November 2, 2022

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From: James E. Enstrom <jenstrom@ucla.edu>

Re: Enstrom Comment on 2022 SCAQMD AQMP Draft Socioeconomic Report

The October 1, 2022 Draft Socioeconomic Report (Draft SES Report) for the 2022 SCAQMD AQMP was written by two SCAQMD Officials (I. Elaine Shen, PhD, Planning and Rules Manager, and Brian Vlasich, Air Quality Specialist), Industrial Economics, Inc. (IEc) staff, and Regional Economic Models, Inc. (REMI) staff. There was no input from the SCAQMD Health Effects Officer, because the position has been vacant this year. Thus, no epidemiologic expertise from SCAQMD was used in the preparation of this report and objective epidemiologic expertise is required because epidemiologic studies provide the primary evidence for the adverse health effects of PM2.5 and ozone.

Numerous important epidemiologic findings showing no California deaths due to PM2.5 and ozone deaths have been omitted from both the main body of 2022 AQMP and the Draft SES Report. The critical comments that I have submitted regarding the 2016 AQMP, the 2012 AQMP, and the 2007 AQMP have been systematically ignored and my publications are not cited in the main text of these AQMPs. In additions, the findings and publications of many other critics are not cited.

As direct evidence of the flaws in the Draft SES Report, I describe eight items below.

1. The Draft SES Report Table 3-3 shows 1619 "Premature Deaths Avoided, All Cause" in 2032 [page 3-7]. The text states "the adult all-cause mortality effects associated with long-term PM2.5 exposure were estimated based on pooling C-R [concentration-response] functions estimated in Jerrett et al. (2005), Jerrett et al. (2013), and the kriging and land use regression results from Krewski et al. (2009) . . . It should be noted that the health effect estimation does not use a concentration threshold below which the affected population would stop benefiting from further reduced exposure to ambient air pollution." [page 3-8]. However, I challenge the validity of this premature death claim and the text that is used to justify this claim. There are no premature deaths due to PM2.5 and ozone in California and current levels of air pollution are below the threshold that is associated with these alleged deaths, as explained in the next paragraph.

2. The Draft SES Report ignores the overwhelming epidemiologic evidence of NO relationship [relative risk (RR) = 1.00] between PM2.5 and total mortality in California. The weighted average of the most recent results from six different California cohorts show RR = 0.999 (0.988-1.010), which means there are NO premature deaths caused by PM2.5 in California. An appended table summarizing this null California evidence was included in my January 30, 2017 comment to then SCAQMD Health Effects Officer Jo Kay Chan Ghosh, PhD. This evidence was also presented in my attached March 28, 2017 Dose-Response Article "Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis" (DOI: 10.1177/1559325817693345). My null findings invalidate the positive nationwide relationship between PM2.5 and total mortality published in the seminal Pope 1995 paper, which is

based on the American Cancer Society Cancer Prevention Study II (CPS II) cohort. Also, my null CPS II cohort findings raise serious doubts about validity of the positive CPS II cohort findings in Jerrett 2005, Jerrett 2009, and Jerrett 2013.

3. There is independent evidence supporting flaws in these three Jerrett studies used in the Draft SES Report. On November 11, 2016 I made a US Office of Research Integrity allegation that Jerrett 2013 falsified and exaggerated the relationship between PM2.5 and total mortality in California. On December 21, 2016 an ORI Investigator stated regarding the Jerrett 2013 results "it appears that the relative risks reported do not seem to rise to the level of clinical significance and do not provide evidence that air pollution is directly responsible for mortality." My US ORI allegation and a table showing NO PM2.5-mortality relationship in California are appended.

4. The Draft SES Report is not based on personal exposure to PM2.5, ozone, and NOx in the SCAB. The personal exposures to these pollutants are much lower than the ambient levels recorded at SCAQMD monitors and the average human exposures are well below the level of measurable health effects for these air pollutants. SCAQMD Board Members and SCAB residents must be informed of their actual exposures to pollutants. Furthermore, they must be informed that these levels are well below the corresponding US EPA NAAQS. Typical personal exposure levels are PM2.5 < 5 ug/m3 and ozone < 20 ppb. These levels are far below the level of known health effects. Detailed evidence is provide in the attached 2022 comments that I have made to the EPA CASAC PM2.5 Review Panel and the EPA CASAC Ozone Review Panel.

5. The Draft SES Report provides no context regarding the impact of air pollution and other risk factors on the overall health of SCAB residents. An appended table shows low 2014 age-adjusted death rates from all causes, all cancer, and all respiratory disease in California and the SCAB. These death rates are among the lowest in the United States and the World. Another appended table shows similiar low 2019 age-adjusted total death rates, particularly for Los Angeles Hispanics.

6. The Draft SES Report DOES NOT comply with California Health and Safety Code Section 40471 (b). Instead of satisfying the requirement "the south coast district board, in conjunction with a public health organization or agency, shall prepare a report on the health impacts of particulate matter air pollution in the South Coast Air Basin." Instead of satisfying the requirement to prepare Health Effects Appendix I "in conjunction with a public health organization or agency," you instead prepared it in conjunction with aggressive regulatory agencies: US EPA and CalEPA (OEHHA and CARB). Instead of satisfying the requirement that the "south coast district board shall hold public hearings concerning the report and the peer review," four October 2022 public hearings were conducted without the SCAQMD Board.

7. The attached April 15, 2022 SCAQMD Notice of Intent to Sue EPA because of Federal Sources of air pollution provides strong evidence that the 2022 AQMP is completely impractical with regarding to achieving the existing PM2.5 and ozone NAAQS. (see pages xx-yy)

8. An additional factor complicating the implementation of the 2022 AQMP is the June 30, 2022 SCOTUS decision regarding West Virginia v. EPA. This decision found that Congress, not EPA, has the ultimate authority regarding costly environmental regulations as per the "major questions" doctrine.

The Draft SES Report must be modified to include a presentation based on NO premature deaths. This presentation needs to be compared with the existing presentation in a way that is understandable to the SCAQMD Board. The monetized public health benefits from avoided premature deaths and reduced morbidity conditions due to the emission reductions resulting from implementation of the 2022 AQMP are estimated to be $20 billion in 2032. The public health benefits from allegedly avoiding 1,619 premature deaths are $19.3 billion in 2032 and the remaining benefits coming from reduced incidence of morbidity conditions. However, the public health benefits are only $0.7 billion in 2032 if there are NO premature deaths and these benefits are far less than the economic costs of $2.85 billion in 2032.

I can make a strong case that the 2022 AQMP should not be implemented because it is NOT justified on a scientific or public health basis. Also, I plan to make a strong case to business and taxpayer groups in Southern California that the 2022 AQMP is socioeconomically unjustified and should not be implemented.

Thank you for fully addressing these comments and modifying the Draft SES Report appropriately.

Sincerely yours,

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Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis

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Abstract

Background: In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter ($PM_{2.5}$), largely because of its positive relationship to total mortality in the 1982 American Cancer Society Cancer Prevention Study (CPS II) cohort. Subsequently, EPA has used this relationship as the primary justification for many costly regulations, most recently the Clean Power Plan. An independent analysis of the CPS II data was conducted in order to test the validity of this relationship.

Methods: The original CPS II questionnaire data, including 1982 to 1988 mortality follow-up, were analyzed using Cox proportional hazards regression. Results were obtained for 292 277 participants in 85 counties with 1979-1983 EPA Inhalable Particulate Network $PM_{2.5}$ measurements, as well as for 212 370 participants in the 50 counties used in the original 1995 analysis.

Results: The 1982 to 1988 relative risk (RR) of death from all causes and 95% confidence interval adjusted for age, sex, race, education, and smoking status was 1.023 (0.997-1.049) for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ in 85 counties and 1.025 (0.990-1.061) in the 50 original counties. The fully adjusted RR was null in the western and eastern portions of the United States, including in areas with somewhat higher $PM_{2.5}$ levels, particularly 5 Ohio Valley states and California.

Conclusion: No significant relationship between $PM_{2.5}$ and total mortality in the CPS II cohort was found when the best available $PM_{2.5}$ data were used. The original 1995 analysis found a positive relationship by selective use of CPS II and $PM_{2.5}$ data. This independent analysis of underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the $PM_{2.5}$ NAAQS. These findings provide strong justification for further independent analysis of the CPS II data.

Keywords
epidemiology, $PM_{2.5}$, deaths, CPS II, reanalysis

Introduction

In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter ($PM_{2.5}$), largely because of its positive relationship to total mortality in the 1982 American Cancer Society (ACS) Cancer Prevention Study (CPS II) cohort, as published in 1995 by Pope et al.[1] The EPA uses this positive relationship to claim that $PM_{2.5}$ *causes* premature deaths. However, the validity of this finding was immediately challenged with detailed and well-reasoned criticism.[2-4] The relationship still remains contested and much of the original criticism has never been properly addressed, particularly the need for truly independent analysis of the CPS II data.

The EPA claim that $PM_{2.5}$ *causes* premature deaths is implausible because no etiologic mechanism has ever been established and because it involves the lifetime inhalation of only about 5 g of particles that are less than 2.5 μm in diameter.[5] The $PM_{2.5}$ mortality relationship has been further challenged because the small increased risk could be due to well-known epidemiological biases, such as, the ecological fallacy, inaccurate exposure measurements, and confounding variables like copollutants. In addition, there is extensive evidence of spatial and temporal variation in $PM_{2.5}$ mortality risk (MR) that does not support 1 national standard for $PM_{2.5}$.

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In spite of these serious problems, EPA and the major $PM_{2.5}$ investigators continue to assert that their positive findings are sufficient proof that $PM_{2.5}$ *causes* premature deaths. Their premature death claim has been used to justify many costly EPA regulations, most recently, the Clean Power Plan.[6] Indeed, 85% of the total estimated benefits of all EPA regulations have been attributed to reductions in $PM_{2.5}$-related premature deaths. With the assumed benefits of $PM_{2.5}$ reductions playing such a major role in EPA regulatory policy, it is essential that the relationship of $PM_{2.5}$ to mortality be independently verified with transparent data and reproducible findings.

