UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Review of the Agency's draft *Proposed Methodology for Particulate Matter Risk Analysis for Selected Urban Areas*; an Advisory by the Clean Air Scientific Advisory Committee

Dear Governor Whitman:

The Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel ("CASAC PM Review Panel" or the "Panel") met via public teleconference on Wednesday, February 27, 2002. In this teleconference, the CASAC PM Review Panel reviewed the draft document *Proposed Methodology for Particulate Matter Risk Analysis for Selected Urban Areas* that outlines part of the procedures to be used in preparing the human health risk analysis for $PM_{2.5}$ that will accompany the Staff Paper on the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM) that will be released later this year. The CASAC PM Review Panel consulted with the Agency's Office of Air Quality Planning and Standards (OAQPS) last summer on the plans for this risk analysis and this document reflects some of the comments and concerns that were raised at that time. We would like to commend OAQPS and its contractors for responding to our comments and substantially improving the proposed plans. OAQPS has asked the CASAC PM Review Panel to comment on the following specific charge questions:

1. Given the goals set forth above for the planned PM risk analyses, has the draft methodology appropriately drawn from the existing scientific and technical information in developing the overall approach? To the extent it does not, what salient features are missing or require change?

2. Have the appropriate sensitivity analyses been included in the proposed methodology? If not, which additional sensitivity analyses should be included and should any of the proposed sensitivity analyses be dropped?

3. The draft methodology report describes the planned approach to adjusting air quality to simulate just meeting alternative $PM_{2.5}$ air quality standards. Is this approach reasonable? Are there other approaches that should be considered?

4. Have the appropriate health effect studies and concentration-response functions been identified for use in the planned $PM_{2.5}$ risk analyses? If not, which additional studies and/or concentration-response functions should be considered? Are there any studies and/or concentration-response functions that should be dropped from the planned analyses?

5. Is the draft report clear and transparent in its description of the proposed approach? Are the various assumptions and judgments that must be made in carrying out the planned risk analyses clear and transparent?

This report will summarize the Panel's consensus findings with respect to the draft document and these questions. Additionally, some of the CASAC PM Review Panel Members have also prepared individual comments on the review document and these are included in Appendix A to this report.

As a prelude to our comments, the Panel would like to indicate the importance that this risk assessment analysis has in the primary standard setting process for PM. While prior EPA policy and the legislative history of the Clean Air Act indicate that assessment of quantitative risks should not play a determinant role in recommending primary, health-based standards, such estimates can provide important information to the Administrator in assessing alternative standard levels. The human health risk assessment analysis helps to provide a quantitative link between the science described in the Criteria Document and the policy implications and recommendations in the Staff Paper and thus, we believe that it is critical that the risk assessment analysis be done at the state of the current science in this field.

In response to charge question 1, the Panel concluded that the general methodology as described in the report is appropriate. It recognizes the need to use concentration/response functions to obtain risk estimates in a series of locations. Thus, the general framework of the approach is the sensible approach to this risk analysis. However, the Panel has a number of comments that relate to the details of application of the method.

One of the most critical questions is the choice of the locations for which the analyses will be made. For two reasons, the Panel strongly suggests including analyses of health risks for PM_{10}, as well as $PM_{2.5}$. First, the small amount of concentration-response data for $PM_{2.5}$ led the proposed methodology to use data from different cities for different health effects. Although short-term and long-term mortality will be examined in seven of the eight proposed cities, only two or three cities will be used for the review of hospital admissions or respiratory symptoms. Recent comparisons of PM_{10} results from different cities demonstrate spatial variations in concentration-response relationships that may also exist for $PM_{2.5}$. Using concentration-response functions from different cities for different health effects may then lead to inaccurate views of the relative potency of $PM_{2.5}$ in causing the different effects. Data for PM_{10} would help clarify these differences and resulting uncertainties by permitting estimation of concentration-response functions for a wider range of health effects such as hospital admissions or respiratory symptoms in the same cities. In doing this, it is important to include comparisons in cities in which PM_{10} has relatively greater and lesser effects, not just those cities showing the highest concentration-response effect. Second, evaluation of PM_{10} concentration-response relationships would provide a bounding analysis for the health burden from $PM_{2.5}$. Although the potency per unit mass could be greater for $PM_{2.5}$ than for PM_{10}, the total public health burden of mortality and morbidity from $PM_{2.5}$ must be contained within the health burden from PM_{10} (i.e., it cannot be greater). Including PM_{10} therefore, would provide a valuable perspective for the likely upper bound of the health impact of $PM_{2.5}$ and help provide some measure of the variability of risk across a wider range of conditions than the eight cities afford. The analysis should include a clear statement of the rationale for selecting the cities that are included

In response to charge question 2, we want to commend the Agency for starting the process with the recognition of the need for: 1) sensitivity analyses; and 2) for building them into the risk analysis process. In general, the sensitivity studies presented are appropriate as part of the understanding of the uncertainties in the results of the risk analysis. However, there are other aspects of the problem that may be useful to examine as well. These aspects include: 1) the seasonality in the baseline rates; and 2) the concentration/response functions for health effects. It will be useful to provide the results of the multiple analyses in terms of the sensitivity of the

overall process to locations across the United States and thus, sensitivity to the likely differences in ambient aerosol compositions that those locations represent. The sensitivity of the risk to the pollutant when used in a single pollutant model as compared with multi-pollutant models is also essential. We are always exposed to a mixture of pollutants and it is important to understand the risk of a single pollutant within the context of the full set of chemical species to which the people displaying adverse effects are exposed.

