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United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510–6175

June 3, 2014

Dr. H. Christopher Frey
Chair, EPA Clean Air Scientific Advisory Committee & Ozone Review Panel
Distinguished University Professor
Department of Civil, Construction, and Environmental Engineering
North Carolina State University
Raleigh, NC 27695-7908

Dear Dr. Frey:

Last week, the Clear Air Scientific Advisory Committee (CASAC) Ozone Review Panel ("the Panel") met via teleconference to attempt to finalize its review of and recommendations on EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standard (PA), Second External Review Draft; Welfare Risk and Exposure Assessment (WREA) for Ozone, Section External Review Draft; and Health Risk and Exposure Assessment (HREA) for Ozone, Second External Review Draft*. The short meeting left unresolved the disposition of key scientific issues that could very well direct the outcome of this important rulemaking. During the call, it became clear that individual CASAC members were still grappling with fundamental issues, not having sufficient time to fully absorb the meaning and implication of testimony received. Key issues left unresolved include:

- *Assessing the Impact of Attainment and Maintenance Strategies*: The call ended without a clear roadmap for how and when CASAC will address the Clean Air Act (CAA) mandate under Section 109(d)(2)(C)(iv) to 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" the lowered ozone NAAQS. A plain reading of the CAA finds that CASAC, in order to meet its statutory obligations, is to evaluate strategies that will be needed to attain and maintain a lowered ozone NAAQS and to advise the Administrator of the adverse effects that will result from those strategies. This advice is to be provided at the same time as other matters upon which CASAC is legally bound by the CAA to advise the Administrator. As of yet, however, there is no plan on how the Panel will accomplish this legal requirement. Given the stringent levels under discussion, the Panel should provide ample opportunity to receive testimony from state and business representatives who will face the challenge of meeting these very low proposed ozone levels. It is incumbent on the Panel that it address this significant omission before moving forward.

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- *Modeling of a Threshold and Its Implications for EPA's Mortality Benefits:* The Panel received significant new evidence supporting the validity of a threshold model for mortality risks from long-term exposure to ozone. Using alternative statistical approaches, the testimony definitively illustrated that a threshold model of 56 ppb provides the best fit for the data.[1] I urge the Panel to endorse this evidence-based approach and to recommend that EPA adopt this threshold model as its core risk assessment result. Although the Panel's statements so far suggest that the mortality data will not be as important in shaping its recommendations as the data on other potential health effects, the Agency will still rely on its core risk assessment to develop benefit estimates that could be highly misleading unless the core model properly reflects the scientific evidence. It is critical that the Agency use the most scientifically supported model as its core estimate if any estimate is to be made at all for mortality risk from long-term exposure.

- *Persistent Errors in the Mortality Data and EPA's Inability to Conduct Its Own Quality Control.* It is unacceptable that EPA continues to make fundamental errors in its estimation of mortality benefits. In my May 19, 2014, letter, I noted that a witness reviewing the draft report identified significant errors which, when corrected, could show a roughly 30 to 82 percent lower estimate of risk in the inner city areas than what was included in the draft HREA. In fact, all of the total risk estimates for the urban study areas in Chapter 7 and its appendices were incorrect. On April 28, 2014, and on May 9, 2014, EPA issued memoranda correcting these errors.[2] Unfortunately, a witness reviewing EPA's "corrections" memoranda found new errors in the tables that provide mortality estimates for inner cities from short-term exposure and mortality estimates for larger population areas from long-term exposure. This pattern of persistent errors significantly undermines all confidence in EPA's technical abilities and reinforces the need for increased transparency. It also supports my longstanding concern over EPA's failure to obtain the underlying data from the key studies upon which EPA relies to estimate mortality benefits. Although the epidemiologic studies are different in nature from EPA's risk calculations, the lack of transparency and scientific vetting prevent errors from being discovered. This is unacceptable in important rulemakings such as this one.

- *CASAC Should Receive and Review a Third Draft HREA and PA Prior to Issuing Recommendations*: It was clear from the rushed call on May 28, 2014 that the CASAC

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[1] According to testimony submitted, the 56 ppb threshold in the Jerrett *et al.* study (Jerrett, Michael, R. T. Burnett, C. A. Pope, III, K. Ito, G. Thurston, D. Krewski, Y. Shi, E. Calle, M. Thun 2009. "Long-Term Ozone Exposure and Mortality." *New England Journal of Medicine* 360:1085-1095.) is equivalent to a NAAQS level that is higher than the current standard of 75 ppb in 10 of the 12 urban areas studied. This is because the study looks at the average of each day's maximum 1-hour ozone level from April to September rather than the three-year average of the annual fourth highest daily maximum eight-hour ozone concentration.

[2] While at first, EPA committed to correcting only the tables in Chapter 7 before the May 28th CASAC call (without correcting the many additional tables that appear in the Appendices to Chapter 7 that show the base-case risks), the Agency released corrections to the tables on May 9, 2014.

process would benefit from developing and reviewing a third draft of the HREA and PA. Not only would errors be fully corrected, but CASAC members would be provided the opportunity to reflect on the corrected data. The additional time would also allow CASAC members to review and assess new issues that have been raised.

These are critical issues worthy of additional time and evaluation by EPA and CASAC.

Sincerely,

David Vitter
Ranking Member
Environment and Public Works

cc: Gina McCarthy, Administrator, EPA
Janet McCabe, Acting Assistant Administrator, Office of Air and Radiation, EPA
Dr. Holly Stallworth, CASAC Designated Federal Officer
Members, CASAC Ozone Review Panel