U. S. ENVIRONMENTAL PROTECTION AGENCY
EPA SCIENCE ADVISORY BOARD (SAB) STAFF OFFICE
CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE (CASAC)
CASAC OZONE REVIEW PANEL

PUBLIC ADVISORY MEETING

Meeting to Conduct a Peer Review of
EPA's 2nd Draft Ozone Staff Paper and
Related Draft Technical Support Documents
(TSDs)

August 25, 2006
8:00 a.m.

Marriott at Research Triangle Park
4700 Guardian Drive
Durham, North Carolina 27703

EPA PUBLIC ADVISORY MEETING
OZONE REVIEW PANEL
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MR. BUTTERFIELD: Good morning. Welcome to day two of the Clean Air Scientific Advisory Committee Ozone Review Panel Meeting. Once again, for those on the telephone, this is a public meeting to conduct the peer review of the second draft ozone staff paper and technical support documents.

We are going to, our agenda has us going today until approximately 2:30 p.m. Eastern time. And at which point, we'll adjourn. This morning, I'd just like to once again welcome everyone. We enjoyed a very nice evening. Most of us were there at the restaurant last night, and we had a delightful time. At this point, I'd like to turn it back over to our Chair, Dr. Henderson, for a recap of yesterday's meeting and other comments.

DR. HENDERSON: Well, I think we had some excellent discussion yesterday, and we've now come down to the, for the health effects, the critical chapter, chapter six. But first, we will have one public commenter, right?

SPEAKER: That is correct.

DR. HENDERSON: And Karen Martin has

reserved, the time that you see on the schedule for Dr. Martin, she's giving over to her staff to present some preliminary information when we go into the secondary standard, chapter seven and eight.

So, we will be very quickly going to chapter six, and we will need a lot of time for discussion on that. So, we will get on to the limited public comment period, now.

MR. BUTTERFIELD: Thank you, and we do have one additional public commenter, Dr. Will Olafson of the American Petroleum Institute, speaking on behalf of that organization. Dr. Olafson?

DR. OLAFSON: Thanks so much the opportunity, and I on here, to present today. Next slide, please. I'd like to ask you to consider doing three things today. One, there is a new integrated APEX FEV exposure model developed by Dr. Donald. You'll see there are a lot of advantages to this, and I'd like you to consider using this in your next risk assessment.

In our runs of the APEX model, we have identified a couple of things that seem to overestimate, and I'll bring those to your attention for some fine tuning, I think, in your final assessment. Fine, I think, is the subject I've harped

on for a couple of times it's ozone monitoring error. I think you ought to be accounting for the measurement humidity and interference problems and that somewhere in the staff paper. Next slide, next slide. Here's one of the things in APEX we found.

We ran, basically, a series of breathing rate, expired ventilation rate, tests and those are plot at the quartile in the higher distribution, distributions for ten year old decade, so zero to nine, ten to nineteen, on up to ninety to ninety-nine. And the distributions begin to look strange, because we find the sixty, seventy, and eighty year olds having higher ventilation rates than their younger compatriots. And we simply don't think this is correct, and I think you ought to be taking a look at the algorithms to generate breathing rate in APEX to try to correct this.

The next slide. We also disparate a validating. We did a 1996 personal exposure monitoring study using hourly values that demonstrated some under predictions from the PNAD model that we used at that time. We went back last summer and used UV continuous monitors, miniaturized, with two to ten second resolution measurement on ozone. And we visited fifty micro-environments thought frequented by children. We

had monitors here in the Raleigh area.

We co-located our monitors with the Millbrook site, and then within three miles of the Millbrook site, we had fifty micro-mionts, micro-environments that we tested and compared APEX runs to those micro-environments with the measured personal exposure values. The ratios here are plotted are APEX over the personal monitor.

When you get a number of one, pretty much, APEX is projecting what we measured for that micro-environment. We found the model did well for new road and outdoor environments. It slightly over-predicted exposures for indoor environments, where you have open doors and windows, but it really over predicted exposures in closed micro-environments like homes with closed, or off, of schools or day care centers with closed windows and doors, or in vehicles with closed windows and doors. Since indoor environments constitute where we spend most of our time, really, you ought to be correcting these over predictions.

Apex reduces ozone indoors, but it doesn't reduce it enough is the problem. Next slide. Here's my one slide on ozone monitoring error. This is a study that we had discussed in the '92 lesson paper. The blue dots are the UV chemiluminescent differences

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in a co-located site at Madison, Connecticut.
MR. BUTTERFIELD: Two minutes.
DR. OLAFSON: The count, the yellow line is sort of three squares fit to the blue data. If you apply the yellow line correction to the differences in UV to CL, it brings it down to it, sort of a mean zero difference, so it sort of normalized it to the chemiluminescent monitor that has been proacted for humidity dependances and if you plug in, as a test, we ran New York City, that monitor is pretty close, New York City, for 2004.
If you make the difference between using the raw data and using the corrected data, it drops the projected data or max exposures fiftyfold, ninety-eight percent. So, monitoring error can have a huge effect on projected exposure to the extent you believe this type of correction process. Next slide. Here's the main point of the talk.
It's the new McDonald model. He developed a pilot model in 1999, using five or six of the studies. The new tool 2006 model uses all fifteen of the EPA chamber studies. We control for age the ozone level, the breathing rate, the durations of exposures, and the exercise effect. The integrated model takes one minute input and provides one minute output. Next slide.

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Here's some fits to the Adams data. Recall that the McDonald model uses only EPA data, so it's a nice ju-, nice test to see if we can fit other data.
The first is Adams simulation of the Hizuka study, where basically zero to 240 parts per billion triangular exposure, with thirty minute exercise, and thirty minute rest. The blue pattern is the exposure, ventilation, product concentration. The magenta or purple line there is the predicted one minute FEV response. And the yellow points are the FEV measurements done on this thirty person cohort, at thirty minute intervals during that study.
The second test is the te-, sorry, go back one. Yeah, the second on the right hand slide, here's the 08 Adams stuff used in the, that's newly used by EPA. The same sort of patterns occur. We seem to predict 80, the Adams 80 square wave exposures pretty well, a little bit low at the peak.
Note it that we follow these subjects for ninety minutes after post-exposure, and we find their recoveries, the model's slightly over Adams subjects recover slightly faster than the model in this case. Next slide. Here we looked at the sixty part per billion. Although the 2006 McDonald model only has exposures now to eighty, it appears you can extrapolate

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it down, at least, to sixty. We seem to match the triangular 06 exposures of the Adams study fairly well. The same --
MR. BUTTERFIELD: You're about one minute over, Dr. Olafson.
DR. OLAFSON: Okay.
MR. BUTTERFIELD: So you need to wrap it up.
DR. OLAFSON: Okay, next, we did the 04, next slide. Here's actual construction worker in postman stuff we put in realistic exposures, yet it matches pretty well. Next slide. Basically, this is the conclusion, 16 above seems to work pretty well. We tend to overestimate below 16. We tend to overestimate recovery rates. Next slide. Here are the main improvements you get if you use this model. You do not have to treat all the EVR's greater than 13 alike. You can take ventilation to count. You don't have to think everybody is 50-10 exercise rest patterns. You can take any of your pattern, any ozone input pattern. You do any exposure you like greater than six hours, and basically, you have an adult age sensitivity. Next pattern. The other couple things we can do to use this, since you have one minute output, you can get much more informative measures of response, in other

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words, how many minutes at given FEV decrements gives you a better idea of the adversity of the effect. Second thing, you can pretty much relate any of the parameters in the risk assessment to the FEV output, so this greatly simplifies sensitivity testing. And finally, it helps in, sort of, your, also, your alternate standard testing. Final slide. Again, recommendations. We think it's a superior tool that's apparently available and that you, basically, ought to use it. And thank you very much.
MR. BUTTERFIELD: Thank you, Dr. Olafson. Any questions from panel members for Dr. Will Olafson, API? Dr. Miller?
DR. MILLER: You said this was available. Has this been, this work been published at this point?
DR. OLAFSON: Well, not published, but as we talked about yesterday, none of the risk assessment stuff is published. It has been made available to the Agency in memorandum. We try to keep them up to date with what we're doing.
DR. MILLER: I see, thank you.
MR. BUTTERFIELD: Dr. Zidek?
DR. ZIDEK: I noticed on the, those ratios of APEX to PAM that there was a, in the doors, where the doors were closed, there was quite a lot of

variability in those ratios, making me think that probably the denominators were quite small in those ratios. Do you have any idea what the magnitudes of those exposures were?

DR. OLAFSON: Yeah, I can, we can pull them out. I don't have the numbers with me right now, but you're right. The model does correct for reduced exposures indoors. It just doesn't do enough of it. And if we have exposures, you know, giving us effects in 040 and 020, it's, gets to be important.

MR. BUTTERFIELD: Dr. Ultman.

DR. ULTMAN: The integrated model, is it --

MR. BUTTERFIELD: Microphone, please.

DR. ULTMAN: The integrated model, can it extend into recovery if there --

DR. OLAFSON: Yeah, I mentioned there were a couple recovery slides up there. I guess, the unique part of this model is that, sort of, response and recovery are going on simultaneously. They're sort of paired differently from equations that handle these effects. The Adams people seem to recover more quickly than the cohort of EPA people. But, so, we're not going to match that. The, what I think what we can do is begin, since EPA has accepted non-EPA data in their

risk assessment, we can begin to add Adams data in some of the older individual response data to the McDonald model to basic, to better fit at these lower levels.

MR. BUTTERFIELD: Dr. Zielinska?

DR. ZIELINSKA: Yes, I have a question concerning about the bias of measurements, and in the staff paper in chapter two, there is some discussion about the bias in case there's high humidity and some automatic compounds. It said that humidity doesn't have very big effect on UV radiation, but your slides are showing something different. Could you elaborate a little about it?

DR. OLAFSON: Okay, are you talking about the variability for, the variability report that --

DR. ZIELINSKA: On the bias measurements.

DR. OLAFSON: On the ozone monitor, the bias?

DR. ZIELINSKA: Yes.

DR. OLAFSON: Yeah, the EPA, the risk assessment support document that have on monitor or I think it's design value variability is that one, that does a pretty good job of looking at the ability to measure zero, to measure ozone in zero air. It doesn't account for ambient measurements, where you have humidity and interference effects. So, while you can

be highly precise under that type of controlled zero air condition, I don't, you, you don't have a prayer of measuring part per billion accuracy outdoors, you know.

DR. ZIELINSKA: Well, how big is the bias?

DR. OLAFSON: How big is the bias? Well, I gave you an example of the UV chemiluminescent, corrected chemiluminescent biases were on the order of ten to twenty parts per billion for this site downwind in New York City.

MR. BUTTERFIELD: Okay, thank you very much, Dr. Olafson. This concludes our public comment period for today. And it's my pleasure to turn the meeting back over to the Chair, Dr. Henderson.

DR. HENDERSON: Thank you, and Karen, am I, do you need, would you like to say anything right now?

DR. MARTIN: I would. I would like to just make a clarification with regard to the commenters comments here. While we have been aware that this work is ongoing, we have not received any documentation or results from the work that was just discussed. I just wanted to make that clear.

DR. HENDERSON: Okay, thank you. Now, we're going to move to the very important chapter six. And the, the lead discussant on this is James Crapo,

and James, we'll just turn it over to you.

DR. CRAPO: Okay, I'd like to say that, in general, throughout this document, the staff has done an excellent job in identifying the body of evidence that demonstrates a variety of adverse health effects at low levels, at exposure levels at and below the current air quality standard for ozone. And in reading the staff paper, I actually started with a lot of smaller comments.

Things I wanted to challenger or look at as I looked, as I looked at the document, but I decided that we actually ought to just focus our energies on, and I'd like to focus mine on looking at the final conclusion, and see how that holds up, and because what I found, in reading the evaluation of the science, was there seemed to be a substantial disconnect between the evaluation of the science, and its interpretation, its obvious interpretation.

The, there's a strong body of evidence that demonstrates from both animal studies and from human studies that there are adverse health effects of low levels of ozone exposure. And demonstr-, it's clearly demonstrated that in a variety of studies, levels as low as .04 parts per million are associated with findings such as decreased lung function by FEV 1, she

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has symptoms such as chest tightness, and has asthmatic symptoms. Medication use, ER visit, doctors visits, hospitalizations and even some suggestion of increased mortality. Those are summarized in a whole variety of documents. What is techni-, a good quote from page 65, 645, line 26, is recent controlled human exposure studies conducted at levels below 0.08 ppm ozone, provide evidence that measurable lung function effects occurred in some individuals for six to eight hour exposures in the range of 0.08 to as low as 0.04.

Kind of summarizing what I just said, a large body of data. Now the problem I have is that our charge is to identify, from a scientific basis, a level of ozone that provides a measure of protection for sensitive individuals exposed to ozone, and I don't think that the conclusions of the document do that, in the face of a very large body of evidence, that there are adverse effects at the levels below the current standard.

So my focus would be on the very summary document, the very summary pages, section 6.3, 6.3.6, where the document in sections, this document reaches the consideration that there are two reasonable approaches that could be taken. One is a retaining a current eight-hour ozone standard, and the other is to

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consider reducing it to 0.07, with a range of forms from the third to the fifth highest daily maximum. And I simply do not think that those conclusions are scientifically justified by the data.

I don't think there is any, after reading this document, I don't think there is any sound basis on which I can recommend keeping the current standard at 0.08. I think that's an indefensible position from a medical perspective if one is asking us to protect human health, protect sensitive human subjects, and provide a margin of safety. And I don't think that there is any uncertainty of substantial measure about that question.

The number of studies demonstrating that there are adverse effects at the current level, I think, meet the Bradford Hill criteria for causality. And I think they meet a level of standard that requires us to acknowledge it and act on it at the present time. So, what I would recommend, I even think that there's not, the next step is to say, 0.07 is another alternative. I think there's solid data that there's a, just, the data is just as solid at 0.7 as it is at 0.8.

The, from Chapter 5, that we reviewed yesterday, in fact it's in, and the same things are in

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the tables that we see in Chapter 6, all of those major findings that we just talked about, were showing substantial improvement, or I'll say decrease in adverse effects, percentage of people that are at risk of adverse effect, as you decrease the level, on a continued to the lower limit that was analyzed, which I think, in those studies in Chapter 5 was 0.64 parts per million. And, if I remember correctly, it was 0.64. The, and but still, we were still finding measurable effects.

So I think that the range that we ought to offer ought to be between 0.640, picking up the extra digit that was talked about yesterday, to 0.40, is the range that we ought to be talking about for an acceptable standard that would have, in my scientific estimate and judgment, have a chance of providing protection against sensitive groups, with the most interment, small margin of safety, because I've got evidence of data, even at those ranges.

So, I want to discuss the rejection of the retaining the current standard or offering 0.07 as an alternative. And suggest that we focus on the levels for which we have, for which the date does start to become a little uncertain, which is more in the range of 0.04. And, I think that the form of the standard, I

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would recommend keeping it as it is, which means an eight hour standard and a probably the third or the fourth occurrence of, merely because the body in epidemiology data, which I'm basing the finding of the adverse events, was best analyzed using that standard over the past decade, using that form. And if we change the form, then we change, we have to re-analyze all the data to be sure that our new form has the same level of impact on protecting human health.

So, I would like to see the discussions a little bit focused on where our recommendations are going go be, and then come back and look, if we need to, at some of the details of the chapter itself that need to arrive at the coherence with that.

Because there are a number of sentences throughout the chapter that makes statements that are inconsistent with the fundamental findings, trying to argue away some of the findings was with somewhat flimsy argument, focused on topics like uncertainty and effect size, but really not addressing the big problem, that there is an effect that's consistently shown by many investigators using different techniques, using different end points, across a broad range of standards, and that, I think that this chapter ought to be coherent with that. But we ought to begin with the

conclusion, and decide where we think this ought to come out as a recommendation that goes forward to the Administrator.

DR. HENDERSON: Thank you, James. Maybe we should hear from some of the other discussants first and then, I agree, that the discussion of the conclusion is really the main thing that, I mean, that's what this chapter's all about, but Maria, what are your thoughts?

DR. MORANDI: I agree with the comments that Dr. Crapo has made. Looking at the summary chapter, in terms of, you know, the evidence in three states, I don't have any argument with that. I certainly agree with the staff paper that, is it on? Oh, I'm sorry. I certainly agree with the staff paper that the standard shouldn't be more relaxed than it is now.

The issue that I have was with the fact that if I compare the prior review, the prior criteria of human with this one, the difference was that this one gave more weight, because there is more evidence, to effects of asthmatic children. And it's n-, it wasn't evident to me from the staff paper that the current standard in this form could be protective of effects of asthmatics. I didn't see the evidence for that in the

chapter.

And I live in one of the spiky areas of the country, and I can tell you that you can comply there with an eight hour standard, but there are, that it will be multiple events in a year where you ha-, you are going to have a short-term elevation of concentrations, and this is related to local emissions and the local atmospheric conditions. And there have been occasions where you didn't have to ask if children were going to the emergency room.

So, it seems to me that either, as Dr. Crapo was indicating before, we change that eight-hour standard, or we may need to add a shorter term standard to that, because of the effect on asthmatic children, because I don't think this is protecting.

DR. HENDERSON: Thank you. Jim, you're the next to be, I'm just trying to get those who were assigned to-. So, you have no comment on where the standard should be?

DR. ULTMAN: No, that's what I'm saying, that's all you want right now.

DR. HENDERSON: Yeah, right now, yeah, no, exactly.

DR. ULTMAN: Well, first of all, I think it's a, this chapter is extremely well written, and I

think that the staff has to be commended for capturing both the results of the quantitative analysis, as well as, bringing in the scientific evidence, and then trying to shade things by the uncertainties that clearly are there.

So, I think it's really an excellent chapter, and I agree with James that really the focus is, the main focus that we should put on this is trying to decide how that final section on recommendations for the standard should be shaded. I think that it's fair to have alternatives presented to the administrator, but I think that, in the end, there has to be some final recommendation from the committee, in terms of what we feel would be the most scientifically advisable thing to do.

And, the, I agree with Maria that the cru-, I think that the strong part of this chapter is that it demonstrates the effects on asthmatic children. If, I think it does a good, the text does a very good job of trying to show, trying to rationalize an FEV 1 greater than 10 percent being a very adverse effect on asthmatic children. It really, says that, I believe, at a couple different places.

And if you look at their, the tables of the risk assessment tables, it's clear from those that you

need to improve the standard, because you have, if you don't, you have children that have multiple accedences during the year, as Maria has said.

So, I think that's really, the asthmatic children are the strongest case. And of course, now with some mortality data brought in, I think that has, that also shades things a little bit, but that data is still, I think, it's relatively new and it still need, there still needs to be additional studies, but that shades it a little bit.

But, clearly asthmatic children, I think, are the, have the biggest influence. And, I guess, the question has to do with uncertainty here. That if you look at the risk assessments, and without any, and you assume there's no uncertainty, then it's totally clear that the standard should be changed. The problem is that a lot of that is based on pulmonary, acute changes in pulmonary function.

And there's a lot of uncertainties, we discussed yesterday, and the exposure response curve, and also in the activity models. So, that has to be balanced, or you have to also keep in mind the uncertainty that is occurring when that decision is being made. On the other hand, you also have to take into account the evidence on experimental animals,

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which is, you know, cannot be quantif-, at least the staff feels it cannot be used in a quantitative manner at this time. They're not, they don't have sufficient confidence in extrapolation modeling that this has been done.

So, but if you look qualitative at the animal experiments, it's clear that there's inflammation and tissue damage that occurs in animals, that clearly occurs below .1 and probably below .08 parts per million, and maybe as low as below .8 parts per million, so if you bring in that weight of evidence, that further skews the consideration that the standard be lower.

So, I, as I said, I think the chapter is fair. I think giving alternatives to the Administrator is a good thing to do, but I think that we're definitely, this document is definitely pushing in the direction of lowering the standard to protect asthmatic children.

I really feel that there's that kind of a pressure in the chapter. And I think that some commitment should be made, some bottom line should be made that, in the document, in terms of what the recommendation is, rather than leaving it totally uncertain.

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DR. HENDERSON: Thank you, Jim. Sverre, you were the other person who was going to look at the specifically at this chapter.

DR. VEDAL: That's correct. I'm going to cover all my comments, actually, 'cause they're germane, I think.

DR. HENDERSON: Let me say, to one thing, Sverre. We've had complaints from those on the phone, we think we're just speaking to those here, but we're really speaking over a phone line, so be sure that you speak directly into a microphone and loud, so they can hear. Excuse me, sir. Go ahead.

DR. VEDAL: Just in keeping with my comments yesterday in this chapter, I see there's a whole bunch of figures that start at the level of .084. I think it is very insightful for our deliberations to have that baseline value as is pollution.

And the reason I say that is it's, it gives us a really a sense of how far we have to go in just meeting the current standard, which puts a current spin on our, I think, our deliberations on alternative standards.

It provides, I think, a fuller perspective, and what we need to make that, to make a practical decision. So, I would recommend that for chapter 4 and

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chapter 6. It was done very nicely in chapter 5, and I think it was very informative. As I had eluded to yesterday, I'm going to make some comments about the level of the standard, but I'd also like to make a plug for the form of the standard. I disagree with James on this issue.

I don't think it has anything to do with the epidemiologic data. They don't use the form of the standard in the analyses. There are no other analyses that need to be done, apart from the analyses that EPA has done, has done now. The issue of the form of the standard is more of a practical issue, and how you effect meeting a level. How that's actually implemented. And I just see some strange anomalies staring us in the face.

You live in Denver. I lived in Denver for a few years, and it should be obvious to us, when Denver is out of compliance, it's a different animal from the way the heavy hitter cities are out of compliance. And yet, they're treated in very much the same way. And that doesn't serve the public well at all.

There should be some differential on the way the form addresses these cities. And as we were talking about this morning, I don't have any great creative ideas of how to do that. Maybe some, some

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incremental approach that addresses the anomalies. The other, sort of, group of anomalies are those that we touched on yesterday, which are these wacky, sort of, exposure scenarios that you get in, comparing, for example, Houston and L.A. to other cities, that are a direct result of the form of the standard.

And so, I think, we need some creative thinking on how, on how we address these, these sort of weirdnesses, that come about directly as a result of the current form of the standard.

The, with respect to, I want to make some comments about the discussion on the thresholds and concentration response and such. And I think there's an attempt in this chapter to say, you know, the EPI studies and such are, they're all done in settings that really don't meet the standard. And as a result of that, we can't say anything about what's going on below the standard.

They don't provide us any evidence about that. And I reject that notion. And I think we have a ton of evidence from the epidemiologic studies that it doesn't matter whether you're dealing with anything that requires .08 or above. If you restrict the data to .08, to .06, to .04, makes no difference at all. And I think that's the telling point. In addition,

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there are epidemiologic studies done in settings that meet the standard, as opposed to what's argued there, if you want to take that tack that show exactly the same thing. So, I wouldn't go down that road that we don't have information in areas that, that don't meet the standard. I think that's just the wrong argument to take.

I think we have a ton of data to support that. Now, with respect to the level of the standard, some of this has to do with, I think, a discussion of our uncertainties. And our uncertainties, in the experimental data, are a different animal from our uncertainties in the epidemiologic data. Our uncertainties in the experimental data are due to a lack of data.

And, I shouldn't say lack, a paucity of data at .04 and .06, and we discussed this yesterday. What we're hanging our hat on, and that's why we have some uncertainty about those types of data. The uncertainty about the epidemiologic data are entirely different. If you look at the epidemiologic studies, the statistical uncertainty of the estimates of effect do not depend on the level.

