

August 14, 2018

To:

Docket ID No. EPA-HQ-OA-2018-0259

“Strengthening Transparency in Regulatory Science”

<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001>

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My public comments below strongly support the importance of the proposed EPA Rule “Strengthening Transparency in Regulatory Science.” My comments consist of my independent March 28, 2017 reanalysis of the 1982 ACS Cancer Prevention Study (CPS II) cohort, which found no robust relationship between fine particulate matter (PM<sub>2.5</sub>) and total mortality. No errors have been identified in my reanalysis since its publication, as explained in my May 29, 2018 response to the December 13, 2017 criticism by Pope and ACS. Additional details are contained in my Spring 2018 article “Scientific Distortions in Fine Particulate Matter Epidemiology.” My comments identify serious problems in what EPA defines as “pivotal regulatory science”: the dose response data and models in the CPS II cohort that were largely responsible for the establishment of the 1997 EPA PM<sub>2.5</sub> NAAQS. Finally, my comments are a highly relevant example of the importance of independent access to underlying data and transparency in regulatory science.

1) My March 28, 2017 *Dose-Response* article “Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis” (<http://journals.sagepub.com/doi/full/10.1177/1559325817693345>) found NO significant relationship between PM<sub>2.5</sub> and total mortality during 1982-1988 in the ACS CPS II cohort, except for replication of the selective positive relationship published in the 1995 *AJRCCM* Pope article. My peer-reviewed results are based on my independent reanalysis of an original 1982-1988 version of the de-identified CPS II cohort data, as explained in my article.

2) My null relationship findings challenge the robustness and integrity of the positive relationship between PM2.5 and total mortality in the 1995 *AJRCCM* Pope article, the 2000 HEI Reanalysis Report, and the 2009 HEI Research Report 140. My findings were criticized in the December 13, 2017 *Dose-Response* Letter “Fine Particulate Air Pollution and Mortality: Response to Enstrom’s Reanalysis of the American Cancer Society Cancer Prevention Study II Cohort” by Pope, HEI Krewski, ACS Gapstur, and three HEI collaborators (<http://journals.sagepub.com/doi/full/10.1177/1559325817746303>). However, in the 17 months since publication of my article, Pope and ACS have failed to assess the validity of my null findings and have identified no errors. Even more troubling, they have shown no willingness to cooperate with me in addressing a matter that is very important to the integrity of both air pollution epidemiology and EPA regulatory policy.

3) My May 29, 2018 *Dose-Response* Letter “Response to Criticism of ‘Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis’” (<http://journals.sagepub.com/doi/pdf/10.1177/1559325818769728>) addresses the Pope and ACS criticism of my March 28, 2017 Reanalysis, provides additional evidence of a null PM2.5-total mortality relationship, and includes detailed county-level CPS II data that does not violate subject confidentiality. The validity of my 2017 Reanalysis is further supported by my Spring 2018 *JAPS* article “Scientific Distortions in Fine Particulate Matter Epidemiology” (<http://www.jpands.org/vol23no1/enstrom.pdf>). It is extremely important that all four items included below be examined in great detail, including text, tables, figures, and references. These items clearly demonstrate the value of independent reanalysis and transparency in air pollution epidemiology and regulatory science.

4) Since my repeated requests to Pope, ACS, HEI, and other CPS II investigators have been rejected, EPA formally should ask ACS to cooperate with transparent analyses of the CPS II data, such as, the analyses that I have conducted and requested. If ACS fully cooperates with EPA, then it might be useful to modify the EPA Transparency Rule to include a full cooperation option that does not require releasing actual data. If ACS fails to cooperate with EPA and other legitimate investigators like myself, then their CPS II research results should not be used for EPA regulations. I am certainly willing to cooperate with EPA on analyses using the 1982-1988 CPS II cohort data that I possess.