUS: Well, again, there's no --
12 there's no way we're going to be able to verify. There's
13 no way we're going to be able to do, you know, a typical
14 validation study on the exposure data before 1976, because
15 it's just not there. So we have to --

16 PANEL MEMBER BESARATINIA: No. No. No. The
17 data that they were used to make their prediction model
18 data. So because they estimated these exposure based on
19 some calculations.

20 DR. STEINMAUS: Oh, the data they used to make
21 the model --

22 PANEL MEMBER BESARATINIA: Yeah.

23 DR. STEINMAUS: -- that they -- they said they
24 lost.

25 PANEL MEMBER BESARATINIA: Yeah.

1 DR. STEINMAUS: Yeah, I wasn't aware of that.

2 PANEL MEMBER BESARATINIA: Yeah, it is indicated
3 here in the report in the public comment section that
4 these data are not available and they're lost. These are
5 electronic data.

6 DR. STEINMAUS: Oh, I wasn't aware of that.

7 CHAIRPERSON ANASTASIO: Karen.

8 PANEL MEMBER MESSER: Yeah. I guess the answer
9 to that is to go by the published record on how they fit
10 the model and the model quality that they report. It
11 seems like the underlying data may not be available for
12 many aspects of this study, but as long as -- so that's --
13 I guess the point is that I don't think it puts that part
14 of the study on any different footing, one would go by
15 the -- their published R squared and other information on
16 how they calibrated the model. So I'm happy to review
17 this part in more detail from a statistical perspective.

18 CHAIRPERSON ANASTASIO: Yeah. I think that would
19 be helpful.

20 Okay. Do we have any other comments from the
21 Panel?

22 All right, seeing none, thank you very much to
23 OEHHA for their work on this IUR.

24 We look forward to seeing it again. Thank you to
25 the Panel for their comments. If you do have written

1 comments, you know, minor issues or even major issues,
2 please send them to OEHHA so that they can incorporate it
3 in the revision.

4 And we're now going to move to public comments.

5 DR. STEINMAUS: Can I make one quick comment or
6 is it too late

7 CHAIRPERSON ANASTASIO: No, go ahead.

8 DR. STEINMAUS: You know, getting back to that
9 exposure, I have the -- I have the exposure paper right
10 here, Hornung. It shows the estimated levels prior to
11 1978 being higher than the estimated levels after 1978.
12 That's Figure 1 on Hornung. That's the exposure paper.

13 CHAIRPERSON ANASTASIO: Okay. That's helpful. I
14 think that contradicts what the public comment said about
15 that.

16 Yeah. Yeah, thank you or the clarification.

17 Yes, Joe.

18 PANEL MEMBER LANDOLPH: Yeah. That curve is very
19 interesting, you know, where you fit it and you get this
20 shape going like that. And I'm wondering if that's two
21 separate processes where there's really a slope with the
22 low curve reflecting one process and the other one a
23 different slope affecting another process. It's -- it
24 needs a lot more thinking to go into it is what I feel.
25 So, you know, I'd like to know more about it. We need to

1 know more about it. The statistical fitting looks
2 fantastic, and -- but we --

3 DR. STEINMAUS: It does. Is your suggestion that
4 we need to have a greater understanding of the mechanisms
5 that are involved in this lower versus higher exposure?

6 PANEL MEMBER LANDOLPH: If that's -- if that's
7 the case. Now, if it's one case -- if it's really, you
8 know, a very high slope at the low dose, which is what
9 that plot looks like, then it reminds me of some curves,
10 you know, in metabolism where you get -- a very high slope
11 then becomes -- something becomes saturated, binding of a
12 molecule to receptor becomes saturated or the metabolism
13 of, you know, a compound becomes saturated at the high
14 dose. So I think we should try and put some more thought
15 into it, if we could. I'll certainly try for you to help
16 out.

17 DR. STEINMAUS: Yeah. I think -- I'm thinking
18 though that ultimately it's going to be unknown. I think
19 we can come up with some very good hypotheses, some
20 rational hypotheses, just like what you described.

21 PANEL MEMBER LANDOLPH: Yeah.

22 DR. STEINMAUS: Maybe there's a saturation of
23 susceptible people, so I think we can come up with some
24 hypotheses. But ultimately, I'm not sure we're going to
25 come up with a hundred percent answer. And I'm also

1 not -- I also don't -- I'm not sure that we need to come
2 up with a hundred percent answer. But yeah, that's
3 definitely an idea that we can put more thought into.

4 CHAIRPERSON ANASTASIO: Yeah, I agree
5 fundamentally. And I think Karen said this before, you
6 know, it's an empirical fit. So regardless of the
7 underlying mechanism, this is the best fit to the data.

8 Yeah. Pam.

9 PANEL MEMBER LEIN: Well, that was pretty much
10 what I was going to say, Cort. You know, I was going to
11 push back --

12 CHAIRPERSON ANASTASIO: Oh, sorry.

13 PANEL MEMBER LEIN: -- a little bit on Joe and
14 say I think for the purposes of risk assessment, while
15 having a biological -- and understanding the biological
16 mechanism certainly helps, I'm not sure it's worth the
17 time and energy for the CARB staff to try and really dig
18 through the literature to determine what is the reason for
19 that kink in the curve.

20 For risk assessment, they don't need it and -- I
21 did a little bit of searching, because I am a mechanistic
22 toxicologist and there's -- what they put in the report is
23 about what's out there for the mechanism of ethylene
24 oxide-induced cancer.

25 CHAIRPERSON ANASTASIO: Yeah. Thank you, Pam.

1 DR. STEINMAUS: Yeah. As a scientist, it would
2 be really cool to figure it out. As a risk assessor, you
3 know, maybe we don't need to.

4 CHAIRPERSON ANASTASIO: Yeah. Karen.

5 Yeah. Just one last comment. I think what would
6 be important from mechanism -- a mechanism of action
7 perspective would be if it were biologically implausible.
8 So I think coming up with biologically plausible
9 mechanisms isn't super helpful here. It's just if you saw
10 something that you thought, oh, wait, that contradicts the
11 biology, then that might cast doubt on the model, but that
12 is not the case here, that no one seems to feel this is
13 biologically implausible. It's just scientific
14 underpinning would be an interesting scientific question.
15 So I agree with Cort that it wouldn't add to the risk
16 assessment.

17 DR. KRISHNAN: And I would just add -- indicate
18 that -- this is Krishnan -- that the application of the
19 IUR is actually limited up to 40 micrograms per meter
20 cubed, you know, as a result of the analysis that was
21 indicated by EPA obviously. And EPA also had indicated
22 that Steenland, while visiting the Cincinnati office found
23 that the electronic data files were not available for
24 conducting the variable approach or -- sort of follow-up
25 somebody had indicated that.

1 With that, we will weave in these comments while
2 revising our document and preparing it for SRP review
3 moving forward, the comments we have heard.

4 CHAIRPERSON ANASTASIO: Great. Thank you very
5 much, Dr. Krishnan. Thank you, Panel, for all your
6 comments.

7 We're going to move now to public comment. So
8 Arash has enabled the feature that allows participants to
9 raise your hands. So if you are a member of the public
10 and you would like to comment on this, please raise your
11 hand and I will just call on you in order.

