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Re: Complaint Against EPA 2018 PM ISA Assessment Lead Jason D. Sacks, MPH

Dear Dr. Grifo,

I am writing regarding the EPA's October 2018 **Integrated Science Assessment for Particulate Matter (External Review Draft)** EPA/600/R-18/179 [2018 PM ISA] (https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=341593). This document was prepared by the National Center for Environmental Assessment—RTP Division of the US EPA Office of Research and Development in Research Triangle Park, NC. I am herewith filing a formal complaint against 2018 PM ISA Assessment Lead Jason D. Sacks, MPH, for serious violation of the EPA Principles of Scientific Integrity (http://www.epa.gov/osa/basic-information-about-scientific-integrity). These principles were published in 1999 after they were developed in conjunction with the EPA's National Partnership Council. Specifically, I have strong evidence that Assessment Lead Sacks violated the basic rule for ethical behavior by all EPA employees regarding "Interpreting and presenting results."

My March 28, 2017 independent, peer-reviewed reanalysis (Enstrom 2017) found NO relationship between PM2.5 and total mortality in the 1982 ACS Cancer Prevention Study (CPS II) cohort, which has been the primary cohort used by EPA since 1997 to claim a ***causal*** relationship between fine particulate matter (PM2.5) and total mortality in the US. My reanalysis (Enstrom 2017) and my response to criticism of my reanalysis (Enstrom 2018) challenge the validity of the existing CPS II-related findings summarized in the 2018 PM ISA. My reanalysis was made possible because I gained access to an original version of the CPS II data, as per the proposed April 30, 2018 EPA Rule "Strengthening Transparency in Regulatory Science" (https://www.epa.gov/osa/strengthening-transparency-regulatory-science). Enstrom 2017 and Enstrom 2018 and additional evidence are presented in my March 28, 2019 Public Comment to the EPA Clean Air Scientific Advisory Committee (https://yosemite.epa.gov/sab/sabproduct.nsf//F3E91876AC28F2F4852583CB007727C4/$File/Enstrom+Comment+re+CASAC+Review+of+2018+EPA+PM+ISA+032819EE.pdf).

My uncontradicted null evidence is supported by the September 28, 2018 Intrepid Insight "Statistical Review of Competing Findings in Fine Particulate Matter and Total Mortality Studies," which found NO relationship between PM2.5 and total mortality in meta analyses including eight US cohorts and six California cohorts (https://www.intrepidinsight.com/pm25_statreview/). Thus, a very large body of peer-reviewed NULL evidence on the long-term relationship between PM2.5 and total mortality in the US has been published since the 2009 PM ISA. A fair assessment of all peer-reviewed epidemiologic evidence, using classical epidemiologic criteria, shows that there is NO ***causal*** long-term relationship between PM2.5 and total mortality in the US.

Unfortunately, Enstrom 2017 and Enstrom 2018 have been essentially ignored in the 2018 EPA PM ISA and presentation and interpretation of the available published evidence is TOTALLY MISREPRESENTED in Section 11.2 'Long-Term PM2.5 Exposure and Total Mortality' (pages 11-57 to 11-99), particularly in Section 11.2.7 'Summary and Causality Determination' (pages 11-93 to 11-99). Key sentences from these two sections, which I understand were prepared by Assessment Lead Sacks are reprinted below. Shown in bold are the only two sentences about Enstrom 2017 and these two sentences grossly misrepresent the findings and significance of Enstrom 2017. Enstrom 2005, Enstrom 2006, Enstrom 2017, and Enstrom 2018 are entirely omitted from Table 11-5 'North American epidemiologic studies of long-term exposure to PM2.5 and mortality' and Enstrom 2017 is barely cited in Figure 11-17 'Associations between long-term exposure to PM2.5 and total (nonaccidental) mortality in the American Cancer Society (ACS) cohort.'

