MEETING

STATE OF CALIFORNIA

AIR RESOURCES BOARD

AIR QUALITY ADVISORY COMMITTEE MEETING

RADISSON HOTEL CONFERENCE ROOM

200 MARINA BOULEVARD

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THURSDAY, JANUARY 24, 2002

8:30 A.M.

Reported by:
James Ramos

APPEARANCES:

For the Air Quality Advisory Committee:

Michael Kleinman, Ph.D., Chairman, UC-Irvine

John Balmes, M.D., Chief, UCSF

Russell Sherwin, M.D., UCSF

Sheldon K. Friedlander, Parsons Professor, UCLA

Constantinos Sioutas, D.Sc., Associate Professor, USC

Michael P. Sherman, M.D., Professor, UC-Davis

Dean Sheppard, M.D., Professor, UCSF

Ira B. Tager, M.D., M.P.H., Professor, UC-Berkeley

Gerry Cropp, M.D., Ph.D., Professor Emeritus, UCSF

George Thurston, Associate Professor, NYU

Also Present:

Richard Bode, Chief, ARB Health & Assessment Branch

Bart Ostro, Ph.D., OEHHA

David Mazzera, Ph.D., ARB Research Division

Michael Lipsett, M.D., J.D., OEHHA

Jeff Cook, Chief, Quality Management, ARB

Sue Wyman, Air Resources Board

George Alexeeff, Ph.D., DABT, Deputy Director, OEHHA

Margaret (Peggy) Jenkins, ARB

Leslie Krinsk, Esq.

Members of the Public:

Bonnie Holms-Gen, American Lung Association

Deborah Sphrentz, American Lung Association

John Heuss, AIR Incorporated

Ted Holcomb, Retired (formerly PG&E)

Mark Samperstein, BP, Western States Petroleum Association

Gina M. Solomon, M.D., Natural Resources Defense Council, UCSF

Jaroslav J. Vostal, M.D., Bloomfield, Michigan

David Schonbrunn, President, Transtaff

Suresh Moolgavkar, Consultant, Engine Manufacturers Association

Ken Kloc, Environmental Law & Justice Clinic/Golden Gate University School of Law, Our Children's Earth Foundation

Robert E. Yuhnke, Environmental Defense

Pamela Soderbeck, Esq. (Retired)

David Fearly, Bay Area Air Quality Management District

P R O C E E D I N G S

DR. ALEXEEFF: Good morning. I'm George Alexeeff, deputy director for Scientific Affairs of OEHHA and I want to welcome you all here. Many of you were here or almost all of you yesterday, and yesterday we heard some presentation and discussion about the particulate matter document that the Air Board and OEHHA put together. So today we're going to be discussing mostly the public's comments, and your comments. So I'd like to just welcome you here and turn it over to Richard Bode.

CHIEF BODE: Thank you, George. I'm actually going to pass it over to Dr. Kleinman pretty soon.

Just a couple of announcements, and that's that we've been asked about presentations that were given yesterday and we'll put those up on the web page when we get back Friday. So everybody will be able to get copies of that and download them off the Internet.

And if you're coming again today, please sign the attendance list. You should also -- Do we have the address for the Internet page? We'll find that out and maybe later on we'll give you guys the address too.

(Thereupon, a recess was held off the record.)

CHAIRMAN KLEINMAN: Good morning. Before we actually start with the public commentary, I did want to take an opportunity to thank our hosts, OEHHA and the California Air Resources Board for setting up the forum, for putting together, working with the University of California to set up a panel that I'm very pleased to serve with, and for putting together a very comprehensive report, which I'm sure will raise some public commentary and I think that's what we're going to hear this morning.

I've got a list of about 12 people who have signed up, said they want to speak. We've got about an hour and a half on our agenda, which means that we can allow about eight minutes per presentation. And so I'd like to get started.

The first speakers are from the American Lung Association, Deborah Sphrentz and, I'm sorry, I didn't --

MS. HOLMS-GEN: Bonnie Holms.

CHAIRMAN KLEINMAN: Bonnie Holms, okay. You're on.

MS. HOLMS-GEN: Good morning. My name is Bonnie Holms-Gen. I'm with the American Lung Association of California. I have to say that I had the opportunity to drive a natural gas car here today,

and I'm very excited about it. I only had to fill up once.

I am extremely pleased to be here today to represent the American Lung Association of California, and my colleague, Deborah Sphrentz, from our national Lung Association, is going to follow. And we have been very pleased with the quick process that ARB and OEHHA have embarked on to review and update the particulate matter standards, and we strongly support the most stringent possible standards for PM 2.5 and PM 10.

We believe that establishing more stringent standards and a new standard for PM 2.5, specifically, is one of the best ways that we can ensure better health protection in California, especially for those sensitive populations that you've spent a lot of time discussing, and especially infants and children, which is the subject of the SB 25 legislation. In particular, we strongly support the proposed tightening of the annual average PM 10 standard, as recommended in the staff report to 20 micrograms per cubic meter, and the establishment of a PM 2.5 annual standard at 12 micrograms per cubic meter, as recommended in the staff report.

The area that we wanted to raise with you and

that you've already raised and had a lot of discussion about yesterday is the lack of a recommendation on the 24-hour PM 2.5 standard. We strongly urge you and your committee to ask and recommend, urge ARB and OEHHA to include a 24-hour standard for PM 2.5 in the report. We view it as of the utmost importance, to improve health protection for sensitive populations, infants, children, people with asthma and chronic lung disease, and the elderly.

As was robustly discussed yesterday, there is a very extensive and sound scientific body of information on short-term health effects from particulate matter exposure that would support the addition of a 24-hour standard. And there really was excellent discussion yesterday on the need for a 24-hour standard, and my colleague, Deborah Sphrentz is going to go into some more detail about our perspective.

I wanted to add a little more broad perspective on why we would like to see this 24-hour standard, and this goes back to the legislative campaign in support of SB 25, the Children's Environmental Health Protection Act. And when we were involved in that campaign, we had a day for individuals to come and talk to legislators about why

they believed this was so important, to have this legislation passed.

And there was a woman from Contra Costa County, specifically, and her ten-year-old asthmatic son that came -- She took a day off from work and came to Sacramento -- and her son had a case of all the equipment and medications that he has to bring with him to school every day to deal with his asthma and manage his asthma attacks. And this woman and the son wanted to specifically show legislators what her son had to deal with. And basically, the message was, you know, this is a lot for a ten-year-old to have to deal with, to be concerned every day about having to suffer from an asthma attack and have to keep all these medications and equipment at his side.

And it really put a human face on what we were trying to accomplish with SB 25, that we're really trying to pay special and particular attention to the needs of children, infants and children, and to make sure their air quality standards are especially protective of children. And as was discussed yesterday, we strongly believe that we need to have a 24-hour standard in order to make sure that we drive down those peak PM measurements so that we can reduce the number of asthma attacks in children, and

hopefully reduce the respiratory symptoms including asthma attacks that children experience. And we believe that it's of utmost importance to improve the health of children, reduce respiratory diseases and asthma attacks in children, reduce lost school days, and just reduce the suffering and distress that children experience.

So I wanted to remind you, as I know that you are aware, that in addition to the mandate on the state to protect public health that there is a special mandate because of SB 25 to particularly include infants and children in the protection afforded by our California particulate matter air quality standards, and that we believe in order to do the best job to protect children that we would urge you to move ahead in recommending a 24-hour standard, in addition to the very good annual PM 10 and PM 2.5 standards.

I'm now going to introduce Deborah Sphrentz to present some more specific information.

MS. SPHRENTZ: Good morning. I'm going to focus our presentation on the case for a short-term PM 2.5 standard. And this is a graph from the recent EPA staff paper on particulate matter. I know you can't read the graph, the print is small, I just show it because of the overall message that's being portrayed

here, which is there are a vast number of studies.

In this particular graph, these are studies of PM 2.5, short-term effects from the US and Canada, and this graph represents 65 distinct effects estimates that have been derived from the recent literature, the vast majority of these studies showing statistically significant associations, working at the full spectrum of health effects here, from mortality to respiratory systems. And another thing that's striking, I think, is that the majority of these studies have been published since EPA did its last review in 1996. And it's the effects adjusted by these studies that we feel critically define the need for a short-term fine particle standard.

An important point here is that we believe that the effects these studies demonstrate are not due solely or primarily to chronic effects, but we believe that they demonstrate distinct short-term effects.

One of the policy implications from the health literature, we believe a 24-hour PM 2.5 standard is indicated. We think it's the indicator to protect against these effects that the studies have demonstrated. A 24-hour indicator would be consistent with a majority of the results from the epidemiological literature. It will protect against

both single-day excursions and also multi-day air pollution episodes.

The staff report makes a number of arguments that we want to try to address. One is I think that the annual average PM 2.5 standard will offer some protection against short-term exceedences. And this, of course, is true, but we believe it is insufficient because an annual standard alone will not place limits on how high daily concentrations can rise. And there will still be seasonal periods of high PM 2.5 concentrations that are not protected by an annual average standard.

We did an analysis of PM 2.5 monitoring data for California, which shows that an annual average PM 2.5 standard alone would leave 5.8 million Californians in 16 counties unprotected from high short-term concentrations of PM 2.5. This data from EPA's airs database and their most recent trends report reports on peak monitoring concentrations in each county. And you can see that in these 16 counties, the annual mean concentrations in 2000 were below the proposed standard of 12, yet the 98th percentile 24-hour concentrations were still high.

For example, in Alameda County, annual mean concentrations for 2000 were 11.2 micrograms per cubic

meter, but the 98th percentile 24-hour concentration was 50. And, as you know, with the 98th percentile form of the federal standard, that means that there were seven days in 2000 when levels exceeded the concentration level shown here. Similarly, Contra Costa County had annual average concentrations of 10.9, 98th percentile, 24-hour concentrations of 46 micrograms per cubic meter.

So it's not just the rural counties that we're talking about, but also the large populations of California that may not be violating the annual average level, yet still showing high daily concentrations.

Another argument that they made in the staff report is that a daily PM 10 standard would offer some protection against PM 2.5 concentrations. And there's a couple of points to be made here. I think the most important one is that fine and coarse particles really are distinct pollutants. They come from different sources, they arise from different processes. And, most importantly, historically the control strategies for mass-based standards like the TSP standard and PM 10 standard have focused on controlling the larger heavier particles, so that if you rely on a 24-hour PM 10 standard, you may not be controlling combustion

sources of fine particulates, which, of course, we're most concerned about from a public health perspective.

Other agencies that have reviewed this issue have come up with 24-hour PM 2.5 standard. The Puget Sound Clear Air Agency has a recommended level of 25 micrograms per cubic meter. As was mentioned yesterday in the staff presentations, the Canada-wide standards, 24-hour standards for PM 2.5 are set at a level of 30 micrograms per cubic meter. And, of course, EPA has the 65 micrograms per cubic meter, 98th percentile form of the standard, which we really want to emphasize is by no means considered protective of public health. And California cannot rely on this federal standard as a backstop measure to protect the health of its citizens, because it is set at such a high level that it would be rarely if ever violated.

The larger point here, of course, is that California has always been a leader in air pollution control, and the work that you're doing here has important implications, not only for the state but for the nation as the whole and the rest of the world. And we are very supportive of the new proposals to strengthen the annual average standards for PM 10 and to establish a new annual average fine particle standard, but we feel that in order to be health

protective it's important to proceed with a stringent 24-hour fine particle standard as well. Thank you.

CHAIRMAN KLEINMAN: Okay. Thank you very much, ladies.

The next speaker is John Heuss from AIR Incorporated.

MR. HEUSS: Good morning. My name is John Heuss with the Air Group of Resources, Incorporated.

In our review we identified a number of major problems with the draft. The first was it does not rigorously evaluate consistency or coherency within the epidemiology. Second is that it does not evaluate the consistency with PM risks in other settings. Third, it does not acknowledge the presence of false positives, and we use in our written comments, the ozone results from NMAPS to demonstrate this.

It neglects the importance of seasonal analyses. We make the point that several studies by Styre, Moolgavkar and Lubay, and Chalk et al., and NMAPS all show that seasonally segregated studies are important. We also list a variety of other studies that show major differences between seasons which need to be understood.

The material downplays for potential confounding by other outdoor pollutants, I'm not going

to get into that a lot; I think other speakers will. I'm going to spend a little more time on the issue last year, neglects confounding by indoor pollutants.

In terms of consistency, our comments included examples from the South Coast basin, and our suggestion for you folks is that you rigorously evaluate all of the studies you have of mortality and morbidity for consistency and coherence. Because when we looked through these studies, we found that they all showed associations with air pollution, but they did not agree on what pollutant, did not agree on what season in some cases, did not agree on one particular end point.

For example, Katie and Noskylak (phonetic) reported associations with a variety of pollutants in 1991 with mortality, but not with fine particles. 1995 associations were shown with ozone PM 10 and CO, and in two pollutant models PM 10 and ozone, the ozone went to zero, and in the two pollutant models for PM 10 and CO they both persisted. And in Ostro in 1995, it showed association with an estimated PM 2.5 in the summer but not year-round.

And when we get to NMAPS, you find an association with PM 10 but not ozone and single-pollutant models. But when they did multiple-

pollutant models, the PM 10 coefficient went to zero in models with PM 10 ozone and another gas. Moolgavkar had a very similar result, no ozone association and associations of single-pollutant models with PM 2.5 and 10, but when other gases, single gases were included, those associations disappeared.

So all these five studies reported associations with air pollution and mortality, but as I pointed out, they do not agree on which pollutants are involved, they do not agree on health end point effect.

The hospital admission studies, when you lay them side by side, also do not agree. If you read any one, it sounds quite convincing, but if you put them all together it is much less conducive. When you add all the morbidity studies together, there is less coherence than one might expect. We really do see inconsistencies, not only in this area, but we demonstrate in our paper that in Philadelphia, in Chicago, in Birmingham and there are many other examples where there are now multiple studies for the same city, and they don't see the same thing. And that raises serious questions.

The issue of confounding by indoor pollutants

we included in the material, a small calculation we made to demonstrate this. In naturally ventilated buildings, which are basically our homes, where we spend about two-thirds of our time and children spend about seventy-five percent of their time, according to the graph, the air exchange depends on two things: wind-driven pressure differences and temperature-driven pressure differences. And the wind is the same factor that is involved in the weather, changing the concentrations of outdoor pollutants from a given source.

Reductions in wind speed will increase the ambient PM exposures, but they will also reduce the air exchange, and that increases the indoor exposure to an indoor source. And this degree of confounding can be evaluated by linking outdoor models with EPA and other indoor air models using standard ventilation and equations. And we've done that in a simple calculation. It was presented to CASAC (phonetic) last July and we provided a copy to you folks.

I want to spend a couple of minutes discussing the basis for the draft recommendations. First is, is PM mass the appropriate indicator? As was discussed yesterday, the question really arises are all particles created with equal toxicity by mass?

And based on the discussion yesterday and the discussion over many years of people trying to evaluate this issue, the answer is nobody really thinks so.

So PM mass is really a stopgap at best until we can get better information. Fortunately, a number of years ago, when EPA promulgated PM 2.5 standards, it was a major national research program initiated, the National Research Council put together a panel to work on defining that with E. J. Allen, and there has been an outpouring of studies on every aspect of this issue. And over time, hopefully, to the extent that PM associations are really causal, that will be demonstrated. If they are not, that will also be demonstrated.

So over time, you should be thinking about moving beyond just PM, but to try to understand the individual components that you're dealing with, whether they're unit sources or chemicals, to try to understand what to do there. And again, to the extent particles are involved in health effects at this point, both fine and coarse are implicated. So we agree with the draft in that sense.

Another statement in the draft is that there is compelling evidence of PM causality. We submit

that is really an alternative view, that causality has not been demonstrated yet, and we offer the major inconsistencies in the epidemiology in the same location as looked at in different locations and by season.

And then we raise the issues of confounding or bias due to both the outdoor gases, the indoor pollutants, etc., demonstrated in measurement issues, and when you look at the toxicology and the symmetry of really directing the effects of these low levels, they're not consistent with our database at this point in time.

The draft recommends annual average standards, to a great extent based on the assumption that there are large chronic effects, and that comes from, as we discussed yesterday, the ACS and Six-City Studies. We don't think those studies are particularly relevant to the current California situation. The effects those two studies found were increased cardiovascular mortality, not respiratory. It was in the less-educated population, in the industrial Midwest and Northeast, where they had very high past exposures to industrial activity and coal combustion. The ACS and Six-City Study originally was designed to look at the influence of coal combustion.

And in the reanalysis, it's been demonstrated that the strongest association is not with particles, but with SO2.

Also in the reanalysis, there are positive associations when they looked at different regions, in the eastern subregions, but there were negative associations for both sulfate and PM 2.5 in western cities. In addition, the chronic signal that you are seeing in California has a number of major differences with a chronic signal in the ACS and Six-City Studies. And if you have, expect a very large chronic mortality signal, there ought to be a strong chronic morbidity signal associated with that, and if you look carefully at that, there are many inconsistencies there too.

So, in conclusion, we want to point out that the time-series associations with outdoor pollutants measurements are confounded by indoor pollutants, based on the known physics of -- confounded by the known physics of air exchange.

And finally, there are many PM associations in single-pollutant models reported and you see many examples of that. The issue is, is a single-pollutant model sufficient, and we submit it's not. And when we look for consistency in rigorous fashion, cutting the data as many ways as possible, particularly when there

are multiple studies in the same city, these studies fail, having the first test of an observation model with individual people looking at the same thing, same place, seeing the same thing.

And then we are concerned that the emphasis on the annual mean may be misdirected because of some very old concentrations in the dosimetry that Dr. Vostal will present to you later in his comments.

CHAIRMAN KLEINMAN: The next speaker is Joe Suchecki from the Engine Manufacturers Association.

MR. SUCHECKI: Oh, I'm not speaking.

CHAIRMAN KLEINMAN: You're not going to speak, okay.

Then Ted Holcomb.

MR. HOLCOMB: Good morning. I'll be brief. My comments are fairly simple.

Less than five percent of the annual average ambient PM 10 in key urban areas --

UNIDENTIFIED SPEAKER: What is the affiliation? Mike, is the affiliation --

Are you going to tell us your affiliation?

MR. HOLCOMB: Well, at the moment I am retired, or I am retiring, it's the same thing. I spent 28 years working for Pacific Gas and Electric Company, and the material that I'm talking about is

very similar to the material that we previously submitted to US EPA back in the 1997 time period.

But this material is my own, it is not Pacific Gas and Electric's, it was not reviewed or approved by Pacific Gas and Electric Company, and I want to make that very clear.

Anyway, getting back, less than five percent of the annual average ambient PM 10 in key urban areas has been directly attributed to incompletely combusted fuels. The vast majority of PM 10 mass is attributed to road, construction or wind dust, sea salt, or secondary particles formed by atmospheric reactions. This allows vehicle manufacturers and industrial sources to argue that particulate control efforts should focus on roadways, excavations and farms.

Narrowing the size faction from PM 10 to PM 2.5 moves attention away from the farm and dust sources, but shifts the attention to secondary particles, not to primary particles. Gasoline fuel vehicles, diesels and most other combustion-related sources will emit 20 times more secondary particle precursor mass than primary particle mass.

The reality is that healthy adults have been exposed to ammonia nitrate concentrations far higher than current mass standards allow without any

observation of adverse effects. But the epidemiological studies suggest that effects might be occurring due to relatively brief exposures to relatively low concentrations.

This suggests to me that it's not the ammonia nitrate but something else we ought to be focusing upon. Unfortunately, the standards before you continue to focus only on mass and size, and, hence, will continue to place greater weight upon control of the higher mass of ammonia nitrate than on the lower mass of primary particles.

When the Health Effects Institute summarized this review of data, comparing mortality statistics to particulate concentrations, it reported wide variations in correlation. The highest positive was in Oakland. The highest negative was in Modesto. They looked at that data as confirming their supposition that overall, particles appear to cause harm. I looked at that data as confirming my belief that primary particles appear to pose higher risk.

