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Written Statement for Consideration by the Clean Air Scientific Advisory Committee (CASAC)  
Ozone Review Panel at the Panel's Teleconference Meeting on February 18, 2011

Dear Ozone Review Panel Members:

The Federal Register Notice for the February 18, 2011 Teleconference of the Clean Air Scientific Advisory Committee Ozone Review Panel indicated that members of the public could provide written comments in advance of the meeting and 5-minute oral comments at the meeting. Accordingly, I am offering written comments at this time and have requested the opportunity to provide oral comments at the meeting. That request has been confirmed.

By way of background, I have carefully followed all of EPA's activities on the setting and revision of the Ozone National Ambient Air Quality Standard (NAAQS) since passage of the Clean Air Act in 1970. Indeed, with the exception of the review culminating in the 2008 NAAQS and the current "reconsideration" proposal I have served on all the CASAC Panels that have advised EPA on the Ozone NAAQS. From 1988 to 1992, I served as the Chair of CASAC. The comments I offer now are informed by that service. I have attached my biography that more fully documents my experience.

I offered written extensive comments (October 9, 2007) on the Proposed Rule for revision of the standard that resulted in the 2008 NAAQS and written comments (March 22, 2010) on the “reconsideration” proposal. I have also offered written and oral comments to the various CASAC Ozone Panels at their teleconference meetings. I have carefully read the legal brief dated January 26, 2011, “Solicitation of CASAC Advice on EPA’s Reconsideration of the 2008 Primary Ozone National Ambient Air Quality Standard” and the attached Charge Questions.

In my opinion as I have previously stated, Administrator Lisa Jackson acted in an arbitrary and capricious manner in offering her January 2010 proposal to reconsider the 2008 Ozone NAAQS. Ostensibly, the action of the Administrator was motivated by the January 20, 2009 memorandum from Rahm Emanuel, Executive Office of the President, to the Heads of Executive Departments and Agencies requesting that “President Obama’s appointees and designees have the opportunity to review and approve any new or pending regulations.” A careful reading of that memorandum does not support Administrator Jackson’s use of that Executive Memorandum as justification for “reconsideration” of the March 12, 2008 NAAQS for ambient ozone. The March 12, 2008 rule published in the Federal Register could hardly be viewed on January 20, 2009 or in January 2010 as a new or pending regulation. Hence, the Administrator’s decision to “reconsider” the March 2008 rule based on science that was already out of date by four or more years can only be viewed as arbitrary and capricious. This is especially the case because activities supporting “reconsideration” of the Ozone NAAQS had the untoward effect of putting on the “back burner” the orderly 5-year review of the Ozone NAAQS that should have been triggered by issuance of the 2008 Ozone NAAQS Rule. The science now being considered in the “reconsideration” proceedings is more than 5 years out of date since it is based on publications in 2005 and earlier.

Thus, if the Administrator proceeds with promulgation of a “reconsideration” rule at this time, she will be making policy decisions on the four elements of the NAAQS; indicator, level, averaging time, and statistical form informed by science that is clearly outdated. It is troubling that the EPA staff, acting on behalf of the Administrator, is now asking the CASAC Ozone Reconsideration Panel to again offer opinions on that outdated science. I can only view this request as an attempt by the Administrator to seek “scientific cover” for her pending policy decisions on the Ozone NAAQS. Decisions on the various elements of the Ozone NAAQS,

specifically, the level of an 8-hour averaging time standard, are policy decisions informed by scientific knowledge as to acceptable risk, i.e. a level that is in “her judgment requisite to protect public health with an adequate margin of safety as required by the Clean Air Act.”

Supreme Court Justice Breyer, in *Whitman versus American Trucking Association*, noted that the Administrator is not compelled to set a standard that eliminates all risk. Rather, he noted the Administrator has considerable latitude to set a NAAQS at a level that will have small public health risks when viewed in the context of the many other factors that influence health. It is noteworthy that the EPA’s “reconsideration” proposal, unlike documentation for the 2008 Standard, did not contain the thoughtful advice of Justice Breyer and was lacking in the “comparative health orientation” he advocated. Justice Breyer, with an extensive background in human health issues, offers advice that is worthy of careful attention by the EPA Administrator, the EPA staff and CASAC as they deal with the specific language of the Clean Air Act – “protect public health with an adequate margin of safety.” As a scientist, I defer to the eminent jurist for guidance. His written opinion has changed my views on how science can inform the setting of the NAAQS and helped me understand the conundrum of setting a standard that will – “protect public health with an adequate margin of safety.” Justice Breyer’s opinion is quoted on pages 3 and 4 of the attached reprint.

Since the four elements of the NAAQS reflect policy decisions informed by the available science, I caution the CASAC Ozone Reconsideration Panel members on assuming the role of an EPA Administrator and indicating that some particular level or range of ozone 8-hour average levels is dictated by the science. The offering of opinions on the specific level of the NAAQS as “consensus advice” from the Panel as requested by Lydia N. Wegman’s January 26, 2011 legal brief does not change the picture. Such “consensus advice” will still represent a collective policy preference as to an acceptable level of risk, a policy decision that is in the exclusive dominion of the Administrator.

