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Clean Air Scientific Advisory Committee  
U.S. Environmental Protection Agency  
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Comments on “Policy Assessment for Review of the Ozone National Ambient Air Quality Standards, Second External Review Draft” at the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel Meeting, March 25-27, 2014, Chapel Hill, NC

Policy Assessment Needs to be Revised to Avoid “Arbitrary and Capricious” Policy Judgments

This meeting of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel will be considering three important documents; (1) Health Risk and Exposure Assessment (REA) for Ozone – Second External Review Draft (January 2014), (2) Welfare Risk and Exposure Assessment for Ozone-Second External Review Draft (January 2014), and (3) Policy Assessment (PA) for the Review of the Ozone National Ambient Air Quality Standards – Second External Review Draft (January 2014). The availability of these documents was announced in the Federal Register on January 29, 2014.

The brief period, less than 2 months, these documents have been available has not allowed sufficient time for CASAC Panel Members and the public to review these very substantial documents. That is especially the case since the two REA documents must be reviewed as a basis for the PA document. In my opinion, it is inappropriate for the CASAC Panel to attempt to critically review and discuss in 3 days these three documents that address a topic of vital national interest – policy judgments that will be summarized in the level and form of the primary and secondary Ozone NAAQS that are neither more nor less stringent than necessary to protect public and welfare. These policy judgments delegated by the Clean Air Act to the EPA Administrator, informed by scientific knowledge, will determine whether it is appropriate to reaffirm or revise the Ozone NAAQS. Yes, I have noted the potential to reaffirm the present Ozone NAAQS because that option must still be considered.

I am concerned that with the CASAC Panel, and the Public, having less than 60 days to review the documents and a CASAC Panel Meeting of less than 3 full days, the contents of these three documents will not be thoroughly discussed and reviewed by the CASAC Panel. A truncated discussion of these three documents will not serve the national interests. In my opinion, the discussions of the CASAC Panel should not be conditioned by previous discussions of these matters and especially the previous decision of CASAC to offer a bright line recommendation, blending scientific information and the collective policy judgment of the previous CASAC Ozone Panel, that the level of the primary Ozone NAAQS must be 70 ppb or lower. In my opinion, that was an “arbitrary and capricious” decision by the CASAC Panel that should be given no special standing as the three recently revised documents are reviewed. The CASAC Panel should advise the Agency on the scientific adequacy of the documents and avoid the temptation to prescribe the level and associated form of the Ozone NAAQS.

In view of the limited time I have had to review the three documents I have focused my attention and, thus, my comments on the Policy Assessment. I repeat here the core content of my comments submitted to EPA’s Ozone Docket.

I offer comments on this periodic review of National Ambient Air Quality Standards (NAAQS) for Ozone based on my more than 50 years of scientific experience in the fields of aerosol science, inhalation toxicology, comparative medicine, and human health risk analyses. A copy of my biography is attached to this letter. Moreover, I draw on my experience as a charter member of the U.S. Environmental Protection Agency (EPA) Science Advisory Board and participant in Clean Air Scientific Advisory Committee (CASAC) activities from the time the Committee authorized by the Congress under the Clean Air Act was formed, including four years of service as Chair of CASAC. My CASAC experience has included participation in the review of all the criteria pollutants, including previous reviews of the Ozone NAAQS. Participation in CASAC advisory activities has given me an understanding of the Clean Air Act, the statute authorizing the promulgation of NAAQS, the role of CASAC in offering advice to the Administrator and the ultimate policy judgments required of the EPA Administrator in either reaffirming or revising a particular NAAQS.

Let me unequivocally state that over the decades the process by which the “criteria” (which has evolved into a set of inter-related documents; the ISA, REA and PA) as required by the Clean Air Act are prepared, reviewed with CASAC and public input and finalized has become more rigorous. As the “criteria” have become more detailed the CASAC review process

has been increasingly guided by prescriptive charge questions posed by the EPA staff. In my opinion, the focus on details and prescriptive questions has led the CASAC to regularly endorse the synthesis and final conclusions drawn by EPA staff. In my opinion, this prescriptive focus has stifled the robust discussion of alternative scientific viewpoints that was typical of deliberations at early CASAC meetings.

