

16 December 2019

US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Docket Numbers: EPA-HQ-OAR-2015-0072; EPA-HQ-ORD-2014-0859

Written Comments of John Bachmann on the 11-13-10 Draft CASAC Report on EPA's Policy Assessment of the Particulate Matter NAAQS CASAC, made on behalf of the Environmental Protection Network.

To: EPA Administrator Andrew Wheeler and the Clean Air Scientific Advisory Committee (CASAC)

We thank CASAC and U.S. Environmental Protection Agency (EPA) for this opportunity to speak and provide these written comments. I am representing the [Environmental Protection Network](http://environmentalprotectionnetwork.org) (EPN), a volunteer organization of former EPA employees and others concerned about public health and the environment. I worked for EPA's Air Office for 33 years in Science/Policy and had a lead role in all reviews of the particulate matter (PM) National Ambient Air Quality Standard (NAAQS) through 2006. Both at EPA and later, I helped sponsor and produce analyses and assessments of the interactions between NAAQS and other regulated air pollutants and climate change.

Our main concerns and recommendations¹ include:

- The process the EPA Administrator has adopted for this review of the particulate matter standards is fatally flawed.
- The draft CASAC report is dominated by the perspectives of the Chair, who continues to argue for the use of causal inference studies that are either not properly vetted or do not yet exist over the use of the large body of epidemiology studies and supporting information from other disciplines that do exist.
- The draft's frequent reference to "most" members of a six-member CASAC, which includes no epidemiologists, is weak, especially in the face of the contrary conclusions of the 20-member IPMRP, whose inclusion would make it 21 to 5.

Process: EPA and CASAC continue to operate under the fiction that the current NAAQS process for PM and ozone will be of any value other than an object lesson in managerial malpractice and hubris. The committee soldiers on through the absurdity of a three-month marathon of sequential reviews of the equivalent of five separate documents for PM and ozone. This culminates in four straight days of public

¹ See also written Comments on the Draft EPA Policy Assessment on PM by John Bachmann on Behalf of the Environmental Protection Network. Submitted 12 November 2019.

meetings to review the PM risk and policy assessments, the ozone integrated science assessment (ISA), and the ozone exposure-risk and policy assessments (PA). This, despite the fact the Administrator denied the committee's requests last spring to restore balance in terms of expertise needed as well as order to the process. As several CASAC members have noted, the consultant "pool" is no substitute for the kind of interactions needed in live CASAC discussions. This forced march of producing simultaneous science and policy documents on an unrealistic schedule is not fair to the CASAC members, EPA staff or the public.

These reviews in no way comport with a sound process for assessing scientific information or separation of science and policy. The many process short-cuts put the lie to a suggestion in the draft CASAC report that the Administrator emphasized "sound science throughout the review process."² The draft PA report is evidence that this understaffed and divided committee lacks the breadth, depth, and diversity of expertise and experience needed to ensure the quality and credibility of the NAAQS review process.

Minority Rules? The Chair has been demonstrably complicit with the compromises in the process, including the elimination of the CASAC PM Review Panel in 2018. He has also attempted to supplant the approach EPA has used for determining causality in the ISA through the use of causal inference methods that Jon Samet³ noted "cannot be considered the current state-of-practice" for air pollution epidemiology. The draft letter on the PA now, in part, advocates the use of Dr. Cox's software to, in effect, conduct new research. While we and others strongly support ongoing and future research using causal inference methods, such as that now being done by Harvard for Health Effects Institute (HEI), EPA policy staff are in no position to conduct new research as part of a risk assessment during a NAAQS review.