Oakland is the sort of area where you would expect particulate data to contain a more consistent percentage of primary particles. Modesto is the sort of area where you would expect the percentage of primary particles and the total particle mass to vary,

defeating efforts to correlate mass to harm.

I am not suggesting ammonia nitrate is harmless, but I am suggesting that you already have ozone, nitrate and total mass standards that are either adequately protective, or can easily be adjusted to be adequately protective against nitrate exposures. But there is not any standard that is aimed directly at primary particulate.

One way to move toward such a standard would be for the ARB to adopt a standard that controlled total PM 2.5 mass left after subtraction of the ammonia, chloride and nitrate masses. A more focused but harder to administer substitute would be to focus on particulate mass traced to primary particles emitted by specifically listed source types like diesels, gasoline-fueled engines, smelters, wood stoves, asbestos processing, etc.

I hope these suggestions prove helpful, either in this review or in some future review. Thank you.

CHAIRMAN KLEINMAN: Thank you very much.

MR. HOLCOMB: And, by the way, the material includes a couple of graphs and stuff I would submit into the record with that.

CHAIRMAN KLEINMAN: Thank you.

The next speaker is Mark Samperstein.

MR. SAMPERSTEIN: Good morning. Mark Samperstein with BP, and also representing WSPA, Western States Petroleum Association. WSPA has submitted some detailed written comments and we hope you'll take those into consideration. They were prepared by epidemiologists that have conducted analyses in these areas, and if you would like further clarification, we would be glad to facilitate any questions that you have to the authors of the comments.

Today I just wanted to briefly highlight a couple of those comments. First is the rationale for the selection of the standards. Obviously, when the document was first released, we looked with great anticipation to see if the standard set would be lower than EPA's 15 micrograms per cubic meter for PM 2.5 and we saw that it was. And then we went to look for what was the rationale behind that, and it just doesn't seem very clear. I realize that the staff has pulled out some average PM concentrations from epidemiology studies, but it's not clear what relationship the average concentration really has to finding a level that's protective of public health.

So the reason for adopting the 12 as opposed

to EPA's 15 doesn't seem to have much support, and I think the chart that was put up yesterday that showed the various average levels and various studies didn't help to make that much clearer in that I think different people could look at that and extract, you know, 12 or 15 or 18 out of that, depending on their views on it. So I think that that part of the report needs to be beefed up.

Also, some of the averages that were put in there may not have been calculated correctly, and there are some comments in there about which are the appropriate ones to use from the ACS study.

The second comment just on the adoption of a linear no-threshold hypothesis for PM, the comment cites some examples where actually non-linear models provide a better fit, and we hope that you'll take those into consideration.

Other comments relate to lack of consideration for potential bias and uncertainties, and previous speakers have gone over some of that. Sometimes the impression is given that, in the time-series studies, that weather has been completely controlled for. I mean, you can attempt to control for weather and you can use various models based on daily temperature or peak temperature, but there can

be residual confounding, and that is much more important when studies are showing fairly weak effects with regard to the relative risks. So that maybe should be given a higher profile as for the potential for that.

Also, the report contends that there is a great degree of consistency and coherence in the epidemiology studies, and we provide several examples of the -- some inconsistency and lack of coherence, many coming from the reanalysis of the Six-Cities and the ACS Studies. Now, that doesn't mean that the studies can't be useful in setting standards. But, you know, the shortcomings and the uncertainties really should be acknowledged more strongly than they are when setting the standard.

And not only when setting the standard, but also when presenting quantitative risk estimates as far as premature deaths averted and other things. There's a little concern that in the executive summary it just launches into these numbers without outlining the assumptions that one must accept before you go into presenting data like that.

So thanks very much for this opportunity to comment.

CHAIRMAN KLEINMAN: Thank you.

The next speaker is Gina Solomon.

DR. SOLOMON: Thank you. Good morning. My name is Gina Solomon and I'm a senior scientist with the Natural Resources Defense Council, and I'm also an assistant clinical professor of medicine over at UCSF.

I'm very sorry that I missed the discussions yesterday, which I heard were excellent, but I did review the report and I was very impressed. I wanted to thank the staff and congratulate them for a job that I think was very well done. Really nice job of summarizing the literature and of basically explaining the reasoning that I think was quite reasonable behind the proposed standards, which NRDC does support, both the proposed PM 10 and PM 2.5 annual average standards.

I really have two comments today, one on the issue of morbidity versus mortality, and the other on the PM 2.5 24-hour standard, which we also are calling for.

Basically, in this situation, in some ways we're kind of lucky. I've gone and reviewed the data on numerous chemicals in the environment, and often we're faced with a set of animal toxicology studies or we're faced with a few scattered epidemiology studies, often in worker populations exposed to levels

significantly higher than the general public is exposed to.

And in this situation actually we've got an abundance of riches. We've got many dozens of very well-designed epidemiologic studies done in geographic areas all around the US and around the world with very large population sizes, very narrow confidence intervals, done at relevant environmental exposure levels, and showing a remarkable consistency. Sure, it's always possible to identify some differences from one study to another that is part of what you expect to see when you see numerous scientific studies. I mean, all of us who do science understand that they're not -- every study doesn't show precisely the same thing.

So we've got a lot of information, and we've got a lot of information to support short-term effects of fine particulate, of PM 2.5, several dozen studies which Debbie Sphrentz showed on her slide, numerous studies both on mortality and on various measures of morbidity. And it seems a shame not to take advantage of that information to do what it's telling us to do, which is make sure that we are protecting people from short-term excursions, short-term high-level excursions to PM 2.5.

A couple of studies that particularly jumped out of me, one was done by Bart Ostro here that was published just last year in the Journal of Epidemiology, it's something that struck me when it came out. It was a study of African-American children in the Los Angeles area, showing that these children may be among the victims of short-term excursions of PM 2.5, indicating that they're more likely to have adverse respiratory symptoms when PM 2.5 levels went up with a 12-hour average of about 41 micrograms per cubic meter.

And that raises the fact that not only is short-term exposure important, but also morbidity is really important. When we're talking about missed school days, we're talking about hospitalizations, when we're talking about increased use of medications in order for a child to manage to get through their day at school or their sports activities after school.

And we're trying -- we need to think about that and protect against that, and if I were to criticize the report about anything, you know, the tendency to rely on the mortality studies is understandable, but is actually, I think, less protective of public health than we should be in this kind of setting.

And then I also think that the study by Peters and Dockery that was published last summer in Circulation, indicating association between myocardial infarction and short-term excursion levels of PM 2.5 in even the two hours prior to the event indicates that we can't just look at annual averages here. We're looking at the variability over time, and, in fact, short-term exposures clearly appear to have an effect on the cardiac system and the respiratory system in a way that can lead, you know, in predisposed individuals can lead to significant health effects.

So I think those are the only comments that I wanted to make today, but I again wanted to thank you for this excellent report and I look forward to seeing how this process develops over time.

CHAIRMAN KLEINMAN: Thank you.

The next speaker is Bob Yuhnke.

UNIDENTIFIED FEMALE SPEAKER: He wanted me to let you know that he had to step out for a moment, and he'd like to be put in later.

CHAIRMAN KLEINMAN: Okay. Then Jaro Vostal.

DR. VOSTAL: I am Jaro Vostal. I am from the (indiscernible) in Bloomfield, Michigan, and my presentation will be restricted only to some

discussion of the weight, how can we be sure that when we are talking about the effects of the pollution by fine particulates that we have already demonstrated that it is really the cause of the effects that we are seeing. And then to look into it, what are the issues, which are we dealing with the explanation of those effects of the particulate.

What I will be concentrating on is the main conclusions of the draft, and we are a little concerned about it, since, as you can see, they are saying that there is evidence which includes toxicology, which includes dosimetrics and human clinical studies, and they all should say that there is compelling evidence that the particles are a real cause of it.

So if we can identify at least three aspects of these concerns, that means that we are a little concerned that the graph is assuming the causal role of ambient particles and it doesn't even consider something like dosimetric evaluation. Yesterday there were some very good comments saying that the chapter is -- describing the general principles of deposition particles in the respective air base, but it's not providing any information about the dosimetry, and although the information existed and were trying to

show it.

The other I think which was also discussed yesterday was that many times the draft depends very highly on toxicology data which are using unbelievably high concentrations, and there is a very difficult, very hard to extrapolate those doses, since, in many cases there are also administered by a non-physiological way, and so we have not only the problem how to extrapolate from high to low concentrations, but also, how to extrapolate from this non-physiological way of administration.

And this is really quite surprising since, if you are looking (indiscernible) committee, just thinking about it in general, and this has been demonstrated by the Mosley Center, evaluation by committee of the National Research Council, and they are still feeling that there is a lack of sufficient understanding which are the constituents for toxicology (indiscernible).

So, first of all, the first question which I would like to discuss is do we have some possibility to say that there is that critical mass which would be aberrated within a relatively short period what we chart in the time-series studies, that means within the 24 hours, to be correlated with the effects which

are happening at the same time. Now, it appears that this is very important, since if we can quantify and if we can find that there is enough of the particle mass or some constituents operating in the lung, then we will be able to really validate or disclaim the hypothesis that means that the particle operation in the lung is responsible for the effects.

And we can do it with -- we can demonstrate it by some studies which have been done on it, and dosimetric evaluation. And maybe I can just take you directly also to the publication to which I am referring in these comments, what we have done, we have used the data which were published in 2000. And they were describing not only what is the annual average of monitoring samplers of the PM 2.5, but also what is the chemical composition of it.

If you look into it, the chemical composition is indicating the total concentration and the annual average was about 17 micrograms, and you can see what is the representation of indoor components, including the toxic matters. Now, when we have finished with our study, we have been quite surprised that we have to use extremely low units of the mass concentration just only to demonstrate that there is something operating there. And you can see this exceedence

expressed in the matters which describes what is the amount of particles normalized by the squares and images of the surface of the alveolar region.

And you can see that even when we are in nanograms, you are talking only about a fraction of the nanograms and we come to the toxic matters, which have been always suspected that they are indeed responsible for the effects. We are coming to the concentrations which are a tenth to the minus 15 of the gram, that means invectograms, and you can see it here, particle components from the heart effects point of view, sulfates, it's units of fibrograms, elemental carbon or iron, fractional fibrograms, elemental carbon or iron, iron has been used as a very good example. It's one of the matters which supports that there could be some initiation of some oxidated mechanisms.

But not in the concentrations which are happening here. Everything has been demonstrated and withdrawn our considerations which are much more higher. When you come to the toxic matters, then the concentrations are (indiscernible) low. You can't even imagine, so that this particulate, we had to conclude that if we want to depend on this I will say just preliminary examination of the possibility if

there is a critical mass, that the evidence is saying that the concentrations operated within a 24-hour period in the system are so low that we cannot demonstrate from any information in the literature that they could either be responsible for such complex effects like increased morbidity and mortality.

So this is either showing one very big question mark in our interpretation, if there is a causal relationship between the monitored particles and between the effects, and we feel that it's very important to identify since if we start to control the particles without the proof that it is the cause, then we might not even see the benefits which are exerted vertically.

Another issue which is coming here in the draft is that the draft really depends on one single brief communication which has been published and which is demonstrating that, as it is described in the draft, that the particles which are administered by interalveolar injection into the lung of a hamster are very rapidly leaving the airways and getting into the blood circulation.

Now, it is very unfortunate that it is only a brief communication, but if you can see all that has been documented there, that when they have -- they

took samples of the blood, and that was after the administration, they had found something like three percent of dose of radioactivity administered to the animal.

Now, this is very interesting that the percentages are practically the same in spite of the fact of increasing the dose, and it is really -- those of us who have been either using the similar possibility of radioactive labeling of very fine particles, there is a big question mark again, so much we can either document the radioactivity which is leaving into the circulation is still in the form of the particles, or if it is just only a radioactive label which left the particles and was freely diffusing into the circulation and probably excreted by the kidney.

Therefore, if we want to use this as an evidence that could either explain some systemic effects seen in the epidemiological studies, we are still having a very big problem in (indiscernible). We have to wait for further documentation, if this is correct or not.

And the last point is the use of the so-called inflammation as the explanation of the effects of the fine particles. Now, we have to say that

inflammation is a physiological mechanism. And unfortunately, in the literature there is a lot of confusion about the use of the inflammatory process and no differentiating when in the presence some real (indiscernible) inflammation like, you know, we can find when there is some very big process happening in the respiratory tissue or when we are talking about the physiological defense.

Now, this is the work that has been done by the EPA team in North Carolina. They have exposed, you know, human volunteers, and they have exposed them to three different concentrations as you can see on the top, from about 50 to 200 micrograms. They have a total of about 40 in it, and what they have done, they have used the Bruncol alveolar lavage. It's really looking if there are some, you know, neutrophils. And you can see they are there. Either if you are talking about absolute amount or more appropriately probably about the concentration, but the concentration means that number, what is the percentage of the (indiscernible).

And it is, you know, very clear that, you know, that where people -- those are the levels that you can find without the exposure. Therefore, in the others which are discussing, you know, what -- if this

really means that this inflammatory process, they are saying probably not, we have to talk more about the fact that there is not too much of the statistical significance, in spite of the fact that there is showing some larger representation of the neutrophils. But they conclude that they cannot really, you know, identify either by some biochemical indices or by the presence of the neutrophils that this should be an epidemiological process.

Again, since this is really a study which has been done on human growth years and it's showing no effects, it's very difficult really to accept that the airway inflammation and absorption of particles into the circulation are responsible for something which we are describing as systemic impacts and, you know, whatever it is. So I feel that we can conclude that there is no question that the evidence which is operated by the time-series studies. It's very compelling to really put the blame on the particles but, as I said before, unless we can be 100 percent sure that we are identifying the particles, even in those small amounts, are capable to produce this type of the response, then we should really be aware that we will be making very wide and important societal decisions which could really cost a lot of

money and not bring the expected benefits. Thank you.

CHAIRMAN KLEINMAN: Thank you.

David Schonbrunn?

MR. SCHONBRUNN: Thank you. I'm David Schonbrunn, the president of Transtaff. We are a Bay Area transportation, land use and air quality advocacy organization. We're part of a coalition of environmental and community groups that brought suit against EPA that led to a finding of non-attainment for ozone. And so we are doing what we can to protect human health.

We're very supportive of the work of the Advisory Committee and we're pleased to hear the comments yesterday on epidemiology and the need for the 24-hour standard for fine particles. We very strongly support that. We're a signatory to the American Lung Association comment letter.

Two points I'd like to raise here, in addition to what was said there. We've been following transportation issues here in the Bay Area, and we've noticed that the one criteria pollutant that's projected to be increasing significantly is PM. So you're in the right field, you're taking aim at something that is of extreme importance, and you're doing it with the right values and the right

attitudes.

So we very much appreciate the work of the Advisory Committee, and would comment that you've heard other kinds of testimony here today and in writing as well. It's clear to me that those interests, the interests represented have nothing to do with health. And so I wouldn't want to put my health subject to the recommendations that you've heard today that are not supportive of the staff work and the Advisory Committee discussions.

So, again, I commend what you're doing and look forward to seeing ARB go forward in protecting the public health. Thank you very much.

CHAIRMAN KLEINMAN: Thank you.

Suresh Moolgavkar?

PROFESSOR MOOLGAVKAR: I'm a professor of epidemiology and biostatistics at the University of Washington, but I'm here in a private capacity as a consultant with the Engine Manufacturers Association, for whom I prepared draft comments on this document.

I would like to begin by saying that I'm aware of the amount of time and effort that went into preparing chapter seven, which I'm going to be commenting on. It's a very tough job and it's not one that I would like to undertake.

But my major, I guess my major problem with the chapter is that it does not look at the problem of particulate matter, PM 10 and PM 2.5, in the broad context of air pollution in general. And what has happened here is that the literature or the that supports a PM morbidity mortality association. It has been given a lot of play and importance, whereas the literature or pieces even, or parts of the paper that seem to question the association have been downplayed and given short shrift.

Now, this is something that perhaps is inevitable with a document of this type, but nevertheless, I think we should guard against it.

So specifically, even though this is a valiant effort, I think the chapter so far falls pretty short of a thoughtful review and evaluation of the literature. I think there are important publications that have been omitted from the discussion. I think by and large, it's a fair selection of the literature. It is not possible, I understand, to cover comprehensively in a document of this type, particularly when the EPA, US EPA is also in the process of writing a document for PM.

Nevertheless, I think there are some important publications that have been omitted, and

I've given a list of a few of these in my write-up. I think at the very least, it is incumbent on the authors to provide some criteria on the basis of which the publications that it chose to review were chosen. So I'd like to see some criteria for the choice of the literature that is reviewed in this chapter.

The second point is that there are actually I think serious factual errors in the reporting of results in some critical publications. I have again examples in my write-up, but I'm talking about one example here. And this I already alluded to in my opening. I think there is selective reporting of results, of cherrypicking, so that studies and results that generally support the PM morbidity hypothesis are given a lot of play, results that call into question this hypothesis are downplayed. And that's I think unfortunate.

So let me give you just one example of what I consider to be an extremely important factual error that has been committed. This study, the Krewski reanalysis of the Harvard Six-Cities and ACS two studies is clearly a central study in this document because the standard, the long-term standard is based on basically on this study. And the (indiscernible) document says the PM effects were not confounded and

were independent of the effects of other pollutants, that's a direct quote.

This is quite false, quite the contrary. Inclusion of sulfur dioxide actually wipes out the PM effects. For total mortality for sulfates, the relative risk goes from 1.17 to 1.05, and becomes insignificant when sulfur dioxide is included in the two analyses. For fine particles, the relative risk goes from 1.18 to 1.03, and also becomes insignificant, and this is in summary table six of the HEI report on page 30.

By contrast, the sulfur dioxide coefficients are (indiscernible) inclusion of PM. There is absolutely no question about it, that in this study, sulfur dioxide is the single-most important pollutant in these analyses. There is absolutely no question about that.

Now, with simultaneous adjustment for all gases, this is a procedure that is fraught with all kinds of dangers, but I still present the results here. The relative risk for sulfates goes down to 1, and this is on the HEI report, page 181. So, I mean, I don't see how the Krewski reanalysis can be used to support a long-term standard.

I'd like to say a few words about exposure

response relationships and the issue of thresholds and linearity of exposure response. Now, there is a curious phenomenon that I've noticed in the literature. If associations are reported between one of the gases and the mortality or morbidity end point at many low levels, the conclusion is, aha, it couldn't be the gas, it's the concentration is too low, so it's got to be something else. It's a stand-in, it's a surrogate.

The same thing is reported for PM: Aha, see, there is no threshold for PM. You know, it's linear down to the lowest doses. And the sociology, the science I find difficulty to understand.

So with respect to exposure response, you know, I would just like to show you a figure. I think one figure is worth a thousand words. And here's some analysis of nine-year data in Cook County that shows a single-pollutant analysis at lags of zero to five days, so you start out with a same-day PM 10, one-day lag, two days, three days, four days and five-day lag. And you can see from these smooth cam analyses with these -- these are single-pollutant that they are highly non-linear. They are highly non-linear. Look particularly at lag one. And the analysis of deviants shows that the non-linear components are significant.

Now, the strange thing is this downturn at the higher concentrations, and this is not inconsistent, this downturn is not inconsistent with what was reported in NMAPS by Samet, et al., who found an inverse relationship between the PM coefficient and the concentration of PM in a given area. That was one of their significant findings. It's not alluded to at all.

So what I did was I looked at days in Cook County on which the pollutant PM 10 exceeded 50 micrograms per cubic meter and restricted my analysis to those days and did a simple linear analysis, generalized the model, controlling for everything, that's weather and so on, but linear in the pollutant. And here you see that the coefficients are either negative or extremely small and highly non-significant, indicating clearly that at the higher concentration levels in Cook County for these nine years, the dose response for over 50 micrograms is essentially flat.