12 Arash, would you like to give a brief instruction
13 on hand raising.

14 DR. MOHEGH: Sure. So thank you, everyone, for
15 participating. If you are on the Zoom app, you should
16 have either a raise-your-hand option at the bottom of your
17 screen or you should have a reaction button where when you
18 click that you have raise hand, lower hand option. You
19 can raise your hand and we will start the queue. And we
20 will basically decide how much you would allocate for the
21 public comments based on the number of the raise hands.
22 We also have some in-person commenters here today and some
23 of them have submitted slides that they want to share,
24 which I will share for them.

25 They have submitted them in advance and I will

1 share them. So let's wait a few minutes to see how many
2 hands we're going to have and how many commenter we have
3 and decide on the time.

4 CHAIRPERSON ANASTASIO: Okay. That sounds good.
5 And in the meantime, I see that Joe is getting us off to a
6 good start by raising his hand, so Joe why --

7 PANEL MEMBER LANDOLPH: No, I lowered it. I
8 thought I lowered it.

9 CHAIRPERSON ANASTASIO: Oh, you lowered it. Oh.
10 I don't have the power to do that for you.

11 Oh, there we go.

12 Arash, while we're waiting for people online to
13 raise their hand, are people in the room set up to do
14 their comments and share the screen?

15 Sorry, you're muted.

16 DR. MOHEGH: Yes, I have their slide right here
17 and they're ready to share. Do you want to start with the
18 people who are in person?

19 CHAIRPERSON ANASTASIO: Yeah, let's do that.

20 DR. MOHEGH: Okay. Let me set the slides and
21 then have -- ask them to come to the podium. So right
22 now, we have seven virtual attendees who raised their
23 hand, but the number is increasing, and then we have one
24 person in the room. So how much time do you think would
25 be appropriate?

1 CHAIRPERSON ANASTASIO: Let's go for two minutes.

2 DR. MOHEGH: Okay. Our first commenter is Dr.
3 Abby Li from Exponent. And let me get the slides and then
4 get the podium for them.

5 (Thereupon a slide presentation).

6 DR. MOHEGH: Can everyone see that?

7 CHAIRPERSON ANASTASIO: Yes.

8 DR. MOHEGH: Okay. So usually, I have to share
9 the -- basically the timer on my screen, but since I'm
10 sharing this, then I will do the timer on my phone. And I
11 will let you know once you are 30 seconds at the end of
12 your time. And at the end of the two minutes, we have to
13 cut you off.

14 So let me start.

15 CHAIRPERSON ANASTASIO: Thank you, Arash.

16 DR. ABBY LI: Hello.

17 CHAIRPERSON ANASTASIO: Hello.

18 DR. ABBY LI: Okay. Hi. My oral comments focus
19 on statistical and biological considerations.

20 Next slide.

21 [SLIDE CHANGE]

22 DR. ABBY LI: The key issue is that the EPA IRIS
23 model with its initial steep slope and shallower second
24 slope -- next side, please --

25 [SLIDE CHANGE]

1 DR. ABBY LI: -- is not plausible based on the
2 biological and epidemiological data. We're now on slide
3 3.

4 [SLIDE CHANGE]

5 DR. ABBY LI: EPA's rationale is based on
6 statistical and visual fit, including the statistically
7 significant log cumulative exposure models. This
8 rationale is flawed because EPA incorrectly calculated the
9 p-values, used figures for visual fit that are not fit for
10 that purpose, and the only biological plausibility
11 discussion was to eliminate the log cumulative exposure,
12 because it was implausible.

13 [SLIDE CHANGE]

14 DR. ABBY LI: EPA did not include the knot as an
15 estimated parameter in the statistics, even though it was
16 optimized. And I'm sorry, I'm now on slide 6.

17 [SLIDE CHANGE]

18 DR. ABBY LI: Hoping you'll grant me the extra
19 time for trying to catch up. I'm on slide 6. When
20 corrected, as agreed to by TCEQ peer reviewers, the
21 p-values are comparable, but the CPH model is more
22 parsimonious.

23 Slide 7.

24 [SLIDE CHANGE]

25 DR. ABBY LI: Visual fit figures are misleading,

1 because the five dots are not the 53 individual lymphoid
2 cancers modeled.

3 Next slide.

4 [SLIDE CHANGE]

5 DR. ABBY LI: Secondly, the figures give -- we're
6 now on slide 8.

7 [SLIDE CHANGE]

8 DR. ABBY LI: -- give the appearance that models
9 over or underestimate the grouped estimate, despite EPA's
10 warning that making such comparisons along the Y axis
11 should not be done.

12 Next slide.

13 [SLIDE CHANGE]

14 DR. ABBY LI: This misleading figures led to both
15 errors being made in the draft IUR when concluding that
16 models dramatically, or over, or underpredict the actual
17 study results.

18 Next, slide 10.

19 [SLIDE CHANGE]

20 DR. ABBY LI: In fact, the TCEQ CPH model
21 accurately predicts the observed number of lymphoid
22 mortalities in the NIOSH study, and this is true overall,
23 and locally below the not of 1,600 ppm years as well as
24 taking into account healthy worker effect.

25 [SLIDE CHANGE]

1 DR. ABBY LI: EPA SAB emphasized any model that
2 is to be considered reasonable must have dose response
3 form that is both biologically plausible and consistent
4 with the observed data.

5 [SLIDE CHANGE]

6 DR. ABBY LI: So I think I'm out of time, but my
7 last remark is, for example, in slide 12, there is strong
8 evidence that EtO is a mutagen. But what's important to
9 integrate into the dose response modeling is the evidence
10 that EtO is a weak mutagen requiring high doses and long
11 exposures.

12 [SLIDE CHANGE]

13 DR. ABBY LI: And so in slide 13, we urge OEHHA
14 to use the standard log linear cost proportional model and
15 the values required to derive an IUR are readily available
16 in either the EPA IRIS or TCEQ. Thank you.

17 DR. MOHEGH: I'm afraid you -- Okay, thank you.
18 Thank you, Abby, for your comments.

19 CHAIRPERSON ANASTASIO: Yeah. Thank you, Dr. Li.

20 Next commenter.

21 DR. MOHEGH: So we have eight commenters right
22 now. The first person who raised their hand is Ana --
23 apologies if I'm mispronouncing -- Ana Kassar, I now
24 allowed you to unmute yourself. I can't unmute you. You
25 have to unmute yourself, Anna, if you want to present.

1 CHAIRPERSON ANASTASIO: Go ahead Anna. You're
2 unmuted.

3 WILLIAM REMAK: Okay. Good afternoon. My name
4 is William Remak and I'm the CEO of the California
5 Hepatitis C Task Force. And I would like to have the
6 opportunity -- thank you for the opportunity to speak on
7 the agenda item number 2 on behalf of the Task Force.

8 And we're concerned that the updated IUR, which
9 currently sets an acceptable risk level, that is below the
10 levels of EtO that exist within the ambient air could
11 unintentionally disrupt vital services within California's
12 health care system, specifically availability of medical
13 devices crucial for treating patients with serious
14 conditions like hepatitis C.

15 We cannot afford shortages or delays in the
16 delivery of medical services and devices, and the vast
17 majority of which are sterilized using EtO. Such
18 disruptions would further strain our health care system,
19 which is already under enormous pressure. Protecting
20 patient access should be a priority and I urge the Panel
21 to keep them in mind as this process continues to move
22 forward and appreciate your consideration.

