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Oral Comments of John Bachmann on the draft EPA Policy Assessment on behalf of the Environmental Protection Network.

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

Thanks for this opportunity to speak. I am representing the Environmental Protection Network (EPN), a volunteer organization of former EPA employees and others concerned about public health and the environment. I worked for the U.S. Environmental Protection Agency's (EPA) 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 Standards (NAAQS) through 2006.

Our main concerns and recommendations are detailed in recent and forthcoming written comments:

- The process the EPA Administrator has adopted for this review of the particulate matter standards is fatally flawed.

- The draft CASAC letter 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 a large body of epidemiology studies and supporting information that does 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 Independent PM Review Panel (IPMRP), whose inclusion would make it 22 to 4.

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 draft Policy Assessment (PA) letter 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 PM panel in 2018. He has also attempted to supplant the approach EPA has used for determining causality in the Integrated Science Assessment (ISA) through the use of causal inference methods that Jon Samet noted "cannot be considered the current state-of-practice" for air pollution epidemiology. The draft letter on the PA now advocates use of Dr. Cox's software to, in effect, conduct

new research. While we and others 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.

While it is appropriate to remind EPA of the distinctions between association and causality, it is wrong to suggest EPA has ignored them in the ISA and the PA. EPA's ISA preamble, which details the weight-of-evidence approach EPA, with CASAC support, has evolved over the past 20 years for assessing causality, notes.

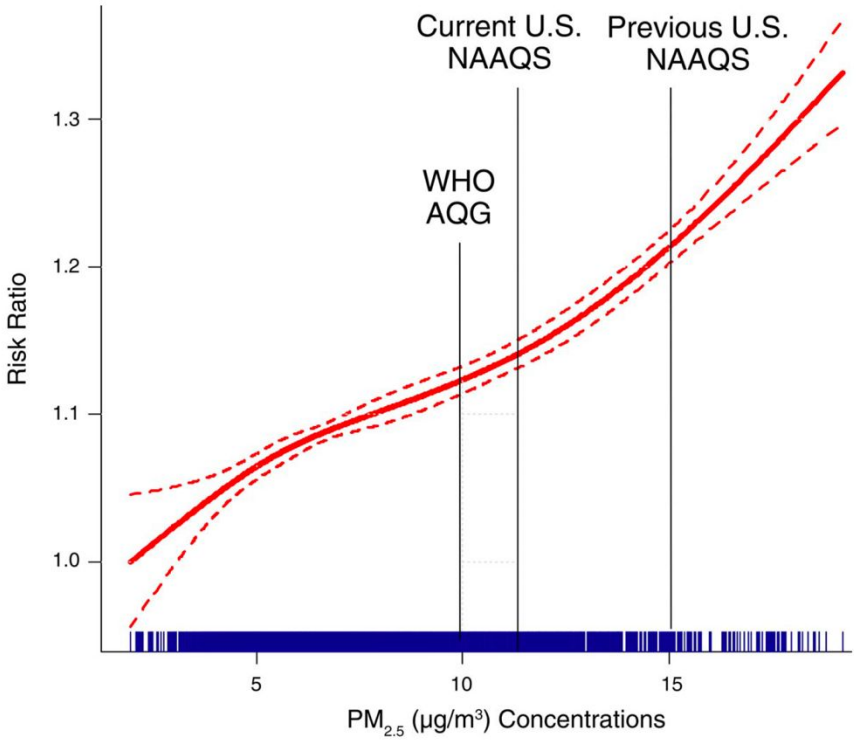
> *An association is the statistical relationship among variables, but alone, it is insufficient proof of a causal relationship between an exposure and a health outcome. Unlike an association, a causal claim supports the creation of counterfactual claims; that is, a claim about what the world would have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

In 2016, CASAC approved the approach to causality that the 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 CASAC as one of a majority/minority. Why are the Chair and the Administrator afraid to include additional PM experts from the panel in the room to participate in the kind of productive interactions that were the hallmark of past NAAQS reviews?