The Panel agreed that the proportional rollback approach is the appropriate method. However, a rationale should be offered for the decision to base the rollback percentage on the "above background" portion of the "as is" concentration distribution. The "background" portion of the "as-is" distribution is unknown, and is almost certainly poorly approximated by the assumption of a constant level equal to the annual average. The annual average "background" is so small relative to some of the probable individual day values that the analysis results will be quite insensitive to the estimate of the constant annual average "background". Given this, and given the difficulty of estimating individual-day "backgrounds", it might be better to calculate the rollback from total observed concentrations.

The Panel believes that the most critical aspect of the choice of concentration-response functions for $PM_{2.5}$ is providing a clear rationale for each choice. It is essential that an appropriate distribution of concentration-response functions be used that represent the range of $PM_{2.5}$ concentrations in various cities across the country. The current review document suggests that there was an intent to select functions that would show the highest response per unit concentration. For example, it is stated that the intent is to use lag models that have the highest corresponding effect estimates. Doing so would present biased estimates of the risk. Therefore, in cities where studies have presented the results for multiple lags, all of the published results should be used in the risk analyses to develop the full range of possible risk estimates.

It is important to make the studies in cities chosen for geographical coverage and a range of PM compositions rather than only looking at cities for which there are $PM_{2.5}$ data. To the extent possible, it will be useful to examine the range of all of the possible health endpoints for each of the selected cities so that the relative morbidity and mortality effects in each city can be put into perspective. Again, we recognize that it may be necessary to use PM_{10} -based estimates in order to address this issue.

In addition, given the new information provided in the recently published paper by Pope *et al.* (J. Amer. Med. Assoc. 287:1132-1141, 2002), it may be appropriate to examine lung cancer as an endpoint in the risk analysis as well as cardiopulmonary mortality and morbidity effects.

Finally, the question of the transparency of the process is raised in charge question 5. The Panel felt that the current review document could be improved by starting the document by describing the set of assumptions that are necessary to make the analysis to be subsequently presented. These assumptions include the causality of effects by particulate matter mass, constancy in levels of individual activity leading to equivalent exposures to the ambient particulate matter and equal toxicity of the particulate matter within the geographical region for which the analysis is being performed. We understand that these assumptions need to be made in order to proceed with the data analysis that are available. However, it would be prudent to present the assumptions explicitly early in the document. This addition in conjunction with more clear presentation of the rationales for making the variety of choices that are needed will improve the transparency of the process and help to frame the uncertainties that all such analyses are typically subject to.

At all stages in the plan and its execution, it is important that EPA and its contractors clearly distinguish between and attempt to characterize uncertainty and variability. The present plan does not always clearly make this distinction. As noted by the NRC Committee on Hazardous Air Pollutants in *Science and Judgement*, it is important to make these distinctions as clear as possible. At this time, there is abundant scientific information to characterize some aspects of variability, i.e., variations in concentrations/response functions in some communities as a function of season at least for PM_{10}. At the same time, there are major uncertainties in our knowledge of PM and these different aspects of the problem should be treated separately and as completely as possible.

The CASAC PM Panel recognizes that the present review document does not represent the complete set of risk analyses that are expected to be performed as part of this NAAQS process. Depending on the extent of data and scientific information presented in the next draft of the Particulate Matter Criteria Document, there may be a need for risk analyses for $PM_{10-2.5}$ and alternative $PM_{2.5}$ standards. The Staff Paper to be presented in July will present a discussion of any alternative $PM_{2.5}$ and $PM_{10-2.5}$ standards. It will be essential that there be a clear rationale for the inclusion or exclusion of specific indicators of PM concentration, the statistical forms of the standards, and the averaging period. If the decision is then made to perform a risk analysis on $PM_{10-2.5}$ or the alternative $PM_{2.5}$ standards, it would be helpful to provide an outline of risk analysis plans for these standards (data sets, endpoints, etc) to the Panel as soon as possible for comment (via an SAB "Consultation") rather than to present a completed analysis without any prior commentary. We would not necessarily suggest a full document with review, but communication of the plans and an opportunity for individual comments back to OAQPS would potentially help provide a better analysis. This consultation could potentially be done as part of the Staff Paper review to be held in September.

These are the major issues that the Panel have identified with respect to the risk analysis. We believe that the basic process is sound and have provided a number of suggestions in this report and in the appendices to refine the analyses that are to be done. We look forward to seeing the final results in conjunction with the PM Staff Paper later this year.

The CASAC Particulate Matter Review Panel is composed of the seven statutory CASAC members along with expert consultants. As such, it represents the full CASAC and no further advisory committee review is needed prior to submission of this final advisory review report to the Agency.

Sincerely,

/ Signed /

Dr. Philip Hopke, Chair
Clean Air Scientific Advisory
Committee

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* Members of this SAB Panel consist of

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.

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APPENDIX A - INDIVIDUAL PANELIST WRITTEN COMMENTS

Note: These are the written comments provided by a number of individual Panelists as a result of their review of the draft f *Proposed Methodology for Particulate Matter Risk Analysis for Selected Urban Areas* at the February 27, 2002 meeting. These individual comments are included here to present the full range of opinion and to document all edits suggested by Panelists. These are individual comments and do not necessarily represent the views of the Clean Air Scientific Advisory Committee (CASAC) nor the EPA Science Advisory Board (SAB). The consensus position of the CASAC Particulate Matter Review Panel is contained in the preceding report.

Contents:

Dr. Koenig

Page10:
Background levels. What is the definition of background? Non anthropogenic??? If so, why are we estimating health effects based on changes from background???

Page 20.
2.6 Calculating health effects. Why not skip days with missing data? Are there that many??

