Comments to the Clean Air Scientific Advisory Committee Ozone Panel on Three Documents and Related Previous CASAC Review:

(a) CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Third External Review Draft, June 2012)

(b) Health Risk and Exposure Assessment for Ozone (First External Review Draft – Updated August 2012)

(c) Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012)

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Introduction

During a meeting held September 11-13, 2012 in Raleigh, NC, the Clean Air Scientific Advisory Committee (CASAC) reviewed four inter-related documents. These documents are:

1. Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Third External Review Draft, June 2012, EPA/600/R-10/076C) (hereafter referred to as the ISA).

2. Health Risk and Exposure Assessment for Ozone (First External Review Draft, Updated August 2012 (hereafter referred to as the HREA).

3. Welfare Risk and Exposure Assessment for Ozone (First External Review Draft, Updated August 2012) (hereafter referred to as the WREA).

4. Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards: First External Review Draft (August 2012) (hereafter referred to as the PA).

The development of those documents was formally initiated in September 2008. As draft documents have been developed they have been released for public comment and review by the Clean Air Scientific Advisory Committee Ozone Panel (hereafter referred to as CASAC). Advice has been offered and new drafts prepared and the next iteration of documents developed to ultimately inform the EPA Administrator's decision on the affirmation or revision of the National Ambient Air Quality Standards for Ozone set on March 27, 2008.

I offered written comments for consideration by CASAC in advance of the meeting (McClellan, 2012a) and also offered oral comments at the CASAC meeting on September 13, 2012. In addition, I filed written comments on these documents to the U.S. Environmental Protection Agency Ozone Docket (McClellan, 2012b).

The EPA has now made available three draft CASAC advisory letters; one relating to the ISA, a second related to the HREA and WREA and a third related to the PA. In this document, I offer comments on the documents and related letters. The comments I offer are my own professional views informed by my personal involvement in the NAAQS setting process since the early 1970s, including service on numerous CASAC Panels and serving as Chair of CASAC. I have previously written on the NAAQS setting and the role of science and judgment in determining how low is low enough (McClellan, 2012c).

COMMENTS

1. Goal of Current Process

The current process is an exercise in using evolving and ever-changing science to inform policy judgments on the four elements of each NAAQS; (a) the indicator, (b) averaging time, (c) the level, and (d) statistical form for determining attainment of the NAAQS. The latter are all determinant and static until legally revised. The current National Ambient Air Quality Standard (NAAQS) set on March 27, 2008 uses (a) ozone as the indictor, (b) an averaging time of 8 hours, (c) a concentration level of 75 ppb (highest daily 8 hour average), and (d) is attained when the 4^{th} highest 8-hour daily does not exceed 75 ppb. The current process is being conducted to integrate and synthesize the available scientific information to inform the EPA Administrator's policy decision on the adequacy of the current ozone NAAQS. It is crucial that CASAC recognize its responsibility is to review the adequacy of the Agency's review of the science and it is the EPA Administrator's responsibility to use that science to inform the policy decisions that are the responsibility of the Administrator. The CASAC needs to be mindful that it is an advisory committee, not a standard setting committee. The CASAC also needs to be mindful that any decision as to the adequacy or lack of adequacy of the current NAAQS should not be made until all the current scientific knowledge has not been completely assembled and documented. A premature decision that the current NAAQS is inadequate based on incomplete science would be arbitrary and capricious.

2. Clean Air Act is Multi-Pollutant Based

The current ISA, HREA and PA do not provide an adequate context for the science being integrated to inform the Administrator's policy decisions on either reaffirmation or revision of the Ozone NAAQS. Each of the current documents is deficient in recognizing that the NAAQS for ozone is only one of the criteria pollutants for which NAAQS must be set. The others are Particulate Matter (PM), Nitrogen Dioxide (NO_2), Sulfur Dioxide (SO_2), Carbon Monoxide (CO) and Lead (Pb). With the exception of Pb, whose effects are quite specific, all of the other criteria air pollutants in combination at sufficiently high concentrations of varied composition impact on human health increasing the risk for various indices of morbidity and mortality.