In 1998, the Health Effects Institute (HEI) in Boston was commissioned to conduct a detailed reanalysis of the original Pope 1995 findings. The July 2000 HEI Reanalysis Report (HEI 2000) included "PART I: REPLICATION AND VALIDATION" and "PART II: SENSITIVITY ANALYSES."[7] The HEI Reanalysis Team lead by Daniel Krewski successfully replicated and validated the 1995 CPS II findings, but they did not analyze the CPS II data in ways that would determine whether the original results remained robust using different sources of air pollution data. For instance, none of their models used the best available $PM_{2.5}$ measurements as of 1995.

Particularly troubling is the fact that EPA and the major $PM_{2.5}$ investigators have ignored multiple null findings on the relationship between $PM_{2.5}$ and mortality in California. These null findings include my 2005 paper,[8] 2006 clarification,[9] 2012 American Statistical Society Joint Statistical Meeting Proceedings paper,[10] and 2015 International Conference on Climate Change presentation about the Clean Power Plan and $PM_{2.5}$-related cobenefits.[6] There is now overwhelming evidence of a null $PM_{2.5}$ mortality relationship in California dating back to 2000. The problems with the $PM_{2.5}$ mortality relationship have generated substantial scientific and political concern.

During 2011 to 2013, the US House Science, Space, and Technology Committee (HSSTC) repeatedly requested that EPA provide access to the underlying CPS II data, particularly since substantial Federal funding has been used for CPS II $PM_{2.5}$ mortality research and publications. On July 22, 2013, the HSSTC made a particularly detailed request to EPA that included 49 pages of letters dating back to September 22, 2011.[11] When EPA failed to provide the requested data, the HSSTC issued an August 1, 2013 subpoena to EPA for the CPS II data.[12] The ACS refused to comply with the HSSTC subpoena, as explained in an August 19, 2013 letter to EPA by Chief Medical Officer Otis W. Brawley.[13] Then, following the subpoena, ACS has refused to work with me and 3 other highly qualified investigators regarding collaborative analysis of the CPS II data.[14] Finally, HEI has refused to conduct my proposed CPS II analyses.[15] However, my recent acquisition of an original version of the CPS II data has made possible this first truly independent analysis.

Methods

Computer files containing the original 1982 ACS CPS II deidentified questionnaire data and 6-year follow-up data on deaths from September 1, 1982 through August 31, 1988, along with detailed documentation, were obtained from a source with appropriate access to these data, as explained in the "Acknowledgments." This article presents my initial analysis of the CPS II cohort and it is subject to the limitations of data and documentation that is not as complete and current as the data and documentation possessed by ACS.

The research described below is exempt from human participants or ethics approval because it involved only statistical analysis of existing deidentified data. Human participants' approval was obtained by ACS in 1982 when each individual enrolled in CPS II. Because of the epidemiologic importance of this analysis, an effort will be made to post on my Scientific Integrity Institute website a version of the CPS II data that fully preserves the confidentiality of all of participants and that contains enough information to verify my findings.

Of the 1.2 million total CPS II participants, analysis has been done on 297 592 participants residing in 85 counties in the continental United States with 1979 to 1983 EPA Inhalable Particulate Network (IPN) $PM_{2.5}$ measurements.[16,17] Among these participants, there were 18 612 total deaths from September 1, 1982 through August 31, 1988; 17 329 of these deaths (93.1%) had a known date of death. Of the 297 592 participants, 292 277 had age at entry of 30 to 99 years and sex of male [1] or female [2]. Of the 292 277 participants, 269 766 had race of white [1,2,5] or black [3,4]; education level of no or some high school [1,2], high school graduate [3], some college [4,5], college graduate [6], or graduate school [7]; and smoking status of never [1], former [5-8 for males and 3 for females], or current [2-4 for males and 2 for females]. Those participants reported to be dead [D, G, K] but without an exact date of death have been assumed to be alive in this analysis. The unconfirmed deaths were randomly distributed and did not impact relative comparisons of death in a systematic way. The computer codes for the above variables are shown in brackets.

CPS II participants were entered into the master data file geographically. Since this deidentified data file does not contain home addresses, the Division number and Unit number assigned by ACS to each CPS II participant have been used to define their county of residence. For instance, ACS Division 39 represents the state of Ohio and its Unit 041 represents Jefferson County, which includes the city of Steubenville, where the IPN $PM_{2.5}$ measurements were made. In other words, most of the 575 participants in Unit 041 lived in Jefferson County as of September 1, 1982. The IPN $PM_{2.5}$ value of 29.6739 $\mu g/m^3$, based on measurements made in Steubenville, was assigned to all CPS II participants in Unit 041. This $PM_{2.5}$ value is a weighted average of 53 measurements (mean of 33.9260 $\mu g/m^3$) and 31 measurements (mean of 29.4884 $\mu g/m^3$) made during 1979 to 1982[16] and 53 measurements (mean of 27.2473 $\mu g/m^3$) and 54 measurements (mean of 28.0676 $\mu g/m^3$) made during 1983.[17] The IPN $PM_{2.5}$ data were collected only during 1979 to 1983, although some other IPN air pollution data were collected through 1984. The values for each county that includes a city with CPS II participants and IPN $PM_{2.5}$ measurements are shown in Appendix Table A1.

Table 1. Summary Characteristics of CPS II Participants in (1) Pope 1995 Table 1,[1] (2) HEI 2000 Table 24,[7] and (3) Current Analysis Based on CPS II Participants in 50 and 85 Counties.

Characteristics	Pope 1995 Table 1	HEI 2000 Table 24	Current CPS II Analysis		
			n = 50 HEI $PM_{2.5}$	n = 50 IPN $PM_{2.5}$	n = 85 IPN $PM_{2.5}$
Number of metro areas	50	50			
Number of counties	Not stated	Not stated	50	50	85
Age–sex-adjusted participants			212 370	212 370	292 277
Fully adjusted participants	295 223	298 817	195 215	195 215	269 766
Age–sex-adjusted deaths			12 518	12 518	17 231
Fully adjusted deaths	20 765	23 093	11 221	11 221	15 593
Values below are for participants in fully adjusted results					
Age at enrollment, mean years	56.6	56.6	56.66	56.66	56.64
Sex (% females)	55.9	56.4	56.72	56.72	56.61
Race (% white)	94.0	94.0	94.58	94.58	95.09
Less than high school education, %	11.3	11.3	11.71	11.71	11.71
Never smoked regularly, %			41.69	41.69	41.57
Former smoker, %			33.25	33.25	33.67
Former cigarette smoker, %	29.4	30.2	30.43	30.43	30.81
Current smoker, %			25.06	25.06	24.76
Current cigarette smoker, %	21.6	21.4	21.01	21.01	20.76
Fine particles, $\mu g/m^3$					
Average	18.2	18.2	17.99	21.37	21.16
SD	5.1	4.4	4.52	5.30	5.98
Range	9.0-33.5	9.0-33.4	9.0-33.4	10.77-29.67	10.63-42.01

Abbreviations: CPS, Cancer Prevention Study; HEI, Health Effects Institute; IPN, Inhalable Particulate Network; $PM_{2.5}$, fine particulate matter.

To make the best possible comparison with Pope 1995 and HEI 2000 results, the HEI $PM_{2.5}$ value of 23.1 $\mu g/m^3$ for Steubenville was assigned to all participants in Unit 041. This value is the median of $PM_{2.5}$ measurements made in Steubenville and is shown in HEI 2000 Appendix D "Alternative Air Pollution Data in the ACS Study."[7] Analyses were done for the 50 counties containing the original 50 cities with CPS II participants and HEI $PM_{2.5}$ values used in Pope 1995 and HEI 2000. Additional analyses were done for all 85 counties containing cities with both CPS II participants and IPN $PM_{2.5}$ data. Without explanation, Pope 1995 and HEI 2000 omitted from their analyses, 35 cities with CPS II participants and IPN $PM_{2.5}$ data. To be clear, these analyses are based on the CPS II participants assigned to each Unit (county) that included a city with IPN $PM_{2.5}$ data. The original Pope 1995 and HEI 2000 analyses were based on the CPS II participants assigned to each metropolitan area (MA) that included a city with HEI $PM_{2.5}$ data, as defined in HEI 2000 Appendix F "Definition of Metropolitan Areas in the ACS Study."[7] The MA, which was equivalent to the US Census Bureau Standard Metropolitan Statistical Area (SMSA), always included the county containing the city with the HEI $PM_{2.5}$ data and often included 1 or more additional counties.

The SAS 9.4 procedure PHREG was used to conduct Cox proportional hazards regression.[18] Relative risks (RRs) for death from all causes and 95% confidence intervals (CI) were calculated using age–sex adjustment and full adjustment (age, sex, race, education, and smoking status, as defined above). Each of the 5 adjustment variables had a strong relationship to total mortality. Race, education, and smoking status were the 3 adjustment variables that had the greatest impact on the age–sex-adjusted RR. The Pope 1995 and HEI 2000 analyses used 4 additional adjustment variables that had a lesser impact on the age–sex-adjusted RR.

In addition, county-level ecological analyses were done by comparing IPN $PM_{2.5}$ and HEI $PM_{2.5}$ values to 1980 age-adjusted white total death rates (DRs) determined by the Centers for Disease Control and Prevention (CDC) WONDER[19] and mortality risks (MRs) as shown in Figures 5 and 21 of HEI 2000.[7] Death rates are age adjusted to the 2000 US Standard Population and are expressed as annual deaths per 100 000 persons. The SAS 9.4 procedure REGRESSION was used to conduct linear regression of $PM_{2.5}$ values with DRs and MRs.

Appendix Table A1 lists the 50 original cities used in Pope 1995 and HEI 2000 and includes city, county, state, ACS Division and Unit numbers, Federal Information Processing Standards (FIPS) code, IPN average $PM_{2.5}$ level, HEI median $PM_{2.5}$ level, 1980 DR, and HEI MR. Appendix Table A1 also lists similar information for the 35 additional cities with CPS II participants and IPN $PM_{2.5}$ data. However, HEI $PM_{2.5}$ and HEI MR data are not available for these 35 cities.

Results

Table 1 shows basic demographic characteristics for the CPS II participants, as stated in Pope 1995,[1] HEI 2000,[7] and this current analysis. There is excellent agreement on age, sex, race, education, and smoking status. However, the IPN $PM_{2.5}$ averages are generally about 20% higher than the HEI $PM_{2.5}$ medians, although the differences range from +78% to −28%.

