August 3, 2020

To:
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FRL-10010-62-OAR
Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process
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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

From:
James E. Enstrom, PhD, MPH, FFACE
Retired UCLA Research Professor (Epidemiology)
President, Scientific Integrity Institute
907 Westwood Boulevard #200
Los Angeles, CA 90024
http://www.scientificintegrityinstitute.org
jenstrom@ucla.edu
(310) 472-4274

I am a retired Research Professor/Researcher from the School of Public Health and Jonsson Comprehensive Cancer Center at UCLA and I am President of the Scientific Integrity Institute in Los Angeles. I hold a PhD in elementary particle physics from Stanford University and an MPH and postdoctoral certificate in epidemiology from UCLA. I have published important epidemiologic research showing that fine particulate matter (PM2.5) is not related to total mortality in the ACS Cancer Prevention Study cohorts (CPS I and CPS II). I am the only independent scientist to obtain and analyze original CPS cohort data. My epidemiologic research provides strong evidence that the EPA PM2.5 NAAQS is scientifically unjustified. My research has been cited in CASAC documents re PM2.5.

The purpose of my comment is to support the efforts described in "Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process" with regard to the misuse of co-benefits in EPA regulations. In 2011 EPA published a report "The Benefits and Costs of the Clean Air Act from 1990 to 2020". This report stated that Clean Air Act regulations will generate benefits that will "reach approximately $2.0 trillion in 2020" and that the benefits of these regulations exceed costs "by a factor of more than 30 to one." However, there are estimates that the vast majority of these claimed monetized benefits did not pertain to the pollutants targeted by EPA regulations, but rather derived from PM2.5 co-benefits. The benefits versus costs of EPA regulations were analyzed in detail in a 2011 NERA Report "An Evaluation of the PM2.5 Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations" and this Report confirmed that most of the quantified benefits were the result of PM2.5 ancillary benefits. My comment focuses on the evidence that there are no proven PM2.5 premature deaths in the US, which in turn means that no monetary value can be assigned to co-benefits supposedly due to PM2.5 deaths. This evidence is another reason that PM2.5 co-benefits are invalid and grossly exaggerate the monetary benefits of EPA regulations.

Primary evidence challenging the EPA use of PM2.5 mortality-related co-benefits is contained in the 257-page December 16, 2019 EPA Clean Air Scientific Advisory Committee (CASAC) PM Policy Assessment (PA) Report. Key summary text from this Report regarding PM2.5 health effects is:
Page 1: The Draft PM PA depends on a Draft Particulate Matter (PM) Integrated Science Assessment (ISA) that, as noted in the April 11, 2019, CASAC Report on the Draft PM ISA, does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to PM, due largely to a lack of a comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways.
Page B-21: "The PA states (p. 3-21) that "The draft ISA concludes that, 'collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term PM2.5 exposure and total mortality'." However, since "this body of evidence" consists primarily of associations in studies that did not fully control for causally relevant covariates (such as month and daily high and low temperatures) and that were not designed or analyzed to permit valid causal inferences, the conclusion that "this body of evidence is sufficient to conclude that a causal relationship exists between long-term PM2.5 exposure and total mortality" is unwarranted. It is not implied by, or consistent with, the principles of sound science previously discussed.

Further evidence challenging the EPA use of PM2.5 mortality-related co-benefits is contained in my June 29, 2020 Comment in support of the EPA Administrator's April 30, 2020 proposed decision to retain the current National Ambient Air Quality Standards for Particulate Matter. The following are six primary reasons that PM2.5 does not *cause* premature deaths in the US:
a) No Etiologic Mechanism: This is no experimental proof that 1-5 lifetime grams (<100 µg/day) of PM2.5 causes death
b) Weak Epidemiologic Risk: Tiny positive relative risks (RR<1.10) do not prove that PM2.5 causes death and reductions of in PM2.5 levels have not clearly reduced the supposed mortality risks
c) Ecological Fallacy: PM2.5 monitors of ambient air provide inaccurate measurements of individual human exposure and there are NO PM2.5 measurements of individual exposure
d) Uncontrolled Confounding Variables: Co-pollutants, temperature, geography, and other factors can reduce or eliminate an apparent relationship
e) Access to Underlying Data: Enstrom independent analysis of American Cancer Society data (CA CPS I and CPS I) demonstrates the importance of access to underlying epidemiologic data (see next section)
f) Totality of US Cohort Studies Shows NO Relationship: Objective meta-analysis shows NO statistically significant relationship between long-term PM2.5 exposure and total mortality in nine US and six California prospective epidemiologic cohorts

