

**STATEMENT OF**

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Hearing on Quality Science for Quality Air

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## **Major Points of Testimony of Roger O. McClellan – October 4, 2011**

- Clean Air Act is primary National Statute governing air quality issues in USA. The CAA requires the Administrator of the U.S. EPA to establish primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards for six criteria pollutants with science-based criteria to be reviewed every 5 years.
- Primary NAAQS are to be established by the EPA Administrator based on the “latest scientific knowledge” at levels “requisite to protect public health” while “allowing an adequate margin of safety” without considering the cost of implementing the standard.
- In March 2008 then Administrator Stephen Johnson revised the Ozone NAAQS as required by the CAA using the scientific record based largely on papers published in 2005 and earlier to inform his policy judgments. He retained (a) Ozone as the indicator for photochemical oxidants, (b) the averaging time of 8 hours, (c) the statistical form (the standard is attained when the 4<sup>th</sup> highest 8-hour average value over a 3-year period does not exceed the numerical level of the standard, and (d) reduced the level from 84 ppb to 75 ppb. In announcing his decision he noted that the Clean Air Scientific Advisory Committee had recommended the standard be set in the range of 60 to 70 ppb, advice based on a blend of science and their policy judgment.
- In January 2010, Administrator Lisa Jackson announced that she was going to “reconsider” Administrator Johnson’s policy decision and set the standard in the range of 60 to 70 ppb. She based this discretionary, arbitrary and capricious action on (a) her personal opinion that if she had been in office 22 months earlier she would have made a different policy choice, and (b) wrapped herself in a “cloak of science” saying I will follow the advice of CASAC. With this proposal she abdicated the specific and exclusive authority delegated to the EPA Administrator to make the policy judgments inherent in setting the NAAQS.
- On September 2, 2011, Administrator Cass Sunstein of the Office of Information and Regulatory Affairs/OMB, advised Administrator Jackson that her proposed final rule was: (a) not mandatory, produced needless uncertainty, and that her Agency was already proceeding with 5-year review cycle set to conclude in March 2013, (b) that her proposed final rule was not based on the latest science, and (c) the President had instructed Mr. Sunstein to return the rule to her – “He has made it clear that he does not support finalizing the rule at this time.”
- I applaud the actions of Administrator Sunstein and the President. My only regret is they did not have this “common sense” discussion with Administrator Jackson in early 2009. It would have avoided the misuse of the substantial EPA resources spent on this misadventure during 2009-2011.
- Building on recent experience in revising the NAAQS for Ozone and PM<sub>2.5</sub>, I will comment on the NAAQS setting process and the role of CASAC.
- I will emphasize that the language of the CAA and the efforts of narrowly focused advocacy groups may not be promoting, but rather damaging, public health.
- I urge the Congress to refocus the nation’s effort on public health revising the Clean Air Act, to allow consideration of costs in setting NAAQS, as part of an omnibus legislative package – “Promoting Public Health” that recognizes a healthy economy with people employed is the cornerstone of a healthy population.

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on the role of science in informing policy judgments on the setting of National Ambient Air Quality Standards.

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 50 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, including the Clean Air Scientific Advisory Committee (CASAC), which I chaired from 1988 to 1992 and on CASAC Panels that have considered all the criteria pollutants at various times. I served on the CASAC Panel that advised on the 2006 revision of the Particulate Matter MAAQS. I served on the CASAC Ozone Panel that reviewed the basis for the NAAQS promulgated in 1997. I did not serve on the most recent CASAC Ozone Panel. However, I closely followed the current NAAQS Ozone review process from its inception in September 2000 to present. The testimony I offer today reflects my own views on that review process and the science used to inform the policy judgments made in revising the NAAQS for Ozone. Attachment 2 is a reprint of a recent paper I authored entitled “Role of Science and Judgment in Setting National Ambient Air Quality Standards: How low is low enough?”, *Air Quality and Atmospheric Health* (published on-line: 01 June 2011).