The PA document was introduced by the EPA “to help bridge the gap” between the Agency’s scientific assessments presented in the ISA and REAs, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. The ISA and REAs have become the scientific criteria called for in the Clean Air Act to inform policy decisions. Increasingly, the CASAC review of the PA has been driven by the prescriptive charge questions of the EPA staff. Rarely has the CASAC review process been extended to ask the over-arching essay question – does the articulation of the science make sense and is it adequate to inform the EPA Administrator’s policy judgment decisions informed by scientific information?

To further complicate the advisory process, the CASAC, in recent reviews of the Particulate Matter (PM) and Ozone NAAQS, has offered “bright line” admonishments to the EPA Administrator to set the level of the NAAQS lower than some specified level or concentration. In my opinion, these admonishments reflect CASAC’s collective policy judgments; policy judgments that are specifically delegated by the Clean Air Act to the EPA Administrator and have not been delegated to CASAC. The Act wisely specified a Clean Air Scientific Advisory Committee, not a Clean Air Standard Setting Committee. The opinion of scientists on CASAC as to the specific level of the NAAQS inevitably represent must involve a blending of science and science policy. Scientific knowledge alone cannot establish the level and form of a NAAQS. I have previously addressed this issue in a peer-reviewed paper [McClellan, R. O. (2012). Role of Science and Judgment in Setting National Ambient Air Quality Standards: How Low is Low Enough? *Air Quality, Atmosphere and Health J.* 5(2): 243-258].

The policy judgments that must be made by the EPA Administrator in setting any NAAQS, and especially the level and form, require context. All of us, as individuals and in institutional settings, recognize that all important decisions require context. Decisions on important matters should not be made in isolation! A critical deficiency in the Agency’s Policy Assessments for Criteria Pollutants, and exemplified by the current Ozone Policy Assessment, is

the absence of any contextual basis for the Administrator's Policy Judgments that must be made to reaffirm or revise the NAAQS. Contextual information is critical to the Administrator deciding how low is low enough for the level and associated form of the Ozone NAAQS? I emphasize the importance of considering both the level and statistical form. It is not sufficient to merely state a decision of the form was made earlier. This is a new review based on new information.

Policy judgments are essential to deciding that the level of the standard and associated form that is "neither more nor less stringent than necessary" to protect public health and welfare. Scientific information alone is not adequate for specifying the level and form of the NAAQS. The present draft "Policy Assessment" leads the reader and, hence, potentially the Administrator, to conclude that the setting of the level and form of the Ozone need only considers the science of ozone health and welfare effects. The document is turgid with numerical estimates of ozone attributable risk that document the expected obvious result – the lower the level or concentration of ozone, the lower the ozone attributable risk. To make a decision as to how low is low enough, the Administrator must be provided information on the health and welfare risks that exist in the real world, because we do not live in an ideal world free of disease and deleterious welfare impacts. For example, does "common sense" lead the Administrator as a matter of policy to conclude that among all the factors associated with the occurrence of asthma, it is necessary to lower the level of the Ozone NAAQS to minimize the occurrence of asthma? Or when considering all the factors that influence plant productivity does it make "common sense" to lower the level of the secondary Ozone NAAQS? As an aside, if these questions are asked of scientists whose careers have been built on studying ozone health or welfare effects the answer is likely to be different than that offered by a policy maker who is expected to have a broader perspective on the complexities of the real world than the individual scientist with a vested interest.

To ensure that the Administrator has the science-based knowledge for making policy judgments on the Ozone NAAQS, it is imperative that a revised Policy Assessment be prepared that includes basic morbidity and mortality data for the USA and various regions over time to provide perspective for the estimated Ozone Attributable risks given in the draft document. It will be important for the revised Policy Assessment to summarize the role of other natural- and human-related activities that impact on population morbidity and mortality. Since we live in a world with complex atmospheres it is imperative that the Policy Assessment address the risks

attributable to co-pollutants such as PM<sub>2.5</sub>. Inclusion of such data in a revised Policy Assessment would be consistent with Section 109(d)(2)(c) of the Clean Air Act which states that the Committee shall “advise the Administrator of any adverse public health, welfare, social, economic or energy effects which may result from various strategies for attainment and maintenance of such national air quality standards.” The CASAC Panel cannot provide advice on these critical matters without a more complete Policy Assessment document.

