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Written Comments on the Draft EPA Policy Assessment on Particulate Matter (PM)
by John Bachmann on Behalf of the Environmental Protection Network

We thank the Clean Air Scientific Advisory Committee (CASAC) and U.S. Environmental Protection Agency (EPA) for the opportunity to provide these written comments at this important stage of the current review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). The Environmental Protection Network (EPN) is an organization comprised of over 450 EPA alumni volunteering their time to protect the integrity of the EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide in-depth analyses and insights into regulations and policies proposed by the current administration that have a serious impact on public health and environmental protections. I worked for EPA's Air Office for 33 years, many of them as Associate Director for Science/Policy and New Programs. I was heavily involved in all PM NAAQS reviews through 2006.

The comments below: contrast what the Clean Air Act (CAA) requires of EPA and CASAC in reviewing the NAAQS with the widening flaws evidenced in the process followed in this review; note some substantive and procedural issues raised in the October meetings; restate recommendations I and others made in clarifying comments made to CASAC at the meeting; and present brief comments and recommendations for EPA as they revise both the Policy Assessment (PA) as well as the Integrated Science Assessment (ISA).

The NAAQS Review Process is still broken: The CAA requires standards for common pollutants that "cause or contribute to air pollution which may reasonably be anticipated to endanger public health." It states that the scientific criteria for such air pollutants "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare." The standards must be "requisite to protect public health with an adequate margin of safety," and yes, they are supposed to be reviewed every five years. In my long experience there, EPA has worked hard to ensure the requirements for a quality scientific review take precedence over meeting the time limit, even when under a deadline suit.

Unfortunately, the last two EPA Administrators have flipped the script, that is the approach followed in all past reviews, and placed meeting what appears to be a political deadline over the quality of the reviews. The current Administrator has refused to respond to CASAC's recommendations for interactive access to the kind of breadth of expertise in PM science as well as the variety of perspectives that are found in the PM panel he dismissed. It is indeed fortunate that members of that panel, now called the Independent Particulate Matter Review Panel (IPMRP), have nevertheless met to review both the ISA and the PA and, after a two-day public meeting have published their own set of comments summarizing their review and recommendations for both the draft PA and the PM standards. As their letter notes, the Administrator also

refused to honor the earlier written recommendations of both CASAC and the IPMRP to permit CASAC and the public to review a second draft science assessment before reviewing a final draft of the Policy Assessment.

The result of bad decisions on process is an inadequate peer review of the science and the standards in the draft PA.

The PA itself is intended to assist CASAC and the Administrator in developing a sound basis for recommendations and decisions in this PM review. The extensive review of the draft Assessment by the 20-member IPMRP should be of significant benefit to CASAC and EPA's efforts here. This panel is particularly strong in PM epidemiology research and has taken issue with the doubts expressed by some on CASAC with respect to the continued use of EPA's weight of evidence approach to determining causality, as well as the idea that a very limited number of causal inference studies somehow invalidates the large body of epidemiology and supporting studies, which has only increased since the last review.

By contrast, the consultants selected by the Administrator are limited to a constrained interaction, and only 2 of the 12 have significant experience in PM epidemiology research. Dr. Duncan Thomas in general found "both the draft PA and the draft ISA to be well written, authoritative, and comprehensive reviews of the literature and thoughtful discussion of the policy implications, including limitations thereof" and rejected the suggestion that EPA's approach should now be scrapped while waiting for additional work using causal inference. His responses to questions merit your attention. Dr. Fred Lipfert takes a very different view in suggesting no long-term effects of PM. In part, his response highlights results from his Veterans Cohort Study work. His sponsor and coauthor for some of that work, Dr. Ron Wyzga, formerly of the Electric Power Research Institute, is a member of the Independent Panel and cosigned today's letter.

As the CASAC itself admitted in their letter to the Administrator, "*The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals."* By comparison with past PM reviews, the current CASAC by itself is particularly ill-suited in terms of breadth of expertise and perspectives. The current committee has no experts in the discipline most at issue in this review, epidemiology; has only two members with experience on past CASAC actions; and only one member with the perspective of an academic researcher. While the CAA recognizes the importance of having a member representing a state air pollution agency, this committee has three, and another who works for a local air pollution agency. By policy, EPA has excluded research scientists who have the ability to win a competitive grant from EPA, and has not made room for other academic experts with competence and perspectives that are more varied than the current panel. This group very much needs the assistance of the IPMRP that has been denied to it. As a result of the Administrator placing speed over quality, the current process cannot result in proper peer review of the science and the standards for the NAAQS.

