

**Summary Minutes of the Clean Air Scientific Advisory Committee (CASAC)  
Particulate Matter (PM) Review Panel Public Meeting**

**Tuesday, July 20 & Wednesday, July 21, 2004**

**Embassy Suites Hotel, Raleigh-Durham-Research Triangle East,  
201 Harrison Oaks Boulevard, Cary, North Carolina**

Panel Members: See Panel Roster – Appendix A

Dates & Times: Tuesday, July 20, 2004, 8:30 AM – 5:00 PM Eastern Time  
Wednesday, July 21, 2004, 8:30 AM – 1:45 PM Eastern Time

Location: Embassy Suites Hotel, Raleigh-Durham-Research Triangle East,  
201 Harrison Oaks Boulevard, Cary, North Carolina

Purpose: The purpose of this meeting was for the CASAC PM Review Panel to discuss the June 2004 revisions to Chapter 7 (Toxicology of Particulate Matter in Humans and Laboratory Animals); Chapter 8 (Epidemiology of Human Health Effects Associated with Ambient Particulate Matter); and Chapter 9 (Integrative Synthesis) of the Fourth External Review Draft of the Air Quality Criteria Document (AQCD) for PM.

Attendees: Chair: Dr. Philip Hopke

CASAC Members: Dr. Ellis Cowling  
Dr. James Crapo  
Dr. Frederick Miller  
Mr. Richard Poirot  
Dr. Frank Speizer  
Dr. Barbara Zielinska (July 20 only)

Consultants: Dr. Jane Keonig  
Dr. Petros Koutrakis  
Dr. Allan Legge  
Dr. Morton Lippmann (July 21 only)  
Dr. Joe Mauderly  
Dr. Gunter Oberdorster (July 21 only)  
Dr. Jonathan Samet (July 20 only)  
Dr. Sverre Vedal (July 20 only)  
Dr. Robert D. Rowe  
Mr. Ronald White  
Dr. Warren White  
Dr. George Wolff

EPA SAB Staff: Mr. Fred Butterfield, CASAC Designated Federal  
Officer (DFO)  
Dr. Vanessa Vu, SAB Staff Office Director

Other EPA Staff: John Bachmann, OAR, OAQPS  
Tim Benner, ORD, OSP  
James Brown, ORD, NCEA-RTP  
Robert Fegley, ORD, OSP  
Jay Garner, ORD, NCEA-RTP  
Lester Grant, ORD, NCEA-RTP  
John Hannon, OGC, ARLO  
Marion Hoyer, OAR, OTAQ  
Jee Young Kim, ORD, NCEA-RTP  
David Kryak, ORD, NERL-RTP  
Russell Luepker, American Heart Association (AHA)  
Tara Lyons-Darden, NHEERL-RTP  
Karen Martin, OAR, OAQPS  
Lucas Neas, NHEERL-RTP  
Jack Puzak, ORD-NCER  
Marti Reinfeld, OA, OPEI  
Harvey Richmond, OAR, OAQPS  
Mary Ross, OAR, OAQPS  
Bill Russo, ORD, NHEERL-RTP  
Vicki Sandiford, OAR, OAQPS  
Chon Shoaf, ORD, NCEA-RTP  
Steve Silverman, OGC, SWERLO  
Susan Stone, OAR, OAQPS  
David Svendsgaard, ORD, NCEA-RTP  
John Vandenberg, ORD, NCEA-RTP  
Jim Vickery, ORD-NERL-RTP  
Lori White, ORD, NHEERL-RTP  
William Wilson, ORD, NCEA-RTP

Other participants: Bryan Baldwin, Southern Co.  
Andrew Ballard, Bureau of National Affairs, Inc (BNA)  
Bob Bessette, Council of Industrial Boiler Owners  
(CIBO)  
Kurt Blase, O'Connor and Hannan  
Robert Connery, Holland & Hart, LLP (on behalf of  
the National Cattlemen's Beef Association)  
Michael Corvese, Thermo Electron Corp.  
Thomas Grahame, U.S. Department of Energy (DOE)  
Daniel Greenbaum, Health Effects Institute (HEI)  
Bob Hermanson, BP America  
Jon Heuss, Air Improvement Resource, Inc. (AIR)  
Philip Johnson, Northeast States for Coordinated Air  
Use Management (NESCAUM)  
Alex Karafilidis, Thermo Electron Corp.  
Cindy Langworthy, Hunton & Williams  
Allen Lefohn, A.S.L. & Associates

Jonathan Lewis, Clean Air Task Force (CATF)  
David Menotti, Shaw, Pittman, Potts & Trowbridge  
(SPPT), LLP  
Will Ollison, American Petroleum Institute (API)  
Ellen Post, Abt Associates  
Greg Shaefer, Arch Coal (on behalf of the Coalition for  
Coarse Particle Regulation)  
Anne Smith, Charles River Associates, Inc. (CRA)  
Joseph Suchecki, Engine Manufacturers Association  
(EMA)  
Deborah Shprentz, American Lung Association (ALA)  
Jeff West, NARSTO

### Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda (Appendix B), although the meeting adjourned at 1:45 PM on the second day (July 21).

### **TUESDAY, JULY 20, 2004**

#### Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the teleconference, called attendance, and welcomed all attendees. He noted that the CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the EPA Administrator. Consistent with FACA regulations, its deliberations are held as public meetings and teleconferences for which advance notice is given in the *Federal Register*. The DFO is present at all such meetings to assure compliance with FACA requirements. Meeting minutes were taken (by the DFO) for this teleconference. The minutes will be certified by the CASAC (and PM Review Panel) Chair and made available on the SAB Web site ([www.epa.gov/sab](http://www.epa.gov/sab)). All Panelists have earlier submitted documentation with respect to possible financial conflicts-of-interest, which was reviewed by a SAB staff member prior to the meeting and found to be satisfactory.

Dr. Vanessa Vu, SAB Staff Office Director, thanked the Chair and members of the CASAC PM Review Panel for taking part in this review. She also gave special thanks to Dr. Les Grant and his colleagues within the Office of Research and Development (ORD), the National Center for Environmental Assessment (NCEA-RTP), as well as to EPA managers and staff from the Office of Air and Radiation (OAR).

#### Purpose of Meeting

Dr. Phil Hopke, CASAC and PM Review Panel Chair, briefly stated the purpose of the meeting. He reminded Panel members of their task to ensure that this Air Quality Criteria Document for particulate matter represents an adequate and fair summary of the science as it is known at this

time. Dr. Hopke hoped that the Panel would be able to move through the updated Chapters 7 (toxicology) and 8 (epidemiology) on the first day of the meeting, leaving their review of the new draft of Chapter 9 (Integrative Synthesis) to the second day.

#### Overview of Revisions to Chapters 7-9 of EPA's 4<sup>th</sup> Revised Draft AQCD for PM

Dr. John Vandenberg, Acting Associate Director for Health, NCEA-RTP, gave brief welcoming remarks, in which he thanked both the Panel members and his staff for their significant efforts in reviewing and producing the multiple revisions to this document, respectively.

He was immediately followed by Dr. Les Grant, Director of NCEA-RTP, who presented an overview of the revisions to the updated chapters of the document (Appendix C). This was followed by an overview on the revisions to Appendix 7A given by Drs. William Wilson and Jim Brown, also of NCEA-RTP.

#### Public Comment Period

Mr. Butterfield kicked-off the public comment period by reminding speakers to limit their oral statements to no more than five minutes. (See Appendix D for a summary listing of all public speakers.)

#### **Dr. Samuel Dorevitch (M.D., M.P.H.), Occupational Medicine Residency Program, University of Illinois at Chicago**

Dr. Dorevitch made two broad points. The first is that, despite the existence of open questions regarding particulate matter, the Agency's current draft air quality criteria document for PM is an excellent distillation of the current state of the science. Dr. Dorevitch's second point addressed the issue of thresholds. He noted that, for each size fraction of particulate matter that it regulates, EPA must specify a standard, or an upper limit of the concentration of particulate matter that is acceptable. Dr. Dorevitch stated that a very convincing body of evidence demonstrates that negative health effects are seen in association with PM levels well below the current standards. He concluded by encouraging the CASAC to review the next draft OAQPS PM Staff Paper with the question in mind as to whether or not the current PM standards are adequately protecting the health of the public, offering his opinion that, based on a wealth of scientific studies, the current exposure standards for PM should be lowered to help the EPA achieve its stated mission.

#### **Dr. Allen Lefohn, A.S.L. & Associates**

Dr. Lefohn presented integrated comments from himself and Professor Paul Switzer from the Department of Statistics, Stanford University. Commenting on the Agency's conclusions in sections 8.5 and 9.2.2 of the revised AQCD for PM which assert that epidemiologic studies demonstrate a consistent pattern of PM association with mortality, and that PM is likely to be causally related to health endpoints, Professor Switzer's conclusion is that, without a clear understanding of the reasons for the inconsistent effects estimates, the possibility that the PM effect estimates are modeling artifacts cannot be ruled-out. Dr. Lefohn also commented that a separate 24-hour standard is superfluous under presumed linearity of exposure-response in the

models that the Agency used for the epidemiological studies in Chapter 8 of the AQCD for PM, and that any proposal for a separate 24-hour standard necessarily must acknowledge a non-linear exposure-response relationship. He also noted inconsistencies associated with the correlation coefficients used to assess spatial variability used in Chapters 5, 8 and 9. In conclusion, Dr. Lefohn commented that the PM assessment contains serious inconsistencies and inconclusive study results.

