September 2, 2020

Letter to the Editor New England Journal of Medicine Retain the Current Particulate-Matter Air-Quality Standard

James E. Enstrom, PhD, MPH University of California, Los Angeles jenstrom@ucla.edu

The August 13 Sounding Board by the Independent Particulate Matter Review Panel (IPMRP)¹ incorrectly claims that fine particulate matter (PM_{2.5}) *causes* premature deaths in the United States and inappropriately criticizes the latest EPA CASAC assessment of PM_{2.5} health effects.² There is no established etiologic means by which PM_{2.5} *causes* deaths. Furthermore, objective meta-analysis of key results from the nine primary US cohorts finds NO relationship between PM_{2.5} and total mortality (Table).³ The original positive relationships used for establishing the 1997 PM_{2.5} NAAQS have been invalidated by my independent reanalysis of the American Cancer Society Cancer Prevention Study⁴ and the Harvard Six Cities Study.³ The null findings of my reanalysis demonstrate the need for study data assess as per the proposed EPA rule "Transparency in Regulatory Science." This rule is opposed by the IPMRP, the *NEJM* Editor-in-Chief, eight Harvard professors who promote PM_{2.5} deaths, and 86 other Harvard professors.⁵ Extensive null epidemiological and toxicological evidence supports retaining the current PM_{2.5} NAAQS. In fairness, the *NEJM* needs to publish a Sounding Board with this null evidence.

I report no potential conflict of interest relevant to this letter.

References

1. Independent Particulate Matter Review Panel. The Need for a Tighter Particulate-Matter Air-Quality Standard. *N Engl J Med* 2020;383:680-683. August 13, 2020 DOI: 10.1056/NEJMsb2011009

2. Cox LA. CASAC review of EPA's policy assessment for the review of the National Ambient Air Quality Standards for particulate matter (external review draft—September 2019): EPACASAC-20-001. Washington, DC: Clean Air Scientific Advisory Committee, Environmental Protection Agency, December 16, 2019 (<u>https://beta.regulations.gov/document/EPA-HQ-OAR-2015-0072-0260</u>) or (<u>https://yosemite.epa.gov/sab%5Csabproduct.nsf/E2F6C71737201612852584D20069DFB1/\$File/EPA-CASAC-20-001.pdf</u>)

3. Enstrom JE. October 17, 2019 Comment Criticizing the 2018 Draft EPA Particulate Matter Integrated Science Assessment and the 2019 Draft EPA Particulate Matter Policy Assessment. (https://yosemite.epa.gov/sab/sabproduct.nsf/F729E7D8E248A2C5852584970009565A/\$File/Enstro m+Comment+to+CASAC+re+090519+EPA+PM+PA+101719.pdf)

4. Enstrom JE. Fine particulate matter and total mortality in cancer prevention study cohort reanalysis. *Dose-Response*. 2017;15(1):1–12. March 28, 2017 DOI: 10.1177/1559325817693345

5. Jacobs WB, Goho SA. COMMENTS ON PROPOSED RULE, STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, 83 FED. REG. 18,768 Harvard Law School August 7, 2018 (https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6111)

Table: Random Effects Meta-Analysis of Nine US Cohorts That Analyzed Fine Particulate Matter (PM2.5) and Total (All-cause) Mortality³

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	R Table	F-U Years	RR 95	5%CI(L) 9	5%CI(U)
Veterans Study	Lipfert 2000	Т6	1986-1996	0.890	0.850	0.950
Medicare (MCAPS) Eastern US	Zeger 2008	Т3	2000-2005	1.068	1.049	1.087
Medicare (MCAPS) Central US	Zeger 2008	Т3	2000-2005	1.132	1.095	1.169
Medicare (MCAPS) Western US	Zeger 2008	Т3	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	Т3	1992-2002	1.260	1.020	1.540
Health Professionals FU Study	Puett 2011	Т2	1989-2002	0.860	0.720	1.020
Harvard Six Cities Study (H6CS)	Lepeule 2012	Т2	1974-2009	1.140	1.070	1.220
Agricultural Health Study	Weichenthal 202	15 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-A	Analysis Summar	ry RR		1.031	0.997	1.066

Cochrane's Q Test for Homogeneity of Studies (Null Hypothesis: Studies are Homogenous) P-Value = $6.69843E-19 \rightarrow$ 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)