

STATEMENT OF

Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis
Albuquerque, New Mexico

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Children's Health Protection
Committee on Environment and Public Works
United States Senate

Oversight Hearing on Science and Environmental Regulatory Decisions

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Good Morning, Chairman and Members of the Committee. Thank you for the invitation to present my views on the use of science in making environmental regulatory decisions. My testimony will focus on two recent examples involving the setting of National Ambient Air Quality Standards (NAAQS), commenting first on the Particulate Matter Standard and then on the Ozone Standard.

My biography is attached to this statement (Attachment 1). Since 1999, I have served as an Advisor to public and private organizations on issues related to air quality in the ambient environment and workplace drawing on more than 45 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. Prior to 1999, I provided scientific leadership for two organizations – the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC and the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM. Both organizations, under my leadership, earned an international reputation for developing scientific information under-girding occupational and environmental health standards.

The testimony I offer today also draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA Scientific Advisory Committees from the origin of the Agency to the present time. In 1977-1978, I chaired an *ad hoc* committee which reviewed the scientific criteria for setting the original NAAQS for lead. That *ad hoc* committee preceded the authorization in the Clean Air Act of the Clean Air Scientific Advisory Committee (CASAC) and in many ways, served as a template for CASAC's early operation. I have served on CASAC, including service as chair from 1988 to 1992, and on CASAC Panels that have considered all the criteria pollutants at various times. I served on both the CASAC Particulate Matter Panel and the CASAC Ozone Panel that reviewed the basis for revision of the NAAQS for particulate matter and ozone in the late 1990s. I also served on the most recent CASAC Particulate Matter Panel related to the 2006 revision of the Particulate Matter Standard. I did not serve on the CASAC Ozone Panel that reviewed the basis for the 2008 revision of the Ozone Standard. However, I have closely followed the current NAAQS Ozone review process from its inception in September 2000 to the present. The testimony I offer today reflects my own views on the role of science and judgment in setting NAAQS standards. In Attachment 2, I briefly review the NAAQS process as background for my comments.

Let me first focus on the recent review of the Particulate Matter Standard directing specific attention to the PM_{2.5} indicator, also referred to as the fine particle indicator. In the Proposed Rule (January 17, 2006), Administrator Stephen Johnson solicited comments on the setting of a PM_{2.5} standard with a 24-hour averaging time in the range of 25-65 µg/m³ and an annual standard in the range of 12-15 µg/m³. The CASAC Particulate Matter Panel recommended that the 24-hour averaging time standard be set in the range of 30-35 µg/m³ and the annual standard be set at 13-14 µg/m³. I, and one other CASAC Particulate Matter Panel member, disagreed with the CASAC recommendation and offered dissenting views. In my opinion, the decision as to where to set the annual standard in the range of 12-15 µg/m³ was a policy judgment and not a decision that could be made exclusively based on scientific information. I took strong

exception to the view that science, in the absence of judgment, would support a 14 $\mu\text{g}/\text{m}^3$ standard and not support a 15 $\mu\text{g}/\text{m}^3$ standard.

Ultimately, Administrator Johnson issued a Final Rule (October 17, 2006) reducing the 24-hour averaging time standard from 65 to 35 $\mu\text{g}/\text{m}^3$ and retaining the annual standard at 15 $\mu\text{g}/\text{m}^3$. In my opinion, this was a reasonable policy choice from among an array of acceptable science-based options. I was disappointed that some of the CASAC Particulate Matter Panel characterized Administrator Johnson's choice as being a political choice that ignored the science. In my opinion, the CASAC Particulate Matter Panel failed to recognize that the selection of a specific numerical standard for any criteria pollutant, including $\text{PM}_{2.5}$, reflects a policy judgment informed by science. The Panel's advocacy of an annual standard of 13-14 $\mu\text{g}/\text{m}^3$ represented their personal policy preferences, although they presented the choice as those it was compelled by the science.