At various times during the December meetings on PM and ozone, the Chair verbally suggested he did not wish to wholly replace the current process or exclude large numbers of studies. Yet, the criteria for causality in the current draft report noted above continues to confuse the process of assessing the existing scientific information and risk characterization with the actual conduct of scientific research. And as noted in our summary of his individual comments on the ISA, Dr. Cox has indeed suggested removing large numbers of cohort studies of PM based on an unfounded speculation regarding temperature:

"In conducting a new search and sorting, EPA should be wary of suggested "systematic" criteria for excluding an epidemiology study, as the panel lacks such expertise. An example of such problematic criteria is found on page A-76 of the draft letter comments, which suggests "*simply excluding studies that fail to control for temperature as an important confounder would 22 eliminate many of the studies in Table 11-5 (North American epidemiologic studies of long-term exposure to PM2.5 and mortality) and other tables and figures summarizing evidence in the Draft ISA.*" It provides no evidence showing long-term temperature metrics as a serious confounder in air pollution studies, and apparently is unaware that the HEI reanalysis of the two cohort studies in 2000 did include adjustment for temperature, finding little if any change in the results. Using this criterion for inclusion without contrary evidence is unfounded. The criteria would also eliminate studies that simply made claims about how changing PM levels would change mortality, if it did not actually measure reductions. At least the author made the goal of these

² Draft CASAC PM report, line 17.

<https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/0a46bdbe59c86531852584b10077b0f6!OpenDocument>

³ Comments Concerning EPA's Integrated Science Assessment (ISA) for Particulate Matter, Jonathan Samet, MD, MS. Submitted March 27, 2019.

criteria clear, stating that “*they would eliminate most (possibly all) of these numerous studies.*” These suggestions are in stark contrast with the position of all PM CASAC review panels.”⁴

We recommend CASAC members pay particular attention to the cautions raised by Dr. Lianne Sheppard⁵ in her written remarks as well as her colloquy with the Chair questioning the technical soundness of the recommendations in the 11-13-19 draft CASAC review with respect to the application of causal inference methods in EPA’s PA. Given her concerns and the lack of review of Appendix by a more qualified group of experts, such as epidemiologists, additional biostatisticians and other experts on the 20-member Independent Particulate Matter Review Panel (IPMRP), we concur that this Appendix be removed from the report, or at most that the product be attributed to the individual member(s) who authored the piece. Because much of this material addresses alternative analytical approaches for risk characterization based on epidemiology studies, some of it might be condensed and included in research recommendations for future reviews.

The confusion between assessing scientific information and conducting new research continues with a repeated comment that the weight of evidence based on the causality framework used in the ISA and followed in the PA is not validated for application to PM_{2.5}.⁶ The criticism is that it is based too much on expert judgment, which is unreliable. The irony is that this critique also applies directly to the draft CASAC report and the committee discussion.⁷ When confronting Dr. Frampton’s statement outlining why use of multiple studies using different measurements and methods speaks to the issue of causality, Dr. Cox replied with the claim—but then you reduce PM_{2.5} and “nothing happens.” Clearly the Chair is expressing a judgement that is based in part in a faith in his own application of a methodology, an application that has been little used or seriously vetted in air pollution epidemiology.

In expressing this judgement, Dr. Cox continues to ignore the findings of a number of accountability studies and other relevant evidence to the contrary.⁸ The two most recent accountability studies (Zigler et al. 2018; Sanders et al. 2019) used causal inference methods to show that EPA designation of areas as non-attainment were followed by reductions in PM_{2.5} and a causal association between particle pollution and mortality, i.e. they were true accountability studies. By contrast, Cox and Popkin (2015) is not an accountability study, and more comparable to the assessment of general reductions from multiple causes assessed in the prospective follow-up of the six-city-study (Laden et al., 2006). Although not using causal inference, the six-city

⁴ Written Comments of John Bachmann on behalf of the Environmental Protection Network. 24 March 2019

<https://www.environmentalprotectionnetwork.org/wp>

content/uploads/2019/03/John_Bachmann_Comments_to_CASAC-for-EPN-.pdf

⁵ Comments to CASAC PM Policy Assessment Letter and Report, Lianne Sheppard, PhD. December 3, 2019.

[https://yosemite.epa.gov/sab/sabproduct.nsf//147C2AAF33D4613A852584C500437CBF/\\$File/SheppardPAreportCommentsSubmitted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//147C2AAF33D4613A852584C500437CBF/$File/SheppardPAreportCommentsSubmitted.pdf)

⁶ The committee would be well served by reviewing published cautions against ignoring the large body of existing evidence in making judgements on causality, notably Dominici F, Zigler C. Best practices for gauging evidence of causality in air pollution epidemiology. *Am J Epidemiol.* 2017; 86(12):1303–1309; Goldman, G.T., and F. Dominici. Don't abandon evidence and process on air pollution policy. *Science* 29 Mar 2019: Vol. 363, Issue 6434, pp. 1398-1400; Carone, M., Dominici, F., & Sheppard, L. (2019). In Pursuit of Evidence in Air Pollution Epidemiology. *23 Epidemiology*, 1.