Finally, I can make a strong case that these bolded sentences in Section 11.2.7 'Summary and Causality Determination' are utterly false regarding US evidence: 'Recent extended analyses and reanalysis of these cohorts continues to support this relationship, demonstrating consistent positive associations for total (nonaccidental mortality),' 'Overall, recent epidemiologic studies build upon and further reaffirm the conclusions of the 2009 PM ISA for total mortality,' and 'Collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term PM2.5 exposure and total mortality.' It is very important that these sentences be changed in the next version of the 2018 PM ISA.

I am willing to assist you in understanding all of the relevant details associated with my complaint. I request a speedy evaluation because the revision of the 2018 PM ISA is currently ongoing and Assessment Lead Sacks is actively involved in this revision.

Thank you very much for your consideration of my complaint,

Sincerely yours,

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Key Sentences from 2018 PM ISA

Page 11-57
11.2 Long-Term PM2.5 Exposure and Total Mortality
The 2009 PM ISA reported that the evidence was "sufficient to conclude that the relationship between long-term PM2.5 exposures and mortality is causal" (U.S. EPA, 2009).79 Two seminal cohort studies, the American Cancer Society (ACS) and the Harvard Six Cities studies provided the strongest evidence for this conclusion (i.e., consistency across studies and among replication and reanalysis of the same cohort; study designs appropriate for causal inference), and were supported by evidence from other cohort studies conducted in North America and Europe.

Page 11-65
A recent reanalysis of early ACS results observed a null association between county-level averages of PM2.5 measured by the Inhalable Particle Network between 1979 and 1983 and deaths between 1982 and 1988 (HR: 1.01; 95% CI: 1.00, 1.02) (Enstrom, 2017). Inconsistencies in the results could be due to the use of 85 counties in the ACS analysis by Enstrom (2017) and 50 Metropolitan Statistical Areas in the original ACS analysis (Pope et al., 1995).
Another benefit of the multiple reanalysis and extended analyses of the ACS cohort is the ability to compare the results of using different techniques to assign long-term PM2.5 exposures (e.g., monitors, models, satellite-based methods, or combinations of multiple techniques). The original analysis of the ACS cohort (Pope et al., 1995) and several extended analyses [e.g., (Jerrett et al., 2009)] used area-wide averages of PM2.5 concentrations measured by fixed-site monitors to assign exposure. As previously mentioned, the most recent extended analyses relied on LUR-BME models (Turner et al., 2016; Pope et al., 2014). In addition, Jerrett et al. (2013) used a LUR model to assign exposure to the subset of the ACS cohort residing in California while evaluating the association between long-term PM2.5 exposure and total (nonaccidental) and cause-specific mortality. Turner et al. (2017) evaluated the interaction between ambient PM2.5 exposure and smoking in the entire ACS cohort. As demonstrated in Figure 11-17, the results of all of these studies are consistent in the direction and magnitude of effect, providing evidence that these associations are not artifacts related to the type of exposure assessment used, and that they are robust to different kinds of exposure measurement error that may be associated with different exposure assessment techniques (Section 3.4.5.2).

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11.2.7 Summary and Causality Determination
Recent cohort studies evaluated since the completion of the 2009 PM ISA continue to provide consistent evidence of positive associations between long-term PM2.5 exposures and total (nonaccidental) mortality from studies conducted mainly in North America and Europe. Many recent analyses further evaluated the association between long-term PM2.5 exposures and the risk of mortality based on the original ACS study (Pope et al., 1995), adding new details about deaths due to cardiovascular disease (including IHD) and respiratory disease (including COPD), and extending the follow-up period of the ACS to 22 years (1982−2004).

Page 11-94
The strongest evidence supporting the conclusion of a causal relationship between long-term PM2.5 exposure and total mortality in the 2009 PM ISA was derived from analyses of the ACS and HSC cohorts. **Recent extended analyses and reanalysis of these cohorts continues to support this relationship, demonstrating consistent positive associations for total (nonaccidental mortality) and across different cause-specific mortality outcomes.**

Page 11-98
Overall, recent epidemiologic studies build upon and further reaffirm the conclusions of the 2009 PM ISA for total mortality.

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Collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term PM2.5 exposure and total mortality.