23 Thank you.

24 CHAIRPERSON ANASTASIO: Thank you, Mr. Remak for
25 your comment. We appreciate that.

1 Next.

2 DR. MOHEGH: Next, we've Richard Reiss. I'm
3 allowing you to unmute yourself.

4 RICHARD REISS: Thank you.

5 Yes. This is Richard Reiss. I'm with Exponent
6 and speaking on behalf of the Ethylene Oxide Sterilization
7 Association. I'm going to focus on the TCEQ Reality
8 Check, which was -- which has been discussed extensively
9 so far.

10 There is --

11 DR. MOHEGH: Sorry to jump in. You had submitted
12 some slides. Do you want them to be --

13 DR. RICHARD REISS: Oh, yeah. Yeah, please put
14 them up. Yes.

15 DR. MOHEGH: Go ahead. Sorry.

16 DR. RICHARD REISS: Yeah. So -- yea, the next
17 slide.

18 [SLIDE CHANGE]

19 DR. RICHARD REISS: So the TCEQ conducted this
20 reality check of the lymphoid mortality predictions. And
21 they estimated the mortalities predicted by EPA's model
22 compared to observed mortalities. We've recast that
23 analysis in terms of excess mortalities, which I think
24 more clearly showed the overprediction.

25 And then a very important point is that EPA and

1 OEHHA cite TCEQ's failure to account for the healthy
2 worker effect. However, they -- in the -- not in the
3 draft, but in the final version of their document, they
4 did do a sensitivity analysis related to the healthy
5 worker effect.

6 So if you look on the next slide --

7 [SLIDE CHANGE]

8 DR. RICHARD REISS: -- this is the base TCEQ
9 reality check comparing their model and EPA's model. And
10 this is recast into excess cancers. So there are 41
11 excess cancers predicted by EPA's model with the central
12 tendency and 90.7 with the upper bound. And that compares
13 to 2.6 observed, assuming standard cancer rates of the
14 population. So those are substantial overestimates.

15 Now, I understand that there's concerns that EPA
16 didn't -- or TCEQ didn't account for a healthy worker
17 effect, but they did do a sensitivity analysis of that.
18 And you can see that on the next spot.

19 They assumed a 15 percent healthy worker effect
20 for males and a 16 percent for females based on data in
21 Kirkeleit. And even in that case, the EPA model, which is
22 three and four there, overpredict the mortalities -- the
23 excess mortalities by 337 percent and 735 percent. Not
24 shown here, we've done that as far as 25 percent healthy
25 worker effect and you still see an overestimate.

1 So I would encourage the Panel -- and as Abby
2 mentioned, they do -- the TCEQ model itself predicts the
3 mortalities in all, you know, in the lower dose range
4 well. So I would encourage the Panel to go back and look
5 at that appendix in the TCEQ assessment, and especially
6 look at the healthy worker effect analysis that they did.

7 Thank you.

8 CHAIRPERSON ANASTASIO: Thank you, Dr. Reiss.

9 Next comment.

10 DR. MOHEGH: Our next comment is Original Dra.
11 The Originaldra, I am allowing you to unmute yourself.
12 You have to unmute yourself.

13 THE ORIGINALDRA: Okay. Thank you. So this is
14 kind of interesting to hear you talking about this. And
15 you know, it's important that the health care workers are
16 not being, you know, exposed to these carcinogens. But
17 the thing is as well is that not only when they're, you
18 know, sterilizing devices or tools, but the masks that
19 they've had people wear actually have ethylene oxide on --
20 in them, as well as the tests for the COVID tests. So
21 even if they're just, you know, cleaning, you know,
22 devices, they're still going to be affected if they're
23 wearing a mask or having to be tested for COVID-19.

24 And FD -- the FDA actually just recently or I'm
25 not sure exactly when, but was endorsing a new method of

1 sterilization that uses vaporized hydrogen peroxide. So,
2 I mean, there are other options that can be used that
3 aren't going to be putting people in danger like this.

4 But I think that if we're looking at the
5 sterilization of that, you should also be understanding
6 that the masks and those tests have it in them as well.
7 That will be affecting those workers and possibly could
8 skew your numbers, because if they're having other things
9 come in that are exposing them to that and it's not being
10 considered. It could possibly, you know, show that you
11 have an influx and it just -- but from the sterilization,
12 but you're not considering the other aspects that could
13 bring in higher levels of that into their system as well,
14 so it would be nice to look into that.

15 But I don't know if any of you have heard of the
16 vaporized hydrogen peroxide. And that's something that
17 you could possibly look into and -- you know, because
18 hydrogen peroxide is also good if people are sick. So, I
19 mean, it could do potentially the opposite, which would,
20 you know, not cause people to be exposed to carcinogens.

21 And I think we need to pay attention to that with
22 Prop 65 when people are wearing the masks and having to
23 get tests. And that when that is required and there have
24 been an influx in a bunch of different cancers, especially
25 when people are stick the tests up their nose, it's

1 causing a lot of cancers in the brain or different areas
2 that --

3 DR. MOHEGH: Dra, your time is up, if you have
4 any closing remarks, please say them.

5 THE ORIGINALDRA: That's okay. Thank you.

6 CHAIRPERSON ANASTASIO: And thank you for
7 comment. And I'm sorry, I didn't catch your name open.

8 Oh, she's back. Audra.

9 CHAIRPERSON ANASTASIO: Audra. Okay. Thank you
10 for your comments, Audra.

11 THE ORIGINALDRA: Thank you.

12 CHAIRPERSON ANASTASIO: Next comment.

13 DR. MOHEGH: Next commenter, I'm hoping I'm
14 pronouncing it correctly. Aracely Campa Ramirez, I'm
15 allowing you to unmute yourself.

16 ARACELY CAMPA RAMIREZ: Good morning. Can you
17 all hear me okay?

18 DR. MOHEGH: Yes.

19 ARACELY CAMPA RAMIREZ: Perfect. Thank you so
20 much. Good morning again and thank you all for the
21 opportunity to provide comments on OEHHA's draft cancer
22 inhalation unit risk factor for ethylene oxide. My name
23 is Aracely Campa Ramirez. I'm speaking on behalf of
24 California Life Sciences and our trade partners. And we'd
25 like to align ourselves with the comments shared by Mr.

1 Remak of the Hepatitis C Task Force.

2 The crux of our concerns stem from the unintended
3 consequences for patients in California, especially around
4 the issues raised pertaining to background levels.

5 Ethylene oxide is used to sterilize approximately 50
6 percent of all medical devices in the U.S. each year.

7 That's over 20 billion surgical kits, heart valves, pace
8 makers, and is the only viable option for many devices.

9 It does ensure stringent FDA requirements are met to meet
10 patient safety, while ensuring effective sterilization
11 that does not degrade the device or impact performance.

12 Hundreds of thousands of medical hospital and lab
13 processes rely on these sterilized devices and equipment
14 to protect millions of patients from the risks of
15 infection caused by bacteria, viruses, and fungi. And any
16 disruption in the availability of sterile medical devices
17 and supplies could lead to delays in patient care.