**Dr. Ron Wyzga, Electric Power Research Institute (EPRI)**

Dr. Wyzga commented on one of his issues of concern as it relates particularly to the time-series studies. A point that he believes is highlighted but not given adequate attention is essentially the whole issue of temporal adjustment, and that these are basically results taken from a few of epidemiological studies that looked at the impact of PM<sub>2.5</sub> and mortality. Dr. Wyzga's point is that you see positive associations in all cases; in some cases, they are not significant, but you see wide variability, which contributes to his overriding concern that there is a tremendous amount of uncertainty. He also believes that a lot more attention could be given to organic compounds. Finally, Dr. Wyzga noted that, in general, while there were no consistent results for respiratory endpoints, the interesting thing is that in eight of the nine studies that looked at cardiovascular endpoints, when you put both British smoke and PM in the same model, British smoke remained significant and positive, and that it dominated PM.

**Ms. Deborah Shprentz, Consultant to the American Lung Association (ALA)**

Ms. Shprentz asked the question as to whether the revised air quality criteria document for PM “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities” — adding that the ALA believes the answer is plainly affirmative, and therefore urging the CASAC to reach closure on the PM AQCD. Ms. Shprentz remarks that EPA staff have prepared a thorough and balanced review of the scientific evidence of the health effects of particulate matter; have carefully distilled over two thousand new studies conducted since EPA's last review on 1996; and have prepared a comprehensive and multidisciplinary, albeit cautious, assessment of the most salient new findings. She also noted that the conclusions of this PM AQCD are in line with mainstream scientific opinion, *e.g.*, the National Academy of Sciences (NAS), the World Health Organization (WHO) Working Group on Health Aspects of Air Pollution, and the American Heart Association (AHA). Ms. Shprentz commented that the health studies summarized in the AQCD for PM point to the critical need to strengthen the long- and short-term air quality standards for fine particles, and to set stringent new standards for coarse particles. The one aspect of this draft AQCD that ALA would like to take issue with relates to the discussion of adverse health effects on infants and children, which they believe is too cautious in light of recent studies of note.

**Dr. Russell Luepker (M.D.), University of Minnesota, School of Public Health, Division of Epidemiology (speaking on behalf of the AHA)**

Dr. Luepker talked about his work with the American Heart Association and how AHA issued their statement on “Air Pollution and Cardiovascular Disease” (2004) because cardiovascular disease is the leading cause of death in the U.S. and critical to the American Heart Association's mission. AHA also concluded: that there was growing evidence that air pollution played a role

in death and disability from heart disease and stroke; that it was analogous in many ways to something with which they had a lot of experience, *e.g.*, local pollution and cigarette smoking; and that there were also a growing number of plausible mechanisms, based on experimental studies. AHA looked at a broad spectrum of literature and saw modest but generally consistent effects in a number of diverse studies in terms of short-term illness. They also saw long-term effects and, again, modest effects in terms of relative risk. In addition, the Association looked at the scientific literature (largely the animal literature). The cardiologists and some physiologists on the committee saw a number of mechanisms that were both plausible and reasonable, ranging from autonomic system stimulation leading to arrhythmias and potentially plaque rupture to oxygen stress and adrenal dysfunction and activation of the clotting mechanisms — all of which are well-recognized as being involved both in the long-term genesis of atherosclerosis as well as in acute triggers of events such as heart attack and stroke. Accordingly, AHA came to a number of recommendations that are published in its statement. Dr. Luepker also commented that the current standards needed to be implemented, at the very least, but that more stringent standards, particularly for PM<sub>2.5</sub>, should be strongly considered.

**Mr. Daniel Greenbaum, President Health Effects Institute (HEI)**

Mr. Greenbaum commented these revised chapters result in an improved PM air quality criteria document, noting that the AQCD continues to summarize the key findings since 1996, including generally stronger epidemiologic evidence on long-term effects, and the advent of more rigorous and systematic multi-city epidemiology studies for short-term effects. Mr. Greenbaum noted other improvements such as: the inclusion of significantly more toxicology on the mechanisms and effects of different components; a better integrated epidemiology and toxicology discussion in several chapters of what we do and do not know about effects of different components of PM; and, in Chapter 8, a more extensive discussion of the time-series studies, questions and model speciation issues. At the same time, Mr. Greenbaum commented there are several challenges in this document, such as: Chapter 9 is inadequate with respect to dealing with the remaining uncertainties, a discussion on heterogeneity, and a summary of the knowledge on questions on mechanism; the treatment of role of gaseous pollutants from epidemiology studies; an inadequate discussion with respect to mutagenesis as how such results are not often the strongest predictors of cancer in either animals or humans; and too-heavy reliance on the bulk of toxicology results which have been instillation results while not including a careful description of some of the limitations of these results.

**Mr. Philip Johnson, Northeast States for Coordinated Air Use Management (NESCAUM)**

Mr. Johnson reviewed the mission of NESCAUM and noted that areas they represent — the six New England states, New York and New Jersey — includes 41 million persons, with extremely high population density. He also remarked that the majority of this population happens to live in areas which coincidentally have the highest PM levels. Mr. Johnson discussed what percent of the population in NESCAUM states would benefit from additional controls as a result of more stringent PM fine standards. In conclusion, he stated that NESCAUM believes that EPA and the U.S. Centers for Disease Control (CDC) should develop a common framework for future health serving priorities, which could provide insights into disease by altering behavioral variability among regions, states, and metropolitan areas, commenting that, with an urban-scale emphasis, the scientific and policy communities could also gain insights into high-risk populations who

reside near source downwind environments. In addition, NESCAUM believes that, with respect to the heterogeneity findings and some of the national epidemiological studies which suggest that the Northeast and Midwest may have higher health effects, harmonization of work with the CDC could provide a better glimpse into why this is happening. And, finally, Mr. Johnson offered the comment that this would provide greater understanding of how the National Ambient Air Quality Standards (NAAQS) for PM will affect sensitive populations across the country.

**Mr. Jonathan Lewis, Clean Air Task Force (CATF)**

Mr. Lewis commented that the current version of the criteria document (CD) for particulate matter is a comprehensive and robust review of the recent medical research on the health effects of particulate matter. CATF believes that the CD provides an adequate basis for revision of the National Ambient Air Quality Standards for particulate matter. EPA should move to finalize the CD expeditiously based on this version. Mr. Lewis noted what he called a “wide divide” that exists between estimated annual health damages caused by PM and EPA’s projected approximate 15,000 avoidable deaths from attaining the NAAQS for PM in the NAAQS Regulatory Impact Analyses (RIA); therefore, he concluded that the level of the NAAQS is insufficiently protective, and furnished studies which provided estimates suggesting that tens of thousands of premature deaths will continue to occur annually despite the attainment of the PM NAAQS. Mr., Lewis wrapped-up his comments by stating that EPA should now begin to focus on finalizing the Staff Paper for PM and moving toward a final decision revising the PM NAAQS. The CATF believes that the strong medical research evidence from the cohort and time-series studies and subsequent HEI reanalyses compels the Agency to move toward significantly more protective standards as indicated in EPA’s first draft of the PM staff paper. In this regard, CATF strongly support the Agency’s move towards the lower end of the more protective ranges for the annual- and 24-hour standards in the first draft of the PM Staff Paper that better reflect the science documented in the PM air quality criteria document.

**Mr. Robert Connery, of Holland & Hart LLP, representing the National Cattlemen’s Beef Association (NCBA)**

Mr. Connery gave a presentation entitled, “Coarse PM: A Vital Policy Issue for the West.” In this briefing, Mr. Connery argued that there were insufficient health-effects data to support a standard for coarse-fraction particulate matter (PM<sub>c</sub>) at this time, offering as a possible solution either the exclusion of PM<sub>c</sub> from the PM NAAQS or adopting a PM standard that reflected “total dust.”

**Maria Weidner, Earthjustice**

John Garder, who read Ms. Weidner’s remarks, urged CASAC to come to closure on the PM air quality criteria document at this meeting, commenting that further delay only harms public health and welfare and compounds violation of statutory deadlines for review and revision of the PM AQCD and the PM NAAQS. Ms. Weidner stated that credible scientific evidence links PM with the premature death of tens of thousands of Americans each year as well as increased respiratory and cardiac hospitalization and other adverse health effects. Earthjustice reiterated the Agency’s NAAQS-related responsibilities under the Clean Air Act (CAA), and with respect to EPA’s review of the PM NAAQS, called on the Agency to strengthen the level and form of both the daily and annual average standards for fine particulate matter. The organization also called on

the Agency to have strong new standards to protect human health against the effects of coarse particles, which Earthjustice deems are both necessary steps if EPA is to fulfill its duty under the CAA to set PM NAAQS requisite to protect the public health with an adequate margin of safety.