Of more relevance maybe to this committee are similar plots from Los Angeles, again nine-year analysis. This is for PM 10 and this is for PM 2.5. Again, highly non-linear. I am not arguing on the basis of this that there is or is not a threshold, all

I'm saying is that the issue of thresholds and linearity has not been explored the way it needs to be explored. And what I'm saying is that so far, I don't think any conclusions about this can be drawn.

So finally, what are my conclusions? I think it is time to -- the most important conclusion is that it is time to stop thinking about pollutants in isolation. I think it is time to bite the bullet and address air pollution as the complex mixture that it is. It is a mixture of thousands of components, and it is I think naive to interpret redirection analysis with just five monitored components as representing the effect of those components.

It is clear that each one of the monitored components is simply a surrogate measure of either a source, a multiple source of the pollution or of the pollution mix, and it is an item to interpret the coefficient for that particular pollution as representing the effect of the pollutant itself.

And finally, I think there is overwhelming evidence, epidemiological studies appearing in the last decade and even before that that clearly indicate that air pollution as indexed by PM and/or the gases is associated with various effects on human health. But these studies, I don't think we have the

technology at the moment to actually tease out the actual components of the air pollution mix that is responsible for this association. And certainly, I don't think that we can actively quantitate estimates to the number of hospital admissions or of mortality that is attributable to single components of air pollution. I just don't think we have the technology to do that. Thank you.

CHAIRMAN KLEINMAN: Thank you.

The next speaker is going to be Ken Kloc.

MR. KLOC: Good morning. My name is Ken Kloc. I'm an environmental scientist representing the Environmental Law and Justice Clinic at Golden Gate University School of Law, and also Our Children's Earth Foundation. We've submitted written comments to the Air Resources Board on the proposed standards and we were joined in this by three other non-profit organizations, Communities for a Better Environment, Blue Water Network, and Bay View Hunters Point Community Advocates.

I'm here today to give you a brief review of the points that we covered in our written comments. Basically we agree with the Air Resources Board and the Office of Environmental Health Hazards Assessment, that the existing PM standards fail to adequately

protect public health; however, we also believe that the newly proposed standards may be inadequate.

We recognize that the agencies' work has been made more difficult due to the lack of an effects threshold in the data. Nonetheless, we remain critical of the proposed standards because we believe the agencies have failed to apply an adequate margin of safety, which is specifically required by state law.

The agencies claim to have operationalized the margin of safety in choosing standards, but unfortunately, no definition of this operationalized safety factor is provided in the report. Instead, the report recommends PM standards based upon a number of subjective and sometimes inconsistent arguments.

For example, the agencies propose to keep the 24-hour PM standard at the previously established value of 50 micrograms per meter, cubed; however, more than 80 percent of the short-term mortality studies, and that was a long list of studies, listed in table 7.1 of the report showed impacts at mean concentrations below 50 micrograms per meter, cubed.

In addition, numerous US studies, some conducted in California, reported significant increases in mortality at mean concentrations in the

range of 25 to 35 micrograms per meter, cubed. The agencies in section 7.3.6 of their report recognized that these lower-concentration studies were meaningful; however, when we get to the section of the report where the agencies are determining standards, somehow the short-term studies aren't taken into consideration.

Regarding the 24-hour PM 2.5 standards, we disagree that the PM 10 standard will suffice to protect against short-term 2.5 exposure. One of our main problems with the agencies' position is that people living near power plants and refineries are likely to be exposed to PM plumes that have 2.5 to 10 ratios which are highly than regional ambient values, so that the failure to define a 24-hour PM 2.5 standard will leave these individuals unprotected and may also create an environmental injustice. Because, in many case, communities of color and low-income families are disproportionately located in industrial neighborhoods. This would be inconsistent with the Air Resources Board's proposed policy on environmental justice.

Moving on to the annual standards, we believe the agencies' own risk analysis shows that both of these standards should be even more stringent than

those that are currently being proposed today; for example, in the case of PM 2.5, tables 10.4 and 10.5 of the report show that after the annual limit has been attained, nearly 3,000 Californians are still expected to die each year, and more than 10,000 individuals are expected to contract serious circulatory or respiratory illness all in the same period, as a result of exposure to the remaining unregulated anthropogenic particulate matter.

Based on these risk numbers, we believe that the agencies have failed to adequately operationalize the required margin of safety. Given the lack of an effects threshold and the possibility that serious effects may be obtained at particulate matter concentrations approaching non-anthropogenic background levels, we'd like to suggest that the agencies consider incorporating an adequate margin of safety by setting the standards at our near background levels.

This may seem radical, but in practice it would not be. As you know, air quality standards can take years and even decades to be fully achieved; for example, take California's ozone attainment plan. The main reason for this slowness is that California's air quality planning process allows for significant

flexibility such that undue economic burdens are not placed upon the business community or the general public.

The Health and Safety Code allows air quality plans to meet standards by the earliest date achievable, using reasonably available control measures and technologies. So setting a very stringent standard today will only mean that reasonably available control technologies and measures will be required in the future.

So, in summary, the current proposed PM standards will allow unacceptable levels of death and disease due to unregulated anthropogenic PM. And this is shown by the agencies' own risk analysis. The problem arises from an inadequate application of the required margin of safety. Therefore, we recommend that the standards be revised downward to make them truly health protective, and that a stringent 24-hour PM 2.5 standard be defined. Thank you.

CHAIRMAN KLEINMAN: Thank you.

The next speaker is Bob Yuhnke.

MR. YUHNKE: Good morning. Thank you very much. My name is Bob Yuhnke and I'm here representing Environmental Defense. You do have in your packet written comments from us and I want to summarize some

of the key points on that.

As a general matter, the main interest that we have here today is to encourage you, which yesterday's discussion seems to suggest you don't need a lot of encouragement, to move towards the adoption of a short-term standard for fine particles. And the first point to make is that there is a legal requirement, we think, in the California Health and Safety Code to do that. The Health and Safety Code requires a standard when you determine or when the state determines that there are adverse health effects associated with exposure to a pollutant. And in this record, we think the evidence is very compelling, as a number of you discussed yesterday, that the short-term effects of fine particles are well demonstrated. And, if that is the case, then a standard is needed to protect against those adverse health effects.

Secondly, the inference from the report is that those adverse health effects of short-term exposures will be prevents by setting an annual standard. And I think the evidence, again, is quite clear that that is not the case. You heard in the American Lung Association testimony examples of cities here in California where the 12-microgram standard is being met on an annual basis, yet the daily

concentrations are in the range of 50.

For fine particles, of course, that means that you're up at the level of the standard for PM 10. If you were to apply the ratio of fine particles to PM 10, you really need to reduce those exposures down to 25 or 30, even to accomplish what the state says would be accomplished by meeting an annual standard of 12; in other words, that the correlation would be enough to accomplish the health protection goals, but that's clearly not happening.

Another point, a factual point that we'd like to emphasize here is that when you look at the health effects research, particularly the Schwartz analysis of the Six-Cities data, there was an effort there to begin to refine that analysis to identify the level at which short-term effects might disappear as being statistically significant. And in the Six-Cities data, what Schwartz did was to cut off all the days that are above 25 micrograms and re-run the analysis and found that the statistical correlation was even more significant for those days that were 25 days and below than for the entire data set.

And when you consider the fact that the statistical power of the analysis obviously diminishes when you reduce those total number of data points in

the analysis, it suggests to us that the mortality effects, at least, of short-term exposures are well demonstrated at 25 micrograms, and that that evidence needs to be taken into account here. It was not discussed in the staff report.

But that also suggests to us an approach for refining this whole analytical approach to setting a 24-hour standard. The staff has focused on the difficulty of trying to extract a level from the data, and we would suggest that that iterative approach of removing portions of the database, based upon the magnitude of the daily concentrations, is a statistical approach that could be used to try to identify at least the point at which the statistical significance of the correlation between daily concentrations and effects then ceases to be significant.

So at least you could identify what might be characterized as a statistical threshold, where the effect no longer is observed. And that that would provide some very useful information for trying to set a standard.

Now, another point that we've made in our comments is drawn from a case example two years ago where a woman with a history of asthma died in an

episode of status asthmaticus, as a result of burning of wheat stubble in the fields in Northern Idaho. This is an area where the annual PM 2.5 concentrations are 10 and below. It's extremely clean air quality.

She died on a day when the 24-hour concentration, and there were four monitoring stations in that area, the 24-hour concentrations ranged from about 27 up to 40, and the hourly concentration which we have from nephelometer and TEOM data ranged from 120 to 160. This was for fine particles. And her death was officially recorded as being caused by air pollution by the State Health Department.

So it's one of those cases where we have an unusual combination of a record of the mortality itself, combined with evidence from four monitoring stations, monitoring PM 2.5 on a short-term basis. And it clearly indicates the importance of addressing these short-term exposures. It's not enough to address the annual concentrations. The annual concentrations in this area are not the problem that are associated with that kind of death.

And, of course, the death is just one example. There were other people who were affected during these high-pollutant episodes. They didn't die and so they didn't get as much attention, but there

were children who were severely affected and had to stay home from school and other effects that we all well know are correlated with these kinds of exposures.

But it simply highlights the importance of not simply assuming a correlation between the annual concentration and your daily concentrations, and using that assumption to conclude that you don't need a short-term standard. So those are the critical points that we would raise this morning.

As a general message, we're very supportive of the effort you're engaged in. This is an extremely important public health issue, and tackling this issue and doing it right is very important to the long-term protection of public health in California. Thank you.

CHAIRMAN KLEINMAN: Thank you very much.

The next speaker is Pamela Soderbeck.

MS. SODERBECK: Good morning. My name is Pam Soderbeck. I don't represent anybody but myself as a member of the public here. I'm a retired lawyer, and became very interested in this subject matter about a year ago, because I live in Morro Bay where a 1200-megawatt power plant is scheduled to go in. It's in the CEC hearing process right now.

I found out doing a little research that it

was going to be emitting an additional 76 tons per year of PM 2.5, primarily elemental carbon. That got my attention, it sounded bad, and I started researching and I ended up reading about 90 percent of the articles that you have cited in the study. It took me about a year, and I got more concerned.

So I'm here to say that I do applaud your efforts to make those standards stricter, and I too would particularly urge a stronger 24-hour PM 2.5 standard. I've been around the existing plant that is there, I know how it operates. It's not constant. It's very much up and down with the peak needs of the industry, as you might imagine, and I don't believe that an annual standard will adequately cover those peaks that we will be experiencing in living around that plant.

One of the other things I have discovered is that the, and perhaps this isn't exactly the right forum but it starts with you, because you're establishing the standards for the ambient concentrations. The power plant people have so far been very successful in arguing that the existing standard has already been exceeded because it exceeded it one time during three years when there was a fire going on in the area, and, therefore, they don't have

to worry about the fact that they're putting out more because it's already being exceeded there, which to me is absurd, but that's the argument that is being accepted so far. And I would urge you to act quickly, before they get all the way through this process, so they do, in fact, have to pay some attention to the new standards.

The other problem that I've discovered is that they are able to proceed because they are able to mitigation credits for emissions. And the fact of the matter is that the concentrations in Morro Bay are going up with the new plant because it's going to have shorter stacks and more temperature velocity and a number of things that will be keeping the PM 10 in town. And there is no mechanism at the state level except with the CEC itself, which we're just now getting into, to look at the fact that the concentrations are going up.

The CEC has accepted the fact that mitigation for emissions is enough. There's a disconnect somewhere in there. But I definitely think that we need to increase the standard in terms of strengthening it -- not raising it, but strengthening the standards, and hopefully they will have to comply with those by the time they actually get underway with

construction if they decide to go forward. Thank you.

CHAIRMAN KLEINMAN: Thank you.

There was one other speaker, I didn't get your name, but did you -- Oh, David, I'm sorry, David.

MR. FEARLY: Hi. My name is David Fearly. I work for the Bay Area Air Quality Management District. I'm here speaking as an individual, and listening to the discussion yesterday I had some thoughts and possible suggestion for a compromise between the annual and the 24-hour standard.

Maybe I should say first, after all the excellent -- I'm definitely in favor of very tough particulate standards, and if you're considering making a stricter 24-hour standard I don't want to stand in your way. In terms of the air pollution in the Bay Area, the particulates, especially fine particles are extremely seasonal. And so the annual averages are often low, whereas in certain seasons, in the winter, in particular, the average is much higher.

And so, as was pointed out by the American Lung Association speaker, for example, in Alameda County and Contra Costa, we'd probably be meeting the proposed standards, but we get some very high levels. And I think at least one study has shown significant health effects in Alameda County.

So what I can see from -- I believe that the standards that are being proposed are probably not going to be any more stringent than the current state PM 10 standard for the Bay Area. So my suggestion is, I understand how hard it is to come up with kind of the bright line, the 24-hour standard, but a possible alternative might be to take your levels and consider a quarterly standard.

In other words, there are quarterly standards for lead, and what this would do is in areas where there is extreme seasonality, this would create a pretty strong cap on the levels that are permitted and would come closer to the ideal of trying to control PM on every day.

On the other hand, I mean, I don't consider this as important an argument, but as somebody who works at a local air quality agency, we deal with how do you control and how do you plan to control these levels. And it's a lot easier to think about controlling on an average basis than it is to control peaks. And you usually think about, well, we need to control wood burning and we need to do something about diesel and so on, and these are the kinds of things that we could say we have inventories, we have some idea of how much is being burned or how much is being

emitted, and it's a lot easier to plan for averages than for peaks.

So anyway, my suggestion is that you might consider quarterly averages. In other words, capping -- using the same levels but on a quarterly basis.

I'd also like to make a comment. This is a little bit out of order, but already we have a pretty good PM 10 standard in California, I think. The problem is that it doesn't have any teeth. And we really need, all of us, to do something about getting to the point where these standards are actually being required to be met.

In my agency we basically ignore particulates, and, you know, I probably shouldn't be saying that, but it's a fact, right? And we concentrate on ozone which, to me, is a much lower level in terms of health detriments. It's really bothered me to learn about what happened, what's been happening in Morro Bay, and the same thing that's happening in the Bay Area. In fact, right in San Francisco they're planning to build a huge power plant and we don't really have any means of counteracting it, because we meet not only the older federal PM 10 standards, we actually will meet probably the new PM

2.5 standards.

And so at the national level, although the standards have teeth, their levels are so high, they're too -- they don't really help us, whereas the California standards already are pretty good, but they don't have any teeth. So anyway, it's something that we all should be thinking about. Thank you.

CHAIRMAN KLEINMAN: Okay. Thank you very much, David.

I believe that was everyone who signed up to make a presentation, and I'd like to just throw it open to the committee for a few minutes, if anyone wants to make any other comments.

Hearing none --

PROFESSOR SHERMAN: I will make one. I was quite disturbed by the comments of Dr. Vostal regarding low-level inflammation in the lung. Having been author with Jim Crepo, Alan Harmson and Bob Munsen regarding an NIH report that had to do with immunobiology in the 2000 American Journal of Respiratory and Critical Care Medicine, we emphasized the fact that the lung actually attempts to reduce inflammation constantly.

And you heard about complex particles that are part of air pollution. Having studied tobacco and

marijuana smoke and their effects for a number of years, I will tell you they are also very complex. They cause these low levels of inflammation that we would have a concern for, and, in addition to the destructive effects they will exacerbate a much more serious event such as a viral or bacterial infection. And, more importantly, they have genotoxic effects over time, as you're all aware of, with regards to lung cancer.

So assuming that low-level inflammation really has no consequence is totally erroneous and not supported by sound scientific data.

DR. SHERWIN: Well, since Dr. Sherwin opened up the subject, I was going to hold this until a little bit later on, but getting back to the basic work we are doing, everyone should bear in mind two big things. Number one is, the lung is a dirty organ. It has billions of PM particles, everybody's lung. And that is only a residual of what you have.

Somebody has shown that the coal miner's lung takes in so much pigment that the whole lung gets black, but it only represents one percent of the coal dust that is taken in over a lifetime. In other words, what you see is a residual, and the lung is clearing. So number one is the lung is

extraordinarily dirty, with billions of particles, and including millions of fibers, most of which are asbestos fibers. So we've got a lot of problems in terms of where are these things coming from and what are they doing.

Now, the second part of the picture is the inflammation. Why we are not paying attention to this, I don't know. But I am seeing, in 15-to-27-year-old young people who die suddenly of accidents, a severe amount of inflammation: chronic bronchitis that involves the glands, that involves the mucosa, that involves the lung perfori, which we call centriasna (phonetic) region inflammation.

That inflammation is associated with overt -- and these are young people who theoretically or ostensibly are mostly a well population. That inflammation is associated with overt pathologic lesions; for example, atrophy of glands -- We introduced a term called chronic sial adenitis to explain why the lung's fluid may have polys in it, but there doesn't seem to be polys in the tissue sections. And the reason it's not there to some extent is because it's very subtle, it's within the glands. The glands get dilated and they get inflamed, and they actually leak polys, but that's a destructive process.

And the thing that's impressed us more than anything else is the amount of bronchial gland atrophy we see in young people, there's disappearing. Lung tissue is disappearing, bronchial glands disappearing. One out of four, as a conservative estimate, in the young group we see. Now, whether it's a biased group or not is beside the point; they are a large number of youths involved, they are Los Angeles residents. I don't have any reason to believe this is any different elsewhere, except worse here.

We've done Miami studies as well, and young people there have inflammation and dirt deposits -- not as bad, but -- we don't have statistically significant data on that -- but the point is, no question about the pathology. There is disease.

So my concern is what do we do about it? How can we reduce that? And if we have information, where there is an epidemiologic link, where there are morbidity links, well, I think that takes into account this area of judgment. And so the message I would like to leave is that this minuscule amount of dust particles that Dr. Vostal referred to is not what nature does; nature collects that dust and sequesters a good deal of it in lymph nodes, but a lot of it is in tissues themselves, and it poses a lot of problems.

Bear in mind two big things. The lung is, lung disease of COPD alone is the fourth-leading cause of death. Very inaccurate designation, because COPD is a lot of diseases. But there are diseases other than COPD. I anticipate by a short time it will be the third leading cause of death.

The last thing is lung cancer is a leading cause of oncologic cancer deaths, so we've got a problem. And the question that's facing us is what have we done responsively to try to reduce that burden of dirt, and the burden of damage and the burden of cancer? And that, I think, is where I feel the job that has been done, the work that has been done is excellent and is very reliable guidance for us.

CHAIRMAN KLEINMAN: Okay. Thank you very much. In that case, what I'd like to do is take about a 15-minute break and then we'll reconvene. So if you can be back by about 20 of 11:00.

(Thereupon, a recess was held off the record.)

CHAIRMAN KLEINMAN: We're going to start off. Bart Ostro is going to present some of the -- a brief summary of comments that were received from the public, and some of the responses to those. Obviously, this is going to be abbreviated, and the

comments will be dealt with in writing later on, as part of the final report.

Bart?

DR. OSTRO: Okay. I'm going to try to provide a review of the comments, and a response to the comments in a general sense. First I wanted to actually thank the commenters for their comments and for the meticulous reading of the document.

In trying to review the hundreds of studies that are out there, I think it's always the case that there are going to be some errors that will be made, and I think the fact that some of those factual errors were pointed out to us, we'll definitely take account of those things and try to make sure that the document is improved in the next go-round.

That being said, I think there are definitely some differences in interpretation of some of the results, and I'll go over some of our own differences of interpretation and just say that in general, we didn't think that the comments would alter our evaluation overall of the data, and of the need for the standards that we've recommended.

The general comments we've put together as follows: First, that not all studies were included and the review was not objective; second, that there

was a flawed assessment of co-pollutants; third, that the weather is an uncontrolled confounder; fourth, there is an issue of whether the results are consistent and coherent; fifth was the evidence of a threshold uncertain; and sixth, I think I heard at least one time, wanting a PM 2.5 24-hour standard.

And these were all the questions and maybe criticisms, and my thanks to Jeff Cook yesterday who suggested that I should at least add one positive comment. And let's go to this one --

[Laughter]

DR. OSTRO: Okay. Do we have any response to that? I think it's good, yeah.