### **EPA Administrator Johnson’s March 2008 Decision**

This morning I would like to comment on 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 Stephen Johnson. That 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 outcome desired by various parties – a lowering of the ozone standard – even before the review of the science was complete. That resulted in a blurring of the boundary between the role of science and judgment in the setting of the standard.

As I will discuss later, Administrator Lisa Jackson took advantage of the CASAC’s blended science and policy advice to initiate in January 2010 reconsideration of the March 2008 decision of then Administrator Johnson.

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 science and judgment in the setting of the standard. Numerous comments were submitted to the official ozone docket. I submitted my personal comments to the ozone docket and also joined with 9 of my scientific colleagues in submitting a document – “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 failed to acknowledge that the setting of the standard involves policy judgments informed by science. The debate has included repeated reference to the Clean Air Scientific Advisory Committee (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, the CASAC Ozone Panel never adequately communicated the extent to which the recommendations they 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 ozone standard. 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 Docket, 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 comments I and nine of my colleagues submitted to the Docket. Both sets of comments also emphasized that the selection of any specific numerical standard is a policy judgment 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.” The CASAC was advancing their collective 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 a collective 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 March 2008 Final Rule 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. The Rule goes on to state – “and fully considering the scientific and policy views of CASAC, the Administrator has decided to revise the level of the primary 8-hour O<sub>3</sub> standard to 0.075 ppm.” Without question, the Final 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.

### **Administrator Jackson’s Misadventure**

During 2009 there were rumors that the President Obama/Administrator Lisa Jackson Administration was going to “fast track” a “reconsideration” of the March 2008 Ozone NAAQS issued by then Administrator Stephen Johnson. Thus, it was not surprising when Administrator Jackson on January 19, 2010 announced a proposed

“reconsideration” Ozone NAAQS to be based on the record used to set the Standard in March 2008. This included the science used for the March 2008 policy decisions, scientific papers which had been published primarily in 2005 or earlier. By initiating the “reconsideration” action Administrator Jackson was in essence saying – “if I had been in office in March 2008 (nearly a year before being appointed and confirmed), I would have made a different policy judgment call.” In my opinion, Administrator Jackson’s action was totally discretionary, arbitrary, capricious and without precedent. I know of many NAAQS that have been revised by EPA Administrators in accordance with the Clean Air Act and using EPA’s now well-established formal rulemaking process. I know of no NAAQS established by a previous Administrator that has been “reconsidered” by a new Administrator based on the old and aging record.

In announcing the “reconsideration” proposal (EPA, 2010) Administrator Jackson put on the “cloak of science” and said that she would set the “reconsideration” standard in the range of 60 to 70 ppb following the advice of the CASAC Ozone Panel. In taking this course, she ignored the documented record of previous Administrator Johnson who noted that the advice of the CASAC Panel was a blend of science and policy. In the fall of 2008, the EPA was already initiating action on the next review of the Ozone NAAQS (Martin, 2008). In initiating the next review, it was noted that the CASAC advice on the previous review was “a mixture of scientific and policy considerations.” By proceeding with the “reconsideration” proposal based exclusively on the advice of the CASAC Panel, Administrator Jackson abdicated her responsibilities under the Clean Air Act to use her judgment in the setting of NAAQS.

The “fast track” reconsideration proposal turned out to be on a slow track with the target date for release of the final rule repeatedly revised. My suspicion was that Administrator Jackson and her senior advisors were continually spinning the “Ozone Science Kaleidoscope” in an attempt to have the science justify a specific numerical level. Indeed, in January 2011 Administrator Jackson went back to CASAC and asked for yet another opinion on the setting of the Ozone NAAQS. The CASAC Panel had a difficult time dealing with this serious question for several reasons.