**Dr. Linda Smith, California Environmental Protection Agency, Air Resources Board (CARB)**

Dr. Smith commented that the CARB appreciated the extra efforts made by EPA staff to develop the comprehensive review document. However, because of significant public health impacts due to PM exposures, the California EPA believes that the U.S. EPA must now move to establish more health-protective ambient air quality standards. Dr. Smith remarked that it is clear that major health effects from PM exposure need to be addressed, adding that, every year, in California alone, thousands of people die prematurely, and hundreds of thousands of people suffer from respiratory symptoms due to PM exposure. She noted that because of the serious nature of PM exposure and the scientific literature demonstrating a clear association between PM exposure and adverse health effects, California has made adoption of stringent PM standards a priority, which were approved in 2002 through an open public-review process which included independent scientific review by a University of California-appointed committee. Therefore, the CARB believes that the CASAC should reach closure on the PM AQCD, so that the U.S. EPA may proceed to promulgate strengthened, health-protective NAAQS for PM. Dr. Smith closed by noted that, with the adoption of California's new standards for PM, the CARB has started developing control measures to protect Californians from the adverse health impacts of PM exposure. Better uniformity in standards throughout the country will help the CARB to better protect the health of their state's residents, which can only occur if CASAC moves ahead to finalize this review process, thereby allowing EPA staff to move ahead with its regulatory process.

**Dr. Bonnie New, Health Professionals for Clean Air**

Dr. New commented that, as a doctor, she has seen first-hand the sense of panic on the face of a child suffering from an asthma attack, and the suffering of men and women hospitalized for heart problems. She added that it is frustrating and maddening to know that many of those cases could have been prevented, in that she concludes that they were caused or worsened by exposure to ambient air pollution. Dr. New remarked that the effects of air pollution reach far deeper into people's lives than health studies can show. She noted that air pollution not only impairs people's health, it saps limited family incomes to pay for medical expenses and in many other ways, big and small, damages the quality of life of affected individuals and their families. Dr. New concluded by strongly encouraging the CASAC to bring closure to its review of the PM Air Quality Criteria Document — adding that there are people suffering and dying of preventable diseases related to particulate exposure, and wishing to convey both a sense of immediacy and an understanding of the real consequences of further delay.

**Mr. Bob Yuhnke, Consultant, speaking on behalf of Environmental Defense**

Mr. Yuhnke focused on the question of how the CASAC proceeds when there are both statutory deadlines to be met under the CAA and open questions that remain to be addressed, and offered some suggestions about how the Committee might proceed in view of what appears to be very strong evidence that there's a need for a more-protective standard. He noted some important

issues such as the relative contribution of various components of PM remain open, but those are issues that are not going to get resolved in the next few months or even in the next few years. Therefore, he urged EPA to proceed with the evidence that the Agency currently has in-hand — which is that particulate matter of small sizes all seems to contribute, though perhaps in differing degrees, to the problem of various adverse health effects — and move on to the PM Staff Paper. Mr. Yuhnke comments that some of these uncertainties will be addressed in the risk assessment document, but a lot of it will have to be left with the judgment call that the Agency has to make. Finally, he suggested that one of the things which would be helpful in this continuing process would be for the CASAC, along with bringing closure to the current document, to identify some of the critical issues that remain open and to suggest to EPA a research program that would be specifically tailored to try to close some of those information gaps over the next five years. In the meantime, Mr. Yuhnke stated that the regulatory process still needs to move forward.

**Mr. Jon Heuss, Air Improvement Resource, Inc. (AIR), speaking on behalf of the Alliance of Automobile Manufacturers (AAM)**

Mr. Heuss began his remarks by commenting on dosimetry, commenting that Chapter 9 does not discuss negative-to-positive doses, particularly those that are associated with the acute severe health outcomes, instead talking about deposition fractions. AAM also believes that Chapter 9 should include information on rat-to-human extrapolation and discuss the implications. Mr. Heuss went on to state that Chapter 9 strains to make a case for biologic plausibility, ignoring the dosimetric discrepancy between the levels that show effects in controlled-exposure studies and the current ambient PM levels. He also commented that no consistent positive findings are presented at or near the ambient exposures for ambient PM that show biological changes which could cause the severe health outcomes implicated by the epidemiology. Continuing, Mr. Heuss remarked on uncertainty with respect to epidemiological model selection. In particular, he cited the recent paper by Koop and Tole, which purports to demonstrate that, with major model averaging, single model regression results underestimate the true uncertainty and may lead to misleading inferences about post-mortality effects. Accordingly, the authors recommend against using point estimates to set regulatory standards. Mr. Heuss also commented that Chapter 9 consistently overstates the consistency of the short-term PM associations, adding that issues of bias are either not discussed adequately or at all. He also commented that, with regard to the integrative synthesis, the consistency and coherence within the epidemiology is overstated; and, in addition, both the dose discrepancy and the wide range of chemical-specific toxicity that is well-known in the literature are ignored. Mr. Heuss concluded his remarks by recommending that Chapter 9 be rewritten to acknowledge and address these substantive comments.

**Dr. Will Ollison, American Petroleum Institute (API)**

Dr. Ollison gave a presentation on water-based PM sources, which he characterized as a missing source of particle exposures. In this briefing, Dr. Ollison gave an overview of the water-based particle generation mechanism and commonly-encountered sources. He concluded that, although these are not currently addressed either in the current revision of the revised draft AQCD for PM or in reports from the NAS, water-based sources of particulate matter should nevertheless be considered in: monitor-placement guidelines; national ambient air quality standards (NAAQS) compliance judgments; and source-apportionment analyses.

**Dr. Anne Smith, Charles River Associates, Inc., speaking on behalf of the Utility Air Regulatory Group (UARG)**

Dr. Smith began by stating one of her main points: that the conclusion of the PM AQCD that there is an increase in strength and coherence in the evidence that there is risk from all forms of PM<sub>2.5</sub> is really unwarranted, adding that if Chapter 9 were to be thoroughly interpreted in the analysis that this ought to jump out. She remarks that Chapter 9 really does not highlight ways that toxicology and dosimetry can inform where the epidemiology is inherently limited in what it can tell us; and, moreover, that Chapter 9 selectively ignores weaknesses in the epidemiological evidence while not really integrating as thoroughly as it could the toxicology and dosimetry information — and therefore it does not provide a balanced interpretation of scientific findings. With respect to toxicology effects, Dr. Smith sees no attempt in this chapter to provide a simple summary by PM type of whether the constituent has even been subjected to toxicological study. In addition, while dosimetry has a lot of interesting new evidence, there is insufficient discussion of what it might imply for possible culprits. She also commented that the chapter does not discuss whether the toxicology points in a similar direction, nor does it acknowledge that the epidemiology is really too limited to support or refute whatever insights come out of this. Dr. Smith also offered the following two points on the epidemiology, that there are biases created (of which she provided examples) and there are materials selectively presented from the full body of information which provides a different view. Finally, she noted that there was a coherence argument as well, but that it is based on a single pollutant only, PM<sub>10</sub>, and does not look at the other gases. In addition, if one looks at these studies behind the coherence argument, the original studies contain results that are not represented in the corresponding PM AQCD chapter.

**Mr. Joe Suchecki, Engine Manufacturers Association (EMA)**

Mr. Joe Suchecki highlighted some of the comments regarding Chapter 9 from Dr. Ferdinand Venditti from Albany Medical College and Dr. Peter Valberg of Gradient Corporation, both of whom have previously commented on the chapters of the PM AQCD. Mr. Suchecki stated that, with regard to Chapter 9, EMA believes that the chapter needs to be improved or revised and is not acceptable in its present form. He remarked that it lacks a truly integrated approach and appears to EMA to be more of a simple summary of previous chapters rather than a synthesis. Mr. Suchecki notes that the chapter does discuss much of the new information on PM; however, it does not do so in an adequate manner, in that it does not provide EPA regulators and policy makers with the information needed to address establishing or revising the NAAQS for PM. With respect to some of the specific problems in the chapter, he commented on the uncertainties and caveats regarding the current PM database that are included in preceding chapters but not adequately brought forward into Chapter 9. In addition, Mr. Suchecki remarked that discussions and conclusions in Chapter 9 are often based on a small number of studies that support the point being made while apparently ignoring other information. EMA believes the Chapter 9 summary and conclusion sections need to be revised if they are to reflect the uncertainties and variability in the PM literature, which certainly would be helped by addressing the uncertainties questions regarding co-pollutants and confounding, as well as model uncertainty, uncertainty in the time-series studies, and the small relevant risks that have resulted from these more comprehensive studies. Finally, and most importantly, Mr. Suchecki presented the conclusion of EMA that Chapter 9 does not provide a clear picture of how the scientific information fits together, nor does it tell the reader what a given level of ambient particulate matter means in terms of human

health — adding that nowhere in the present chapter is there a discussion or analysis relating health effects to ambient concentrations of PM.