Let me now turn to the role of science and judgment in the "Final Rule for the National Ambient Air Quality Standard for Ozone" announced on March 12, 2008 by EPA Administrator Johnson. This Final Rule revises the 1997 Standard and concludes a process begun in September 2000. Throughout the review process, there was debate over the numerical level of a revised standard. In my view, much of the debate was premature and focused on the desire of various parties for lowering of the standard even before the review of the science was complete. This resulted in a blurring of the boundary between the role of science and judgment in the setting of the standard.

As required by a Court Decree, the EPA published a Proposed Rule on July 11, 2007 and requested public comments on anticipated action in issuing a Final Rule for the ozone standard. Release of the Proposed Rule intensified the debate over the numerical level of the standard and continued to blur the distinction between the role of science and judgment in the setting of the standard. Numerous comments were submitted to the official ozone docket. I submitted my personal comments¹ to the ozone docket and also joined with 9 of my scientific colleagues in submitting a document² – "Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone" to the docket. The debate over the numerical level of the standard continues even today as evidenced by this Hearing.

Much of the debate fails to acknowledge that the setting of the standard involves policy judgments informed by science. The debate has included repeated reference to the CASAC Ozone Panel recommendation that the primary standard be set within a specific narrow numerical range, i.e. 0.060 – 0.070 ppm. In my opinion, the CASAC Ozone Panel moved from the Science arena into the Policy arena in advocating an upper bright line value of 0.070 ppm for the primary standard. That value represents the personal judgment of the Ozone Panel Members, not just their interpretation of the science. It is my opinion that the CASAC Particulate Matter Panel never adequately communicated the extent to which their opinions on the numerical level of the standard communicated to the Administrator represented both their interpretation of the science and their personal policy judgments on the numerical level of the standard.

The EPA Administrator, under the authority of the Clean Air Act, has the exclusive responsibility and authority for making policy judgments, informed by science, in setting the NAAQS for criteria air pollutants. Supreme Court Justice Stephen Breyer, in the landmark case, *Whitman versus American Trucking Association* (531 U.S. 457, 2001), offered “common sense” guidance for setting the standards for criteria pollutants such as ozone (Attachment 3). Justice Breyer expressed the opinion that while the Administrator cannot consider cost in setting air quality standards for the criteria pollutants, the EPA Administrator need not set standards at zero risk. He advised the Administrator to use judgment in a "comparative health" context when "deciding what risks are acceptable in the world in which we live."

In short, Justice Breyer recognized that every day life carries with it a variety of risks. Justice Breyer’s opinion provides “common sense” guidance for deciding how low is low enough in setting air quality standards – the numerical level of the standard and the associated acceptable risk level, even if not specifically articulated, are policy judgments that should be informed by science. In my opinion, the Administrator could have made a policy judgment, informed by science, with selection of a numerical value for the ozone primary standard as high as the 1997 primary standard of 0.08 ppm. His selection of a lower value was consistent with the original advice of his own staff – 0.075 ppm up to a level slightly below the current standard.

In my own comments to the Ozone Docket¹, I reviewed the science available on the health effects of ozone. In my comments, I noted the substantial uncertainty and variability in the findings of an increase in common health effects with ozone exposure in the range of the current standard and below. These scientific uncertainties were also detailed in the comments² that I and nine of my colleagues submitted to the Docket. Both sets of comments emphasized that the selection of any specific numerical standard should be a policy judgment that is informed by science.

The CASAC Ozone Panel, in proposing a bright line upper limit of 0.070 ppm, offered their collective judgment on, in the words of Justice Breyer, – “what risks are acceptable in the world in which we live.” That was their policy choice, it should not be postured as being exclusively science based. Science alone can never provide a basis for deciding how low is low enough, policy judgments are always required in deciding “what risks are acceptable.” Any specific numerical value for the standard has an associated implied “acceptable risk value,” even if the level of acceptable risk has not been explicitly stated.