My detailed October 17, 2019 Comment on the 2019 Draft EPA PM PA contains strong evidence that there is NO causal relationship between PM2.5 and total mortality in the US and it demonstrates the importance of access to underlying data as per the proposed EPA Transparency Rule. To illustrate the severe flaws in 2019 PM PA, I focus on the "All-cause mortality" portion of Figure 3-3 within Section 3.2.3 PM2.5 Concentrations in Key Studies Reporting Health Effects of Chapter 3 REVIEW OF THE PRIMARY STANDARDS FOR PM2.5 of the 2019 PM PA. A key sentence on page 3-52 states "To evaluate the PM2.5 air quality distributions in key studies in this review, we first identify the epidemiologic studies assessed in the draft ISA that have the potential to be most informative in reaching conclusions on the primary PM2.5 standards."

Unfortunately, Figure 3-3 on page 3-54 does not properly describe the results from the nine US prospective cohort studies of PM2.5 and total mortality. Figure 3-3 of 2019 PM PA deliberately misrepresents the US epidemiologic evidence on the relationship of PM2.5 to total (all cause) mortality and obscures the null relationship that exists in a proper meta-analysis of the nine major US cohort studies with published findings. Particularly troubling is the unjustified omission from the 2019 PM PA of my March 28, 2017 "Fine Particulate Matter and Total Mortality in Cancer Prevention Study Reanalysis" in *Dose-Response* (Enstrom 2017) and my May 29, 2018 "Response to Criticism" in *Dose-Response* (Enstrom 2018). My seminal reanalysis of ACS CPS II identified major flaws in Pope 1995, the key study underlying the 1997 PM NAAQS.

Instead of properly examining the detailed findings in my reanalysis, SECTION 11.2: Long-Term PM2.5 Exposure and Total Mortality of the 2018 PM ISA dismissed my reanalysis in two *inaccurate* sentences: "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)."

A proper meta-analysis of the relationship between PM2.5 and total mortality in nine US cohort studies is given in the September 28, 2018 Intrepid Insight (II) article **"**Statistical Review of Competing Findings in Fine Particulate Matter and Total Mortality Studies".

II Table B3: Intrepid Insight Computation of Fixed and Random Effects Meta-Analysis

Nine US Cohorts That Analyzed Ambient Fine Particulate Matter (PM2.5) and Total (All-cause) Mortality

Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 $\mu g/m^3$ in PM2.5

US Cohort Studies	Author Year	RR Table	F-U Years	RR	95%CI(L)	95%CI(U)
Veterans Study	Lipfert 2000	T6	1986-1996	0.890	0.850	0.950
Medicare (MCAPS) Eastern US	Zeger 2008	T3	2000-2005	1.068	1.049	1.087
Medicare (MCAPS) Central US	Zeger 2008	T3	2000-2005	1.132	1.095	1.169
Medicare (MCAPS) Western US	Zeger 2008	T3	2000-2005	0.989	0.970	1.008
ACS Cancer Prevention Study (CPS II)	HEI RR140 2009	T34	1982-2000	1.028	1.014	1.043
Nurses Health Study	Puett 2009	T3	1992-2002	1.260	1.020	1.540
Health Professionals FU Study	Puett 2011	T2	1989-2002	0.860	0.720	1.020
Harvard Six Cities Study (H6CS)	Lepeule 2012	T2	1974-2009	1.140	1.070	1.220
Agricultural Health Study	Weichenthal 2015	T2	1993-2009	0.950	0.760	1.200
NIH-AAPR Diet and Health Study	Thurston 2016	T2 F3	2000-2009	1.025	1.000	1.049
National Health Interview Survey	Parker 2018	T3corr	1997-2011	1.016	0.979	1.054
Intrepid Insight Random Effects Meta-Analysis	Summary RR			1.031	0.997	1.066

Q Test Statistic = 109.5100704 I^2 90.87%
Cochrane's Q Test for Homogeneity of Studies (Null Hypothesis: Studies are Homogenous)
P-Value = 6.69843E-19 → Since Studies fail Test for Homogeneity, Random Effects Meta-Analysis Yields Summary RR = 1.031 (0.997-1.066), which is statistically consistent with 1.000 (NO relationship)