⁷ See part 8 on the role of expert judgment in the NAAQS in the written comments of Dr. Chris Frey on the CASAC review of the PM Policy Assessment. December 3, 2009.

[https://yosemite.epa.gov/sab/sabproduct.nsf//B9165A397FBF2659852584C50073D8C1/\\$File/Written+Statement+H+Christopher+Frey+CASAC+PM+Draft+PA+191203+Submitted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//B9165A397FBF2659852584C50073D8C1/$File/Written+Statement+H+Christopher+Frey+CASAC+PM+Draft+PA+191203+Submitted.pdf)

⁸ See End Notes on U.S./Canada PM Accountability And Related Studies of PM Reductions

investigators found the greatest decrease in mortality risk occurred in the cities with the largest reduction in PM_{2.5}; the six-city study had the advantage of access to subject-specific health data.

We submit that the judgement reflected in Dr. Cox's statement above is not consistent with the weight of the evidence from recent accountability studies using causal inference and other relevant epidemiologic assessments of PM reductions. The opinion is clearly influenced by his own work, which as Jon Samet and Lianne Sheppard note, has not received adequate vetting.

All judgments made by CASAC and the Administrator on whether standards provide adequate protection should be informed by a comprehensive and fair assessment of the available scientific literature. In calling for a margin of safety, a focus on risks that research has not yet identified, and creating a panel to provide expert scientific judgement, the Clean Air Act clearly calls for reliance not only on science, but judgments that clearly go beyond the available science. Even with the lack of expertise and experience as compared to all past PM reviews, this CASAC has provided a number of useful comments with respect to strengthening the presentation and assessment of the scientific information. What they have not done is to make a credible case that in the middle of this review, there is a better approach to assessing causality based on the available information we have today than the weight of evidence approach.

In 2016, CASAC, supported by a larger panel, approved this approach to causality that EPA's National Center for Environmental Assessment (NCEA) followed in developing the 2018 draft ISA. It is impractical and unrealistic for the Chair to continue to push for a wholesale change in the ISA and the PA based on an untested and impractical approach in the middle of the review process. It is also inappropriate to continue to represent the divide, in what is for PM a six-member CASAC, as one of a majority/minority. Why are the Chair and the Administrator afraid to include additional PM experts from the disbanded PM panel in the room to participate in the kind of productive interactions that were the hallmark of past NAAQS reviews?

As research provides an improved application and understanding of the strengths and weaknesses of adapting causal inference methods to air pollution epidemiology by various groups, EPA will be in a better position to determine what changes in the approach for reviewing the standards will be appropriate. We're not there yet.

The draft CASAC report is too critical of some basic issues regarding the characterization of epidemiology studies in the PA, and earlier the ISA. While it is appropriate to remind EPA of the distinctions between association and causality, it is wrong to suggest EPA has ignored these distinctions throughout the ISA and the PA. EPA's ISA preamble, which details the weight of evidence approach EPA, with CASAC support,⁹ has evolved over the past 20 years for assessing causality, states:

“An association is the statistical relationship among variables, but alone, it is insufficient proof of a causal relationship between an exposure and a health outcome. Unlike an association, a causal claim supports the creation of counterfactual claims; that is, a claim about what the world would have been like under different or changed circumstances.”

CASAC is on firmer ground in stressing that the uncertainties in terms of causality and confounding are clearly stated in using individual studies for quantitative risk characterization. CASAC might reasonably

⁹ See part 2 on the history of EPA's Causality Determination Framework in the written comments of Dr. Christopher Frey cited above.