The CASAC Ozone Panel’s letter to the Administrator dated April 7, 2008, commenting on the Final Rule, continues to suggest that somehow science and scientists alone can establish the appropriate numerical level of the NAAQS for ozone. In that letter, the CASAC Ozone Panel again failed to clarify the distinction between their interpretations of the science and their policy judgment in offering an opinion on the numerical level of the ozone standard. The Panel should have clearly acknowledged that the numerical level they have advocated reflects their personal policy preferences. Likewise, in arguing for “further lowering the national ambient ozone standards,” the

Panel fails to acknowledge that this is their collective policy outcome wish that goes well beyond considering just the available scientific information. How low is low enough for the ozone standard is ultimately a policy judgment informed by scientific information and analysis. The Clean Air Act clearly specifies that the EPA Administrator has the exclusive authority and responsibility for using judgment in the setting of the Standard.

Without question, the Administrator, in setting the standard, should consider scientific advice received from many parties, including the special advice provided by the Clean Air Scientific Advisory Committee. However, it is clear that the Clean Air Act calls for an Advisory Committee and not a Clean Air Standard Setting Committee. This places a special responsibility on the Committee to distinguish between their scientific advice and their personal policy judgments as to the numerical level of the Standard.

It is noteworthy that the Final Rule for the Ozone Standard states – “the Administrator observes that he reaches a different policy judgment than the CASAC Panel based on apparently placing different weight in two areas: --” The Final Rule goes on to detail these differences and states – “and fully considering the scientific and policy views of CASAC, the Administrator has decided to revise the level of the primary 8-hour O₃ standard to 0.075 ppm.” Without question, the Final Rule Ozone Rule clearly acknowledges that the CASAC Ozone Panel offered both their scientific and policy views. It is unfortunate that the CASAC Ozone Panel did not make this important distinction in its communications to the Administrator in their public statements on the Final Rule.

In closing my testimony, I want to make several important points. As a scientist, I am a strong advocate of conducting research that will provide an improved scientific basis for the policy judgments that are essential in the setting of NAAQS for pollutants as well as many other policy decisions that have important implications for the health and well being of Society. However, I am concerned about the extent to which many scientists, and I should add, Special Interest Groups, frequently champion particular courses of action purporting that the course of action being advocated is being driven exclusively by the science. The Special Interest Groups range from environmental and disease-oriented groups to industry coalitions. Each group postures that good science is driving their advocacy position. Each group fails to recognize that science alone does not provide the answer, well-reasoned judgments are an essential ingredient for making decisions.

I am concerned as a scientist, and more broadly as a private citizen, that single issue science used as a tool for advocacy can lead to bad decisions that may not be in the best interest of Society as a whole. For example, when the Administrator makes decisions on air quality standards I would hope the Administrator is also considering the overall health of Society and not focusing exclusively on a single pollutant in isolation. In my opinion, the kind of “common sense” approach that Justice Breyer offered should be used. My concerns about the role of science and judgment in making policy decisions extends to a broad range of societal issues that are impacted by scientific information.

References

1. McClellan, R. O. Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.
2. Brauer, M., Frampton, M.W., Koutrakis, P., McClellan, R.O., McDonnell, W.F., Moolgavkar, S., North, D. W., Smith, A.E., Smith, R.L., Utell, M.J. Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone. Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.

ATTACHMENT 1

BIOGRAPHY

**ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary),
Dipl-ABT, Dipl-ABVT, Fellow-ATS**

Advisor: Human Health Risk Analysis
Inhalation Toxicology

13701 Quaking Aspen NE
Albuquerque, NM 87111-7168, USA
Tel: (505) 296-7083
Fax: (505) 296-9573
e-mail: roger.o.mcclellan@att.net

ROGER O. McCLELLAN is currently an advisor to public and private organizations on issues concerned with inhalation toxicology and human health risk analysis. 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, a Diplomate of 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. During his tenure, the organization achieved international recognition for the development of science under-girding important environmental and occupational health 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 toxic 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 and human health risk analysis. He has authored or co-authored over 300 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 continuing service 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 8 federal agencies. He is 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 recently completed a term on the Board of Scientific Councilors for the Centers for Disease Control and Prevention for Environmental Health Research and the Agency for Toxic Substances and Disease Registry. He is currently serving on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods and 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 of standing 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. He received the Society of Toxicology 2005 Merit Award for a distinguished career in toxicology. 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 2006 he received the New Mexico Distinguished Public Service Award. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-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.

