August 31, 1995

EPA-SAB-CASAC-LTR-95-005

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Re: Clean Air Scientific Advisory Committee (CASAC) Comments on the April 1995 draft *Air Quality Criteria for Particulate Matter*.

Dear Ms. Browner:

The Particulate Matter Criteria Document Review Panel of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) reviewed the document entitled *Air Quality Criteria for Particulate Matter* (PM) at a meeting on August 3 and 4, 1995. At that meeting and in subsequent written comments, the Panel made numerous recommendations for improving the document, and they have been forwarded to your staff. This report includes input from the Particulate Matter Criteria Document Review Panel and has been approved by the Clean Air Scientific Advisory Committee.

The Panel was impressed with the breadth and scope of the Criteria Document (CD) especially given the extremely tight schedule imposed upon the Agency. The CD is a comprehensive review of the PM literature. However, many of the CASAC panel members expressed concerns that the Agency does not have sufficient time to make the changes necessary for the document to serve as a basis for regulatory decisions. Because the CD requires such extensive revisions, the Panel recommends that it be given the opportunity to review the revised draft. In reviews of previous Criteria Documents, CASAC had the opportunity to review the second, and in some cases the third draft. This was done to yield a CD that was of sufficient scientific quality for regulatory decision-making and one the CASAC could reach closure on.

I will summarize the principal concerns expressed by Panel members. It should be pointed out that not all of these concerns were expressed by all the Panel members. However, in order for the Panel to reach consensus on closure on the CD, EPA needs to

address these concerns. In general, the concerns were expressed by multiple Panel members who, because of their specific expertise, were assigned to review the chapters on which they commented.

Many Panel members expressed the view that the CD has not adequately demonstrated several important linkages that are crucial in relating PM to mortality and/or morbidity. The first example occurs in Chapter 7 where the Agency attempts to establish a link between personal exposure (PE - the exposure one would measure with a personal PM monitor) and the exposure estimated from a fixed-site monitor located at some central monitoring (CM) site. This is a key issue because all of the epidemiological studies linking PM to mortality/morbidity use data from CM sites. In Chapter 7, fourteen studies are cited which show no relationship or a poor relationship between PE and exposures estimated from a CM for both PM_{10} and $PM_{2.5}$. One other study shows an excellent correlation between particulate sulfate PE and outdoor concentrations which the Agency embraces. One positive result out of 15 studies is not a strong case for the relationship.

Second, the linkages between the animal studies and the human clinical studies presented in Chapters 10 and 11 to the epidemiological results in Chapter 12 are not established. In fact, almost nothing from the encyclopedic Chapters 10 and 11 is cited in Chapter 13, the integrated health effects synthesis chapter, or Chapter 1, the Executive Summary. The focus of Chapter 13 should be to take the exposure analysis, dosimetry, toxicology, and epidemiology and integrate them into a comprehensive review. Chapter 13 does contain a discussion about the "coherence" of results among the excess daily mortality and excess daily hospital admissions for respiratory disease. However, this needs to be broadened to identify coherence among the different types of epidemiological studies, as well as among the toxicological and controlled human studies.

Third, a number of the Panel members indicated that the confounding influences due to stressful meteorological conditions on mortality/morbidity may not have been completely removed in any of the epidemiological studies and that this could inflate the mortality/morbidity ascribed to pollution. This is pointed out in the CD on pages 12-32 to 12-36 and in the appendix for chapter 12. However, it is ignored in the discussions of the results of the PM-mortality/morbidity studies. Although it is unlikely that all of the excess mortality/morbidity would be ascribed to adverse meteorological conditions, it would be

advantageous if a reanalysis was performed which removed the meteorological influences using methodologies similar to those recommended in the appendix.

The fourth and, perhaps the most important link that has not been adequately discussed and is not established, is the link between mortality/morbidity and a specific component of air pollution. Although the studies show a consistent statistical association between some measure of PM and mortality/morbidity, it does not necessarily follow that PM is the responsible agent. In fact, the inclusion of additional air pollutants (i.e., O_3, SO_2, NO_2, or CO) usually results in the additional pollutant(s) accounting for some of the excess mortality/morbidity. The recent reanalyses of the Philadelphia data set by the Health Effects Institute (HEI) and Dr. Lester Lave presented at the CASAC meeting underscores this point. The HEI report concludes: "However, the findings do not clearly indicate that the increased mortality associated with increasing indexes of air pollution can be assigned to either TSP or SO_2 alone." Some individuals have proposed that the PM is an indicator of air pollution and is not necessarily the causative agent. Others have proposed that the causative agent is some specific component of the PM. For example, some argue that the acid sulfate component of the PM is the causative agent. The CD considers this possibility as well, but also considers a variety of other causative agents including $PM_{2.5}$ and ultrafine PM (PM with diameters less than about 0.1 μm), and arguments are made for each. Unfortunately, there are only a limited number of data sets that include measurements of $PM_{2.5}$ or ultrafine PM. Indeed, the number of data sets with PM_{10} is not large. Consequently, we have a dilemma in not being able to definitively identify the possible causative agent(s), and hence, not being able to identify the air pollution component(s) that needs to be reduced in order to reduce mortality/morbidity. Depending on the choice of a risk management strategy, this dilemma may also exist if we accept the hypothesis that PM is an indicator of overall pollution. It appears that EPA is leaning towards $PM_{2.5}$ as the constituent that needs to be addressed. However, the scientific basis for this has not been established in the CD or reflected in Chapter 13.

Fifth, the CD does not establish a link between evidence on the biological mechanisms and the reported epidemiological findings. The epidemiological studies, by themselves, do not provide this knowledge, which some consider essential to establish a cause and effect. Only an intervention study or an experimental exposure study can demonstrate cause and effect. The Agency needs to more adequately explore in the CD mechanisms

of action as a basis for biological or clinical plausibility. The results of this exploration need to be emphasized in the introduction and conclusion of the Executive Summary and in Chapters 10, 11, 12 and 13.

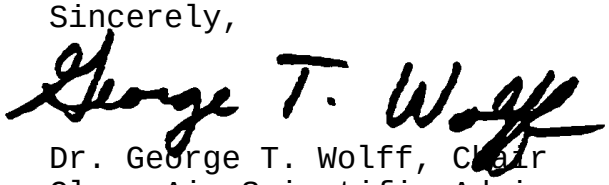
A number of the Panel members noted the absence of a sixth link, namely the rationale for using a 24-hour averaging time for the NAAQS (National Ambient Air Quality Standard). The justification for using any specific averaging time, including a 24-hour averaging time, is not established

A number of Panel members also noted a deficiency in the CD in that it did not include a discussion of biological aerosols in either the indoor or outdoor environments. These would include potential allergens like pollens, spores, molds, mites etc. If these agents are to be excluded, the rationale for their exclusion needs to be developed and stated.

In summary, a case can be made for concern for health effects associated with particulate matter. However, information presented in the CD does not provide a basis to select the agent or agents which need to be regulated nor does it provide a basis for predicting the health benefits of any control strategies. The Panel urges that sufficient time be given to allow EPA staff to make the necessary changes in the CD so that the CASAC can come to closure on a document of acceptable scientific quality for regulatory decision-making.

The Panel would welcome the opportunity to review another version of the CD, and looks forward to reviewing the Staff Position Paper on Particulate Matter. However, in closing, it should be noted that it would be difficult to create an acceptable Staff Position Paper absent a fully satisfactory Criteria Document on Particulate Matter.

Sincerely,



Dr. George T. Wolff, Chair
Clean Air Scientific Advisory Committee

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