Problems and issues at the October meetings on the PA.

The discourse at the public meetings in October shows the problems created by the Administrator's decisions to fix obvious shortcomings in the process. The EPA staff who prepared the PA had to base their science assessment on a nearly year-old draft science assessment that CASAC and IPMRP recommended should be revised and reviewed again. They had to base important decisions on causality and which studies would be most useful in reviewing the standards on a guess as to which of the disparate recommendations on these issues from a divided CASAC, as well as the IPMRP and others, would be adopted when the ISA authors were freed to revise the earlier draft. The ISA staff could not update the PM document sooner because the accelerated review of ozone meant priority had to be placed on developing the first draft of the ozone ISA.

The deep divisions of the panel as well as the critical lack of relevant expertise and alternative perspectives in the room were on full display at the October meeting. It is not an accident that the two CASAC members most steadfast in their views about the conduct of the meeting were those who had been associated with past CASAC actions. These members valued their experience in an open, interactive discussion and debate by a much larger group of experts with a variety of perspectives. Dr. Frampton in particular was adamant that the arguments and assertions presented by the chair on issues regarding confounding and other issues in epidemiological studies should have taken place in a forum where the experts of the IPMRP could respond to them.

One of these issues was an assertion that any study that did not include maximum and minimum daily temperature (whether a long- or short-term study) was flawed, based on work Dr. Cox had done using National Morbidity, Mortality, and Air Pollution Study (NMMAPS) data. When at the end of the first day Dan Greenbaum of the Health Effects Institute (HEI) pointed out the NMMAPS investigators used a variety of techniques to control for temperature and did not reach that conclusion, Dr. Cox was adamant that HEI had likely not considered using maximum and minimum temperature. Yet the 2003 Special Report on NMMAPS, page 98, suggests otherwise:

> "The same methods were used as in the previous study except for increasing the stringency of the stopping rule. Briefly, a Poisson regression model was fit with GAM terms for day of year and trend with the best fit determined by minimizing Akaike information criterion (AIC). GAM terms for minimum and maximum temperatures were added to this model and again the model with the minimum AIC was determined. The degrees of the smooths were the same as found previously. Various pollutant terms were then added to this best fitting model."

Whether the specifics of the analyses are sufficient to satisfy Dr. Cox is not the issue; he was wrong in suggesting the HEI work had not examined the issue. A frequent topic of discussion on both days was based on assertions on temperature confounding made by the chair based on his own study, which apparently wasn't included in the ISA, much less the PA.[1] Moreover, most air pollution epidemiologists would disagree with the chair extending his short-term study work to cohort studies, as evidenced in the IPMRP report:

> "In studies of long-term exposure to particulate matter, there is neither rationale nor empirical support for concern over confounding by temperature."

On several occasions, Dr. Frampton pointed out it would have been nice to have actual epidemiologists in the room to provide additional expertise and balance to produce a more informed discussion. While Drs. Frampton, Lange, Cox and Boylan each made comments EPA should consider in their document, the inclusion of the IPMRP members in the room would have produced a far more thorough, informed, and productive discussion. This would be of particular importance rebutting the unfounded conclusion reached

[1] At the meeting and in his premeeting comments, Dr. Cox also suggested that studies by Greven et al., 2011 Pun et al. (2017) found no effects of PM2.5 at the local level. In the previous PM review, the authors of the Greven study submitted public comments in 2012 that explain their work in greater detail. This month, the authors of the Pun study submitted comments explaining why they disagreed with the erroneous interpretations of their work by Dr. Cox as well as another public commenter, Mr. Holm.

by some on the panel that recent epidemiology studies finding PM effects at levels well below the standards added nothing new with respect to the adequacy of the current standards. None of the CASAC panels in the previous four PM reviews would have failed to recognize the relevance of the new studies to the decisions. These evidence-based findings, not the risk assessment, have been the main drivers of the previous NAAQS reviews of the $PM_{2.5}$ standards.