The original Zeger 2008 analysis of the Medicare cohort (MCAPS) was included in this meta-analysis rather than the Di 2017 analysis, because of the serious concerns about Di 2017 that I stated in my October 12, 2017 *NEJM* letter. Dominici, the key author on both studies, does not explain how the overall RR increased from 1.044 in the Zeger 2008 analysis to 1.073 in the Di 2017 analysis. Di 2017 does not even cite Zeger 2008. If the Medicare (MCAPS) cohort is removed from the meta-analysis because it does not properly control for confounders, II Table B4 shows that the Summary RR = 1.014 (0.973-1.057), which is also NO relationship.

Contrary to the evidence in the detailed II Table B3, the 2019 PM PA Figure 3-3 misrepresents the US evidence and inappropriately includes Canadian evidence. For instance, Figure 3-3 omits the null findings in the original Veterans Study (Lipfert 2000), as shown in II Table B3. In addition, Figure 3-3 includes results from the CPS II cohort twice (Pope 2015 and Turner 2016) and does not mention that my reanalysis found serious flaws in Pope 1995, HEI 2000, and HEI 2009. These flaws raise doubts about the validity of subsequent 'secret science' CPS II analyses by Pope and Turner. Figure 3-3 includes results from the Medicare cohort five times (Di 2017, Shi 2016, Wang 2017, Kiomourtzoglou 2016, Zeger 2008). There is no mention that the original Medicare study (Zeger 2008) is not consistent with the recent study (Di 2017). Figure 3-3 includes results from the Nurses Health Study twice (Puett 2009 and Hart 2015) and there is no mention that Puett 2009 and Puett 2011 omitted California subjects, who most likely had null findings. Inclusion of multiple hazard ratio (RR) results from the same cohort is inappropriate and gives the misleading impression that the RRs in most of the US cohorts are positive. Inclusion in Figure 3-3 of results from Canadian studies is totally inappropriate because these positive Canadian RRs are not relevant to PM2.5 findings and policy assessment in the US. To show how the 2019 PM PA presented these results, Figure 3-3 on page 3-54 of the 2019 PM PA is reproduced below. First, I document that there is NO relationship between PM2.5 and total mortality in California.

II Table B7: Intrepid Insight Computation of Fixed and Random Effects Meta-Analysis

Six CA Cohorts That Analyzed Ambient Fine Particulate Matter (PM2.5) and Total (All-cause) Mortality

Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 $\mu g/m^3$ in PM2.5

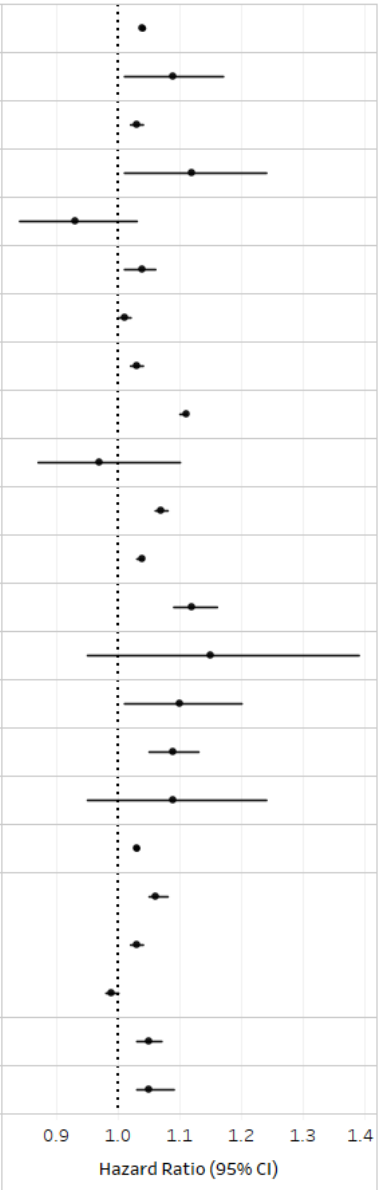
California Cohort Studies	Author Year	RR Table	F-U Years	RR	95%CI(L)	95%CI(U)
Adventist Health Study (AHSMOG)	McDonnell 2000	T3+	1977-1992	1.000	0.950	1.050
CA ACS Cancer Prevention (CA CPS I)	Enstrom 2005	T7	1983-2002	0.997	0.978	1.016
Medicare (MCAPS) Western US	Zeger 2008	T3	2000-2005	0.989	0.970	1.008
CA ACS Cancer Prevention (CA CPS II)	Krewski 2010	T2	1982-2000	0.968	0.916	1.022
California Teachers Study	Ostro 2015	Appx	2001-2007	1.010	0.980	1.050
CA NIH-AAPR Diet and Health Study	Thurston 2016	T2 F3	2000-2009	1.017	0.990	1.040
Intrepid Insight Fixed Effects Meta-Analysis		Summary RR		0.999	0.988	1.009
Intrepid Insight Random Effects Meta-Analysis		Summary RR		0.999	0.988	1.009