Table 2. Age–Sex-Adjusted and Fully Adjusted Relative Risk of Death From All Causes (RR and 95% CI) From September 1, 1982 Through August 31, 1988 Associated With Change of 10 μg/m^3 Increase in $PM_{2.5}$ for CPS II Participants Residing in 50 and 85 Counties in the Continental United States With 1979 to 1983 IPN $PM_{2.5}$ Measurements.[a]

$PM_{2.5}$ Years and Source	Number of Counties	Number of Participants	Number of Deaths	RR	95% CI Lower Upper	Average $PM_{2.5}$
Age–sex adjusted RR for the continental United States						
1979-1983 IPN	85	292 277	17 321	1.038	(1.014-1.063)	21.16
1979-1983 IPN	50	212 370	12 518	1.046	(1.013-1.081)	21.36
1979-1983 HEI	50	212 370	12 518	1.121	(1.078-1.166)	17.99
Fully adjusted RR for the continental United States						
1979-1983 IPN	85	269 766	15 593	1.023	(0.997-1.049)	21.15
1979-1983 IPN	50	195 215	11 221	1.025	(0.990-1.061)	21.36
1979-1983 HEI	50	195 215	11 221	1.082	(1.039-1.128)	17.99
Age–sex adjusted RR for Ohio Valley States (IN, KY, OH, PA, WV)						
1979-1983 IPN	17	56 979	3649	1.126	(1.011-1.255)	25.51
1979-1983 IPN	12	45 303	2942	1.079	(0.951-1.225)	25.76
1979-1983 HEI	12	45 303	2942	1.153	(1.027-1.296)	22.02
Fully adjusted RR for Ohio Valley states (IN, KY, OH, PA, WV)						
1979-1983 IPN	17	53 026	3293	1.096	(0.978-1.228)	25.51
1979-1983 IPN	12	42 174	2652	1.050	(0.918-1.201)	25.75
1979-1983 HEI	12	42 174	2652	1.111	(0.983-1.256)	22.02
Age–sex adjusted RR for states other than the Ohio Valley states						
1979-1983 IPN	68	235 298	13 672	0.999	(0.973-1.027)	20.11
1979-1983 IPN	38	167 067	9576	0.983	(0.946-1.021)	20.18
1979-1983 HEI	38	167 067	9576	1.045	(0.997-1.096)	16.90
Fully adjusted RR for states other than the Ohio Valley states						
1979-1983 IPN	68	216 740	12 300	0.994	(0.967-1.023)	20.09
1979-1983 IPN	38	153 041	8569	0.975	(0.936-1.015)	20.15
1979-1983 HEI	38	153 041	8569	1.025	(0.975-1.078)	16.89

Abbreviations: CI, confidence interval; CPS, Cancer Prevention Study; HEI, Health Effects Institute; IPN, Inhalable Particulate Network; $PM_{2.5}$, particulate matter.
[a]Analysis includes continental United States, 5 Ohio Valley states, and remainder of the states. Appendix Table A1 lists the 85 cities and counties with $PM_{2.5}$ measurements.

Table 2 shows that during 1982 to 1988, there was no significant relationship between IPN $PM_{2.5}$ and total mortality in the entire United States. The fully adjusted RR and 95% CI was 1.023 (0.997-1.049) for a 10 μg/m^3 increase in $PM_{2.5}$ in all 85 counties and 1.025 (0.990-1.061) in the 50 original counties. Indeed, the fully adjusted RR was not significant in any area of the United States, such as, the states west of the Mississippi River, the states east of the Mississippi River, the 5 Ohio Valley states (Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia), and the states other than the Ohio Valley states. The age–sex-adjusted and fully adjusted RRs in the states other than the Ohio Valley states are all consistent with no relationship and most are very close to 1.00. The slightly positive age–sex-adjusted RRs for the entire United States and the Ohio Valley states became statistically consistent with no relationship after controlling for the 3 confounding variables of race, education, and smoking status.

However, the fully adjusted RR for the entire United States was 1.082 (1.039-1.128) when based on the HEI $PM_{2.5}$ values in 50 counties. This RR agrees quite well with the fully adjusted RR of 1.067 (1.037-1.099) for 1982 to 1989, which is shown in Table 34 of the June 2009 HEI Extended Follow-up Research Report (HEI 2009).[20] Thus, the positive nationwide RRs in the CPS II cohort depend upon the use of HEI $PM_{2.5}$ values. The nationwide RRs are consistent with no effect when based on IPN $PM_{2.5}$ values. The findings in Table 2 clearly demonstrate the large influence of $PM_{2.5}$ values and geography on the RRs.

Table 3 shows that the fully adjusted RR in California was 0.992 (0.954-1.032) when based on IPN $PM_{2.5}$ values in all 11 California counties. This null finding is consistent with the 15 other findings of a null relationship in California, all of which are shown in Appendix Table B1. However, when the RR is based on the 4 California counties used in Pope 1995 and HEI 2000, there is a significant inverse relationship. The fully adjusted RR is 0.879 (0.805-0.960) when based on the IPN $PM_{2.5}$ values and is 0.870 (0.788-0.960) when based on the HEI $PM_{2.5}$ values. This significant inverse relationship is in exact agreement with the finding of a special analysis of the CPS II cohort done for HEI by Krewski in 2010, which yielded a fully adjusted RR of 0.872 (0.805-0.944) during 1982 to 1989 in California when based on HEI $PM_{2.5}$ values.[21] In this instance, the California RRs are clearly dependent upon the number of counties used.

Table 4 shows that the ecological analysis based on linear regression is quite consistent with the proportional hazard regression results in Tables 2 and 3, in spite of the fact that the regression results are not fully adjusted. Using 1980 age-adjusted white total DRs versus HEI $PM_{2.5}$ values in 50 counties, linear regression yielded a regression coefficient of 6.96 (standard error [SE] = 1.85) that was statistically significant at the 95% confidence level. Pope 1995 reported a significant regression coefficient for 50 cities of 8.0 (SE = 1.4). However, this positive coefficient is

Table 3. Age–Sex-Adjusted and Fully Adjusted Relative Risk of Death From All Causes (RR and 95% CI) From September 1, 1982 Through August 31, 1988 Associated With 10 $\mu g/m^3$ Increase in $PM_{2.5}$ for California CPS II Participants Living in 4 and 11 Counties With 1979 to 1983 IPN $PM_{2.5}$ Measurements.[a]

$PM_{2.5}$ Years and Source	Number of Counties	Number of Participants	Number of Deaths	RR	95% CI of RR Lower Upper	Average $PM_{2.5}$
Age–sex adjusted RR for California during 1982 to 1988						
1979-1983 IPN	11	66 615	3856	1.005	(0.968-1.043)	24.08
1979-1983 IPN	4	40 527	2146	0.904	(0.831-0.983)	24.90
1979-1983 HEI	4	40 527	2146	0.894	(0.817-0.986)	18.83
Fully adjusted (age, sex, race, education, and smoking status) RR for California during 1982 to 1988						
1979-1983 IPN	11	60 521	3512	0.992	(0.954-1.032)	24.11
1979-1983 IPN	4	36 201	1939	0.879	(0.805-0.960)	25.01
1979-1983 HEI	4	36 201	1939	0.870	(0.788-0.960)	18.91
Fully adjusted (44 confounders) RR for California during 1982 to 1989 as per Krewski[21]						
"Same" Standard Cox Model 1979-1983 HEI	4	40 408		0.872	(0.805-0.944)	~19
"Different" Standard Cox Model 1979-1983 HEI	4	38 925		0.893	(0.823-0.969)	~19

Abbreviations: CI, confidence interval; CPS, Cancer Prevention Study; HEI, Health Effects Institute; IPN, Inhalable Particulate Network; $PM_{2.5}$, particulate matter.
[a]Also, fully adjusted RR for California participants in 4 counties from September 1, 1982 through December 31, 1989 as calculated by Krewski.[21]

Table 4. Linear Regression Results for 1979 to 1983 IPN $PM_{2.5}$ and 1979 to 1983 HEI $PM_{2.5}$ Versus 1980 Age-Adjusted White Total Death Rate (DR) for 85 Counties With IPN $PM_{2.5}$ Data and for 50 HEI 2000 Counties With IPN $PM_{2.5}$ and HEI $PM_{2.5}$ data.

DR or MR, $PM_{2.5}$ Years and Source	Number of Counties	DR or MR Intercept	DR or MR Slope	95% CI of DR or MR Slope Lower	Upper	*P* Value
Entire continental United States						
DR and 1979-1983 IPN	85	892.68	6.8331	3.8483	9.8180	0.0000
DR and 1979-1983 HEI	50	910.92	6.9557	3.2452	10.6662	0.0004
MR and 1979-1983 IPN	50	0.6821	0.0102	0.0044	0.0160	0.0009
MR and 1979-1983 HEI	50	0.6754	0.0121	0.0068	0.0173	0.0000
Ohio Valley states (IN, KY, OH, PA, and WV)						
DR and 1979-1983 IPN	17	941.77	6.0705	−0.0730	12.2139	0.0524
DR and 1979-1983 HEI	12	1067.29	1.3235	−7.3460	9.9930	0.7408
MR and 1979-1983 IPN	12	0.8153	0.0077	−0.0054	0.0208	0.2202
MR and 1979-1983 HEI	12	0.9628	0.0020	−0.0080	0.0121	0.6608
States other than the Ohio Valley states						
DR and 1979-1983 IPN	68	921.45	4.8639	0.9093	8.8186	0.0167
DR and 1979-1983 HEI	38	934.66	4.8940	−0.4337	10.2218	0.0706
MR and 1979-1983 IPN	38	0.8111	0.0020	−0.0054	0.0094	0.5891
MR and 1979-1983 HEI	38	0.7334	0.0072	0.0000	0.0144	0.0491
States west of the Mississippi river						
DR and 1979-1983 IPN	36	920.10	4.0155	−0.9396	8.9706	0.1088
DR and 1979-1983 HEI	22	930.11	4.1726	−5.2015	13.5468	0.3642
MR and 1979-1983 IPN	22	0.8663	−0.0025	−0.0162	0.0112	0.7067
MR and 1979-1983 HEI	22	0.6413	0.0134	−0.0018	0.0285	0.0807
California						
DR and 1979-1983 IPN	11	921.71	3.6516	−1.8230	9.1262	0.1656
DR and 1979-1983 HEI	4	992.50	1.9664	−46.6929	50.6256	0.8780
MR and 1979-1983 IPN	4	0.9529	−0.0074	−0.0600	0.0453	0.6072
MR and 1979-1983 HEI	4	0.8336	−0.0021	−0.0618	0.0576	0.8935

Abbreviations: CI, confidence interval; HEI, Health Effects Institute; IPN, Inhalable Particulate Network; MR, mortality risk; $PM_{2.5}$, particulate matter.
[a]Linear regression results are also shown for 1979 to 1983 IPN $PM_{2.5}$ and 1979 to 1983 HEI $PM_{2.5}$ versus MR for the 50 "cities" (metropolitan areas) in figures 5 and 21 in HEI 2000.

misleading because both DRs and $PM_{2.5}$ levels are higher in the East than in the West. Regional regression analyses did not generally yield significant regression coefficients. Specifically, there were no significant regression coefficients for California, the 5 Ohio Valley states, or all states west of the Mississippi River. These findings reinforce the CPS II cohort evidence of statistically insignificant $PM_{2.5}$ MR throughout the United States.