18 Further, as others have relayed, the EPA IUR
19 factor is lower than the naturally occurring ethylene
20 oxide background levels currently. I believe the team at
21 South Coast Air Quality Management District pointed out in
22 their letter their extensive monitoring campaign to
23 characterize ethylene oxide levels near medical
24 sterilization facilities, as was raised by the Chair
25 earlier, and the levels were found at these facilities to,

1 in fact, not be, you know, as a -- as a result of the
2 facilities being on-site.

3 So, they did mention they were not aware of what
4 sources were contributing to the background levels. So
5 noting that the potential cancer risks at background
6 levels alone would more than double the cancer risk from
7 all other Pollutants and sources combined, and the
8 significant implications this ruling would have on
9 patients, additional information around these resources --
10 these sources is needed.

11 So we respectfully urge the Panel to take these
12 issues into consideration, to not unnecessarily affect
13 patients without all necessary data to adequately address
14 the environmental concerns.

15 With that, I'll conclude my remarks and thank you
16 again for the opportunity to address the Panel.

17 CHAIRPERSON ANASTASIO: Thank you for your
18 comment. We appreciate it.

19 Next comment.

20 DR. MOHEGH: Next, we have Alex Khan. Alex, you
21 can unmute yourself.

22 ALEX KHAN: Good morning. Can you hear me okay?

23 DR. MOHEGH: Yes.

24 CHAIRPERSON ANASTASIO: Yes.

25 ALEX KHAN: Thank you. Thank you for the

1 opportunity to speak today. My name is Alex Khan. I
2 serve as Senior Policy Counsel for the California Chronic
3 Care Coalition. The Chronic Care Coalition is a unique
4 alliance of about 30 leading consumer health
5 organizations. It includes physician and provider groups
6 representing Californians with chronic conditions.

7 We really appreciate and commend the Panel's
8 deliberative process and attention to this important
9 issue. We'll leave the complex scientific considerations
10 to the experts, but we do want to be here this morning to
11 provide a patient perspective and ensure that patients
12 have a voice.

13 Ethylene oxide, as has been mentioned, is one of
14 the most common ways to sterilize medical technology.
15 It's crucial for preventing infection in patients
16 undergoing surgical procedures and other medical
17 treatments. The sterilization of medical devices and
18 instruments is critical to patient health and nearly 50
19 percent of all medical devices, or over 20 billion
20 annually as was just mentioned, are sterilized using EtO.

21 Patients with urgent health needs cannot afford
22 shortages or delays in the availability of needed medical
23 devices. In many cases, it is truly a matter of life or
24 death. We urge the Panel to consider the real-world
25 impact on California patients and arrive at a decision

1 that ensures uninterrupted continuation of critical
2 medical services.

3 Patients within our organization have expressed
4 concern and we are just proud to be here and grateful for
5 the opportunity to provide their perspective and I thank
6 you all for the time.

7 CHAIRPERSON ANASTASIO: Thank you, Mr. Khan. We
8 appreciate your comment.

9 Next comment.

10 DR. MOHEGH: Next Commenter that we have is Dr.
11 Lucy Fraiser. Dr. Fraiser have submitted slides in
12 advance. Let me load that.

13 (Thereupon a slide presentation).

14 DR. LUCY FRAISER: Good afternoon. Thank you. I
15 was wondering if I could comment on the exposure model
16 that was the subject of discussion before I get started
17 with my planned comments. There was --

18 CHAIRPERSON ANASTASIO: Dr. Fraiser, you have two
19 minutes. You can use it however you'd like.

20 DR. LUCY FRAISER: Okay. Well, as opposed to
21 going -- I'm not going to talk about these slides then.

22 So the exposure modeling that we discussed as
23 part of the Steenland evaluation, the -- I believe it was
24 someone with OEHHA who referred to the Hornung study and
25 indicated that the first figure in that study indicated

1 that the model predicted that exposures earlier were
2 higher than later. But that figure that he referred to
3 refers to concentrations from 1978 to 1986. Those are the
4 measured concentrations. I believe that figure was just
5 showing -- that was part of their model validation. But
6 the exposure concentrations that are at issue are the
7 concentrations that were modeled pre-1978 when there was
8 no exposure data or no exposure measurements available.

9 And the modeling predicted that exposure levels
10 going all the way back to the 1940s were actually lower
11 than the measured concentrations in 1978. The data have
12 been lost. We don't have a way to validate what's
13 correct, but what we do know from historical experience is
14 that that almost never happens in industry. In industry,
15 you know, you tend to have higher concentrations early on.
16 And then once we learn more about the toxicities, the
17 occupation exposure levels are lowered, and the levels in
18 the workplaces go down. So the trend that was predicted
19 by that model doesn't make sense by comparison to what we
20 know about other chemicals. And it also biases the
21 inhalation unit risk estimate that EPA did, because by
22 assuming that concentrations were lower in the early
23 years, it significantly overestimates the carcinogenic
24 potency of --

25 DR. MOHEGH: Dr. Fraiser, you are out of time.

1 If you have any closing remarks.

2 DR. LUCY FRAISER: The one other closing remark
3 that I will make is that on our initial slide, it
4 indicated that my comments were on behalf of the Coalition
5 for Life Sciences. That's not correct. I was asked to do
6 an evaluation by AdvaMed, although all the comments that I
7 have expressed are my own.

8 Thank you.

9 CHAIRPERSON ANASTASIO: Thank you, Dr. Fraiser.
10 Yeah, as we discussed earlier, members of OEHHA, it would
11 be great if you could address this issue in the revised
12 document.

13 Next comment.

14 DR. MOHEGH: Our next commenter is Jane Teta who
15 has -- who couldn't raise their hand, but they told me
16 that they want to give a comment.

17 Jane, can you unmute yourself, please?

18 DR. JANE TETA: I did. Can you hear me?

19 CHAIRPERSON ANASTASIO: Yes.

20 DR. MOHEGH: Yes.

21 DR. JANE TETA: Okay. The IRIS assessment for
22 ethylene oxide includes a steep increasing risk at low
23 exposures. This would imply that ethylene oxide is a
24 potent carcinogen. Now, both the NIOSH study and the UCC
25 study do not really support this implication. When you

1 look at the UCC study, it shows no increased risk in
2 lymphoid tumors. They don't have breast cancer. We
3 didn't have women in that study. The NIOSH study does
4 have some positive findings, but where are they? They're
5 in males only and they're at high -- the highest exposure
6 categories.

7 In fact, females have very low risk of lymphoid
8 tumors in that study and they have a negative trend with
9 increasing exposure. So why do we see the pattern we see
10 in toes dots, the categorical odds ratios, because they've
11 combined males and females into that, the odds ratios of
12 both together. And if you looked at 10 odds ratios and if
13 you look maybe just at males, you might have seen a whole
14 different pattern. So I don't believe a visual fit should
15 be done looking at those points.

16 My other main issue is missing cases in the NIOSH
17 breast cancer incidence study. Statistically significant
18 deficit in the SMR analysis. And there is no health
19 worker effects. Steenland says it. It's a very long
20 follow-up study. What's the deficit? He said it. They
21 didn't get all the cases. Okay, we understand that.
22 That's a problem.

23 But the interview study is taken as a subgroup of
24 that group. And there's more -- and then there's 32
25 percent who didn't participate. So now, you're missing a

1 huge number of breast cancer cases in the interview of
2 study analysis, and that's what's used in the risk
3 assessment, that data. I believe there's too much
4 underascertainment. The mortality data is complete. The
5 breast cancer mortality is complete. The incidence data I
6 think is too problematic.