Any study, whether done at low levels, you get the same level of statistical significance. So,

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that's not relevant for determining our level of uncertainty.

What our uncertainty reflects is something outside of these studies altogether, in kind of in deference to Jim, in a very, it's kind of a Bayesian flavor. We come at this uncertainty quite differently. And it's based on, first of all, levels of exposure that we think people have at low concentrations.

That has to, that has to, sort of, enter into the equation. Do we think that when the ambient concentration of ozone is .02, that the concentrations of elderly people indoors is relevant to their health effects. Well, that's got to, that's got to enter into anyone's thinking about how certain they feel about those observations.

The reason I say, bring up .02, by the way, is that in the bell study, you can cut out days above .08, .06, .04, .02, and it doesn't change the estimate of effect. It changes the level of statistical significance a little bit, but it doesn't change the level, the estimate of effect, .02.

So that's got to start you thinking a little bit about how certain you feel about those observations. The, now with respect to the, with respect to the level, I think it should be lowered. I

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am in favor of a range of, I put my cards on the table, .06 to .07 type of range, and we can quibble about the decimal points and such. I don't think .04 is on the table, based on the certainty that we feel, nor on, I just don't think that's a credible option. But, those would be, sort of, my recommended ranges. So, those are, that's the extent of my comments.

DR. HENDERSON: Thank you, sir. That was very helpful. Now, do others want to chime in saying, particularly, about people are laying their cards on the table, where the, what range should be offered to the Administrator. Are there other people who want to jump in there, Fred or Mort, Mort just for --

DR. LIPPMAN: Before I respond directly to your challenge, I think, as it goes forward from here, and to the extent that our recommendation will have any influence on decision makers, the chapter needs to beef up its discussion of adversity.

Ozone is different from all of the other criteria pollutants, in that, we have all this wealth of data on quantitative exposure response, or concentration response, and so there's, there's nobody's questioning that the data don't point to effects. The discussion in past reviews of ozone was on really adversity. In a public health protective

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sense, how important is it that the asthmatic child, since that's the frame of reference we've started with, is affected by ten percent decline.

We can take the kind of definition that's in the book, but I think we, we're obligated to beef it up. We have enough people with medical background here to, perhaps, craft some statement that we can all endorse as to the medical and health, public health significance of this level of change as being truly adverse in the sense that the Clean Air Act talks about adversity.

I think that's one of the best contributions this panel can make, and it's perhaps difficult for the staff to be very firm on what it, how it looks at adversity, and how it defines adversity in a quantitative sense. And, you know, if we're, if our recommendation is to get even below the range, and Sverre seems more conservative about going down than Jim, for example.

Okay, we do, we both, you both are talking about, at least considering something lower than .07. You included .06. So, that, now this is where the rubber hits the road, and if we're going to be taken seriously, we have to really help the Agency with justification on what is truly an adverse effect; how

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many, what percentage of children are affected in a way that would be considered adverse in a clinical individual sense, or in a broader public health sense. And so, that's the comment I'd like to put in.

DR. HENDERSON: Thank you, Mort. Fred?

DR. MILLER: I want to follow up with one thing that Sverre said, and say I totally agree, and it had to do with statements there about the studies that were done in areas where they were above the standard, that they didn't shed light.

I actually wrote in the paragraph margin, this is weasel wording to be able to keep the current standard. And I saw that throughout, and I'm very glad that I lost my detailed write-up on the plane about all the inconsistencies in chapter 6 on the data that are in chapters 3, 4, and 5, and how they are discussed. So, I personally do not think that the chapter is well written.

It really takes a bias slant in a number of areas to justify what I believe staff were coming in to saying, we must provide an option that we're going to keep the current standard. In my mind, when I look at another memo that was provided by EPA staff, for the purposes of these deliberations, where some of the different studies in the EPI had used one hour, or

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eight hour, or different things, and they went through and obtained the equivalent eight hour, as I've indicated earlier, they identified 22 studies, just as a sample here.

Eighteen of them were statistically significant. None of them had a number above 0.075. Twenty-one of them were below, or less than 0.06, and of that, twenty-one were statistically, you know, at that number. Thirteen of them had studies below 0.05, and of those about eighty percent were statistically significant.

And they vary in the kinds of effects in terms of lung function in the morning, peak exploratory flow, shortness of breath, various kind of symptomatology, and when you have that number of studies down at that low of level, you can't, in my mind, scientifically defend keeping 0.08 to 0.084. So, we have to go down.

And I find it incredulous that we would back off and say that anything that relates to the current standard is acceptable. So, I endorse the previous statements here about it having to go down, because I think the body of evidence is clearly there. And the thing that really thrusts me for going down is of the work that I had to do extract from the appendices and

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everything in chapter 4, for example, where in Boston, seven percent of the children had occurrences, three or more accedences expected in an ozone season. And I don't think seven percent of a population, a sub-population is a trivial number. That was just for Boston.

And I, and you can't go to any place in the current document and really get what Sverre was getting at of understanding of how much in the overall population and what's, you know, what kind of numbers are we talking with. One place .08 will be presented. Another place, data for .07 will be presented. You know, and, this comes across as a masking effort to really make it more difficult to get at the bottom line.

And I think the bottom line is very clear, that there are, and they'll go back to that same appendix in four, when you look at the number of children that were there that had five or more accedences. Okay, for, and this was for Boston, and in that appendix, only Boston and Houston were presented. Again, we're only given part of the data. Now, that was also going to an appendix.

So, you have to take a look at the entire population across. And for one of the tables, it was

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presented, I summed it up, and it was 170,000 children that were having accedences greater than three, and that was at, I believe, with the .08.

Now, if you go, I mean, these are not trivial numbers. And so, I don't see how you can scientifically defend, given the cadre of kinds of studies that have been done, and our knowledge about the adversity of ozone exposures, changes on lung function, the animal studies showing continued inflammation and restructuring of the lower respiratory tract at, you know, levels that are within a factor of two of these exposure levels.

I find, in addition, I accept the fact that you don't have currently data for outdoor workers that you could include them in the risk assessment, but in terms of the dose that they're receiving and the length of time, and the time that they spent, I think that we, it would be scientific indefensible to try to argue that the current standard is providing protection of public health with an adequate margin of safety.

So, when it comes down to the bottom line, I would do 0.055 to 0.070, and I'd be willing to go up to .06, because, quite frankly, by specifying 0.070, I think it's the lowest that you're going to get this current administration to do. And I don't want to

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cross over into the political aspect here, but I think you could defend, and this is where the discussion about the amount of uncertainty comes in, but clearly the upper range for considering any of this is 0.070, and you just have to look at the tables that have been provided for the frequency of incidents and, again, I come back to that it's repeated exposures.

And I still say that this staff paper needs to explain how you can have statements in here that most of the children, and most means the vast majority, are only going to have one accedence.

Now, when you had these two episodes in Denver, okay, I doubt very seriously that the children only had one accedence. They, it comes in inversions, and I know we can argue about, well, it was .080 and now it was .079, but I don't think that that's a totality that defends when I see plots of the numbers that have five or more, and other places in the staff paper in chapter 6 talk about nine or more accedences, how you can average that all out to say that it's one. So, something is not hoyle.

But, that aside, the real emphasis here is on repeated exposures, and the current standard in the oscillations with the number of studies that we see showing effects that clearly, from the American

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Thoracic Society definition, in terms of functional changes in percentages and the things of this nature, are of clinical significance, I don't see how that kind of information can be ignored and any kind of recommendation go that the standard not be lowered, and lowered significantly enough that, as Sverre brought up about some of the other cities on the margins here, where they kind of have uniqueness, and this is where some other analyses of creativeness, like what staff did for the course PM, you know, and other ways to approach, maybe needs to be investigated here for ways that could actually come to some of these other cities, and make some progress on the protection of the health.

And I'll go back to the last, because I realize that I didn't make it clear yesterday, that when I was talking about Avogadro's number and the molecule of ozone, I was saying, treat each molecule as an, a snowflake --

DR. VEDAL: There we go, right.

DR. MILLER: -- okay, as a snowflake, and what it would do would be --

DR. VEDAL: That was the missing link--

DR. MILLER: Yes, I forgot to say that. I forgot to say that and what it would do would dump a

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foot of snow on a city Detroit's size, represents the kinds of, with .08 parts per million, in those lower levels, on the number of molecules of ozone in every single one of them, attacks the carbon carbon double bond or other action, it, ozone reaction rates are on the order of ten to the minus ninth.

And this stuff, in my mind, is the most toxic of all the NAAQS, okay, and so, it just is unconscionable to me to think that we could have, at this point, with the additional studies, that we could not recommend that the upper limit of our letter, is away from anything that relates to the current standard.

DR. HENDERSON: I see Phillip raising his hand and then I'll come back.

DR. HOPKE: Again, getting, even getting a little away from the health effects, I'd like, again, for us to think more holistically about the atmosphere. And the driver in the astmos-, in atmospheric chemistry is oxidative chemistry. If we reduce the oxidant, we reduce a whole variety of air pollutants, and we're always exposed to this mixture of air pollutants.

So, we need to be thinking, yes, we have to, in this case, make a specific recommendation on a specific pollutant, but by bringing down the oxidant,

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we also bring down other important pollutants. And, there will be, then, a synergistic effect of increased control on ozone that will also reflect in other things. And I think it's important for us to recognize that we have good justification for lowering on the basis of ozone alone, and now when we start to think of it in terms of the entire effect of ozone and related photochemical oxidants on atmospheric processes, we get significant additional advantage from lowering ozone.

DR. HENDERSON: And Mort has something to add.

DR. LIPPMAN: Yeah, just to put what Phil said in a little firmer context under the Clean Air Act. We're not talking about an ozone NAAQS, we're talking about an ozone and photochemical NAAQS, for which ozone is designated the indicator. So, it's just, putting those words into what Phil said, you covered the scienti-, the science aspect of it, but ozone is desi-, it's a designated indicator.

It's not just the, this, the material being regulated. And, so, it's products of ozone that we can't fully define, but we've dealt with indicators, certainly PM 2.5 mass is an indicator of something. It's not certainly the pollutant that's causing the effects. It's part, it's an indicator of the class of

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pollutants that are causing the effect. So, it's a distinction worth noting.

DR. HENDERSON: Yes, though this is, Fred.

DR. MILLER: Just further on that, I mean, Mort didn't bring out his own studies. The camp, the field studies are out there with the oxidants, and they show greater decrements in changes than in the control chamber studies. So, the overall mix of the oxidative stress is something that is covered by the indicator variable that he's referring to, but it also is evidence that just the pure ozone chamber studies, alone, aren't saying the magnitude, necessarily, of the entire possibility for change.

DR. HENDERSON: Okay, yes.

DR. BALMES: Just a follow up comment.

DR. HENDERSON: Sure, John.

DR. BALMES: And I thank Fred for making that comment, because, as I said yesterday, on page 644, so it's bullet A, under 3, line 9, I mean, that paragraph was the one I said I found offensive. I still do. Because it gives the Administrator the opportunity to consider the current standard, which I agree with all the previous speakers, it's not justifiable. And to say that we know that there's lower risk on the exposure response function for lung

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function based on the Sigmoid curve with the Adams data, and I don't have any quibble with the Adams data, or the Sigmoid curve model. It's probably, you know, right for those thirty subjects, but to say that that now means we understand that the exposure response function is different, than it was at the last review, I think, is not credible.

Especially, given the point that Fred just made, that in the real world, kids and adults seem to have greater effects than they do in the exposure chambers, probably for the reason that Phil mentioned, that it's the total oxidant burden, not just ozone. And it also, that same paragraph also says, the lack of clear evidence of statistics significant respiratory effects, and I just, you know, that's, makes it sound like there are no, there's no clear evidence respiratory effects below the current standard, which is patently absurd.

DR. HENDERSON: Okay, we've had Jim wanting to speak for a while, here.

DR. ULTMAN: First, I wanted to --

DR. HENDERSON: You need to get to the mike, Jim.

DR. ULTMAN: Oh, I'm sorry. First of all, going back to Fred's comments, I agree that there's

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some inconsistencies in the chapter, but there are, on page 640, on line 19, well, actually, just, do I have both, yeah. There, it is stated that using a new standard .07 would reduce the exposures of concern by ninety to a hundred percent.

And I can't find the other page, now, but there's another point in the chapter, where they indicate that the children could have up to nine accedences per year, when you roll back to current standard. So, they do make the points in the chapter of the large number of accedences that are possible in the population of children, and also, the fact that bringing the standard down to .07 would greatly reduce that point.

So, there may be inconsistency, but I think the flavor of the chapter is that it is, I think, it's brought out. As far as what John just said, I agree that these, the statements about the improvements or the reassessment of lung function at the lower exposure levels, leading to less risk in the current review.

There's a couple of places that's put in the chapter, and I agree that I don't think they should be in there, unless they're carefully qualified by the fact that, that's only if you believe that the logistic function fit to the exposure response curve is correct,

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and that the, that the model is correct, and that the data on which it's based, which doesn't show any uncertainties, which do exist, is absolutely correct. So, either those statements should be taken out, or they should be highly qualified where they're put in, so that that's clear.

But the, in that paragraph, that summary paragraph that John was talking about, the last sentence in that, basically, says that you, an option would be to keep the standard, and that would still, that would still result in an adequate margin of safety. And we haven't talked about that yet.

But I think the discussion around the table has so far said that there are adverse effects at .08, that that's clear, and the standard should be lowered, but in addition to that, there should be a margin of safety. So, that's an additional consideration that should be considered in lowering the standard as well, but we're talking as if we just want to get bel-, I think, my sense of the conversation is, we're talking about just getting down to the point where we lower the risk significantly.

But we need to put in a margin of safety as well. And so if you add, you know, in that paragraph A, I don't agree with that last sentence. And I think

that should be shifted over to the paragraph B, and it should say there that, you know, the suggestion is to lower the standard, so we do have a margin of safety.

DR. HENDERSON: Yes at the --

DR. ZIDEK: So, I came this morning with a 060 based on my discussions last evening with Charley. Now, the basis for this really draws from a lot of the discussion we've had about all the uncertainty. And so, the process we're going through sort of works like this, I guess.

That there is an existing standard, and then there's this vast body of evidence that we now have, and there's also this vast amount of uncertainty, which we've been talking about now for a lot of this past day. And so, when you take the uncertainty together with the evidence, you ask whether there's enough compelling evidence in the face of this uncertainty to lead to a change in the current standard.

And of course, the tendency in these cases is to say, well, you know, there's evidence of association and so on, but then there's so much uncertainty, et cetera, that all things considered, let's keep the existing standard.

So, by putting the existing standard forward, in this kind of process, you already enshrine it with a

special status against all the competitors and when you throw in the uncertainty, you sort of, have to end up accepting that original level. So, so, when I came here this morning with the 060, it was based on the idea of actually throwing out the old standard completely, and starting this discussion afresh, and going back to the first discussants, who very, so very eloquently argued for his range on the basis of the need for public, protection of public health, and to build in a margin of safety.

And so, when I came here this morning to hear this discussion, I, starting with my 060, I was looking for some evidence to suggest that my hypothesis was, or my proposal was incorrect, that it should be higher, for example, 'cause there's some evidence they ought to be higher.

And taking that as the starting point. So, enshrining, in other words, the 060 as my starting point, rather than the current standard. Why not go lower.

Well, I'm a little bit mindful of the fact that, although, we're very uncertain about the public, about the policy related baseline, as to what it means, whether it's controllable and so on, it does set some sort of a lower boundary, so that although we have to

have this margin of safety, and might be inclined to go below 060, we also run up against this other boundary of possibly of the policy related background, whatever it is exactly, and whatever it means. So, so that's sort of how I came to the 060, and so I'm, I've already benefitted much this morning from the discussion that's already gone on. And I appreciate it and I thank you. So, those are my comments.

DR. HENDERSON: Thank you. Does somebody else want to throw in a number. All right, give a reason, I am very concerned that, I mean, what I hear is that, there seems to be a general agreement that the current standard should not be an option, even though it's a, we can understand the reasons for putting it in.

And that we should go, we should suggest something in a lower range, and we'll have to discuss what that range is. I think we have to keep very much in mind what Mort said.

That to be credible, we have to point out that the effects that we're seeing at these low levels are clinically significant. And describe them so that anyone can understand it, because that's really what, and of course, with the margin of safety.

But I, that's, I'm trying to think, down the

road, we need to justify that. Mort, did you have something else to say?

DR. LIPPMAN: We've already, recently, said that the current standard was not protective and that the annual PM 2.5 should be no higher than .14 micrograms per cubic meter. And so, there's no assurance whatsoever that our advice will be paid any heed.

DR. HENDERSON: Exactly.

DR. LIPPMAN: But, I think there, I've heard no one on this panel defend going away and we might make it clear, if it's true, and some people haven't spoken, that we all find .08 to e clearly unacceptable. And a unanimous statement, if it was true, I think would have some weight in this. Then we, in past, we should, you should determine whether that is, in fact, true, that there is no objections to the statement that .08 is too high. And then, move on to discuss what we think is an appropriate range.

DR. HENDERSON: I think that's a very good idea. So, anyone who would object to the statement that the current standard is not protective, what -- urgent, I'm sorry. When you're to the right of me, for some reason you have to yell at me, 'cause I didn't see you.

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DR. BALMES: Well, I'm just say-, I think that the .08 standard wasn't justifiable the last time it was reviewed, because, because, in fact, there was no margin of safety. There were significant effects, both lung function and airway inflammation, inflammatory effects occurring in the 6.6 hour exposures at Chapel Hill, you know, done by the EPA. So, that's my starting point.

DR. HENDERSON: Oh, okay. But I, Sverre, what is you --

DR. VEDAL: Well, and just to, just to address the issue that you were talking about on Mort's observation about justifying adversity. You know, we're putting a lot of our marbles on the lung function response, and then in trying to, you know, extrapolate that to what would happen in asthmatics and such. I think there's, I don't think we want to just put our hat on those data, and that little element of adversity, which we could argue about there. I think there are other, there are other logs in the fire that we can use to, you know, to make that point.

DR. BALMES: If I might, that's why I keep harping on the asthma E.D. visit data, which I think, you know, support that asthmatics are going to get in trouble when exposed below the current standard.

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DR. HENDERSON: Okay, I don't hear anyone who wants to defend the current standard. So, let's, can we list what we want to put down as what is not met by the current standard. You were just beginning to do that, or can I get some of you physicians, our medical clinical people to list, you know, I'd like to really pin it down. What, what is not being protected at 0.8.

DR. BALMES: Well, I think that a very compelling case can be made for exacerbations of asthma --

DR. HENDERSON: Yes.

DR. BALMES: -- based on both lung function criteria and E.D. visits and hospital admissions, and I think that --

SPEAKER: And medication use.

DR. BALMES: -- and medication use. Yeah, the, again, it's figure 3.4, I think, is pretty compelling. Especially, if you have to take out Canadian studies, 'cause below the line in respiratory hospital admissions, I believe, or similar Canadian studies, but, in any event, and I don't, I'm not particularly in favor of taking out Canadian studies, but I think you can make a very compelling case, that asthmatics are going to get in trouble. Not just have, you know, problems with a ten percent drop in FEV 1,

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but they will have increased inflammation that will cause them to be sick enough to show up in emergency rooms and actually be hospitalized. And that, by the time an asthmatic is hospitalized, that's, you know, they're seriously compromised.

DR. CRAPO: Now, that's backed up by animal data that suggests that there's airway inflammatory injury at those levels, and it's backed up by a suggestion there's even an increase in mortality in the whole population. I'm allowing an increase in uncertainty, but those two things need to be dropped in, because those, that, we don't just have pulmonary function data in isolation.

DR. HENDERSON: Yeah. And can we say that repeated episodes would cause remodeling of the lungs. It would be --

DR. BALMES: Well, we can't say that for sure, based on human data. We can say that that occurs clearly based on animal experimental data.

DR. CRAPO: Yeah, but that's the coherence --

DR. BALMES: Yes.

DR. HENDERSON: Yes.

DR. CRAPO: -- that's made up by the animal data that gives you the coherent story that

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there's, but that's not a simple temporary medically less important reaction, those two.

DR. HENDERSON: Sure. It doesn't just go away, I mean. Okay, I think we are in agreement, so somebody, Fred, go ahead.

DR. MILLER: I think Frank wants to say, and to mine is on a slightly different point as we're compiling this. I'd like to point out on page 633, line 19, throughout chapter 6, they give a scenario, then they say, using the more precautionary definition, and I'd like to see that kind of wording eliminated, 'cause I think that we have agreed that ten percent change in an asthmatic population is not, necessarily, a more precautionary.

That's a more expected kind of thing that could have an implication. So, throughout the chapter here, there's the standard, and then saying, well, you know, of the decrements of fifteen percent or greater, then say, well, using the more precautionary. Well, that to me, wherever that's written, that allows the Administrator to say, oh, they're going overboard.

But I, my personal feeling is that, and I thought this was endorsed, was that, in terms of asthmatics, that a ten percent reduction could be more problematic, and so, I'm not sure that using a more

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precautionary definition phraseology is appropriate. And then, correct me if I'm wrong, because that appears numerous times throughout the chapter, and kind of sets the tone of, well, we're really going overboard, but we'll go ahead and cite those numbers.

DR. VEDAL: Well, it is more precautionary, strictly it is correct. It's just your, it's just how you, what the connotation of precautionary is that's troubling you. This ten percent, you know, drop in asthmatics, I mean, I think Henry sort of put it right yesterday.

A ten percent drop in people with COPD, with significant COPD, is perhaps something we worried about more. There are lots of asthmatics where a ten percent decline is not significant, although they are severe asthmatics, where it's, where critically it certainly is.

So, you know, I think it's, we have to be a little bit, it's not that, you know, the global population of asthmatics, that a ten percent decline is necessarily important for, although, you know, I don't dispute the fact that we really would be concerned more in people with asthma. People with COPD, I think, is another story. That's --

DR. CRAPO: Could I put this in a little

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different medical perspective, applicant this, I perc-, see this and say why I think it's so important. It's not that an asthmatic, a ten percent drop in the FEV 1, for most people, including most asthmatics, is not detectable by the person that has that decline. Now, you might detect it if you're at a maximal exercise, and some kind of an ergometer measuring performance, but you can't tell when your FEV 1 drops by ten percent under most conditions, and, virtually, always asthmatics.

The problem with it is, is that it's a beginner of an inflammatory cycle. And the thing that's really important here is that medication use and hospitalizations went up. Now, when you get hospitalized, you don't have a ten percent decline. You have a fifty or seventy percent decline in the FEV 1. And that episode that leads you to the hospital begins with a little trigger that gives you a ten percent decline, and then, combined with something else, or a repetitive event, that suddenly exacerbates, and that person has a full asthmatic attack and ends up in the ER and starts using their medications.

The, what you're looking at is an early indicator of that inflammatory signals that triggers these kids off. And so, we're not trying to make the

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ten percent decline by itself be the adverse event that impairs the child. It's the, it's the signal that that child is being, inflammatory airway cycles are being activated in those children, then suddenly you have this huge cascade in a subset of those children.

DR. VEDAL: Well, I think that's what we all feel in our gut is correct. It's an interesting hypothesis, but you know, this change in lung function, you know, we're kind of all forgetting what the significance of this change in lung function is.

If it does, in fact, indicate the start of, you know, inflammation and all of that, that's nice and it's a good story, and as I said, I think we all feel that in our gut.