2.7 Baseline health effects incidence data. Page 21. It seems to me that the baseline incidence of health will be based on data from "as is" pollutant levels. Certainly it is not baseline air poll days--not manmade pollution??? Can not the average health indicators on the days of , say the 25th percentile be used??

> 2nd para. Incidence varies by air pollution levels?? If that has already been shown, that could be our report!!!
>
> 3rd para. Make it clear that the incidence rates described here are NOT air pollution-free rates.
>
> 4th para. it may introduce serious exposure error to use county wide population and city wide air monitors. In King County, there are no air monitoring data for the rural sections of the county. King County is very large and includes populations for which Seattle air quality data are not representative.

3.2.1.
page 29. first para. Criteria of at least 11 observations per quarter. Surely we can be more robust than that!

Page 30. 2nd full para. 2nd line. I think that should be morbidity??

4.2
page 33 no effect of the four gaseous pollutants. With what certainty can that be stated.?

5. Baseline health effects. Same issue I have commented on. What is meant by the annual number of cases in a location *before* a change in PM air quality? How is that different from incidence at "as is " air pollution levels???

Page 37. First full para <u>These</u> data Don't hospital discharge records show date of admission??

6. Sources of uncertainty. FYI, Data have been published on S in children with asthma residing in Seattle. Yu et al, 2000.

Exhibit 6.1. Page 45. Define background and differentiate from 'as is"

6.1.1
PM2.5 and PM2.1 How about PM 1.0 (nephelometry data) These can be transformed to PM2.5.

Page 47. Repeat comment. How can we be certain that PM effects are not confounded by other gaseous criteria pollutants?? And then of course there are all the unmeasured co-pollutants!!

6.1.2
page 48 PM is only dominated by windblown particles in areas where there are no mobile source pollutants. Why is that even mentioned??

6.3.1
Use of nonresidents of a city in data analysis is a problem. That is why we use zip code data.

Dr. Legge

I have only one comment on the draft document entitled 'Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas' dated January,2002. The comment is very basic and relates to using PM mass, in any form, as a surrogate for various health endpoints. PM chemistry is essentially ignored. While I understand that the focus to this point in the process has been on PM mass, the document as written understates the importance of PM chemistry (see page 48, para 1). The document should clearly state that PM chemistry is important eventhough it is recognized at this time that more data are required.This is an important 'next step' issue. All the best in pulling together all of the CASAC comments.

Dr. Miller

The Panel was charged with addressing and providing comments on five questions related to the methodology and proposed course of action by EPA relative to potential risk assessment activities in conjunction with the reevaluation/revision of NAAQS for PM. While comments are provided below for the five charge questions, some aspects of these comments could be placed under more than one of the questions.

Of particular concern to this Panel member is the focus on PM2.5 to the exclusion of other indicators of PM. In that sense, the overall approach being proposed in the document is not as much at issue as is the scope of the document. The current document presents to critics of EPA the notion of a pre-bias towards PM2.5. Beyond the wording of sections of the document, the need to address the broader aspects of the various indicators of PM is scientifically compelling and prudent for public health protection.

> Question 1: Given the goals set forth above for the planned PM risk analyses, has the draft methodology appropriately drawn from the existing scientific and technical information in developing the overall approach? To the extent it does not, what salient features are missing or require change?

EPA has drawn from their previous experience in the 1996 PM risk analyses that they conducted to refine the methodology and provide some additional types of analyses. I would agree that the figures on pages 8 and 9 of the document contain the basic elements and components of risk analyses that could be conducted for short term and long term effects, respectively. Most features or other approaches that might be incorporated basically fall into implementation methods for activities within the various major boxes contained in the figures. To this extent, my overall response to charge question #1 is that the draft methodology is appropriate.

However, there are two major elements of concern. First, while currently complying with the existing way standards are set, the use of the simple arithmetic mean for averaging quarterly values from a monitor and then continuing with the arithmetic mean of the four quarters should be reexamined. Just as there have been significant improvements in statistical methodologies for the analysis of epidemiological study responses, so have there been advances in the ability to do bootstrapping or windsorized trimmed means in sampling statistical survey or air quality data.

The current simple arithmetic average has significant deficiencies and needs to be reevaluated as the basis for obtaining the value to use in standard setting.

Second, the current approach has a significant weakness in that analyses based upon seasonal data are not used to the fullest extent possible. Given the regional heterogeneity of PM composition and level in conjunction with period of the year, I believe it is critical that seasonal analyses be used to the greatest extent possible. The aspect of seasonality can be used for background incidences of response rates, potential rollback strategies, and the list goes on.

> Question 2: Have the appropriate sensitivity analyses been included in the proposed methodology? If not, which additional sensitivity analyses should be included and should any of the proposed sensitivity analyses be dropped?

There is a discrepancy in the document relative to the listing of types of sensitivity analyses that are being considered. The Agency should recast the sensitivity analyses identified in Exhibit 6.1 so that they fall into comparable categories as presented earlier in Exhibit 2.5. The Panel brought up a number of additional sensitivity analyses that should be conducted as part of the broader category of examining the nature of the concentration response function, the selection of the distribution of lag times or distributed lags, and the approach to handling rollbacks.

Collectively, the conference call advisory review on February 27, 2002 identified a number of areas that would benefit from sensitivity analyses from the perspective of either exploring alternative hypotheses, bounding the level of risk, or assessing the reasonableness of the preferred approach compared to alternative approaches for handling a specific technical question. It would behoove EPA to consider all of the proposed sensitive assessments and provide CASAC with a prioritization for addressing what EPA believes would be the most critical sensitivity analyses to be performed. Here, the intent would be to ensure that within the time and resources available, EPA conducts the most critical sensitivity analyses.