Conclusion

This independent analysis of the CPS II cohort found that there was no significant relationship between $PM_{2.5}$ and death from all causes during 1982 to 1988, when the best available $PM_{2.5}$ measurements were used for the 50 original counties and for all 85 counties with $PM_{2.5}$ data and CPS II participants. However, a positive relationship was found when the HEI $PM_{2.5}$ measurements were used for the 50 original counties, consistent with the findings in Pope 1995 and HEI 2000. This null and positive evidence demonstrates that the $PM_{2.5}$ mortality relationship is not robust and is quite sensitive to the $PM_{2.5}$ data and CPS II participants used in the analysis.

Furthermore, the following statement on page 80 of HEI 2000 raises serious doubts about the quality of the air pollution data used in Pope 1995 and HEI 2000: "AUDIT OF AIR QUALITY DATA. The ACS study was not originally designed as an air pollution study. The air quality monitoring data used for the ACS analyses came from various sources, some of which are now technologically difficult to access. Documentation of the statistical reduction procedures has been lost. Summary statistics for different groups of standard metropolitan statistical areas had been derived by different investigators. These data sources do not indicate whether the tabulated values refer to all or a subset of monitors in a region or whether they represent means or medians."[7]

The Pope 1995 and HEI 2000 analyses were based on 50 median $PM_{2.5}$ values shown in Appendix A of the 1988 Brookhaven National Laboratory Report 52122 by Lipfert et al.[22] These analyses did not use or cite the high quality and widely known EPA IPN $PM_{2.5}$ data in spite of the fact that these data have been available in 2 detailed EPA reports since 1986.[16,17] Lipfert informed HEI about the IPN data in 1998: "During the early stages of the Reanalysis Project, I notified HEI and the reanalysis contractors of the availability of an updated version of the IPN data from EPA, which they apparently obtained. This version includes more locations and a slightly longer period of time. It does not appear that the newer IPN data are listed in Appendix G, and it is thus not possible to confirm if SMSA assignments were made properly."[23]

Thus, the HEI Reanalysis Team failed to properly "evaluate the sensitivity of the original findings to the indicators of exposure to fine particle air pollution used by the Original Investigators" and failed to select "all participants who lived within each MA for which data on sulfate or fine particle pollution were available."[7] Furthermore, HEI 2009 did not use these data even though the investigators were aware of my 2005 null $PM_{2.5}$ mortality findings in California,[8] which were based on the IPN data for 11 California counties, instead of the 4 California counties used in Pope 1995 and HEI 2000. Indeed, HEI 2009 did not cite my 2005 findings, in spite of my personal discussion of these findings with Pope, Jerrett, and Burnett on July 11, 2008.[24] Finally, HEI 2009 did not acknowledge or address my 2006 concerns about the geographic variation in $PM_{2.5}$ MR clearly shown in HEI 2000 Figure 21,[7] which is included here as Appendix Figure C1. HEI 2009 entirely avoided the issue of geographic variation in $PM_{2.5}$ MR and omitted the equivalent to HEI 2000 Figure 21.

Since 2002, HEI has repeatedly refused to provide the city-specific $PM_{2.5}$-related MR for the 50 cities included in HEI 2000 Figure 21.[15] I estimated these MRs in 2010 based on visual measurements of HEI 2000 Figure 5, and my estimates are shown in Appendix Table A1.[25] Figure 21 and its MRs represented early evidence that there was no $PM_{2.5}$-related MR in California. Appendix Table B1 shows the now overwhelming 2000 to 2016 evidence from 6 different cohorts that there is no relationship between $PM_{2.5}$ and total mortality in California. Indeed, the weighted average RR of the latest results from the 6 California cohorts is RR = 0.999 (0.988-1.010).[26]

The authors of the CPS II $PM_{2.5}$ mortality publications, which began with Pope 1995, have faced original criticism,[2-4] my criticism,[6-10,14,15] and the criticism of the HSSTC and its subpoena.[11-13] Now, my null findings represent a direct challenge to the positive findings of Pope 1995. All of this criticism is relevant to the EPA claim that $PM_{2.5}$ has a *causal* relationship to total mortality. The authors of Pope 1995, HEI 2000, and HEI 2009 need to promptly address my findings, as well as the earlier criticism. Then, they need to cooperate with critics on transparent air pollution epidemiology analyses of the CPS II cohort data.

Also, major scientific journals like the *New England Journal of Medicine* (*NEJM*) and *Science,* which have consistently written about the positive relationship between $PM_{2.5}$ and total mortality, need to publish evidence of no relationship when strong null evidence is submitted to them. In 2015, *Science* immediately rejected without peer reviewing 3 versions of strong evidence that $PM_{2.5}$ does not *cause* premature deaths.[5] In 2016, *Science* immediately rejected without peer reviewing this article. Indeed, this article was rejected by *NEJM*, *Science*, and 5 other major journals, as described in a detailed compilation of relevant correspondence.[27] Most troubling is the rejection by the *American Journal of Respiratory and Clinical Care Medicine*, which has published Pope 1995 and several other $PM_{2.5}$ mortality articles based on the CPS II cohort data.

In summary, the null CPS II $PM_{2.5}$ mortality findings in this article directly challenge the original positive Pope 1995 findings, and they raise serious doubts about the CPS II epidemiologic evidence supporting the $PM_{2.5}$ NAAQS. These findings demonstrate the importance of independent and transparent analysis of underlying data. Finally, these findings provide strong justification for further independent analysis of CPS II cohort data.

Appendix A

Table A1. List of the 85 Counties Containing the 50 Cities Used in Pope 1995, HEI 2000, and This Analysis, as well as the 35 Additional Cities Used Only in This Analysis.[a]

State	ACS Div-Unit	FIPS Code	IPN/HEI County Containing IPN/HEI City	IPN/HEI City With $PM_{2.5}$ Measurements	1979-1983 IPN $PM_{2.5}$, $\mu g/m^3$, (Weighted Average)	1979-1983 HEI $PM_{2.5}$, $\mu g/m^3$ (Median)	1980 Age-Adj White Death Rate (DR)	HEI Figure 5 Mortality Risk (MR)
AL	01037	01073	Jefferson	Birmingham	25.6016	24.5	1025.3	0.760
AL	01049	01097	Mobile	Mobile	22.0296	20.9	1067.2	0.950
AZ	03700	04013	Maricopa	Phoenix	15.7790	15.2	953.0	0.855
AR	04071	05119	Pulaski	Little Rock	20.5773	17.8	1059.4	0.870
CA	06001	06001	Alameda	Livermore	14.3882		1016.6	
CA	06002	06007	Butte	Chico	15.4525		962.5	
CA	06003	06013	Contra Costa	Richmond	13.9197		937.1	
CA	06004	06019	Fresno	Fresno	18.3731	10.3	1001.4	0.680
CA	06008	06029	Kern	Bakersfield	30.8628		1119.3	
CA	06051	06037	Los Angeles	Los Angeles	28.2239	21.8	1035.1	0.760
CA	06019	06065	Riverside	Rubidoux	42.0117		1013.9	
CA	06020	06073	San Diego	San Diego	18.9189		943.7	
CA	06021	06075	San Francisco	San Francisco	16.3522	12.2	1123.1	0.890
CA	06025	06083	Santa Barbara	Lompoc	10.6277		892.8	
CA	06026	06085	Santa Clara	San Jose	17.7884	12.4	921.9	0.885
CO	07004	08031	Denver	Denver	10.7675	16.1	967.3	0.925
CO	07047	08069	Larimer	Fort Collins	11.1226		810.5	
CO	07008	08101	Pueblo	Pueblo	10.9155		1024.1	
CT	08001	09003	Hartford	Hartford	18.3949	14.8	952.0	0.845
CT	08004	09005	Litchfield	Litchfield	11.6502		941.5	
DE	09002	10001	Kent	Dover	19.5280		959.4	
DE	09004	10003	New Castle	Wilmington	20.3743		1053.7	
DC	10001	11001	Dist Columbia	Washington	25.9289	22.5	993.2	0.850
FL	11044	12057	Hillsborough	Tampa	13.7337	11.4	1021.8	0.845
GA	12027	13051	Chatham	Savannah	17.8127		1029.6	
GA	12062	13121	Fulton	Atlanta	22.5688	20.3	1063.5	0.840
ID	13001	16001	ADA	Boise	18.0052	12.1	892.6	0.600
IL	14089	17031	Cook	Chicago	25.1019	21.0	1076.3	0.945
IL	14098	17197	Will	Braidwood	17.1851		1054.0	
IN	15045	18089	Lake	Gary	27.4759	25.2	1129.8	0.995
IN	15049	18097	Marion	Indianapolis	23.0925	21.1	1041.2	0.970
KS	17287	20173	Sedgwick	Wichita	15.0222	13.6	953.4	0.890
KS	17289	20177	Shawnee	Topeka	11.7518	10.3	933.7	0.830
KY	18010	21019	Boyd	Ashland	37.7700		1184.6	
KY	18055	21111	Jefferson	Louisville	24.2134		1095.7	
MD	21106	24510	Baltimore City	Baltimore	21.6922		1237.8	
MD	21101	24031	Montgomery	Rockville	20.2009		881.9	
MA	22105	25013	Hampden	Springfield	17.5682		1025.3	
MA	22136	25027	Worcester	Worcester	16.2641		1014.6	
MN	25001	27053	Hennepin	Minneapolis	15.5172	13.7	905.3	0.815
MN	25150	27123	Ramsey	St Paul	15.5823		935.7	
MS	26086	28049	Hinds	Jackson	18.1339	15.7	1087.4	0.930
MO	27001	29095	Jackson	Kansas City	17.8488		1090.3	
MT	28009	30063	Missoula	Missoula	17.6212		938.0	
MT	28011	30093	Silver Bow	Butte	16.0405		1299.5	
NE	30028	31055	Douglas	Omaha	15.2760	13.1	991.0	0.880
NV	31101	32031	Washoe	Reno	13.1184	11.8	1049.5	0.670
NJ	33004	34007	Camden	Camden	20.9523		1146.9	
NJ	33007	34013	Essex	Livingston	16.4775		1072.7	
NJ	33009	34017	Hudson	Jersey City	19.9121	17.3	1172.6	0.810
NM	34201	35001	Bernalillo	Albuquerque	12.8865	9.0	1014.7	0.710
NY	36014	36029	Erie	Buffalo	25.1623	23.5	1085.6	0.960
NY	35001	36061	New York	New York City	23.9064		1090.4	
NC	37033	37063	Durham	Durham	19.4092	16.8	1039.2	1.000