But there's also this notion that the change of lung function is a peculiar thing. I mean, it, basically, indicates a decrease in interparietory capacity, which, it is not correlated with inflammation. So, we have to be a little careful about getting our ducks in a row when we're talking about lung function.

DR. CRAPO: But in this case, we've actually measured ER admissions, hospital use --

DR. VEDAL: No, no, I understand that.

DR. CRAPO: -- and medications so that the

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end sequel of the hypothesis has been verified.

DR. VEDAL: No, no, no. It's not that necessarily the sequence of events that's causing, you know, that it's not this necessarily this drop in interparietory capacity that's sort of this initial trigger of all of this. It could all be entirely independent from that. As I say, it's a very nice story, but the data for that sort of sequence are not, are not there. In fact, you know, we have data showing that, in fact, they're not correlated.

DR. CRAPO: Remember, I think, I think you're struggling with the fact that the, I mean, it's clear we can't ever prove one event has a cause and effect for every decline of ten percent in FEV 1, there's probably a thousand of those for every hospitalization that actually occurs. So, that's why you can't put those two together. But, I think that anyone who takes care of these children would find that anything that exacerbates that child's airways, is at, is a significant at-risk trigger for combining together with other triggers to lead to the hospitalization event.

DR. HENDERSON: Okay, Frank?

DR. SPEIZER: I wonder one way out of this slight dilemma is to look elsewhere. Now, the ATS did

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a adverse health effects piece in the last five years. And I'm not, I don't know what they actually, I can't recall what they actually said.

DR. BALMES: It's in the document, actually, somewhere.

DR. SPEIZER: About the FEV 1 at a decline. If, indeed, it said it was between ten and fifteen percent as an adverse effect, we've got the information we need. I just don't recall what the number was.

DR. CRAPO: It is, the number's in the ten or fifteen percent range is defined as adverse. And we use it as our criteria for our methacholine challenge test for being positive.

DR. SPEIZER: Right, so we've got, so from a more legalistic perspective, we've got a independent definition of an adverse effect, which we're demonstrating as being met here. Now, the other problem I see has to do with what staff has done to this point, which is, to sort of stop at 0.64. And the question is, do you have data of your estimates below that level for us to look at, so that we can, indeed, help in defining what the range ought to be, below .64. I mean, you've given us the information to that level, but you haven't given us anything lower than that.

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DR. MARTIN: We've given you the full range of analyses that we've done.

DR. CRAPO: Rogene?

DR. HENDERSON: Yes.

DR. CRAPO: You know, I think, we've reached a strong consensus of the panel that the current standard's not --

DR. HENDERSON: Yes, we'll go --

DR. CRAPO: -- has risk, it has, is not acceptable to us a CASAC panel. The next question, and I, when I came here, I was considering .7, I knew we had to change it, and I was willing to consider the .7. As I really read all the data, though, I kept asking myself, could I, in good conscious, look at my colleagues and say, at .7, I have now a body of scientific evidence that tells me that I'm, that I, that I have, don't have risk and I have a margin of safety for sensitive populations.

And after looking at all this data, I came up with the data for .07 being just about as bad as .08. I recognize this one paragraph that we read that said that we got rid of a lot of accedences, but that was based on a modeling set of experiments, which has its, I think most of the uncertainties are with the model. If you look at the rest of the data, there, all these

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curves from chapter 5 show steady declines in the number of people that are being injured as you go right straight through .07 down to .6. In fact, I think that at .06, there's a body of data, that Fred cited, twenty some odd studies, that pick up data down in the range of .06. So, I think it might be worth going around the panel and having people, and I understand why you'd pick .07, because we've accomplished something. We've changed the standard.

We're moving in the right direction. Those are all kind of pragmatic reasons. But does it, do we really have data that says that .07 is now a safe standard with the margin of safety. And if the answer to that's no, we shouldn't consider .07, which is why I dropped it from my initial recommendation.

But, I think we ought to find out if our panel, actually, feels, you know, give some data, other than simply saying that, well, .07 is lower than .08, and hasn't been studied as much, therefore, I'll pick it. Use the data to say where do you have a safe standard with a margin of safety for sensitive populations, and I stretched to make .06 get there.

DR. HENDERSON: Well, let's, I mean, I think the next step is that we have to decide if we, we've, if we're, don't find .08 acceptable, what is the

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range we'd like to off-, we would recommend offering to the Administrator, who has, Mort has said will achi-, has achi-, but go ahead Mort, you had something to say.

DR. LIPPMAN: I've generally been hesitant to push work that was done by my NYU group, but in this context of the discussion, there's a study that's cited, but not given much play at all, and that was Thurston, et al, '97, in which we went to a camp that had moderate to severe asthmatic children, and we found that in relation to ozone, there was physician designated medication use increase.

Because it was the kind of camp it was, there was a physician on site, and when the kid came and said, I need medication, the doctor decided whether or not it was warranted. So, it wasn't just self-reported medication use.

It was a physician approved medication use. And both respiratory symptoms and the medication use were in direct proportion to the ambient ozone. Now, there were a few days that were above the standard, but most of the days determined the slope, were below the standard.

So, if, I think, that paper deserves a little more prominence, especially in terms of the arguing for the adversity of effect that we're, we've been doing

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that you initiated, Jim.
DR. HENDERSON: What was the lowest, I mean, did you, you said it was dependant on the ozone, how low did the ozone go and have an effect. I was just curious.
DR. LIPPMAN: Well, it was an observational study, a real world study in which ozone and other pollutants were measured. Ozone was the pollutant that was clearly the one that was --
DR. HENDERSON: Associated.
DR. LIPPMAN: -- regressed and correlated with the response, but it wasn't just an ozone exposure. It was ozone in the real world, which is, we're setting a standard for ozone in the real world, not for a standard to protect people in exposure chambers.
DR. HENDERSON: Okay. Okay, we have what, Fred, John or Fred going with this?
DR. BALMES: This is just a direct follow up. The study that I like to use in this context to try to make it real world, is the study by, I think it was, Friedman, et al, from, and published in JAMA, with the '96 Olympics, when, obviously other things were going down with the decreased traffic congestion than ozone, but the, there was a tremendous decrease in

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asthma ED visits, hospitalizations, medication use, and urgent care visit, you know, three different databases in Georgia were used. It's a tremendously rich data set, showing real world effects related to decreasing ozone exposure.
DR. HENDERSON: All right, go ahead, Fred.
DR. MILLER: Sort of like an intervention study, basically.
DR. BALMES: Yes.
DR. MILLER: I wanted to return to Sverre's comment about cascade that we can't defend inflammation. All of the clinical studies done that also looked at inflammatory cytokines, and that. You know, they had twenty-fold increases at, you know, .08, so you do not ozone exposure without inflammation. So, and the magnitude of those changes of twenty-fold in the increase of cytokines and that, I have no problem saying, well, maybe it was only a tenfold at .06 or something, but the inflammatory cascade independent of whether or not you perceive the FEV 1 changes occurring with ozone exposure.
DR. VEDAL: Well, don't, don't misunderstand me. I don't dispute the inflammatory effects of ozone. I mean, that's staring you in the face.

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DR. MILLER: I thought you were citing that as to --
DR. VEDAL: Oh, no, no --
DR. MILLER: -- project James' taking it to the sequella.
DR. VEDAL: -- I'm, I'm, I'm saying --
DR. MILLER: I'm sorry if I conveyed it wrong.
DR. VEDAL: -- the beautiful story of a drop in FEV 1 being a result of inflammation and indicating this sort of beginning of the cascade is a nice story. But, you know, ozone clearly has inflammatory effects, and it's concerning that it occurs at .08.
DR. BALMES: I would agree with Sverre that we shouldn't tie the decrement FEV 1's directly to inflammation because we could be challenged, because there's direct evidence that the, those, they're separately controlled, you know, that the FEV 1 response doesn't correlate with airway inflammatory response.
DR. HENDERSON: Yes, I think, kind of, we're talking about two different things, so I, but, no one's disagreeing that ozone causes inflammation and eventually can lead to exacerbation of asthma. Go

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ahead, Jim.
DR. GAUDERMAN: So, I keep staring at this logistic curve that we were looking at yesterday of the Adams data. And we were talking --
DR. HENDERSON: Can you give us --
DR. GAUDERMAN: -- yesterday --
DR. HENDERSON: -- the cite where it is.
DR. GAUDERMAN: Yeah, it's on, it's figure 5-2, it's on page 517, 5-17. And, you know, we talked a lot about yesterday at the lower levels it shows reduced risk of response relative to the linear function.
But the thing that I think I just realize that it does point out is, if you compare to the response rate at .08, which for a ten percent decrement is about thirty percent, and you follow the logistic curve with the response rate at .06 is ten percent. So, it's about a factor of one-third the response rate at .08. And it really, if you believe the logistic curve, and you look at the difference in response from the standard to, to something down at .06, for example, it points out the large improvement that we would expect by comparing those two points.
And the factor of about a third improvement in response rate holds whether you look at a ten

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percent decrement or a fifteen percent decrement or a twenty percent decrement. But that, it seems to me to be a compelling reason, or an additional rationale that we could offer for the improvement that we might expect is that large factor of reduction in response to FEV decrements that we'd see following that logistic curve.

DR. HENDERSON: That's a good point. Thank you for brining that up. Leanne?

DR. SHEPPARD: How much do the physicians believe that curve? I mean this curve is giving me heartburn.

The more I think about it, the more I think that if we had the real data on that figure that the straight line that was there before would be completely consistent with the data. And that, actually, I would recommend that the, an additional sensitivity analysis be done on the risk assessment that use the straight line as well.

And I know that's not the point Jim was making, but, this curve is, a lot of conclusions are drawing from this curve, and we need to make sure the data analysis, based on it, is well grounded, which it's not right now. And I'd like to hear a little bit more from the people with the scientific background about the scientific basis for believing that curve.

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DR. BALMES: Well, I gave my opinion yesterday, and I suggested, yesterday, that they use the straight line curve. I don't have a problem with both, but --

DR. VEDAL: And I think that's the i-, I mean, it's not a clinical issue. It's a statistical issue.

DR. BALMES: Statistical, exactly.

DR. VEDAL: The only issue is, is that before, when John was talking about the straight line, it was a total extrapolation because we had no data. Now, we've got data, but it's, it's so thin, as to be almost non-existent, so you've got, you know, incredible confidence intervals that would be consistent, as you say, with just a straight line. So, I think, displaying the at-risk estimates in linear terms, as well as you suggested, I think, just using a non-parametric sort of, using linear interpolation between points, makes good sense. But as long as we have all of the options, I don't think you can, credibly, make a good case that this is definitely sigmoid. It intellectually makes some sense to me, but I think the data are not there.

DR. SHEPPARD: Well, if it's, if it's statistical rather than clinical, then we definitely

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have some work to do.

DR. MILLER: It may be, but, with an N of 30, and a value of ten percent at .06, you will not have the mean response with the linear going through 20. So, I have to disagree with you about where the mean responses are going, and what gives the credence of which curve is more likely to be correct. It's the logistic.

DR. VEDAL: All right, you got three people determining that thing, so this --

DR. MILLER: I know, and now multiply it--

DR. VEDAL: -- the level of uncertainty is like ridiculously wide.

DR. MILLER: It's within a factor of two, okay.

DR. VEDAL: What is within a factor of two?

DR. MILLER: The confidence interval around it, probably.

DR. VEDAL: Oh, no, no, no, no, no.

DR. MILLER: Sure. By the time you would blow it up to a population.

DR. VEDAL: Well, we're not talking about a po-, we're talking about experiment, here, of thirty

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subjects, with --

DR. MILLER: I understand, but, you know, you're, you would have to be making the argument that you had bad luck in the three that you saw, okay. Okay. But the weight of the evidence would say that the overall mean response is going to be closer to the way the logistic is showing it now, than it would be the linear.

DR. VEDAL: That's what I feel in my gut, but the data don't show that.

DR. SHEPPARD: Well, actually, if that's, if that point is a binomial, then I think the upper end of the confidence interval would be about .16 higher than what it is at the point, which would include the straight line.

DR. CRAPO: Could I just add that, I think both answers are this, I mean, this is an interesting debate, but if you look at -- but if you look at the real question, which is, as you drop below .08, do you have, does it go to zero at .07. Neither curve argues that. Both curves show that your, you've got to at least get to .06 to have even, either curve suggest that you might get to a protection at the highest level of FEV decrement.

So, if you, if you, if you allow both

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arguments to go forward, I see a strong argument on this data to say that .07 does not ori-, the point, a level of .07, under any circumstance, would not offer a margin of safety, and would still have retained adverse health effect.

DR. GAUDERMAN: And whether you use logistic or linear, it's somewhere between what looks like a ten or twenty percent reduction in response rate going from .08 to .06. I'm not arguing for the logistic, necessarily, but I'm just saying that if we're going to use it, yesterday to criticize and say that now the risks are lower, the other way to use it is to point out that difference that it enhances between the .08 and .06 levels that is not quite as large when you look at the linear.

DR. HENDERSON: Yeah, whatever curve you use, it goes down. Okay, did you have something, Jim?

DR. ZIDEK: I was just going to observe that, I didn't do Leanne's calculation, but I guess that zero would also be included, would it, in the, at that point?

DR. SHEPPARD: Yes.

DR. ZIDEK: So, it's somewhere between zero and that line at .6.

DR. HENDERSON: So, at which point is the

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zero if this in --

DR. SHEPPARD: At .06.

DR. HENDERSON: At .06, zero is included. That's informative, but go ahead.

DR. HOPKE: Might I suggest, based on what we can measure, that we could think about five PPB intervals, and we could be then thinking about a range of say, .055 to .065, so that a .070 would be in violation.

DR. HENDERSON: We could go around the room and see what people are thinking in their heads as what they've got in their head. I don't know that that's too informative, but we've had suggestions all the way from 04, which I think is a bit low, up to 07. And --

DR. CARPO: I think we need to find out what the group thinks, since we have to write a letter when we finish. And we have to put a real number there, so you might as well start getting people to commit.

DR. HENDERSON: I'm thinking of that letter. Yeah, Jim.

DR. ULTMAN: I'd like to, before we discuss that, I'd like to put policy relevant background back on the table, because before --

SPEAKER: Why?

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DR. ULTMAN: Well, before I commit to a level, I'd like to know where I am relevant to what's doable. It's just, it would just be helpful, I think.

DR. HENDERSON: Okay, Rich, did you have something that you wanted to, that's a, well, I keep thinking of the fifth room.

DR. POIROT: Maybe it was getting at the same plan a slightly different way, but I want to preface this by saying, I have no expertise, whatsoever, to vote on a number that the standard should be set at from a healthy perspective.

But, from what James' initial comment suggested to me, is that, essentially, we're saying, this is a pollutant for which there are health effects without threshold.

And that's, I think, that's fairly clear, down, if we're talking down to .4, we're playing natural background or policy relevant, whatever, so we clearly have a threshold-less pollutant for in terms of health effects, and yet we're charged with helping the Administrator set a standard at a level that provides an adequate margin of safety. So, our task is impossible.

DR. HENDERSON: Yes.

DR. POIROT: And that brings me back to, I

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thought, Mort's point was critical, that is, what we need to really be kind of using some judgment on is, a level of adversity that we can really say, this is, there's some inflection here.

And then, maybe that's a difficult level to find, but, and I hate to be the one to raise this issue, but .06, that's the whole country into non-attainment, and of all of the substantial control efforts that we've put forth in the past, reduced both VOCs and NOCs, we've hugely brought down the extreme peak concentrations.

We really haven't much influenced those moderate low levels, so, I don't want to, I just want to be a little bit careful, or at, you know, advocate some, I think it's absolutely critical to really nail down this adversity flux point here. Otherwise, we're kind of throwing up our hands and saying, oh, this a pollutant without threshold, which is, maybe what it is, so, I don't know, just wanted to raise that point.

DR. HENDERSON: Thank you. That was a very good definition of our impossible problem, but anyway.

DR. SPEIZER: Yeah, I want to second this point, because it's one I wanted to make as well.

DR. HENDERSON: Okay, Frank.

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DR. SPEIZER: That we would be out of compliance throughout the country, but it really does say that we've got to come up with what we think is an acceptable risk. Because if we say there is as much risk at .7 as, at .07, as there is at .06, as there is at .05, and we just have a little more uncertainty at .05, the Administrator is faced with the problem of some group coming back to him and say, you have not included a margin of safety.

I think it's important for us to say what we accept as a margin, as an acceptable risk, recognizing that there is no, that there's no threshold. That, we have, I think we're going to have to come up with what we think is a best estimate of the most protection, but perhaps even define what we think is an acceptable risk.

DR. VEDAL: I want to second that perspective that, and just to put another little perspective on it, is the, I mean, this is not unique. This is the same issue we were faced with in the PM deliberations.

And so, we're going through the same exercise now, trying to, basically, find, shift the paradigm a little bit to an acceptable risk type of paradigm. I think the words, where we talk about acceptable margin

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of safety are sort of, have evolved and I've made this point before, that, when we talk about margin of safety, this is not, although most of us, I think, would take the words to mean, absence of risk.

In fact, it doesn't mean that the way it's applied in this setting. And, in fact, the emphasis has now, kind of, shifted to the acceptable part of absence of risk, acceptable absence of risk.

So, that's what we're kind of struggling with, is what kind of, what kind of acceptable margin of safety are we willing to argue over, and so, we're very much in a different paradigm now, where we're not able to say that we're in a complete absence of risk scenario, just impossible.

DR. HENDERSON: That's very true, and I think that's even stated in the Clean Air Act. It doesn't mean they get down to no risk, there, that isn't possible. And, so, we need an acceptable risk. I find, despite it being a model, on page 640, where the, if the standard, it states that if a standard is set at .07, fourth daily max would provide substantial reductions in estimates of exposures of concern of ninety to a hundred percent. And that had me thinking about .07 as one of the levels that we, part of the range.

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DR. CRAPO: It did me too, but I, but my, if my exposure of concern was .06, and this, it's a matter of definition of terms.

If we have data that says .06 causes injury, then how could you eliminate, and since most of the country would be out of standard on that, how could you eliminate a hundred percent or ninety percent of the standards at risk. I mean, that's a, this doesn't make sense to me, is what I'm trying to tell you. If you think there's adverse health effects at .06, and if you think that level occurs commonly, how could you say that you eliminate those by dropping the level to .07.

DR. VEDAL: Yeah, but that argument would take you down to .04 as well.

DR. CRAPO: Well, I know that, I'm just trying to --

DR. VEDAL: And maybe lower, so, you know.

DR. HENDERSON: I think Karen's going --

DR. CRAPO: I know that, I was just trying to say that this argument was not a convincing argument to me, that if you change the level to .07, that you eliminate all ozone risk in the United States.

DR. HENDERSON: I think Karen Martin is, needs to say something.

DR. MARTIN: Yes, with apologies for

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interrupting your discussion, I would like to make an observation about what you're talking about, and then pose a question for you that I think would be very helpful to us for you to think about as you're working your way through your conversation.

The first observation is that if you think about what the standard means and how it's implemented, we're looking at the fourth highest day at the highest monitor in an area, and comparing it to the level of the standard, when that's averaged over three years.

The implication of that is that when you move an area into attainment with a standard at a given level, you have moved a whole lot of days that were originally below that level, to even lower levels. So, you are, you are reducing exposures, not just at and above the level of standard, but you are reducing the whole distribution of exposures.

Now, the lower you go, the more compression you get at the bottom, so you know, that's why we use a quadratic approach to rolling things back, but my point is that the level of the standard and the level at which you have concern about an individual exposure are really two different things. And I would encourage you to think about them as two different things. One reason why you see exposures of concern going to near

zero, even when you simulate attaining an .07 standard, one has to do with how you define level of concern. Is that an exposure above .08, at and above .08, or is it at and above .07, or is it at and above .06. That's an important issue that I would encourage you all to think about to help us with what metrics we use to determine what benefits we're getting from different standards.

But I would also encourage you to think about the level of the standard isn't the same as the level of concern for the reason that I talked about. You really do get substantially lower levels being lowered even more when you target on one given standard level. The issue about exposure of concern, though, really relates to, a lot of your discussion has been about the inflammatory effects.

Effects that cascade from inflammation. And inflammation, of course, is one effect that we don't have data to do a quantitative risk assessment for, and the only way we can use a quantitative metric to address that effect, is to say at what level do individuals experience inflammation, what is the level of concern that we ought to be trying to keep people from, in order to avoid the start of an inflammatory cascade.

We have evidence at .08 and no lower. So,

how do you grapple with, how do you set a level of concern for inflammation below .08, and if you think we should, that discussion would be of great use to us, because we have choices to make about the metrics we present.

As you pointed out, in some places we talk about exposures of concern above .07, others .08. In the last review, we focused exposures of concern at .08. Our thought was, in this review, maybe we ought to be looking at some lower levels, but it's unclear to us what is the most appropriate metric therein. And as I said, guidance from you in that regard would be very helpful.

DR. HENDERSON: Thank you, Karen. If you have questions, Mort?

DR. LIPPMAN: I think maybe you've given us a practical approach of deciding what a margin of safety is. That is, since you look at the highest monitor in an area, and that represents something higher than the exposures will be, that difference is the margin of safety.

Because we have no other way of defining it, I mean, it's an arbitrary and capricious, perhaps, measure, but it's something that gives us some, you know, that people will be exposed to less than what the

highest monitor in the city really shows.

DR. HENDERSON: Phil?

DR. HOPKE: The standard, also, we also have to think about in terms of the precision of the measurement. Have you started to think, then, about where we are with round off. I mean, are we going to, are you going to consider going to, to, you know, the 5ppb interval sort of things, as, I think, would be a reasona-, 'cause then the effective standard becomes, you know, if we put it at 70, the effective standard's really 75, not 80. So, it makes a difference.

DR. MARTIN: I'm glad you asked that, because I had wanted to mention that before and I neglected to. You've seen the staff memo that we've done looking at the precision. What you didn't see in it and someone observed was lacking was a conclusion from staff as to what the implication of that assessment was.

Following that memo, staff has continued discussions, and the conclusion that we would intend to put in the final staff paper is that it would be appropriate, based on precision, to specify the standard to three significant figures, okay. Having said that, let me just offer one other comment.

Having said that, that still is a separable

question from the level of the standard. All that says is, if that recommendation is adopted, is that you now have a finer tune to set the level. That doesn't mean the level couldn't be set at .084 or .074 or .076. All it says is you have a little finer dial to dial it in. You could still specify a standard in two significant figures, however, and instead of rounding, you could truncate. You could specify a .08 standard, and adopt a truncation, rather than rounding, and end up with an 080. So, I would encourage you to keep those things separate.

DR. HOPKE: Right, but they're interrelated, so they can't be --

DR. MARTIN: One allows for the other, but they don't necessarily link.

DR. HOPKE: Right.

DR. HENDERSON: Okay, Ted has been holding his hand up.

