August 16, 2018

To: Docket ID No. EPA-HQ-OA-2018-0259 "Strengthening Transparency in Regulatory Science" <u>https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001</u> U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

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The value of my March 28, 2017 *Dose-Response* reanalysis of fine particulate matter (PM2.5) and total mortality in the ACS Cancer Prevention Study (CPS II) cohort

(<u>http://journals.sagepub.com/doi/full/10.1177/1559325817693345</u>) is reinforced by the extensive epidemiologic evidence presented below that there is NO relationship between fine particulate matter (PM2.5) and total mortality in the United States as a whole or in the state of California. Summary Table 1 shows that the meta-analysis summary relative risk for the latest follow-up results from eight major United States cohorts is RR (95% CI) = 1.008 (0.992-1.025). The details for the meta-analysis and these cohorts will be presented in a future publication and on my website

(http://www.scientificintegrityinstitute.org/USPM25RR081618.pdf). Summary Table 2 shows that the meta-analysis summary relative risk for the latest follow-up results from six major California cohorts is RR (95% CI) = 0.999 (0.988-1.010). The details for these California cohorts have already been presented in my 2017 reanalysis and other cited sources.

As explained in my May 29, 2018 Dose-Response Letter

(http://journals.sagepub.com/doi/pdf/10.1177/1559325818769728), Table 3 shows that for the 47 counties with 1979-1983 PM2.5 measurements from both the EPA Inhalable Particulate Network (IPN) and the Health Effects Institute interpretation of the IPN data (HEI) the relative risk (95% confidence interval) declines from RR = 1.081 (1.036-1.128) based on the HEI data to RR = 1.021 (0.984-1.058) based on IPN data. This large RR difference was determined only because I was able to conduct an independent reanalysis of the CPS II cohort data. This is an indication the differences that may exist in the cohorts that have not been independently reanalyzed. In any case, the summary relative risks for the United States and California are consistent with RR = 1.000 and well within the RR difference found in the CPS II cohort.

Both my reanalysis and the extensive null evidence on PM2.5 deaths support of the importance of the proposed EPA Rule "Strengthening Transparency in Regulatory Science," which would make possible independent reanalysis of the "pivotal regulatory science" used as the primary basis for EPA regulations.

Summary Table 1. Epidemiologic cohort studies of PM2.5 and total mortality in the United States, 2000-2018 Relative risk of death from all causes (RR and 95% CI) associated with increase of 10 μ g/m³ in PM2.5

| Study First Author & Year & Table | Cohort | RR | 95% CI | F-U Years | | | |
|---|------------------------------------|---------|--------------|-----------|--|--|--|
| Eight United States Cohorts Compiled b | y Enstrom as of June 11, 2018 | | | | | | |
| Forthcoming Meta-Analysis of US Cohorts (<u>http://www.scientificintegrityinstitute.org/USPM25RR081618.pdf</u>) | | | | | | | |
| Lipfert 2000 Table 6 (Enstrom 2005) | Veterans | 0.890 (| 0.850–0.950) | 1986-1996 | | | |
| Krewski 2009 Table 34 (Enstrom 2017) | ACS Cancer Prevention (CPS II) | 1.014 (| 0.980-1.049) | 1999-2000 | | | |
| Puett 2009 Table 3 | Harvard Nurses Health | 1.260 (| 1.020-1.540) | 1992-2002 | | | |
| Puett 2011 Table 2 | Harvard Health Professionals | 0.860 (| 0.720-1.020) | 1989-2002 | | | |
| Lepeule 2012 Table 2 | Harvard Six Cities | 1.190 (| 0.910-1.550) | 2000-2009 | | | |
| Weichenthal 2015 Table 2 | Agricultural Health | 0.950 (| 0.760-1.200) | 1993-2009 | | | |
| Thurston 2016 Table 2 & Figure 3 | NIH-AARP Diet and Health | 1.025 (| 1.000-1.049) | 2000-2009 | | | |
| Parker 2018 Corrected Table 3 | National Health Interview Survey | 1.016 (| 0.979-1.054) | 1997-2011 | | | |
| Meta-Analysis Summary of Latest Follow | v-up Results from Eight US Cohorts | 1.008 | 0.992-1.025) | | | | |

Summary Table 2. Epidemiologic cohort studies of PM_{2.5} and total mortality in California, 2000-2016 Relative risk of death from all causes (RR and 95% CI) associated with increase of $10 \mu g/m^3$ in PM_{2.5}

| Study First Author & Year & Table | Cohort | RR | 95% CI | F-U Years |
|-----------------------------------|--------|----|--------|-----------|
| | | | | |

Six California Cohorts Compiled by Enstrom as of March 28, 2017

Spring 2018 JAPS Table 4 (<u>http://www.jpands.org/vol23no1/enstrom.pdf</u>) March 28, 2017 *Dose-Response* Table B1 (<u>http://journals.sagepub.com/doi/full/10.1177/1559325817693345</u>) December 21, 2016 US Office Research Integrity (<u>http://scientificintegrityinstitute.org/Hohmann122116.pdf</u>) November 11, 2016 Summary of PM2.5 Deaths in CA (<u>http://scientificintegrityinstitute.org/Jerrett111116.pdf</u>)

| Thurston 2016 Table 2 & Figure 3 | CA NIH-AARP | 1.017 (0.990-1.040) | 2000-2009 |
|----------------------------------|-----------------------|-----------------------|-----------|
| Ostro 2015 Table S3 | CA Teachers | 1.010 (0.980-1.050) | 2001-2007 |
| Krewski 2010 (re 2009) Table 1 | CA CPS II | 0.968 (0.916-1.022) | 1982-2000 |
| Zeger 2008 Table 3 | MCAPS "West=CA+OR+WA" | 0.989 (0.970-1.008) | 2000-2005 |
| Enstrom 2005 Table 7 | CA CPS I | 0.997 (0.978-1.016) | 1983-2002 |
| McDonnell 2000 Table 3 & Text | CA AHSMOG | ~ 1.000 (0.950–1.050) | 1977-1992 |

Meta-Analysis Summary of Latest Follow-up Results from Six CA Cohorts 0.999 (0.988-1.010)