**Dr. William Beckett (M.D.), University of Rochester Medical Center, speaking on behalf of the American Thoracic Society (ATS)**

Dr. Beckett began his remarks by complimenting EPA on a generally thorough and highly-informed review of a very large and complex topic. The remainder of his comments focused on drawing the CASAC's attention to some areas which either omitted, or did not assign sufficient importance to, aspects of the existing scientific database. Regarding Chapter 7, Dr. Beckett remarked that EPA's review and summarization of animal and human toxicological studies of cardiovascular effects is incomplete. With respect to Chapter 8, he commented that the effects of airborne PM on human reproduction, including effects on fetal growth and development in the normal, non-compromised pregnancy, are only briefly mentioned, and few of the available studies are cited, adding that, in Chapter 9, this area is also under emphasized. In addition, Dr. Beckett notes that, in several places the synthesis emphasizes knowledge gaps where in fact there is already considerable directly relevant science available. In other places, the synthesis implies that since there is so much new scientific information, a coherent summary cannot be made due to non-homogeneity of study designs and study results. He also comments that important new information on the effects of particles on the growth of lung function in normal children — linked to many health outcomes later in life — is not given appropriate notice. Dr. Beckett comments that the summary discussion of diesel and lung cancer is inappropriately limited to genotoxicity studies, apparently overlooking the large data base which led to classification of diesel exhaust particulate as a "probable human carcinogen." He concluded by stating that the Agency must make its own independent risk assessment for diesel and lung cancer; however, a large body of research that went into these designations by other scientific groups is apparently not reflected in the summary statement.

**Mr. Thomas Grahame, U.S. Department of Energy (DOE)**

Mr. Grahame began by stating that his comments mainly have to do with whether a discussion in the PM air quality criteria document — ostensibly about health effects of airborne pollutants in the U.S. — should be based on health effects from fuels as combusted differently with different end characteristics in developing countries. DOE suggests that most observers would find it unrepresentative of emissions from gasoline engines in the U.S. should the PM AQCD base health effects of gasoline on emissions from, for example, a two-stroke engine with no controls, as is used in many developing countries today. However, Mr. Grahame notes that findings in the interpretive summary of the toxicology chapter and Chapter 9, in discussing the mutagenicity of coal, appear to be based almost entirely on a discussion of residential coal burning in China with the attendant high levels of partly burned hydrocarbons and polycyclic aromatic hydrocarbons (PAH). He commented that, with regard to the mutagenicity of PM from coal burning in the U.S., the AQCD reports that ash from conventional coal-fired power plants was found not to be mutagenic in all tests done. The Department of Energy would note that conventional coal-fired power plants represent 90 to 99 percent of coal-fired generating capacity in the U.S. Thus, DOE would recommend in the toxicology chapter and in Chapter 9 that any discussion of health effects from combustion-related PM from any fuel type which may involve combustion of the fuel in a different country in a use or manner different than that in the U.S. with different PM

characteristics should be heavily caveated, if retained, and that these caveats should discuss the differences in combustion and the PM characteristics between the studies. Finally, Mr. Grahame urged that, in any ranking of mutagenicity of different fuels as occurs in the integrative synthesis of Chapter 7, the final PM AQCD should base any such ranking on mutagenicity tests reflecting combustion-related PM that is representative of major uses of the fuel in the U.S.

There was opportunity for questions-and-answers between the presenters and the members of the Panel following each of these presentations.

### Summary of CASAC PM Review Panel Discussion and Deliberations re: the AQCD for PM

#### **Chapter 7 (Toxicology)**

Overall, Panel members found the revised Chapter 7 to be greatly improved from the last draft. Numerous content issues previously identified have been resolved, and the text is much cleaner. The reorganization looks good, and the chapter now represents a thorough and well-balanced review and analysis of the large, complex, and less-than-definitive literature on the associations between laboratory-based PM exposures and biological responses in humans, laboratory animals, and *in vitro* preparations.

Nonetheless, several items that still need to be addressed by the Agency include the following:

- The Integrative Summary section of Chapter 7 is still missing various important points such as the fact that concentrated ambient particles (CAPs) used in most of the cited studies do not concentrate the gaseous phase and ultrafine particles.
- The Appendix 7A on rat-to-human dose extrapolation provides valuable information for putting into perspective the relationship between various exposure levels and instillation doses used in animal studies relative to the comparable kinds of exposure levels or doses that would be needed in humans. Unfortunately, some of these examples have failed to find their way into Chapter 7.
- The issue of dose-response could still use some tuning up. Specifically, the summary needs to include a mention that the dosimetry modeling predictions describing the doses in the animal and some of the human studies were relatively high and the relevance of the results to real-world exposures is uncertain.
- There is no inclusion in the new Section 7 of Chapter 7 that relates to the intra-tracheal instillation studies for the Utah Valley dust that was handled very well in the appendix (considered by one member to be a major omission).
- The type of information found in Appendix 7A on the residual oil fly ash (ROFA) that shows some of the calculations on the dose that was delivered in those studies needs to find its way into chapter 7.
- In Section 7.9, “Interpretive Summary of PM Toxicological Findings,” the PM toxicity information is somewhat confusing to read.

It should be noted that the draft PM AQCD covers relevant papers published or accepted for publication prior to April 30, 2002. Members of the Panel discussed at length the inclusion of papers published after April 2002 and recommends that, for consistency, the Reed *et al.* (2004) paper referenced in Chapter 7 should not be included. The Panel concluded that, although this paper does add to the overall body of information, it nevertheless does not make any substantive change in the overall evaluation of the effects of airborne PM from controlled exposures to animals or people.

The Panel closed on Chapter 7 with the understanding that NCEA-RTP staff will make necessary revisions to address issues raised by members of the Panel both during the meeting (and in the Panel's subsequent report), as well as in the Panelists' individual review comments provided to the Agency.

### **Appendix 7A**

Several CASAC PM Review Panel members had extensive, albeit relatively minor, comments on Appendix 7A, "Rat-to-Human Dose Extrapolation." The overall consensus of the Panel was that this appendix provides good and thoughtful discussions, and furnishes valuable information for putting into perspective the relationship between various exposure levels and instillation doses used in animal studies relative to the comparable kinds of exposure levels or doses that would be needed in humans. One Panelist remarked that Appendix 7A "provided good and thoughtful discussion," while another Panel member noted that "the first part of this [appendix] is a great explication of the issues," adding that Table 7A-7 alone "is worth the price of admission, and it is a very valuable addition."

However, aspects of Appendix 7A that still require additional revisions, clarification or other edits include the following:

- Appendix 7A contains information on comparative biological responses that belongs in the main body of the chapter. A Panel member noted that it is exactly for the purpose of appropriately comparing the findings of animal studies to human study results that the comparative dose modeling is required, adding that the purpose of the appendix is to provide a foundation for judging the value of animal study data, with the comparison of animal and human responses included in the body of the Chapter 7. Therefore, the health response comparisons belong there, not here.
- It would be desirable to provide some concluding comments after the individual sections similar to what's done in the summary of the appendix. Specifically, it would be useful to emphasize more the complexity of dosimetric extrapolations, stressing that this is highly dependent on PM parameters, exposure scenarios, the breathing and activity patterns of different species (which are not yet fully-achievable by models), and expected differences between the response of a compromised host versus the healthy host. The summary does a nice job in this regard, and in-between conclusions after individual sections would only strengthen this.
- One Panelist commented that the appendix would be substantially improved by clearly identifying the very few biological observations that provide the basis for the extensive

mathematical extrapolations, and that the text should reflect that some of the calculated parameters such as deposited or retained dose per unit surface area are unlikely to ever be actually measured. Thus, all of the table and figure captions should be reviewed and the words “estimated” or “calculated” be placed in front of any estimated or calculated quantities. Including “measured” values for comparison with “calculated” values would also substantially strengthen the appendix.

- One Panelist remarked that the revised chapter provided an interesting and useful analysis of the similarities and differences in particle deposition, retention, and dose between humans and rats used in controlled-exposure studies. He added, however, that while many of the complexities are presented and appropriately discussed, others are not addressed or fully discussed. Another Panel member felt that Appendix 7A would be substantially improved by clearly identifying the very few observations that provide the basis for the extensive mathematical extrapolations.

The Panel closed on Appendix 7A with the typical understanding that Agency staff will make the minor necessary revisions and clarifications in response to Panel members’ review comments.

### **Appendix 7B**

A new Appendix 7B — entitled, “Ambient Bioaerosols — has been added in response to the Panel’s prior suggestions to move this material from the body of Chapter 7. Panel members’ reactions to this appendix varied. One Panelist found the entire appendix adequate for citing the large amount of information related to these bioaerosols but not particularly useful for putting in perspective the magnitude of the material that it takes to produce adverse health effects. Another Panel member felt that, while there are acknowledged problems with Appendix 7B, its inclusion represents “a landmark start for the Agency” that has been “largely dodged” for many years, a “first effort ... of the Agency of trying to pull together in some comprehensive way information on bioaerosols, exposures [and] possible effects ... done in response to ... repeated requests for such material.”