Q Test Statistic = 4.7683 I^2 -4.86%
Cochrane's Q Test for Homogeneity of Studies (Null Hypothesis: Studies are Homogenous)
P-Value = 0.4448 → Since Studies satisfy Test for Homogeneity, Fixed and Random Effects Meta-Analysis Yield Summary RR = 0.999 (0.988-1.009), which is statistically consistent with 1.000 (NO relationship)

2019 PM PA Figure 3-3. Epidemiologic studies examining associations between long-term PM2.5 exposures and [all-cause] mortality.

All-cause mortality

Exposure Proxy	Country	Citation	Cohort	Health Data	Air Quality Data	Reported PM Mean (Range)(ug/m3)
Modelled	U.S.	Di et al., 2017b	Medicare	2000-2012	2000-2012	11 (5th and 95th: 6.21- 15.64)
		Hart et al., 2015	Nurses Health	2000-2006	1999-2006	12.0 (NR)
		Pope et al., 2015	ACS CPS-II	1982-2004	1999-2004	12.6 (1.0–28.0)
		Puett et al., 2009	Nurses Health	1992-2002	1988-2002	13.9 (5.8–27.6)
		Puett et al., 2011	Health Professionals	1989-2003	1988-2003	17.8 (NR)
		Shi et al., 2016	Medicare	2003-2008	2003-2008	8.12 (0.8-20.22)
		Thurston et al., 2016	NIH-AARP	2000-2009	2000-2008	12.2 (2.9-28.0)
		Turner et al., 2016	ACS CPS-II	1982-2004	1999-2004	12.6 (1.4-27.9)
		Wang et al., 2017	Medicare	2000-2013	2000-2013	NR (Median: 10.7) (6.0-20.6)
		Weichenthal et al., 2014	Ag Health	1993-2009	2001-2006	Iowa: 8.8; North Carolina: 11.1 (NR)
	Canada	Crouse et al., 2012	CanCHEC	1991-2001	2001-2006	8.7 (1.9- 19.2)
		Crouse et al., 2015	CanCHEC	1991-2006	1984-2006	8.9 (0.9- 17.6)
		Pinault et al., 2016	CCHS	2000-2011	1998-2011	6.3 (1.0-13.0)
Monitor	U.S.	Goss et al., 2004	U.S. Cystic Fibrosis	1999-2000	2000	13.7 (NR)
		Hart et al., 2015	Nurses Health	2000-2006	2000-2006	12.7 (NR)
		Kiomourtzoglou et al., 2016	Medicare	2000-2010	2000-2010	12.0 (Mean Range: 9-13) (NR)
		Lepeule et al., 2012	Harvard Six-City	2001-2009	1979-2009	1974-2009: 15.9; 2000 onwards mean range: <15-<18 (NR)
		Lipfert et al., 2006	Veterans	1997-2001	1999-2001	14.3 (NR)
		Zeger et al., 2008	MCAPS	2000-2005	2000-2005	Central region: NR (Median: 10.7) (NR) Eastern region: NR (Median: 14.0) (NR) Western region: NR (Median: 13.1) (NR)
	Canada	Crouse et al., 2012	CanCHEC	1991-2001	1987-2001	11.2 (NR)
		Weichenthal et al., 2016a	CanCHEC	1991-2009	1998-2009	9.8 (4.74-13.62)



For additional perspectives on the benefits and costs associated with Clean Air Act regulations, please examine the Global Energy Institute Compilation of Comments .