DR. RUSSELL: Just a quick point is that, we can't assume, actually, that the monitor is picking up the highest ozone in the location. In fact, that's probably a very unlikely event. So, we shouldn't assume that that, that we can use that as being an argument that it's somewhat more protective, particularly in locations, and there's a number of

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smaller cities that only have one monitor.
DR. HENDERSON: Tom, okay, Fred.
DR. MILLER: Also, there's this aspect of margin of safety, and the Clean Air Act states in protection against effects not yet demonstrated. And we're starting to see things in terms of cardiovascular and other things that, by the time the next go around, we're probably going to have data on the table.
So, to me, I don't accept a statement to say that we have evidence of inflammation and quantitative data we could use at .08, but we have nothing below. Now, if you take, you know, if we, if we had taken that aspect, we never would have gotten away from TSP, and I wouldn't have modeled PM10, okay.
And I can tell you that, with a twenty-fold change in cytokine going from .08 to .07, is not going to go to zero. So, to me, it's unrealistic to say, for reinforcing aspects of inflammatory responses, to imply that .08, just because we don't have data below it, doesn't say that that doesn't factor in to the overall cadre of effects that are being seen.
DR. HENDERSON: Well, I, okay, go ahead, Frank.
DR. SPEIZER: Well, I wanted to answer some, answer Karen on that point as well. It's not

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clear to me that you have to do a risk assessment for inflammation. I mean, I think the biology is sufficient that we understand it, and it's part of the process. And what you've done with FEV is sufficient. And, to at least tell us, that there's something going on, and we can deal with the biology that says that inflammation is part of that.
DR. MARTIN: I certainly, to clarify, certainly wasn't suggesting that we wanted input from you that would allow us to do a risk assessment on inflammation, given that we don't have dose response functions that we could do that with, at least help us understand, to follow the point, Fred, that you've just made. .08's our lowest data point on inflammation. One option is, therefore, to stop there and say that's our level of concern.
We did that in the last review. Alternatively, we could take this panel's advice and do something different in terms of a level of concern that could be used as a metric to help us understand how inflammatory effects relate to considerations in setting a standard that you could help us with now.
DR. CRAPO: I wanted to say something, Karen, you said something that gives me a substantial measure of comfort in what we're talking about here,

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and I wanted to acknowledge that, but if you're telling me that if we drop the level, the standard, to .070, that that would then have a profound impact on the number of days that exceed .06.
DR. MARTIN: Sure.
DR. CRAPO: You're saying that, right. And I'm not sure if that's what I can assume then was eighty to ninety percent protected.
DR. MARTIN: That's what you're seeing in the exposure and risk assessments.
DR. CRAPO: Yeah, but is --
DR. MARTIN: The whole profile is down.
DR. CRAPO: The whole profile goes down. Now, can I, can you tell me, or can I rely on the number being that this ninety to a hundred percent decrease really related to that, or ho-, because what you're really doing is, you're telling me we are controlling .06. And that adds a good measure of comfort to what we're doing.
DR. VEDAL: That really does, but I, you know, it's clear from here and it's stated in several of the chapters that much, most of the oomph, most of the benefit that you're getting is occurring exactly in those intermediate ranges. I mean, that's where the adversity occurs, and that's where the improvement

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occurs.
DR. CRAPO: So, you're saying that we need to, so it's adequate or it's not adequate to drop it to only to .07?
DR. VEDAL: Well, I would, we can talk about our individual ranges in a bit, but what I'm saying is, with you know, that any drop in the standard is going to have substantial implications, as Karen has said, in those ranges below .07. It's just not just lopping off the top.
DR. HENDERSON: Okay.
DR. MARTIN: That's why we've tried to do as much quantitative exposure and risk assessment as we could, because that's the way in which you can see how the whole distribution is changing when you change the level of a standard. So, you're not just relating a measured health effect at an exposure level to a standard level. It's just not that simple of a match.
DR. HENDERSON: I would like to bring this to a close, if we can.
DR. MILLER: I'd like an ecology break.
DR. HENDERSON: I would like that, too. Shall we have a break first, and then come back. Why don't we all put our ranges, we could take up a little collection, put your range on a sheet of

paper, while you're taking a potty break, and then we'll come back and discuss it. Okay, and to improve our attention span, we need a potty break. Five after ten, back here, and think about what your range would be.

(WHEREUPON, there was a break in the morning session.)

DR. HENDERSON: We're behind time, so as quickly as you can take your seats, we'll get going. Okay, I have the results. This is, I got --

DR. MILLER: I never gave you anything.

DR. HENDERSON: I know, I was going to say, I just got eleven back. So, I presume the others weren't interested, no. I, if you have, if you haven't turned it in, turn it in.

DR. ZIELINSKA: Can't we just tell what we see.

DR. HENDERSON: Sure, you can tell.

DR. ZIELINSKA: Well, I would be very hesitant to go below .6, just because, looking at the table we get, it's a .64 for as maximum gives like fifty ni-, ninety-five percent of the country out of compliance.

DR. HENDERSON: Yes.

DR. ZIELINSKA: We can go as low as we want, actually, but if you put something like .5, which

is totally unrealistic, how we are going to achieve this? So, we'll have to propose something which is possible to achieve eventually.

DR. HENDERSON: Yes.

DR. ZIELINSKA: And not something which is up over the sky and totally unrealistic. So, my recommendation would be not to go below .6, or 6.7 would be a range I feel okay.

DR. HENDERSON: So, sixty to seventy. You've joined the majority, actually. Is there anybody else. Okay, actually, now I have thirteen and out of those thirteen, the upper level recommended by, for, let's see, how many. There were six, seven, eight, nine of those thir-, whoop, nine of those, we keep dribbling in, were seventy.

SPEAKER: Rogene, more is coming.

DR. HENDERSON: Huh? Oh, okay. Well, maybe we can wait. Actually, it's turning out that seventy seems to be the, almost, well, the majority has seventy as their top level.

DR. MILLER: My seventy has three significant digits.

DR. HENDERSON: It has 74. Okay, I assumed that the person who turned in 74 was thinking of using the current form where the fourth, the 70 is

considered 74, is that what you, is that yours, Fred, that said 74?

DR. MILLER: No.

DR. HENDERSON: Oh, it was, I don't know who, and I'm trying not to associate names with these because I don't want, you know, to get legalistic or, I mean, I don't.

DR. HOPKE: I would like to suggest, I think about 72 as the effective max, where 73 then, rounds to 75, and that would be out of compliance.

SPEAKER: They're wrestling with what to do with the primary standard.

DR. HENDERSON: [Laughs.] And can you be quiet.

MR. BUTTERFIELD: Okay, John Rice and Ellis Cowling, we hear you on the line. Do you hear us?

SPEAKER: Yes, I've been having a nice conversation.

MR. BUTTERFIELD: Very good.

SPEAKER: If you would have people speak into the microphone, again, if you will remind everyone so we don't have trouble hearing.

MR. BUTTERFIELD: We will make that reminder, John, yes, okay, but we're back live from

Durham.

SPEAKER: That's a threshold.

DR. MILLER: Could I ask Phil to clarify his rounding algorithm, then, because some people use with an even, that the number next is rounded up or down. So, there are several rounding methods that are out there, so, it could or could not go to.

DR. HOPKE: Okay, my thought is that at this point, we have a precision of around 2 ppd, that in terms of practical field kinds of things. And so, if we, we would then think about 72 rounding to 70, 73 rounding to 75, and that that would then be, so that that, you know, 73 would then be effectively out of attainment. 72 would be effectively in attainment. That's all.

DR. MILLER: Thank you.

DR. HENDERSON: I, getting down to the decimal point, oh, I'm sorry, go ahead.

DR. MORANDI: Yeah, but my concern is that if, you actually leave an uncertainty analysis on the measurement, so it seems to me that you, you would need to use, if I remember, was it four and a half five part per billion, your ever analysis in the measurement. No, that my argument with Phil would be that there was an error analysis made on the measurement, and that

was, as I remember, four and a half or five. So, that going to 2 ppd would not agree with your ever analysis.
DR. MARTIN: Yeah, there were two aspects to that. One was the precision of a given measurement, the other the bottom line focused on the precision in the design value calculation. And that was about one part per billion.
DR. MORANDI: Okay, one part per billion.
DR. MARTIN: Leading to what will be the staff conclusion that it would be a reasonable to specify the standard to a part per billion or a third significant figure.
DR. MORANDI: Okay, thank you for the clarification.
DR. HENDERSON: Well, most people did not, they just put zero. They did use the three decimal places, but used zero. Now, if we, Phil, why would it be good to put, what were you suggesting 72? No, he's. Well, I'm trying to avoid getting this more complicated than we have, than our information suggests we should get.
DR. HOPKE: Again, the practical thing is that we make .070 the maximum value. They're still going to, they still have to present, they've yet to present their proposal for changes to the monitoring

rules. But, I would, you know, thinking about what's practical to do, they could think about it in terms of effectively making .075 the cut point for where things went out of compliance. Now, whether they will or not, that's, you know, we won't know that till we see what the tentative notice of rule making says, but that's if --
DR. HENDERSON: But for, for the --
DR. HOPKE: But in terms of our considerations, I think, we can, you know, we still can be thinking about .070 where it effe-, it's not necessarily going to have to round all the way up to 80 in order to, in other words, the effective max then, under the current system, the effective max would then be .074.
DR. HENDERSON: Yes, and that's --
DR. HOPKE: And, I think we can get a, we can shave it a little bit with current instrumentation, but that's really not terribly critical to our discussion.
DR. HENDERSON: Well, I am going to suggest so that we can bring some closure to this, that we're not that far off as far as this upper level of our, of the range. The majority wanted 70. The next highest is the 65, so the, there is no one who was

different from either the 65 or 70. So, that's pretty tight. Yes, Allen.
DR. LEGGE: I think we should say something about how the vegetation would respond to this, and I, even though we're, that's in the welfare area, I, if this would help any, the lower the better
So, if you want to protect people and the environment, then the idea is, and you're only, and you end up with a primary and secondary the same, then the lower the better.
DR. HENDERSON: Well, right now, I think we have to stick to our human, because that's the way we're going to have to justify, but that's a good point, 'cause, I know when you come at the plant, some were more sensitive than the people, as I recall, yes. So, the upper range, can we live with 70, that's the majority, let's see, one, two, three, four, five, six.
DR. LIPPMAN: As long as it's put at .070, not just 070.
DR. HENDERSON: Yes, .070, so that the majority had that, and.
DR. CRAPO: I was one of the strongest advocates for even lower, and I would accept the higher level as a consensus, so 0.70.

DR. HENDERSON: Okay, so we've got our upper level. Now the lower, people have suggested, I won't say their outliers, two people suggested as low as 45. Some people, there were several people had 55, and then 60 was commonly. I haven't, that's not as tight a group. So, I'm thinking that maybe if we go with 55, probably, everybody could agree to that, but I don't know. Phil, go ahead.
DR. HOPKE: Maybe we should just say, not to exceed .070, and leave the bottom end of the range undefined.
DR. HENDERSON: That's fine with me. What do others think of that? The bottom --
DR. CRAPO: I think we're politically better to give it a range. I mean, we know they're going to take the top, we know that, they're going to work on the top of the range, anyway.
DR. VEDAL: And I don't think we're going to be able to agree on the lower range, so I would suggest that you put some sort of, you know, distribution on what we felt was the lower range. I don't think we're going to be able to agree on a fixed lower range.
DR. HENDERSON: Well, let's see. You mean, actually --

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DR. VEDAL: Unless everybody wants to agree with me.
SPEAKER: What's your lower.
DR. MILLER: There's always a minority report.
DR. HENDERSON: But a minority report it really would consider.
DR. MILLER: You can't come down to 055?
DR. VEDAL: Well, we all have our different range.
DR. MILLER: It's not going to matter in the end, but it's sending the message, I think, relative to --
DR. VEDAL: Well, yeah, but I mean the WHO has the luxury of, you know, of doing airy fairy recommendations, and showing our green card, and all that, and we don't. We are in the practical world of trying to, you know, do something about the public health. And, that's what really influences my lower bound.
DR. HENDERSON: Well, nine of the sixteen were at 60, and so, I mean, that's, and then there were four at 55. So, I, if I've got it right.
DR. SPEIZER: Well, there's nothing wrong with saying with a lower bound between 55 and 60.

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DR. MILLER: That'd be fine.
DR. HENDERSON: Would that be okay?
DR. MILLER: That'd be fine.
DR. HOPKE: Yeah, that'll work.
DR. HENDERSON: 55 to 60.
DR. GAUDERMAN: Take a weighted average.
DR. HENDERSON: Okay, so you all are good folk. We got it, now, in writing this letter, and it's been pointed out to me, that we need to be very careful. If we're really serious about this, and we want effect a change, then we can't just say we've got a gut feeling this is the right thing.
And we really can-, and I've heard a lot of gut feelings here. And so, we need to carefully lay out why we think that the EPA, that the recommendations given in this staff paper, should not include that following the current standard. And we have to point out exactly why we don't think that that should be so. Then we have to point out our exact reasons why we think the range that we're giving is required. So, I want you all to help me on this.
I don't want any in the messages, I just feel that's the right thing to do, Rogene. I, that doesn't help me. I want you all to write out exactly why you think these ranges are appropriate and why it is not

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acceptable to go with the current standard, so.
DR. CRAPO: Rogene?
DR. HENDERSON: Yes.
DR. CRAPO: I'd like to say something about this, because I think that we do want to say why, but we want to say it very tersely and very succinctly. We don't want to write a twenty page letter that cites all the documents that, that say why there's health effects at the current standard or adverse health effects at the current standard, because then our message gets lost.
I think, that's the role of the staff paper, and of all the documents we've got. I would argue that the letter that we want to write needs to be at most a couple of pages long, and needs to make our points. It needs to, it needs to point out our position on the current standard. It needs to point out what we think about adversity.
What the primary adverse effects we've found to make our, and make a statement, that we think these are significantly adverse, and it needs to make a recommendation, and it needs to talk about a consensus of the panel. But, we should not have a scientific discussion of the nature that's in the staff paper, because this document, as we learned from working with

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PM, if we provide a lot of discussion about the pros and cons and other kinds of issues, then it provides an opportunity for our document to be ignored. And, I think this has to be very powerful, very succinct, and very clear, in order for us to be effective.
DR. HENDERSON: Frank Speizer and then.
DR. SPEIZER: Well, I'd to get some clarification here. We are making recommendations now, which I thought would influence how the final staff paper will appear. Now, is the staff paper still going to have, if we come out with this recommendation, is the staff paper still going to have a .08, because we're saying no. And that's what we're tell you as advisors.
DR. MARTIN: I can't tell you what the final paper will be, because we need to go away and think about what we've heard today, and we need to read the letter you write. What I can say is that in the past, the final staff paper has reflected conclusions on the part of staff that implicitly took into account CASAC advice. One could envision a final staff paper that more explicitly reflected your advice and your conclusions.
Whether or not it was identically the same range as what we end up identifying as, from our

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perspective, being a potential consideration, it could be very explicit there, and I think that would go a long way to represent your views.

It's hard, off the top of my head, in the absence of hearing your final words and reading your final letter, to say exactly how I think that ought to translate into what the final document would say. I'm just not going to say off the top of my head, and the answer's not --

DR. SPEIZER: But, and our letter is being written to staff as well as to the Administrator, is that right?

DR. CRAPO: Yes, of course.

DR. SPEIZER: And staff --

DR. HENDERSON: It's going to the Administrator, but certainly the staff will --

DR. SPEIZER: -- the staff needs to respond to it.

DR. HENDERSON: Yes.

DR. CRAPO: And it's a public document.

DR. SPEIZER: And it's a public document, so --

DR. HENDERSON: Oh, yes, it's public.

DR. MARTIN: Right, right, but, and what I'm saying is, we can certainly go more than what we

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have in the past and much more explicitly recognizing in that final staff paper what your views are.

I do, while I'm talking, I do want to just make an observation, that a very strong statement saying, this is what we believe, is a clear statement, but it isn't a statement grounded in the reasons why you believe it. And I would encourage you to think about incorporating the reasons why, at least from the perspective of what types of effects and what types of evidence or what types of quantitative results were most influential in helping you reach your bottom line recommendations.

A recommendation, without even that much, hangs out as a trust me we're right statement without good grounding.

DR. HENDERSON: Yes, that's what I meant. No gut feelings here, okay. Mort and then Phil.

DR. LIPPMAN: It's easy to understand why Karen made the statement she just made, but now we, we're going through the process of closure, in our minds, if not in the minds of the EPA, on the document, and therefore, at this point in time, we don't know what the staff paper final document will look like. So, we're forced, seems to me, into the position that we took previously with PM, that we are not closing, in

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our parlance, on the final chapter.

It's clear that from things that were said, that on all the other chapters, save of course the ones we haven't heard yet on welfare effects, that the committee is very pleased with the responses of OAQPS staff to our previous recommendations, and that we fully trust them to make further changes reflecting the discussion, in the sense we're closing on those chapters.

But considering the position that Karen's in right now, and not knowing what the chapter 6 will say, we have to make it clear that we do not endorse chapter 6 as it stands, and we will want to see the final chapter. If, because of the court deadlines, that means it will be after the fact, as it was with PM, then so be it.

DR. HENDERSON: That's, I sense that is the consensus of the group, that we will want to see it, chapter 6. Yes, Phil.

DR. HOPKE: I mean, again, in terms of crafting this letter, we don't have to repeat everything that's in there. We can highlight or reference. I mean, again, they've done a really good job in many, in most cases of summarizing the thing. So, I think, all we have to do is point back to the

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things where we say, we find this compelling, and therefore, don't feel, you know, or don't see this level of uncertainty, et cetera, et cetera.

So, I don't think we have to recast all of the arguments they've made, but I think we can, can, can use much of the, of, with appropriate referencing of the staff paper, to buttress why we, then, come away with a different set of final conclusions, with respect to the options that are available to the Administrator.

DR. HENDERSON: Yeah, yes, that's what we want to do to, oh, Jim, Michael, and I'll, you, Jim, you first, and Michael.

DR. ZIDEK: Okay, just a procedural matter. So staff has already heard the discussion today, and some of the scientific arguments and so on. The question I was going to ask is, with respect to our letter, is it necessary to provide our letter, prior to seeing the final staff paper?

DR. HENDERSON: Yes.

SPEAKER: Yes, absolutely.

DR. HENDERSON: Yes, we, go ahead.

DR. MARTIN: I would certainly hope so.

DR. HENDERSON: They don't just go by what we say here, they need the letter. So, yes, there will be a letter.

DR. MARTIN: As well as the individual final comments that reflect your deliberations here with that.

DR. HENDERSON: I should emphasize, we're talking about, James is suggesting a brief letter, but there will be extensive, all of your comments, you can say everything you want to say in these comments. They can be as long as you want. And they will be attached to the letter, and those are used. They're very useful, so, even, I mean.

DR. MARTIN: I do, yet, have a couple of issues that I'm going to come back and ask before you stop discussing this, that really would be helpful to reflect in the final chapter to better understand where you're coming from.

One is with regard to the level of exposures of concern. Right now, chapter 6 brings forward exposure assessment results, in terms of reductions in exposures of concern as defined by a level at and above .08. If you agree with that, it would be useful to hear you say that.

If you think a lower level of concern, again, reflecting the inflammatory type effects, the airway responsiveness type effects, those effects we don't have quantitative risk assessment for, be really good

to hear your views on that particular issue. We've looked at it in the exposure assessment at other cut points. What are your views as to the metrics that we should be putting most weight on.

The second issue that I heard that didn't get much discussion, but it was one that certainly peaked my attention, was the comments that, on one hand, some thought, looking at studies done in areas that would likely have met or likely not have met the current standard was a useful perspective, at least in part. And another view that said, no, that wasn't a useful perspective that expressed the view, Dr. Vedal, that regardless of whether the area would or would not have attained the current standard, we see EPI studies in which there were effects observed at levels below the current standard.

And I would like a little better sense of the committee, how much weight you would put on the kind of assessment we did here in looking at, where studies done in areas that didn't meet the standard or they did, versus the thorny question of how to use time series EPI studies done in areas that tell us something about level, without looking at whether or not the area would have or would not have attained the standard.

DR. VEDAL: Two responses. First of all,

there are studies done where they don't attain the level, both for overall mortality and for respiratory hospitalizations.

Second of all, the issue of studies that truncate the concentrations in an upper bound, I mean, I kind of like that as a way of showing that effects are occurring below that, but I, but that's too easy, in a way, because, as you pointed out, and I think that's right, is this whole issue of the distribution of concentrations that would be affected by a given level.

And so, what is reflected in the time series studies, and in studies that are where most of the information clearly is due to concentrations below the standard, is, that's kind of off the point a little bit, because you still have one sta-, one at, one monitor that's, you know, meets the being out of compliance sort of issue. So, I think we need to put most of our evidence on the fact that, first of all, you can restrict to absurdly low levels and see effects.

And secondly, that there are studies that are clearly, in areas that are clearly in compliance. And certainly you can pick subsets of those data, time wise, where they would be clearly in compliance and

show similar effects. So, you know, to argue that you need, you can just throw out those studies because, you know, everything is, they're out of compliance at times, to me, is just, is try to stretching that point too much.

DR. HENDERSON: Okay, Michael.

DR. KLEINMAN: Yeah, I just wanted to go back to this issue of low, you know, levels of concern, and you've got table 5-5, where you've looked at a sensitive population, active children having one lung function response greater than ten percent, greater than fifteen percent. When you look at the numbers, the percent of this sensitive population that's having adverse effects greater than ten percent, in most of the cities you've modeled, you've got more than ten percent of the sensitive population showing adverse effects.

Now, if, you know, I don't know the exact, remember the exact wording, but I thought the Clean Air Act called for protecting the most sensitive 99 per, or 99 percent of the most sensitive population, or something like that. Or, you know, some-, or, well, anyway, we're supposed to protect the most sensitive population. At the meeting the standard, we've got around ten percent still having adverse effects. This

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table would be great if it went down and looked at the alternatives, you know, which you start to do in chapter 6. I didn't realize I was going to.

Okay, so anyway, tables like this are useful, it does cover the modeling and it does answer this issue of levels of concern in terms of a adverse effect that's recognized, does that help you?

DR. MARTIN: That's coming out of the risk assessment for FEV effect, but what I was speaking to was levels of concern specifically related to inflammatory airway responsiveness type effects for which we don't have the means to do a quantitative risk assessment and we can only do an exposure assessment.

DR. MILLER: You just go to figure 3-4, 3-4 has it all. You know, affects asthma and pneumonia, respiratory infection and you have emergency department visits and so on.

DR. BALMES: What level of concern would you...

DR. MILLER: I give it a 95.8% confidence limit with the lower bound of .984.

DR. SPEIZER: No, that table, that figure might very well be in our summary letter and a discussion of it.

DR. MARTIN: Let me try to clarify the

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point because I still think we're not communicating. If I wanted to say to what extent does lowering the standard to a given level reduce the likelihood that a given sensitive population will be protected from experiencing exposures that are of concern from the point of view of triggering inflammatory related or airway responsiveness related cascades of effects? What would that target level be?

In our exposure assessment we assessed the extent to which different standards limit exposures at and above .08, at and above .07, at and above .06, but we only have data down to .08 for information, so my question is which of those, or any other metrics, are appropriate to think about in those terms?

DR. BALMES: So Charlie, I think you may have the best knowledge with regard to a level of concern for inflammation based on your monkey data, I mean what's the level, lowest level that you see inflammation in your monkeys, since we don't have human data?

DR. KLEINMAN: Yeah, I think we've actually seen it down to about .05.

DR. PLOPPER: But in terms of human data, don't we have a clear human at .080?

DR. VEDAL: Well, we do, but .080, which

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is already below the current standard and then the argument was made, well if you see it there. You know, I don't know why you need, I don't know what's so important about that request, why you need that.

DR. MARTIN: It helps, to the extent that you all have discussed a lot how important inflammatory and airway responsiveness type effects are in influencing your judgements about the nature of ozone and standards.

It provides some quantitative metric for assessing how well different standard levels would provide protection that's related to those specific types of health effects, which as you point out aren't correlated to lung function decrements and which are decidedly different from and a different evidence base than what we have for mortality, per se.