Okay. Now, in all studies reviewed, I'm going to look at some of the specific comments and use them as a format to address things more generally.

As I mentioned, the report covers hundreds of studies, and as I mentioned yesterday in our overview, we wanted to basically address the issue is there evidence of effects at current levels, and what is basically the weight of evidence. And it's certainly possible to find some contradictory results on cases where, among these studies, you don't find statistically significant effects or find less linear functions and so on. So I don't want to say that the

evidence is absolutely 100-percent behind it, but certainly, as I think I indicated yesterday, the weight of the evidence is certainly very compelling.

There were some comments from the Engine Manufacturers that I'll deal with here. There's an issue about what about the critical papers, and this was going to be an example about how we cherrypick results. And we did look at some of the critical papers, and among the papers that were mentioned were the ones here, Burnett in '98, two of them are from '98, the Zmirou study, and the Lipfert 2000 study.

And our response to that is that the first two are Canadian studies, and, in general, we try to use or focus a little bit more on the US studies. But the bigger problem here is that in some of the original Burnett studies from Ontario, there are very high correlations between sulfate and ozone and fine particles, making it very difficult to distinguish effects from one pollutant from the other. So we didn't put a lot of attention on the Ontario studies.

These studies, though, were not necessarily Ontario studies, but the '98 Burnett study of 11 Canadian cities didn't even measure PM. So although it's an interesting study, I didn't think it was necessarily a critical flaw to not include that study.

Burnett in '98 (b) was a study of mortality in Toronto, and again, PM 10 was not measured directly nor was PM 2.5. It was estimated from TSP sulfates and COH, coefficient of haze. The estimated PM 10 did have an association with mortality, as expected. A lot of the pollutants in that area, since they're highly correlated, in general showed a relationship. And ultimately, they say that the complex mixtures in that area can almost be completely explained by CO and TSP.

They go on to say that CO is a pretty good proxy for traffic volume and density and has very low, as we know, intersite correlation, that it's basically a hot spot pollutant. You put that all together and CO and TSP are basically surrogates for combustion sources I think in this case.

So, again, we didn't think that the study was crucial to our review, given the wealth of other studies where you don't have those confounding, and where you have PM 10 directly measured. It is interesting to point out, as some commenters have pointed out, that there might be effects of things besides PM, which might not surprise people, that there might be effects from some of the gases as well.

What about the Zmirou paper? It's a study of

ten European cities. Again, PM 10 is not measured nor is PM 2.5. Instead, black smoke is measured. And one could try to figure out what the association is between black smoke and PM 10 and PM 2.5, but it is highly dependent upon the area that you're looking at. And again, we didn't think it was a study that was crucial to the understanding of what the other studies were showing. Regardless, in the study for Western Europe, both their measure of PM and SO2 were associated with mortality.

Finally, there's a Lipfert et al. 2000 study, which I mentioned yesterday is a long-term cohort study of veterans recruited from 32 different centers in the '70's. They're all army veterans with hypertension. They were recruited from hypertension clinics. Probably not very representative of the general population, and George Thurston might want to discuss that study more in general.

But the author himself describes the results as preliminary in the publication of proceedings in Inhalation Toxicology, and I know when I put something out and call it preliminary, that means that things could change and the analysis is not really complete. But, nevertheless, we will include it in discussion in our next draft.

Now, interestingly enough, what is concluded from this study -- well, there's a lot of analysis in this study, and it's actually -- three is a little hard to get through what the major conclusions and analysis was. It was a long-term cohort study of about 20 or 30 years, but the pollution measures are broken up into different periods of time, and the mortality is broken up into different periods of time. And there's a lot of negative associations that are reported, which to me would indicate that the model probably is not well constructed.

But there is, in the back end of the paper, a statement which was intriguing, which says that the responses to PM 2.5 and PM 15 differ greatly to, in a single period -- that is, when the whole analysis was done for one continuous period -- versus when the times were broken up into very short intervals. And then he goes on to say that the single mortality period responses, without the ecological variables, are qualitatively similar to what has been reported before, which I take to mean the Harvard Six-City Study and the ACS cohort. No results are presented for this, so there's no analysis presented, no numbers presented, but I found this result to be intriguing, needless to say.

So if we put all these studies in context, these are the long-term cohort studies, I first wanted to repeat that the annual average standards are not based totally on the long-term mortality studies. When we factor in both the morbidity short-term time-series studies as well as the mortality time-series studies, and, as I mentioned yesterday, the pollution range for those studies tends to be about the same, that you don't see suddenly greater effects as you go up to, or different subgroups coming into play when you go up to different levels, but there is a consistency among the different effects regarding the concentrations that are generating those things.

But if we look at the chronic exposure studies, actually there are some intriguing things here. And, I don't know, hopefully everyone can see it, I know the numbers are small. This is the original Six-City analysis with the relative risks. The Six-City reanalysis by Krewski showed about the same effects, and also showed effects for men and women separately. The 500,000-person American Cancer Society using PM 2.5 and changes of 24 1/2 micrograms also reported results for the total population and men and women separately.

And then I just listed some of the different

reanalyses that were done. Again, there was literally hundreds of different sensitivity analyses that were conducted. And I won't go through all the details except to show that associations are continued throughout the range, and here's what was referred to as a study with SO2 where the coefficient drops down to 1.03 as a relative risk, and I'm going to say more about this issue of what happens when you throw in lots of other pollutants into a model.

Then we haven't talked very much about the Seventh Day Adventist studies, but I wanted to show at least that they used PM 10 -- Actually, they didn't use PM 10 for the whole period of time, most of the time they had TSP data. They had PM data later on, so again, there are some measurement errors that were introduced into this, making it more likely that you wouldn't find an effect. They do find an effect for higher levels of PM 10. They start to see associations, particularly among men.

In a subsequent study by McDonald, they looked at a subset of the Seventh Day Adventist group, and this time they used PM 2.5 based on visibility measurements, where you take inverse visibility and correct it for humidity and you get some proxies for PM 2.5. Again, there is going to be measurement error

in determining what is actual PM 2.5 here, so you would expect it to be more difficult to find effects.

But for men in general, they got effects that were pretty well related to what the earlier studies have found for males. And then when they looked at a subset which were people in relatively high housing density, and I would take that to mean in cities, where probably the monitoring and associations with the pollutant measures might be a little better, they actually did find, if you want to use statistical significance as a measure, they actually did find statistical significance here.

But again, the general associations appear very consistent, actually, with the earlier studies. So taken together, I think the evidence is pretty compelling.

Then the comments go on to say that the authors commit two more serious errors here. One of the errors that's considered serious is that the means of the cities in the NMAPS studies, in the 88-city analysis and the 20-city analysis that we reported 24 to 46 are simply not available, our response is, well, I don't think it's a serious error anyway, but the response is it is available in the appendix.

Another comment was that the NMAPS people

report no association between the estimated effects of the cities and the mean level of PM 10. Again, I don't think this is a major point, but what the initial analysis tried to do is it looked at the individual beta coefficients for all the cities, for the 88 cities. Then it tried to see if there was an association between the beta coefficient and the mean concentration of PM 10.

And basically, they found in univariate models -- that is, when you look at one pollutant at a time -- there was no association between the concentrations of PM or any of the other pollutants and the actual coefficient, indicating a fairly linear response.

Now, they do go on to show in another table that when you have models with three pollutants to try to explain the beta coefficient, the individual city regressions, that PM 10 and NO2 play a role. I have a little bit more difficulty interpreting that. I think the proper test is this univariate test. And they report no statistically significant effects from mean concentrations. And, again, I don't think it's a major point, but we did feel like we had to respond.

Next is the commenter saying that we say that co-pollutants such as ozone, SO2, NO2 did not confound

the estimated effect of PM. There is simply not enough information in the paper to conclude this. Our response is that the Samet article on page 72 says, "As for the 20 cities, the effects of PM 10 change little with control for the other pollutants." The review panel says that -- basically concurs that there is no convincing evidence that suggests the effects of mortality are changed by the addition of any of the gases, suggesting that none of the other pollutants is responsible for the observed PM 10 effect.

And then in the New England Journal of Medicine article that I quoted from yesterday, the same conclusions were indicated, that the gases did not seem to have a significant confounding effect.

And this is one of the graphs that they use to show it, looking at marginal posterior distributions, looking at what the effects, the probability distribution of what the effects were likely. And here's the effect at about .5 percent or ten micrograms when only PM 10 is used, and you can see it does shift a little bit, which is not surprising when you throw other co-variable pollutants into the model, but not really a dramatic shift in the PM 10 coefficient.

Next is the chronic exposure mortality study

comments. The inclusion of SO2 in the model reduces SO4 in PM 2.5. We will be more clear about this in the next draft, with the explanation that these pollutants are co-linear and, according to the authors, the association still exists for PM 2.5.

We also indicated something about the spatial correlation and we're going to add into the draft that, into the text that attenuation of the effect does occur when you do the spatial correlation corrections, but again, that the effects, there are still associations reported between PM 2.5 and sulfates with mortality.

Now on to another general comment is about co-pollutants and weather. The general comment has been that there is inadequate control for weather in all these time-series models. And our response is that, as I indicated yesterday, that temperature, humidity and dew point has been controlled for in many ways. The most blunt way to do it is using a linear term, and in our text we indicate that a lot of these models probably would be better served using models of just the extremes and temperatures, which is what really might affect these health end points.

So using just linear terms for temperature, humidity and dew point, again, might be taking away

some of the effects of other factors, including air pollution, and you really don't expect moderate levels of temperature to affect mortality. So people have used linear terms that modeled extremes and non-parametric smoothing techniques have been used which were totally data-driven, which allow for non-linear, even non-monotonic types of responses.

In addition, several authors have brought in meteorological experts and looked at synoptic weather patterns with Dr. Kaufstein at the University of Delaware, which take into account not just single-day or multi-day but whole entire periods of time, and not just temperature and humidity, but barometric pressure and whole movements of weather patterns. And, again, those studies, published studies show no differences, no real effects from different controls of these weather patterns through synoptic use. And also, the data typically as indicated yesterday are de-seasonalized so that seasonal influences are taken out very well from these models.

A broader response to the question of what about the control from weather is indicated by the fact that, again, when we have a multitude of studies in very different cities, it gives us a lot more ability, a greater ability to talk about causality and

be able to deal with potential confounders. And, for example, the fact that we have very similar associations with PM observed in cities and climates that are very cold, like Montreal, Minneapolis and Canadian cities and Helsinki, and you get the same effects in very warm climates, and likewise in high and low humidity; therefore, the likelihood of a common confounder causing that association that we see with PM is extremely unlikely.

Also, effects have been reported in cities where PM peaks in the summer, where PM peaks in the winter, and we actually even found one city, Helsinki, where it peaks in the spring. Actually, in LA it peaks in September/October, not even in the summer. So you get a good variety of seasonal patterns, in terms of particle exposure, which is another way of dealing with and being able to control for seasonal affects and weather effects.

Okay. On to co-pollutant models, which is mentioned a lot in the comments, and the idea is, I think, that you have to use multi-pollutant models, it's not good enough to just look at particles, you should be looking at particles and also include all the gases and air and CO and some other things, and, in fact, when you do it, lo and behold, the PM

coefficient decreases. And, therefore, the commenters suggest there is no real effect from PM or it's difficult to really determine an effect.

I think this is a very flawed statistical approach to the data. First, it's important to note that the PM associations have been reported in a variety of studies with different levels of and correlations with co-pollutants. So, for example, studies have been done where PM and SO2 are very highly correlated, and then studies where SO2 is not correlated at all or SO2 is basically at very, very low levels, like it is in lots of parts of California.

And most of these studies, but not in all cases, these co-pollutants don't impact the particulate matter co-efficient. Also, many people have selected studies specifically so that they can look at the issue of what happens when you have high co-variation with other pollutants versus no or low co-variation with pollutants. And again, seem to find the same effects for PM.

And part of the issue is that we know that the monitors from NO2, SO2 and CO are generally more, capturing more localized ambient conditions and not more homogeneous exposures that you see from fine particles.

Now, often co-pollutants are correlated with PM due to common sources, we certainly know that, or because of weather. In that case, adding another pollutant to a model which already has particles in it cannot really help you determine which pollutant is most important.

Now, in a way you can prove the obverse. If you have a particle effect and you throw in another pollutant or series of pollutants, if there's no change in PM, then clearly there's no problems with the confounder, and, you know, you have a very clear conclusion that PM is of concern. But if you have PM in the model and suddenly, and then you throw in NO2 or SO2 and the particulate matter coefficient changes and is significant, it's most likely, in fact, extremely likely that that change and the significance is due to the predictable and very well known statistical aspects of multi-colinearity that occurs in models where you have variables that are very correlated.

It's very well known in the statistical literature, the econometric literature and the biostatistical literature that if you have variables that are correlated as explanatory variables that the initial variable is there, and then when you add the

second one, it's very easy to show statistically that the variance of the initial variable will be increased in direct proportion to the amount of correlation it has with the other variable.

So you throw in another variable that's highly correlated, you're almost always going to get an increase in the variance, you get a lower T statistic and, lo and behold, you get a lower statistical significance of your main pollutant of concern.

So I submit that adding multiple pollutants into these models, particularly when you have high correlation which you often do, it tells you nothing about the relative importance of the different pollutants. But I do say, certainly sometimes only using PM is, and not including the other variables, will allow PM to take on the role of other related pollutants. So PM in those cases may be acting as a surrogate for, let's say, combustion particles in general.

Also in this regard, the results of a recent paper by Sarnet at the Harvard School of Public Health were very important. Now, this is only one paper, it certainly has to be replicated in other cities, but this was a paper done by Maltomar, and what they found

was first that, as you might expect in very many cities, that ambient PM 2.5 was correlated with ambient ozone, NO2, CO and SO2 in different ways, but there were correlations in that data.

Then they looked at personal exposures to PM 2.5 and all the other pollutants, and they found in the study that personal PM 2.5 was associated with ambient PM 2.5, but for none of the gases were personal exposures associated with ambient exposures. So only for the case of PM 2.5 were personal exposures related to ambient exposures. The measurements outside ambient air did not say very much about what people were exposed to in terms of the gases.

In addition, they found that personal PM 2.5 was associated with ambient concentrations of the other gases -- I mean, probably because they're related to the ambient PM 2.5 they're moving together. So these things actually, the outdoor levels of these gases actually relate to personal exposure to PM 2.5.

So the conclusion of all this is that, as the authors indicate, this indicates that ambient PM 2.5 is a suitable surrogate for personal PM 2.5, which we've talked about from our indoor exposure studies. But more importantly or equally important that the ambient gases concentrations are surrogates, not

confounders of PM 2.5. In other words, they're just other ways of measuring personal exposure to PM 2.5. Therefore, multi-pollutant models may not be suitable and the health effects attributable to ambient gases and may actually be a result of PM 2.5 exposure.

So, again, this is only one study and it has to be replicated in other areas, but it's very intriguing and has very large implications for the interpretations of studies.

Another way of looking at the effects of co-pollutants is do this analysis, conduct this analysis that was reported by Samet, et al. This is actually the hospital admissions analysis of 12 cities in the US, and it looks a little fuzzy, but the -- Let me just read this. Cardiovascular disease, COPD and pneumonia, and on the axis is the -- the Y axis is the percentage change in daily hospital admissions. It's the beta coefficients from each study. And on this axis is the correlation between, in this case, PM 10 and SO2, and in this case, PM 10 and ozone.

And the argument is, if the effects of PM are actually due to other pollutants, then the higher correlation, and as you go in this direction, the higher the correlation, say, between PM 10 and SO2, the higher the coefficient you should see for the PM

10 coefficient. So if the PM 10 is really taking on most of the effects of SO2, you would expect that as you move along this axis, as you're looking at higher correlations between PM 10 and SO2, you would expect to see higher beta coefficients.

And, in fact, what the analysis says, and again, this is 12 cities but you can certainly get a sense of what's going on with the beta coefficients, it basically shows that the beta coefficients are not subject to change, based on the correlation of particles with either SO2 or ozone, indicating that there is likely to be independent effects of those pollutants but, more importantly, that these effects that you're seeing are PM 10 specific effects in this case.

What about consistency issue? Effects for Los Angeles were mentioned and I was honored to have one of my earlier papers cited in that, but unfortunately that was a paper that again did not have direct measurements of particles. It was an earlier paper when interest was generated in fine particles, and I used airport visibility to estimate fine particles in that.

But if you look at the papers that actually measured PM 10, the Kinney, the Samet and Moolgavkar

papers, the lags are different and, as Suresh indicated, you do get some noise, at least in his models, between the different lags that are used. But if you use the lags and show the highest association and highest T statistic, not necessarily the highest magnitude, but just the strongest association. I think you see pretty consistent effects among three different authors using somewhat different years and different modeling approaches. And, likewise, the studies all showed that when you added ozone into the models, you didn't see any changes, really significant changes in the PM 10 coefficient.

Now, I could do the same analysis for other types of cities, but it is interesting to see that that is the case in LA, and I think it's most difficult to show probably in LA, because the monitoring probably in LA is among the more difficult to measure exposure, because LA is so huge; there are microenvironments and micro-climates. And the fact that you still got consistent results in LA, which I think is inherently difficult to monitor, I think is pretty striking.

What about coherence and inconsistency? Well, here's a list of cities that have reported positive associations for both mortality and hospital

admissions, so separate city analyses for both mortality and hospital admissions, usually cardiovascular-related hospital admissions for all these studies. And it's important to indicate that in some of these cities there have been multitudes of studies.

For example, in the Utah Valley area, Arden-Polk have shown that not only mortality and hospital admissions but also respiratory symptoms and other end points -- school loss, school absenteeism, and I think some other outcomes have also been shown in that area.

With the Harvard Six-City Studies, normally long-term exposure mortality, mortality related to short-term exposure, bronchitis related to chronic exposure, respiratory symptoms, all those things have been shown to be related to particles. So you really do get a nice picture of coherence from these studies.

Also, recently some multi-city studies out of Europe, where also they've shown both mortality and hospitalization in a series of cities, so this list is only a partial list of those places where we show not only mortality but morbidity as well, which helps put together the whole picture and I think makes the whole argument a lot more compelling.

The issue of thresholds, these are just using

quartile or quintile of the analysis. Again, I don't know how well you can read these, but Philadelphia, Sao Paolo, St. Louis, Utah, London and another city to be named -- What city is that Rachel, do you remember? I don't know, another city -- you see pretty consistent linear associations across the data, again not really showing evidence for a threshold.

Here are some other sets of data. This is looking at eight cities in Spain, where many techniques were used, again showing not much of a threshold for black smoke in this case. This was SO_2, where no effect was shown. Here's the 20 cities from the NMAPS studies, the 20 largest cities in the US, an interesting analysis by Daniels, where they look at the 20 cities together and for both total mortality and cardiopulmonary mortality, when you look at the data as a whole, you've got a flattening of the curve but no evidence of a threshold.

Again, when you look at non-cardiopulmonary mortality, you do see more of a threshold type of effect. But for the real effects of interest, Daniels et al. report there is really no evidence of a threshold based on the analysis of the 20 largest cities in the US.

Likewise, some more analyses of threshold,

these are using smoothing effects, smoothing models where you specifically allow the data, you take into account all the other factors and then you just look at the relationship between particles and mortality, allow the data to show you what the functions look like, and again, no evidence of a threshold from these studies either.

I think this is one I reported yesterday of ten cities, again similar conclusions. And that's it for my slides. I just wanted to add one or two more points, if I can remember them.

Oh, the question about indoor pollutants, it might be the case that on days where you have reduced wind speed and increased ambient concentrations, you might see increases in indoor concentrations. But that certainly doesn't explain the effects that are seen over a wide range of concentrations, over a wide range of cities where stagnations may or may not be an issue in those areas, so I don't think you can explain all of that.

And I think I'll probably stop here and I think Michael wants to address some comments as well.

DR. LIPSETT: Let's see, I have some on my laptop here, but rather than taking the time to do this because this is going to be short, I'm only going

to respond to the -- This is only going to take a few minutes.