(continued)

Table A1. (continued)

State	ACS Div-Unit	FIPS Code	IPN/HEI County Containing IPN/HEI City	IPN/HEI City With $PM_{2.5}$ Measurements	1979-1983 IPN $PM_{2.5}$, $\mu g/m^3$, (Weighted Average)	1979-1983 HEI $PM_{2.5}$, $\mu g/m^3$ (Median)	1980 Age-Adj White Death Rate (DR)	HEI Figure 5 Mortality Risk (MR)
NC	37064	37119	Mecklenburg	Charlotte	24.1214	22.6	932.8	0.835
OH	39009	39017	Butler	Middletown	25.1789		1108.3	
OH	39018	39035	Cuyahoga	Cleveland	28.4120	24.6	1089.1	0.980
OH	39031	39061	Hamilton	Cincinnati	24.9979	23.1	1095.2	0.980
OH	39041	39081	Jefferson	Steubenville	29.6739	23.1	1058.6	1.145
OH	39050	39099	Mahoning	Youngstown	22.9404	20.2	1058.4	1.060
OH	39057	39113	Montgomery	Dayton	20.8120	18.8	1039.5	0.980
OH	39077	39153	Summit	Akron	25.9864	24.6	1064.0	1.060
OK	40055	40109	Oklahoma	Oklahoma City	14.9767	15.9	1050.4	0.985
OR	41019	41039	Lane	Eugene	17.1653		885.5	
OR	41026	41051	Multnomah	Portland	16.3537	14.7	1060.8	0.830
PA	42101	42003	Allegheny	Pittsburgh	29.1043	17.9	1115.6	1.005
PA	42443	42095	Northampton	Bethlehem	19.5265		998.6	
PA	43002	42101	Philadelphia	Philadelphia	24.0704	21.4	1211.0	0.910
RI	45001	44007	Providence	Providence	14.2341	12.9	1006.1	0.890
SC	46016	45019	Charleston	Charleston	16.1635		1023.5	
TN	51019	47037	Davidson	Nashville	21.8944	20.5	981.9	0.845
TN	51088	47065	Hamilton	Chattanooga	18.2433	16.6	1087.9	0.840
TX	52811	48113	Dallas	Dallas	18.7594	16.5	1024.9	0.850
TX	52859	48141	El Paso	El Paso	16.9021	15.7	903.5	0.910
TX	52882	48201	Harris	Houston	18.0421	13.4	1025.7	0.700
UT	53024	49035	Salt Lake	Salt Lake City	16.6590	15.4	954.3	1.025
VA	55024	51059	Fairfax	Fairfax	19.5425		925.7	
VA	55002	51710	Norfolk City	Norfolk	19.5500	16.9	1139.3	0.910
WA	56017	53033	King	Seattle	14.9121	11.9	943.6	0.780
WA	56032	53063	Spokane	Spokane	13.5200	9.4	959.2	0.810
WV	58130	54029	Hancock	Weirton	25.9181		1094.8	
WV	58207	54039	Kanawha	Charleston	21.9511	20.1	1149.5	1.005
WV	58117	54069	Ohio	Wheeling	23.9840	33.4	1117.5	1.020
WI	59005	55009	Brown	Green Bay	20.5462		931.0	
WI	59052	55105	Rock	Beloit	19.8584		1019.4	

[a]Each location includes State, ACS Division Unit number, Federal Information Processing Standards (FIPS) code, IPN/HEI county, IPN/HEI city with $PM_{2.5}$ measurements, 1979-1983 IPN average $PM_{2.5}$ level, 1979-1983 HEI median $PM_{2.5}$ level, 1980 age-adjusted white county total death rate (annual deaths per 100 000), and HEI 2000 figure 5 mortality risk for HEI city (metropolitan area). List also includes 35 additional counties containing cities with IPN $PM_{2.5}$ data used in this analysis. These 35 counties do not have HEI $PM_{2.5}$ data.

Appendix B

Table B1. Epidemiologic Cohort Studies of $PM_{2.5}$ and Total Mortality in California, 2000 to 2016: Relative Risk of Death From All Causes (RR and 95% CI) Associated With Increase of 10 $\mu g/m^3$ in $PM_{2.5}$ (http://scientificintegrityinstitute.org/NoPMDeaths081516.pdf).

Krewski 2000 and 2010[a,b]	CA CPS II Cohort	N = 40 408	RR = 0.872 (0.805-0.944)	1982-1989
(N = [18 000 M + 22 408 F]; 4 MSAs; 1979-1983 $PM_{2.5}$; 44 covariates)				
McDonnell 2000[c]	CA AHSMOG Cohort	N ~ 3800	RR ~ 1.00 (0.95-1.05)	1977-1992
(N ~ [1347 M + 2422 F]; SC&SD&SF AB; M RR = 1.09 (0.98-1.21) & F RR ~ 0.98 (0.92-1.03))				
Jerrett 2005[d]	CPS II Cohort in LA Basin	N = 22 905	RR = 1.11 (0.99-1.25)	1982-2000
(N = 22 905 M and F; 267 zip code areas; 1999-2000 $PM_{2.5}$; 44 cov + max confounders)				
Enstrom 2005[e]	CA CPS I Cohort	N = 35 783	RR = 1.039 (1.010-1.069)	1973-1982
(N = [15 573 M + 20 210 F]; 11 counties; 1979-1983 $PM_{2.5}$)			RR = 0.997 (0.978-1.016)	1983-2002
Enstrom 2006[f]	CA CPS I Cohort	N = 35 783	RR = 1.061 (1.017-1.106)	1973-1982
(N = [15 573 M + 20 210 F]; 11 counties; 1979-1983 and 1999-2001 $PM_{2.5}$)			RR = 0.995 (0.968-1.024)	1983-2002
Zeger 2008[g]	MCAPS Cohort "West"	N = 3 100 000	RR = 0.989 (0.970-1.008)	2000-2005
(N = [1.5 M M + 1.6 M F]; Medicare enrollees in CA + OR + WA (CA = 73%); 2000-2005 $PM_{2.5}$)				

(continued)

Table B1. (continued)

Jerrett 2010[h]	CA CPS II Cohort	N = 77 767	RR ~ 0.994 (0.965-1.025)	1982-2000
(N = [34 367 M + 43 400 F]; 54 counties; 2000 $PM_{2.5}$; KRG ZIP; 20 ind cov + 7 eco var; slide 12)				
Krewski 2010[b] (2009)	CA CPS II Cohort			
(4 MSAs; 1979-1983 $PM_{2.5}$; 44 cov)		N = 40 408	RR = 0.960 (0.920-1.002)	1982-2000
(7 MSAs; 1999-2000 $PM_{2.5}$; 44 cov)		N = 50 930	RR = 0.968 (0.916-1.022)	1982-2000
Jerrett 2011[i]	CA CPS II Cohort	N = 73 609	RR = 0.994 (0.965-1.024)	1982-2000
(N = [32 509 M + 41 100 F]; 54 counties; 2000 $PM_{2.5}$; KRG ZIP Model; 20 ind cov + 7 eco var; Table 28)				
Jerrett 2011[i]	CA CPS II Cohort	N = 73 609	RR = 1.002 (0.992-1.012)	1982-2000
(N = [32 509 M + 41 100 F]; 54 counties; 2000 $PM_{2.5}$; Nine Model Ave; 20 ic + 7 ev; Figure 22 and Tables 27-32)				
Lipsett 2011[j]	CA Teachers Cohort	N = 73 489	RR = 1.01 (0.95-1.09)	2000-2005
(N = [73 489 F]; 2000-2005 $PM_{2.5}$)				
Ostro 2011[k]	CA Teachers Cohort	N = 43 220	RR = 1.06 (0.96-1.16)	2002-2007
(N = [43 220 F]; 2002-2007 $PM_{2.5}$)				
Jerrett 2013[l]	CA CPS II Cohort	N = 73 711	RR = 1.060 (1.003-1.120)	1982-2000
(N = [~32 550 M + ~41 161 F]; 54 counties; 2000 $PM_{2.5}$; LUR Conurb Model; 42 ind cov + 7 eco var + 5 metro; Table 6)				
Jerrett 2013[l]	CA CPS II Cohort	N = 73 711	RR = 1.028 (0.957-1.104)	1982-2000
(Same parameters and model as above, except including co-pollutants NO_2 and Ozone; Table 5)				
Ostro 2015[m]	CA Teachers Cohort	N = 101 884	RR = 1.01 (0.98-1.05)	2001-2007
(N = [101 881 F]; 2002-2007 $PM_{2.5}$) (all natural causes of death)				
Thurston 2016[n]	CA NIH-AARP Cohort	N = 160 209	RR = 1.02 (0.99-1.04)	2000-2009
(N = [~95 965 M + ~64 245 F]; full baseline model: $PM_{2.5}$ by zip code; Table 3) (all natural causes of death)				
Enstrom 2016 unpublished	CA NIH-AARP Cohort	N = 160 368	RR = 1.001 (0.949-1.055)	2000-2009
(N = [~96 059 M + ~64 309 F]; full baseline model: 2000 $PM_{2.5}$ by county)				

[a]Krewski D. "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality: HEI Special Report. July 2000". 2000. Figure 5 and Figure 21 of Part II: Sensitivity Analyses http://www.scientificintegrityinstitute.org/HEIFigure5093010.pdf.