7 One other quick issue. Smoking we do not see a
8 relationship lymphoid cancer in smokers, so many studies
9 of smokers. The Surgeon General doesn't see it. The two
10 studies cited by OEHHA are irrelevant. I won't go into it
11 now, but they had the wrong disease and they had the wrong
12 gender.

13 If I have any time left, I would just clarify --
14 DR. MOHEGH: Jane, you're out of time.

15 DR. JANE TETA: Okay, I'm out of time. Thank you
16 very much for the opportunity.

17 CHAIRPERSON ANASTASIO: Thank you, Jane, for your
18 comments.

19 Next comment.

20 DR. MOHEGH: Next, we have Claire Conlon.
21 Claire, you can mute yourself.

22 CLAIRE CONLON: Hi. Good morning or good
23 afternoon. I'm Claire Conlon here on behalf of Biocom
24 California representing 1,700 companies, California
25 research and academic institutions, medical device and

1 biotechnology companies. We appreciate your deliberate
2 approach to weighing this proposal and request that you
3 take into account the real-world impact of this adjusted
4 factor as it relates to current FDA sterilization method
5 requirements.

6 Biocom California aligns our comments with the
7 patient groups focused on the large-scale need for
8 sterilized medical devices and the limitation of
9 sterilization services without a workable alternative
10 ready to replace the existing sterilization capacity could
11 jeopardize access to medical services ranging from
12 preventative care to critical surgeries. So we urge OEHHA
13 to leverage your own expertise and revise the draft IUR to
14 protect public health.

15 Thank you.

16 CHAIRPERSON ANASTASIO: Thank you, Claire.

17 Next comment.

18 DR. MOHEGH: Next, we have Keya Gupta. Keya, you
19 can unmute yourself now.

20 KEYA GUPTA: Good morning. Can you all hear me?

21 DR. MOHEGH: Yes.

22 KEYA GUPTA: Wonderful. Thank you for the
23 opportunity to be here today and comment on agenda item
24 number 2. I do work in health care.

25 As you assess the updated risk factor for

1 ethylene oxide, I would urge the panel to recognize the
2 irreplaceable role that EtO plays in the sterilization of
3 numerous medical devices, as many of devices cannot be
4 sterilized safely without any -- with any other proven
5 methods.

6 I believe that we should do everything in our
7 power to avoid a disruption in the supply chain of
8 critical medical tools, which would intern severely hinder
9 the delivery of essential health care services from life
10 saving surgical procedures to routine preventative care,
11 and could potentially compromise patient safety across the
12 state of California and beyond.

13 Additionally, it's crucial to evaluate the
14 validity of the research, particularly considering it is
15 predicated on an EPA assessment dating back to 2016.
16 California's health care system is already navigating very
17 formidable challenges, including workforce shortages. And
18 in this context it is paramount that regulatory decisions
19 do not exacerbate these struggles by constraining access
20 to vital medical equipment.

21 Thank you for your time and for considering the
22 insights that all participants are offering today.
23 Appreciate it. Thank you

24 CHAIRPERSON ANASTASIO: Thank you, Keya, for your
25 comment.

1 Next comment.

2 DR. MOHEGH: We don't have anyone else currently
3 raising their hand. I do see one phone call-in listener.
4 If they want to give comments, they can press star nine on
5 their phone and raise their hand. If not, I don't see any
6 more hand raised.

7 CHAIRPERSON ANASTASIO: Great. I'd like to thank
8 everyone who gave a comment. And I see that Kathy has her
9 here raised. So, Kathy.

10 PANEL MEMBER HAMMOND: I would like to thank the
11 commenters as well and just make a general comment.
12 They're -- to remind people, this came up earlier, that
13 there are two steps in this process. One is to evaluate
14 how risky a chemical is, and then if it's risky, there's
15 another step for managing that risk. And the management
16 of the risk is actually where these issues and the
17 trade-offs will come into play. So you don't want the
18 people who are managing the risk to be using inappropriate
19 risk assessment. So we need to have good -- the best
20 estimates of what the risks are for the chemicals. And
21 then that information can go into trying to figure out how
22 to control those risks. And it may be controlling the
23 exposures. It might be a question of making sure there
24 are more controls to the exposure not eliminating
25 something.

1 But that is the next step that's outside of this
2 Science Review Panel. Our goal is just to get the best
3 estimate of the risk and to evaluate that based on OEHHA's
4 work.

5 CHAIRPERSON ANASTASIO: Yeah, that's a very good
6 point, Kathy. Thank you for that. Right, we are not
7 considering risk management aspects of EtO. That would be
8 a secondary -- or a second process.

9 Okay. Well, thank you, everyone. Thank you to
10 OEHHA for the presentation. Thank you to the Panel for
11 your comments, and then also thanks to the public for
12 their comments.

13 We're going to move on now to our next agenda
14 item, which is informational update on the Community Air
15 Protection Program. The California Air Resources Board
16 staff from the Office of Community Air Protection, OCAP,
17 are going to update us on Blueprint 2.0, which is the
18 updated statewide strategy to reduce exposure in
19 communities most impacted by air pollution. We, as the
20 Panel, are one of several groups that CARB has regularly
21 consulted with about the implementation of this program.

22 On October 26th 2023, the CARB Board approved
23 Blueprint 2.0, which includes goals and action items, and
24 renews CARB and air district commitments to implement the
25 strategies in the community emission reduction programs

1 approved by the Board.

2 Significantly, Blueprint 2.0 provides new
3 pathways to support communities that have been
4 consistently nominated for the program. CARB staff will
5 also provide a brief update on the recent award of \$10
6 million to a total of 24 -- or sorry, 42 tribal and
7 community-based organizations throughout the state and
8 their plans to conduct third-party programmatic evaluation
9 of program as committed to in the Blueprint.

10 So I am now going to introduce Dr. Brian Moore,
11 who's the Supervisor of Community Planning Section from
12 CARB to give us this informational item. And thank you,
13 Brian, for coming to speak to us.

14 (Thereupon a slide presentation).

15 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

16 Great. No. Thank you all. I hope you can see
17 my slides okay right now and hear me all right.

18 CHAIRPERSON ANASTASIO: Yes.

19 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

20 Oh, great. Great. So again, I am Brian Moore
21 and I'm a manager in the Office of Community Air
22 Protection. And we are responsible for the implementation
23 of Assembly Bill 617 and the Community Air Protection
24 Program. It's really nice to see you all again and I am
25 excited to update you on the latest progress that we've

1 made since the last update as well as our plans moving
2 forward.

3 And just quickly before I start, I just wanted to
4 point out the relevance of the SRP activities to the
5 Community Air Protection Program. We work in some
6 communities in Southern California that are home to a lot
7 of these sterilization facilities that use ethylene oxide.
8 So that's just a -- you know, one example of the direct
9 connection between the work you all are doing and, you
10 know, how we implement things, you know, on the ground in
11 these communities.

12 [SLIDE CHANGE]

13 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

14 And so this slide here is just a brief outline of
15 this update. I did want to share the new direction for
16 the program now that we have those revised -- everybody's
17 guide document, the Blueprint 2.0 that has been approved
18 by our Board. And I wanted to highlight three new
19 components of that program to help us moving forward, and
20 then kind of end with just focusing on some priority
21 actions for this next year specifically.

