
Ex Parte Meeting Summary: Ozone NAAQS

Date: December 20, 2007, 9:00 – 10:00 am

Attendees:

Visitors:

Dr. Anne E. Smith
Vice President
CRA International
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Dr. Roger McClellan
Advisor, Toxicology and Human Health Risk Analysis
13701 Quaking Aspen PI NE
Albuquerque, NM 87111

Dr. Richard Smith
Mark L Reed III Distinguished Professor of Statistics
Department of Statistics and Operations Research
University of North Carolina,
Chapel Hill NC 27599-3260

Dr. Mark Utell
Professor of Medicine and Environmental Medicine
University of Rochester Medical Center
601 Elmwood Avenue,
Rochester, NY 14642

EPA attendees:

George Gray, ORD
Pamela Williams, ORD
Bob Fegley, ORD
John Vandenberg, ORD
Bill Briggs, Office of Public Outreach, EPA
Ila Cote, ORD
Lydia Wegman, OAR
Harvey Richmond, OAR
Dave McKee, OAR
Mary Ross, ORD
Debra Walsh, ORD
Jim Brown, ORD

Tom Bateson, ORD
John Langstaff, OAR

Summary of discussion:

Dr. McClellan introduced the visitors as contributors to a workshop report submitted to the Ozone Docket (“the Rochester Report) and that individual comments also had been submitted to the Docket by Dr. McClellan including input from Dr. Richard Smith, and also individual comments had been submitted to the Docket by Dr. Anne Smith.

Dr. Utell summarized background on the Rochester workshop and related Report and noted that the goal was to review and evaluate ozone evidence germane to setting ozone policy. He stated their concentration was on areas of uncertainty, that they did not focus on developing recommendations regarding the NAAQS, and that Dr. McClellan had taken the lead on writing up the workshop report. There was no EPA nor API (the organization that funded the workshop) input on the Rochester Report.

Dr. McClellan stated that there was controversy regarding national background levels of ozone (i.e., policy relevant background, PRB) related to the ‘bluntness’ of the geochemical model used by EPA to estimate PRB, and that air quality related to ozone had been improving. Dr. Gray asked the visitors if they were aware of better alternatives to the current model and Dr. McClellan indicated there was “no right way” but that alternative approaches (not specified) added comfort to the interpretation of model results. Dr. Anne Smith noted that the comparison of model outputs and monitoring data indicated variability in time and space (e.g., the monitors at Trinity Head were double the modeled PRB). Dr. McClellan stated there was no simple algorithm with respect to estimation of policy relevant background.

Dr. Utell then described the human clinical evidence reviewed at the Rochester workshop. He stated that whereas there was substantial new evidence at the time of the [1997] ozone NAAQS review, there was but one “interesting and important” new study for the current review, the Adams study. Further, he stated there was a debate over the interpretation of the findings from the Adams study and, as there is uncertainty related to there just being this one study, the clinical evidence was inconclusive. Dr. Richard Smith then summarized the use of the Scheffe correction for multiple comparisons and stated the Adams study did not provide definitive conclusions and needed replication.

Dr. Gray asked the visitors to comment on how human exposure chamber ozone concentrations related to ambient ozone exposures. Dr. Utell stated that chamber exposures “pretty nicely” represent ambient ozone exposures.

Dr. McClellan then noted comments on the other line of evidence, related to epidemiological evidence, had been submitted in his docket comments and was summarized also in the Rochester Report. Dr. Richard Smith then summarized the Rochester approach to literature review and that he had some additional unpublished data analysis, including analysis of NMAPPs data that had not been fully elaborated in the

Dominici paper (JAMA, 2004). Dr. Richard Smith stated that his unpublished analyses were based on 24-hour ozone metric, and there was substantial intercity variability in effects due to copollutants, for example particulate matter. Dr. Richard Smith did not provide to the participants any copies of his unpublished analyses.

Dr. Anne Smith then discussed her docket comments on the evaluation of time series data. She stated that there is a risk distribution across days e.g., most of the risk is from days with less than 60 ppb ozone. Her analyses of days with ozone above 70 ppb, and of days above the current standard, indicate small relative risks at current exposure levels. Further, she stated that in the ozone NAAQS proposal that EPA had collapsed risk estimates down to simple aggregate estimates of risk, and that in her opinion this was inappropriate. She stated that city-specific risk estimates show risks above 70 ppb were small with a broad range of uncertainty.

Dr. Anne Smith then commented on policy relevant background (PRB). She stated that much of the risk that was estimated was due to exposures near PRB and therefore the risks estimates near PRB were speculative. For example, she stated that risks can decrease by 50% or more with small PRB changes, and she stated that this “squishiness” needed to be communicated (she pointed to Figure 2 in the Rochester Report as relevant to this point).

Dr. McClellan then made some concluding statements, that the Rochester workshop participants had not stated a preference with respect to the NAAQS, that the limitations in evidence made for a tough decision, and that science doesn’t drive the policy but judgment was needed. Further, Dr. McClellan felt that CASAC combined both science and policy in their development of NAAQS recommendations and in his opinion the level of discourse was not as high as had been the case in prior reviews. Lydia Wegman noted to Dr. McClellan that CASAC had many lengthy discussions of the ozone evidence over a several year period that such discussions had served as the basis for their recommendations to the Administrator.

Dr. Gray thanked the visitors for their time, noted that the Administrator had not decided about the NAAQS, and that their comments had been heard and the comments played an important role in the decision process.