Basically, I just wanted to respond to Dr. Vostal's comments regarding dosimetry. I think they were useful comments and we may revise our document to take into account some issues related to dosimetry. Nonetheless, I have some concerns about the overall point that the doses reaching sensitive alveolar intersticial tissue are too low in the nanogram or less per square centimeter range to cause any meaningful health effects.

This is based on analysis using a model developed by the International Commission on Radiological Protection, and these are, this is -- he used data that were taken from Texas and applied this to come up with some estimates of doses that were in the alveolar range, but really, following the example set by Snipes on whose work Dr. Vostal's work was based, Snipes also reported average doses to tracheobronchial tissue as well, and also, they looked at the doses in terms of numbers of particles per square centimeter.

And if you look at these other dosimetrics, they don't appear to be quite so trivial. Looking, for instance, in the tracheobronchial area, you're

looking at somewhere in the microgram, up to the microgram per gram of tissue range, which is somewhat higher than the nanogram or fentogram per square centimeter dosage that Dr. Vostal referred to, or if looking at the number of particles per square centimeter of vulnerable tissue, you could see 10,000 or 100,000 particles per square centimeter. These are other ways to express the doses that intuitively don't seem so trivial.

But I guess, even going beyond this, this is a modeling exercise based on average kinds of deposition patterns. And these calculations ignore what are pretty well-known non-uniformity of deposition patterns and major interindividual differences that occur with respect to particle retention.

For instance, people with airway disease, they can have up to about three times the total deposition of people who are healthy, and in studies done on autopsies, people who have been in Vancouver, which has very low particle levels, about 20 micrograms per cubic meter on average, Andy Churg has found up to ten million particles per gram of dry lung tissue in the airways of these individuals. So these are real data, these are not sort of modeled exercises

showing trivial doses. I mean, intuitively, it seems like ten million particles per gram might be something that one would be concerned about.

In addition, a number of studies have indicated that there really is a lot of focal hyperdeposition, particularly at branchings of airways, where you can get up to 100 -- where the airways branch about 100 times more particles deposited there, and again, the airways, the kinds of diseases we were interested in may be just as if not more vulnerable than the alveoli.

In addition, one of the things that Churg has found is that there can be several-hundredfold differences in particle retention among different individuals. And so I think taking all these sorts of things into account, it would be a little bit premature and logically difficult to say that these findings unequivocally show that under present US urban conditions, daily alveolar deposits of fine particles are too low to be responsible for complex health effects. I think the comments are useful and we should be looking at this, but I think the case that was made here by the commenter really sort of overstates. And that's it.

Dr. Kleinman?

CHAIRMAN KLEINMAN: Thank you.

I'd like to again throw it open to the committee, if they have any additional comments that they want to make.

PROFESSOR TAGER: Well, I have a comment, a question for Bart. It appears your responses were, and I thought they were very good, but inversely related to the number of times the question came up. So you didn't comment about the 24-hour standard issue.

[Laughter]

DR. OSTRO: I think that was Michael's, yes.

[Laughter]

DR. OSTRO: Well, I thought we would save that until the afternoon when we're going to talk more generally about the standards, so I guess my one response to some of the presentations I heard, as well as the written comments in the analysis, say, of California I think there was a figure shown of areas where the counties would have met the PM 2.5 annual average of 12, but they still had high values of PM 2.5, some above 50. I mean, certainly that wouldn't be acceptable, even based on the PM 10 standard. So they have to be below 50, that's clear.

The other thing relating to that is that in

most urban areas we know PM 2.5 and PM 10 are pretty highly correlated. Usually the correlations are .7 to .8. So we could infer that control of PM 10 on a daily basis will also give controls for PM 2.5 in most areas when the controls are applied uniformly. I mean, we don't usually apply things just on a one-day or one-week basis.

So if the de facto ratio between PM 10 and PM 2.5 is about .5 or .6, you can make the adjustments of the de facto PM 2.5 standard would be in most urban areas in California, and it's going to be roughly 30, 25 to 35, depending upon what ratio you want to apply.

So that's my partial response, and Michael will give you the rest of the answer this afternoon.

DR. LIPSETT: Actually, I wanted to just follow up on that, I won't wait until this afternoon.

In our discussions with the ARB about controlling particles at PM 10 at 50 micrograms per cubic meter, there is no way that this would not also entail strict controls on combustion sources as well. I mean, I know that historically there have been problems throughout much of the rest of the country, with people trying to control the coarse fraction, and part of that is related to the US, the national standard being set at 150 micrograms per cubic meter,

which is three times higher than the California standard.

And we've been assured by our colleagues at the Air Resources Board that this situation is in general not likely to obtain here in California. There may be exceptions, as we've heard, though, today from that woman from Morro Bay, where that may become an issue. And it is something that I think merits additional discussion.

But in general, as Bart said, trying to control that PM 10 will result in substantial controls on a lot of the sources of PM 2.5 in California.

PROFESSOR SHEPPARD: I know we are going to discuss this more this afternoon, but since we have a few more minutes before lunch, could one of you address the issue that was raised this morning about logical inconsistency? And it seems to me that the arguments that you just made would suggest that you don't need to regulate PM 2.5, not a conclusion I agree with, but if control of PM 10 controls PM 2.5, what's the separate rationale -- and this was raised this morning, I just thought it would be worthwhile addressing -- what's the separate rationale for an annual standard for PM 2.5 but no 24-hour standard?

DR. OSTRO: Basically, when you look at the

long-term studies you do see very significant effects from PM 2.5 and sulfates in those studies, so there's clearly concern for 2.5, and what would we -- One of the things that we would be concerned about is that on a longer-term basis that control of PM 10 not be substituted for control of PM 2.5.

So when we're talking about offsets and things like that, we would not find it acceptable, based on the science, to have people put out more PM 2.5 and offset that by reducing coarse particles. So we thought that, it was very clear that there should be concern for fine particles, that the standard would play that role and play that public education role as well as the policy role down the line, that the fine particles are of concern.

And I have to say that it may sound that we are very much opposed or opposed to a short-term standard, but we're not. We just find it difficult to determine a bright line to choose. We also are not attributing all of the effects to chronic exposure, as some commenters have indicated. We definitely believe that there are effects of short-term. And short-term might be defined as one day, it might be multi-day, or it might be, you know, several weeks, so we are concerned about that.

And if the committee wants to help suggest some methods for coming up with other standards for short-term PM 2.5, we'll be very open to hearing them. So our position is not based on a lack of concern of short-term effects, but just difficulty in finding a number that is easy to defend.

DR. LIPSETT: I wanted to reiterate Bart's request and maybe some of the committee can discuss amongst themselves during lunch a variety of scientifically sound sorts of approaches to principal ways to identify a short-term PM 2.5 standard. This is something that, again, we agree that the evidence is there; otherwise, we wouldn't put it forth in our document, but in terms of developing a standard when you're looking at exposure response curves that are linear and apparently, at least to this point, no threshold has been identified, the science doesn't guide you to a given standard.

So if the committee could come up with some constructive suggestions for us this afternoon, we'll be more than happy to discuss them with the committee.

PROFESSOR SHERMAN: This question is for Dr. Ostro and has to do with this issue of seasonal variation, what is or isn't in the document. Certainly, you could engender a hypothesis in which PM

10 minus PM 2.5 or PM 2.5 would affect nasopharyngeal or lower respiratory host defenses against bacterial or viral infection. And there would be many ways that that would occur.

But in talking about seasonal variations, there isn't, that I could see clearly, addressing the effects of PM in viral infections, per se, such as influenza or respiratory sensational virus, which would affect the elderly to a greater extent or infants to a greater extent.

Is there a reason for that? I assume it's the lack of any information on that, but again, it gets down to why you might want to have a short-term PM 2.5 standard.

DR. LIPSETT: Okay. If I can restate your question to make sure we understand it correctly, it's that it's possible that short-term exposures to fine particles suppress immune responses against infection?

PROFESSOR SHERMAN: Right, particularly the seasonal variation, particularly in the winter.

DR. LIPSETT: Right, and that this is a factor that ought to be considered in setting a standard. And I'm not as familiar with all the epidemiologic studies that have been done on this as Bart is, but there are certainly plenty of studies

that look at, say, exacerbations of asthma that take people to the emergency room or the hospital. Many of those, if not most of them in the winter, are related to respiratory infection and might well be related to exposure to PM.

But in terms of looking specifically at incidents of respiratory disease, just symptomatic, that doesn't require emergency care or hospitalization, I'm not aware that there are many studies or any that look at that specifically. I know that people have tried to address this with ozone incompletely.

But it is certainly something that you would think about in the wintertime when you have sort of a shallow mixing bath and you have a lot of -- particularly in the inland valleys of California, a lot of wood smoke that accumulates. And that was one of the reasons -- in fact, we cited that several times -- one of the reasons why we do need to have at least some short-term standard in areas that are otherwise clean, say particularly between Thanksgiving and New Year's, that there would be likely to be a lot of accumulation smoke that may have these kinds of effects that you're talking about.

But I don't think that there's definitive

evidence other than, say, from people exposed to high levels of smoke, like from structural fires, for example, that you have these kinds of immune suppression and evidence of increased infection.

PROFESSOR SHERMAN: Right, but a short-term, say 72-hour heavy exposure --

DR. LIPSETT: Right.

PROFESSOR SHERMAN: -- certainly could suppress nasopharyngeal and/or lower respiratory host defense.

DR. LIPSETT: Sure.

PROFESSOR SHERMAN: And, of course, if you look at the lags, when you had influenza and/or RSV in the environment, you could then see a peak in those infections after such an episode, and that's what I'm, that's why I'm saying that maybe the information, the epidemiologic information is not there but maybe needs to be there, and would help in future setting of the standard.

DR. LIPSETT: Okay. Well, I think George wanted to respond to this.

PROFESSOR THURSTON: Well, I would just add that there are studies by a number of people, especially Joel Schwartz, looking at pneumonia among the elderly, showing that acute exposure to pollution

and, in particular, particulate matter. Can I say that, in particular, particulate matter?

Anyway, exacerbating, you know, increasing the risk of pneumonia, and there is indeed some new toxicological evidence which supports this. I know that Dr. Judy Zelkoff out at NYU -- That's why I'm familiar with the work -- I don't know if she's published it yet, but she's finding effects of PM on immunological responses in animals. And so I think there's a developing -- First of all, it makes some logical sense, but also, there's a developing toxicologic base that supports that epidemiologic finding as well.

So there's some there to discuss this. It could be just brought out more in the document, perhaps.

CHAIRMAN KLEINMAN: Okay. We have comments from Dr. Friedlander and then Dr. Tager.

PROFESSOR FRIEDLANDER: I want to return to the issue of the chemical nature of the particles. I wanted to revisit this issue of the chemical nature of the particles.

What is the ARB position on this? That is, is the issue only particle size? Are the sensors set for particle size? Are all 2.5-micron particles the

same? All 10-micron particles the same? We know they're not, but it's a rhetorical question to perhaps stimulate some response and some -- I'd like to have the philosophy of the ARB in addressing this issue, and there might be some discussion of it in the document.

CHIEF BODE: Well, actually, that's a very big question, and, you know, part of our concern is, and I think it's the information that we've gotten from the OEHHA in their review of the science and health effects, what we need is the best information to set the standard on. I think also, just a review, and you've seen that in the report itself, that probably all particles aren't alike.

PROFESSOR FRIEDLANDER: That's very clear in your document.

CHIEF BODE: A lot of the chemistry also gets back into the mechanisms, and a lot of that is still unknown, the mechanisms, the particulate effects and health effects. We do have a big section in the report where we talk about chemistry. The standard-setting itself is going to be based on the interpretation of the health studies.

But there are other things that we are looking at, in terms of, you know, ultrafine particles

is a whole new area of study that we're looking into. And then again, you brought up the issue of the mass and the effect, and a lot of it we -- the preliminary data on ultrafines, which really isn't covered in this document, since it's so new, is that particle number in that case may be a much more important measure than mass itself.

But those are things that we're going to be addressing with new research studies and the next review of the standard as we go ahead.

Now, the other thing that this kind of leads me to talk about is maybe some of the control issues, but those are really separated from the whole standard-setting process itself, that after we get done from the standard setting, we'll go and look at some of the control issues of what types -- and I think Michael kind of alluded to this earlier, in terms of what types of processes might be controlled in the future.

PROFESSOR TAGER: I want to just revisit, to sort of have on the table for the discussion this afternoon the issue about choosing a 24-hour standard. And I'm partly repeating for the record something I said to Bart and Michael before.

I mean, I think, the issue is, assuming for a

minute there is a linear exposure response curve, then you can't escape the fact that the decision has to be a judgment. It's really not any different than the annual standard. I mean, why is it not 22 instead of 20? So I think you can't get away from judgment.

The other point which I think is equally important here is that even if we suspect that there was a threshold -- in fact, the paper that was used to argue that we can't know or not know there isn't -- thresholds, and this I mentioned to both of you but I think it needs to be considered, doesn't get around the problem with judgment. Because the threshold is not measured without error.

And, in fact, the paper that's cited, in fact, has a graph that shows the errors, depending on the underlying correlation from the simulation studies. So even if you had it, if you thought there was a threshold, you're going to have estimates of where that threshold is and that's going to have error around it. You're going to have to make a judgment where in that error you're going to set the threshold.

So I think it's sort of inescapable -- There is not going to be one best method, it seems to me, that somebody can argue has a certain judgmental quality to it, even if you had a threshold. So I

think really the issue is to set out a priority, and it's my understanding of the district court's decision initially about the way the standard is set, is setting out a priority, what the principles were on which the final decision is made. And then people can argue with it, no matter what it is.

But as long as it's based on a set of a priority, reasonable set of assumptions, at least to my understanding is the legal situation, you've complied with what it is and it takes into account the scientific fact that there is not going to be a hard number anywhere, whether you have a threshold or not.

So I think when we discuss this this afternoon, at least from my point of view, that's the backdrop to whatever decision is made about how to do it.

DR. SHERWIN: I'd like to respond to what Dr. Friedlander raised and what Dr. Lipsett brought up earlier with Churg's paper, and then the question of particulate species.

When I find myself behind diesel buses or behind diesel trains, I worry about what on earth I'm breathing in. And that paper you mentioned by Churg is the first one to show the aggregation of ultrafine carbonaceous particles inhaled -- Well, they're in the

lung. Now, he can't prove that that in the ambient air is exactly the same, but those are ultrafine particles that have aggregated.

Now, I'm seeing almost the same thing when I take the dust off my car and a big diesel goes by, but it's a little bit different. But the big point is, is that those particles, aggregates of diesel dust, for the first time I'm thinking to myself they're in the lung, they get into macrophages, and here's the important thing about dosimetry. I don't worry about what gets in, in terms of where it distributes, as much as I do about the clearance of it.

And clearance is in macrophages. And I teach all my students and give my lectures and say the single common denominator for all lung disease, not all of it, but a large part of fibrosis, emphysema is macrophage, phagocytosis or particulates, they are loaded with hydrolyses, and when you damage a macrophage, they break down and release hydrolyses, and I think they are the -- I'm not, this is not my original idea, but they are the central focus where injury starts.

So if you think of macrophages as miniature snakes with venom and you put something in there that's toxic, and they release these bags of venom,

you've got yourself a problem. So now, one of the things that that Churg did for me is they're telling me, well, I do have to worry about one species of particulates in terms of toxicity. Once absorbed to those theoretically bland carbonaceous aggregates of ultrafine particles, if they're strictly carbon, well, that's fine. But diesel fuels are loaded with all kinds of aromatic hydrocarbons and who knows what else.

So to take a point from what Dr. Friedlander raised, not only is the species important, but what it brings in with it and what happens to it, in terms of disposition. And the macrophage would be central and, of course, that would give you your immunologic.

And I think these are critical things that say large numbers aren't quite as important as what happens, even if only a few macrophages, percent-wise, break down.

CHAIRMAN KLEINMAN: I have one issue that I would like to put out on the table relating to the correlation between PM 10 and PM 2.5. Because PM 10 is an aggregate measure and contains PM 2.5, it's almost a virtual certainty that those measures are going to be correlated. The problem is that the PM 2.5 has a different chemical composition and comes

from different sources than the coarse particle fraction that is represented in PM 10.

And so, although at the present time we can't really develop a standard, I think, to look at individual components, the point of having separate standards for PM 2.5 and PM 10 allows us to at least differentiate between classes of sources. So the sources that generate the very fine particles, atmospheric chemistry being part of that, and that being partially augmented by mobile sources and gaseous emissions that are converting, as well as other combustion sources, versus the coarse particles which are more mechanically generated will lead us to think about -- maybe not deal with entirely, but think about how do you look at the emissions from these different sources eventually.

So I think there is a utility to considering a short-term PM 2.5 standard, just from that context.

CHIEF BODE: One thing I wanted to add, and it's in addition to what we talked about, some of the chemical species. And just to add that, you know, the Air Resources Board, with the assistance of OEHHA, does look at different chemical species through our toxics program. We do look at a number of different toxic metals and diesels. Diesels came to mind as

actually probably the greatest potency and greatest health hazard now, from a toxics perspective. And it's mostly that we look at carcinogenic risk through that program.

So we do look through a separate way of setting assessments and controls for individual chemical species that way. But one thing that really comes to my mind is that when you look at the impacts of all those carcinogenic compounds, when you look at the impacts at what's coming from particulate matter PM 10 and PM 2.5, the particulate matter as a group really overwhelms the toxic effects. I think one of our estimates was that from our entire toxics programs, in the assessment methods that we use right now in carcinogenic potency, we're looking at about 500 deaths a year from cancer.

I think the assessment actually is in the document right now, and it really brings in mind the importance of what we're doing here, is if we brought down our statewide averages of PM 10 down to the 20 recommended, 20-microgram standard, that we would basically save about 6,000 lives a year from particulate exposure, and we would order a magnitude higher from the entire work we see with our toxic program.

So we are doing some -- I think this really brings to the forefront the importance of the standard.

CHAIRMAN KLEINMAN: Okay, thank you.

On that note, I want to break for lunch. What's our reconvening time?

CHIEF BODE: One thing, before we break, Leslie Krinsk, our attorney, wanted to make some comments about just the opening meeting requirements and discussions during lunch.

So, Leslie, why don't you --

MS. KRINSK: Okay. I just want to caution the committee that you are an advisory committee, advising the OEHHA and the Air Resources Board, and, as such, it's very important that your substantive discussions take place in public. And I wouldn't want to see a majority of the members of this committee discussing any of the substantive matters that we talked about this morning or yesterday during lunch, unless you want to sit here and have lunch and let all of us watch you and listen at the same time.

[Laughter]

CHAIRMAN KLEINMAN: Can we do that?

[Laughter]

CHAIRMAN KLEINMAN: When are we reconvening?

CHIEF BODE: Michael, I think we're pretty much on schedule.

CHAIRMAN KLEINMAN: What time is our reconvening time, Richard?

CHIEF BODE: Why don't we just break right now and we'll come back at 1:15?

CHAIRMAN KLEINMAN: 1:15?

CHIEF BODE: And that gives everybody time to check out of their rooms?

CHAIRMAN KLEINMAN: 1:15, yell it out.

CHIEF BODE: Okay.

(Thereupon, the luncheon recess was held off the record.)

--oOo--

A F T E R N O O N   S E S S I O N

CHAIRMAN KLEINMAN: We're going to reconvene, and the first order of business is Richard Bode has agreed to just very briefly summarize the issues about a sulfate standard, and we'll deal with that and then we'll move on with the summary of the committee's report.

CHIEF BODE: All right. I'm going to very quickly cover the issues regarding the sulfate standard and very briefly say that as part of the review that we have conducted, they spent most of their time on the PM 10, PM 2.5 effects. Their recommendation was that, for the sulfate standard, that we retain the standard at its current level, that they did identify there were serious health effects from exposure to sulfates, ambient sulfates, and that we basically retain the level we've got right now, but also added that in the next cycle of standard reviews that come up that we take a more intensive review of the sulfate effects at that time.