> Question 3: The draft methodology report describes the planned approach to adjusting air quality to simulate just meeting alternative PM2.5 air quality standards. Is this approach reasonable? Are there other approaches that should be considered?

The planned approach for adjusting air quality to simulate just meeting alternative PM 2.5 air quality standards appears to be reasonable. However, Panel members noted other approaches that could be considered such as seasonal rollback or peak shaving that might be examined in various sensitivity analyses. In view of the regional heterogeneity identified in the latest epidemiological analyses, these alternative methods for adjusting air quality data may be more relevant for one region compared to another. By examining some of these alternative approaches, EPA scientists will be in a better position to inform the Administrator on potential courses of action for PM standards.

> Question 4: Have the appropriate health effect studies and concentration-response functions been identified for use in the planned PM2.5 risk analyses? If not, which additional studies and/or concentration-response functions should be considered? Are there any studies and/or concentration-response functions that should be dropped from the planned analyses?

The current proposed methodology is not very explicit relative to alternative C-R models that might be used that allow an assessment of the existence of a biologically plausible threshold. Clearly, the current document heavily emphasizes robust and extensive datasets for a select number of responses. The Panel discussed the desirability of examining a broader set of health

indices with an indicator such as PM10 and an adjustment of inclusion criteria such that a more expanded analysis may be done with a greater number of cities. I would endorse such an approach. EPA staff have acknowledged that the next draft of the PM Criteria document may inform them as to other concentration-response functions or indicators that should be examined.

> Question 5: Is the draft report clear and transparent in its description of the proposed approach? Are the various assumptions and judgments that must be made in carrying out the planned risk analyses clear and transparent?

There are a number of assumptions that are inherent in the proposed methodology. I would agree with other Panel members that these assumptions need to be explicitly stated. Currently, the various sections do not adequately convey the underlying assumptions. In addition, by clearly stating the underlying assumptions, EPA can provide insights on the validity of some of these assumptions through sensitivity analyses.

Dr. Lippmann

1. Given the goals set forth above for the planned PM risk analyses, has the draft methodology appropriately drawn from the existing scientific and technical information in developing the overall approach? To the extent it does not, what salient features are missing or require change?

Yes, appropriate use has been made of the existing literature and technical information. However, the next version should include a risk analysis for lung cancer associated with long-term $PM_{2.5}$ exposure. This association can be based on findings in a paper by Pope et al. that is in press in JAMA and based on a 16-year follow-up of the ACS cohort.

2. Have the appropriate sensitivity analyses been included in the proposed methodology? If not, which additional sensitivity analyses should be included, and should any of the proposed sensitivity analyses be dropped?
Yes, the outline provided on planned sensitivity analyses describes a reasonable approach.

3. The draft methodology report describes the planned approach to adjusting air quality to simulate just meeting alternative $PM_{2.5}$ air quality standards. Is this approach reasonable? Are there other approaches that should be considered?
Yes, this approach is quite reasonable, and I have no other approaches to suggest.

4. Have the appropriate health effect studies and concentration-response functions been identified for use in the planned $PM_{2.5}$ risk analyses? If not, which additional studies and/or concentration-response functions should be considered? Are there any studies and/or concentration-response functions that should be dropped from the planned analyses?

Yes, appropriate selections have been made. As noted in response to charge Question #1, the concentration-response function for lung cancer from Pope et al. (2002) should also be included and used in a risk analysis. Consideration should also be given to the inclusion of the risks associated with $PM_{2.5}$ reported for the Childrens Health Study in 12 Southern California communities.

5. Is the draft report clear and transparent in its description of the proposed approach? Are the various assumptions and judgments that must be made in carrying out the planned risk analyses clear and transparent?

Yes, the report was quite clear and transparent in its description of the various assumptions and judgements made.

In summary, the Abt Associates report was very well done, and represents a maturation of specialized field of risk analysis for air pollution health effects.

Dr. Mauderly

General Comments

For the most part, the approach seems reasonable. However, it seems both a mistake and misleading to avoid including PM_{10} in the risk analysis. We know more about PM_{10} than the other fractions, and the total health burden of the other fractions must be contained within the burden from PM_{10}. It seems like that would be the place to start a thorough assessment of PM-related health risks.

Specific Comments

P 3, para 3: Given that the purpose of the document is to lay out an approach for quantitating concentration-response relationships, it stretches credibility to imply that quantitation of risks is not a central purpose, and that quantitative risks will not play a significant role in recommending standards (and defending them).

P 3, footnote: It is not reasonable that assessment of risks for PM_{10} will not be a part of the strategy. We still have more information, and increasingly detailed information (e.g., NMMAPS), on associations between health and PM_{10} than we do for all other PM indicators combined. PM_{10} should be included in the assessment. This is especially important if you are going to propose a standard for PM_{coarse} ($PM_{10-2.5}$). Data on $PM_{10-2.5}$ vs. health are scarce. Presumably, information on PM_{10} would provide a background for estimating the health burden from both the fine and coarse fractions. Because both are contained within PM_{10}, the sum of the health burdens of PM fine and coarse must be contained within the health burden of PM_{10}. Of course, the specific toxicity of either fraction (but not both) could be greater than that of PM_{10}, but the estimated risks and health burden from PM_{10} would provide some context for consideration of the other fractions.

P 16, footnote: Gosh – I wish you'd define "heteroskedasticity" so I won't have to look it up. I want to use that one at cocktail parties!