In reviewing the charge questions, I was struck by the extent to which they address the same issues that have been discussed and debated since the review process began nearly a decade ago and were addressed in the 2006 Criteria Document, the 2007 Staff Paper, CASAC deliberations, CASAC letters, numerous public comments and in the 2008 Ozone NAAQS Rule. These issues were considered at a Workshop held June 5-6, 2007 in Rochester, NY at which my colleagues and I discussed and debated these and other related issues. The results of those

deliberations were submitted on October 9, 2007 to the EPA Ozone Docket as part of my written comments. Subsequently, the deliberations were published as a review article entitled – “Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone: A Conference Report” (McClellan et al., 2009). A reprint of that paper is attached.

The Rochester paper essentially addressed the science being considered in the 8 Charge Questions with the paper elaborating on both certainties and uncertainties in the scientific information. The paper also included discussion of the issue of policy relevant background for ozone, a topic that EPA elected to not address with a specific Charge Question. This is unfortunate, since if the Charge Questions are to be addressed, the questions should be addressed in the context of background levels of ambient ozone. This issue, as noted in the Rochester paper, was not appropriately addressed in the 2006 Criteria Document and 2007 Staff Paper as a basis for the setting of the ozone NAAQS. It was apparent then that EPA had not adequately considered the uncertainties in the spatial and temporal dimensions of background ozone. The Policy Relevant Background levels purported to exist across the United States were unrealistically low, especially for the western United States. As a result, the potential benefits of setting the NAAQS at lower levels were grossly exaggerated. Moreover, the lower levels that were projected for various scenarios could probably never be achieved in the absence of complete elimination of emissions of ozone precursors. The newest information available on background levels of ozone indicate the previous concerns were well-founded. To ignore background levels of ozone and suggest that background levels should not inform the policy decisions of the Administrator in setting the NAAQS is an invitation to advance poor public policies.

The abstract of the Rochester paper concluded with the following statement –  
*“This paper summarizes deliberations of a small group of scientists who met in June 2007 to review the scientific information informing the EPA Administrator’s proposed revision of the 1997 standard. The Panel recognized that there is no scientific methodology that, in the absence of judgment, can define the precise numerical level, related averaging time, and statistical form of the NAAQS. The selection of these elements of the NAAS involves policy judgments that should be informed by scientific information and analyses. Thus, the Panel members did not feel it appropriate to offer either their individual or collective judgment on the specific numerical level of the NAAQS for ozone. The Panel deliberations focused on the scientific data available*

*on the health effects of exposure to ambient concentrations of ozone, controlled ozone exposure studies with human volunteers, long-term epidemiological studies, time-series epidemiological studies, human panel studies, and toxicological investigations. The deliberations also dealt with the issue of background levels of ozone of non-anthropogenic origin and issues involved with conducting formal risk assessments of the health impacts of current and prospective levels of ambient ozone. The scientific issues that were central to the EPA Administrator's 2008 revision of the NAAQS for ozone will undoubtedly also be critical to the next review of the ozone standard. That review should begin very soon if it is to be completed within the 5-year cycle specified in the CAA. It is hoped that this Report will stimulate discussion of these scientific issues, conduct of additional research, and conduct of new analyses that will provide an improved scientific basis for the policy judgment that will have to be made by a future EPA Administrator in considering potential revision of the ozone standard."*

It is unfortunate that Administrator Lisa Jackson decided to not proceed expeditiously with the next Ozone NAAQS review using new scientific information, a review that could have been completed as early as 2013. It is not too late for the Administrator to recognize that the best interests of the Nation will be served by withdrawing the "reconsideration" proposal and immediately initiating the next periodic Ozone NAAQS review based on the latest available science. In my opinion, there is substantial new information available on ambient ozone and its health effects that should inform policy decisions on the specific elements of the NAAQS. That new information must obviously be known to the EPA staff.

As the EPA moves forward with its review and revision of the Ozone and other NAAQS, I urge the Agency to move the important activities of CASAC more clearly into the public arena. Specifically, I ask that CASAC and CASAC Panel meetings, with perhaps rare exceptions, be held as face-to-face open meetings rather than as teleconferences such as that proposed for February 18, 2011. The scientific discussions and advice offered have multi-billion dollar impacts on Society whether quantified as health benefits or as mitigation costs, the public is not well served by having these issues considered in half-day or less teleconferences. Further, I urge that more time be provided for public comments from a wide range of interested constituencies. The practice of restricting public commentors to 5-minute sound bites satisfies in only the most perfunctory sense the definition of CASAC having received public comments.