One of the additional issues we identified was that the current monitoring method for sulfates is basically a TSP-based method, that there's limited monitoring now in California since most of the TSP monitors have been shut down, and we brought up the

idea of maybe we should move to a more PM 10-based method, that it would do a couple of things. One, it would greatly expand our monitoring network and ultimately give us more information to better understand sulfate air quality in California.

So what are the impacts of the change if we did? One of the things we wanted to look at was would we be moving away from the original health basis when this standard was set in 1976? And I put up there no, we did a review of the 1976 staff report and the sulfate standard. In that report, that the standard itself was based on a review of animal toxicology studies, human exposure chamber studies, and a variety of epidemiology studies that existed at the time.

That the staff of then the Department of Health Services and the Air Resources Board brought a recommendation of setting what is called a critical harm level. At the time they thought we needed more studies to set a national classical standard, set that at 25 micrograms, and that was reviewed by the Air Quality Advisory Committee in 1976.

That in that staff report, in the Air Quality Advisory Committee meetings, they actually identified particles of greatest concern to them and their reason for setting the standard with particles from .1 to 1

micron range, respirable particles, which was stated often in that staff report. That the TSP monitoring method was then identified and a portion of that document that talked about setting the method, TSP was identified because at the time, that was the major method for monitoring for PM that existed.

They also talked about they would rather set a size-selective monitoring method, but at the time technology did not exist that it allowed them to accurately and to reliably set that method, so they passed on that for the time being.

SO that led us really to come to our initial conclusion that we move to the PM 10-based monitoring method for sulfate. And that's a recommendation in the staff report. It came up out of that. After that was then the realization of the artifact that exists on the glass fiber filters through the TSP monitoring method itself.

And we sat internally and we talked about what effect this would have on the standard: Did the artifact take any -- was it weighed at all when we, AQAC, Department of Health Services and the ARB, reviewed the standard? Did it affect their decision-making on where that standard level should be? And the answer is no, it went back again to the staff

report. The original '76 staff report did not know that there was an artifact through the use of these glass filters.

That the Air Resources Board, Department of Health Services and, again, the Air Quality Advisory Committee revisited the sulfate standard in 1977, again reviewed the sulfate standard, what it was based on, and at that time they had results from some very quick studies, monitoring studies, and they were aware of the artifact in 1977. In '77, they went through and decided to retain the standard at the same 25 microgram level. So definitely at this time, we know where the artifact is, they didn't adjust the standard at all.

Our conclusion was that, it told us that the artifact does not have any effect on the health basis, where that standard for sulfates is right now, that still our conclusion is that we want to modify the monitoring method to PM 10-based method, that it meets what we think are the original concerns brought up in the original standard-setting process in 1976 and '77, and that is that we look at respirable particles.

And that by doing so, it immediately expands our sulfate monitoring network, and, like I said, ultimately as this new data comes in we'll have a much

better understanding of sulfate air quality all through California. So that's the end.

Any questions?

CHAIRMAN KLEINMAN: Questions?

Well, what we're going to do now is a summary of the comments and suggestions of the Air Quality Advisory Committee. Each of the members were asked to answer certain questions about the document. Some of these we've discussed yesterday. And what I've done is I've taken the comments that I've taken notes on, plus comments that individuals have given me in writing. I have tried to summarize them as best I can and put them on slides as just bullets, so this is a very abbreviated version of the comments that will be in the written report that we will try to put together in the next few weeks.

There are a number of issues. One of them, for example, were relevant studies identified and interpreted. For the most part, there was agreement within the committee that the literature review was very good. There were some minor discrepancies in specific citations, and/or one or two factual errors and those are captured in the written reports and will be submitted to the authors.

Also, the discussions of susceptible

populations have been identified. The question of other populations that should be considered, one population that was mentioned by several members of the committee were people with diabetes, and we will recommend that that will be discussed to some extent in the report as well.

The report does seem to work or deal effectively with the issue of infants and children. There are some suggestions we have for future research that would be needed, and we'll get to those in a few minutes. We also discussed very heatedly, obviously, the idea of metrics and averaging time, especially with respect to the short-term standard for PM 2.5.

There were some questions raised as to whether uncertainties were described adequately and treated adequately, and we had some specific suggestions with regard to that. Also, we suggest that the report make it very clear that there are differences in exposure patterns for some of the susceptible individuals to the extent that it can be done.

I'm going to -- I thought I'd move this, but I guess I moved it in a version that we then removed. So let me, sort of taking the tail first, let me just move on to this and we'll back up.

In the section on introduction, one issue that's raised is that Phil Hockey, who is now the chairman of the Clean Air Advisory Committee for federal EPA has said that federal EPA is planning to promulgate a coarse PM standard, particles between 2.5 and 10. And some mention of these particles and their importance, especially the contribution they make to PM 10 and the separation between PM 10 and PM 2.5 should be added to the introduction, and also mentioned in the executive summary is our suggestion.

Also, over the years there has been an evolution of PM standards, and I think it would be useful to highlight the fact that as we develop more information, we'll be able to characterize more completely specific components, the biological activity of these components and subfractions such as the ultrafines, oxidants and acids. And eventually, it's hoped that we could move to a more integrated way of dealing with the health consequences of airborne pollution.

The committee asks the question were the sulfate and PM 2.5 standards to some extent overlapping, and since sulfates are part of PM 2.5 I guess there are some issues about the overlapping. I don't know that this impacts on where one would set

the standard at this point, but for the future it may be if we have a PM 2.5 standard, a separate sulfate standard may not be necessary.

In terms of sources and emissions, the Air Resources Board and, in fact, some of the local air quality management districts have been doing speciation of airborne particles, usually on a campaign basis, sometimes on a more systematic basis; however, several individuals on the committee have suggested that more systematic approaches at doing speciation would really benefit a number of issues, including assessment of source receptor relationships, help to identify the toxic compounds that could be separately regulated, and also to develop or provide the data for development of mechanistic hypotheses so we can understand how air pollution affects human health.

In terms of issues on monitoring, we strongly endorse the work being done on qualifying continuous PM monitors. Eventually we would like to see both PM 2.5 and PM coarse, the 2.5 to 10 fraction measured on a regular basis.

There was some discussion about the use of quartz filters which eliminate some artifacts with sulfur dioxide, and Dr. Sioutas points out that quartz

filters absorb organic vapors so there's a possibility of trading one artifact for another, which will probably need to be reviewed. But there are ways around that, including using fluorocarbon-based filters that don't absorb.

If sulfates are going to be part of the standard, then a continuous sulfate monitor might be a very useful addition to the monitoring techniques. And there are commercially available now sulfate monitors, and Dr. Sioutas will provide that information to Jeff Cook.

There have been attempts, both in various studies to look at the difference between PM 10 and PM 2.5 as a measure of coarse PM, and the committee wanted to just caution that that can lead to overestimates of the coarse PM fraction in some instances, because during measurement of PM 2.5 there can be loss of labile materials like nitrates and some of the organics. And also, there are large measurement errors when you try to subtract two large numbers that already have errors associated with them.

So we'd strongly endorse, if in the future there is a need to develop a standard for coarse particles, that monitors be developed and qualified for making measurements of coarse particles directly,

rather than relying on the difference method.

Artifacts, including the organic artifact and artifacts involving sulfur dioxide and reactions with other compounds in the air such as peroxides do need to be better understood. And I'm sure that some of the monitoring techniques that are being used always have some form of artifact and the better we characterize these techniques, the more accurately we can use those data in attributing particle exposures to human health effects.

In terms of exposure assessment, the section should make it very clear that in California, and perhaps more so than anywhere else in the country, there is a great deal of spatial variability between the mass of particulates and also the various components, like polycyclic aromatic hydrocarbons and metals. And these variations occur between sources where the material is freshly emitted, and places where people are actually exposed, receptor sites where these materials have had an opportunity to undergo atmospheric chemical reactions.

A variety of differences have been noted in particles collected, for example, in a source region such as Los Angeles versus measurements taken downwind several hours later, after the air parcel has moved.

And we see large numbers of oxidized and chemically changed species that were not in the original air mass. So these things can, these changes can occur with seasonal variations, because of photochemistry, and also, there can even be diurnal pattern changes.

All of these things need to be taken into account if we're going to really understand the relationship between central station values and personal exposures to potentially toxic chemicals associated with particles.

There are also differences between aerosols in coastal environments versus inland environments. Some of those are dominated by meteorological factors. And Glenn Kass pointed out at one meeting that if you plotted concentrations simultaneously at Long Beach versus Riverside, the concentration patterns for PM 10 and for PM 2.5 were actually 180 degrees out of phase. So at times when Riverside was high, Long Beach was low and vice versa. And so trying to apply those kinds of data to time-series analyses without being very localized with respect to the city could lead to very unusual conclusions and often conflicting conclusions.

And I wanted to point out that again, California, while probably not unique, certainly has

very extreme cases such as this. So that whereas it might be perfectly acceptable to look at Massachusetts and New York and a few other Northeastern cities which are within a large air mass where there's good mixing and a lot of regional pollutants, California has a number of microenvironments and those need to be assessed very carefully.

And in addition to variations in chemical composition, the particle size distributions vary spatially as well. And so all of these things need to be taken into consideration as we evaluate the data that is going to be used for setting a standard.

One of the questions that was raised was the relationship between indoor and outdoor -- not indoor, but personal versus outdoor exposures. And this is more in mind with a recommendation for future research in terms of evaluating personal exposures. But Dr. Sioutas has suggested the possibility of using the ratio of personal sulfates to outdoor sulfates to correct for the -- to identify the outdoor PM contribution to personal exposures. It's an interesting approach to be considered for research.

In terms of nitty-gritty details, there were in the report, especially in the exposure assessment and monitoring sections, there were large numbers of

figures that -- where the captions and presentations of size distributions, it's a large number of very important but nitty-gritty sorts of corrections and amplifications will strengthen up this report quite a bit.

CHIEF BODE: I'm assuming that first term was personal PM?

PROFESSOR SIOUTAS: Yes, it's personal attributable to outdoor.

CHIEF BODE: Okay.

PROFESSOR SIOUTAS: So it's PM out, personal, or whatever you want to call it, yes.

CHIEF BODE: All right.

CHAIRMAN KLEINMAN: One of the things that came up several times in the discussions was the interrelationship between the chronic effects and the acute effects, especially with regard to mortality. And the committee would like to see a more detailed discussion of that in the report. I think this is especially important as we try to answer the question are the methods used in setting the standards transparent and obvious to the readers.

Dr. Tager mentioned the possibility that there are alternative measures of uncertainty for epidemiological outcomes that can be used instead of

confidence interval. And again, this is in the realm of future research, but those sorts of improved ways of understanding uncertainty should be applied and should be explored.

In addition, there were several examples in the report of very large short-term excursions in airborne particle concentrations. These generally have not been taken into account in the standard-setting process except insofar as setting 24-hour or longer-term standards helps to moderate some of the impact of those short-term excursions; however, again, in terms of future research, the potential effects of these excursions should be evaluated and, as we begin to develop and qualify the continuous PM monitors, some of this research will become feasible on a reasonably large scale, whereas now there are very limited studies available where this could be done.

Biological mechanisms: The section in the report is relatively brief, but could be important. And the report should make it clear how these mechanistic studies enter into the thinking on developing standards. And within that context, the uncertainties such as variations in the route of exposure, the doses that were used, etc., especially where these might influence how you think about

setting a standard, we really need to be at least addressed and documented.

Another point that came up in discussions was that particles accumulate in the lung, they don't just get inhaled and get cleared. And that over long periods of time, particles can be stored in interstitial tissues as well as in the pleural area and lymph nodes, and they are literally retained for many years. These retained particles can also contain toxic substances -- insoluble metals, organic compounds -- that can influence health over long periods of time. And so it's not impossible to see how the cumulative effect of breathing particle-laden air can affect health chronically as well as acutely.

In terms of mechanisms also, in looking at the studies reported in the document, four important mechanisms -- lung injury, inflammation, increased blood coagulation and incidence of cardiac arrhythmias, also, I guess, changes in heart rate variability -- have all been associated with short-term changes in ambient PM. And so these potential mechanisms lead us to suggest, among other things, other reasons, that short-term standards for fine particles are probably needed.

So we were asked to evaluate whether the

approach for arriving at recommendations were transparent. I think we've discussed that to some extent. There are some areas that could be amplified in the report that will help in making it very clear how the standards that are suggested were arrived at. By and large we feel that appropriate methods were used, and were the suggested standards supported by scientific rationale.

One of the key questions is, is there sufficient or insufficient evidence to develop a 24-hour or other short-term standard for PM 2.5. And the questions of whether the 24-hour PM 10 and the annual average PM 2.5 would provide adequate protection were raised several times. And the committee's consensus, and since we're not allowed to discuss these things except in a public forum, this is the first time anybody has seen this particular slide -- most of these slides have not been seen before -- so this is the opportunity for people on the committee, if there are objections to any of this, to jump up and say so.

PROFESSOR SHEPPARD: Yeah, I object. I think, I'd say that there's strong support for the need for a PM 24-hour standard, not for reevaluation. I don't think I support reevaluation. I support a standard. I'd be curious what other people think.

PROFESSOR TAGER: I would agree with that. I think I support the need for setting a standard, not reevaluating.

CHIEF BODE: And I third that. But I also want to say, I want to take this opportunity to say that, just to clarify again the discussion yesterday that I also strongly support the lowering of the annual PM 10 standard and the establishment of an annual PM 2.5 standard. And I again want to take the opportunity to say that I think this report, by and large, is really excellent work. I commend the authors, and I think that it's really a tribute to California that we actually have scientists who are doing work in this area, writing this kind of report.

I don't think you would find people like Bart Ostro and Mike Lipsett at their level of science actually writing a report that would support the establishment of air quality standards. And it's not just because I know them. I really mean the fact that, you know, these are people who know the science, so they know the problems with the science and where it's strong and where it's weak, and I think the report reflects that, except on the issue of the 24-hour PM 2.5 standard.

[Laughter]

CHAIRMAN KLEINMAN: I have to say that I am also actually a strong supporter for the 24-hour standard, and I put that up because I wanted the committee to be able to spontaneously respond, rather than my ramming something down people's throats.

So I don't hear anyone who -- Is anyone on the committee against modifying that statement to say strong support for a PM 2.5 24-hour standard?

(No audible response.)

CHAIRMAN KLEINMAN: Okay. Then that will be changed.

Given that, we've actually gone a little bit beyond that, and Dean Sheppard has come up with or helped me compile, he gave me the suggestions for some possible ways in which one can arrive at a PM 2.5 standard. So I think I'll go pass the mic to Dean and let him explain this.

PROFESSOR SHEPPARD: Well, I'm not trying to suggest that we have, after hearing this for one day, we have the final solution for how the standard ought to be set. So I think I'm going to start off just by underscoring what Ira said this morning, that no matter what model you use for which pollution you think about, there's always going to be some degree of uncertainty and you always have to make a choice for

what standard you're going to choose.

The first critical point is that there's sufficient evidence to justify a standard, some rationale that makes sense and is internally logical and consistently needs to be chosen. So two that came to mind, I actually favor the first one. So what I'm suggesting for this first standard is that within the document that we saw, there were data that showed that at, for example, levels of annual means of somewhere around 25 micrograms or 20 to 25 micrograms per cubic meter of PM 10, there were attributable effects of 10-microgram-per-cubic-meter increases over 24 hours.

And so one reasonable conclusion one might draw from that is that a standard that was higher than 35 micrograms per cubic meter for PM 10 would certainly not be preventing adverse effects and it could probably make an argument lower than that. But if we're going to say that they have confidence that at 24-hour levels of 35 micrograms per cubic meter have effects, you know, probably the standard ought to be lower than 35 micrograms per cubic meter.

Similarly, for --

CHAIRMAN KLEINMAN: Dean, do you mean 2.5 or 10?

PROFESSOR SHEPPARD: What's that? That's for

PM 10. So I was criticizing actually the rationale for the 24-hour standard of PM 10 of 50.

And similarly, for PM 2.5, the data in the document suggest that somewhere around 10 to 12 micrograms per cubic meter, PM 2.5 in communities of somewhere around that for an annual average, increments of 10 micrograms per cubic meter higher cause believable effects that are adverse health effects. So, you know, that would suggest a standard somewhere in the range of 20 to 25 micrograms per cubic meter for PM 2.5.

That first suggestion makes the most logical sense to me. It's more consistent with the way, from my understanding. Other standards have been set in the past.

Now, the second suggestion was based on some free-flowing discussion with employees of the Air Resources Board that, you know, another way that one might look at this is to reevaluate the data from all the cities where data exists to get around the fact that in all these areas there are occasional peaks that make it difficult to interpret the effects of one day in a year, and use some valuable metric like the 98th or 99th percentile of the highest 24-hour values in areas where there's data that 24-hour peaks are

shown to increase morbidity and mortality.

I think that's a little bit more complicated but potentially an alternative approach. And I'm perfectly open or would welcome other alternative approaches. I just can't understand the point of view that just because it's challenging to pick a number, we should abrogate our responsibility to pick one.

CHAIRMAN KLEINMAN: Does anyone else on the committee want to comment on that?

Other research issues: First off, I again wanted to commend the concept of the five-year cycle because we're not going to answer all the questions this year, and by knowing that we're going to reevaluate this, this allows us to set up a research agenda to provide the information to fill the gaps in our knowledge base, identify more information about susceptible groups, improve sampling methods, revisit the issue of the coarse versus fine in terms of measuring techniques and interpretation.

And so we've looked at a number of suggestions for parts of that future research agenda, evaluation of regional differences between PM and relationships between PM and the gaseous co-pollutants, to better understand and develop ways of separating the effects of the gaseous components from

the particulate components of air pollution, to obtain more data and better data to characterize short-term and PM exposures at the hourly level to see whether peak exposures do have an effect on some susceptible populations, continue speciating the components of PM, so that we can get a better idea of where they come from, and eventually develop better strategies for control and improvement of human health.

Ultrafine particles are an area that we're now able to really address. Up until a few years ago it was very difficult to measure them in any useful way. Now we can not only measure the numbers of particles, but we can actually collect them, speciate them, and we've got new monitoring techniques that allow us to start to examine that.

Ira?

PROFESSOR TAGER: I just want to raise one point about some of these, and they came up in earlier slides, and I guess I have -- I mean, from the point of view of understanding, obviously, sort of the scientific questions about mechanisms by which ambient air pollutants may cause disease, I certainly think getting this kind of information is absolutely important.

But I think we ought to be really careful

what we're saying here in terms of standard-setting, because if you imagine all those items replacing the five, leaving the lead, things that we regulate now, you'll have a lot of the same problems. They're going to be correlated with each other, they're going to be interacting with other things in the environment, and so I'm not sure, unless some giant bullet comes out of this pile, which I doubt is the case, we probably would have seen it already, that that's necessarily going to make this process any easier.

It may make the mechanistic discussion that underlies it more credible, saying, look, okay, we now know that PAH's actually really do influence IGE responses and it's real. Okay, fine, but that still doesn't get you out of the dilemma about all of the variability you can see in an environment, and the fact that PAH isn't measured with other things and come from lots of sources.

So I think the notion that by getting this information that the process may somehow be easier to pick a number or a metric, whether it's a size metric, a chemical metric or whatever is going to be easier, is actually yet to be proven and may be a search for the holy grail never to be had. So I'd be a little bit careful about what's expected once this

information is obtained, because I remain to be convinced that it's going to make this any easier five years from now if we knew all of these things.

PROFESSOR SHEPPARD: Yeah, I want to second that idea and expand it maybe a little bit more, suggest that certainly we want to try to learn as much as we can about these particles, I'm completely supportive of that. And obviously, the biggest challenge for us now in understanding some of what's going on is that we don't really understand the mechanisms by which these particles make people sick.

But it actually might turn out that regulating particles is a more robust way to control air pollution because of the complexity. So the particle standard in different parts of the world may actually be protective, because in each part of the world there are different toxic materials and combinations of toxic materials that are actually causing the health effects.

