



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

May 16, 1994

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW (1101)
Washington, DC 20460

Subject: Data Sets for PM₁₀

Dear Ms. Browner:

As you are aware, the Agency is in the early stages of preparing an updated document on "Air Quality Criteria for Particulate Material" which will in turn lead to a related Staff Position paper. The Agency staff has briefed the Clean Air Scientific Advisory Committee (CASAC) on the plans for developing the two documents. CASAC is charged with reviewing the scientific and technical underpinnings of Agency proposals for National Ambient Air Quality Standards. As scientists affiliated with CASAC, we are concerned that the appropriate analyses be conducted prior to our review.

In that spirit, we request that the Agency take steps to assure that crucial data sets linking exposure to particulate matter and health responses are available for analysis by multiple analytical teams, thereby assuring the validity of the results before they are used in making regulatory decisions on the National Ambient Air Quality Standards for Particulate Material.

From the Agency briefings, it is clear that substantial new data are available that will need to be considered in the new Criteria Document and Staff Position Paper. In particular, several recent published reports have indicated effects on both morbidity and mortality at about the level of the current PM₁₀ standard. In some cases, the analyses are extremely complex because of the need to correct a wide range of potential confounders, such as temperature, cigarette smoking and other pollutants.

It is already apparent that these analyses and the related published papers will have a central role in the Criteria Document and Staff Position Paper, the related discussions and recommendations of the Clean Air Scientific Advisory Committee, and in your final decision on reaffirmation or revision of the standard for particulate material. In view of their importance, it is crucial that two or more groups analyze the same key data sets linking exposure and morbidity/mortality response to verify the adequacy of the complex analyses and that different analysts using the same data reach similar conclusions. The importance of such validations and



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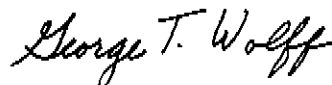
the difficulty in carrying them out was apparent from presentations on PM₁₀ effects at a recent meeting at the National Academy of Sciences Beckman Center in Irvine, CA. At that meeting, divergent results were obtained by two different analytical teams which were reputed to have analyzed the same data. As it turned out, the data sets for the same city and time period analyzed by the two research teams had subtle differences. Hence, we are left with uncertainty as to the validity of either reported analysis.

The answer to this dilemma seems clear: The EPA should take the lead in requesting that investigators make available the primary data sets being analyzed so that others can validate the analyses. Further, the Agency should actively facilitate the conduct of such validating analyses. For example, the Agency could take steps to insure that the data are made available in an electronic media format that will facilitate transfer of the data to other teams for analysis.

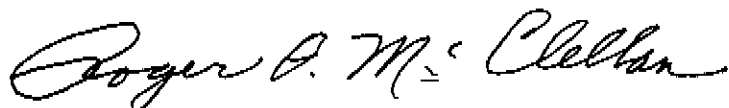
Efforts such as we have proposed may be time-consuming and require some expenditures. Nonetheless, modest expenditures to assure the scientific validity of key analyses that impact on regulatory decisions would seem to be appropriate investments where the regulatory decisions will have multibillion dollar impacts on society. Some might also argue that the kind of actions recommended infringe on the rights of individual scientists to control their own data. This is obviously a hollow argument recognizing that in almost all instances federal funds were used at least to some extent to obtain the original data. Moreover, it would appear that the steps outlined are essential steps for the Agency to take if it is to assure the scientific validity of any reaffirmation or revision of the National Ambient Air Quality Standards for Particulate Material.

The Clean Air Scientific Advisory Committee would appreciate being advised of the Agency's plans for addressing the issues we have raised.

Sincerely,



George T. Wolff, Ph.D.
Chair, Clean Air Scientific
Advisory Committee



Roger O. McClellan, D.V.M.
Past Chair, Clean Air Scientific
Advisory Committee