Moreover, I urge that all CASAC and its Panel's deliberations, including the preparation of letters to the EPA Administrator, be conducted in public view. The practice of the last decade of having limited discussion in public, frequently via teleconferences, and components of letters to the Administrator drafted by a few individuals out-of-public view is not appropriate for a democratic, participatory Society when dealing with issues as important as the setting of NAAQS. I recognize that what I am proposing will likely result in much shorter letters from CASAC to the Administrator. In my opinion, this has an advantage in that the CASAC letters are more likely to address the most important issues and be less prescriptive as to the specific elements of each NAAQS. As always, individual CASAC Panel members have the opportunity to offer extensive comments on their own for inclusion in an Appendix to the Panel or Committee letter. I recognize that what I propose places increased time demands on CASAC members and consultants, EPA staff and the public. In my opinion, that is a small price to pay for greater public confidence in the process and the product. It is important to remember CASAC's advice is to inform the Administrator's policy decisions not to dictate them.

#### Declaration of Interest

The views I share in this documentation are my own professional views. I regularly serve as an advisor to both public and private organizations on air quality issues. This includes the American Petroleum Institute (API) and various companies in the energy and transportation sectors. The views I have expressed are not necessarily those of the API or any organization I advise.

Respectfully,

Roger O. McClellan

Attachments: McClellan Biography  
Reprint of McClellan et al. 2009 Paper

## **BIOGRAPHY**

**Roger O. McClellan, DVM, MMS, DSc (Honorary),  
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Roger O. McClellan is currently an advisor to public and private organizations on inhalation toxicology and human health risk analysis issues. He received a Doctor of Veterinary Medicine degree with Highest Honors from Washington State University (1960). He is a Diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences, American Association for Advancement of Science, Society for Risk Analysis and American Association for Aerosol Research.

He is an internationally recognized authority in the fields of inhalation toxicology, aerosol science and human health risk analysis. He is also well known for the leadership he provided to the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM and the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC. Both organizations are internationally recognized for their research on the mechanisms of action of pollutants and assessing human health risks. He has authored over 300 scientific papers and reports and edited 10 books. He frequently speaks on risk assessment and air pollution issues in the United States and abroad. He is a Past President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including continuing service as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

McClellan has served in an advisory role to numerous public and private organizations including service on senior advisory committees for 8 federal agencies and on many committees of the National Academy of Sciences/National Research Council. He served as an elected member of the National Council on Radiation Protection and Measurements (NCRP) and has been elected as a Distinguished Emeritus Member of the NCRP. He is past Chairman of EPA's Clean Air Scientific Advisory Committee and served on Panels that have reviewed the National Ambient Air Quality Standards for all of the Criteria Pollutants.

McClellan's contributions have been recognized by receipt of a number of honors. He was elected in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He received the Society of Toxicology Merit Award and Founders Award and the New Mexico Distinguished Public Service Award. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to the science under-girding improved air quality. In 2008, Washington State University presented him the Regent's Distinguished Alumnus Award, the highest recognition the University can bestow on an alumnus. He is a strong advocate of risk-based decision-making integrating information from epidemiological studies, clinical investigation, laboratory animal bioassays and mechanistic studies using molecules, cells, tissues and intact mammals.

REVIEW ARTICLE

# Critical considerations in evaluating scientific evidence of health effects of ambient ozone: a conference report

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## Abstract

The U.S. Environmental Protection Agency (EPA), under the authority of the Clean Air Act (CAA), is required to promulgate National Ambient Air Quality Standards (NAAQSs) for criteria air pollutants, including ozone. Each NAAQS includes a primary health-based standard and a secondary or welfare-based standard. This paper considers only the science used for revision of the primary standard for ozone in 2008. This paper summarizes deliberations of a small group of scientists who met in June 2007 to review the scientific information informing the EPA Administrator's proposed revision of the 1997 standard. The Panel recognized that there is no scientific methodology that, in the absence of judgment, can define the precise numerical level, related averaging time, and statistical form of the NAAQS. The selection of these elements of the NAAQS involves policy judgments that should be informed by scientific information and analyses. Thus, the Panel members did not feel it appropriate to offer either their individual or collective judgment on the specific numerical level of the NAAQS for ozone. The Panel deliberations focused on the scientific data available on the health effects of exposure to ambient concentrations of ozone, controlled ozone exposure studies with human volunteers, long-term epidemiological studies, time-series epidemiological studies, human panel studies, and toxicological investigations. The deliberations also dealt with the issue of background levels of ozone of nonanthropogenic origin and issues involved with conducting formal risk assessments of the health impacts of current and prospective levels of ambient ozone. The scientific issues that were central to the EPA Administrator's 2008 revision of the NAAQS for ozone will undoubtedly also be critical to the next review of the ozone standard. That review should begin very soon if it is to be completed within the 5-year cycle specified in the CAA. It is hoped that this Report will stimulate discussion of these scientific issues, conduct of additional research, and conduct of new analyses that will provide an improved scientific basis for the policy judgment that will have to be made by a future EPA Administrator in considering potential revision of the ozone standard.

**Keywords:** Ozone, air quality, national ambient air quality standards, air pollution, respiratory effects, clean air act, risk assessment

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