The consensus view of the Panel was that this appendix, while important, inundates the reader with information about fungi, bacteria, viruses, pollens, plant fragments, etc. Significantly, most of this information indicates the quantities of bioaerosols that are present in the air in various locations but, unfortunately, seldom presents effects of this material on humans or animals. This disparity in coverage between exposure and health effects was of particular concern to the Panel and needs to be rectified.

The Panel closed on Appendix 7B with the same understanding that NCEA-RTP staff will make necessary additional revisions in response to Panel members’ review comments.

### **Chapter 8 (Epidemiology)**

The Panel concluded that the revised version of this chapter on the epidemiological evidence of the health effects of particulate matter is significantly improved both in terms of its balance and representation of the body of epidemiological studies. Members of the Panel noted that certain important factual errors were corrected, and that there was also substantial improvement in how

the Agency treated the interpretation on the cardiovascular endpoints discussion. In addition, the chapter now properly offers the view that “correct” models for approaching analysis of time-series or other observational data can never be identified, and that there is always a potential for confounding, with one Panelist adding that this is not limited to air pollution epidemiology but rather to any observational study. Moreover, there was improved discussion on methodological uncertainties in terms of such things as model specification and measurement error. In summary, EPA has adequately addressed the vast majority of the Panel’s prior criticisms and suggestions for improvements of the previous draft document, with the result that this current revision of Chapter 8 improves on what was already deemed to be a generally well-written review of the scientific literature published since 1996 on this topic.

Members of the Panel held a lengthy discussion concerning their prior decision to include the *Hoek et al.* paper (2002), in addition to other studies published since the agreed-upon 2002 cut-off date. Panel members judged that it was critical to include work on the GAM reanalyses; however, there were concerns expressed about the use of several exposure metrics such as NO<sub>2</sub> and black carbon in this *Hoek* paper, concerning which the Panel stated that the results need to be more carefully caveated or excluded from the discussion. Panel members also believed that the updated results from ARIES presented by Metzger *et al.* (2004) should not be included in this version of the PM air quality criteria document, while appropriate discussion of the problems of preliminary publication of partial results such as in the Tolbert *et al.* (2000) paper should be included in the chapter.

With respect to the Utah Valley steel mill closure study and its reference to both respiratory hospitalizations and mortality, members of the Panel felt that there was an absence of statistical power to look at mortality, concluding that continued reference to mortality in the PM AQCD is not justifiable without appropriate qualifiers.

The Panel closed on Chapter 8 with the standard understanding that NCEA-RTP staff will make revisions and clarifications as necessary in response to Panel members’ review comments.

### **Chapter 9 (Integrative Synthesis)**

This Chapter of the PM AQCD was completely revised based on the Panel’s recommendation from its August 2003 meeting, and the subsequent outline and “framework questions” provided to the Panel in September 2003 by NCEA-RTP and agreed-to by the Panel in its October 2003 teleconference. Overall, the Panel felt that this version was much improved as a draft, and very different from what the Agency had presented before, but still too long for a true integrative synthesis (141 pages, plus a 26-page appendix). The chapter also still contained an inordinate amount of detail, owing to an in-depth discussion of specific studies as opposed to a synthesis of the material presented in the earlier chapters, which would then represent a summary of the Agency’s current level of understanding with respect to particulate matter. To address this, most references to individual papers should be eliminated except in those limited cases where the facts presented clearly require a reference. In addition, while Panel members felt that the organization around the five framework questions was good, the lack of a section that was “truly integrative across these different questions and brought the whole story together” and which would “talk about how certain we are overall” was noted.

Panel members questioned the basis for the descriptors chosen in the chapter, remarking that there an excessive use of adjectives such as “considerable,” “strong,” “very,” and “extensive” throughout than what may be warranted by the data contained in preceding chapters of the PM Air Quality Criteria Document. A similar concern was expressed with the terms “coherence,” and “consistency,” both of which are used frequently throughout the document. One member also commented that, in general, in terms of the tone of the synthesis, he found the chapter “less careful, less qualified than, for example, the rest of the document is,” adding that it is “not as even-handed or fair as the [PM AQCD] is in its current version.” Indeed, while the sections of the integrative synthesis chapter on epidemiology and toxicology were deemed to be too long, the Panel expressed concern that many of the caveats and uncertainties described appropriately in the preceding chapters are not adequately reflected in Chapter 9. It was also felt that the section was weak on epidemiology issues, *e.g.*, interpretation of the HEI reanalysis data (in that it did not really look at issues of statistical model specification), and the topic of gaseous co-pollutants as PM surrogates; and that the chapter did a poor job at summarizing the epidemiological findings. Specifically, the timing of PM exposures with acute cardiac-related health effects and asthma needs additional discussion. There was also the same claim as in Chapter 8 that the Utah Valley steel mill closure study reported effects on mortality as well as on respiratory hospitalizations (*i.e.*, no statistical power).

One member remarked that he was “missing a bottom line here ... the bottom line that’s framed around the ... knowledge that’s brought forth that ... has the most important bearing on those ... [PM] standards.” He went on to say that EPA’s Office of Air Quality Planning and Standards (OAQPS) should be able to pull whatever the policy-relevant science found in the PM AQCD has “to say specifically about those components of the standard” from this integrative synthesis — adding that, “science doesn’t have a very strong voice” in this chapter. (OAQPS is the Agency’s office that prepares the PM Staff Paper, a document that is intended to “bridge the gap” between the scientific review contained in the AQCD for PM and the public health and welfare policy judgments required of the EPA Administrator in reviewing the National Ambient Air Quality Standards for PM.) In other words, despite the fact that the science is complex, a set of clear and explicit conclusions should be made in this chapter.

The Panel discussed the issue of “lags,” *i.e.*, the approximate time interval between ambient PM insult and a measurable effect such as an asthma attack or onset of myocardial infarction, and what it considered to be a lack of justification for the use of “best” lag (lagged effects). While there is agreement as to the uncertainty in terms of the estimated effects of any given lag within a particular study, no consensus on their inclusion in the document was reached. This led to a lengthy discussion on the Koop and Tole (2004) paper, which concerns a statistical technique known as Bayesian model averaging (a statistical method). Two Panel members and several public commenters argued for the inclusion of this paper, which addresses the “correct” model issue and questions the legitimacy of the model selection procedures used in most of the time-series studies that have been published. One point of controversy centered around the fact that Koop and Tole “imputed” (estimated) two-thirds (66 percent) of their data for the PM variable. This paper was acknowledged to represent a very complicated approach, which, as one CASAC member commented, may take “a decade of perspective” in view of other published research to determine if it is “truly an important paper.” After considerable deliberation among the members of the Panel and the Agency, it was decided not to include this paper in the AQCD for PM, but

rather to expand the discussion of the Clyde *et al.* (2000) paper which raises some of the same issues.

The Panel discussed each of the following five sections of Section 9.2, “Synthesis of Available Information on PM-related Health Effects”:

- “Does the newly-available information continue to support consideration of fine and coarse particles as separate subclasses of PM pollution?” (Section 9.2.1)
- “How does the newly-available information inform our judgments about the strengths and limitations of the epidemiologic evidence for health effects related to ambient fine and coarse thoracic PM, acting alone and/or in combination with other pollutants?” (Section 9.2.2)
- “How does newly-available information inform assessment of biological plausibility and coherence of health effects attributed to ambient fine and coarse thoracic PM and/or their components?” (Section 9.2.3)
- “How does newly-available information inform our understanding of subpopulations potentially susceptible to PM-related health effects?” (Section 9.2.4)
- “What does the newly-available information imply with regard to potential public health impacts of human exposures to ambient PM in the United States?” (Section 9.2.5)

The Panel also discussed Section 9.3, “Synthesis of Available Information on PM-related Welfare Effects.” However, as one Panel member noted, only seventeen out of approximately 120 pages in this integrative synthesis chapter are devoted to welfare effects, adding that there are no accompanying figures or tables dealing with welfare effects. Moreover, he is left to conclude that it is primarily in urban areas where things like visibility may be of concern, rather than certain impairments of visibility which exist in rural or scenic vistas such as the Grand Canyon, noting that “the human satisfactions of perceiving landscapes is one of the things that visibility does to people” (although it was acknowledged that visibility effects were not equivalent to thoracic influences or pulmonary effects). Panel members remarked that this section on welfare effects did not really converge to any “bottom line” with respect to either potential changes to any existing welfare standards or additions of new ones. In general, it was felt that the welfare effects of PM — including visibility impairments, ecosystem responses to increased atmospheric deposition of PM, and the direct effects of PM on materials (*i.e.*, materials damage) — and the associated desirability of a possible secondary standard for PM were dealt with in too cursory a fashion. The history of considering a secondary particulate matter standard to protect against adverse visibility effects in EPA’s PM air quality criteria documents was reviewed. Several Panel members expressed the need to “move forward” not only on visibility issues but all those involving the protection of ecosystems, with one member commenting that “there needs to be a philosophical change ... towards the concept of the application of critical loads,” to include nitrogen deposition.

Members of the Panel had a lengthy discussion on the somewhat-arbitrary “cut point” between fine- and coarse-fraction particle sizes, in addition to their associated human-health implications and measurement methods (sampling techniques) — and limitations. The Panel also discussed the issue of considering socioeconomic status as a susceptibility factor (as opposed to a risk factor) for adverse health effects from PM exposures.