First, the CASAC members found it difficult to offer an opinion on the old science since many of them were already involved in reviewing the new science that would inform policy judgments on potential revision of an Ozone NAAQS in March 2013. Second, the CASAC Panel meetings were actually teleconferences. With about 20 “official” participants such teleconferences are much like a “Tower of Babylon.” The third issue was the challenge of separating the Panel members’ views of the science from their personal policy preferences. The CASAC Chair, Dr. Jonathan Samet, wisely offered the following summary comment to Administrator Jackson in his letter dated March 30, 2011. Dr. Samet wisely noted that establishing a margin of safety was apparently a blend of science and policy. I offered comments to Administrator Jackson on Comments on EPA-CASAC-11-004 Clean Air Scientific Advisory Committee (CASAC) Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standards (Attachment 4).

Apparently Administrator Jackson and her senior advisors spun the “Ozone Science Kaleidoscope” without a firm endorsement of CASAC and in mid-summer sent

forward a final rule for review by OMB's Office of Information and Regulatory Affairs. Administrator Jackson has testified that she had proposed 70 ppb. I have seen no indication as to specifics of a revised Secondary Standard. It is important to recognize that the CASAC Ozone Panel (Henderson, 2008) in a letter dated April 7, 2008 based on a meeting scheduled even before then Administrator Johnson had issued a final rule protested both the Primary and Secondary Standard. They also expressed their displeasure with the involvement of then President Bush and Susan Dudley who then headed OMB's Office of Information and Regulatory Affairs. Such involvement was not a surprise to students of the history of the NAAQS process. President Clinton conferred with the EPA Administrator Carol Browner on the Ozone and Particulate Matter NAAQS revisions in 1997.

The misadventure of Administrator Jackson with the "reconsideration" Ozone NAAQS was brought to a close on September 2, 2011. The legal basis for the decision to abandon the "reconsideration" proposal is contained in a memo from Cass Sunstein, Administrator of the Office of Information and Regulatory Affairs within OMB (Sunstein, 2011) (Attachment 5). In his memo, he notes the proposed final rule was (a) not mandatory and produced needless uncertainty and that his Agency was already proceeding with the next review that should be concluded in March 2013, (b) her proposed final rule was not based on the latest science, recall the record is largely based on pre-2006 scientific publications, and (c) the President had advised Mr. Sunstein to return the proposal to Administrator Jackson – "He has made it clear that he does not support finalizing the rule at this time."

I applaud the actions of Mr. Sunstein and President Obama for making a sound common sense decision. My only regret is that the key parties had not conferred in early 2009 and never have launched this misadventure that wasted valuable EPA resources and those of many other interested parties. In this time of crisis, the scarce resources could have been used better on other endeavors. The really good news is that a potential precedent setting actions did not take place. It is hard to imagine the uncertainty and chaos that would occur if every change in Presidential Administration were to be accompanied by a new EPA Administrator that would "reconsider" the policy judgments of the previous EPA Administrator.

### **The Wrong Scientific and Policy Focus**

Remarkable progress has been made in improving air quality in the United States during the last four decades using the various regulatory tools provided by the Clean Air Act including the establishment of NAAQS. Clean air is automatically equated with better health. Every lowering of a NAAQS for each of the criteria pollutants has been justified on the basis of health benefits.

It has been argued by some that a linear relationship, without a threshold, exists between ambient concentrations of criteria pollutants and increased risk of morbidity and mortality over and above the baseline morbidity or mortality rate. Some scientists have argued that the absence of a threshold and a linear concentration-response relationship extends to background concentrations. Using that logic, which I do not necessarily agree with, it can be argued that health benefits result from every reduction in concentration,

even reductions in background. With this flawed logic and a prohibition in considering cost in setting NAAQS the answer to how low is low enough becomes zero. That is hardly realistic and certainly does not meet the common sense comparative health approach advanced by Supreme Court Justice Breyer.

In my view the USA is reaching a point of diminishing returns in setting the NAAQS at lower and lower concentrations with each review and treating each reduction as a success story for public health. In examining this viewpoint it is important to remember that each NAAQS is a federal goal. The achievement of the goals is by and large left to the States through the development of State Implementation Plans and their actual implementation and, finally, to actions on the part of private firms and the public.