ATTACHMENT 2

Setting National Ambient Quality Standards

Each NAAQS consists of four elements: (a) an indicator (such as ozone for photochemical oxidants), (b) an averaging time (such as 8 hours), (c) a numerical level (such as 0.08 ppm ozone averaged over 8 hours), and (d) a statistical form (such as the annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years).

Under the Clean Air Act, the EPA Administrator is required to review the NAAQS for the criteria pollutants at 5-year intervals to evaluate whether or not the four elements of the NAAQS are still deemed to be acceptable based on current scientific knowledge as it applies to the assessment of public health risks. In practice, the interval between reviews has been longer. The process for review and promulgation of a NAAQS, either continuation of the existing standard or establishing a new NAAQS, consists of multiple phases. The initial phase, which is obviously on-going, consists of conduct of research on the various criteria pollutants. This includes a broad spectrum of activities; understanding emissions of pollutants, transport and transformation of pollutants in the atmosphere, ambient measurements of pollutants, estimation of personal exposures to pollutants, assessment of toxic effects and mechanisms of action in cells, tissues and animals, conduct of controlled exposure studies to pollutants in human volunteers and epidemiological investigations of human populations. Most of the research is funded by the EPA, some in the Agency's own laboratories and some in academic and other laboratories, the National Institutes of Health and, to a modest extent, private industry. The dominance of federal government support of research on criteria pollutants relates to their effects being of broad societal concerns with the pollutants, by and large, having no unique industrial emission source.

The findings of this research are used by the EPA's Office of Research and Development to prepare a criteria document (CD). Each CD traditionally has been essentially an encyclopedia of everything known about a given criteria pollutant and is used as a basis of information for the preparation of a Staff Paper (SP) by the EPA's Office of Air Quality Planning and Standards. This is a Policy Assessment of Scientific and Technical Information; in short, an integration and synthesis of the information in the CD that is most relevant to setting the four elements of a NAAQS. In recent years, the Staff Papers have made substantial use of risk assessments for the criteria pollutant being considered. These risk assessments have been conducted by a single EPA Contractor organization. The various versions of the CD and SP are released to the public with an invitation to provide comments as a basis for improving the documents.

Throughout this process, a Clean Air Scientific Advisory Committee Panel, operating as an element of the EPA's Science Advisory Board, is involved in reviewing and advising on the scientific content of both the CD and the SP, including the related risk assessment. This has typically involved several revisions. Prior to the current cycle of ozone review, the CASAC Panel sent a closure letter to the EPA Administrator when

the CASAC was of the opinion that the revised documents were suitable for use by the Administrator in promulgating a NAAQS. In the current ozone review, the “closure letter” process was abandoned. Instead, the current CASAC Ozone Panel has focused on offering a consensus opinion.

At the next step, the Administrator proposes, via a Federal Register Notice, a NAAQS including specific proposals for each of the four elements of the NAAQS; the indicator, averaging times, numerical levels and statistical forms. Comments are solicited from the Public with the opportunity to submit written comments to a specific Docket. The Administrator, acting under a Consent Decree, signed a “Proposed Rule.”

The next step is for the Administrator to promulgate a NAAQS consisting of the four elements discussed previously. I purposefully do not use the phrase – “final step,” because the Courts may have a role in deciding whether the Administrator’s proposed NAAQS for Ozone will stand. The NAAQS are to be based on the available scientific information reviewed in the CD and SP and summarized in the notice of proposed rules. The primary, health-based NAAQS are to be set at a level that will protect public health, including sensitive populations, with an adequate margin of safety. The Administrator is precluded from considering cost in the setting of the NAAQS.