[b]Krewski D. August 31, 2010 letter from Krewski to Health Effects Institute and CARB with California-specific $PM_{2.5}$ mortality results from Table 34 in Krewski 2009. 2010. http://www.arb.ca.gov/research/health/pm-mort/HEI_Correspondence.pdf

[c]McDonnell WF, Nishino-Ishikawa N, Petersen FF, Chen LH, Abbey DE. Relationships of mortality with the fine and coarse fractions of long-term ambient PM_{10} concentrations in nonsmokers. *J Expo Anal Environ Epidemiol.* 2000;10(5):427-436. http://www.scientificintegrityinstitute.org/JEAEE090100.pdf

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[f]Enstrom JE. Response to "A Critique of 'Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973-2002" by Bert Brunekreef, PhD, and Gerard Hoek, PhD'. *Inhal Toxicol.* 2006:18:509-514. http://www.scientificintegrityinstitute.org/IT060106.pdf, and http://www.scientificintegrityinstitute.org/ITBH060106.pdf

[g]Zeger SL, Dominici F, McDermott A, Samet JM. Mortality in the Medicare Population and Chronic Exposure to Fine Particulate Air Pollution in Urban Centers (2000-2005). *Environ Health Perspect.* 2008;116:1614-1619. http://ehp03.niehs.nih.gov/article/info: doi/10.1289/ehp.11449

[h]Jerrett M. February 26, 2010 CARB Symposium Presentation by Principal Investigator, Michael Jerrett, UC Berkeley/CARB Proposal No. 2624-254 "Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort". 2010. http://www.scientificintegrityinstitute.org/CARBJerrett022610.pdf

[i]Jerrett M. October 28, 2011 Revised Final Report for Contract No. 06-332 to CARB Research Screening Committee, Principal Investigator Michael Jerrett, "Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort" Co-Investigators: Burnett RT, Pope CA III, Krewski D, Thurston G, Christakos G, Hughes E, Ross Z, Shi Y, Thun M. 2011. http://www.arb.ca.gov/research/rsc/10-28-11/item1dfr06-332.pdf, and http://www.scientificintegrityinstitute.org/Jerrett012510.pdf, and http://www.scientificintegrityinstitute.org/JerrettCriticism102811.pdf

[j]Lipsett MJ, Ostro BD, Reynolds P, et al. Long-term Exposure to Air Pollution and Cardiorespiratory Disease in the California Teachers Study Cohort. *Am J Respir Crit Care Med.* 2011;184(7);828-835. http://ajrccm.atsjournals.org/content/184/7/828.full.pdf

[k]Ostro B, Lipsett M, Reynolds P, et al. Long-Term Exposure to Constituents of Fine Particulate Air Pollution and Mortality: Results from the California Teachers Study. *Environ Health Perspect.* 2010;118(3):363-369. http://ehp03.niehs.nih.gov/article/info: doi/10.1289/ehp.0901181

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Appendix C

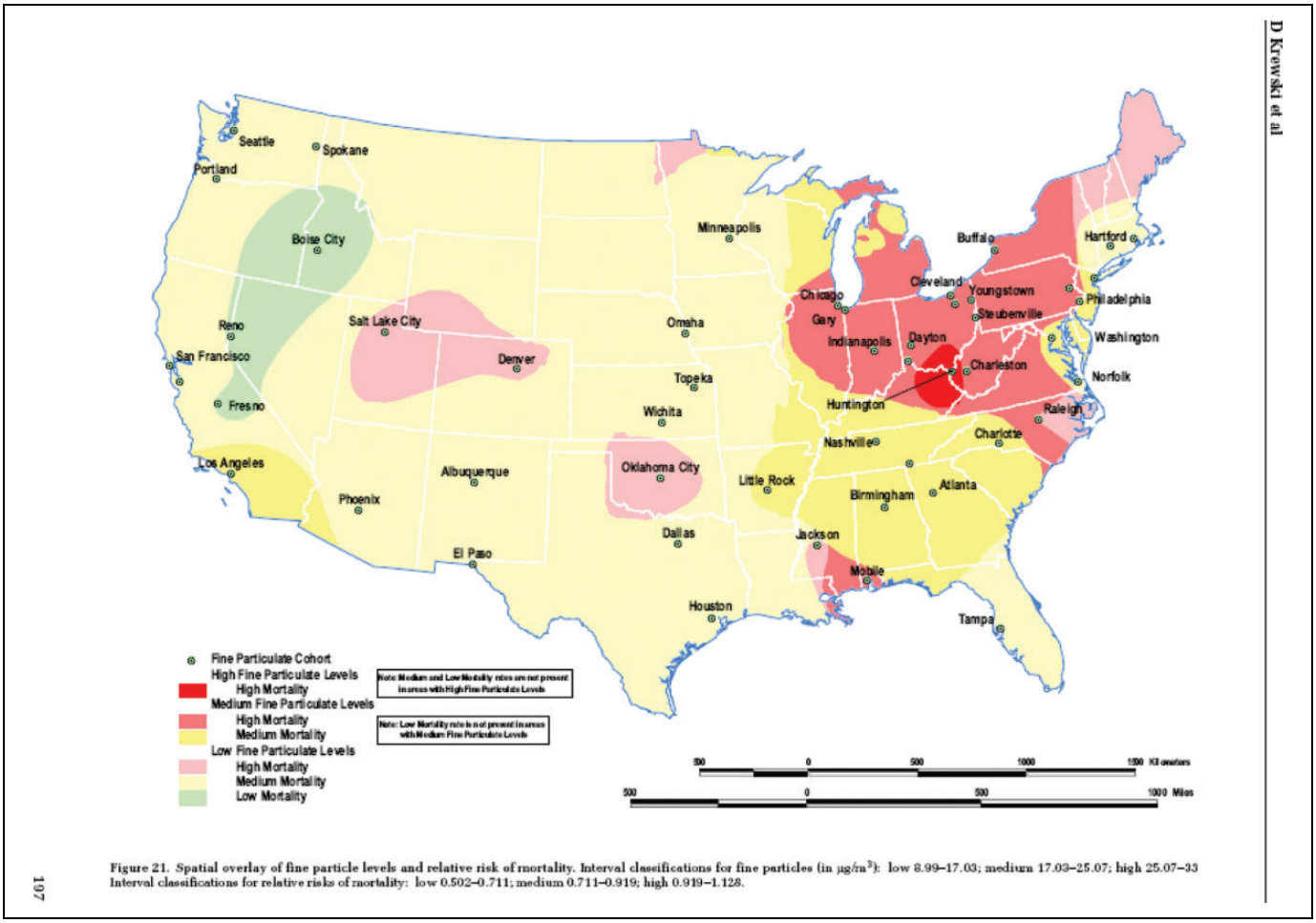

Figure C1. 1982 to 1989 $PM_{2.5}$ mortality risk (MR) in 50 cities (metropolitan areas) shown in Figure 21 on page 197 of HEI 2000[7,9] and listed in Appendix Table B1. Figure 21. Spatial overlay of fine particle levels and relative risk of mortality. Interval classifications for fine particles (in g/m^3): low 8.99 to 17.03: medium 17.03 to 25.07; high 25.07 to 33. Interval classifications for relative risks of mortality: low 0.052 to 0.711; medium 0.711 to 0.919; high 0.919 to 1.128.

Acknowledgments

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Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Supplemental Material

The online supplemental material is available at http://journals.sagepub.com/doi/suppl/10.1177/1559325817693345.

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August 29, 2022

US EPA CASAC Ozone Review Panel Regarding Ozone NAAQS Reconsideration
https://casac.epa.gov/ords/sab/f?p=113:19:17031850757072:::RP,19:P19_ID:976
https://youtu.be/UkmVujyGsq0 (minutes 18-24)
http://scientificintegrityinstitute.org/OzonePanel082922.pdf

Dr. James Enstrom's Verbal Comment to EPA CASAC Ozone Review Panel

I am Dr. James Enstrom. I have had a long career as an epidemiologist at UCLA and I have made significant contributions to air pollution epidemiology, particularly regarding the importance of transparency and reproducibility. I have made oral public comments to CASAC on November 17, 2021 (http://scientificintegrityinstitute.org/PMpanel121021.pdf), February 25, 2022 (http://scientificintegrityinstitute.org/PMpanel022522.pdf), and June 8, 2022 (http://scientificintegrityinstitute.org/Ozonepanel060822.pdf) and I have submitted detailed written criticism based on these comments. My criticism is highly relevant to the PM2.5 and Ozone NAAQS. Thus far, the criticism by me and numerous other public speakers has been totally ignored by CASAC. This lack of response represents disrespect for objective science by CASAC.

I described this disrespect in my August 16, 2022 DDP talk "Politicized EPA Promotes Anti-American Pseudoscience" (https://rumble.com/v1gvnuf-politicized-epa-promotes-anti-american-pseudoscience.html). I pointed out that the January 20, 2021 Presidential Order Protecting Public Health directed immediate review and action to "address the promulgation of Federal regulations and other actions during the last 4 years" (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/). This order challenged the validity of all Federal regulations during the Trump Administration and lead to the unjustified creation of the current CASAC. This order is a prime example of how regulatory science in America has become highly politicized. An ongoing Federal Lawsuit makes a strong case that the current CASAC is illegally constituted because it violates the Federal Advisory Committee Act requirements of viewpoint diversity and no conflicts of interest (https://junkscience.com/2021/10/former-casac-chair-added-as-plaintiff-in-young-v-epa/).