P 29, para 2: I am not very comfortable with dropping monitors that might yield higher than average concentrations. People might not live there, but they work there, shop there, and drive through there. Besides, it's been argued for years that PM_{fine} concentrations at monitors are broadly representative because of dispersal. Of course, tossing out the higher values will give you an apparently greater concentration-specific PM effect, if the effect is really due to a combination of the higher and lower exposures. The rationale for tossing the higher monitors is not convincing.

P 30, para 2: This paragraph indicates that no generalization will be made to national PM-related health burden, and that national-level "body counts" will not be invoked in setting or defending the standard. Again, that stretches credibility.

P 31, Exhibit 3.1: A serious weakness of the proposed strategy is the use of different cities for mortality and morbidity estimates. The rest of the document repeatedly notes that PM composition, exposures, populations, and therefore likely risks probably vary among locations. The proposed strategy purposefully looks at different kinds of morbidity in different cities, and at morbidity in one city (Seattle) for which mortality data are not to be used. It is recognized that morbidity data are not as broadly available as mortality data. Regardless, a strong effort should be made to compare the different types of morbidity data in the same cities, and in cities for which there are mortality data. This should be done even if forces the use of data that are a bit weaker than those from another city. At least you would be comparing "apples to apples".

P 52, para 2: Does this mean that "admissions" data (which you say are really discharge data) do not include people entering the hospital and dying there? Considering the evidence and emphasis on mortality, why wouldn't those entering the hospital and dying there also comprise an important part of the population affected by morbidity (arguably the most important part)? If they are excluded, the morbidity data are skewed by under-reporting of both the numbers affected and those who are most seriously affected.

P 53, para 4: Instead of using an annual average baseline incidence rate (i.e., annual divided by 365), couldn't you at least use quarterly rates? It seems unlikely that the incidence rate would be identical year-round.

Dr. McClellan

I am pleased to offer the following comments to augment my input to the CASAC Particulate Matter (PM)Panel review of the EPA's Proposed Methodology for Particulate Matter Risk Analyses For Selected Areas held on February 27, 2002.

As a point of departure I wish to emphasis that I view this document and the analyses to be performed as an exceptionally important bridge between the science reported in the PM Criteria Document and the more policy relevant PM Staff Position Paper. These analyses are critical to helping assess how the science on PM can inform decisions on the four key elements of the National Ambient Air Quality Standard for PM, namely, the indicator, the averaging time, the numerical level, and the statistical form.

Because of the importance of the document I am baffled as to why the document is not authored by EPA staff but rather by contractor personnel with some apparent EPA ghost writing. I would have strongly preferred that a document of this type impacting very directly on policy decisions be authored by EPA staff. If this had been done it would have been much easier to document the linkage between the risk analyses being performed, the Staff Paper(SP), and the ultimate decisions to be made by EPA on the PM NAAQS. In the absence of clear documentation the public is left in the dark as to how EPA will make science-based decisions on the PM NAAQS and especially the core decision of "how low is low enough?" to provide an adequate margin of safety.

Despite the critical shortcoming noted the document and, most importantly, the proposed methodology it is improved relative to the earlier version. Unfortunately, the document and methodology is still not adequate for performing the analyses essential to setting a science-based NAAQS for PM. IN the following text I will relate the deficiencies of greatest concern.

An over arching deficiency in the document and plan is the failure to clearly distinguish between uncertainty and variability. The authors and EPA are urged to review the discussion of

this issue contained in the National Academy of Science/National Research Council report--Science and Judgement in Risk Assessment. In the present document many times matters of variability are erroneously presented as uncertainty. The document and the methodology it is describing must clearly distinguish between uncertainty and variability and then do a better job of addressing both matters.

The issue of variability is of special concern with regard to regional variability. The document and methodology is improved by including more cities in the current version. However, it still falls short. More cities must be included to help understand the range of variability in PM related health effects across the United States, which appear to range from clearly substantial impact in some areas to no impacts in other areas. By failing to adequately cover the United States the document leaves the impression that the authors and EPA are only interested in documenting health effects rather than providing a complete and balanced exposition. One approach to illustrating the high degree of variability for cities is to include in the analyses all the cities include in the analyses performed on PM10 by the Johns Hopkins team.

Another area that needs to be more adequately analyzed with regard to both variability and uncertainty is the matter of indicator. It is imperative that the document provide balanced analyses of PM10, PM10-2.5 and PM2.5. The excessive attention to PM2.5 leads some to conclude that EPA is only interested in analyses that will support some pre-determined decision as to the details of the PM NAAQS. Indeed, rigorous analyses based on today's science might lead to the conclusion that a PM10 indicator might provide equal or even better protection of public health than a PM2.5 indicator for many regions of the USA or even the entire USA. Of course, it is not possible to know this if the analyses of multiple indicators are not performed.

The document and methodology will also be improved by directing more attention to analyses that will inform decisions on the numerical level, averaging time and statistical form of the NAAQS's for PM. The issue of the statistical form of the NAAQS tends to be left to the end of the process and does not get the attention it deserves. One way to correct this deficiency is to make it less of a black box decision by performing the analyses now that will provide science based results that will stimulate discussion of these critical matters.

And finally, I want to comment on the issue of the extent to which the document and methodology are quantitative or qualitative. The EPA staff appear to be concerned with showing their hand as to how the results of the analyses will be used. Obviously, if the results are not going to be used then the work should not be done. Clearly, the analyses are going to be quantitative. It is hard to argue otherwise in view of all the planned number crunching.