With respect to the document’s length and style, one member of the Panel recommended that NCEA-RTP remove “60 percent of the words,” thereby reducing the chapter to about 60 pages, adding that the document was in need conciseness and crispness so that it would read more like a journal article than a Government document or something that “was put together by committee.” Dr. Grant indicated that his goal would be to shorten Chapter 9 to just over 50 pages. The Panel agreed that there was no need for NCEA-RTP to draft an Executive Summary, *per se*, for the PM AQCD.

### Summary, Wrap-up, Next Steps and Closing Remarks

The Panel concluded that Chapters 7 (Toxicology) and 8 (Epidemiology) had been sufficiently improved and did not require further review by CASAC, with the understanding that NCEA-RTP will make further revisions based on CASAC comments. However, the Panel made a number of specific recommendations on Chapter 9 and wished to see a revised version before they would be able to close on this chapter. If NCEA-RTP was able to provide the Panel with a revised Chapter 9 by the end of August, a teleconference meeting could be held in mid- to late September, with the goal of completing the review of the AQCD for PM. Dr. Grant stated that his NCEA-RTP staff should be able to make an updated Chapter 9 available to CASAC PM Review Panelists for their review and comment by no later than the end of August. Mr. Butterfield will work with all Panelists to schedule a mutually-agreeable date for a September 2004 teleconference.

Dr. Hopke asked the Panel members to submit any final comments as soon as possible to both himself and Mr. Butterfield. The Panel’s consensus comments on these three chapters will be summarized in its forthcoming report, with the individual review comments of Panel members presented in an appendix to that report.

### **Action Items:**

- Panel members are requested to send their individual review comments on the revised Chapters 7 through 9 to Mr. Butterfield as soon as possible. [Completed]
- Dr. Hopke will prepare and circulate a draft consensus report from the Panel on this meeting within two weeks of the date of this teleconference. [Completed; the Panel’s report from this July 20-21, 2004 meeting (EPA-SAB-CASAC-04-008, dated August 16, 2004) can be found on the EPA Web Site at: <http://www.epa.gov/sab>.]
- Dr. Grant’s staff will update the revised Chapter 9 (Integrative Synthesis) of the PM AQCD, and NCEA-RTP will provide this revised chapter back to the Panel by the end of August 2004. [Completed]

[Update: Since the date of this teleconference, Dr. Grant and his staff did indeed update the revised Chapter 9 of the AQCD for PM, and provided this to the members of the CASAC PM Review Panel on August 29, 2004. The Panel met again on September 20, 2004 via a public teleconference. After an extensive discussion, the Panel concluded that this revised chapter had been sufficiently improved that it could close on Chapter 9, with the understanding that NCEA-RTP will make further revisions as necessary to address the issues raised both in this report and in the Panelists' individual review comments, as provided in Appendix B of the Panel's report dated October 4, 2004. This action completes the Panel's review of the revised AQCD for PM.]

Respectfully Submitted:

Certified as True:

/s/

/s/

*Fred A. Butterfield, III*

*Philip Hopke, Ph.D.*

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Fred A. Butterfield, III  
CASAC DFO

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Philip Hopke, Ph.D.  
CASAC Chair

Date: November 9, 2004

## **APPENDICES**

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- Appendix A: Roster of the CASAC Particulate Matter Review Panel
- Appendix B: Meeting Agenda
- Appendix C: Overview Presentation of Revisions to Chapters 7-9 of EPA's 4<sup>th</sup> Revised Draft AQCD for PM [Dr. Les Grant, NCEA-RTP, July 20, 2004]
- Appendix D: List of Public Speakers

## Appendix A – Roster of the CASAC Particulate Matter Review Panel

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**U.S. Environmental Protection Agency  
EPA Science Advisory Board (SAB) Staff Office  
Clean Air Scientific Advisory Committee  
CASAC Particulate Matter (PM) Review Panel\***

### **CHAIR**

**Dr. Philip Hopke**, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY  
Also Member: SAB Board

### **CASAC MEMBERS**

**Dr. Ellis Cowling**, University Distinguished Professor At-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

**Dr. James D. Crapo**, Chairman, Department of Medicine, National Jewish Medical and Research Center, Denver, CO, and Chief Executive Officer (CEO) of Aeolus Pharmaceuticals, Inc.

**Dr. Frederick J. Miller**, Vice President for Research, CIIT Centers for Health Research, Research Triangle Park, NC

**Mr. Richard L. Poirot**, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

**Dr. Frank Speizer**, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

**Dr. Barbara Zielinska**, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

### **CONSULTANTS**

**Dr. Jane Q. Koenig**, Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

**Dr. Petros Koutrakis**, Professor of Environmental Science, Environmental Health, School of Public Health, Harvard University (HSPH), Boston, MA

**Dr. Allan Legge**, President, Biosphere Solutions, Calgary, Alberta

**Dr. Paul J. Liroy**, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

**Dr. Morton Lippmann**, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

**Dr. Joe Mauderly**, Vice President, Senior Scientist, and Director, National Environmental Respiratory Center, Lovelace Respiratory Research Institute, Albuquerque, NM

**Dr. Roger O. McClellan**, Consultant, Albuquerque, NM

**Dr. Günter Oberdörster**, Professor of Toxicology, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

**Dr. Robert D. Rowe**, President, Stratus Consulting, Inc., Boulder, CO

**Dr. Jonathan M. Samet**, Professor and Chair, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Sverre Vedal**, Professor of Medicine, National Jewish Medical and Research Center, Denver, CO

**Mr. Ronald H. White**, Research Scientist, Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Warren H. White**, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

**Dr. George T. Wolff**, Principal Scientist, General Motors Corporation, Detroit, MI

#### **SCIENCE ADVISORY BOARD STAFF**

**Mr. Fred Butterfield**, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 ([butterfield.fred@epa.gov](mailto:butterfield.fred@epa.gov)) [Physical/Courier/FedEx Address: Fred A. Butterfield, III, EPA Science Advisory Board Staff Office (Mail Code 1400F), Woodies Building, 1025 F Street, N.W., Room 3604, Washington, DC 20004, Telephone: 202-343-9994]

\* Members of this CASAC Panel consist of:

a. CASAC Members: Experts appointed to the statutory Clean Air Scientific Advisory Committee by the EPA Administrator; and

b. CASAC Consultants: Experts appointed by the SAB Staff Director to serve on one of the CASAC's National Ambient Air Quality Standards (NAAQS) Panels for a particular criteria air pollutant

## Appendix B – Meeting Agenda

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**U.S. Environmental Protection Agency  
Clean Air Scientific Advisory Committee (CASAC)  
CASAC Particulate Matter (PM) Review Panel**

**Public Meeting & Teleconference  
Tuesday, July 20, 2004 – 8:30 am to 5:30 pm Eastern Time  
Wednesday, July 21, 2004 – 8:30 am to 3:00 pm Eastern Time**

**Embassy Suites Hotel, Raleigh-Durham-Research Triangle East,  
201 Harrison Oaks Boulevard, Cary, North Carolina**

### Ongoing Review of EPA’s 4th Revised Draft Air Quality Criteria Document (AQCD) for Particulate Matter

#### Final Meeting Agenda

#### Tuesday, July 20, 2004

8:30 a.m.	<b>Convene Meeting; Call Attendance; Introductions and Administration; and Overview of Meeting Agenda</b>	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
8:45 a.m.	<b>Welcome &amp; Opening Remarks</b>	Dr. Vanessa Vu, EPA Science Advisory Board (SAB) Staff Office Director
8:50 a.m.	<b>Purpose of Meeting</b>	Dr. Phil Hopke, Chair
8:55 a.m.	<b>Welcome from EPA’s National Center for Environmental Assessment (NCEA)</b>	Dr. John Vandenberg (tentative), Acting Associate Director for Health, NCEA
9:00 a.m.	<b>Overview of Revisions to Chapters 7-9 of EPA’s 4<sup>th</sup> Revised Draft AQCD for PM</b>	Dr. Les Grant, Director, NCEA-RTP
10:00 a.m.	<b>Break*</b>	
10:15 a.m.	<b>Begin CASAC PM Review Panel Discussion and Deliberations (Chapter 7)</b>	Dr. Hopke, PM Review Panel Members
11:00 a.m.	<b>Formal Public Comment Period</b>	Mr. Butterfield (Facilitator)
12:00 p.m.	<b>Lunch (Hotel)</b>	

\*Note: Periodic breaks will be taken as necessary and at the call of the Chair.