In addition, CASAC refuses to address the evidence that current average levels of human exposure to PM2.5 and ozone in the US are below the levels of known human health effects. In my office in the supposedly polluted city of Los Angeles, my ozone monitor reads about 10 parts per billion (ppb) and my PM2.5 monitor reads about 3 $\mu g/m^3$. These levels are far below the current NAAQS (https://www.epa.gov/criteria-air-pollutants/naaqs-table).

Also, CASAC refuses to acknowledge the extreme publication bias against null air pollution health effects findings that I documented in my earlier comments. The 2021 EPA Policy Assessment for PM2.5 ignored at least 60 authors, including me, who have published null findings or criticized the PM2.5 NAAQS (http://scientificintegrityinstitute.org/PMpanel121021.pdf). Similar publication bias exists regarding the Ozone NAAQS, but even with this bias the April 2022 EPA Ozone Policy Assessment Reconsideration recommended leaving the Ozone NAAQS unchanged (draft 2022 policy assessment).

Also, CASAC refuses to support the fundamental principle of the scientific method that air pollution health effects must be based on findings that are transparent and reproducible. My 2017 and 2018 reanalysis of the ACS CPS II cohort found serious flaws in the seminal Pope 1995 article and the 2000 HEI Reanalysis and demonstrated the importance of access to underlying data (http://scientificintegrityinstitute.org/DRPM25JEEPope052918.pdf). However, on April 18 *Science* Editor-in-Chief Holden Thorp reinforced his strong bias against EPA transparency by personally writing to me that he will not publish any article, letter, or electronic letter that I submit to *Science* that supports "Strengthening Transparency in Regulatory Science" (http://scientificintegrityinstitute.org/ThorpJEE041822.pdf).

As my final evidence of anti-science bias, CASAC Member Christina Fuller gave a misleading presentation in the June 26 HEI Webinar "Setting Ambient Air Quality Standards—What's Science Got to Do With It?" (https://www.youtube.com/watch?v=XAcrlTxeiXA). Furthermore, she has not addressed my June 30 evidence that science has nothing to do with the current NAAQS (http://scientificintegrityinstitute.org/JEEFuller081822.pdf). Even worse, the HEI Board of Directors Chair Richard Meserve rejected my June 30 request to initiate an independent investigation of misconduct by HEI and my July 6 request to arrange a debate on whether particulates cause premature death (http://scientificintegrityinstitute.org/JEEMeserve072222.pdf). These developments challenge the scientific integrity of HEI.

In conclusion, CASAC must address the extensive evidence that Americans are not being harmed by their current personal exposure to PM2.5 and ozone, but are being harmed by the regulations that are due to scientifically flawed PM2.5 and ozone NAAQS. However, regardless of what CASAC does, this evidence is being presented to the American people.

Thank you very much.

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February 25, 2022
US EPA CASAC PM Panel Webcast re PM2.5 NAAQS based on 2021 PM ISA Supp & PM PA
(https://www.youtube.com/watch?v=ZkMsBXwyenw)
(https://casac.epa.gov/ords/sab/f?p=113:19:22380851460992:::RP,19:P19_ID:966)

Dr. James Enstrom's Verbal Comment to EPA CASAC PM Panel re PM2.5 NAAQS

I have 50 years of experience in conducting epidemiologic cohort studies and I have published important peer-reviewed PM2.5 death findings based on ACS CPS I and CPS II cohort data. The February 4 PM Panel letters do not address the detailed public criticism of the 2021 PM ISA Supplement and PM PA. The EPA staff has made NO changes in these documents in response to this criticism. In particular, they ignored Richard Smith's evidence of NO PM2.5 deaths below 12 μg/m³ and my 36 pages of evidence that PM2.5 DOES NOT *cause* premature deaths in the US (http://scientificintegrityinstitute.org/pmpanel121021.pdf).

The recommendations of the PM Panel and EPA staff to tighten the PM2.5 NAAQS are based on a deliberately falsified research record regarding PM2.5-related deaths. Falsification is serious scientific misconduct as defined in the January 11 White House OSTP Scientific Integrity Task Force Report. Thus, I request that Jennifer Peel, with a PhD in Epidemiology, confirm that the PM PA is "a robust and comprehensive evaluation of the epidemiologic literature" and that public comments like mine do not alter her evaluation.

There is NO scientific or public health justification for tightening the PM2.5 NAAQS because there is no etiologic mechanism by which inhaling about 100 μg of PM2.5 per day can cause death and the US already has a very low average PM2.5 level of 7 μg/m³ whereas our competitor China has a very high level of 48 μg/m³. Indeed, there are adverse public health, welfare, social, economic, and energy effects associated with tightening the PM2.5 NAAQS. This tightening will hurt America at a time when it is facing military and economic dangers from Russia and China, as well as rapidly increasing energy costs. Finally, I strongly support the ongoing Young and Cox v. EPA lawsuit because the Biden CASAC and its PM Panel are illegally constituted and in gross violation of the Federal Advisory Committee Act. The current misguided effort to tighten the PM2.5 NAAQS must be stopped.

Thank you.

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January 30, 2017

Jo Kay Chan Ghosh, Ph.D.
Health Effects Officer
South Coast Air Quality Management District
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Dear Dr. Ghosh,

I am writing to express my extreme disappointment with your December 8, 2016 Final Draft 2016 AQMP Appendix I Health Effects. Your January 3, 2017 198-page document, Responses to Comments on Appendix I, DOES NOT address the numerous critical comments that I submitted to you on January 11, 2016 and July 26, 2016 and August 15, 2016. Below I describe six major problems with the final version of Appendix I.

1. Appendix I DOES NOT comply with California Health and Safety Code Section 40471 (b). Instead of satisfying the requirement "the south coast district board, in conjunction with a public health organization or agency, shall prepare a report on the health impacts of particulate matter air pollution in the South Coast Air Basin," you stated on page 188 of your Responses document "it is not the intention of this Appendix to assess whether there is or is not an effect of a specific air pollutant on any particular health endpoint . . . ." Instead of satisfying the requirement to prepare Appendix I "in conjunction with a public health organization or agency," you instead prepared it in conjunction with two aggressive regulatory agencies within CalEPA: OEHHA and CARB. Instead of satisfying the requirement that the "south coast district board shall hold public hearings concerning the report and the peer review," you held four November 2016 public hearings which were conducted without the SCAQMD Board Members

2. Appendix I and your Responses document DO NOT describe the overwhelming evidence of NO relationship [relative risk (RR) = 1.00] between $PM_{2.5}$ and total mortality in California. The weighted average of the most recent results from six different California cohorts show RR = 0.999 (0.988-1.010), which means there are NO premature deaths caused by $PM_{2.5}$ in California. An appended table shows this null California evidence. This table, which is page 5 of my August 15, 2016 comments, was deliberately omitted from your Responses document.

3. Appendix I and your Responses document completely ignore this statement in my August 15, 2016 comments: "I have now submitted for publication a manuscript with null findings that invalidate the positive nationwide relationship between $PM_{2.5}$ and total mortality published in the seminal Pope 1995 paper, which is based on the American Cancer Society Cancer Prevention Study II (CPS II) cohort. My null CPS II cohort findings raise serious doubts about validity of the positive CPS II cohort findings in Jerrett 2005, Jerrett 2009, and Jerrett 2013, which have been used as the basis for the $PM_{2.5}$ premature death claims in the PPTs of Drs. Oliver and Shen." My manuscript, entitled "Fine Particulate Matter and Total Mortality in Cancer Prevention Study II Reanalysis," is now in press in a PubMed recognized scientific journal and should appear online in February 2017. This paper provides important new evidence that $PM_{2.5}$ does not cause premature deaths anywhere in the United States, including California.

4. Appendix I and the 2016 AQMP SES Report rely heavily the $PM_{2.5}$-mortality publications by Dr. Michael Jerrett and his co-authors. You have co-authored with Jerrett seven air pollution related publications during 2011-2016. This co-authorship raises serious doubts about your objectivity, particularly since you have ignored null $PM_{2.5}$-mortality results and have ignored my challenges to the validity of the Jerrett publications. On November 11, 2016 I made a US Office of Research Integrity allegation that Jerrett 2013 falsified and exaggerated the relationship between $PM_{2.5}$ and total mortality in California. An ORI Investigator agreed that the Jerrett 2013 results "do not provide evidence that air pollution is directly responsible for mortality." My US ORI allegation and a table showing NO $PM_{2.5}$-mortality relationship in California are appended.

5. Appendix I does not describe the ACTUAL human exposures to $PM_{2.5}$, ozone, and NOx in the SCAB. The human exposures to these pollutants are much lower than the ambient levels recorded at SCAQMD monitors and the average human exposures are well below the level of measurable health effects for these air pollutants. SCAQMD Board Members and SCAB residents must be informed of their actual exposures to pollutants. Furthermore, they must be informed that these levels are well below the corresponding US EPA NAAQS.

6. Appendix I provides no context regarding the impact of air pollution and other risk factors on the overall health of SCAB residents. An appended table shows low 2014 age-adjusted death rates from all causes, all cancer, and all respiratory disease in California and the SCAB. These death rates are among the lowest in the United States and the World. This table, which is page 6 of my August 15, 2016 comments, was deliberately omitted from your Responses document.

If the 2016 AQMP is approved by the SCAQMD Board on February 3, 2017, I will make a strong case to the new US EPA Administrator, the US House Science Committee, the US House Energy Committee, and the US Senate Environment Committee that the AQMP should not be implemented because it is NOT justified on a scientific or public health basis. Also, I will make a strong case to business and taxpayer groups in Southern California that the 2016 AQMP is scientifically unjustified and should not be funded. Many concerned scientists like myself are doing everything we can to stop SCAQMD from implementing new unjustified environmental regulations in Southern California, as part of a national effort to reduce unjustified regulations.

Finally, I am sending this email letter to all UCLA School of Public Health faculty members who have been involved with SCAQMD and/or with your 2011 Ph.D. in Epidemiology. I request that these faculty members assess my above comments and inform SCAQMD whether they believe the 2016 AQMP is justified on a public health basis. These faculty members are directly responsible for your training as an environmental epidemiologist and you, as a prominent public health official, are a direct reflection of the values and integrity of the School of Public Health.