And so it might actually turn out, at the end of the day, once we know everything we can possibly know about these particles, that regulating the particles is still going to be the best strategy.

PROFESSOR TAGER: I want to make one other comment, which I had to think about the suggestions on

the slide about how to set the standard, so as the slides went by -- I would actually like to suggest that the second choice is less good than the first, not only because it's more complicated, because it's doing something else that I think is sort of a bad idea.

It's letting the extreme values drive where you set the point, rather than the data saying, okay, we think, as in Dean's first approach, which really says here's where the data at least makes a plausible choice. And it's not dependent on a couple of years of extreme data, because that would mean in any given time period -- three, five years -- it will change the location of it, rather than focusing on the average population effects.

If you're worried about the fact that these could happen, you can allow more than one exceedence a year in certain areas where, for example, the winds blow and PM 10 may get really high and there's nothing anybody can do about it. But I think setting the standard, based on the second mechanism, is kind of throwing away a lot of the value of assessing the health data about where we think the effects might be occurring.

So I actually would suggest that while it

should be on the table for discussion, I'd like to at least go on the record as saying I think it's a far less desirable way to do it than the first way, which makes better use of the health data.

PROFESSOR CROPP: Yeah, I would like to second that and I was going to say something very similar; namely, I think we should be bold and not set a low standard, rather -- based on reasonable information that is available, rather than allowing to drift, have that standard drift up too high by, for instance, taking 98 percent confidence limits.

Because I think this would just delay clearing up the air to the best way, in the best way we can, and consequently reducing maximally the risk to health that we would allow to occur if we set the standard too high.

DR. FRIEDLANDER: I'm afraid I don't agree with most of the last few comments. I think that there should be much more stress on trying to evaluate the mechanisms based on the chemical components of the particulate matter, and I find -- I remain very uneasy when I look at the epidemiological evidence, as a non-epidemiologist. I just find it very difficult to see in the presentations that I have seen a persuasive relationship between the health effects and the

concentrations.

I think it's the best that we have at this point, and I think that's the best justification for linking the standard to the total mass concentration. But I think that as far as -- I can't understand how one could try to avoid improving the scientific understanding of what the mechanisms are that link the -- from a scientific point of view, from a biochemical and chemical point of view, health effects to the concentrations of particular components.

I think that also, if we can do that, that it will have very beneficial effects, because my view is the sources of the pollutants differ from city to city. And lumping everything together, as we're doing now, is to me as a scientist very unpersuasive. Lumping Los Angeles with Cincinnati and Boston and so on just doesn't make sense. I think that at this stage, that's all we can do.

But I think it's our responsibility to deconvolute that and to do everything we can to deconvolute it. So I think we should be -- I just don't share the points of view expressed.

CHAIRMAN KLEINMAN: I also wanted to point out that the purpose of this was more in identifying mechanisms and understanding the biological

plausibility and certainly the intent was not to suggest that we are going to regulate elemental carbon or PAH's specifically.

PROFESSOR TAGER: I just want to make clear, I think you perhaps misunderstood my statement. I'm all for doing this, and we need to have this information. My comment was to say that we should be careful about what we expect to get from it, through the process of setting a standard. Because many of the problems that we're having now in picking, whether it's PM 10 or ozone, because of colinearity and variations over time and space, will apply here.

So I wasn't suggesting for one minute we shouldn't pursue mechanistic understanding, and if we're lucky enough that we can deconvolute and disaggregate these things to pick a number, fine. But I think to imply -- All I was trying to say was to imply that somehow moving in this direction is going to make this process easier five years from now may be overly simplistic from the point of view of what's involved in trying to set a standard and not trying to understand the science of all of this and relating it.

PROFESSOR SIOUTAS: I would like to respond to this, to Dr. Tager. It isn't just a matter of understanding the biological mechanisms, you know, but

this monitoring wouldn't just provide information to the much needed field of understanding of biological PM. But this is essential also in promulgating and implementing effective control strategies.

I mean, if you see certain PM species that are signatures of certain sources being much more responsible than others, then I just don't see how this is not important in setting standards, because that leads you to essentially controlling the right source.

PROFESSOR TAGER: But as I understand it, setting the standard and the mechanisms to getting the standard are two different things. I don't disagree with you. I agree that getting this information is important, and it may be critical for abatement.

But I'm suggesting that that information has all of the properties, in terms of managing the data and interpreting individual, how these individual things are affecting human health, that many of the problems we have now with PM and ozone or CO or NO2 have, that's the only point.

And I'm simply trying to make it clear that the document shouldn't imply that somehow, if we get this information, picking a number for the standard is going to be any easier than it is now. It might make

abatement easier in certain places, it certainly will lend credence to mechanistic underpinnings and the scientific basis of having a standard in the first place. But in my view, we may be not having any easier time picking a number than we are right now. That was really my entire point.

CHAIRMAN KLEINMAN: Yeah, I think the point you last made, it's -- you know, part of the utility of this is achieving the standard once the standard has been set, as opposed to setting the standard. But I think those are two issues that the Air Resources Board and Cal EPA really face every day and I think they are tied together in that respect.

Dean?

PROFESSOR SHEPPARD: Yeah, I actually don't think there's all that much disagreement here, not being an epidemiologist or a particle chemist. The reason I don't think there's that much disagreement is I think that everybody on the panel, as far as I've heard the discussion, agrees that there has to be a very high priority to extend the science, to understand much more about how these particles are composed in the real world, and which components of the particles, which characteristics of the particles produce which biological effects. And that we can

only understand the way that pollution is producing these effects by pushing that science forward, and to approach it clearly, include that information as a major priority.

And I also don't think -- I've heard much disagreement that despite our limitations of understanding the science the way we would like to understand it, there's a sufficient body of data now to set a standard, based on the information that's available about particles.

So I actually think there's a broad area of agreement, and that the disagreements are more a matter of emphasis than contact. Because really, in terms of the contact, I've heard what I think is pretty broad agreement.

PROFESSOR SHERMAN: Since this slide is titled Future Research, the people that are here now have decided upon a safe drug dosage in which there's going to be minimal side effects. And I hope that the ARB will look at this as the future, that you keep monitoring what's going to happen.

And what concerns me, I guess, about this whole process is if there is enforcement of whatever the new standards happen to be, how are we going to judge that, in fact, it had a positive effect on the

health of California citizens? And so I think that there needs to be some type of prospective evaluation of what the new standards are as being set, that they really -- we can look at ourselves here as people on the FDA panel, even though this is a physical phenomenon that we're discussing, we're really looking at health effects and we need to evaluate that what we've done is, in fact, improving health.

CHAIRMAN KLEINMAN: Yes?

DR. FRIEDLANDER: The fact is that by moving toward a 2.5-micron, PM 2.5-micron standard, what you've done is to say, well, we have more evidence that suggests that a better -- there's a need for an additional standard. In other words, I think that some of us are in kind of a mass mindset, and that's the way it's been done for many years -- you make it a mass of something -- and that's the way it will always be.

But you may break down the particulate matter into many different components. It may be that, for example, people like Lipman at NYU have tried to use acidity which has not been altogether successful, but there can be oxidants, there's the Ames test activity. There are subset, there are metrics -- other than mass, is the point.

We talked about ultrafine particles. There you have -- I mean, you may have a number as a different metric. So there's no reason to be afraid of having other metrics and having to break down the analysis to take into account other components. It may be difficult, but think of all the years you could spend doing epidemiological studies to reduce the confounding effects of the ultrafine particles, the oxidant, the acidity. It's a wonderful rich field, still to be explored.

[Laughter]

PROFESSOR TAGER: I couldn't agree more. You know, it always used to be said jokingly the worst fear that an epidemiologist had is that the American public would take the message seriously and stop smoking.

[Laughter]

PROFESSOR TAGER: So I'm not worried that we'll have plenty to study.

CHAIRMAN KLEINMAN: A few other points: There was a suggestion also that along with traditional epidemiological studies, more panel studies that can directly assess personal exposures, short-term exposures, and especially look at regional differences and seasonal differences to help

deconvolute some of these things.

Additional toxicological studies can certainly be suggested. We definitely need better information on dose response, the effects of chronic exposures, and chronic exposures perhaps with superimposed acute peaks to try to understand what are the important parameters, what are the metrics that we need to look at. We can use concentrated ambient particles now in a way that we couldn't do five years ago.

We also need to continue to evaluate the importance of co-pollutants along with PM so that we can understand whether there's a possibility somewhere in the future of having a more integrated approach to setting standards, where you might want to take into account the combinations of ozone and PM and carbon monoxide.

We definitely need both chronic toxicology studies and long-term perspective studies of populations to follow up on some of these questions. Perhaps even to get some idea of if we improve the air, and we have areas where there has been substantial improvement in air quality and we expect to have future improvements, it would be nice to see that those are reflected in better health.

As mentioned earlier, the PM standards tend to evolve, and we may find better ways of measuring, find better surrogates for the components that cause health effects. These are all areas of research that could be pursued to improve our understanding.

Very important, I think, and many of the committee members have pointed out that we really need to understand the differences between adults and children, both in terms of their exposures and their responses to inhaled toxic chemicals.

And this is a partial, I think, list of some of the suggestions that were made. I tried to be as complete as I could, but I'm sure I missed some point, so if the committee has any other comments that they want to make, now is a good time.

DR. OSTRO: Will we get a chance to respond?

CHAIRMAN KLEINMAN: You certainly do.

DR. OSTRO: Okay.

CHAIRMAN KLEINMAN: So I'll turn it over to Bart.

DR. OSTRO: I have some responses to both the research side and the standard-setting side. But maybe I'll wait for later for the research suggestions.

But I'd like to go back to Dr. Sheppard's two

proposals or suggestions, and have you go through them a little bit more. And specifically indicate the choice of the ten-microgram change that you had indicated that must be a basis, or whatever change you're talking about and how we can help -- how we can develop a principal (indiscernible).

PROFESSOR SHEPPARD: Sure. Basically, I was using the material that was in the document that you've prepared, and that shows that in areas that have annual -- So we'll start off with PM 10, because there's more data, it's simpler to discuss. There are data from several studies that look at a range of cities with different ambient annual concentrations of PM 10, and from the document, the point of view, and it seemed to be supported by the consensus of the committee, was that there were convincing data describing effects in cities where the average annual concentration was as low as 20 to 25 micrograms per cubic meter.

And then the incremental effects were found to be approximately linear or not statistically significantly different from linear, looking at 10-microgram-per-cubic-meter increments over 24 hours. So you can attribute an increase in mortality or morbidity to Delta, to increments of 10 micrograms per

cubic meter above that baseline annual mean, and with 10 micrograms per cubic meter increment above, say, 20 or 25 in the areas with the lowest annual pollution, significant effects that were detrimental to health were documented.

So I'm saying that a way you could interpret those data is that there's evidence of effects at a concentration of 10 micrograms per cubic meter above the level that was the annual average concentration in that region. And then you could use that consistent methodology to take the same approach for PM 2.5 where in that case, the way I was reading the document, the data would suggest that in regions where the average annual concentration was in the range of 10 to 15 micrograms per cubic meter, PM 2.5, similarly, effects were demonstrable with increments as small as 10 micrograms per cubic meter above that in a 24-hour period.

So that was the basis for that. The nice thing about it is that it's internally consistent. You can use the same metric for both particle sizes. It makes it easier for people to understand how a number was chosen.

DR. LIPSETT: I just have a question for clarification. I appreciate getting some suggestions

like this, but would you say, then, look at the areas that have had the lowest mean levels of PM 10 or PM 2.5, and use those as a basis for setting a standard? That is, the lowest there is, where there has been some documentation of health effects associated with short-term exposures?

PROFESSOR SHEPPARD: Yeah, that's what I'm suggesting, that you normally try to set a standard with at least a minimal margin of safety, so you find a concentration -- you're setting a 24-hour standard, finding a 24-hour concentration where you're convinced that there's effect, and set a standard that's below that.

So I'm suggesting a method by which you can do that, and that's to look at the areas where there's the -- Because the data that we have from the studies are increments above an average baseline. The total 24-hour is the sum of the baseline and that increment. Yeah, does that -- That's what I'm suggesting.

DR. LIPSETT: Okay, I just want to be clear on that, because, and Bart, you can correct me if I'm wrong on this, my recollection is that the lowest long-term mean concentrations of PM 2.5 in areas where some short-term effects have been seen were around 13.

PROFESSOR SHEPPARD: So I said 10 to 15 was

the --

DR. LIPSETT: Yeah, okay.

PROFESSOR SHEPPARD: So actually, since we just -- This is just something I made up.

[Laughter]

PROFESSOR SHEPPARD: I'd be interested in thinking what other people on the panel thought. Ira already said he thought it was a good idea, I guess.

DR. LIPSETT: It was. It's something that I certainly think is worth exploring. Now, you chose the 10 as kind of -- the 10 micrograms per cubic meter as your sort of standard metric here because of -- this has traditionally been done or as kind of a standard candle?

DR. BALMES: If you look at the document, or actually all the epi data the document summarizes, it's always expressed -- the effect is always expressed in 10-microgram-per-meter, cubed increments, so I think it's --

DR. LIPSETT: Right, it's a convention.

DR. BALMES: It's a convention, you know. Mike Sherman just pointed out that we treat patients for seven or ten days with a course of antibiotics because it's convention. You know, it's easy, but I think actually there's some internal consistency with

the document and Dean's proposed standard. I like it too.

PROFESSOR TAGER: As far as which one to pick, Mike, you know, in your table 7.2 where you've given the estimates, I mean, you can look down here, you've got some pretty precise estimates. If you wanted to be something a little less arbitrary and say, you know, somewhere between 20 and 25 cubic meter annual mean, there are some reasonably precise estimates of what the effects are.

So somewhere in that range, you know, you would be -- Now, admittedly, there are some studies where the precision is lower, but there are still plenty with very good precision of the estimates, and so you could certainly justify choosing something there because there's a fair bit of precision in the data.

So whether you picked it at 20 or 22 or -3 it's going to be arbitrary no matter what, but if you wanted to add some other level of pseudorationality to it, you could just look at the precision distribution and make a judgment sort of in the middle, in that lower range where the most precise estimates are and pick that as the level.

I mean, there's -- No matter what you do,

there's going to be a certain arbitrariness here. I mean, you just have to -- But I think if you set out the ground rules in advance, and I think the idea of using the metric that people have used, ten micrograms which, you know, if people want to argue with it, then you can argue with all the other ways the data have been expressed. And then if people want to argue about, well, the data are not necessarily the best, you can look at the graph you have, 7.2, and point out that most of the studies down there are fairly precise estimates of the effects.

So I think you're on reasonable, as reasonable grounds as any for taking that kind of approach.

DR. OSTRO: Just for information, I think it turns out that the lowest US city that has a statistically significant effect is Buffalo-Rochester with a mean of 24.

PROFESSOR TAGER: That's PM 10.

DR. OSTRO: That's PM 10, yeah.

PROFESSOR TAGER: Okay. So, I mean, again, I don't want to quibble about whether it's 20, 22 or 23, but the point is you just came up with a criterion: Look in the low range, find the US city that has the most precise estimate at the lower end of the range

and start with that. I mean, that's one simple approach which would be, at least in my mind, completely justifiable.

PROFESSOR THURSTON: Well, you know, looking at the second option here -- and first of all, it's talking about the 98th percentile, which I think the way California sets our standards, you --

PROFESSOR TAGER: You're talking about option one.

PROFESSOR THURSTON: Okay. Well, I'm not allowed to talk about option one?

PROFESSOR TAGER: Yeah, you are. I just wanted to clarify you were talking about option one.

PROFESSOR THURSTON: All right. Now I'm talking about option two. Of course, first of all, the 10 microgram is totally arbitrary. You know, it's just something somebody made up, and actually, I prefer not to use -- I like to use, when doing effects, something that has a physical meaning, like the max minus the mean, so you're getting the difference between a high-pollution day and the average day.

But anyway, so the 10 is sort of some number that I can't physically relate to myself. I don't know about you, maybe you have a feeling for what 10

micrograms does.

PROFESSOR TAGER: So it's arbitrary, it's because the coefficients are so small per unit change that people had to make them understandable, so they multiplied by 10 and 100, and then people said, well, that's pretty arbitrary, so let's use the interquartile range, which is equally arbitrary.

PROFESSOR THURSTON: Right. Well, at least it gives you some way of comparing cross-pollutants, but anyway --

PROFESSOR TAGER: Well, interquartile makes a little bit more sense.

PROFESSOR THURSTON: -- the thing I wanted to talk about, the 98, is that California is usually the second-highest. But also, if you're going to go back and try to do where the studies were done, you're probably not going to be able to easily get a hold of the data from the various studies and evaluate this. Because, you know, they're not in the published papers and you would have to go back and contact the investigators, they would have to reproduce their data set.

One option, though, is now that we have the nationwide PM 2.5 data is you could go to the same cities using the last couple of years of data and

evaluate -- It wouldn't be exactly the period when the study was done, but that's doable. You go on AIRS and you can get the PM 2.5 data and you can get the second-highest for each of these cities.

Is that what's being proposed here, to go and get the AIRS data and do this? Or are you proposing to go back and get the original data sets from the investigators, which will not be easy?

PROFESSOR TAGER: No, none of the above.

UNIDENTIFIED SPEAKER: Actually, we really generally prefer the first method, which hasn't been brought in.

PROFESSOR BALMES: I have a friendly amendment to what was stated, by using the lowest US city -- Nothing against cities in your state that you've studied, but Vancouver I actually think might be equally if not more relevant to the situation here in California, and I think Vancouver is another city where effects were seen at a relatively low annual mean.

CHAIRMAN KLEINMAN: I was just waiting for -- I thought they had another comment.

A couple of other things that probably should be considered in this process is, looking at the data sets again, it probably would be important to select

those studies for -- that would be used in this analysis that have measured PM 2.5 rather than studies where they've estimated it from PM 10 or from other ways of doing it.

So, as Ira said earlier, setting up some A-priority criteria for the inclusion characteristics for the studies that are going to be involved, pretty much in parallel with the way you selected PM 10 hourly studies for setting the PM 10 hourly standard. I think the same set of criteria should be applied to the PM 2.5. And then using a consistent method for developing a standard, go through the exercise and come up with what seems to be a reasonable number.

DR. OSTRO: Yeah, two comments. Getting back to Ira's point on the second one, it is true that the luck of the draw happens to be the distribution of the city that was studied, but it is evidence. It is a city where a study has been undertaken and, for better or worse, it's the evidence that we have. So I don't know if I'm ready to throw out entirely that option of at least looking at some of those cities and looking at what the percentiles look like at those higher ends and trying to be below the 98th percentile of cities that have shown effects. That's one possibility.

And I have another suggestion for another

approach, but go ahead.

PROFESSOR SHEPPARD: Well, I certainly don't -- I think it might be constructive to do the second sort of analysis, because for one thing, if the two methods of analysis come up with reasonably close estimates for what a standard ought to be, you have a stronger rationale for a particular number.

PROFESSOR TAGER: I mean, when I said earlier I had a preference for the first, I thought the purpose of this was, because the concern Michael raised this morning or the request was to offer some suggestions for getting start. I didn't take the slide to be the ultimate set of possibilities, but really, hopefully a starting point, and that you guys might come up with equally reasonable ways of doing it. And I think the last point is a good one. In fact, it probably is to the advantage to do it several ways, and if they come to fairly similar conclusions, it just strengthens the argument.

And I don't think you -- at least I'm not assuming that you're obligated to only restrict your consideration to these two approaches, but just to say there are, on the face of it, two approaches right away. You guys could probably think of other ones.

PROFESSOR TAGER: Okay. Well, in that light,

let me suggest another one and get some feelings from the committee. Another possible approach is to pick a 24-hour average that is consistent with the annual average. So one could, say, start with 12, or whatever number for the annual average for PM 2.5, and then look at the empirical data in California cities or counties, and see what the distributions look like and what the 98th percentile value would be for a 24-hour average associated with the 12 annual average, and see where that takes you in terms of what kind of outlyers, what kind of higher-end distributions are consistent with getting down to a level of 12. And, therefore, in a way, affording the same protection.