**Tuesday, July 20, 2004 (Continued)**

1:00 p.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations (Chapters 7 &amp; 8)</b>	Dr. Hopke, PM Review Panel Members
5:15 p.m.	<b>Summary and Wrap-Up</b>	Dr. Hopke
5:30 p.m.	<b>Adjourn Meeting for the Day</b>	Mr. Butterfield

**Wednesday, July 21, 2004**

8:30 a.m.	<b>Reconvene Meeting; Call Attendance</b>	Mr. Butterfield
8:35 a.m.	<b>Re-cap of Previous Day's Meeting</b>	Dr. Hopke
8:45 a.m.	<b>Public Comment Period*</b>	Mr. Butterfield (Facilitator)
9:00 a.m.	<b>Additional NCEA-RTP Comments</b>	Dr. Grant
9:05 a.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations (Chapter 9)</b>	Dr. Hopke, PM Review Panel Members
10:30 a.m.	<b>Break**</b>	
10:45 a.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations (Chapter 9)</b>	Dr. Hopke, PM Review Panel Members
12:00 p.m.	<b>Lunch (Hotel)</b>	
1:00 p.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations</b>	Dr. Hopke, PM Review Panel Members
2:45 a.m.	<b>Summary, Wrap-Up, Next Steps and Closing Remarks</b>	Dr. Hopke
3:00 p.m.	<b>Adjourn Meeting</b>	Mr. Butterfield

**Notes:**

\* The purpose of the public comment period on the second day of the meeting is to permit members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

\*\* Periodic breaks will be taken as necessary and at the call of the Chair.

**Appendix C – Overview Presentation of Revisions to Chapters 7-9 of EPA’s 4<sup>th</sup> Revised Draft AQCD for PM**

# **Air Quality Criteria for Particulate Matter**



## **Revised Chapters 7, 8, and 9 (June 2004) Overview of Key Revisions & Issues**

***Presented By:***

Dr. Les Grant, Director & Dr. William Wilson, Senior Phys. Science Advisor  
National Center for Environmental Assessment – RTP Division (NCEA/RTP)  
U.S. Environmental Protection Agency, Research Triangle Park, NC

***Presented At:***

Clean Air Scientific Advisory Committee (CASAC) Public Meeting  
Embassy Suites Hotel, Harrison Avenue, Cary, NC



**July 20-21, 2004**



## **EPA PROJECT TEAM FOR DEVELOPMENT OF AIR QUALITY CRITERIA FOR PARTICULATE MATTER**

### **Executive Direction**

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Dr. William E. Wilson—Air Quality Coordinator  
Dr. Joseph P. Pinto—Physical Scientist  
Dr. Brooke Hemming, Physical Scientist  
Dr. J.H.B. Garner—Ecological Scientist  
Dr. Lori White – Health Scientist  
Dr. James Brown – Health Scientist  
Ms. Beverly Comfort—Health Scientist  
Dr. Dennis J. Kotchmar—Medical Officer  
Mr. William Ewald—Health Scientist

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Ms. Diane H. Ray—Program Specialist  
Ms. Donna Wicker—Administrative Officer  
Mr. Richard Wilson—Clerk

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#### **NCEA-RTP Senior Environment Employee**

Dr. David Svendsgaard—Statistician

## CHRONOLOGY FOR DEVELOPMENT OF REVISED PARTICULATE MATTER AIR QUALITY CRITERIA DOCUMENT (PM AQCD)

Major Milestones	Dates	Major Milestones	Dates
PM NAAQS Review Schedule Published in Federal Register	October 1997	HEI Special Report on GAM Reanalyses	May 2003
Federal Register Call for Information	April 1998	4 <sup>th</sup> External Review Draft	June 2003
CASAC Meeting on Development Plan for PM AQCD	May 1998	Public Comment Period on 4 <sup>th</sup> Draft	July-Aug 2003
Workshop Review of Draft Chapters	April 1999	CASAC Meeting on Fourth Draft	August 2003
1st External Review Draft PM AQCD	October 1999	Status Report on Chap. 6,7,7A,8,9 at CASAC meeting	November 2003
CASAC Meeting on First Draft AQCD	December 1999	Release Revised Chap 7,7A & 8	December 2003
Public Comment Period on First Draft	Oct 1999 –Jan 2000	Public Comment Period	January 2004
PM 2000 Meeting (Charleston, SC)	January 2000	CASAC Teleconference Review	February 2004
2 <sup>nd</sup> External Review Draft	March 2001	Release Revised Chap. 7,7A,8 & 9	June 2004
Public Comment Period on 2 <sup>nd</sup> Draft	April-July 2001	CASAC Public Review Meeting	July 20-21, 2004
CASAC Meeting on 2 <sup>nd</sup> Draft	July 2001	Close of Public Comment Period	July 30, 2004
3 <sup>rd</sup> External Review Draft	April 2002		
Public Comment Period on 3 <sup>rd</sup> Draft	May-July 2002		
CASAC Meeting on 3 <sup>rd</sup> Draft	July 2002	Final PM AQCD	? *
CASAC Consultation on GAM Issues	August 2002		
EPA Workshop on GAM Issues	November 2002		

\*EPA motion to extend Consent Degree Agreement deadline filed with the Court. Decision expected July 26, 2004

## AIR QUALITY CRITERIA FOR PARTICULATE MATTER FOURTH EXTERNAL REVIEW DRAFT: CONTENTS & STATUS

<u>Chapter</u>	<u>Status</u>
• Introduction	Closed
• Atmospheric Sciences, Measurement of PM	Closed
• Sources, Emission, Air Quality	Closed
• Environmental Effects	Closed
- Vegetation & Ecosystems	
- Visibility	
- Materials Damage	
- Climate Change	
• Human Exposure	Closed
• Dosimetry of PM	Closed
• Toxicology of PM	Under Review
• Epidemiology of PM	Under Review
• Integrative Synthesis	Under Review

## SUMMARY OF SALIENT REVISIONS (JUNE 2004) TO PM AQCD CHAPTER 7 (TOXICOLOGY)

- Tables & text reorganized throughout the chapter to more clearly separate presentation and discussion of toxicology studies of ambient PM (e.g., CAPs) versus combustion source PM (e.g., ROFA).
- Several additional controlled human exposure and laboratory animal studies of cardiovascular and respiratory system effects of CAPs inhalation exposures added to chapter. Findings of some tend to point toward thrombus formation effects (fibrinogen ↑; factor VII ↓). Need to decide on whether or not to include Reed et al (2004) study.
- Mutagenicity/carcinogenicity section expanded to include studies of wood/biomass, coal, and gasoline combustion emission effects, in addition to diesel emission PM effects. Also, added important studies (by Hanningan, et al) of ambient PM (from Los Angeles) effects.
- New section added on dosimetric comparisons. Examples: PM Effects on PNM influx and AM phagocytosis. Also, extensively revamped Appendix 7A on extrapolation modeling, as summarized in other slides.
- Former detailed Bioaerosols section moved to Appendix 7B and replaced in main chapter text by much briefer summary.
- Interpretative Summary Section 7.9 revamped to more clearly present key findings and conclusions, including on susceptibility (noted as particularly weak in previous CASAC review).

## SUMMARY OF SALIENT REVISIONS (JUNE 2004) TO PM AQCD APPENDIX 7A (EXTRAPOLATION MODELING)

- More extensive discussion of quantitative interspecies extrapolation added to set the stage for interpretation of model results.
- Also added an extensive discussion of the MPPD model used in ensuing dosimetric calculations.
- Figures added to show differences in clearance rates for humans and rats, to illustrate the concept of retained PM burden, whereby slower clearance in humans leads to greater relative accumulation of PM in the lungs of humans than rats.
- More information given on the sources of the normalizing parameters used in modeling efforts
- Additional modeling results presented. Three sets of comparisons given for deposited mass, surface area, and number for four breathing patterns:
  - Rat and human each exposed to the same single mode (Aitken, accumulation, or coarse)
  - Rat exposed to resuspended PM, human exposed to all three modes
  - Rat exposed to each of the three modes separately, human exposed to all three modes together
- More extensive discussion of long term burden & difficulty of matching retained dose in rats and humans. (Will add discussion of matching integrated as well as instantaneous dose as per Mauderly recommendation).
- For the comparison of rat and human experimental toxicologic studies, rat and human doses were recalculated. Input values were clearly stated, more realistic particle sizes and breathing pattern were used, and both deposition and clearance were modeled. Description of the comparison results reorganized to clarify them.
- Section also added that discusses clearance overload in the rat.

## SUMMARY OF REVISIONS (JUNE 2004) TO PM AQCD CHAPTER 8 (EPIDEMIOLOGY)

- Some revisions made to discussion of single-city time-series analyses of short-term PM exposure effects. Added Metzger et al (2004) update analyses of Atlanta Study results to augment earlier Tolbert et al (2000a) preliminary analyses based on data for ~50% of participating hospitals. Keep Metzger et al (2004)?
- Added expanded discussion of Lipfert et al prospective cohort study of chronic PM exposure effects and added more effect estimates derived from the study to summary table for cohort studies. Also added discussion of Lipfert and Morris (2003) ecologic study.
- Made small revisions to discussion of Hoek et al (2003) Netherlands Study on associations of mortality to traffic-related PM. Need to decide on whether to downplay or, possibly, drop Hoek study (as per one recent CASAC comment).
- Revamped section on PM-mortality intervention studies, including clearer exposition on Clancy et al (2003) and Hedley et al (2002) studies.