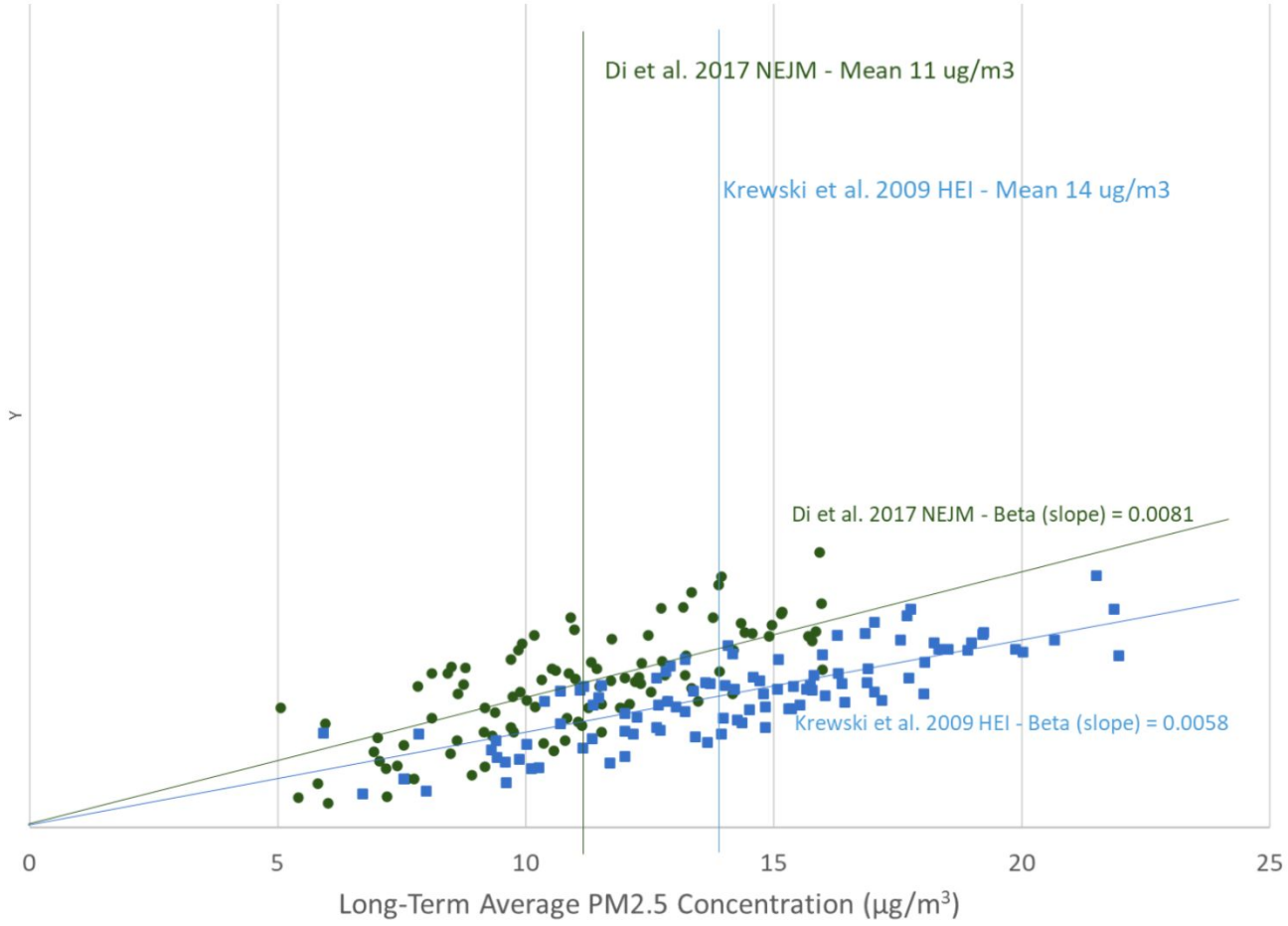
The suggestion that the new evidence since 2009 adds nothing new to this review is wholly without foundation. The simple graph showing linear concentration-response (CR) functions, which were not used as the basis for the current standards, ignores earlier summary in the PA of how evidence-based assessments of these kinds of studies are used in standard setting. The PM standards have never been based on the risk characterization estimates, which are used more as a relative indicator of whether the data suggest the possibility of a significant risk. It is the evidence-based assessment of the studies that 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. In setting standards, EPA recognizes that uncertainties increase at levels well below the mean.

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. does not represent the analysis that excluded all data above standard. 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 a 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. If you are serious about climate, CASAC would do well to recommend to the Administrator the compelling need for action on a far broader range of pollutants than just PM.



Preface Figure 1. 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.


Di et al. 2017 NEJM - Mean 11 ug/m3
Krewski et al. 2009 HEI - Mean 14 ug/m3
Y
Di et al. 2017 NEJM - Beta (slope) = 0.0081
Krewski et al. 2009 HEI - Beta (slope) = 0.0058
0
5
10
15
20
25
Long-Term Average PM2.5 Concentration (µg/m³)