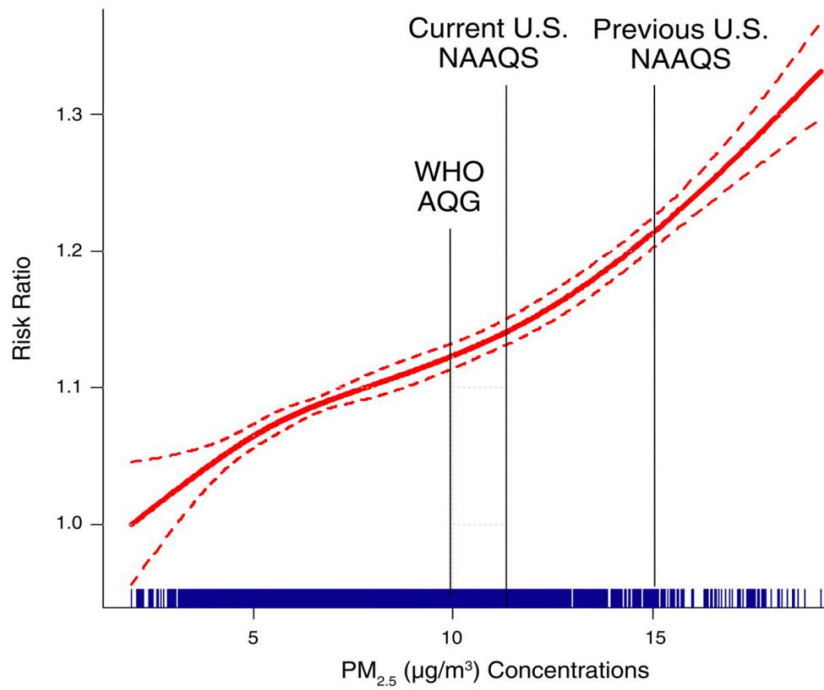
recommend using the concentration-response (CR) function derived from actual reductions of fine particles in the Laden study as a comparison, in addition to providing a more robust qualitative discussion of the uncertainties in the absolute numbers. Because of the major uncertainties long recognized in past EPA and CASAC reviews of separate PM risk assessment plans and documents, EPA has never used the absolute risk characterization estimates as a principal basis for deciding the appropriate level of the standard. Yet no reasonable tweaking of the risk numbers to account for confounding and other would alter the conclusion that the potential public health risks appear to be significant. It is unfortunate that the process did not permit these issues to be addressed before preparing the draft PA.

CASAC should have spent more time considering the details and implications of the evidence-based approach. The draft report suggestion that the evidence since 2009 adds nothing new to this review is wholly without foundation. The rationale CASAC offers is absurd. The simple graph included in the report showing linear CR functions ignores the earlier summary in the PA of how evidence-based assessments of these kinds of studies are used in standard setting. As a result of the need to focus on the risk assessment issues in a simultaneous review of two documents, CASAC has missed the point that the evidence-based assessment of the studies has driven the standards.

The draft letter willfully ignores the obvious implications of newer studies in which the mean concentrations are well below the current NAAQS. 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, and indeed these results drove the recommendations of the EPA staff as well as the 20 members of the IPMRP. In setting standards, EPA recognizes that uncertainties increase at levels well below the mean. And the recent studies summarized in the PA have pushed the mean to lower concentrations.

Nevertheless, it is useful to compare the draft CASAC figure with a CR function derived from one of the more recent Canadian cohort studies; the figure was included in the recent HEI phase I report on low levels of air pollution (See below). The range and density of data as well as the central tendencies are clearly different and at lower concentrations as compared with the straight line/fake data plotted in the draft CASAC figure. Moreover, the CASAC plot of Di et al. (2017) does not represent the alternative analysis that excluded all data above standard. Therefore, even with the myopic view that only CR functions from these studies are relevant, the newer studies go below the range of those in 2009. The actual results of the new studies and CASAC continued confusion about the role of the risk assessment in PM standard setting bely the draft CASAC conclusion that the new studies do not provide important evidence suggesting the current standards are not adequate.