## SUMMARY OF REVISIONS (JUNE 2004) TO PM AQCD CHAPTER 8 (EPIDEMIOLOGY) cont'd

- Added expanded discussion on resurfaced issue of impacts of model specification on PM effect estimates and their statistical significance (especially with regard to control for weather effects), including:
  - recapitulation of key points from 1996 PM AQCD on approaches to control for weather factors
  - description of important points derived from Ito (2003) GAM reanalyses explicitly addressing the issue
  - findings reported from several other studies (e.g., by Smoyer et al 2000 a,b; Braga et al 2001, 2002) tending to implicate humidity as an important factor.
- Added new figures and revised discussion in Interpretative Analysis Section 8.4 pertaining to (a) lags and (b) sampling frequency/spatial representativeness (measurement error factors).
- Revised Summary of Key Findings and Conclusions (Section 8.5) in order to sharpen exposition on main points derived from the epidemiologic evidence data.

## SUMMARY OF SALIENT FEATURES OF RESTRUCTURED (JUNE 2004) PM AQCD CHAPTER 9 (INTEGRATIVE SYNTHESIS)

- Introduction
- Synthesis of available information on PM-related health effects
  - Does the newly available information continue to support consideration of fine and coarse particles as separate subclasses of PM pollution?
  - How does the newly available information inform our judgments about the strengths and limitations of the epidemiologic evidence for health effects related to ambient fine and coarse thoracic PM, acting alone and/or in combination with other pollutants?
  - How does newly available information inform assessment of biological plausibility and coherence of health effects attributed to ambient fine and coarse thoracic PM and/or their components?
  - How does newly available information inform our understanding of subpopulations potentially susceptible to PM-related health effects?
  - What does the newly available information imply with regard to potential public health impacts of human exposures to ambient PM in the United States?

## SUMMARY OF SALIENT FEATURES OF RESTRUCTURED (JUNE 2004) PM AQCD CHAPTER 9 (INTEGRATIVE SYNTHESIS) cont'd

- Synthesis of available information on PM-related welfare effects
  - Airborne particle effects on visibility
    - How does newly available information inform our understanding of how ambient PM and its major constituents affects visibility?
    - How does newly available information inform our understanding of how the public values improvements in visibility, especially in urban areas?
  - Effects of ambient PM on vegetation and ecosystems
    - What are the direct and indirect effects of ambient PM?
    - What are the components in ambient PM that are major ecosystem stressors?
    - How can exposures of concern for ecosystem stressor components of PM be characterized?
  - What does the available information indicate about the relationships between atmospheric PM and climate change processes?
  - What does the available information indicate about the effects of man-made materials associated with ambient PM and its major constituents?

## APPENDIX 7A: RAT-TO-HUMAN DOSE EXTRAPOLATION

- Health endpoints are commonly presented and analyzed as a function of exposure concentration.
- Appendix 7A provides an analysis of the relationship between exposure and lung dose for both rats and humans under a variety of scenarios.
- As no single dose metric nor normalizing factor appears to be appropriate for all situations, numerous scenarios were considered in Appendix 7A.

## APPENDIX 7A: PRINCIPLE APPLICATIONS FOR DOSIMETRIC ASSESSMENTS

- Exposure concentrations can be estimated that give a rat the same dose as received by a human exposed to various levels of ambient PM as a function of dose metric, normalizing factor, and level of human exertion. The estimated concentrations will vary widely depending on the selection of these parameters.
  - While human and rat doses may be matched for a specific dose metric, normalizing factor, and level of human exertion, the dose estimated for other dose metrics and normalizing factors may be quite different. Thus, it may not be possible to match all relevant dose metrics.
  - Particle characteristics and biological normalizing factors which mediate effects should be carefully considered in study design.

## APPENDIX 7A: PRINCIPLE APPLICATIONS FOR DOSIMETRIC ASSESSMENTS (Cont'd)

- Dose to the lung can be estimated for both animal and human inhalation studies, making it possible to compare biological responses as a function of dose rather than exposure.
  - This provides a method for identifying differences in species responses in assessments.
  - In order to compare doses, it is essential that investigators provide accurate and complete information regarding exposure conditions, i.e., not only PM concentration and duration of exposure, but also the particle size distribution.
  - Several comparisons suggest that rats may be slightly less sensitive than humans to instilled extracts of ambient PM but that rats may be much less sensitive than humans to inhaled PM. However, if rats receive sufficient PM to be placed in a clearance overload situation, they may become more sensitive than humans.

HUMAN VS RAT DOSIMETRIC COMPARISON FOR INFLAMMATORY  
RESPONSE TO AMBIENT PM (1986 Utah Valley Dust) INSTILLATION  
(Humans: Ghio and Devlin, 2001; Rats: Dye et al, 2001)

- Soluble extracts of Utah Valley Dust - Human, 0.5 mg extract into 5% of lung ( $170 \mu\text{g}/\text{m}^3$ ); Rat, 0.25 mg into whole lung ( $840 \mu\text{g}/\text{m}^3$ ). Lavaged at 24 hours post-instillation
- About 180-220  $\mu\text{g}$  PM would deposit daily in human alveolar region at  $120 \mu\text{g}/\text{m}^3$  (approx. ambient  $\text{PM}_{10}$  level during winter in 1986 Utah Valley when steel mill was open). Instilled lung surface dose in human could be achieved with 44-55 days ambient PM inhalation exposure at  $120 \mu\text{g}/\text{m}^3$
- Instilled mass per alveolar surface area - 5 times greater in the rats than the humans. Instilled mass per body mass - 100 greater in rats than humans
- Neutrophil influx - 3 times greater in the rats (10-fold increase) than in the humans (3.5-fold increase)

## CONCENTRATED AMBIENT AIR PARTICLES (CAPs) INHALATION STUDIES (Humans: Ghio et al, 2000; Rats: Kodavanti et al, 2000 and Clarke et al, 1999)

Ghio	120 $\mu\text{g}/\text{m}^3$ (6 h/day, 3 days), MMAD = 0.65 $\mu\text{m}$ , $\sigma_g = 2.35$
Kodavanti	590 $\mu\text{g}/\text{m}^3$ (6 h/day, 3 days), MMAD = 0.98 $\mu\text{m}$ , $\sigma_g = 1.41$
Clarke	515 $\mu\text{g}/\text{m}^3$ (5 h/day, 3 days), MMAD = 0.18 $\mu\text{m}$ , $\sigma_g = 2.9$

- Lavaged at 18-24 hours post-exposure
- Rats had 40 $\times$  (Kodavanti et al., 2000) and 67 $\times$  (Clark et al., 1999) greater dose than humans
- Rat PMN influx was N.S. (Kodavanti et al., 2000) and similar (Clark et al., 1999) to humans

## Appendix D – List of Public Speakers

### List of Public Speakers

**U.S. Environmental Protection Agency  
Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel  
Ongoing Review of EPA's 4<sup>th</sup> External Review Draft Air Quality Criteria  
Document (AQCD) for PM**

**Public Meeting & Teleconference ❖ July 20-21, 2004**

**Embassy Suites Hotel, Raleigh-Durham-Research Triangle East,  
201 Harrison Oaks Boulevard, Cary, NC**

#	Speaker's Name	Organizational Affiliation	Organization(s) Represented [or Funding Organization(s)]
1	Dr. Samuel Dorevitch (M.D., M.P.H.)	Occupational Medicine Residency Program, University of Illinois at Chicago	same
2	Dr. Allen Lefohn	A.S.L. & Associates	same
3	Dr. Ron Wyzga	Electric Power Research Institute (EPRI)	same
4	Ms. Deborah Shprentz	Consultant	American Lung Association (ALA)
5	Dr. Russell Luepker (M.D.)	University of Minnesota, School of Public Health, Division of Epidemiology	American Heart Association (AHA)
6	Mr. Daniel Greenbaum	Health Effects Institute (HEI)	same
7	Mr. Philip Johnson	Northeast States for Coordinated Air Use Management (NESCAUM)	same
8	Mr. Jonathan Lewis	Clean Air Task Force (CATF)	same
9	Mr. Robert Connery	Holland & Hart LLP	National Cattlemen's Beef Association (NCBA)
10	Maria Weidner [comments read by Mr. John Garder]	Earthjustice	same
11	Dr. Linda Smith	California Environmental Protection Agency, Air Resources Board (CARB)	same
12	Dr. Bonnie New	Health Professionals for Clean Air	same
13	Mr. Bob Yuhnke	Consultant	Environmental Defense
14	Mr. Jon Heuss	Air Improvement Resource, Inc. (AIR)	Alliance of Automobile Manufacturers (AAM)

#	Speaker's Name	Organizational Affiliation	Organization(s) Represented [or Funding Organization(s)]
15	Dr. Will Ollison	American Petroleum Institute (API)	same
16	Dr. Anne Smith	Charles River Associates, Inc.	Utility Air Regulatory Group (UARG)
17	Mr. Joe Suchecki	Engine Manufacturers Association (EMA)	same
18	Dr. William Beckett (M.D.)	University of Rochester Medical Center	American Thoracic Society (ATS)
19	Mr. Thomas Grahame	U.S. Department of Energy (DOE)	same