Perhaps what EPA is trying to relate is that the risk analyses results will be used to inform decisions on the PM NAAQS but the analyses are not the only input, hence, the use is qualitative. One solution to this dilemma is for EPA to more clearly articulate how it plans to establish the four key elements of the NAAQS: the indicator, the averaging time, the numerical level, and the statistical form.

I argue that public interest would be best served by debating the approaches to how to set the NAAQS now rather than after the NAAQS for PM is set and the debate about approaches is complicated by the results on the table. Consideration of the risk analysis document and the under laying methodology is very difficult in the absence of EPA having laid out for the public how it intends to make critical decisions on the setting of the PM NAAQS.

Dr. Oberdörster

I have just a few comments following yesterday's conference call on the PM risk analysis document. Before the teleconference, I had questions/comments in three areas, all of which were addressed during the meeting:

One is the issue of lag effects of PM since results of the Epi group of our PM Center specifically points to such effects for cardiac responses of certain particles. However, data on lag effects in general are probably too limited at this point.

The other is to consider long-term effects with the endpoint cancer, and I was very interested in Mort's announcement of the pending publication which will be quite useful.

Thirdly, the issue of background or baseline PM with consideration of anthropogenic versus natural PM contributions. This requires knowledge about PM chemistry. Increases of specific PM constituents relative to existing background levels will carry different risks, and risk estimates for PMx reflect always an integration over very diverse particles. This makes C-R relationships very complex and, depending on compositions, different for different locations (as if a toxicologist would attempt to average effects of many particles ranging from highly cytotoxic crystalline SiO2 to benign TiO2). I think a future need for PM risk analysis is to identify mechanisms of effects, for which PM compositional data are one requirement. That will allow a mechanism-based risk analysis as a goal for the future. I don't have additional comments on the document.

Dr. Rowe

Below are comments on the proposed EPA PM Risk Assessment, as outline in the methodology report of January, 2002 and discussed at our teleconference earlier today. I am in agreement with most all of the resolutions of the conference call today, which largely covered my comments on the methodology.

1. *The overall approach is appropriate, subject to revisions and clarifications as suggested by the panel*. I concur with the key recommendations to retain the PM_{10} component of the analysis, to do more to try to measure all included health endpoints for each selected location, to revise the basis for selecting lags for coefficients, and to better address some of the assumptions outlined in the methodology (e.g., assuming uniform HA/ERV ratios). The recommendation to include even more cities seems to me to be nice but a lower priority.

2. *Appropriate sensitivity analyses are included*, but others need to be included, as identified by the panel on the teleconference.

3. *The approach to simulating air quality meeting current $PM_{2.5}$ (using linear rollback) is reasonably*, but not by it self sufficient. The report was vague on alternatives, and not necessarily tied to reality. I believe attention should be given to evaluating reality based "seasonal" rollbacks (or peak shaving) for locations where that appears merited in terms of the peak episodes routinely occurring in a specific season and where seasonal shaving could occur via episodic or seasonal controls (recognizing this will require attention to seasonal C-R coefficients and seasonal baselines for health events).

4. Generally, *the appropriate health effects studies and C-R relationships have been identified for use in the analyses*.

5. *The report is generally clear and transparent*. However, more documentation is particularly required in terms of the decision rules for including PM metrics, cities, and C-R relationships. Some key assumptions need are missing and can be directly stated (e.g., assumed causality, lack of detail on constituents resulting in an assumption of constant toxicity, and uncertainty about the most relevant exact dose metric (hourly, annual, $PM_{2.5}$).

Additional comments and questions not covered in the meeting follow:

Page 10 discussed the AIRS data and the proposal to use either 2000 data (where it exists) or 1999 data (where 2000 data does not exist). I am curious why EPA would not use both 1999 and 2000 data where both exist for a city, at least for the health endpoints relating to annual average values (and reflecting the long-term standard is based on a 3 year average).

The characterization that EPA will not rely on the quantitative results seems misleading (page 1, and EPA cover memos), and undercuts the motivation for the study. Clearly the risk assessment is used as a quantitative input for consideration to Staff Paper insights (even the FR text referenced on page 1 discussed order of magnitude events caused by air pollution). It may be more appropriate to communicate that EPA does not use the risk assessment to generate specific definitive quantification of the number of health impacts in a location or nationally, but does use the results as "an indicator" (rather than "rough sense") of the magnitude of events, and to understand the potential significance of alternative specifications of components of the standard (level, statistical form, averaging time).

Minor editorial comments:

The title should be "Proposed Methodology for ... **Human Health** Risk Analyses..." After the introductory paragraph of the report, the "human health" text can be dropped.

Page 29, be clear that the Monte Carlo analysis is used to accumulate quantified elements of the uncertainty.

In Appendix C, an event-days metric value of 9 is used to select mortality studies, even though some studies are just below 9. No such discussion occurs for morbidity endpoints (where many studies are selected with values less than 9). The 9 cut-off seems particularly arbitrary.

Future results will likely be presented as absolute numbers of events. However, given the differing sizes of the locations to be studies, it may be useful to also report numbers across locations on a consistent metric, such as x/100,000 people.

Comments on January 2002 Draft Report "Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas"

Dr. Taylor

This correspondence follows the telephone conference earlier today on the "*Proposed Methodology for Particulate Matter Risk Analysis for Selected Urban Areas"*. The correspondence enumerates the concerns that I have relative to the document.

The specific issues are as follows:

1. ***Risk Analysis versus Risk Assessment***. There is some confusion on this issue. The ecological community uses the term "risk assessment" in a very specific and formal way.