CHAIRMAN KLEINMAN: That is certainly a consistent way to do it.

DR. OSTRO: I actually don't understand how that helps.

CHAIRMAN KLEINMAN: Well, but the problem with that is you're going to have distributions that vary from city to city, and it might be considered more arbitrary to do it on the basis of a statistical distribution than on the basis of a health effect.

PROFESSOR TAGER: But we're still basing it on the health effects that relate to the annual. I mean, there is some basis to starting with that point.

PROFESSOR CROPP: But what if you favor the low, the city with low levels, with low peak levels? You know, if you just take an average, you know, 98 percent confidence limits of the high values, you would -- you know, 24-hour high values for PM 10's, you would give a lot of weight to the cities that never have high PM 10 values. And we are worried about the ones that have a high PM 10 24-hour value or PM 2.5 value, so you only want to take the ones that have the high one.

DR. OSTRO: Yeah, ultimately you would go through that and take the lowest, clearly only the lowest would be acceptable. You couldn't take the minimal, or the higher values. It would have to be the set that contains the lowest value, which would be the protected level.

So if you looked at two different metropolitan areas and one gave you a 98 percentile 60 and another gave you 40, clearly, the 60 would not be protective and you'd have to go down to that 40, which would be the one in the city that is consistent with the annual average of 12, whatever the numbers turn out to be. But yeah, it would have to be the most restrictive of the numbers; otherwise, it wouldn't be protective for the other cities.

PROFESSOR SHERMAN: It would seem like that last approach is solely based on a concentration and not a health effect, and that doesn't make sense with what we're talking about. You know, there has to be vital statistic data. And granted, that mortality is a very crude estimator, but I would think if you have at least two good years of monitoring data on PM 2.5, why has not anybody taken that mortality data in the Office of Vital Statistics for the state, added the PM 2.5 in various locales, and tried to put it together of what the high and low end is and you can come up with a reasonable Cal standard. I just don't understand it.

Maybe you can explain it to me.

DR. LIPSETT: One reason is we've been too busy writing this down.

[Laughter]

DR. LIPSETT: I just wanted to make a couple of comments too. Certainly, I appreciate that my colleague, Dr. Ostro, would favor this, looking at the 98th percentile, which is consistent with his extremist views on many things.

[Laughter]

DR. LIPSETT: But I guess one question I would pose to the committee with respect to

Dr. Sheppard's proposal is we're charged with developing a standard that has an adequate margin of safety. And if you're looking at studies, say, where the mean value, let's say is 20, and we take an increment of 10 micrograms per cubic meter over the 20 as a basis for setting the standard, there is, I guess, we don't know where the effects really began to kick in, in the distribution of exposure to PM.

But taking this approach, the underlying assumption is that they are somewhere 10 micrograms per cubic meter greater than what the mean level is, unless I'm misconstruing things.

PROFESSOR SHEPPARD: So if you could make a convincing argument for setting the standard at the annual mean value in the regions where there's an incremental effect, if I understand what you're arguing correctly, you're saying that since the smallest value that was measured, the smallest incremental difference that's express is 10 micrograms per cubic meter, you don't know whether there was an effect at a one-microgram-per-cubic-meter increase above the annual mean.

I mean, you could certainly make an argument in that respect. That would make the standard more stringent than what I'm proposing. I was trying to

give you a compromise between the very lax proposal that was made in the report and a 24-hour standard.

[Laughter]

MR. LIPSETT: Does anybody else have any response about the issue about the margin of safety?

DR. BALMES: I mean, Michael, I understand your point, there should be a margin of safety, but what you guys have proposed as no margin of safety because there's no standard, so we're trying to give you something with some margin of safety.

PROFESSOR TAGER: You know, and in reality, Michael, you can apply the argument -- I mean, since a lot of the mechanisms are not clearly worked out, a lot of the ways in which people come, assuming for a minute that there are -- there will be definable pathways by which these ambient pollutants affect certain disease outcomes, and they're going to be interacting with lots of other things, if we don't -- we're never going to know exactly on a continuous distribution of exposures mixed in with a lot of other exposures where the bottom is. Even if there's a threshold, it's still going to be uncertain.

So the question is, the concept of an adequate margin of certainty, if you want to look at it from that point of view, has no real meaning.

Because if you don't understand exactly what's going on, and maybe we never entirely will, then you don't know. So if you take your argument to the extreme, you shouldn't have set an annual standard either at any number, because what's the margin of safety? I think that's the whole issue of the judgment.

And I think the way you get around the real problem that you're pointing out is for you and Bart and whomever is involved in this is to sit down, set out a set of criteria in advance that you're going to assess the data, apply preferably multiple approaches that take into account both extreme and mean views, as it were, and look at what the numbers show. And then you're going to have to make a choice.

Because otherwise, you're going to make an argument for having -- you know, I know there are probably people who would like the argument to achieve that we have no standard, but that's going to be a problem, wherever you set the standard, assuming that even if there's a threshold phenomenon, after the threshold, the thing has a shape to it. And the question is where do you put it on that shape with a reasonable margin of safety?

So it's a problem no matter what. And I think you guys will only solve it by just stating the

process in advance, following through and provide some quantitation, and then you'll have to defend it, no matter what number you come up with.

DR. LIPSETT: Yeah, that's fair. The legislation specifically articulates the adequate margin of safety --

PROFESSOR TAGER: Well, I understand that, but --

DR. LIPSETT: -- and that's what I wanted to try and get from the committee about, their feelings about this position.

DR. OSTRO: So here's a fourth possibility. There's actually two studies that have been published in California, or using California cities with PM 2.5. One is our study in Coachella Valley, which may be less relevant since it's very dominated by coarse particles, but there still might be information there. And then David Fearly's study in Santa Clara.

I've heard from sources that he's done some additional analysis, looking at potential thresholds in that data; that is, looking at lower and lower cuts of the data to see at what point do you basically add enough uncertainty that you no longer have a statistically significant association.

So one could use California-specific cities

or other cities and, if time permits, repeat that type of analysis for as many cities as you have, and see what kind of results you get from that.

PROFESSOR CROPP: Would it be possible to take the data from California that show short-term effects, measurable short-term effects on health, whether that's myocardial infarctions, lung function tests in children, respiratory symptoms in children, asthma attacks, ER visits, see at what level are they being reported for short-term exposures. Then take that level and then subtract from that a margin of safety.

So you end up then with a level at which you have a margin of safety that will assure that you never reach the level at which symptoms or consequences occur. I mean, that data must be available.

CHAIRMAN KLEINMAN: Michael, and this is kind of a loaded question, but do you believe that there is an adequate margin of safety in the 24-hour PM 10 standard?

DR. LIPSETT: I'm going to stick with what we've written in our document about that, that basically, the focus in that was to shift the distributions of exposures to PM 10 and PM 2.5 down,

and basically, the short-term standard is basically just a backup.

CHAIRMAN KLEINMAN: So this is sort of an operational definition for a margin of safety.

DR. LIPSETT: Yes, correct.

CHAIRMAN KLEINMAN: As a way to get out of the dilemma, because we're operating with even fewer data to try to set a PM 2.5 standard than you had for PM 10. Why don't we think about the idea that we have a reasonable average value for PM 2.5 to the PM 10 ratio? If we say that, as an upper limit on the PM 2.5 standard, we would take the PM 10 adjusted for that ratio, and that would provide the upper limit, and then if you go through the calculation of establishing using these other mechanisms, a PM 2.5 standard, as long as they are below that ratio-derived value, then I would consider that to be, you know, within the limits of your operationalized, I guess, margin of safety.

I don't know, what does the committee think of that approach? It's a little --

PROFESSOR SHEPPARD: So a couple of comments. The first is in relation -- A problem I see, if I understood what you're saying correctly, is that it seems to accept the 50-micrograms-per-cubic-meter PM

10 24-hour standard as being rational, based on the data. And I have difficulty with that.

I mean, although Michael was cagey in his response, the argument wasn't convincing, quite frankly, that that standard has a margin of safety. And, you know, it's based on the rationale that underlies all of the recommendations in the document, that an annual standard is really the metric that we're after here. And so I just have difficulty with starting from that point.

It seems to me that there are data for PM 2.5 and there are data for PM 10, and you would be on a much more defensible ground if you based the standard-setting on the data that we have available for each of those articles.

PROFESSOR TAGER: The other problem with using an average is it's a zero sum gain, and you're going to have a problem in those parts of the year where PM 10 is dominated by 2.5, if you set the average ratio. You just know that that has to happen as you get the average, the highs and the lows. So you would be setting up certain times of the year in certain areas for failure if you used the average.

CHAIRMAN KLEINMAN: I'm not saying that we use that average as the standard.

PROFESSOR TAGER: No, no, no --

CHAIRMAN KLEINMAN: What I'm saying is there is a dilemma in that they need to be able to specify that they've got a margin of safety.

I don't know that from our database we would be able to identify margin of safety, because we really have very sparse data. And so I'm looking for a potential way of providing an operational definition that will hold for now and can be revisited in five years.

PROFESSOR TAGER: But the problem would -- Even if we didn't have sparse data, if you believed there were a linear exposure response relationship, let's put aside -- let's just accept that for a moment, you'd still have the problem. Because the linear exposure response relationship says that an incremental change at the low end and an incremental change at the high risk carry the same incremental risk. So where is the margin of safety?

I don't think it's a problem of the sparsity of the data, it's inherent in operating where there's no floor, or at least not a floor that we can identify. And that's why I think it's more defensible to take the health data as they are, the PM 2.5 health data and try to make a judgment using a number of

approaches on PM 2.5 and the health data that comes from it, rather than trying to move back and forth, trying to reason from PM 10 down to PM 2.5.

CHAIRMAN KLEINMAN: I'm not disagreeing with that. I'm saying that that's how they should set the standard. I'm just saying that as long as the standard they set is below that ratio value, then they can, for the time being, not address it in terms of a margin of safety issue.

PROFESSOR THURSTON: One option with the idea of taking the PM 10 standard and adjusting it according to ratio would be to maybe look throughout California, seasonally, look at the ratio of PM 2.5 to PM 10, and find the lowest ratio. There you're putting in a safety factor. By choosing the lowest ratio of PM 2.5 to PM 10, you then get a lowest estimate of the equivalency. You know, it will range from, I don't know, .5 to .9 or something, and by choosing the lowest ratio, then you're coming up with a safety factor.

DR. LIPSETT: We've already looked at this.

PROFESSOR THURSTON: You have, okay.

DR. LIPSETT: And it -- you'll end up with a PM 2.5 standard that will be exceedingly low, because there really -- there's tremendous variation

throughout California by location, by season, where you can get up to -- the ratio could be, like, 80 percent or more or down to less than 30 percent.

So you might end up -- Well, with 30 percent you might end up with a 24-hour standard of about 15 or so. So it's one way to think about it, but as I said, I like my suggestion of initially, of putting a ceiling on it by the average overall ratio over the state, but, you know, as Ira was saying, there is this huge variability within the state. This is this dichot monitoring system that I think is no longer operating throughout the state. The ARB did provide us with these data, and I guess I'd be a little bit hesitant to follow this suggestion, at least a priori.

DR. OSTRO: CHAIRMAN KLEINMAN: I didn't get any comments on my -- on the data --

PROFESSOR SHEPPARD: I thought your fourth proposal sounded like a reasonable way to look at the data and could potentially work. You haven't looked at it yet, so it's hard to say. But if you had the two methods that are proposed up here and your fourth proposal, and you did all of that analysis and looked at the whole composite of the data, that would also potentially provide a larger database for you to pick a number, which is what you're trying to accomplish.

But don't wait too long.

CHAIRMAN KLEINMAN: We have a little bit of time for anyone on the committee who has other comments that they want to make.

Yes?

DR. FRIEDLANDER: What are the time constraints on the development of a 24-hour PM 2.5 standard? My questions are addressed to our friends from the ARB. What are the time constraints? When does this document have to be -- When do the recommendations have to go out? Do you have some kind of legislative mandate?

CHIEF BODE: Well, our legislative mandate is to be done by December of this year.

DR. FRIEDLANDER: This year or last year?

CHIEF BODE: 2002. Our chairman asked that it be done in the spring because he thought the importance of just the effects of PM pollution and wanted to move it up to basically April or May.

Right now our timing is in May -- we planned, before this meeting, that we were on target for going to May. That's some of the things actually we will probably discuss after this meeting is what we want to do. Definitely, from the discussions we had today, we're going to look for an extension from that May

deadline. We probably --

On our current schedule we need to have a draft document out to the public in the end of March to be able to meet all the legal deadlines of Office of Administrative Law review and 45-day public comment requirements, by law to meet that. And that I think would be very problematic, not so much with the overall changes to the whole document, which I think could be done in our time frame, but from the short-term standard for both PM 2.5, and whether that affects the PM 10 as well short term. Those I think are going to be hard to meet in this short time frame we have here.

So I think coming out of this meeting what we'll do is sit down and collectively put our heads together between ARB and OEHHA, get back and talk to our upper management or chairman's office and the director of OEHHA, set an appropriate time frame. We need Michael and Bart and some of my staff who have been working on the PM effects to work out a plausible direction we want to go with this, and then see how we want to handle it.

I mean, one of the suggestions we went through is whether we want to basically take the document and make amendments to it and go with the

annual PM standards, and --

DR. FRIEDLANDER: Right, but you also have the federal standards, although you feel that it's much too --

CHIEF BODE: Lax.

DR. FRIEDLANDER: -- the concentrations are much too high, so -- but still, that is something in place until you replace it. And what would counsel -- I think you have a chance of trying to set a, develop a methodology that would be ahead of its time, and I think in order to do that, though, you might be better off to get some additional time for this component of the standard, rather than to make hasty decisions in order to satisfy this previous time limit.

So my point would be is to proceed with the document you have, and ask for a six-month delay on the PM 2.5 short-term standard or whatever seems reasonable, in terms of the data you expect to become available or what you need to do.

CHIEF BODE: Yeah, I think that's something that when we leave here, we'll try and probably set a strategy. And some of the options we may have is, like I said, split this into a document that continues with the annual standards and set the short-term standards and do that in a separate phase.

On the other hand, since we have such a comprehensive PM document, whether we might want to just keep it as one single package and then just get an extension. Definitely I think what we want to do is go with the best and most defensible recommendations and methodologies when we go to our board.

PROFESSOR SHEPPARD: Since I for the last half-hour might be perceived as beating up on Mike and Bart, I just want to underscore what John Balmes said, that overall, I think the Air Resources Board really should be commended for the job that you've done in putting together a document that allowed all of us to very clearly see what the scientific basis would be for making these kinds of decisions. You really did do an extraordinary job.

And also, it's important to keep in mind that in this respect California is ahead of most of the rest of the country in the kinds of issues that we're considering and the types of standards that people are discussing, even the annual standards that were in the document. So I think that's -- my own personal point of view is that you really ought to be commended for the job you did.

DR. LIPSETT: I just want to say thank you to

both Dean and John for that. We actually don't take the other comments personally, and we do appreciate all the input, because, as you can see, these are very thorny, difficult issues. And it is good to get external expert opinion to help guide our thinking about this, so we do appreciate everything you said, even -- and we know it's meant in the best of spirit -- even when it comes across a little harshly sometimes, so thank you.

DR. SHERWIN: Well, what I'm about to say comes from one of the least knowledgeable people in the area, and I'm mentioning it only because there's a little lull in the meeting at this point, and I remember we ran into this problem one time with ozone, and the word I'm about to mention may make you ballistic, but it's called probablistic theory or statistics. And I'm wondering if it's maybe not a worthwhile thing just to look into it, not to necessarily depend upon it.

I think there's a tremendous amount of resistance to probablistic theory, but it was done by EPA, they published a big paper on ozone, as to where do you think that whole standard ought to be with ozone? What came out of it? I'm positive it was -- I participated in it and I have no idea what they did.

[Laughter]

DR. SHERWIN: But that's because I know nothing about statistics.

DR. LIPSETT: But Russ, you're referring to that -- It's not just statistics, you're talking about is the Delphi technique that they were using back in the 1980's --

DR. SHERWIN: Oh, okay.

DR. LIPSETT: -- and I don't think it ever resulted in any kind of concrete standard-setting, it was just sort of an interesting exercise.

DR. SHERWIN: Was it Whitman or somebody by the name of Whitman who did this? It was an extra --

DR. LIPSETT: Wasn't it Harvey Richman? Harvey Richman.

DR. SHERWIN: There we go. It was an extraordinarily complex process. I think it was a mixture of a lot of approaches, but it does have this merit to it: It almost gets to be like pornography, you can't separate it, but you know when you hear it and see it. So it's the same thing, if somebody came up to me and said where do you think the standard should be? I would say, well, of course, I have no more insight, and least insight into what you have.

But if a whole bunch of people got together,

I could give you some kind of an impression as to whether something was too low or too high, and from my knowledge of what the hazards are, I could tell you what I personally believe is the likelihood that that would be adversely, have an adverse effect on health. So if enough people got together, you might find there is some sort of concordance of where that level should be.

Now, again, and I'm apologizing for it, all I'm saying is that kind of approach might in itself tend to formalize a more mathematical approach or a more systematized approach. But it is -- Probablistic statistics or approach is something that has been used. I know ears go up and eyebrows go up amongst statisticians, but we are in the position and we have to face there is no sharp line that we can cut.

There's got to be something that is under the heading of best available scientific judgment, how do you approach that?

DR. LIPSETT: Russ, actually I have to say that I'm -- Well, I find it interesting that you would use that metaphor with pornography and think that our document would carry any kind of prurient interest, but this is California, so that's all right.

[Laughter]

DR. SHERWIN: But the Supreme Court used it, the Chief Justice.

CHAIRMAN KLEINMAN: I think on that note --

[Laughter]

CHAIRMAN KLEINMAN: -- we'd better adjourn.

I'd like to thank Barb, Mike, Rachel Broadwin, and all the folks from ARB that worked extremely hard to write this document. I think you've heard from us that we really appreciate the amount of scientific effort that goes into it, and the suggestions that we make and the criticisms that we make are certainly only offered in the spirit of improving the science.

I'm glad that there is a strong consensus for developing a PM 2.5 hourly standard --

UNIDENTIFIED SPEAKER: Twenty-four.

CHAIRMAN KLEINMAN: -- 24-hour standard, sorry.

[Laughter]

CHAIRMAN KLEINMAN: We almost had a new cardiovascular end point.

And we will provide a copy or several copies of the comments, once they've been cleaned up and circulated through the committee.

Now, I presume that the draft document that

we circulate to make sure that everybody in the committee understands that, is that legal for us to do?

MS. KRINSK: Yes.

CHAIRMAN KLEINMAN: As long as everybody reads it by themselves, right?

[Laughter]

CHAIRMAN KLEINMAN: So we will do that, and as soon as we have a copy with all the corrections on it, it will be submitted to OEHHA and the ARB, and we'll look forward to hearing what is going to, what the PM 2.5 24-hour standard might look like.

CHIEF BODE: I would just like to add that I want to thank the committee for all the time they've taken over the last, not only the last two days, but the time taken to review this document, and that we're very thankful for what you've done and the advice you're giving.

And I think actually, the work that's going to be coming out of this document and the review of the PM standards I think is going to set some groundbreaking actions, by not just that affect California but I think may affect the entire nation. And I think we're taking a big giant step here. And I think actually PM pollution is something that its time

has come to look closer at this.

So your contributions I think are going to be very worthwhile in this cause. So thank you very much.

CHAIRMAN KLEINMAN: We're adjourned.

(Thereupon, the meeting was adjourned at 3:20 p.m.)

CERTIFICATE OF REPORTER

I, JAMES RAMOS, an Electronic Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing Air Resources Board, Air Quality Advisory Committee Meeting was reported by me and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties in this matter, nor in any way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 5th day of February, 2002.

James Ramos
Official Reporter