The inter-relationships between the various criteria pollutants in causing disease over and above disease caused by other factors are complex and not fully understood. For example, NO_2 has a role in both the formation and degradation of O_3 through complex, non-linear chemical

reactions. Volatile organic hydrocarbons, not regulated as criteria pollutants, are precursors for the formation of O_3 and give rise to secondary organic aerosols that are also measured as PM. Both NO_2 and SO_2 as gases are precursors to constituents of PM. These complex relationships are not adequately described in the current documents. This information is important to the Administrator's policy decisions on the Ozone NAAQS. It is important that any policy decisions on the Ozone NAAQS take into account impacts that will be associated with attainment of the current O_3 NAAQS and the currently established NAAQS for PM, NO_2, SO_2 and CO.

3. Current Documents Do Not Adequately Consider Multi-Pollutant Health Effects

The current ISA, with the HREA and the present very rough draft PA, place excess emphasis on the results of epidemiological studies using single pollutant models. The present documents note the importance of multi-pollutant models for investigating the hazards of Ozone and the development of ambient concentrations – response coefficients for individual pollutants, including ozone. Nonetheless, excess reliance is given to the results obtained using single pollutant with an attendant failure to relate the high degree of uncertainty in the results obtained with single pollutant models. A paper "Time-Series Analyses of Air Pollution and Mortality in the U.S.: A Subsampling Approach" by Moolgavkar et al. (2012) recently accepted for publication by Environmental Health Perspectives, addresses this issue using a new statistical approach. This paper and the importance of using multiple approaches to analyzing and interpreting epidemiological data on ozone and related air pollutants should be cited in the revised ISA and HREA and, ultimately considered when a definitive PA is developed.

4. Need for Further Improvement in Describing Background (Non-anthropogenic Origin) Ozone

Each iteration of the ISA has provided an improved description of background ozone that arises from non-anthropogenic local or regional precursors of ozone. It is recognized that this is a very complex topic, however, it is important that the topic be adequately covered in the ISA and appropriately used in developing the HREA and PA. In particulate, one area that needs improved discussion is the complex nature of the chemistry associated with ozone formation and degradation, especially at lower concentrations, including background levels across the United States. This issue relates back to the issue I raised earlier concerning the complex role of NO_2 in both the formation and degradation of ozone and the setting and attainment of the recently

established revised NO_2 NAAQS. It is important to recognize that reductions in NO2 do not always lead to reduction in Ozone.

5. Need for Substantial Improvement in the Risk Assessments for the Current and Alternative Ozone NAAQS

It is crucial that future iterations of the HREA include calculated estimates of various indices of morbidity and mortality for a range of ambient ozone scenarios. This should include estimates for "as is" concentrations, concentrations with attainment of the current Ozone NAAQS, various alternative Ozone NAAQS (varying both as to level and statistical form), and background ozone as estimated in various ways. It is crucial that this broad array of data be clearly conveyed in the PA to help inform the Administrator's policy decisions on reaffirmation or revision of the current Ozone NAAQS.

6. Baseline Morbidity and Mortality Data Are Needed to Provide Context for Policy Decisions

Information on baseline morbidity and mortality provide essential context for interpretation of published epidemiological studies and in calculating estimated risk associated with various ambient ozone exposure profiles. The ISA needs to be reviewed and revised as necessary to be certain that this essential information is included in the final ISA. The HREA should clearly cover this baseline data along with any calculated estimates of morbidity and mortality attributed to various ambient ozone profiles across the United States. It is of utmost importance that this information be clearly presented in the final PA to provide context for the Administrator's policy decisions on reaffirmation or revision of the current Ozone NAAQS.