Conversely, there is no conventional use of the term "risk analysis". I assume the Agency used the term "analysis" for a reason so there was no misunderstanding that a formal assessment was being proposed. Assuming my assumptions are correct, I would recommend that the Agency make this point clear. In my judgment, a great deal of the committee's comments today was assuming that a more formal assessment was in progress. (Charge No 1)

2. ***Primary versus Secondary Standard***. The document presents the argument that the proposed methodology is in support of the NAAQS for particulate matter (PM). The charge document to the committee from the SAB alludes to the NAAQS but does not specifically state that the focus is solely the primary standard. There is no intent by the Agency to address the secondary standard in this document (and I concur with that), but my request is that the document states this boundary condition.

My rationale for requesting this is straightforward. There are many secondary standard issues that are appropriate for consideration with respect to PM, and these are addressed in the CD (e.g., visibility, biogeochemistry in terrestrial and aquatic landscapes of PM-deposited contaminants). None of these issues are addressed in this methodology, and appropriately so. However, it should be stated that the methodology focuses exclusively on the NAAQS primary standard.

At the CASAC meeting last summer I was approach by OAQPS staff who stated their intent to nest secondary standard issues in a subservient manner to the primary standard, operating under the assumption that any air quality improvement due to the primary standard would benefit ecology, natural resources and visibility. I would disagree with that position as a blanket condition; it also is at odds with the CAA. My more obvious concern is that this could establish a precedent for all air quality standards so the importance of secondary standard would be even further eroded.

My recommendation is simple: clearly state that the proposed methodology addresses solely the primary standard. (Charge No. 1)

3. ***Southern States***. On my list of concerns but voice ardently by others is the omission of Southern States from the list of cities to be analyzed. I would recommend that the Agency re-address the issue of the Southern region. If the criteria for selection are sufficient to justify the inclusion, that would suffice. But that argument has not been made. (Charge No. 5)

4. ***Rural Areas***. My perspective is ecology so I may be uninformed, but it struck me as odd from a sample perspective that areas without a marked urban signature were not part of the methodology. The rationale for their inclusion would be the absence of a marked urban signature in air quality, loss of some difficult confounding factors, introduction of some new confounding factors, elevation of the importance of geochemical background factors in PM, and the inclusion of an unrecognized group of the population (rural). The sampling protocol would be more difficult for sure, but the omission seemed to be an obvious one. There may be a simple answer to this but there was never any mention of whether rural areas were ever considered. (Charge No. 5)

5. ***Scaling Up and Aggregation***. This section is missing from the document. I would prefer to see clearly in one place how the Agency plans to scale the results to represent the cities as whole or aggregate results by region (e.g., West versus East). While I suspect the Agency is not intending to do that in a formal sense, it is likely that this will happen anyway. (Charge No. 5).

The opportunity to participate in the review process is appreciated.

Dr. Vedal

The following is organized by section. I have identified the "charge" to which comments are relevant when possible. Otherwise, the comments refer to the section only without obvious relevance to any of the charges.

2.2
1. Is background PM really that low? Yes, for PM2.5, but there must be seasonal variability that complicates the rollback procedures proposed.

2.3
1. [Charge 1 & 4] No southern city was included. What about Texas? Why San Jose? This raises a much larger issue which is the likely biased picture we get by just including only cities that were included in published health studies and had PM2.5 data. NMMAPS has taught us that not only is there regional heterogeneity in the response to PM, but that likely the published studies as a whole reflect a publication bias. The resultant risk analysis is therefore also likely to be biased, or at least not reflective of the heterogeneity that is likely also present for PM2.5.

2.4
1. [Charge 2 & 3] What about also including a "shaving" rollback approach as a sensitivity analysis? p. 15-16. Add to analysis 2 in exhibit 2.5 (p.25)

2.5
1. [Charge 2] Some argue that looking at only one day of pollution (vs. say a composite of lags) underestimates the effect of PM (p.17). OK, p.18. Sensitivity? Yes, p.25 (exhibit 2.5, analysis 4)
2. [Charge 5] Notation (p.16,17): isn't it more standard to use x_0 and y_0 as baseline?
3. [Charge 5] Motivate use of lowest level observed in any study as the lower PM (p.18 & exhibit 2.2) What is the purpose of using it? OK, not counting effects below data used to estimate it, since there may be a threshold there (p.44, 2nd row).
4. [Charge 5] Given the notation, why is x_0 lower than x (background)? p.19

2.6
1. Point about short-term mortality being included in long-term is interesting. Maybe not, since short-term estimates of effect do not depend on long-term level. That is, same short term effects at low concentrations as at high. p.20

2.8
1. What about a Bayesian approach to uncertainty, if such a thing is realistic here?

3 .2.1
1. [Charge 1 & 4] natural log of 9.0, therefore 8103 total deaths over time. Why not use a rate, i.e., #/day and a given period of follow up, since the proposed could include a long series with few daily deaths?
2. [Charge 2] Concentration-response functions for the "long-term" mortality studies have been shown to differ by level of education (Krewski reanalysis of ACP data) (bottom p.29 & exhibit C.4). The distribution of educational levels in the cities studied will then affect which function to use. Also, accounting for population mobility (measured ecologically) affected the estimates. Which model of Krewski's was selected? A sensitivity analysis is appropriate here as well.

3. Interesting statement about not using risk estimates as principal basis for recommending standards (p.30). What is the alternative at this time?
4. For respiratory symptoms, do we have any data on regional heterogeneity in estimates of effect? p.30

4.3
1. Would not use the distributed lag model resulting in the largest RR. Should be based on what the best model is. p.33

5.1
1. Fixed ratio of hospitalizations to ER visits is probably an untenable assumption (p.37)
2. Why are there no mortality rates for locations by type of mortality? p.38 (exhibit 5.2), etc.

