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

January 5, 1996

EPA-SAB-CASAC-LTR-96-003

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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 November, 1995 Drafts of the *Air Quality Criteria for Particulate Matter* and the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (OAQPS Staff Paper)

Dear Ms. Browner:

A Panel of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) reviewed a draft of the document entitled *Air Quality Criteria for Particulate Matter* (PM) at a meeting in Research Triangle Park, NC on August 3 and 4, 1995. At that meeting and in subsequent written comments that were provided to EPA staff, the Panel made numerous recommendations for improving the document. On December 14 and 15, 1995, the Panel met in Chapel Hill, NC to review a revised draft of the *Air Quality Criteria for Particulate Matter* and a first draft of the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Office of Air Quality Planning and Standards - OAQPS - Staff Paper).

The Panel was impressed with the breadth and scope of the Criteria Document, especially given the extremely tight schedule imposed upon the Agency by the Court. The Panel believes that it is an extensive review of the PM literature. Although the Panel members' comments reflect their satisfaction with the improvements made in the scientific quality and scope of the Criteria Document since our first review in August, the Panel Members provided additional extensive comments to your staff at the December meeting and subsequently in writing. The most serious concerns were directed towards Chapter 13, the integrative health assessment chapter. Unfortunately, the chapter reviewed in December still only summarizes the information from the earlier chapters and does not integrate it into a cohesive assessment. The net result of these deficiencies in Chapter 13 is that Chapter 1, the Executive Summary, is also flawed. Because of these and a number of other problems that the Panel had with the Criteria Document during the second review (these will be described below), it was the consensus of the Panel that the document does not provide an adequate review of the available scientific data and relevant studies of PM Further, many members of the Panel felt strongly that scientific quality, as

intended by Congress in creating CASAC and mandating its role as a review and advisory body, not a court-imposed timetable, should be the determining factor for reaching closure on the Criteria Document. Consequently, the Panel did not come to complete closure on the Criteria Document, and recommends that the Agency brings a redrafted version of the Criteria Document to CASAC for consideration as soon as is practical.

The Panel was also impressed with the first draft of the Staff Paper. Some felt it was the best first draft of any Staff Paper that CASAC has reviewed. However, the Panel could not come to closure on the Staff Paper for reasons that will be articulated below. Some members raised issue with the process of the preparation of the Staff Paper. Because the Criteria Document had not been revised to meet the scientific standards of CASAC, the Staff Paper could not draw upon the consensus advice of CASAC as intended by Congress in the Clean Air Act. Although the Agency made an admirable effort in producing the Staff Paper under a tight timetable, the current draft does not provide an adequately articulated scientific basis for making regulatory decisions concerning a PM National Ambient Air Quality Standard (NAAQS).

Many of the Panel's comments apply to both the Criteria Document and the Staff Paper. The objectives of Chapter 13 of the Criteria Document should be to integrate the health effects and exposure information from the earlier chapters and synthesize the material that will form the scientific basis for the recommendations made in the Staff Paper. The objectives of the Staff Paper should be to build on the information presented in the Criteria Document integrating the scientific information on PM and drawing out the policy implications for setting a PM National Ambient Air Quality Standard. The majority of the Panel members who were assigned to address the health effects aspects of the two documents felt the Agency fell short of achieving these objectives. Besides this insufficient integration, Panel members raised a number of serious concerns which are discussed below.

First, many Panel members felt that, as presented, the case for a $PM_{2.5}$ standard was not compelling. The arguments made in the Staff Paper implicating $PM_{2.5}$ as the best available surrogate measure for the causative agent are based principally on epidemiological studies, and while the epidemiological evidence is reasonably consistent and convergent across mortality and morbidity endpoints, it is not unambiguous. The risk factors being reported are not large and they have relatively large uncertainties. In studies where multiple pollutants have been considered, some implicate a measure of PM as the most important, while others implicate a different pollutant. Different models using the same data implicate different pollutants, and some do not implicate any pollutants. These results are not unexpected given the degree of correlation among the various pollutants and the necessarily observational nature of the data. Nevertheless, it is not possible to single out $PM_{2.5}$ as the best surrogate.

More fundamentally, the Agency does not adequately justify the selection of $PM_{2.5}$ as the best surrogate measure for the causative agent. Most of the epidemiological studies did not use $PM_{2.5}$ as a measure. Most used PM_{10} or total suspended particulates (TSP), which are only roughly correlated with $PM_{2.5}$, and therefore, do not allow one to conclude that $PM_{2.5}$ is the causative agent or indeed that any specific component of the PM_{10} is the causative agent. Some

studies used sulfate, which is usually a significant chemical constituent of the $PM_{2.5}$. A number of studies used British Smoke, coefficient of haze (COH), or other filter reflectance measurements which are measures of the amount of black elemental carbon in the air and not a measure of $PM_{2.5}$. Still others used ambient visibility, an indicator of the accumulation mode within $PM_{2.5}$. It is sometimes unclear from the Staff Paper which of the studies in fact actually measured $PM_{2.5}$ and which of the studies estimated $PM_{2.5}$ from other measures of particulate air pollution.