DR. BALMES: I think that would be, I think it would be a positive to move things out of FEV1, solely FEV1, so I appreciate Karen's question and I agree, we have definite evidence of human inflammation at .080 and I'm sure it goes lower than that, that's why I was asking Charlie.

Maybe we could say we have definite evidence at .080 in Reeses monkeys which have an airway biology very similar to ours, it goes down to 0.50, 0.050 and

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so that, you know I would think that it would be appropriate to look a level of concern below .080 given the monkey data. You know, whether we should look at, I think certainly 07.

DR. MILLER: You also have though the human studies with the very cytokines and you can go to those and show ILA was a 20 fold difference.

Anyone who would say that ILA, I'm just picking that out, I don't remember, you'd have to go to the study, to say that a 20 fold difference now going to 070 is zero, wouldn't pass the laugh test biomedically, so you have plenty of data from those studies on inflammatory changes and that's why I'm coming back to what Sphery was getting at, to me this is reinforcing but not relying that you can quantify the percent reduction.

I think it's more of building the case of why that other is an indicator that now that tracks with other events that are most likely to be occurring.

DR. CRAPO: And also, while you don't have human inflammatory markers like cytokines at the really low levels, you do have evidence of increased medication use, doctor's visits, ER visits, those are all strong correlates with inflammation and I would say it's a rare child we see in an ER with an asthmatic

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attack who does not have inflammation if you have any way to get to it to measure it, it's 100% correlation where you get to the measurement. The, so looking at that instead of FEV1 should also be seen as a surrogate or marker for human inflammation and those are only the worse cases because the milder cases don't show up in the ER.

DR. BALMES: There are data from my own institution where we did an induced sputum study of asthmatics showing up in ERs, and your right, most of them, I mean virtually all of them have airway inflammation.

DR. MILLER: Is it published?

DR. BALMES: Yeah.

DR. MILLER: There you go. No, no, I don't mean it, I'm just saying I think we're spending too much time getting weighted down by that you've got to shore this up, we can shore it up, but I'd like to spend a little more time and I firmly believe that set aside the boiler plate part that Fred has to add that our letter should not exceed two additional pages.

DR. VEDAL: Well, I think we're getting confused a little bit about this letter. I mean this letter is meant to inform staff as well as to be addressed to the administrator. A letter somewhere

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down the line, if things don't happen the way we recommend, then I agree the letter should be in the form that James recommended, very crisp and to the point, but that's not the stage we're at now.

DR. MILLER: It may not be the stage, but it's called trumping okay? And what needs to happen is you can have the detail, but our detailed paragraphs that write now that take 10 pages can be an appendix to our letter providing all that information, but we need something succinct to grab them in the right place.

DR. HENDERSON: Perhaps we should move on to, someone has pointed out to me that we skipped over some of the general comments on Chapter 6, now in the interest of time I'd like to move on to the secondary standard, but is there anybody who has something really vital about Chapter 6 that they can't express in their individual comments that they think should be brought up now? If you do, speak now, Leane had...

DR. SHEPPARD: I wanted to make the comment that I thought that the, a lot of the comparisons should be, a public health criteria should be defined in the beginning of the chapter for what's important, particularly with respect to the risk assessment and many of the comparisons are relative instead of absolute and the percentages appear

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different but the absolute numbers tell a completely different story and I'd say 1000 deaths or 1000 kids with lung function changes is 1000 kids, whether the denominator is 7000 or 5000, but the percentages are different and the same thing, so there's a lot of I think misleading interpretation of the data because of the use of the relative criteria and I think the most important thing to do first would be to define from a public health point of view what's important and then to frame the conversation around that.

DR. HENDERSON: Was that all Leane? No, you're looking...

DR. SHEPPARD: Let's see, I would also agree with Jim that I didn't feel like this chapter was as well written as Chapter 5 and the point that I made yesterday that somehow that focusing on the risk assessment trumps the scientific evidence that needs to be worked on, particularly in Chapter 6, so the scientific evidence doesn't get ignored in favor of the numbers. I guess those were the most important things I wanted to say.

DR. HENDERSON: Okay. Well with that I think, unless somebody else has a burning point about Chapter 6, that we can move on to Chapter 7 and get on with the secondary standard. Oh, go ahead.

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MR. BUTTERFIELD: I just want to go back to Dr. Lippman's point. We will be adding a summary paragraph in the letter that's very similar to what appeared for the ozone AQCD, where the CASAC wishes to see the final ozone staff paper and at that point we'll decide if additional unsolicited advice was warranted.

If so, we will look to hold a teleconference as soon as possible, probably late October, early November with a view toward informing the agency's efforts in developing the proposed rule for ozone and other photochemical oxidants.

It's a little bit different than PM in that with the, once we were done with the PM staff paper we said we want to see it and the committee had made a decision a priori that they would provide advice, this gives you the option to provide advice, but it doesn't constrain you to do so. Dr. Speizer?

DR. SPEIZER: Clarify, I thought we heard, I thought you said that we do want to see Chapter 6, is that what you're saying?

MR. BUTTERFIELD: I'm saying you will see the entire final staff paper when it comes out and...

DR. SPEIZER: When it comes out, yes, but the question is do we want, I thought what we wanted to review specifically was Chapter, was the revised

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Chapter 6 and probably have a teleconference on that.
MR. BUTTERFIELD: Okay, okay that's why I wanted to clarify that. So, if you're saying right now that you not only want to see the revised staff paper or I'm sorry, the final staff paper and you are making a decision a priori that you will want to have a teleconference, I'll move forward and schedule that for the end of October.
DR. CRAPO: I vote for that. We're asking for such a fundamental change in Chapter 6, we need to see it and have a teleconference.
MR. BUTTERFIELD: Okay, and if need be, if there's not, if you all see the final staff paper and decide that you don't really need a teleconference, that it meets your approval, we can always cancel that, but I will move towards scheduling a teleconference for the end of October.
DR. SPEIZER: Well yes, except that I was thinking about saving some trees and I though we had signed off on everything short of Chapter 6. If we have, it's not clear that we have to see all that other stuff again.
MR. BUTTERFIELD: Nevertheless, we will ask the agency to send all members a CD and a hard copy of Chapter 6.

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DR. HENDERSON: Yeah, it's Chapter 6 that is our concern that we want to see. Okay, now let's, is Ellis on the phone?
DR. COWLING: Yes, he is.
DR. HENDERSON: Okay, Ellis you're the, oh that's right, excuse me Ellis, we have a brief introduction of the secondary standard work, Karen?
FEMALE SPEAKER: Yes, we wanted to make some brief points about the environmental assessment that was done before you all begin. Jeff Harrick and Vicki Sandiford ,who've worked on this, are here to do that.
MR. HARRICK: Oh, we also have our contractors from AFT behind us that helped us do some of these analyses and Bill Hoggset, who worked on the CD. I just have a few slides, four slides. There is some new data that we have that wasn't in the staff paper, so can you go to the next slide.
Just as a little introduction, we're building off a lot of the studies that were done in the last review and the new studies that were on the CD also, I'm sorry I'm distracted. The new studies reaffirm what they found in the previous document and so we found that still ambient levels of ozone still can cause decreased yield, biomass of many crops, forests,

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plants and reduce the nutritional quality of the ergonomic forage species.
Also, something new that we put into this staff paper is we looked at the leaf injury data that the USDA Forest Service goes out and collects every year, so they have teams of people that actually go out and look for specific diagnostic ozone injury and while that can't tell you a lot about how that's making the ecosystem function, it does tell you that there are photo toxic levels of ozone in the atmosphere, so the maps we presented there showed that it was widespread across the country.
And as far as ecosystems, they affect different plants differently, so we don't have the advantage of just looking at one species, we are looking through the whole plant kingdom in this particular analysis and so, in an ecosystem you might have more sensitive individuals in that ecosystem that are more affected by ozone than affecting competition, so we believe that's an important thing to consider and finally the last bullet on here we wanted to point out that since 1988 it's been known that a seasonal cumulative concentrated weighted form is a better form than an average, like the eight hour average form that we have right now and we think that Sum06 and W126

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perform rather well and track well with effects on vegetation and that would be more appropriate index. Can I have the next slide?
And in response to CASAC's, some of CASAC's comments early on, we were looking at the issue of, especially for the crop analysis, that the actual monitors are between four and five meters on average above the ground and crops don't generally grow that tall, so we're looking at how we could look at that uncertainty a little bit, so there is no easy way to do that because you have to take into account the exact height of each monitor, the canopy roughness, seasonal and diameter nature of turbulence and so, a simple thing we did was we readjusted the hourly data by 10% downward throughout our entire exposure surface to see how much that effect would have and there was some evidence in the literature that that was sort of an upper end of how much difference we would see between the top of where the measurements actually happening and the top of the canopy and so, the next slide, this is data that we just got yesterday, so we haven't had time to completely digest it.
But this is the axiom run models and showing the benefits for the agriculture, basically the agriculture benefits based on the yield increases if

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you reduced ozone to those different rollbacks.
So, we have .084, the current standard and luckily we did also do .0870 and we have some with 6 of 25, and some with 6 of 15, we also are doing W126 of an equivalent magnitude of those some of 6 to 25 and 15, so you see the 10% adjusted is with adjusting those monitors downward 10% and then on the right hand side is the new data we have that if you account for all the different crops that we have data for, this is what we would expect and this model was run for 14 years because the axiom model actually has functions that allow farmers to change their behavior based on yield changes and the changes in the commodity price.
And so, what we sort of get from this brand new data is that 10% adjustment on the whole is not really affecting a lot, the actual benefits that we see if you look at the whole, but that doesn't mean individually some crops might have a more, have a more significant effect if you do a 10% adjustment and then you don't, so this is just to sort of illustrate what this potential uncertainty, how it might come out in the economic analysis and that was basically all I had to present.
DR. HENDERSON: Are there any questions?
DR. CRAPO: I have a question, I'd like to

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know, this is a fairly substantial change we're talking about switching a form to some...
MR. HARRICK: Yeah, we proposed that in the last staff paper.
DR. CRAPO: Yeah and what's the impact from a regulatory point of view? So, we set a primary standard, let's say we follow our current advice and it goes .06, .07, eight hour average.
We set a cumulative for seasonal average or total maximum limit, what on the vegetation it's a very different number, now is there, how does the low implement in terms of regulation and one could be substantially tighter than the other, does that mean that you regulate and enforce the tighter of the two standards? I'm trying to ask what the impact of our decision is.
DR. MARTIN: The most fundamental difference between a primary and secondary standard is you have time tables for reaching attainment of the primary standards that are built into the statute and vary depending on various things.
But for the secondary standard, the statute only says one is to achieve those standards as expeditiously as practicable and so in practice you have an undefined time horizon in which to come into

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attainment with a secondary standard.
So, to the extent that there would be a secondary standard that's different that may involve different areas or be more stringent in the same areas, you have differences in terms of the time frame in which attainment's required.
DR. CRAPO: So, the secondary standard really only has impact on the behavior of what we're doing if it's more stringent than the primary standard? Including different forms.
DR. MARTIN: Well, more stringent is not a simply construct here because it may be no more stringent than the primary in the urban areas where the primary standard is the focus, but it may involve non-attainment of other areas that aren't non-attainment for the primary.
So, it's a question of the reach of the standard as well as the degree of control that it might require or even the nature of control, seasonal controls may be different than trying to limit more peak daily distributions. So, there could be a lot of differences, there's no simple answer, the only clear difference is the time horizon in which one has to attain it.
DR. CRAPO: Okay, but if you make it

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identical to the primary standard as it has been in the past, then it really has no impact because the primary standard has a greater enforcement policy.
DR. MARTIN: Well, if they're identical, even if they had the same importance, they'd still be identical.
DR. CRAPO: Yes.
FEMALE SPEAKER: Excuse me, one of the benefits we see to having the separate form is the ability to generate information that is easier to understand and the impact on vegetation. So, it generates different kinds of information.
DR. HENDERSON: Are there other questions? It's okay to talk about cost, I mean this is quite different when you talk...
DR. MARTIN: No, no, it's not.
DR. HENDERSON: I just, when I saw those dollar signs.
DR. MARTIN: The issue is, the Court rulings have been absolutely clear, we do not consider the cost associated with meeting the standard regardless of whether there's a primary standard or a secondary standard, what you see here are monetized benefits to protect vegetation that is grown for the sake of its economic value. One way to assess the

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public welfare benefit of protecting that crop is to identify what is the economic loss associated with not protecting that crop. That has absolutely nothing to do with the cost of meeting the standard.

DR. HENDERSON: Okay, that's a distinction I had not made in my mind. Okay, Fred?

DR. MILLER: You said that the data you didn't feel had much of an effect with the 10% downward, yet I saw consistently where it would have less of an economic impact.

MR. HARRICK: Yeah, it was between 10 and 20%.

DR. MILLER: 10 and 20% on .08, you know we've been arguing a lot here in terms of, I was surprised that that is dismissed as in the noise level of economic value if I multiplied it by all the crops and it makes me wonder about economists, maybe you're not an economist.

MR. HARRICK: I'm not an economist and that sort of, those numbers, those ranges I showed for minimum and maximum, they sort of overlapped so there's about a 10% difference, but the ranges sort of overlapped, so it might be within the noise.

FEMALE SPEAKER: If I could speak to that too, when we looked at the impact on the exposures air

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quality, it actually, using that Sum06, it reduced the Sum06 exposures by about 53%, but that did not translate to the same magnitude of impact in the economic analysis, which is why we were characterizing it that way.

MR. HARRICK: And a lot of that might be driven by just very small Sum06s changing, so if you had a Sum06 of 4 and go down to 2, that's a reduction of 50%, but that's not biologically a huge difference and most of the, looking at a Sum06 or W126, most of the impacts happen at those higher levels, it's a non-linear relationship.

DR. HENDERSON: Thank you, any more questions?

DR. GAUDERMAN: Yeah, I had one.

DR. HENDERSON: Okay, yes.

DR. GAUDERMAN: I was wondering whether you know on a nationwide basis how well correlated the eight hour averages with the Sum06?

MR. HARRICK: Yes, actually can you put my presentation back up, I have a couple slides of that. It depends on the year, so if you have a high ozone year or a lower ozone year. It's actually on the desktop, it's on the desktop. Oh, it's gone now. Well, if you have your staff... It's in the document,

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if you go on page 719, figures 7-1 and 7-2 show the relationships for the years 2002, which is a relatively high year overall and 2004, which is a relatively low year. And, as you can see, if you're all there yet, we sort of broke it up into quadrants, and so the lower right quadrant of that part of the graph, that will tell you how many counties would be out of attainment that would be in attainment for the primary standard. Yeah, that's the right one.

So if you could just flip through and I can find that slide, I think it might be near the end. That lower, so we have the proposed 1996 standard, which the Sum06 is on the X axis, on the Y axis we have the fourth highest, this is just for one year, so this is also difficult to compare because the actual standard is an average of three years.

So it makes it really difficult to compare things and so what we have, if you just had a one year value, those in the lower right hand quadrant, those were the few counties that would actually be out of attainment for the secondary standard but still be within attainment for the primary standard.

And if you go to the next slide, can you go the next slide for me? This is 2004, then you have lower air quality as far as a primary is measuring it,

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but the secondary standard you actually have, you actually have more counties that would be out of attainment if you were to attain the primary standard, but they would still be out of attainment for the proposed 1996 standard.

DR. COWLING: Have you done that calculation for both W126 and for Sum06?

MR. HARRICK: Yeah, we have that done now for both W126 and Sum06, they show pretty similar relationships, I don't have that with me.

DR. COWLING: So the number, you have numbers of counties with both the Sum06 and W126 form of the proposed standard, is that correct?

MR. HARRICK: I don't have that with me, but we can calculate that and put it in the final.

DR. COWLING: That's a point I think would be worth while to show, I think they'll turn out to be rather similar, but it would be reassuring to actually see how very similar the two standards would be in terms of the county distribution of areas that would not be in attainment of either of the two proposed secondary standards.

MR. HARRICK: Okay, we can do that. Rich?

DR. HENDERSON: Rich?

DR. POIROT: Minor question on this

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figure, in many of the preceding figures and in Chapter 2 depicting data from AQS and from CASMAT, it's broken into urban sites from AQS and then the rural sites are defined as the CASMAT sites and I was wondering if this plot and the other one were using those same subsets of, a subset of AQS data that's urban or is that all AQS data?

MR. HARRICK: That's all AQS data. The dark dots are actually CASMAT data, so these are the highest county, these are the highest numbers in each county for the eight hours, we picked out the highest monitor in that county for the eight hour and so not all the CASMAT are on there because there might have been an AQS monitor in the same county.

DR. POIROT: And, also coming back to the question raised earlier where Vicki had pointed out that the change, by dropping the concentrations by 10%, this astounds me by the way, by dropping the concentrations by 10% to account for the monitor height potential effect, we could have 53% reduction in the Sum06 metric.

So, I might be getting the math wrong, but by dropping them by 10%, that drops the metric by 10%, so now we've got another 43% that is caused by concentrations falling out of the greater than .06 bin,

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so in other words, 43% or almost half of the whole Sum06 metric must therefore be contributed by concentrations that fall between 60 and 66 PPB, am I getting the math wrong on that, that astounds me? I'd like a double check on that number at some point.

MR. HARRICK: We have to look at it more closely, maybe the very low values, they might only have a few, very low Sum06s might only have a few places where they get above 06, so that might be in that range, so the very lowest Sum06s might be disproportionately affected by this 10% rollback.

DR. GAUDERMAN: Isn't that because it's a strongly non-linear relationship where we see an expidential curve?

DR. POIROT: I don't know, anyway it just really surprised me.

MR. HARRICK: It might be better to look at the absolute change rather than the percent change, it might give us sort of a skewed look at how that's actually affecting the Sum06, so we may not have a big absolute change.

DR. POIROT: But then what I still am not quite understanding is there's something about the dismal science of economics that makes this 53% change insignificant or not insignificant, but relatively

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minor or is there something in how you're dose response and functions, is it more that or is it some quirk of the...

MR. HARRICK: Yeah, it could be a couple of things, the dose response, they're less responsive at these lower levels, so it's a non-linear, not until you get to higher Sum06s do you start to see effects and also when we quote that 53% number, it actually was for the whole country, not maybe, it could be different for actually the crop growing regions. So, maybe that would be a better way to calculate that reduction just for the crop growing regions. What we did was we calculated for the whole surface.

DR. HENDERSON: Paul?

DR. HANSON: Rich, I think you've hit on an important point about how the Sum06 relates to this calculation is that all values below 60 are discounted as zero, so they're not added up and that accounts for the discrepancy, while you're looking for a 10% reduction, but you get a 53%. Ellis' point about lets see these calculations for the W126 should fall somewhere in between because there are numeric values for quantities below 60 PPB in that calculation, so the W126 values should lead to a percent reduction in the overall W126 index that's closer to the 10% that your

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looking for, I think.

MR. HARRICK: Well, when we did it across the whole country for W126 we got a 43% reduction, it's just also because the W126 has a very, that inflection point is very steep, so.

DR. HANSON: Right, I mean it still exhibits that characteristic, so it should be less.

MR. HARRICK: I believe it's 52% for Sum06 and 43% for W126, so it's the less of an effect, but it's still dramatic across the country.

DR. HENDERSON: Okay, Karen did you have some more you wanted to present before we do a general review?

DR. MARTIN: I do not.

DR. HENDERSON: Okay, let's go to Ellis, you're the lead discussant for Chapter 7, can you lead us off on that?

DR. COWLING: Okay, I was glad to hear that Mr. Poirot is there as the leading and Rich and I have communicated very often about these matters and there's some things that I comment about that Rich would like to amplify or disagree with, I hope he will speak up. Rich is not shy about that and I'm sure he won't. Let me also say that I appreciate the indulgence of the CASAC membership in allowing me to

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participate in this meeting by telephone. Today is my 50th wedding anniversary.

MALE SPEAKER: Happy Anniversary.

DR. COWLING: And we are here, talk about institution grounds, where my wife and I began our courtship 52 years ago, so I thank you for your indulgence for my participation today on m wedding anniversary. The second thing I would like to say in general is that I find that Chapter 7 is well done and I have responded in my written comments to all of the questions that Karen raised in her charge questions and I have been positive in my response to all of the questions except one and maybe Rich could make his comments.

We, if you, those of us who have read Chapter 8, and I hope all the members of CASAC will have read Chapter 8, what the second staff paper has done is proposed that we abandon the long standing tradition that EPA's maintained and I think it's been maintained for all the criteria pollutants, maybe I'm incorrect in that, that we what is being proposed by OAQPS staff is a secondary standard differing substantially from the form and the level and all the other characteristics of the standard from what the primary standard would be. I believe, and have believed for a long time, that a

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secondary standard different in form from the primary standard is quite essential in a welfare based standard from a health based standard.

But, we're discussing now only Chapter 7 and not Chapter 8, but I find Chapter 7 to be well done and because it is being recommended that the administrator implement or promulgate a standard that is very different in form from the primary standard that some illustrations of the impact of ozone be included in this staff paper. Charge question number 7 asks, "To what extent do the figures aide in clarifying the text? Should more or less information of this type be included in the final Chapter 7 or it's appendices?"

And I recommended in my comments last December that it would be valuable, I think, to increase the likelihood of persuading the administrator to do something which he or she, as it has been in the past, has never done before and that's to have a secondary standard, a least for ozone, different in form from the primary standard and for that reason I believe it would be persuasive to add figures or add photographs that show some of the factors that are necessary to understand and suggestions I made was a picture of the stomata on a leaf surface, for example it would be wonderful if you could get a picture that

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would show a leaf surface with stomata open and stomata closed. I think it would be valuable to include pictures of crop plants and floral plants growing under different concentrations of ozone and I know there are such pictures, I have used the myself and so have my colleagues.

I think it would be valuable to have an illustration of the difference in grain heel with and without exposure to different concentrations of ozone. I believe it would be valuable to have an image that would show the greater effect of ozone exposure on root growth than on shoot growth, which is I think for many people rather surprising. And my last suggestion was that a collage of pictures might be included that would show for example, that would illustrate the kinds of economic impacts that ozone has on leafy vegetables like spinach, for example, or cut flowers or Christmas trees and that such pictures.

I believe, would add to the persuasiveness for the administrator to make this previously unprecedented decision, that is to have a secondary standard in a different form from the primary standard. So, that is the only relatively negative comment that I have to offer in response to each of the eight charge questions. I think all of the other questions, my

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comments were very positive towards what the staff has done with regard to the questions asked by Karen in her charge questions. So, that's all that I would like to offer, maybe Rich would have some other comments that he would like to make as well.

DR. HENDERSON: Yes, we'll go to Rich now, you're the next designated reviewer Rich.

DR. POIROT: I'd certainly like to defer to my more ecologically educated colleagues Paul and Allen for more final words.

DR. COWLING: Could you speak up a little please?

DR. POIROT: I agreed largely with Ellis' view that the chapter was I thought very well organized and clearly written. Some, I think especially valuable questions were raised and answered for example, what constitutes an adverse effect, something that I hadn't seen before that I think makes a very positive addition. I think the truth of the matter is there hasn't really been an awful lot of new work since the last review cycle in this particular area.

DR. COWLING: I agree with that.

DR. POIROT: You disagree?

DR. HENDERSON: He agrees.

DR. COWLING: I agree there has not be a

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large quantity of work to add to what was done in 1996 or '97.