22 [SLIDE CHANGE]

23 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

24 And again, our statewide strategy was approved
25 unanimously from the CARB Board in October. And I --

1 here, I just wanted to revisit the figure that kind of
2 illustrates the structure of this -- of this document --
3 this guidance document.

4 So on the left side, we illustrate part one in
5 that green. And it's a five-year strategic plan centered
6 on civil rights, environmental justice, and Equity
7 principles. This plan is based on guiding principles that
8 were developed from lessons learned over the first five
9 years of the program. And an example of this would be our
10 priority to support power sharing between community
11 members and agencies. We did notice that stronger
12 collaborations definitely led to more successful plan
13 development. And this happened when public agencies
14 became willing to create some space for community
15 direction whenever possible as these plans are being
16 developed.

17 So on the right side of the screen, in the blue,
18 we have our part two, which is our implementation
19 guidance. And that implementation guidance is really
20 split into two parts. So on that left side of the blue,
21 we really want to emphasize that we are committed to
22 successfully implementing the 19 current community
23 emissions reduction programs that are in involvement. So
24 we have 19 communities that are kind of in the process of
25 our traditional way of developing plans. And so we really

1 want to see those through and really focus on tracking of
2 progress and accountability within those plans, which we
3 call CERPs.

4 And then on the right side of the blue, this is
5 our new implementation strategy. And so this focuses on
6 outreach and action in the communities that have been
7 consistently nominated, but have not yet been selected for
8 that traditional community emissions reduction program or
9 CERP development.

10 And with this new strategy of three pathways to
11 accomplish this, the first, we want to take those
12 communities air grants that were mentioned that were
13 awarded to the community-based organizations to fund the
14 development of local plans, which we are calling L-CERPs
15 this moment. So that's one way.

16 Another way we want to implement the strategy is
17 to increase the way air districts and communities can use
18 our community air protection incentive funds by revising
19 their guidelines to make them a little more flexible.

20 And then the third way is CARB enforcement -- our
21 Enforcement Division is partnering with a lot of
22 communities to implement community-focused enforcement
23 efforts.

24 [SLIDE CHANGE]

25 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

1 So this slide kind of represents one of those new
2 pathways that I mentioned, the community air grants. So
3 these grants are designed to provide resources to support
4 community-based non-profit organizations and tribal
5 governments in the push for cleaner air in their
6 communities. And this slide here describes the latest
7 round of the community air grants that were awarded and
8 kind of the three major types we see. So if you look at
9 that pie chart, we had educational grants awarded, as well
10 as technical ones, which this includes like any citizen
11 science or community led air monitoring. And then we also
12 had some targeted projects approved. And this include
13 that idea to fund these local plans, these L-CERPs that I
14 mentioned earlier, you know, that are part of one our new
15 pathways.

16 So eight of these targeted awards to create these
17 local plans were awarded this year. And, in general, 18
18 of these 42 projects that were awarded are based in our
19 consistently nominated communities. So those are those
20 communities we want to reach out to. So we see this as a
21 way that we can direct resources into those communities
22 really quickly and start building capacity. And I guess
23 just to kind of finishing things off with the community
24 air grants, we are actually having another round of
25 solicitations for the next cycle of grants. That would be

1 our fifth year and that is coming up this year.

2 [SLIDE CHANGE]

3 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

4 So now, I'll focus on our community air
5 protection incentive program. So these are -- this
6 program is statewide and these incentive funds are -- can
7 be used in disadvantaged and low-income communities across
8 the state. And they're implemented by the air districts,
9 but based on CARB guidance. So the CARB guidelines
10 currently provide criteria and guidance for air districts
11 to implement a wide variety of different project
12 categories, which we would call chapters, because each one
13 is a chapter in this guideline document. And we intend to
14 update some of the existing categories add new ones.

15 So over the past three years, air districts and
16 communities have taken advantage of this community
17 identified project pathway and created a dozen new kinds
18 of projects for these selected communities that are
19 developed during a traditional CERP. So these are --
20 these are projects that the community got together with
21 the air districts to develop guidelines for that CARB had
22 not. And then we at CARB look at those guidelines and
23 then either tweak them or approve them based on, you know,
24 funding guidelines.

25 So the idea is that we want to take the more

1 popular and successful of these community identified
2 projects and make them available statewide by creating new
3 projects and chapters that are just available to use right
4 off the shelf. So no new communities will have to go
5 through that process of starting from scratch to develop
6 these projects. And that's what's shown kind of on the
7 right side of this figure in the blue. And so these are
8 examples of those new chapters and new projects that will
9 ready to go, stuff like agency partnerships to work on
10 truck rerouting, vegetative barriers, urban greening,
11 paving projects. We just had a groundbreaking of a paving
12 project in Heber in Imperial County. Bike paths and
13 sidewalk installation. And then also ag burning
14 alternatives and like incentivizing low dust nut
15 harvesters in ag communities. So these are all new
16 chapters that will be added to the guidelines.

17 [SLIDE CHANGE]

18 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

19 This slide just indicates the timeline for the
20 community air protection incentive guidelines revisions.
21 Air districts requested a longer public process, so we did
22 expand our timeline to work on our guideline revision --
23 revisions in collaboration with the air districts and
24 community members. So we've seen more discussions we've
25 had with the various air districts. And actually this

1 week right now our incentive team with the air district
2 incentives staff are participating in a retreat to go over
3 the draft guidelines. And then also, we're hoping in
4 April, we will finalize the incentive -- new incentive
5 guidelines and after workshopping the draft guidelines
6 with the public.

7 [SLIDE CHANGE]

8 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

9 And just to kind of end up, I wanted to panned
10 out to the bigger picture of the program. So looking at
11 the goals moving forward for the program, you know, with
12 our five-year strategic plan, it really focuses on these
13 eight goals here presented on this slide. And some of
14 these goals carry over from themes in the original
15 blueprint, such as the emphasis on partnering and using
16 regulatory authorities at CARB and the air districts. And
17 really related to this, you can see that the -- I want to
18 note goal 4 in the top right corner that -- which speaks
19 to working on both mobile and stationary sources at CARB
20 and with air district collaborations.

21 Lessons learned from the -- from the first five
22 years of the program and our extensive engagement helps
23 shape and refine these goals, such as making sure it is
24 centered work in -- our work in civil rights, equity, and
25 environmental justice. Other new goals reflect the

1 reality that in the next five years of the program, we
2 must focus on communities that have been consistently
3 nominated for the program, but not selected. So our kind
4 of historical pattern of only being able to select, you
5 know, two, to three, to four communities for CERP
6 development just isn't going to get it done. We need to
7 be able to roll out benefits and resources faster to more
8 communities.

9 So with that, each goal area includes actions
10 that we've committed to.

11 Oop. Sorry.

12 I'm sorry. Unless, Arash, you intentionally shut
13 me down.

14 DR. MOHEGH: I did not.

15 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE: I
16 think -- I think my arm hit my space bar. Sorry about
17 that. I know everyone wants -- okay. So let's see. Let
18 me do this again.

19 Awesome. Wait. Here we go. Did that pop back
20 up okay?

21 DR. MOHEGH: Yes.

22 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

23 Oh, okay, great. Here we are.

24 And so sorry about that interruption, but as I
25 was mentioning that we have these kind of not lofty but

1 larger umbrella goals. And for each of these we have
2 developed some key actions to implement these goals. And
3 I wanted to share just a few that are priorities for this
4 upcoming calendar year for 2024.