In summary, the January 2014 Draft “Policy Assessment for Review of the National Ambient Air Quality Standard” does not include critical contextual information necessary to inform the Policy Judgments of the EPA Administrator in deciding on the levels and forms of the Ozone primary (health) and secondary (welfare) NAAQS that are neither more or less stringent than necessary to protect public health and welfare. In everyday language, the Policy Judgments are essential to answer the question of how low is low enough? The answers, in turn, determine whether it is appropriate to reaffirm the present primary or secondary NAAQS for Ozone or revise them. In the absence of this contextual information the Administrator’s decision on reaffirming or revising the NAAQS may to be viewed as “arbitrary and capricious.” A decision of the Administrator grounded in a CASAC collective recommendation, no matter how well intended, that the Ozone NAAQS must be set lower than some specified level would clearly be arbitrary and capricious since the inherent policy judgments of CASAC in offering such a recommendation have no special standing unlike the Policy Judgments of the Administrator.

As the CASAC Ozone Panel discusses the Policy Assessment, I urge the Panel Members to not feel constrained by the Charge Questions asked by the EPA staff. I urge you to go beyond the Charge Questions and address an over-arching essay question – Does the Policy Assessment provide all of the background information needed by the Administrator to make the policy judgments that must be made as to the level of form of the primary and secondary Ozone NAAQS neither more nor less stringent than necessary to protect public health and welfare? As I noted above, I submit that the present Policy Assessment document is incomplete and must be revised to avoid the Administrator making Policy Judgments that are “arbitrary and capricious.” In reaching a decision on the adequacy of the current draft Policy Assessment, it is not appropriate for CASAC members, individually or collectively, to offer a Policy Judgment on the specific level and form of the Ozone NAAQS. As I have noted, that would be inappropriate. Your role is to address whether the Policy Assessment is scientifically adequate for the

Administrator to use in making the required policy judgments. It is important that CASAC critically review and debate these critical issues in public view.

Respectfully,

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## BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary),  
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**ROGER O. McCLELLAN** serves as an advisor to public and private organizations on matters concerned with aerosol science, inhalation toxicology, comparative medicine, and human health risk analysis focusing on issues of air quality in the ambient environment and work place. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. 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.

He served as Chief Executive Officer and President of the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from September 1988 through July 1999. The CIIT continues today as The Hamner Institute for Health Sciences. During his tenure, the organization achieved international recognition for the development of scientific information under-girding important environmental and occupational health decisions and regulations. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute. During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the health effects of airborne radioactive and chemical materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). In these assignments, he was involved in conducting and managing research directed toward understanding the human health risks of internally deposited radionuclides.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science, comparative medicine, and human health risk analysis. He has authored or co-authored over 350 scientific papers and reports and edited 10 books. In addition, he frequently speaks on risk assessment and air pollution issues in the United States and abroad. He is active in the affairs of a number of professional organizations, including past service as 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 service since 1987 as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He has served on senior advisory committees for the major federal agencies concerned with human health. This included service as past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committees on Toxicology (served as Chairman for 7 years), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine. He has served on the Board of Scientific Councilors for the Center for Environmental Health Research of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry and on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods. He recently served on the National Aeronautics and Space Administration Lunar Airborne Dust Toxicity Advisory Group.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the American Association for Aerosol Research, the Health Physics Society, and the American Association for the Advancement of Science. In 1998, he received the International Achievement Award of the International Society of Regulatory Toxicology and Pharmacology for outstanding contributions to improving the science used for decision making and the International Aerosol Fellow Award of the International Aerosol Research Assembly for outstanding contributions to aerosol science and technology. In 2002, he was inducted into the University of New Mexico Anderson School of Management Hall of Fame for contributions to the effective management of multi-disciplinary research organizations. He received the Society of Toxicology Merit Award in 2003 for a distinguished career in toxicology and the Society's Founders Award in 2009 for contributions to science-based safety/risk decision-making. In 2012, he received a career achievement award from the International Dose-Response Society and the American Association for Aerosol Research and in 2014 from the Academy of Toxicological Sciences. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to comparative medicine and the science under-girding improved air quality. In 2006, he received the New Mexico Distinguished Public Service Award. In 2008, Washington State University presented Dr. McClellan the Regents Distinguished Alumnus Award, the highest recognition the University can bestow on an Alumnus.

Dr. McClellan has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment, and air quality and in the management of multidisciplinary research organizations. He is a strong advocate of science-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials and to inform policy makers in developing standards and guidance to protect public health.