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Comments on  
Proposed “Reconsideration” National Ambient Air Quality Standard for Ozone  
for presentation to the  
Clean Air Scientific Advisory Committee Ozone Panel  
U.S. Environmental Protection Agency

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I am Roger O. McClellan, an advisor to private and public organizations on inhalation toxicology and human health risk analysis issues. I have a long-standing interest in air quality issues. I have served in multiple scientific advisory roles with the U.S. Environmental Protection Agency. I have served on numerous Clean Air Scientific Advisory Committee (CASAC) panels dealing with all the criteria air pollutants, including ozone, and served as Chair of CASAC for four years.

It is my understanding today that the CASAC will be considering the “reconsideration” Standard for ozone recently proposed by Administrator Lisa Jackson. I appreciate the opportunity to share with you my views on that Standard. By way of background, I commented in October 2007 on Administrator Johnson’s proposal to revise the 1997 ozone Standard. I intend to submit written comments on the 2010 “reconsideration” proposal. It is my understanding that Administrator Jackson is considering exactly the same scientific information considered by Administrator Johnson in setting the 2008 Standard. Of course, Administrator Jackson may offer different policy judgments in revising the Standard.

I offer the following comments for consideration by CASAC as it begins its deliberations.

(1) In offering advice to the Administrator on the proposed “reconsideration” Standard, I urge CASAC to clearly distinguish between its views on the science that will inform the Administrator’s policy judgments on the final rule and the personal policy judgments of committee members as to the level and statistical form of the Standard.

(2) Scientific information alone is not sufficient to set a Standard. This is the case because the setting of a standard requires judgment as to an acceptable level of risk associated with the level of the Standard. Science alone cannot establish an acceptable level of risk.

(3) Thus, when CASAC offers a specific recommendation as to the level and form of a standard, it is offering a policy judgment as to an adequate margin of safety or acceptable level of risk for the pollutant at the recommended ambient level and form.

(4) The CASAC recommendation to Administrator Johnson that he set an 8-hour primary ozone standard in the range of 60 to 70 ppb represented the Committee's policy judgment, not merely a statement of the science. All members apparently preferred, as a matter of judgment, that the standard be set below 70 ppb. However, some members viewing the same science offered the judgment that the Standard should be set as low as 60 ppb. For neither value did CASAC give a clear explanation for the judgment as to why these ambient levels of ozone had acceptable levels of risk nor why the standard could not be set at some higher based on judgment.

(5) Administrator Johnson, using the judgment exclusively reserved to the Administrator under the Clean Air Act in 2008, set the 8-hour primary standard for ozone at 75 ppb.

(6) Giving deference to the collective policy judgment advice of CASAC, Administrator Jackson is now "reconsidering" the same scientific information used in setting the 2008 Standard and proposing to set the standard at some level within the range of 60 to 70 ppb.

(7) To inform the Administrator's policy decision, it is crucial that CASAC accurately describe in quantitative terms the nature of the science that the Administrator should consider in making a policy judgment to retain the Standard at 75 ppb or set a revised Standard at 70 ppb, 65 ppb or 60 ppb. It is not sufficient for the CASAC to merely state its preferred policy preference outcome – that judgment is reserved for the Administrator.

(8) I urge CASAC to recognize the following points concerning ambient ozone in reviewing and commenting on the science that should inform policy judgments in setting the Standard.

(a) Background levels of ozone vary markedly across the United States and for many locations are under-estimated by the previously described "Policy Relevant Background," that was clearly a policy judgment – not a statement of scientific fact.

(b) There is substantial heterogeneity in short-term mortality associated with ozone across the U.S. The vast majority of cities, including many that would be in non-attainment for a standard set at 70 ppb, show no statistically significant association between elevated ozone and short-term mortality. Very few cities show statistically significant associations between elevated ozone and short-term mortality. Moreover, those cities are generally in non-attainment with the 75 ppb Standard set in 2008 and many were in non-attainment with the 84 ppb Standard set in 1997.

(c) The clinical studies to be considered in setting a “reconsideration” standard do not provide convincing evidence of clinically significant effects with exposures below 80 ppb.

In my opinion, the scientific information on ambient ozone and its health effects and the policy judgment authority given the Administrator under the Clean Air Act allow Administrator Jackson substantial latitude in selecting a level and statistical form for a “reconsideration” primary NAAQS for ozone. The decision will be driven by her policy judgment choices, not by the science.

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, 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 fails to note the thoughtful advice of Justice Breyer and is lacking in the “comparative health orientation” he advocated. I urge CASAC to comment on this deficiency in the proposed rule.

The views I have shared with you today are my own professional views. While I have been engaged by the American Petroleum Institute (API) to review EPA’s proposed “reconsideration” ozone standard, the views I have expressed today are not necessarily those of the API.

Thank you for the opportunity to speak to you today.