It should also be pointed out that the Staff Paper downplays the diversity of results, and instead emphasizes those results where PM, and especially $PM_{2.5}$, provide the strongest signal. Unfortunately, the one acute epidemiological study (Schwartz, Dockery and Neas) to which the Agency gives the most credibility is not in the peer-reviewed literature. A revised Staff Paper should adequately discuss the recent reanalyses presented by the Health Effects Institute (HEI) and others which conclude that a single causative agent cannot be identified in the limited number of studies that have been reanalyzed. Based on the above, some Panel members are not confident that a reduction in ambient $PM_{2.5}$ will produce a decline in daily mortality or morbidity. On the other hand, some other Panel members, looking at the cumulative epidemiological evidence, believe that reducing ambient $PM_{2.5}$ will decrease acute and chronic mortality and morbidity.

In contrast to the Criteria Document, the Staff Paper fails to acknowledge the lack of direct biological or clinical evidence supporting a causal relationship for the epidemiological findings that implicate PM. Furthermore, focusing on $PM_{2.5}$ ignores the extensive clinical evidence that asthmatics can respond to particles larger than 2.5μm in diameter. The Staff Paper needs to make a case that retention of an annual PM_{10} NAAQS can provide sufficient protection from these larger particles within the thoracic fraction of ambient PM.

As a result of this major, and perhaps, premature focus on $PM_{2.5}$, the Staff Paper failed to critically review the available data as a basis for either reaffirming or revising the PM_{10} standards. EPA should correct this deficiency in a revised Staff Paper and not just direct primary attention to a $PM_{2.5}$ standard. Furthermore, some members felt that the selection of a 2.5 μm cutpoint was arbitrary, and that the Agency should consider other cutpoints (i.e., 1.0 μm) as well.

The issue of premature mortality displacement of individuals who are already seriously ill (harvesting) needs to be more fully discussed. This is a critical issue. It is of paramount importance to know whether some, most, or all of the deaths are advanced by only one or several days due to harvesting. Unfortunately, the discussions in the Staff Paper are inconclusive and highly speculative. These discussions need to be revised and expanded.

As with ozone, there appears to be no apparent threshold for biological responses to PM exposures. In the ozone Staff Paper for which CASAC recently sent you its closure letter on the primary standard portion (EPA-SAB-CASAC-LTR-95-002, November 30, 1995), quantitative risk assessments based on methodologies that had undergone extensive CASAC review showed the relative public health benefits provided by the various alternative standards. The PM Criteria

Document and Staff Paper contain no quantitative risk assessments which allow one to judge the benefits of having an annual $PM_{2.5}$ standard between 15 $\mu g/m^3$ and 30 $\mu g/m^3$ or a 24-hr standard between 25 $\mu g/m^3$ and 85 $\mu g/m^3$. The Staff Paper should provide more detailed justification for the quantitative ranges proposed for the $PM_{2.5}$ standards, especially since there may be no threshold for biological responses to PM exposures. There should also be tables showing the expected reductions in mortality and morbidity that would occur if the present PM_{10} standards were revised to include $PM_{2.5}$ standards within the proposed ranges. It would be helpful if these tables were broken down by geographic region or city since the effect of a $PM_{2.5}$ NAAQS would probably be different in different regions or cities. In addition, this information should be compared to similar data that reflect mortality and morbidity statistics due to the relevant diseases so that the magnitude of the PM public health issue can be put into perspective relative to other public health issues. Furthermore, there was concern that the Staff Paper inadequately justified and potentially inflated the susceptible population by including virtually all individuals except young healthy adults into the sensitive subpopulations.

In closing, I would like to add two more general, but equally important comments. First, past Criteria Documents and Staff Papers did not rely so heavily on nonpeer-reviewed reports. Both the present PM Criteria Document and the present PM Staff Paper cite numerous unpublished reports, many of which are recent EPA contractor reports. As a result, it is hard to judge the scientific credibility of many key studies that the Agency uses as a basis for their conclusions in the Staff Paper. The Panel recommends that if the Agency cannot fully support their judgments without these references, they should be clearly identified in the text as nonpeer-reviewed reports. Furthermore, the Panel recommends that the Agency make these reports part of the Public Docket, so all reviewers have access to them. The Panel is concerned that the excessive use of nonpeer-reviewed reports will set a precedent that will erode the scientific credibility of the NAAQS review process. This illustrates the need for EPA to begin work immediately on developing the information that is needed for the next PM review cycle so this problem does not occur in the future.