Recommendations for CASAC

I acknowledge that members of CASAC have provided a number of important comments and insights that will be of value to EPA as it works to revise the ISA and PA. Yet the limitations noted above remain. The committee should recognize that the Administrator has largely ignored your requests for a more rational process for this review. He has disbanded and refused to reinstate the PM panel or anything close to its equivalent in terms of expertise on PM or the ability for interactive discussion. He has refused you a second look at a revised ISA, which is unprecedented for any first draft of an ISA or Criteria Document. You are already dealing with the uncertainties in the ISA in your review of the PA. While you speak of sound science, you also must recognize the requirements of the kind of sound comprehensive review process that is required in the CAA. Past NAAQS decisions and their defense in subsequent legal proceedings have placed heavy reliance on the consensus comments and recommendations by CASAC, which has always been heavily supported by subject matter experts. EPA has won and lost NAAQS decisions based on how well it followed CASAC advice. If you continue your current path of pressing forward with this review when major portions of the underlying science and policy issues depend on disciplines that are not even included in your active discussions -- especially given the divisions on major issues -- it will be all too easy for plaintiffs to argue successfully that your advice is irrelevant. You should consider seriously Dr. Frampton's suggestion not to continue down this path, and advise the Administrator that he should adopt a sound science review process, before you are willing to proceed. In Dr. Frampton's words of last spring: *"In order to provide the needed expertise in the review process, EPA should immediately re-appoint the PM review panel, and convene an additional CASAC public meeting to review and discuss the panel's comments, before CASAC finalizes its advice on the current draft ISA.*" And you should add to that a second review of the PA after the review of the new draft of the ISA is completed.

Recommendations and Comments for EPA

Having been a lead in producing staff assessments of science/policy issues for NAAQS reviews, I believe EPA staff should be commended for a well done first draft, especially given the deadlines and lack of a peer-reviewed draft of the ISA. The approach used in the risk assessment adapted new and more realistic modeling approaches and provided wider coverage by far than earlier efforts. The questions posed and the criteria presented for selecting studies for the evidence-based assessment were sound and well addressed. I also fully agree with draft PA preliminary conclusions regarding the adequacy of the current standards. The rationale for developing alternative annual standards makes good use of the evidence from newer long-term studies. Even with a strengthened annual standard, however, I recommend a harder look at adequacy of the daily standard using the 98 percentile pseudo-design values currently in the Appendix.

I believe you should carefully consider the many useful and appropriate comments provided by both the CASAC and the IPMRP throughout, recognizing the strengths and limitations of the expertise of both groups.

I agree with the CASAC's recommendation that more attention should be paid to relevant accountability studies, but EPA should not rely on two recently published reviews that include studies of varying quality all

over the world. Instead EPA should assess both older and more recent studies from the U.S. and Canada. I have provided a partial list of studies that should be considered below. At least one of these provides the basis for a concentration-response function for a reduction in fine particles. The list excludes the extended lifespan American Cancer Society studies and the Southern California Children's Health studies that EPA staff already listed in the PA. It would be best to add a new section of the ISA to have that review all of these, including the four listed in the PA. Although each study has strengths and limits, the collective results of these serve to strengthen the evidence of a causal relationship between PM and health.

U.S/Canada PM Accountability Studies:

Utah Valley Steel Mill Strike Studies: Studies found reduced mortality and morbidity during the 13-month strike as compared to before and after the strike.

Pope, C.A., III. Respiratory Disease Associated with Community Air Pollution and a Steel Mill, Utah Valley; *Am. J. Public Health* **1989**, 79 (5), 623-628.

Pope, C.A., III. Particulate Pollution and Health: A Review of the Utah Valley Experience; *J. Expo. Analys. Environ. Epidemiol.* **1996**, 6 (1), 23-34.

Parker, J.D.; Mendola, P.; Woodruff, T.J. Preterm Birth After the Utah Valley Steel Mill Closure: A Natural Experiment; *Epidemiology* **2008**, 19 (6), 820-823.

Ghio, A.J. Biological Effects of Utah Valley Ambient Air Particles in Humans: A Review; *J. Aerosol Med.* **2004**, 17 (2), 157-164.

Southwestern U.S. Regional Copper Smelter Strike Study: An 8.5 reduction in regional sulfate levels during an 8.5-month strike at multiple smelters found reduced mortality.