Finally, the draft letter cites an environmental news reporter as the basis for CASAC's recommendations on climate instead of looking at the far more complete discussion of the issue in the ISA. Given the lack of expertise relevant to visibility or climate expertise on the CASAC, the absence of any meaningful comments on climate by CASAC in the review of the ISA, and the shallowness of the assessment in the letter, it is hard to understand what these recommendations in the draft letter really mean. They ignore that we already know much about the major difference in the direction of aerosol effects on radiative forcing and cloud effects among black and brown carbon vs. other particles. They cannot be simply lumped into a single box—or standard. Given the comments we do have, the committee appears to have serious concerns about the implications of pollution effects on climate. If the committee is indeed serious about the serious effects of climate on public welfare, CASAC would do well to recommend to the Administrator the compelling need for action on a far broader range of pollutants than just PM, including ozone and all greenhouse gases.



Preface Figure I. Shape of the concentration–response function for mortality associated with fine particulate matter in a Canadian Cohort. (Courtesy R. Burnett). NAAQS = National Ambient Air Quality Standard; WHO AQG = World Health Organization Air Quality Guidelines.

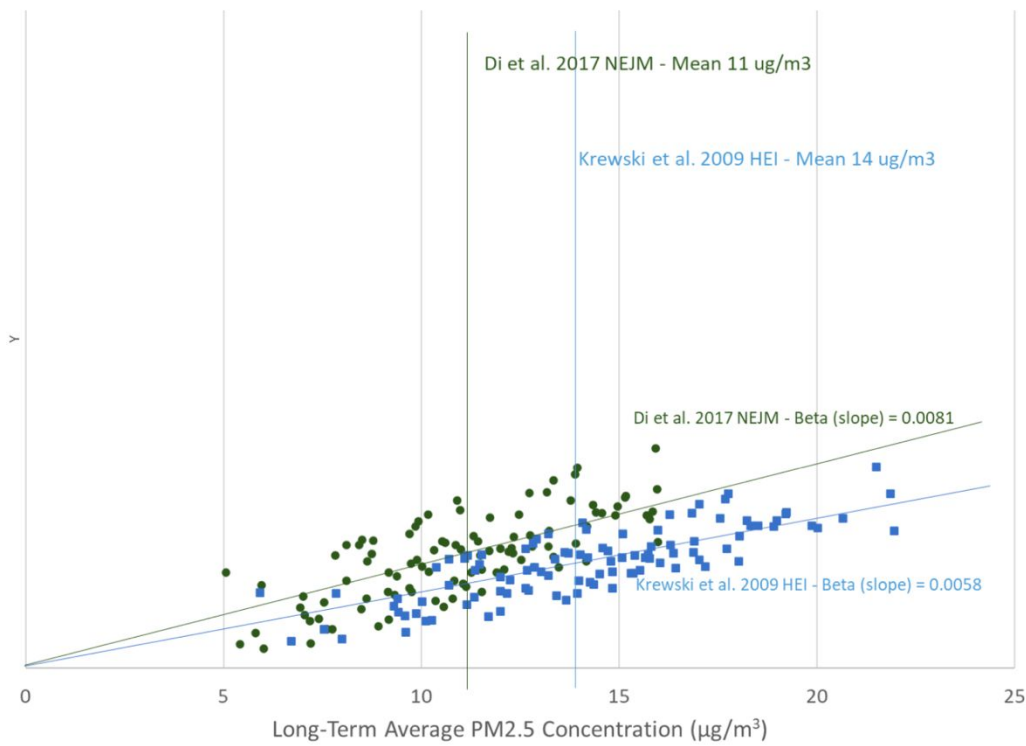


Figure included in the CASAC draft report: simulated data points do not appear to have any basis in the original studies.

End Notes – Accountability and other long-term studies of PM reductions.

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.

Causal Inference Studies

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

Sanders, Nicholas J Barreca, Alan I; Neidell, Matthew J. **2019** Estimating Causal Effects of Particulate Matter Regulation on Mortality. *Epidemiology*: [December 10, 2019 - Volume Publish Ahead of Print - Issue - p](#) doi: 10.1097/EDE.0000000000001153

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 ug/m³ 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. **2018**. Fine particulate matters: The impact of air quality standards on cardiovascular mortality. *Environ Res.* 2018 Feb: 161: 364-369.