Second, it should be emphasized that the Panel feels strongly that EPA should negotiate with the plaintiffs for a meaningful extension of the court-imposed deadlines for review of the Criteria Document and Staff Paper. Such an extension should allow the Agency time to respond to the Panel's comments and to produce revised drafts of the documents, and should allow sufficient time for CASAC to adequately review the documents. In the present review, the Panel had less than a month to review a voluminous amount of material. Some of the material was not adequately reviewed because of time constraints and because some of the Panel members never received portions of the Criteria Document that they were assigned to review. Although both the Agency and the Panel tried their best to complete this review on the mandated schedule, the schedule was unrealistic. Again, it must be the scientific quality of the Criteria Document and Staff Paper that drive the review process and not some arbitrary and unrealistic court-imposed time-table. This is the only way to avoid seriously compromising the entire review process.

In summary, the Panel found both draft documents to be generally well done. A few members were of the opinion that the documents were scientifically adequate, but most of the

members expressed the view that the documents did not provide a scientifically adequate basis for revising the NAAQS for PM. Consequently, CASAC cannot reach closure on either document at this time.

CASAC would appreciate being kept informed of progress on extending the court-imposed deadline for completion of this review. If EPA is successful, we look forward to receiving and reviewing the revised documents. If a sufficient extension is not granted, CASAC would appreciate being kept informed of progress on establishing revised or new PM standards. We also wish to be informed of EPA support of research to fill the important gaps in knowledge and data that limit our ability to set effective PM standards for the protection of public health and welfare. The EPA Staff, the CASAC Panel, and the public commenters have pointed out many of these gaps and noted major uncertainties concerning the health impacts of ambient PM during this review process.

As more information accumulates between now and the promulgation date, CASAC may, from time to time, provide you with further advice and comments. Please do not hesitate to contact me if CASAC can be of further assistance in this matter.

Sincerely,

George T. Wolff

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

U.S. Environmental Protection Agency
Science Advisory Board
Clean Air Scientific Advisory Committee
Particulate Matter Review Panel

Chairman
Dr. George T. Wolff
General Motors
Environmental & Energy Staff
Detroit, MI

Members
Dr. Stephen M. Ayres
Office of International Programs
Virginia Commonwealth University
/Medical College of Virginia
Richmond, VA

Dr. Jay S. Jacobson
Boyce Thompson Institute
Cornell University
Ithaca, NY

Dr. Joe L. Mauderly
Inhalation Toxicology Research
Institute
Lovelace Biomedical & Environmental
Research Institute
Albuquerque, NM

Dr. Paulette Middleton
Science and Policy Associates
Boulder, CO

Dr. James H. Price, Jr.
Texas Natural Resource Conservation
Commission
Austin, TX

Consultants
Dr. Phil Hopke
Department of Chemistry
Clarkson University
Pottsdam, NY

Dr. Petros Koutrakis
Harvard School of Public Health
Boston, MA

Dr. Morton Lippmann
Institute of Environmental Medicine
New York University
Tuxedo, NY

Dr. Kinley Larntz
Department of Applied Statistics
University of Minnesota
St. Paul, MN

Dr. Allan Legge
Biosphere Solutions
Calgary, Alberta, Canada

Dr. Roger O. McClellan
Chemical Industry Institute of
Toxicology
Research Triangle Park, NC

Dr. Daniel Menzel
Department of Community
and Environmental Medicine
University of California, Irvine
Irvine, CA

Dr. William R. Pierson
Energy & Environmental Engineering Center
Desert Research Institute
Reno, NV

Dr. Carl M. Shy
Department of Epidemiology
School of Public Health
University of North Carolina
Chapel Hill, NC

Dr. John Samet
School of Hygiene & Public Health
Johns Hopkins University
Baltimore, MD

Dr. Christian Siegneur
NSR Consulting & Engineering
Alameda, CA

Dr. Frank Speizer
Harvard Medical School
Channing Lab
Boston, MA

Dr. Jan Stolwijk
Yale University
New Haven, CT

Dr. Mark Utell
Pulmonary Disease Unit
University of Rochester Medical Center
Rochester, NY

Dr. Warren White
Washington University
St. Louis, MO

Science Advisory Board Staff
Mr. A. Robert Flaak
Designated Federal Official
U.S. EPA
Science Advisory Board
Washington, DC

Ms. Connie Valentine
Staff Secretary
U.S. EPA
Science Advisory Board
Washington, DC

G:\USER\SAB\ROSTERS\PM-RPT.ROS

NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

DISTRIBUTION LIST

Administrator
Deputy Administrator
Assistant Administrators
Deputy Assistant Administrator for Science, ORD
Director, Office of Science Policy, ORD
Director, Office of Air Quality Planning and Standards, OAR
Director, National Center for Environmental Assessment, ORD, RTP, NC
EPA Regional Administrators
EPA Laboratory Directors
EPA Headquarters Library
EPA Regional Libraries
EPA Laboratory Libraries
Library of Congress
National Technical Information Service
Congressional Research Service