DR. POIROT: And you know I think this is unfortunate and it's kind of been a neglected area for inquiry and that being said, I guess my one major criticism is that it seems to me that we leap rather quickly to these old indices and old numbers, 25 PPB hours for the Sum06 that were raised in the last review cycle. I think there's some fairly significant point blank statements and observations that are very important and worth restating.

You know in various locations in the chapter it's observed that there continue to be observed symptoms of foliar injury for example in locations that currently meet the eight hour proposed standard, or the eight hour existing standard. In addition, there are observed injury symptoms in areas that would fall below the previously proposed bound of 25 PPM hours for the proposed secondary standard last time, so what was proposed last time, even though it was somewhat more stringent in a way than the primary, has been observed since then to have been inadequate to protect against these various effects.

I was very pleased to see that staff did include a fairly extensive inclusion and discussion of

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the foliar injury data, granted it's a very difficult proposition, I understand, to make linkages between visible symptoms of foliar injury and then some of these other biological metrics. That's not, I'm a little concerned though that it a little bit somehow minimized the importance of these visible injury symptoms as if they're not nearly as important as the invisible injury that we can model.

What if this were a human health effect and we said well, it will make your skin blotchy and in some cases patches of it might fall off, but we don't know that this will affect long term mortality, you know that's kind of the same thing. This is not a second class kind of an effect for sure, it's I think nicely identified as an area for research needs in the future and am I getting into Chapter 8, I can't partition clearly what belongs in each one, they seem to flow one into the other.

Let me make a couple of, just another query, as I said before it just astounds me that the, that there could be a 53% drop from a 10% deduction, but I trust you if you assure me the math is right. It, a couple of other details that I had noted, I thought that there was a lot of information actually and a couple of errata figures that you redistributed that

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were apparently miscalculated the first time comparing the W126 to the Sum06 and also showing the time series at a number of sites over different years for the W126. The mistake that was made the first time around was to use all 24 hours of day, I believe, that's the way it was described and then the correction is to use just the 12 so called daylight hours.

I use so called because if we're going to narrow this down to the summer months, probably daylight is more like 14 hours throughout most of the country if we're being persnickety, but actually that makes quite a difference 12 to 14 and then as Al Lefohn suggested yesterday, there are some reasons to expect that we might see some effects during night time hours as well, maybe not as severe, maybe not as many species would be affected, but oh man when you look at those plots, they're going from 24 to 12 changes everything, especially at the higher elevation locations.

So, we've got these kind of these metrics that we're kind of rigid about, but then we make a little adjustment to it and all of a sudden it changes the level or the level of what we're observing relative to standards by a large amount, so it's something I think that needs to be considered fairly carefully. I noted, for example, also that when one of the factors

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that enhances the adverse effect of ozone is higher relative humidity, which of course is going to occur during the off-peak and not during the peak midday hours, so again some careful consideration of the early morning, later evening kinds of exposures would be maybe worth looking at.

There's kind of a muddled discussion a little bit, and maybe appropriately so, on page 714 that kind of looks at combined effects of increasing CO2 and temperature and ozone and it surprised me to see that most of the historical literature apparently that looks at ozone in combination with these other two things has considered increasing CO2 and increasing temperature as totally independent from each other and so we need to resort to some sort of a speculative conclusion that well, if we increase CO2 that may offset some of the effects of increased ozone.

But then if we were to consider increased temperature effects that may negate most of these effects, but it's all kind of stated in a very speculative way and there was sentence I kind of just inherently objected to where it says, "it is known from limited experimental evidence and evidence obtained by computer simulation," and I would submit that should never be the preface to any conclusion, it's suggested

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perhaps by that and anyway, I think that's kind of getting into the minor details more than not. I wanted to make also an observation on this 10% reduction.

You know we have to be clear then that our assumed concentration and effects calculations are based more or exclusively on monitors that are right at the level of the tree or leaf or plant seeing the same levels, I mean to the extent that these are well mixed open topped exposure chambers that's probably a good assumption, but I don't know, I'm a little uncomfortable just knocking these things down by 10%, especially if that reduces the total by 53%.

I know in Vermont, for example, which is largely a transport affected state for ozone concentrations and has lots of trees that show symptoms of injury even though we don't exceed the current standard, nor would we exceed 25 PPB, PPM hours, the proposed former, yet we observe the foliar damage symptoms, we find that our ozone concentrations increase as wind speed increases and that's going to be true, illogically, but yet it's true through most of the northeast and I would submit probably many transport affected rural areas.

You know, ozone transport is a little different than PM transport in the sense the pollutant

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tends to be shorter lived and so rapid transport of previously accumulated high concentrations is a good way to get your dose down wind in a remote forest or agricultural area, so under those higher wind speed conditions we might get much better mixing and maybe the 10% would be an overestimate.

DR. COWLING: Rich, let me just say I think that you're calling attention to the stomata and the difference between high and low elevation ozone concentrations and the behavior of stomata, many people think that the stomata are closed at night, that they are closed when drought occurs, for example, but I think that you've raised some additional things that maybe deserve a little bit more explanation in the text material.

The, it's also in terms of your comments about the height of the canopy, in Rich's state there are many trees who hold their canopies far above the monitors height. It's not uncommon in much of the eastern and particularly the western forests to have canopies that would extend to, where the canopy would not even begin until 60 feet above the soil surface, so the effect in canopy height in the forest and particularly you think of a tall douglas fir forest or redwood forest, those things are really high up in the

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air, so I guess I'm inclined to think where is this calculation or the difference between the height of the monitor and the mid point or the height of the canopy, there are lots of agricultural crops that never get above a meter or even a few feet of height, it's astonishing to see what corn looks like in western New York, nine feet tall corn plants are sort of the rule of what you see on the most productive forest land that we've seen in this percentage. So, that is some additional comments that I would like to make in light of what Rich offered here.

DR. HENDERSON: Thank you Ellis. Rich, do you have anymore?

DR. POIROT: I thought I had, oh this is more of a just a question, a double check. In many cases the Sum06 and W126 are put together where the so called equivalent 126 values, W126 values are shown in parentheses and just wanted to make sure those calculations were correct. I noted in the old, before the correction plot of just scattering the W126 and Sum06, it looked to me like the slope was somewhere around .9, that is even though 24 hours were considered of the W126, it was still lower, at least according to the line, than the Sum06, but after it was corrected that slope dropped down to like about .75, but yet

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you're, when you put these equivalent W126 numbers, they all look like they're about .9, I assume those are right, but.

MR. HARRICK: Yeah, we'd have to correct that, that's something we'd have to, it wouldn't change terribly much, but we'd have to correct those equivalent numbers in Chapter 8.

DR. POIROT: Yeah and maybe they've already been corrected, it was just something that caught my eye, we wouldn't want to go forward with a recommendation, especially since you seem to be somewhat pushing, emphasizing how better responsive 126 is in some ways than the Sum06, we wouldn't want to then go forward with a number that we didn't need. That's all I have to say, on balance I thought it was a nice job, nice and short and concise and to the point. It's unfortunate that we don't have more new work to support this in more detail.

But I certainly want to echo what Ellis said, I think it's just so important that we at least consider if there's a biological response that responds to a different metric, than we shouldn't try to keep covering it with, by this rubber stamping procedure. That being said, the discussions that we just had earlier on Chapter 6 may turn all of this into a rather

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moot discussion because I suspect that, for the ranges that have been proposed by staff for consideration of a secondary standard, probably a primary standard at .7 and below will be below the lower end of the range that we've been talking about.

And so therefore, my last point will be that I did observe you quoted from the 1997 consensus building workshop reported out by Hector and Ellis that for effects on natural ecosystems we were looking at, at least for visible injury symptoms, something like 8 to 12 PPM hours was the range there and yet the minimum range considered later on is up around 15, so that's all I have to say.

DR. HENDERSON: Thank you, Rich. Paul, you're next.

DR. HANSON: I also thought it was, to characterize Chapter 7 I'd say it was an incredible job with the information that was available including a few surprises, pleasant surprises and I'll come back to that. I'm going to move through, not cover everything that I've written up, you can read on those yourselves, but I'll hit some highlights.

On page 7, question four that we were supposed to address was, "Have you done a good job of addressing the uncertainties associated with the expose

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analysis?"

And my assessment was given the data available, you've done an excellent job with characterizing the physical uncertainties of the of the exposures, whether that's internal or external, but you sort of not allowed for the fact that there are biological uncertainties associated with the database that you have available and not that you can do that, I don't think the data would support a strict analysis in that respect, but you need to recognize verbally in the document that there are significant uncertainties associated with the availability of biological information covering the full range and the genetic variability of the sensitivity of plants and animal, what have you, located throughout the nation.

The studies that we have available target very specific species and subset or cultivars of those species and you just need to recognize it, allow for the fact that we have a big unknown in terms of the biological responses that really exist in the real world.

The next comment deals with the 10% adjustment which you've already actually done a pretty good job of addressing my concern and that was that you'd included and you'd gone back to include the

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background calculation, I think that's really important. You don't want to fall into the trap of only providing there is only a one correct answer scenario for the decision makers and for the panel to deal with or yourselves to deal with in your staff paper deliberations.

In the ecosystem section, I think the sentence that you propose is perfect. It's difficult to quantify the contribution of ozone due to the combination of stresses present in the ecosystems. Clearly the connection of ozone to ecosystem response as a whole is important, but we're not really in a position to judge it's fractional contribution to changes that might be seen in ecosystems.

Rich brought up a point which I wasn't going to emphasize, but since he brought it up about the section on 714, some of his concerns about maybe it not being clear what they were getting at or what they were wondering, I think might be helped if that section were subtitled "Climatic Change," and he did include the fact that we really don't have enough information about the combination of all of the factors that will be relevant in the future. We have CO2 studies, we have one really decent CO2 by ozone study, we don't have CO2 by temperature by ozone studies in any system under any

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experimental regime and so it is important that you in the document suggest what information is available. I think you should cite some modeling results where they're appropriate and where they have dealt with multiple interacting factors, but you have to recognize that they're model results and not reality and there are some of those out there that aren't included here and I think they've come out more recently than what it would appear to the CD.

DR. POIROT: Could I just butt in quickly while we're on that point and there's that sentence that I objected to especially where, we're talking about what's known, talked about the effect of enriched CO2 as more than offsetting the effects of ozone. It wasn't clear what effects of ozone are we talking about, the existing effects of ozone, the effects of increasing ozone that would be caused by the increasing temperature that we haven't considered, so it was just not...

DR. HANSON: Just for information purposes, in the studies in question, it's actually across the board, it's photo synthetic responses, it's growth responses, they're seeing a general pattern. Let me just to something else Rich mentioned before I finish with my list of things. Rich, you asked the

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staff to make sure they provided response curve data relevant to Sum06, W126 recalculated appropriately. My question is when you go back and you try to regenerate based on old crop response data or whatever data, the preceding response data might be available, and you want to generate a new index that wasn't generated by the original researchers, do you have hourly ozone data from which to regenerate that response surface, in which case it could be calibrated to a 12 hour daylight scenario, which is like the point you were making before?

MR. HARRICK: We do already have a 24 hour, we do have 24 hour indexes already calculated against the enclan and the tree seedling data, so we already have that done. But, there is a database out there, it takes a long time to do something like that, I mean to do a completely new index.

DR. HANSON: Yeah, but when you talk about generating a W126 that maybe you hadn't had a figure for, when you go back to do that, is the X axis for those figures generated from original hourly ozone data or are you approximating some conversion from one index to another.

MR. HARRICK: I'm confused what you figure...

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DR. HANSON: I'm not asking about a specific figure, I'm asking we've been, there's been some request that in some cases you provided W126 figure analogous to Sum06 information that's already in the document. To get the X axis, do you get the W126 value from original ozone data or are you some how or another doing a translation, an approximation of Sum06 to 126 conversions?

MR. HARRICK: The values that we have in Chapter 8 are approximations from that relationship between W126 and Sum06 and the actual reason we picked 21 is Henry Lee's analysis of the enclan data and the tree seedlings, that was an analogous number to, approximate analogous number to Sum06 to 25 with the effects.

DR. HANSON: Okay.

MR. HARRICK: So, they're sort of two different ways of looking at it.

DR. HANSON: That's for characterizing the exposure from the existing concentration database, but if you want to relate that to the response, the original response surfaces enclan data for example, wouldn't have been calculated with 126, correct? How do you generate a revised enclan response that's appropriate for application to W126?

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MR. HARRICK: We have all the hourly data.

DR. HANSON: Okay, that's all. On 728, line 26, this is briefly, there was a statement that the current max may not provide adequate protection at this point, that the current max may not provide adequate protection, I thought at that position within Chapter 7, this is page 728, line 26, that was a premature statement, you really hadn't talked about effect issues yet, you just talked about the exposure metrics.

On page 741, you begin to talk about briefly the new studies developed with face technologies and I think they really do hold promises and means for generating exposure response data on down the line, but we need to recognize that that's not how they've been utilized to date, they've been set up and run primarily in a climate change manipulation mode and some serious consideration is going to have to be applied to using those data in an ozone exposure response arena as it relates to where the plants were in the ring, gradients of ozone within the ring, where the concentrations are measured in the ring.

If you don't know and you're on the panel, the ozone is released in a circle around the ring, there's one point in the middle that's used as a

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control point and a monitoring point for ozone and there are gradients that exist across the ring.

It may in fact be a good opportunity to develop exposure response surfaces, it may in fact be a continuous response across the ring, but it's going to have to be supported by some sort of concentric ring based assessment of the ozone concentration and exposure.

On page 743, the authors attempt to use some soy face data in contrasting that from year to year with model expectations from crop response functions, but I think it's totally confounded by the Hale data, I would recommend removing that section all together, I don't think you can make the conclusions you're making at that point.

Page 757, you talk about populous data and the only thing I wanted to say about the populous data, it comes back to available information on plant or clonal specific responses is that an extrapolation of those data in particular, they cover a great range of the clonal sensitivity to ozone ranging from plants that are hypersensitive to those that essentially exhibit no response to ozone.

The question becomes how do you average that data, how do you export that to the national landscape?

There's a map in one point, I forget which figure it is, it's listed in my comments, where it's listed as the mean populous response for the United States and my question is, you know what clonal data supported that map, what exposure response surface supported that map?

And then to my pleasant surprise is that on page 758 to 760 where you're discussing the use foliar injury, that section starts out actually with a long litany of reasons why this isn't going to work and I was really pleasantly surprised to see how useful the analysis you conducted turned out to be. I really believe the foliar injury data my have actually found, in my opinion, a really useful role as a semi-quantitative assessment of exposure.

The data will never become a quantitative measure from which you can characterize appropriate exposure or standard levels with respect to welfare approaches, but it nicely demonstrates the magnitude and the regional nature of the vegetation response to ozone.

I guess I've got one more thing and then the rest I have is for Chapter 8. There were some figures, or on figures 5-5 to 5-9 in the technical document, these are box and whisker plots associated with individual crop responses to ozone and there's a whole

section of graphics that deal with tree seedlings as well, I thought those were really useful and a subset or an example of those would be useful to be brought forward in Chapter 7.

I thought that those in a decision making position, it would be of interest to them how the individual species differ and the different tree species differ, but if you're going to put them in, you're going to have to give them some information on whether or not they should put any weight on a given species.

That represents the data that are available, but it doesn't provide the decision makers with any information about how they should judge the importance of one versus another. I think that's it.

DR. HENDERSON: That's it. Okay, well move on to Allen, who is our last designated reviewer for this chapter.

DR. LEGGE: Well, I don't really know how to begin because I'm afraid I'm an outlier from the other three. That being said, I found the chapter to be extremely well done and well written, I didn't have a problem with that at all. My problem is the fact that basically what is here is what was here a decade ago in the other, in the previous CD and the decision,

the way I felt about the use of open talk chamber data in the 1996 CD is exactly the same as I feel today. I do not feel that you can use it.

Now, what that all means is that the presentation is kind of a house of cards and the reason I say that is you have to read the little red book, and I guess I wasn't feeling very well at the time, so I read the red book first and then I read the staff paper and Chapter 7 and I think it would really, really be informative for people to actually go through and look at each one of the steps that staff undertook in order to do the calculations to reach the endpoints in, for example, making the agricultural crop assessments, how did they generate the monitoring data across the country? Because what's missing is the uncertainties and how error is propagated from the very beginning to the end.

I mean, I thought what staff did was elegant, I thought it was really, really very imaginative, but I had a hard time determining whether I was dealing with science or science fiction in the end of the day. But, I don't blame you, you had no choice for, if you read in, I believe it's in Chapter 8, the administrator makes a point where it says, "in the final rule, the administrator points out to the results of this

workshop," and this was this expert workshop, that there was a rationale for having a secondary standard and it was needed and I agree, I just don't think that the science is there in the indices that are proposed to support that and I'll say why in a minute.

But it goes on to say, "she felt that this consensus report foreshadowed the direction of future scientific research in this area, the results of which would be important in future reviews of the secondary standard." and nothing was done for a decade, so we're basically where we were ten years ago, with a few kind of hints that vegetation are extremely sensitive, that we need some sort of a standard to protect vegetation, but I find it difficult to accept the idea that you can use concentration response functions that were generated by open top chambers on cultivars that were generated in the '70s, used in the '80s and are being applied to cultivars in the '90s or in 2001 and assuming they're genetically the same and have the same tolerance profile or sensitivity profile.

I mean, that may be the case, but it's like years ago where people talked about buying hamburgers and not finding any beef in and they say, "where's the beef," I mean where's the proof, where's the, you need to have some research, you need to have evidence to

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support the secondary standard, you need to have the science. I mean we can see it in the foliar injury and we definitely need a secondary standard, I just don't think from what I've seen that the case is made. But, I'm one out of three or one out of four, so.

DR. HENDERSON: Okay, I'd like to know if others have comments on Chapter 7 in addition to the four that we asked to review it specifically? Okay, Ellis you're our lead person here, do you have anything more to add?

DR. COWLING: Well, I guess I would add one thing. The statement that was just quoted from the administrator thinking that we ought to learn something in the next decade as was pointed out, this area of research, even ozone as a criteria pollutant is now very much off the radar screen of the leadership of the EPA today.

EPA did not choose, and neither did the other federal agencies for that matter, choose to make investments in additional research of the sort that was just suggested and the evidence that, the question of the susceptibility or sensitivity of the genetics of crop plants is certainly a valid criticism, but I would say that the genetics of the tress involved is not so very different as the crop plants could be, so that

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once again we're, shall we base our judgements on the crops that are important to the welfare or the people or should we also deal with the questions of the forest, which are not by comparison with agriculture, very much different genetically than they were.

The only part of the United States where significant changes have taken place in the genotypes of forest plants is in the southern states where we have had significant genetic improvement, but the way the trees are tested, they're tested for ability to grow under ambient conditions and ambient conditions certainly include ozone exposures and other oxidant exposures, so that's the only additional comment that I think I should make.

I gather you're planning to break up for lunch and I'd like to know what time I should get back on the line here so that I can rejoin the group after the lunch hour is completed.

DR. HENDERSON: Well, to answer that I'll let Fred tell you about our lunch plans, but are there anymore comments on Chapter 7 and did you get what you wanted from CASAC for Chapter 7? Your nodding your head, I'm just telling the people on the phone that he's nodding his head. Okay, well let's let Allen and then Fred.

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DR. LEGGE: I do have a question to get some follow-up, is there anyway that starting from the very beginning going from the, going back into some of the enclan data and not just assuming that the response functions are, do reflect reality, can you get some kind of an idea of how uncertainty is propagated when go from the beginning all the way through the various analytical steps and if you just look at the table of contents in the front of the associates report, you can see the various steps.

Because for example, when you look at how concentrations the potential ozone response surface, I think that's what it's called, is created you really have to pay attention to the text to figure out exactly what, how this was done and you're not really sure whether it's really worked to the extent that you're making the assumption that it has and Rich would actually be in a better position to talk about this than I am.

But if you look at the eastern U.S. you're 12 kilometer grids and then you come to the west and you use 36 kilometer grids and you did that because of the monitoring data. In the, I believe in the east you used the monitoring data whereas in the west, you generated the air quality data or it's the other way

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around. There's just so many places where there's uncertainty, I'm just not, if I looked at those economic estimates, I wouldn't believe them, they could be really, really low or not high enough, I just, but to go back to what I said initially, I think this is elegant, I really do, I think you did a fabulous job, I just don't think the evidence is there to support what you've done. That's all.

MR. HARRICK: I think it's possible to better characterize uncertainty, I can say in general that we under predicted exposures when we compared them to actual monitoring data, so we're being conservative with the actual exposures, I don't think we're overestimating our effects.

DR. LEGGE: Well, it's just when you go from one step to the next step, you're using data from the previous step to generate things in the next step which is used to generate things in the next step which is used to generate things in the final step and what does this mean, I mean which direction are we going?

I just, I stopped at that point and I said well, maybe I should read the health stuff and then I've listened to everybody in the health stuff and they're just in the same, they have more "evidence" to base what they're doing and yet we see effects on

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vegetation. You know, I feel like I'm trapped.
DR. HENDERSON: Fred, you want to...
DR. MILLER: I have a question for Allen and that is if you looked at the figures that they showed on the slides with 719 and 720 where they're showing the comparison to the Sum06 and the current ozone fourth highest and that correlation pattern, given you're statement about you don't really have the data, I guess I'd like to ask you what harm is there in the conversion starting to move towards something that is more relevant because and so that's the first part and then the second, I want to make sure that James did his math right here that the 25 PPM hour upper range, that corresponds to basically the current standard of 0845 or 085 in terms of exceedance so that the range proposed is anywhere from the current equivalent translating the eight hour max thing over, how you got 25 PPM hours, how does it compare with the current 8, .08 I think it's the same?
MR. HARRICK: I'm sorry, can you ask that again?
DR. MILLER: Explain the range 15 to 25 PPM hours, I think 25 PPM hours for this calculation corresponds to the same as the 8 hour fourth max.
MR. HARRICK: That's what was proposed

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last time and they came up with that number from the enclan data to protect 50% of the crops that were studied.
DR. MILLER: I see.
MR. HARRICK: And from 10% yield loss, so 50% of the crops would have more than 10% yield loss at that number and 50% would have less, so that's where that number came up in the last review.
DR. MILLER: So, it's just coincidence that the amount of time above .06 that you're adding the hours adds up so close to that number?
MR. HARRICK: I believe so.
DR. MILLER: Okay. So, then Allen, please answer my question to you about the concern you're raising if it still makes you back off and say you'd still rather see the eight hour max, you know average used.
DR. LEGGE: Well I guess, I don't know, the response functions were generated in chambers, which is not an environment that is the same as you're going to find in the ambient, especially for crops and so while you can make a comparison, I don't know whether the Sum06 for PPM hours of 25, where they've made comments about there being very negative effects, would if you measured that out in the ambient

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environment, correspond to the same level of effect. In other words, are the response functions reflective and the limits that are put on them, are they reflective of reality in the ambient environment? They're reality in the open top chambers and the cultivars time, but today, I just don't know.
DR. MILLER: But, is this any different than in the health area of saying that the personal exposures are lower than the central monitoring site and yet we still are talking about the relativeness, so of it carrying forward that you can still assess the effect, so I'm trying to understand the strength of your objection and whether or not it would mean that I would vote differently.
DR. LEGGE: Well, I just don't think that the evidence that they've used, using open top chamber concentrations response functions can form the basis for the decisions cause the science, the science is good, but it's not relevant to the ambient environment, we don't have, we only have a little bit of information which suggests that there may be some relationship between the open top chamber data and the face data, which is more ambient.
DR. HENDERSON: Paul had a response.
DR. HANSON: I think you're searching for

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the reality as opposed to an assessment. I think the staff has done an incredible job using the data available to produce an assessment. It is a valid question to discuss and for them to speculate on, how uncertain that might be with respect to reality, but the data set are what we have available and I think we have to use that.
DR. LEGGE: Well, you know I just felt that ten years have elapsed and we don't have any new data and I just didn't think that the case was made, like I said, I'm one out of four.
FEMALE SPEAKER: Allen, could I ask you the weight you would put on the foliar injury, I'm sorry, could I ask you the weight you would put on the foliar injury information to be able to inform the selection of a standard or form of a standard or approach?
DR. LEGGE: Well, injury as you know is different plants will respond to different levels of a given pollutant, you know in different ways, so you really can't necessarily relate the presence of symptoms to a given concentration. So, it would be very difficult, the only thing you can really do, and I think that Paul really said it, and that is you can be, it's a qualitative comparison and I thought that that

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section in the chapter was excellent and that's why it was suggested that you try to do that because that's a new piece of information which supports the idea that yeah, even under the levels of the current standard, there are effects on the vegetation and these effects are reflected in visible injury.