5 [SLIDE CHANGE]

6 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

7 So here's some of those key actions that we'll be
8 working on this year to hopefully push us towards
9 achieving the five-year strategic plan. So the first one
10 is a programmatic evaluation from a third party. We have
11 seen with other similar programs, like the transformative
12 climate communities work over at the Strategic Growth
13 Council. They've really benefited from these third-party
14 evals. So that's something we are doing this year.

15 Another action is the standardized and required
16 training environmental justice, public participation, and
17 civil rights for all our staff and management at CARB that
18 worked on Assembly Bill 617.

19 And we are also prioritizing developing
20 engagement strategies for the 60 plus consistently
21 nominated communities that we have identified over the
22 five years. So it's been a long process creating this
23 list, so we need to start our outreach as soon as possible
24 with these communities.

25 And as we -- I already mentioned, we do want to

1 complete the revision of our community air protection and
2 incentive guidelines to create more flexibility and
3 streamline the process. And as well, we want to provide
4 training and support for future community air grant
5 recipients. They're trying to develop those local plans,
6 those L-CERPs. We actually have a pilot one going on now.
7 And we're learning a ton about how those could be
8 successful with this pilot. So hopefully moving forward,
9 we can really support these community-based organizations
10 that receive these grants to develop their own plans.

11 And finally, the last one is a little more
12 practical one, but our goal is to redesign our web
13 presence so it is more accessible and really reflects the
14 revised guidance of Blueprint 2.0, because it's getting a
15 little dated, so we do want to make sure that we get all
16 the tools, resources, and information on the program up to
17 date and available as soon as we can.

18 [SLIDE CHANGE]

19 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

20 And with that, that is -- that is the end of my
21 update. If anyone has any questions or concerns, I'm more
22 than happy to answer them. And can you always give me a
23 call or email us or go through Arash to get in touch with
24 me if anything comes up in the future. So thank you.

25 CHAIRPERSON ANASTASIO: Great. Thanks very much

1 Brian.

2 Are there comments or questions from the Panel?

3 Ahmad.

4 PANEL MEMBER BESARATINIA: Thank you, Cort.

5 Thank you, Brian, for the update.

6 I was just wondering in one of your slides you
7 mentioned that you are approaching the solicitation phase
8 for grant proposal. And I'm wondering do you inform the
9 potential applicants about your priority areas? Do they
10 know what are the priorities when they apply? Is there a
11 website or are there other mechanisms in place?

12 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

13 Yes. Just to clarify, you mean like priority
14 geographic areas, not like whether it's a technical,
15 educational, or targeted grant.

16 PANEL MEMBER BESARATINIA: (Nods. Head)

17 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

18 Oh, yeah, so we do. And I can share that with
19 the group. We have a -- we have a list of these 65 plus
20 communities that we really want to focus on and then we
21 also have kind of the methodology for how we -- how we
22 came up with developing this list. It was, I'd say,
23 semi-quantitative effort. You know, we didn't just want
24 to rely on the -- developing one like ubermetric that
25 could, you know, misclassify things or could be biased.

1 So we really based it on a lot of the community input
2 we've received, air district capacity. So it was a --
3 yeah, it was a -- quite a process to develop that list.
4 And it is posted.

5 And our plan is -- you know, we have this list
6 for this first year, but we plan over the next few years,
7 not maybe this first year, is to really reach out to other
8 communities to add to that list, so it's not a static
9 list. And we'll be updating it at regular intervals
10 moving forward. And I'll share that list with Arash, so
11 that you all can check it out.

12 PANEL MEMBER BESARATINIA: Thank you very much.

13 CHAIRPERSON ANASTASIO: Great. Other questions
14 or comments.

15 So Brian, if I caught it correctly, you have an
16 increase in budget for the community programs in the
17 coming year?

18 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

19 Oh, yeah, so -- and I want to make sure I have
20 that right, so that the community air grants they've kind
21 of been staggered, and with COVID where we sometimes have
22 combined budget years into one solicitation, so I don't
23 want to say yes. But I guess, yeah, we should have close
24 to 16 million, which is more than the last cycle offered,
25 but maybe due to like combining years of allocations from

1 the Legislature, right, because we were -- we have
2 setbacks. So I'm not positive if that's due to a
3 legislative increase. I can't remember off the top of my
4 head or if it's due to kind of the word staggering of when
5 the grant cycle comes around versus legislative funding.

6 CHAIRPERSON ANASTASIO: Gotcha. Okay. Well, I'm
7 hoping for a legislative increase, but --

8 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

9 Oh, we were -- I do want to say like we were
10 really supportive of this latest round of budget cuts so
11 far that the Legislature and community have been really
12 supportive. And so we've been able to -- and not to see
13 some of the cuts of some other programs, you know, across
14 the state. Yeah.

15 CHAIRPERSON ANASTASIO: That's great.

16 Okay. Well, thank you again, Brian and than you,
17 Panel. I'm now going to open it to public comments. So,
18 as Arash mentioned, you should -- if you're connecting via
19 Zoom, you should be able to use the raise-hand function on
20 the lower right-hand side of your Zoom screen. And if you
21 raise your hand, we'll call on you and you'll have two
22 minutes to make your comment.

23 DR. MOHEGH: Okay. I can see two people who have
24 raised their hand.

25 CHAIRPERSON ANASTASIO: Okay, fantastic. Let's

1 start and maybe other people will join in.

2 DR. MOHEGH: Okay. Our first commenter, and
3 apologies if I'm mispronouncing, Kathy Kerridge. You can
4 unmute yourself, if you want to provide oral comment.

5 KATHY KERRIDGE: Hi. Thank you. And thanks for
6 the presentation. And you did get my last name right, so
7 congratulations.

8 I have more of a question than a comment. I live
9 in Benicia. This is -- we are a refinery community, but
10 we are not an EJ community. And I think that I've
11 nominated our community maybe in the past. I'm not quite
12 sure. But is there any hope that communities that have
13 large stationary sources -- I mean, we're by EJ
14 communities but not ourselves. Is there any hope that we
15 can ever get any of these community grants. Right now, we
16 do run an independent air monitoring station through the
17 Benicia Community Air Monitoring Program, but we have
18 limited funds for that. So, you know, in the future, we
19 may not be able to run it any more. So just -- I've just
20 got a question about accessibility of any of these grants
21 for non-EJ communities.

22 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

23 Yeah, real quick, Kathy. I hope -- let me --
24 I'll put my email -- I don't know if I can chat you my
25 email. But I guess the short answer is yes, there are

1 mechanisms to supply funding for even, like you mentioned,
2 like a community air monitoring network. And we do --
3 some of our current communities that we're trying to
4 develop strategies for, Richmond is one that we're working
5 in that's by you, and then also down south in some of the
6 refinery communities. So part of this program is trying
7 to attack the issues with stationary sources, even those
8 larger ones.

9 So yeah, if there's a way, I'll get you my
10 contact information and I can introduce you to our
11 community air grant staff and talk about ways that
12 hopefully we can get some resources to you.

13 KATHY KERRIDGE: Okay. That would be great.
14 Yeah, I think I got your email. It's -- is it
15 brian.moore@arb.ca.gov?