At this point, I would like to emphasize that there exists no absolute and unambiguous scientific methodology that can determine which specific indicator, precise averaging time, numerical level or statistical form will be adequate to protect public health. The available scientific information can inform the NAAQS decisions, however, the Administrator must ultimately use policy judgment in making decisions on each of the four elements from among an array of scientifically acceptable options including consideration of their attendant scientific uncertainties. Beyond the language in the Clean Air Act, Justice Breyer in *Whitman v. American Trucking Association* (531 U.S. 457, 473) has given very useful guidance for the Administrator in exercising policy judgment in the setting of NAAQS (see Attachment 3).

ATTACHMENT 3

Justice Breyer on Using Policy Judgment (from *Whitman v. American Trucking Association*, 531 U.S. 457, 473)

In setting standards that are “requisite” to protect public health and welfare, as provided in section 109(b), EPA’s task is to establish standards that are neither more or less stringent than necessary for these purposes. *Whitman v. American Trucking Associations*, 531 U.S. 457, 473. In establishing “requisite” primary and secondary standards, EPA may not consider the costs of implementing the standards. *Id.* At 471. As discussed by Justice Breyer in *Whitman v. American Trucking Associations*, however, “this interpretation of § 109 does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of “hurtling” industry over “the brink of ruin,” or even forcing “deindustrialization.” *Id.* At 494 (Breyer, J., concurring in part and concurring in judgment) (*citations omitted*). Rather, as Justice Breyer explained:

“The statute, by its express terms, does not compel the elimination of all risk; and it grants the Administrator sufficient flexibility to avoid setting ambient air quality standards ruinous to industry.

Section 109(b)(1) directs the Administrator to set standards that are “requisite to protect the public health” with “an adequate margin of safety.” But these words do not describe a world that is free of all risk – an impossible and undesirable objective. (citation omitted). Nor are the words “requisite” and “public health” to be understood independent of context. We consider football equipment “safe” even if its use entails a level of risk that would make drinking water “unsafe” for consumption. And what counts as “requisite” to protecting the public health will similarly vary with background circumstances, such as the public’s ordinary tolerance of the particular health risk in the particular context at issue. The Administrator can consider such background circumstances when “deciding what risks are acceptable in the world in which we live.” (citation omitted).

The statute also permits the Administrator to take account of comparative health risks. That is to say, she may consider whether a proposed rule promotes safety overall. A rule likely to cause more harm to health than it prevents is not a rule that is “requisite to protect the public health.” For example, as the Court of Appeals held and the parties do not contest, the Administrator has the authority to determine to what extent possible health risks stemming from reductions in tropospheric ozone (which, it is claimed, helps prevent cataracts and skin cancer) should be taken into account in setting the ambient air quality standard for ozone. (Citation omitted)/

The statute ultimately specifies that the standard set must be “requisite to protect the public health” “in the judgment of the Administrator,” § 109(b)(1), 84 Stat. 1680 (emphasis added), a phrase that grants the Administrator considerable discretionary standard-setting authority.

The statute's words, then, authorize the Administrator to consider the severity of a pollutant's potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate. (citation omitted). They permit the Administrator to take account of comparative health consequences. They allow him to take account of context when determining the acceptability of small risks to health. And they give her considerable discretion when she does so.

This discretion would seem sufficient to avoid the extreme results that some of the industry parties fear. After all, the EPA, in setting standards that "protect the public health" with "an adequate margin of safety," retains discretionary authority to avoid regulating risks that it reasonably concludes are trivial in context. Nor need regulation lead to deindustrialization. Pre-industrial society, was not a very health society; hence a standard demanding the return of the Stone Age would not prove "requisite to protect the public health."