Pope, C.A., III; Rodermund, D.L.; Gee, M.M. Mortality Effects of a Copper Smelter Strike and Reduced Ambient Sulfate Particulate Matter Air Pollution; *Environ. Health Perspect.* **2007**, 115 (5), 679-683.

Other Long-term Assessments of PM Reductions:

Six City Prospective Cohort Study: Improved overall mortality was associated with decreased mean $PM_{2.5}$ (10 ug/m3) between periods (RR, 0.73), and the reduction in risk was greatest for the cities with the largest reduction in $PM_{2.5}$. The PM reductions were due in part to regulation and in part to other factors.

Laden, F.; Schwartz, J.; Speizer, F.E.; Dockery, D.W. Reduction in Fine Particulate Air Pollution and Mortality: Extended Follow-Up of the Harvard Six Cities Study; *Am. J. Respir. Crit. Care Med.* **2006**, 173 (6), 667-672.

Assessment of U.S. PM NAAQS Reductions: A significant association between the change in $PM_{2.5}$ and the change in CV-mortality rate before (2000-2004) and after (2005-2010) the implementation of NAAQS. Health benefits per 1 $\mu g/m^3$ decrease in $PM_{2.5}$ persist at levels below the current national standard.

Corrigan, A.E.; Becker, M.M; Neas, L.M.; Cascio, W.E.; and Rappold, A.G. Fine particulate matters: The impact of air quality standards on cardiovascular mortality. *Environ Res.* 2018 Feb: 161: 364-369.

Woodsmoke Intervention Studies:

Some evidence of reduced respiratory symptoms in children after a moderately successful wood stove replacement program/reduced measures of inflammation after filtering indoor air.

Noonan CW, Ward TJ, Navidi W, Sheppard L, Bergauff M, Palmer C. Assessing the impact of a wood stove replacement program on air quality and children's health. Research Report 162. Boston: Health Effects Institute; 2011.

Allen, R.W.; Carlsten, C.; Karlen, B.; Leckie, S.; Eeden Sv Vedal, S.; Wong, I.; Brauer, M. An Air Filter Intervention Study of Endothelial Function among Healthy Adults in a Woodsmoke-impacted Community. Am. J. Respir. Crit. Care Med. 2011, 183, 1222–1230 (Canada).

Causal Inference Study

This award-winning accountability study showed local controls beyond those included in attainment areas resulted in significantly reduced effects.

Zigler CM, Choirat C, Dominici F. **2018**. Impact of National Ambient Air Quality Standards nonattainment designations on particulate pollution and health. *Epidemiology* 29: 165–74

Additional Recent Studies

My December comments recommended consideration of the following studies, some of which use causal principles in the analysis. These include:

Vodonos A, Awad YA, Schwartz J. The concentration-response between long-term PM2.5 exposure and mortality; A meta-regression approach. *Environ Res.* 2018; 166: 677–89.

Pope, CA, III; Ezzati, M; Cannon, JB; Allen, RT; Jerrett, M; Burnett, RT. Mortality risk and PM2.5 air pollution in the USA: an analysis of a national prospective cohort. Air Quality, Atmosphere & Health 2017 Published on-line December 8, 2017; doi.org/10.1007/s11869-017-0535-3).

M. Makar, J. Antonelli, Q. Di, D. Cutler, J. Schwartz, F. Dominici. Estimating the Causal Effect of Low Levels of Fine Particulate Matter on Hospitalization. *Epidemiology* **28**, 627–634 (2017).

J. Schwartz, K. Fong, A. Zanobetti. A National Multicity Analysis of the Causal Effect of Local Pollution, NO2, and PM2.5 on Mortality. *Environ. Health Perspect.* **126**, 87004 (2018); Schwartz, J.; Wang, Y.; Kloog, I.; Yitshak-Sade, M.; Dominici, F.; and A. Zanobetti. Estimating the Effects of PM2.5 on Life Expectancy Using Causal Modeling Methods. EHP. 126(12) December 2018.
https://doi.org/10.1289/EHP3130;

Hsiao-ChiChuang, Kin-FaiHo, Lian-YuLin, Ta-YuanChang, Gui-BingHong, Chi-MingMa, I-JungLiu, Kai-JenChuang, Long-term indoor air conditioner filtration and cardiovascular health: A randomized crossover intervention study Environment International. 106, 91-96. September 2017.
https://www.sciencedirect.com/science/article/pii/S0160412017306827?via%3Dihub