16 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

17 Yep, it's in the presentation. And then some of
18 these -- I mentioned disadvantaged communities, but some
19 of these incentive funds and CAGs can be spent in other
20 locations. Now, the majority we try to spend -- and the
21 law compels us to spend them in disadvantaged communities,
22 but there are other pathways. Yeah.

23 KATHY KERRIDGE: Okay. Great. I will be
24 emailing you. Thank you.

25 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

1 Sounds good.

2 CHAIRPERSON ANASTASIO: Thank you.

3 DR. MOHEGH: Thank you, Kathy. Brian, if you'd
4 like, I can put your email and contact information in the
5 chat.

6 KATHY KERRIDGE: Oh, that would be great. That
7 would be great.

8 CHAIRPERSON ANASTASIO: Our next commenter is The
9 Originaldra. Dra, you can unmute yourself.

10 CHAIRPERSON ANASTASIO: So Audra, before you
11 start, can you give us your full name?

12 THE ORIGINALDRA: Sure. Audra Morgan.

13 CHAIRPERSON ANASTASIO: Thank you.

14 THE ORIGINALDRA: Um-hmm.

15 CHAIRPERSON ANASTASIO: What is your comment?

16 THE ORIGINALDRA: Well, my comment is that, you
17 know, as we sit here and incentivize different things, you
18 know, the County of San Diego, SANDAG, for their 2025
19 regional plan wanted to do a vehicle miles traveled for
20 the community and charge us to travel per mile. And, you
21 know, I know that they took that away, because, you know,
22 the people weren't happy with it, but it's still coming
23 down the pike from the state, that that's going to be
24 something that's implemented.

25 But with all of the regulations if -- you know,

1 the problem is is that all of these things are pushing us
2 into not walking -- I mean, not driving, and walking, or
3 biking, or using public transit. And if the plan doesn't,
4 you know, encourage just that, then a lot of times we
5 don't get funds for things that we need in the community.
6 And it's sad to see that, you know, like they will
7 demonize driving and say, you know, all of these crazy
8 things to the people when a lot of this stuff is -- like
9 everything that we're doing for the green energy is
10 totally toxic to the environment, and to people, and when
11 you're mining for it.

12 So I mean, I don't understand why we can't look
13 at those things when you're talking about, you know, air
14 pollution, and, you know, the public health and safety of
15 people. But then we do things like engage in stuff that's
16 toxic to the environment, and also again the people's
17 health, because all of this green energy, I mean, it emits
18 radiation when you're using it, first of all when it's
19 made. But just to make all of these -- this technology,
20 it will never save as much greenhouse gas as it produces
21 while it's being made and manufactured.

22 And so it's almost as if like we can acknowledge
23 some things and not others, because this like -- it has
24 become the climate God. And people are willing to
25 sacrifice anything to this God. It doesn't matter if it

1 costs us more money and we'll put us -- everybody in debt
2 just to push this agenda. It's really hard when, you
3 know, there's things that it's causing that nobody wants
4 to acknowledge. And it's blatantly ignored, because
5 there's a bigger picture into this and it's just -- I just
6 don't understand how you guys can work on things like
7 that, and then --

8 DR. MOHEGH: Dra, you're at the end of your
9 allocated time. If you have any closing remarks,
10 please --

11 THE ORIGINALDRA: Yeah. I just would like to
12 know why it's being ignored when we're saying that we care
13 about those things. I would just hope that you could
14 acknowledge that. And even the chem trails that are above
15 us that affect the weather that affect the air. So it
16 would behoove you to look into it.

17 CHAIRPERSON ANASTASIO: All right. Thank you,
18 Audra, for your comments.

19 Are there any more public comments, Arash?

20 DR. MOHEGH: There is no more.

21 CHAIRPERSON ANASTASIO: Okay. Then we will close
22 public comments.

23 And any further comments from the Panel on either
24 of our items, EtO or the Blueprint 2.0?

25 All right, if not, we'll move on to our final

1 item, which is consideration of administrative matters.
2 So, we are hoping to have our next meeting in June. As I
3 mentioned at the beginning of this meeting, Paul Blanc,
4 Kathy Hammond, and Mike Kleinman are all rotating off the
5 Panel. I'd like to thank all three of them for their
6 years of service. I'd also like to thank them for --
7 well, Kathy, for attending this meeting. We really
8 appreciate your input, Kathy.

9 Just to note, two Panel members, your term may
10 end, but you can actually serve until there's a
11 replacement named for you. And the replacement naming
12 process sometimes is a little slow. So Kathy, if we don't
13 have a new person for you by June, I hope you might join
14 us.

15 Oh, wait, and Beate is also ending? Is that
16 true, Beate?

17 So Beate, you ended December '23 or is it going
18 to December '24?

19 PANEL MEMBER RITZ: No, '23, but I was asked,
20 since there's no replacement, to be participating until
21 somebody is nominated.

22 CHAIRPERSON ANASTASIO: Oh, okay. I didn't
23 realize that are also. Well, thank you for your many
24 years of service as well. So I hope that retiring members
25 will continue to serve until we have new members, because

1 otherwise quorum is very difficult and we appreciate your
2 input.

3 One other item might. Mike was the SRP Community
4 Liaison. So with his stepping off the Panel, we need a
5 new liaison. I was going to ask him at this meeting what
6 the liaison entailed. But since he's not here, I'll do
7 that over email and then I'll send it out to the Panel in
8 the hopes of finding a new liaison from the Panel to OCAP
9 items.

10 Okay. And that is all I have on my list. Are
11 there any final thoughts?

12 It looks we're all good.

13 All right. Well, I appreciate everybody coming
14 today and spending the time. And I hope you have a great
15 rest of your day and a great weekend.

16 DR. MOHEGH: How much -- I just want to mention
17 that you can find all the materials available on our
18 website for this event, which I just posted and I have
19 been posting throughout the meeting. You can find the
20 slides that are shared. I will make available the
21 recording and the transcripts that will be available in
22 the next few weeks. And we will also make available the
23 slides that people have shared unless they object to it.
24 So everything will be made available publicly

25 CHAIRPERSON ANASTASIO: No, that's great.

1 Well, thanks to OEHHA and CARB for the
2 presentations. Arash, thank you for being the man behind
3 the scenes, even though it looked like you cut Brian off
4 there for a second.

5 OCAP COMMUNITY PLANNING SECTION MANAGER MOORE:

6 No, that was totally my fault. I confirmed that
7 was user error. I didn't mean to blame Arash. That was
8 me.

9 (Laughter).

10 CHAIRPERSON ANASTASIO: We're going to think now
11 about giving Arash real power over any speaker to mute and
12 stop you from saying anything further. That will be under
13 consideration at our next meeting.

14 And I think that's it. The meeting is now
15 adjourned and have a great weekend, everyone.

16 (Thereupon the California Air Resources Board,
17 Scientific Review Panel adjourned at 12:37 p.m.)

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CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, do hereby certify:

That I am a disinterested person herein; that the foregoing California Air Resources Board, Scientific Review Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California;

That the said proceedings was taken before me, in shorthand writing, and was thereafter transcribed, under my direction, by computer-assisted transcription.

I further certify that I am not of counsel or attorney for any of the parties to said meeting nor in any way interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of February, 2024.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
License No. 10063