7. It is Important that CASAC Not Reach Premature Conclusions on the Science or Assume the Policy Making Role of the EPA Administrator

I concur with the view of CASAC that the Third Review Draft ISA is approaching a state where with some further improvement it will be considered to be acceptable for regulatory-decision making. However, it is not yet ready for closure as evidenced by the number of substantive comments offered in the draft CASAC letter, the responses to chanre questions and the comments of individual Panel members.

Thus, it follows that essential input data for preparation of HREA were not avaukabke when the First Draft HREA was prepared. The extensive comments offered in the draft CASAC letter, the response to charge questions and the comments of individual Panel members will be of

major assistance to the Agency in improving this document. However, it is apparent that a Second Draft HREA will need to be critically reviewed by CASAC and the public.

I fully concur with the CASAC view expressed in the draft letter on the PA – "the PA needs substantial improvement." As I noted in my earlier comments to CASAC (McClellan, 2012 a,b) the first Draft PA was by and large a placeholder document. It was released pre-maturely. It would be unfortunate if the contents of the First Draft PA were used to reach conclusion on the need to reaffirm the present Ozone NAAQS and propose the appropriateness of alternative NAAQS with regard to level and statistical form. Without question the following statement in the draft CASAC letter on the PA is <u>inappropriate</u> – "Nonetheless, the PA provides strong rationale for consideration of ozone standards (8 hour averages) of 60 ppb and 70 ppb. The PA also provides adequate justification for considering concentrations below 60 ppb in the 50 to 60 ppb range."

A PA that needs substantial improvement clearly does not support such a statement. It should be removed from the letter. The PA does not provide decision-making guidance or scientific content to support decisions on the consideration of specific alternative NAAQS specified as to level and statistical form. As noted earlier, no clear basis has been provided based on current scientific evidence for the Administrator to not consider reaffirmation of the current level and statistical form of the Ozone NAAQS as set on March 27, 2008. The CASAC should exercise caution in interpreting the significance of its earlier advice on setting the NAAQS in the range of 70 to 60 ppb (presumably retaining the previous statistical form). Likewise, I suggest caution should be exercised in over-interpreting the Administrator's actions on the reconsideration Ozone NAAQS which the President requested be withdrawn. The new science presented in the ISA requires that the Ozone NAAQS review process start with the current NAAQS.

<u>References</u>

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Time-Series Analyses of Air Pollution and Mortality in the U.S.: A Subsampling Approach

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Abstract

BACKGROUND: Hierarchical Bayesian methods have been used in previous papers to estimate national mean effects of air pollutants on daily deaths in time-series analyses.

OBJECTIVES: To obtain maximum likelihood estimates of the common national effects of the criteria pollutants on mortality based on time-series data from 108 metropolitan areas in the U.S.

METHODS: We used a subsampling bootstrap procedure to obtain the maximum likelihood estimates and confidence bounds for common national effects of the criteria pollutants, as measured by the percentage increase in daily mortality associated with a unit increase in daily 24-hour mean pollutant concentration on the previous day, while controlling weather and temporal trends. Five pollutants, PM_{10}, ozone, CO, NO_2, and SO_2 were considered in single and multi-pollutant analyses. Flexible ambient concentration-response models for the pollutant effects were considered as well. Limited sensitivity analyses with different degrees of freedom for time trends were performed.

RESULTS: In single pollutant models, we observed significant associations of daily deaths with all pollutants. The ozone coefficient was highly sensitive to the degree of smoothing of time trends. Among the gases, SO_2 and NO_2 were most strongly associated with mortality. The flexible ambient concentration-response curve for ozone showed evidence of non-linearity and a threshold at about 30 ppb.

CONCLUSIONS: The differences between the results of these analyses and those reported from the Bayesian approach suggest that estimates of the quantitative impact of pollutants are dependent on choice of statistical approach. Additionally, the estimate of the ozone-mortality coefficient depends on the amount of smoothing of time trends.