Now, the extent to which that visible injury is going to have an economic consequence would relate to the end use, so if you're dealing with the lettuce crop or you know something where you're going to eat the foliage, you know then you could put some values on it, but in the case of looking at trees, maybe it would be an esthetic thing, but the problem is it's qualitative, you know either way, but I think it's very informative cause it's across the entire country.

DR. HENDERSON: Frank Speizer.

DR. SPEIZER: If I'm correct in remembering you introductory remarks, my concern would be how they relate to table 7-3 on page 754, because if indeed what you presented initially was an economic assessment of crops and you concluded that there was no benefits of reduction, I read table 7-3 as showing a rather dramatic difference of no overlap of maximum and minimum. Now, if I misremembered what you said initially, have you talked about something different

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than what's in this table?

MR. HARRICK: Well, what this table is showing is what benefits would we calculate at different rollback scenarios and no, we're not suggesting that these are not significant, we were saying between the 10%, doing a 10% adjustment from the monitor height to the canopy height didn't have a lot of difference, I mean you've got greater benefits calculated, but that's somewhere in the uncertainty, it wasn't very dramatic, this is very new data without the 10% adjustment so we haven't had time to really digest it all, we just sort of present the summary.

DR. SPEIZER: How do you interpret, in light of what's in table 7-3, which there is clearly a different here that you can not say is noise between 08 and 07...

MR. HARRICK: Oh yeah, between the different standards, we're not saying...

DR. SPEIZER: So, how does what you presented initially impinge on this or does it?

MR. HARRICK: It doesn't really change the story that the metrics or the levels that we're looking at don't have different benefits and that when you remove the 10% adjustment, they fall the same way, so we're not saying that's changing the relative

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difference between those standard levels. So, we're not suggesting that these aren't different between the different standard levels.

DR. SPEIZER: The other question I have is really back to Ellis who suggested that we use some qualitative pictorial demonstrations, are those going to be easy for staff to find as examples, I mean I can remember the height of tomato plants grown in a room with a Xerox machine versus a room without a Xerox machine, but the question is do we have, will they be able to have demonstrable pictures to use easily obtained?

DR. HENDERSON: Maybe Ellis has some pictures.

MR. HARRICK: I mean, there's a problem with producing them in a way that people can see them when you print them out and also copyright issues, if someone owns that picture I don't know if we're allowed to put it into the staff paper.

DR. POIROT: I think there's a Forest Service document that has some spectacular pictures.

DR. MILLER: Just do a Google search with pictures rather than with text and you'll find all of them that are available.

DR. MARTIN: If we can find relevant

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pictures that make the point, we're not going to be limited by how well they reproduce on paper, we can make them available as electronic files on a website, so that wouldn't be a constraint.

DR. HENDERSON: Okay.

DR. MILLER: I want to follow up on Frank's comments here on Table 7-3 because I hadn't looked at this, but now that I see it, this tells me that the proposed change with the Sum06 is a relaxation.

MR. HARRICK: Those are benefits.

DR. MILLER: This is a plus benefit, not the cost.

MR. HARRICK: Right.

DR. MILLER: Small detail.

DR. HENDERSON: Go ahead, Allen.

DR. LEGGE: Since I'm one out of four, if you had to make a choice as to what the summation index or the cumulative index to reflect exposure and you wanted to make a decision and put something forward, I would use W126 and the reason I'd use W126 is because it doesn't have a threshold. Now, of course the problem will come about with the higher concentrations, but in fact if you shift everything down so that you don't have many concentrations above 100, then you

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won't really have the problem, but more importantly you're dealing with, you're not assuming a threshold because there is an issue which is not covered in the staff paper and it's called hormesis.

Hormesis is an issue, it really comes out of medicine, but it's a case where you can have something that's toxic, but in a low concentration it actually stimulates and you get a positive response.

Well, there's evidence in the ozone vegetation literature that shows that in fact there's strong suggestions that that's the case. So, you know it's something to keep in mind because one could potentially use this to define, at least for a specific species, a potential threshold because initially you go up to a point where there's stimulation and then you're going to reach a point where the stimulation ends and then things will begin to drop off, now how fixed this is in time and space is another matter and it gets into detoxification and repair and you know a bunch of details, but I mean I like the idea of having a summation, I just would feel a lot more comfortable if the evidence supporting it was stronger.

DR. HENDERSON: I think we're going to need to break for lunch, but I'm going, because of the time and because we need to, we have to cover Chapter 8

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still and have some sum up, I think we're going to have to have a working lunch, unless you object to that. What did you say? I didn't hear that.

MR. BUTTERFIELD: Some people have to check out.

DR. HENDERSON: Oh, some people have to check out. If we could just have as brief a break for lunch as we can and we can bring our lunch things in here and finish eating, right Fred?

MR. BUTTERFIELD: Right. We've checked with the hotel, if you can have the buffet which we would recommend, go, pay immediately, bring your food back here if you can't eat it in the next 30 minutes and do whatever else you need to do in terms of checking out. Also, if you've not signed your travel voucher, Marsha asked me to remind everybody to do that before you go to lunch.

BREAK FOR LUNCH

BACK ON THE RECORD

DR. HENDERSON: Ellis, are you with us?

DR. COWLING: Yes, I am.

DR. HENDERSON: Okay. We're going to begin on Chapter 8 which is of course closely related to Chapter 7 and so we have the same designated reviewers and Ellis is the lead off person for Chapter

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8, so Ellis it's all yours.

DR. COWLING: Okay, well thank you Rogene. My reviews with regards to Chapter 8 can be summarized very, very quickly in just a few sentences and I formulated these sentences and they are in the written text of my comments that were sent in to Fred and Rogene.

The question that I'm answering from Karen Martin's charge questions was this, "Does the panel agree that the secondary standard options identified by the staff, including the indicator average time form and level, are consistent, are generally consistent with the available scientific and technical information and are appropriate for consideration by the administrator?"

My answer to that question and I'll just read this because I carefully crafted these sentences to be very precise. I believe that EPA staff have done precisely what should be done with regard to recommending firmly and persuasively to the administrator of EPA that the time has come to formulate and implement a secondary welfare based national ambient air quality standard for ozone that is distinct in averaging time, form and level from the primary standard.

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The scientific and technical evidence in support of the staff recommendations for serious consideration of the alternative cumulative Sum06 or W126 secondary standards is well developed and persuasively presented.

As shown by the references cited at the end of Chapter 8, the consensus view among expert persons in the ecological communities of this country and elsewhere around the world is that a secondary standard of cumulative form and extending over a whole growing season will be far more effective than a secondary standard that is not cumulative in form and does not include the whole growing season.

Thus, it is simply not appropriate to continue to try to protect vegetation from the substantial known or anticipated direct or indirect adverse effects of ozone by continuing to promulgate identical primary and secondary standards for ozone. This generalization is true for a wide variety of commercially important crop plants, but it is also true for the vegetation and a intensively managed and wild land forests, scenic vistas in natural parks and wilderness areas, ornamental shrubs and shade trees in urban, suburban and rural areas as well as the vegetation and natural grasslands, rangelands and other

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natural systems all over the United States. That is my conviction and I would commend something of this language for consideration for incorporation into the letter to the administrator. I think that's all I need to say.

DR. HENDERSON: Thank you, Ellis. Rich, what do you have to say?

DR. POIROT: I certainly don't disagree with everything that Ellis just said. I think there are some, I found some fairly...

DR. COWLING: Could you speak up a little, I'm having difficulty hearing.

DR. POIROT: I agree with you Ellis.

DR. COWLING: Well, how very nice. I'll shut up now.

DR. POIROT: I felt there are a number of very clearly crafted sentences in Chapter 8 that I think tell a story that are worth considering and among other things, I think it's key to note that vegetation effects continue to occur at levels that impact public welfare at air quality levels that just meet or are below the current standard, number one. Also, that a secondary standard option of Sum06 at 25 PPM hours didn't appear to offer more protection from foliar injury than the current 8 hour standard did, that was

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an important observation. In addition on page 10, there's the conclusion that the W126 form is a more appropriate biologically based and policy relevant cumulative concentration weighted form than Sum06.

Then as noted before, in the 1997 workshop results the consensus level for Sum06 was in the range of 8 to 12 for protection against foliar injury for natural ecosystems and so when we put all of these things together then I don't know necessarily then that the staff conclusion, which is essentially first to recommend as one option retaining the current 8 hour standard at 80, I don't know where that comes from, it's not supported by all of the preceding discussion. Nor would it be supported to set or propose an upper bound at the formerly proposed level of 25 PPM hours for Sum06 if the indications are that there are adverse effects on vegetation occurring at levels below that 25 PPM hours.

Furthermore, in setting a proposed lower bound standard, it's even stated in the, let's see what page is this on, close to the end of Chapter 8, they're picking a lower bound because it's close to the higher bound estimate that was derived from effects on seedlings in both natural settings and plantation settings that came out of the 1997 workshop, so it's

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illogical to me to pick a lower bound based on the upper bound of something else, and so overall then I didn't feel as though the range of recommendations from keep the current 8 hour .08 PPM standard to consider W126 or Sum06 in the range of 25 PPM hours, which is in many cases even less stringent than the .08 max 8 hours would be.

That range from 25 to 15 and the option to retain the current 8 just didn't seem to be supported by all the rest of the information presented in the chapter and the preceding chapter 7, so my inclination would be to consider a lower level of range and to also advocate as a first and preferred option a cumulative index using something like the W126. So, those were my comments.

DR. HENDERSON: Paul?

DR. HANSON: I think, I mean I agree with Ellis that I think the, well let me read my sentence and then I'll move on to a few specifics. Given the reality of the available data and the status of our understanding of the response of vegetation to ozone exposure and uptake, the proposed indicators averaging time forms are appropriate. I had levels in there, but I think that's the item for most discussion here I think, the group of us and the broader panel are

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probably in agreement that there is a need for a change in the form of the secondary standard. The concern about the age of the database available and the uncertainties around it leave open the question of what the level of that new form might take.

Along those lines, since Chapter 8 includes a discussion of key uncertainties in research, I'm going to say a few soap box words about research related to welfare effects in the past and then I'll pass the baton. But, Al in his earlier discussion on Chapter 7 points out that the data is aging.

In addition to that the people available to do the data collection related to welfare effects are aging or are gone and there's, I mean this is a real serious issue, we've got a real, I mean it's been upwards of ten years since the last significant big push of research was done on ozone, there's a few things going on, not funded by EPA, but there's a serious danger that institutional knowledge will be lost if baseline funding at the very least isn't maintained in this area.

Along those lines, following the last staff paper and criteria document, there was in fact a series of workshops held to identify research needs, perhaps, and I understand why money has been shifted from one

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thing to another to follow the squeaky wheel. I mean PM issues, legal issues came up and that's where the money wandered to and that's understandable and perhaps just looking at it from afar a diagnostic critique that I could point out would be the last summaries of research needs that I went back and looked at seem to be more of a wish list.

These are all of the things that everybody came to the meeting wanted to do with ozone. The problem with that is that represents a really scary financial number when you think about all of these things that need to be done and so my recommendation and my soapbox comment is that as we think about research needs we are going to have to look at all of the things that need to be done and prioritize them and make them available to the folks that are in the power to put money behind research as to items one, two and three that are cost A, B and C so that they can look at logical reasonable amounts of investment in a fiscally limited time.

DR. HENDERSON: Okay, Allen?

DR. LEGGE: Well, I guess given what I said earlier, you know at the very end where I say well I'm only one out of four, so I think the point has been made about the issue of really uncertainty in the

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database that's being used and the way in which it's been scaled up and the issues of uncertainty.

The one thing I didn't mention this morning was something I should have and that was related to the use of trees and in fact what's been done is they're using enclan or functions derived from open top chambers using pots, taking the biomass data generated by those chambers and then inputting that into a model called TreeGrow, which has not been validated for ozone and I was surprised nobody really said anything about that, but you can do this, but you don't really know what it means and so I think that the trees are getting the short end of the stick here and I'm surprised Ellis you didn't say anything.

Anyway, I think there may be a way out of this because I do believe that there needs to be a seasonal cumulative index of some type and the one that's been proposed that probably is the, well neither of them are biologically, totally biologically relevant, but the Sum06 or the W126 comes at least closer. The catch, and I think that Paul really made it clear, is debating upon how to set the level for this, the upper and lower bound and one way I would suggest as a possibility and I'll have to work out the exact phrasing so it's clear, but if you can go back

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into the air quality data that was used related to, especially if you can go into the hourly data, and look at the onset of foliar symptoms and see if you can get sense of at what level did these foliar symptoms occur, for example.

If you created a database where you could look at, for example .07 for eight hours and find out what the equivalent value would be for 126 for that time period and just see if there's some sort of a qualitative way of coming up with ambient, an ambient sense of how, for example the trees are responding. Now the crops, how do we deal with the crops? Well, there isn't really a clear cut way of dealing with the crops because there isn't, I'm not aware, maybe some of my colleagues are aware of visible symptoms that have been documented that could be related then to air quality in some way where you could come up with an indication.

The problem with going this way is that foliar symptoms do not necessarily relate to damage in the sense of biomass loss or yield loss, it's just an indication that there's a response and perhaps you're being too conservative by going that direction. But, at least it's a possible, you know way of getting at it. I would be somewhat concerned if you used methods

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to "generate the air quality," and then try to relate that to foliar symptoms, that would be, cause that adds an additional level of uncertainty cause what you really want to do is you want to try to come up with a way of describing the levels with a minimum amount of mathematical manipulation.

How you do that, you've got people who are far more smarter, far smarter in mathematics than I am, but there must be a way of doing it.

MR. HARRICK: I just wanted to ask, are you talking about the foliar injury reported by the U.S. Forest Service?

DR. LEGGE: Right.

MR. HARRICK: I'm not sure we could, they only look once a year at the end of the season for foliar injury, so they don't look periodically throughout the season to see when the exact moment it happens, so I think generally they go out in August or September so they're most likely to see, that's the time of year you'd see foliar injury, so they just do it one time a year.

DR. LEGGE: They don't do it over a period of time, so you can see the development?

MR. HARRICK: No, they don't. They just send, they have plots that they won't tell anybody

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where they are and they go out, we know what county they're in, but anyways, they only look once a year, so they send teams out and they're all trained to look for foliar injury, but this only happens once a year, that's why we have so many, they're able to have such good great coverage across the country. So, I don't think that would be possible to do unless we knew they're sampling date and we might have some sort of indication from that.

DR. LEGGE: Well, let me ask the question, how did you determine then that foliar injury was occurring in areas where the current standard was being exceeded?

MR. HARRICK: We used the data from, if there was a monitor in that county and they found foliar injury in that county, so these, cause the forest service, this is a whole other issue, but they do not make public where they're sites are, so they can tell us what county they're in, but they won't tell us exactly where they're at.

So, we have a problem to know if exactly, if that ozone that we're measuring in that county is very relevant to where they're measuring foliar injury and that is a problem with it, but as far as the way that EPA looks attainment, they look at the county level.

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DR. LEGGE: So, there isn't an easy way, that's what you're telling me?

MR. HARRICK: There is not an easy way.

DR. LEGGE: I think the challenge will be setting a level, whether it's, and you'll probably have to set two, one from trees and one for crops and maybe you can just do that by setting a range. I'll have to give that some more thought I think.

DR. HENDERSON: Okay, Phil you have something?

DR. HOPKE: Yeah, I just wanted to chime in here that this, we know ozone is the criteria pollutant at this point that's most important with respect to welfare effects in terms of crop and tree damage and I would suggest that, you know we've looked at setting knew standards in the face of significant uncertainties.

We've added PM2.5, we've added PM course standards with limited data on which to base it. I think in this case we have more than adequate bases to say that there is a significant effect of ozone on crops and trees and that we need to move forward with a secondary standard in this case to indicate that we need to get serious with regard to environmental protection as one of the important aspects of the

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Environmental Protection Agency and you know.

Therefore I agree with Ellis that we need to have a very ringing endorsement of this creation of the secondary standard. At this point, I don't get all that worked up over the level because it will get revisited, but I think setting the precedent of having a standard of significantly different form which matches the needs of the welfare endpoint is a very important precedent and I think it's incumbent upon us to strongly support this staff recommendation with respect to going forward and trying to make or convince the administrator, which I think this chapter helps to do in a good way, that it really is important, useful and necessary to do at this time.

DR. HENDERSON: Fred?

DR. MILLER: Well, I partially agree with you Phil, I strongly endorse what you're saying about the need for the different form of the standard, but if I'm hearing things right the Sum06 that was proposed at the upper level of 25 is equivalent to the current standard and there are studies that show demonstrable effects on crops and trees, so given we've been bold on the help, I don't see why we should accept a recommendation of 25 as the upper limit on if the Sum06 was used, so I'll throw that out, but then it wasn't

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clear to me on page 814 if staff is going to propose both Sum06 and the W126, you know and say pick on administrator as opposed to coming down on the side of one or the other and because this talks about comparable ranges and one of my questions would relate to does 13 to 21 correspond to the same range as the 15 to 25 on the other by the way they're calculated. So, that if you accepted my premise that 25 is too high on the Sum06, that you're 21 number would be lowered also.

MR. HARRICK: They're calculated the same way from essentially enclan type studies, I mean that's where, they're equivalent based on those studies. 10% of, generally 10% yield loss for 50% of the crops that were studied.

DR. HENDERSON: Am I correct in understanding that, I know that we all endorse the use of this cumulative seasonal standard for the secondary standard, there's no doubt in my mind about that, but what I heard was from the people most involved that the W126 was a better, better than the Sum06, is that part of our recommendation?

DR. COWLING: Rogene, I would say that W126 has a considerable advantage in part because it emphasizes the lack of a threshold, the Sum06 encourages the notion of threshold type of thinking,

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which I think both in the health effects area and in the ecosystem effects area we've come to think thresholds don't exist and therefore we shouldn't act as though they do exist. I think W127 avoids that implication and in that sense it is superior.

DR. HENDERSON: Okay, thanks Ellis, I thought I heard that from other people too, go ahead Rich.

DR. POIROT: Well, I wanted to maybe draw our attention to page 762, there's a table that summarizes the foliar injury data at different levels, both of an 8 hour max and also at Sum06 and just make the observation that in most cases the Sum06 at 15 PPM hours, which is the lower end of the range that the staff has proposed for consideration for Sum06.

In most cases the percent of foliar injury is greater than it would be were a standard set at .074 with the 8 hour max. What we're proposing .070 for the health standard and we want to have, well we kind of got into this with PM you know, is it most important to just get the different averaging time and metric on the table even if it's less stringent and therefore has no function than the primary, is that more important than it is to kind of do it right.

We went through this with PM, I argued that

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it served no purpose to have a secondary less stringent in all cases than the primary and in fact that was the way the administrator rejected consideration of the secondary PM standard was by making the observation, well if I pick a number towards the upper end of the range, it's not any more protective than the primary and so we don't have one or we'll set it equal to the primary. So, anyway I just think this 7-4 table has some useful information in it.

DR. HENDERSON: Well, what I, go ahead Paul.

DR. HANSON: I think we should be a little bit cautious in trying to match the two up so much. If in fact the administrator were to decide not to make a change in the primary, the administrator still has the option to make a change in the secondary.

In that event, we should have a level that we can support. Another issue related to the choice of the level is that from a human health standpoint, the decision has been sort of based and targeted towards protecting the most sensitive component of research, of interest.

In the case of vegetation or other welfare effects, I don't necessarily believe that that's the level of standard that we're searching for, are we

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going to the most sensitive plant species that's out there, no I don't think so. My own personal opinion, we're looking more at a mean species or mean crop cultivar type response as the basis for the standard for the response upon which we base a level.

DR. HENDERSON: Yes, Allen?

DR. LEGGE: I have a question to ask staff and it's related to averaging time. If you go back through the text there's the discussion about nighttime uptake and the fact that there's an underestimate of the amount of exposure.

I was wondering if you think about what the Europeans have done with their critical levels and they have similar problems with their level one descriptions, but rather than using 8 hours for example, they use daylight hours and I think that you might find daylight hours during the ozone growing season might be a really good, yeah the ozone exposure season, might be a really good compromise between using the 8 hours versus 24, because the suggestion has been made about using, you know all 24 hours because of nighttime uptake and the fact that at nighttime experiments have been run as 15% that's taken up at night.

The reason the Europeans chose daylight hours

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was because they felt that at least maximum uptake would take place during that period.

MR. HARRICK: Just to be clear, we're proposing, not proposing, we've laid out 12 hour Sum06s and not 8 hour Sum06s, so they'll be 8am to 8pm.

DR. LEGGE: Well, depending upon what latitude your at, other than California which the ozone season is all year long, I mean you're going to have, it just makes it a little bit easier to cover the other issue and reduce the amount of uncertainty associated with the nighttime stuff.

Just a thought. Because most of that was, you know the comparisons were done as I recall 8 hours, they were 8 hour to 24 hour comparisons weren't they? Or were they 12 and 24?

MR. HARRICK: For the Sum06? We had 12 and 24.

DR. LEGGE: 12 and 24. Because you know during the summer you're going to have 16 hours of daylight, it depends what you use as a cut off point for daylight hours.

DR. HENDERSON: Can the members of our ecological panel, the four members, can you tell me what you want to recommend, have you come to a consensus of what you want to recommend to the

administrator? I realize you all can get together and recommend something for the letter, but I'd like to hear now what you're proposing because on 814, nobody supports this continuing to set the secondary standard identical to the primary, I haven't heard any support for that, so what do we suggest? We suggest number one setting the biologically relevant secondary standard and what would you like from then on, I mean I thought there was a, because of what Ellis said that there was a preference for the W126 over the Sum, but I'd like to hear that from you all and what level, the level, do you have a range of levels?

DR. POIROT: Well, as I argued it initially, I didn't feel that the proposed options at the end of Chapter 8 followed from the information that preceded it in Chapter 8 and Chapter 7.

Specifically that maintaining the current 8 hour level just flat out should be off the table, rejected, we reject it. That it's critically important to establish a standard that does represent the different biological uptake mechanism, that kind of point number two.