6.1.1
1. Multi-pollutant issue: in NMMAPS, confounding was not addressed at city level, and not with seasonal stratification (important for ozone) p.47 Therefore not comparable to approaches used in other individual city studies.

Dr. W. White

I generally accept the proposed assessment as a useful exercise. My main suggestion would be to emphasize more clearly the much greater order of uncertainty that is introduced when the short-term (24h) standard is considered.

A rationale should be offered for the decision to base the rollback percentage on the above-"background" portion of the "as-is" concentration distribution. The "background" portion of the "as-is" distribution is unknown, and is almost certainly poorly approximated by the assumption of a constant level equal to the annual average. The annual average "background" is so small relative to some of the probable individual-day values that the assessment results will be quite insensitive to the estimate of the annual average "background". Given this, and given the difficulty of estimating individual-day "backgrounds", I would rather see the rollback calculated from total observed concentrations. The fact that EPA can't actually roll back all natural emissions would then just be another consideration to be dealt with under the heading of implementation, along with such other facts as that rolling back coal-fired power plants and diesel motor vehicles would have different impacts on the distribution of individual-day concentrations.

A minor comment on page B-5: The slopes of regression lines such as those in exhibits B2 and B3 will ALWAYS be statistically significant, regardless of the nature of the change in concentration distribution. By its very nature, a decile-decile (or percentile-percentile) plot will ALWAYS show a monotonic relationship, which will always look fairly good statistically. This finding therefore offers no positive evidence to support a conclusion (middle of page) that "the change in PM2.5 concentrations ... is consistent with a proportional rollback model."

Dr. Wolff

1. The authors should be explicit in stating the assumptions and caveats necessary to perform a risk assessment. They should explain that epidemiology studies do not and cannot, by themselves, demonstrate a cause and effect relationship. However, for the purposes of this exercise, it is assumed that the statistical relationships indicate cause and effect relationships. Furthermore, it should be stated that it is also assumed that all ambient fine particle mass is equally toxic regardless of chemical composition or size in a given city.

2. Statistical association does not prove causation" is the first statement in exhibit 6.1 on page 43 of the draft. The fact is that $PM_{2.5}$ has not been demonstrated to be the cause of mortality and other health effects reported in the myriad of recent epidemiology studies at present U.S. ambient concentrations. Thus, there is a chance that the cause of the effects is something other than $PM_{2.5}$ mass. Consequently, any risk assessment of the effects of $PM_{2.5}$ must include zero in the range.

3. For the C-R functions that are not statistically significant, the lower risk estimate should be the value of the 95^{th} percentile limit.

4. For cities with multiple studies, all of the results should be used.

5. Results from single pollutant and multiple pollutant studies should be used where available.

6. Background is not a constant. It is affected by meteorology and has a distribution, which will vary, from city to city. Sensitivity runs should be performed with various distributions for background.

7. All of the above comments also apply to $PM_{10-2.5}$ as well.

8. Page 47, lines 5 – 9 – NMMAPS cannot be used as the definitive word that PM is not confounded by gases because NMMAPS did not treat PM and gases equally and they used 24-hour averaged ozone which is inappropriate.

9. Why are the EPRI Veterans Study and the AHSMOG study not included in Exhibit C.4? For balance, these studies need to be included, as they show no statistically significant effects.

10. The C-R functions derived from Krewski et. al. (2000) should also include the multi-pollutant relationships.

Dr. Zielinska

1. In my opinion there is a missing link between ambient $PM_{2.5}$ concentrations and the health effect endpoints, namely the exposure estimation. We do not spend 24 hr per day outdoors and an exposure model that includes some activity pattern would be more realistic. Besides, the indoor PM has different sources (especially during the time when air exchange rates are low, due to the heating or air conditioning usage) and may have different composition than outdoor PM.
2. I'm concerned with the estimation of background $PM_{2.5}$ concentrations. As stated on page 10 of the report, the authors propose to use 2.5 $\mu g/m^3$ in the Western and 3.5 $\mu g/m^3$ in the Eastern U.S. as a background $PM_{2.5}$. If the background PM includes PM from natural sources and transport from outside of North America, it may vary seasonally and regionally. For example, the atmospheric transformation of biogenic emissions will be more important in summer than in winter, and will depend on a geographical location. It has been estimated (Griffin et al., 1999) that between 13 and 24 TgC yr^{-1} of secondary biogenic organic aerosol is produced each year from terpenes and other biogenics. These secondary organic aerosols contribute to the fine particle mass.
3. Similarly, the city-specific baseline health effect incidence rates depend on the season of the year.

4. I understand that in order to be consistent with the approach used in the epidemiological studies, the average daily $PM_{2.5}$ concentrations are used, but if the hourly $PM_{2.5}$ data are available, why not to use them?
5. I think that if the risk analysis is performed for $PM_{2.5}$, it should also be done for PM_{10} and possibly for $PM_{10-2.5}$. This may provide some reality check.
6. Section 4.3, page 33-34. If the only reason for the use of a particular model is that it produces the greatest relative risk, this is not a legitimate reason.
7. Section 6 of the document discusses sources of uncertainty, but it is not clear to me how these uncertainties will be reflected in the proposed methodology. Will the final risk estimate for a given area include these uncertainties in some numerical way?

References:

Griffin Dr. J.; Cocker, D.R.; Sienfeld, J.H.; Estimated of Global Atmospheric Organic Aerosol from Oxidation of Biogenic Hydrocarbons, *Geophys. Res. Let*, 26, 2721-2724, 1999.