In my opinion, this approach is flawed in that it fails to recognize any untoward consequences of setting lower standards and attempting to attain them. I submit the untoward consequences may be substantial. Let me illustrate by discussing health impacts using a common metric-all-cause mortality. Major population studies have suggested that a  $1 \mu\text{g}/\text{m}^3$  increase in Particulate Matter – 2.5 micron size causes a 0.5% increase in mortality. You may not recognize the 0.5% value because it is usually expressed as 2.5% increase per  $5 \mu\text{g}/\text{m}^3$  of  $\text{PM}_{2.5}$ . In reality, 5 to  $10 \mu\text{g}/\text{m}^3$  is the background level for  $\text{PM}_{2.5}$  in most areas in the USA. Does it make sense to talk about a  $5 \mu\text{g}/\text{m}^3$  change in  $\text{PM}_{2.5}$ ? In my opinion, No! Thus, I use a more realistic  $1 \mu\text{g}/\text{m}^3$  change.

Some population studies suggest a 0.24% change in mortality for a 5 ppb change in 8-hour Ozone concentration. Again, you may not recognize the value because it has frequently been presented as 3.6% for a 75 ppb change in 8-hour Ozone. This is hardly a realistic presentation recognizing background levels for the 8-hour highest ozone concentrations approaches 60 ppb, the level simulated by models when all man-made ozone precursors are shut off. I view a 5 ppb shift in Ozone as being more realistic.

Let me now turn to a real risk factor -- socio-economic status (SES). The ratio of the mortality rate for all-cause mortality for men in the lowest quartile of SES over the top quartile was found to be 2.02 by Steenland et al. (2004). In other words, a doubling of the mortality rate by dropping from the top quartile to the bottom quartile. Put another way, moving to the second quartile from the lowest quartile reduced the ratio to 1.69 and a move from the second to the third quartile reduced the ratio to 1.25. Socio-economic status matters – employment and jobs matter. If the U.S. wants to improve the health of the Americans we need to create employment – JOBS.

Setting aside the issue of socio-economic status, does it make sense to keep pursuing risk factors that only contributes marginally to our overall burden of disease? I think the answer is No! Recognizing the small estimated burden of disease attributed to air pollution, it would appear to make more sense to pursue what are the major factors that contribute to the baseline incidence of disease. For example, there is appropriate increasing concern for rising asthma rates. However, when it is recognized that air pollution decreased substantially while asthma rates increased, it would appear that the focus on air pollution and asthma is misdirected.



## **A Path Forward**

I am increasingly concerned that our policy for advancing public health is being driven by advocacy groups with narrow interests. Perhaps it is time for all the advocacy groups to step back and ask what can be done to further improve the health of all Americans. A starting point is to recognize that the steady progress made in improving the health of Americans over the last half century has been driven by a strong economy that provided jobs and improving income. Perhaps the answer to the question of how low is low enough for each of the NAAQS is low enough for now. I suggest it is appropriate for time out on moving the goal posts.

I urge the Congress to refocus the nation's effort on public health revising the Clean Air Act, to allow consideration of costs in setting NAAQS, as part of an omnibus legislative package – “Promoting Public Health” that recognizes a healthy economy with people employed is the cornerstone of a healthy population.

## **Attachments:**

- 1 - Roger O. McClellan's Biographical Sketch
- 2 - Reprint of McClellan's manuscript
- 3 - Justice Breyer on Using Policy Judgment (from *Whitman v. American Trucking Association*, 531 U.S. 457, 473)
- 4 - Letter to Lisa Jackson -- Comments on EPA-CASAC-11-004 CASAC Response to Charge Questions on the Reconsideration of the 2008 Ozone NAAQS
- 5 - Cass Sunstein, Administrator of the Office of Information and Regulating Affairs within OMB Memo on Ozone

## **References**

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