Point number three for me would be something like the proposed range of the Sum06 standard between 15 and 25, to me seems to be higher than what is

justified by the information presented in the chapter and in Chapter 7 that precedes it, specifically 25 PPM hours in many cases is more lenient than the old 8 hour standard was and there is visible damage symptoms routinely observed at that level

So I think that now we're talking about criticizing and seeking I think to lower perhaps the 15 to 25 range, just to throw some numbers on the table, I would suggest something more like 10 to 15 PPM hours as the, for the Sum06 and to quasi justify that, I think that's the level at which tree seedling visible symptoms were observed in the consensus workshop in 1997 and it's even above the 8 to 12 level that we're talking about for foliar injury, so that would be my recommendation would be to reject the 8 hour max entirely, to go with a more biologically relevant index to suggest a lowering of the proposed range from 15 to 25 down to the 10 to 15 range and then finally to recommend the W126 as a more responsive index than the Sum06 and I don't have the math in front of me to do the conversion and we're a little confused about exactly what that was, but whatever it's equivalent, that would be my first preference.

DR. HENDERSON: Thank you, that was clear.

DR. MILLER: It's a non-linear conversion

obviously, you don't get proportionality, but you, if I'm hearing you right though, the biologically based, but the preferred is the W, then for the range for you said go off and calculate what that comparable is for the 126 and that would be your first recommendation, is that what I'm hearing?

DR. POIROT: That's what I mean.

DR. MILLER: That sounds quite reasonable.

DR. HENDERSON: And we could just call it the equivalent for the W126. What about you Paul, I mean is that what you have in mind?

DR. HANSON: I think that sounds fine, the only, I would think we would want, maybe we could add to that statement or version thereof, that the staff paper will then include, if you will, the examples of what you get for those standards.

Whatever metrics seem appropriate, maybe they're not dollar values, but whatever is acceptable, point out you know to go from where we're at now to this range, this is what you're buying in terms of yield or productivity in the forest or whatever you're able to produce given the data that's available. And then it becomes a value judgement you know, how much more productivity do you want to invest in, if in fact soybean yield is your example, if it's visual damage on

roses in somebody's back yard, that's a little tougher.

DR. HENDERSON: Allen, what do you think of those suggestions?

DR. LEGGE: I, again I'm one out of four so. I think you could get away with it as long as you define the level of uncertainty that you have when you're doing all your calculations. For example, like your agricultural loss estimates and whatnot, because there's uncertainties in the beginning from the concentration response functions, but that being said, those are the data, they've got pluses and minuses, that's what we have to use, we've concluded that we need a cumulative seasonal standard, so we just, as long as everything is made clear I think it's okay.

But, you must define the uncertainties associated with, you know with generating those levels. Either that or you're just making them somehow or other equivalent to the ranges that are currently being set and proposed for the primary standard, mean you're just making them equivalent when in fact we have basically said that vegetation is more sensitive than people, so you have to go and make sure that you're actually lower than the ranges set for the most stringent levels set for the primary standard.

It's kind of a goofy way to do it, but I

think that's the practical way to do it.
DR. HENDERSON: Do others have comments on Chapter 8 or what we've just been talking about? Well, I am going to depend on, I forgot, Ellis you're just not here in person, so I'm sorry, I overlooked you. Yes, what are your comments?
DR. COWLING: Let me, I think several very useful points have been made in the last, Bill Hopke, Fred, Paul, Allen and Rich all have made I think very useful contributions and I would like to commend those things, but I would like also to mention something else that was brought up earlier and this has to do if we are successful in getting recognition of the need for a secondary standard different in form from the primary standard, it will have two other important influences that were incorporated in the testimony that Waltec and I gave in 1997 before the then existing CASAC Committee and I'd like to read just a very small portion of that statement.
DR. HENDERSON: Sure, go ahead.
DR. COWLING: What we said was, "A secondary standard different in form from the primary standard will also accelerate and improve the process of public education about many aspects of the tropospheric ozone problem. These aspects include,

among others, contemporary ozone pollution causes a significant harm to crops, forests, ornamental plants and natural ecosystems in many parts of the United States.
Ozone pollution is a serious threat to the welfare of people and ecosystems in many rural as well as urban areas of our country. Ozone is the chemical precursor, ozone and it's chemical precursors are frequently transported from rural areas to urban areas and from urban areas to rural areas in many parts of the U.S. That is not often understood.
The air concentrations of ozone and other oxidants that cause harm to crop plants, forests are appreciably lower than the concentrations of ozone and other oxidants that cause harm to most people, that point was just made. Ozone pollution is not just an urban problem associated with high peak concentrations of ozone during exceptional weather episodes, but also a problem of longer term chronic exposures of plants to much lower, but still toxic concentrations under persistent weather conditions."
Then we added something about the research that all of us I think would be happier if we had and we went on to say, "A secondary standard, clearly different in form from the primary standard, will also

have significant and pronounced effects on the nature, quality and policy relevancy of ozone related scientific research that will be undertaking," and we said at that time, "during 1997 and beyond," we'd have to say now in 2007 and beyond.
"The very important objective of that research should be to fill the persistent gaps in available knowledge that have been mentioned by several persons here, decrease the continuing scientific uncertainties that have plagued those decision making in the past and if we do not change the way we think about the ozone problem, we'll continue to plague the periodic updates and CASAC reviews of the ozone criteria documents that are now scheduled to occur in 2002, 2007 where we are now, 2012 and 2017.
Those statements which were written in 1997 could just as well have been written as a result of this meeting of CASAC in 2006. That's my last word.
DR. HENDERSON: Thank you, Ellis. I am going to depend on the four ecological experts to get together and draft something for our letter. We've discussed as a committee What we want to do, but can I depend on, I'm looking at Rich because if you would take the lead, Ellis is celebrating his 50th anniversary, congratulations Ellis, by the way. And...

DR. COWLING: I'll be glad to join in this exercise.
DR. HENDERSON: Sure, okay, to see that that happens, because I think it's important that all four of you do that. Now, what I would like to ask now is with the exception of Chapters 6 and 8, well let me ask, do we want to see Chapter 8 again after it's revised, I mean do we want it to come along, we've asked to see Chapter 6 again, do you want to see it, the revised Chapter 8?
DR. POIROT: I don't really feel personally like there are major wording revisions that we're seeking. I think we're kind of really just proposing a little bit lower range. Either they'll do it or they won't, whether we see it or not isn't going to...
DR. HOPKE: There is one major change and that is removing the current, the primary form and so we would, we obviously would like very much to see that disappear from Chapter 8.
DR. HENDERSON: So, you would like to see it?
DR. POIROT: I would defer to the more experienced members of the panel in terms of desirability of seeing it again.

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DR. HENDERSON: Well, I see, Fred...
DR. MILLER: It's not that big, I want to see it.
DR. HENDERSON: I think there's a general concern that we see Chapter 6 and 8 again, but on the other chapters, if we can, are we satisfied with the science that is in the other chapters that if the comments we have made are taken into account that the science in those chapters is adequate for rule making and that I need to know from everyone. Is there anyone who is not satisfied? Yes, Barbara?
DR. ZIELINSKA: I would like to only say that we discussed this problem of policy relevant background in Chapter 2 and I don't know if anything is going to be done concerning the subject.
DR. HENDERSON: Okay, that was a subject that, what are you plans?
DR. MARTIN: I'm sorry, I didn't understand your...
DR. ZIELINSKA: Well, this topic of policy relevant background in Chapter 2, we had some problems with that and I don't know if it's going to be changed in the next version or not, so this is my question.
DR. HENDERSON: Policy relevant background.

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DR. MARTIN: There will clearly be changes in the discussion of policy relevant background, of that I'm sure, to reflect the discussion we had the other day. We also talked about we still need to maintain that concept and deal with it, but in the broader context that we discussed the other day and that's what we'll intend to do.
DR. HENDERSON: So, there will be changes in the wording? Anybody else, yeah Mark?
DR. LIPPMAN: The issue of policy relevant background as I recall never arose in our discussion of Chapter 6, is that correct?
DR. ZIELINSKA: No, it was in Chapter 2.
DR. HENDERSON: It was just briefly brought up I think by Jim.
DR. LIPPMAN: It was brought, but I don't think it was in the document, the Chapter 6 document, any reference to policy relevant background.
DR. MARTIN: Because the use of it is embedded in the quantitative risk assessment, we talked about the quantitative risk assessment results, but it doesn't have any independent function in terms of the standard recommendations outside that quantitative assessment.
DR. LIPPMAN: Well, frankly I don't much

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care what you say about it as long as it doesn't influence the setting of the standard, you know that was my concern, that it would influence the setting of the standard and if it doesn't, I don't care what you say.
DR. VEDAL: Well, it depends Mark whether you think those plots in Chapter 6 influence you decision on the setting of the standards.
DR. SPEIZER: It also plays into how much of the uncertainty is discussed because I think if you accept what we talked about yesterday in terms of dealing with the Deltas, that tend to minimize the importance of the uncertainties and that's in Chapter 5 or 4, I can't remember which it is, but I think that would have to be sort of brought into those chapters as well, even though we're talking about how it's used in Chapter 6 and along those same lines, if we are to use, I think we had a consensus that we wanted to use emergency room visits for asthmatics, that will have to be I think expanded in Chapter 5 a little bit as well, I just don't know where it fits exactly, maybe Chapter 4.
DR. MARTIN: I don't recollect that the end result of our discussion on emergency department visits that we would formally include it as part of an

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additional risk assessment. We did talk about how we would differently discuss this perhaps.
DR. SPEIZER: Okay, fair enough, fair enough, so it would be discussed differently. But, I think, do you have to carry that discussion back to Chapter 4 and Chapter 5 as well, I think, so that's sort of assumed if we're going to deal with it in Chapter 6, you're going to have to make some changes in the earlier chapters as well.
DR. HENDERSON: And I think the use of the Delta is very important because it eliminates the problem of the background, I mean but that will appear right?
DR. MARTIN: I see no reason why we wouldn't include changes in estimated risks from one standard to another as another metric that we put, calyculate and include in Chapter 5 and bring forward in Chapter 6.
DR. SHEPPARD: Along the same lines as policy relevant background and things that happened earlier that are going to affect Chapter 3 is the use of the FEV data and the logistic function and the implications that may have. I wouldn't mind seeing what that new figure looks like with the uncertainties, but I guess if that gets incorporated appropriately in

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5 then we don't have to see 5, but it has huge implications for 6, potentially, so.
DR. SPEIZER: I understood from Fred that we will actually see the whole document.
DR. HENDERSON: After it's final though, right?
DR. SPEIZER: Well, no the next version we see.
MR. BUTTERFIELD: The next version you see is not, is no longer a draft. There is not the time into the schedule right now for another review draft because we go out, not only to CASAC, but also to the public. So, on the first of October you will be getting the CD ROM version, or shortly after the first of October, you'll get a CD ROM version of the entire staff paper and I presume the technical support documents as well?
DR. MARTIN: By the end of October, we talked about.
MR. BUTTERFIELD: By the end of October you'll see the...
DR. MARTIN: Our target for completing the staff paper and the related assessments was the end of October, not the 1st of October.
MR. BUTTERFIELD: Oh, I'm sorry, I thought

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it was the first of October. Okay. Very good.
DR. SPEIZER: That's okay, is it possible, Karen, for you to provide us when we get that CD with some kind of cover letter indicator where some of the changes are?
DR. MARTIN: I would be more than happy to.
DR. SPEIZER: That are in the other chapters that we're not formally reviewing, but to sort of point us to where you've made some of those modifications.
DR. MARTIN: I think it's perfectly reasonable that the cover that we use to send that out would highlight the key changes we've made, reflecting these discussions and where to find them.
DR. SPEIZER: Good.
DR. HENDERSON: But what can we do about 6 and 8?
MR. BUTTERFIELD: Okay, Karen I'd like to ask your staff at the same time you send the CD ROM that we also include hard copy versions of Chapter 6 and Chapter 8 and I will schedule a teleconference to take place, I was thinking three to four weeks after you all release that, so now we're looking at the end of November to have a teleconference, four hour

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teleconference with the ozone panel, public teleconference to provide advice, additional unsolicited advice on Chapter 6 and 8. Now, of course if the panel, if there's a consensus among the panel informally that you don't need to do that, we can always cancel that, but we will schedule that teleconference for the end of November.
DR. HENDERSON: Okay, now as far as the letter to the administrator from this meeting which is going to be difficult to write, I would like for everyone to get their final comments on the document to Fred and I by the end of next week, a week from today and then suggestions for what you would like to have in the letter are always helpful, so if you could send those at the same time, particularly for the welfare section because that's something that I really need your words on what you want. I made notes on the changes you wanted, but I really need that. Yes Fred?
DR. MILLER: Can you clarify if we agreed or we didn't agree in terms of our letter what James was suggesting of it being shorter?
DR. HENDERSON: Well, I was informed by other people that if we really wanted this to have an effect, we better be emphasizing clarity rather than brevity, so in completeness, because if we don't give a

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complete argument why we want what we want, it will be...
DR. MILLER: And I understand and you can do that in two ways, you can do it shorter in the main body and have it expounded upon in an attachment and then part of the reason for asking is you've forgotten to say lead discussants I want you to draft the thing, so I need to know if it's going to be in something separate or is it be drafted as part of a single letter.
DR. HENDERSON: Oh, okay. Fred Butterfield has another suggestion, on Friday 9/1?
MR. BUTTERFIELD: Yeah.
DR. HENDERSON: Well, that's next...
MR. BUTTERFIELD: I'm thinking one week from today, any members who need to provide individual review comments, either your initial comments or revised comments, get them in to Rogene and to me and also all panel members get inputs into your letter to the lead discussants for your chapter or technical support document also by next Friday. And then I would like to ask the lead discussants by the following Tuesday or really Wednesday, because it's a long weekend, get their compiled or synthesized letter inputs into Rogene by Wednesday the 6th and then Rogene

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you can probably have that synthesized or compiled by a day or so and I'll turn that around in 24 hours. So, I'm hoping by the 12th of September you will have a V1 draft without appendices of course, but by the 12th of September you will have first draft of this letter for circulating for concurrence.

DR. HENDERSON: The lead discussants should get together with the members of their team by 9/1, but get those, you're agreed upon paragraphs for the letter by the 6th. It has to be the 6th because I am leaving, I will be reachable, but I will be in Europe from September 7th through September 20th and I'll be looking and I can edit things and okay things by email, but I don't want to be putting it together, so really if you would get it to me by the 5th, then that would give me the 6th to pull it together.

MR. BUTTERFIELD: I will reiterate this in an email to Pete the first thing Monday morning.

DR. LIPPMAN: As the lead discussant on Chapter 4, I will be leaving for a European trip on August 31st, so if you really want to influence Chapter 4, get it to me early next week.

DR. SPEIZER: As the lead discussant on Chapter 5, I'm leaving for Europe on September 2nd.

DR. HENDERSON: Okay.

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DR. BALMES: Why doesn't everybody go to the ISCE meeting?

DR. HENDERSON: So, that's good that we know these schedules because we need to get, I would like to see this done, you know taken care of as soon as possible. Yeah, Fred?

DR. MILLER: Maybe it was sent and I lost it, but could you resend, I might be the lead discussant for 3, who else you asked to provide comments so we really know who is on our team?

DR. HENDERSON: Sure, it's on my...

DR. MILLER: As I said, I probably lost it.

DR. BALMES: Charlie, me and Jack, I don't know Jack.

DR. MILLER: I'm telling you that I'd like you to resend it because I have had computer problems, etc and I don't trust that I have, unless it's a hard copy that I can take away right now from the package, then I'd be glad to do it.

MR. BUTTERFIELD: It's in the package, but I will send that to by email as well.

DR. HENDERSON: It's called chair memo July 21st. Yes, Allen?

DR. LEGGE: I'd like to ask the staff one

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more question, if I could?

DR. HENDERSON: Sure, of course.

DR. LEGGE: It's an easy one. We talked about the seasonal cumulative sum for, you know for crops and that was three months, but what about trees because there are some numbers and ranges set for the trees, but I didn't see anything anywhere where the duration for the trees, unless I missed it, was it six months, was it a year?

MR. HARRICK: It's three months also, the maximum three months.

DR. LEGGE: Because I wasn't sure and if Ellis is still on the phone, do you recall Ellis from the meeting in Raleigh where they talked about the range for, in this particular case, it was for three months, 12 and W126, 12 hours for W126, whether or not the averaging of the length of the season for trees was it six months or three months?

DR. COWLING: I believe that the consensus judgment was three months, but it was a matter of contention, I mean those of us who live at lower latitudes know that the growing season isn't just three months long and this, I must say that my sense is that the consensus view at that time was that giving a secondary standard different in form in the first place

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was sufficiently important so that an attitudes taken by the administrator when she rejected it, the arguments for having a standard different in form. If we were to get a secondary standard different in form, whether it's perfect or not, we will soon learn whether we still get damage to our crops and forest plants or the shade trees or whatever, in time. But, the major step is to get a standard different in form and then to start tweaking it to improve it.

DR. LEGGE: Then I think what needs to be done, I think staff would need to indicate in the text that the uncertainty associated with that growing season with respect to trees and the fact that if you're only using the three months, that in fact the numbers would likely go up, if you're talking about the six. And then the same thing would be true for looking at the "the averaging time" in terms of 12 hours versus daylight hours versus 24 hours, so that that issue is covered and then I think you're fine.

FEMALE SPEAKER: The data we had for tree seedling, I'm sorry, the data we had for tree seedlings was made into equivalent exposures of like 92 days, three months, and so that's why we have those concentration response functions in terms of that, but we do recognize that it would be the whole growing

season for deciduous trees and then of course for coniferous, who knows.
DR. LEGGE: I think that should be mentioned in there, but you don't need to make a big deal out of it, but I think it would make a difference if it was there.
DR. HENDERSON: Okay, any other final questions or concerns?
MR. BUTTERFIELD: I just need to clarify something from the staff. Okay, on the basis of now OAQPS completing the final staff paper by the end of October and presuming that you're going to be able to get that out to members by the end of that following week, i.e. the 3rd of November
We need to have two weeks for members to look at that so the dates I'm looking at for the teleconference are the 20th and 21st of November, which is Thanksgiving week, Monday and Tuesday or the following week, 27th of November though the 1st of December and possibly the following week, 4, 5 and 6, Monday through Wednesday, those are the dates that I will canvas member's availability.
My question to staff is is that going to be adequate considering it will probably not be then until the end of December until we get a letter back to you

with the results of that teleconference? Is that an adequate time frame?
DR. MARTIN: There's no bright line adequate, sooner is always better than later, but that clearly is within the time frame that we will be deliberating on the issue.
MR. BUTTERFIELD: Very good, thank you.
DR. HENDERSON: Okay, Fred is there any other thing...
DR. SPEIZER: Can I raise one other issue?
DR. HENDERSON: Of course.
DR. SPEIZER: Karen, the deadline is in March. If we were to find some really significant issue at the end of what turns out to be I guess December, is it possible for your to incorporate it? I mean we're talking about three sentences.
DR. MARTIN: Well, by definition it's possible that the input you have could be incorporated into the thinking that will inform the rationale put forward in the proposal, which would come out at the end of March, if that's what you're asking, so it's possible.
DR. SPEIZER: I'm just saying that it's not like we're dealing with a fait accompli at the end of November that we just simply get to read.

DR. MARTIN: That's fair to say.
DR. HENDERSON: Good, so we can make our comments. I have, I think we have done a wonderful job considering how complex and difficult this task was and I want to thank everybody for the huge effort that went in from both the EPA Staff and from the CASAC panel. A tremendous amount of work was put into this, so we haven't quite finished, but we are well on our way and I want to thank everyone for coming and for such a great meeting and...
DR. MILLER: Rogene?
DR. HENDERSON: Yes?
DR. MILLER: Harvey Richmond set me straight and I have to make it available for the public record. I misread the memo and there were only five of those studies that were actually below the current standard, I was looking at the mean for the studies, so disregard all of that diatribe and but there's still some there.
DR. HENDERSON: John?
DR. BALMES: As another person who had an occasional moment of diatribe, I just wanted to say that I really appreciated the staff work up to this meeting, but during the meeting as well and I thought you were incredibly responsive and appropriately

interactive and I look forward to seeing the next version of the staff paper.
DR. HENDERSON: And Fred has the final word, Fred Butterfield?
MR. BUTTERFIELD: I too want to thank the members of the panel and EPA staff for an excellent meeting. This is likely the last face to face meeting of the CASAC Ozone Review Panel during this review cycle of the max and I want to thank you for excellent work. We will of course be meeting at least one more time via teleconference.
It is also the last face to face meeting for Dr. Fred Miller and Dr. Barbara Zeilinska as full CASAC members and I would be remiss if I did not thank them from the bottom of my heart for all their efforts over the past six years. They're not being bounced from the panel, they're simply or the committee rather, they've simply reached the limit of their time allowed, however I do expect that we're going to able to convince them to remain on both the ozone panel and the lead panel until we complete our efforts there, but thank you very much for all your service.
And no decisions have yet been made of course on membership for the two CASAC members who will be coming on board to fill those slots and I don't expect

the appointment will take place until around the first of October. But, Dr. Legge, do you have a comment too?

DR. LEGGE: Yeah, in the last cycle we had, we met and discussed the research needs document, which never went anywhere. Is there going to be a research needs document produced by the Agency after the CD's finished, but after the staff paper is done?

MR. BUTTERFIELD: Karen, would you like to comment on that?

DR. MARTIN: It's hard to speak for the Office of Research and Development, but I am not aware of any plans to produce such document. We have of course embedded some research highlights here which would be carried forward out of this review into future planning work to the extent that your comment letters offer any further specificity in that regard, that would be helpful.

DR. LEGGE: I guess what I'm driving at is how do we motivate the Agency to do something after ten years?

DR. MARTIN: You don't expect a simple answer to that question, do you?

DR. LEGGE: Just thought I'd ask.

DR. MARTIN: And while I'm speaking, let me just also add my thanks to you all, I've found the

discussion to be extremely helpful, well focused and we will come away with a lot of good thoughts to inform how we finalize this document, so I do appreciate all your good thinking on this subject.

MR. BUTTERFIELD: All right and two last brief items of housekeeping. If you have any documents that you need to have shipped back to you, please put them in a small pile on your chair and put your name tag there. Now, I'm going to ask people to be as discreet as possible on that because we don't, we have a lot of expense associated with CASAC, we're about 30% of the SAB budget even though we're one committee, so if at all possible, if you carried documents where, we'd appreciate it if you could carry them back, any needful documents.

And lastly, we have the shuttle set up to pick five of us up at 2:30, there are six people who are going at 3:00 and four people going at, six people going at 4:00, but do check in before your time that you indicated on the paper just to make sure that the shuttle will be there so you know you don't get caught short, it may be necessary to call a taxi if the shuttle is out making another run, but the five of us who are going at 2:30, we do have the shuttle standing by. Once again, thank you very much and this meeting

is adjourned.

(WHEREUPON, the meeting was adjourned at 2:05 p.m.)

CAPTION

The foregoing matter was taken on the date, and at the time and place set out on the Title page hereof.

It was requested that the matter be taken by the reporter and that the same be reduced to typewritten form.

Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.

CERTIFICATE OF REPORTER

COMMONWEALTH OF VIRGINIA

AT LARGE:

I do hereby certify that the witness in the foregoing transcript was taken on the date, and at the time and place set out on the Title page hereof by me after first being duly sworn to testify the truth, the whole truth, and nothing but the truth; and that the said matter was recorded stenographically and mechanically by me and then reduced to typewritten form under my direction, and constitutes a true record of the transcript as taken, all to the best of my skill and ability.

I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I certify that I am not a relative or employee of either counsel, and that I am in no way interested financially, directly or indirectly, in this action.

MARK REIF, COURT REPORTER / NOTARY

SUBMITTED ON AUGUST 25, 2006