Thank you for taking this message seriously, because it is a VERY SERIOUS message.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
UCLA and Scientific Integrity Institute
http://climateconferences.heartland.org/james-enstrom-iccc10-panel-8/
http://climateconferences.heartland.org/iccc-12/
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Summary Table. 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 µg/m³ in PM2.5
(http://scientificintegrityinstitute.org/NoPMDeaths112215.pdf)

Krewski 2000 & 2010 CA CPS II Cohort N=40,408 RR = 0.872 (0.805-0.944) 1982-1989
(N=[18,000 M + 22,408 F]; 4 MSAs; 1979-1983 PM2.5; 44 covariates)

McDonnell 2000 CA AHSMOG Cohort N~3,800 RR ~ 1.00 (0.95 – 1.05) 1977-1992
(N~[1,347 M + 2,422 F]; SC&SD&SF AB; M RR=1.09(0.98-1.21) & F RR~0.98(0.92-1.03))

Jerrett 2005 CPS II Cohort in LA Basin N=22,905 RR = 1.11 (0.99 - 1.25) 1982-2000
(N=22,905 M & F; 267 zip code areas; 1999-2000 PM2.5; 44 cov + max confounders)

Enstrom 2005 CA CPS I Cohort N=35,783 RR = 1.039 (1.010-1.069) 1973-1982
(N=[15,573 M + 20,210 F]; 11 counties; 1979-1983 PM2.5) RR = 0.997 (0.978-1.016) 1983-2002

Enstrom 2006 CA CPS I Cohort N=35,783 RR = 1.061 (1.017-1.106) 1973-1982
(11 counties; 1979-1983 & 1999-2001 PM2.5) RR = 0.995 (0.968-1.024) 1983-2002

Zeger 2008 MCAPS Cohort "West" N=3,100,000 RR = 0.989 (0.970-1.008) 2000-2005
(N=[1.5 M M + 1.6 M F]; Medicare enrollees in CA+OR+WA (CA=73%); 2000-2005 PM2.5)

Jerrett 2010 CA CPS II Cohort N=77,767 RR ~ 0.994 (0.965-1.025) 1982-2000
(N=[34,367 M + 43,400 F]; 54 counties; 2000 PM2.5; KRG ZIP; 20 ind cov+7 eco var; Slide 12)

Krewski 2010 (2009) CA CPS II Cohort
(4 MSAs; 1979-1983 PM2.5; 44 cov) N=40,408 RR = 0.960 (0.920-1.002) 1982-2000
(7 MSAs; 1999-2000 PM2.5; 44 cov) N=50,930 RR = 0.968 (0.916-1.022) 1982-2000

Jerrett 2011 CA CPS II Cohort N=73,609 RR = 0.994 (0.965-1.024) 1982-2000
(N=[32,509 M + 41,100 F]; 54 counties; 2000 PM2.5; KRG ZIP Model; 20 ind cov+7 eco var; Table 28)

Jerrett 2011 CA CPS II Cohort N=73,609 RR = 1.002 (0.992-1.012) 1982-2000
(N=[32,509 M + 41,100 F]; 54 counties; 2000 PM2.5; Nine Model Ave; 20 ic+7 ev; Fig 22 & Tab 27-32)

Lipsett 2011 CA Teachers Cohort N=73,489 RR = 1.01 (0.95 – 1.09) 2000-2005
(N=[73,489 F]; 2000-2005 PM2.5)

Ostro 2011 CA Teachers Cohort N=43,220 RR = 1.06 (0.96 – 1.16) 2002-2007
(N=[43,220 F]; 2002-2007 PM2.5)

Jerrett 2013 CA CPS II Cohort N=73,711 RR = 1.060 (1.003–1.120) 1982-2000
(N=[~32,550 M + ~41,161 F]; 54 counties; 2000 PM2.5; LUR Conurb Model; 42 ind cov+7 eco var+5 metro; Table 6)

Jerrett 2013 CA CPS II Cohort N=73,711 RR = 1.028 (0.957-1.104) 1982-2000
(same parameters and model as above, except including co-pollutants NO2 and Ozone; Table 5)

Ostro 2015 CA Teachers Cohort N=101,884 RR = 1.01 (0.98 -1.05) 2001-2007
(N=[101,881 F]; 2002-2007 PM2.5) (all natural causes of death)

Thurston 2016 CA NIH-AARP Cohort N=160,209 RR = 1.02 (0.99 -1.04) 2000-2009
(N=[~95,965 M + ~64,245 F]; full baseline model: PM2.5 by zip code; Table 3) (all natural causes of death)

Enstrom 2016 unpub CA NIH-AARP Cohort N=160,368 RR = 1.001 (0.949-1.055) 2000-2009
(N=[~96,059 M + ~64,309 F]; full baseline model: 2000 PM2.5 by county)

Allegation of Research Misconduct by Dr. Michael Jerrett and Co-Authors

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November 11, 2016

I allege research misconduct (falsification) by UCLA Professor Michael Jerrett, Ph.D., and his primary co-authors C. Arden Pope, Ph.D., Daniel Krewski, Ph.D., George Thurston, Sc.D., Richard T. Burnett, Ph.D., Michael J. Thun, M.D., and Susan P. Gapstur, Ph.D., regarding their attached September 1, 2013 *AJRCCM* paper "Spatial Analysis of Air Pollution and Mortality in California" (http://www.atsjournals.org/doi/abs/10.1164/rccm.201303-0609OC). The authors received a portion of their funding for this research from NIEHS and CDC within DHHS. While claiming that fine particulate matter ($PM_{2.5}$) was associated with mortality from all causes (total mortality) in their study, the authors omitted their own null findings and the null findings of others. These omitted findings clearly show NO association. Thus, they have engaged in falsification as defined by DHHS and the Public Health Service: "omitting data or results such that the research is not accurately represented in the research record" (Section 93.103(b) of 42 CFR 93) (http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf).

The *AJRCCM* paper claims there is a positive relationship between $PM_{2.5}$ and mortality from all causes in California because their "conurbation" land use regression (LUR) model yielded a slightly positive relative risk of RR=1.060 (1.003-1.120), as shown in Table 6. However, complete study results are in the October 28, 2011 Jerrett CARB Final Report "Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort: Final Report" (http://www.arb.ca.gov/research/apr/past/06-332.pdf). The eight entirely null models, shown in the attached Report Table 22, were omitted from the paper. The results for all nine models are shown in my Summary Table on the next page. The weighted average relative risk for all nine models is RR=1.002 (0.992-1.012), which means NO relationship.

Furthermore, the *AJRCCM* paper does not cite any of the null California $PM_{2.5}$-mortality results from other papers and reports dating back to 2000, including earlier findings by Dr. Jerrett. These results are shown on the next page, as well as on the attached August 15, 2016 Summary Table that I presented to SCAQMD (http://www.aqmd.gov/home/library/clean-air-plans/air-quality-mgt-plan/Draft2016AQMP/2016-aqmp-appendix-i-comment-letter (letter #7). The weighted average relative risk for the most recent result from each of the six different California cohorts is RR=0.999 (0.988-1.010), which means NO relationship.

I contend that the falsification in the paper was deliberate because it was done after extensive criticism of the June 9, 2011 Draft Report and the October 28, 2011 Final Report. This criticism was presented to the authors via CARB by myself, William M. Briggs, Ph.D., John D. Dunn, M.D., S. Stanley Young, Ph.D., Gordon Fulks, Ph.D., and Frederick W. Lipfert, Ph.D. A compilation of all criticism of the 2011 Report is attached (http://www.scientificintegrityinstitute.org/JerrettCriticism102811.pdf). Detailed criticism of the *AJRCCM* paper, including its misrepresentation of the results contained in the CARB Report, was given by Dr. Briggs in his statistical blogs of August 6, 2013 (http://wmbriggs.com/blog/?p=8720), September 11, 2013 (http://wmbriggs.com/blog/?p=8990), and September 25, 2013 (http://wmbriggs.com/blog/?p=9241).

In conclusion, Dr. Jerrett and his co-authors falsified the relationship between $PM_{2.5}$ and total mortality in California in their *AJRCCM* paper by deliberately omitting their own null evidence and the null evidence of others. This is quite disturbing because $PM_{2.5}$-mortality claims in the paper are being used as public health justification for the very costly SCAQMD 2016 Air Quality Management Plan (http://www.aqmd.gov/).

Summary Table. 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 µg/m³ (IQR=10) in $PM_{2.5}$

Study (Year)	Cohort	RR	95% CI	F-U Years
Jerrett 2013 (*AJRCCM* Table 6 Model)	CA CPS II	1.060	(1.003–1.120)	1982-2000
Jerrett 2011 (CARB Report Figure 22)	CA CPS II			
KRG IND Model (Table 30, IQR=8.52902→10.0)		0.992	(0.965-1.020)	1982-2000
KRG ZIP Model (Table 28, IQR=8.4735→10.0)		0.993	(0.964-1.023)	1982-2000
KRG IND+O3 Model (Figure 22 extrapolated, IQR=10.0)		1.020	(0.980-1.060)	1982-2000
IDW IND Model (Table 29, IQR=8.74→10.0)		1.003	(0.978-1.028)	1982-2000
IDW ZIP Model (Table 27, IQR=9.37→10.0)		0.995	(0.967-1.025)	1982-2000
BME IND Model (Figure 22 extrapolated, IQR=10.0)		1.000	(0.975-1.025)	1982-2000
LUR IND Model (Table 31, IQR=5.35→10.0)		1.009	(0.980-1.039)	1982-2000
LUR IND+5 Metro Model (Abstract Table 1, IQR=10.0) [Jerrett 2013 Model]		1.080	(1.000-1.150)	1982-2000
RS IND Model (Table 32, IQR= 5.39→10.0)		0.998	(0.968-1.029)	1982-2000
Weighted Average of All Nine Models		1.002	(0.992-1.012)	1982-2000
Other Results by Jerrett and Other Investigators				
Krewski Jerrett 2000 (RR for CA 2010)	CA CPS II	0.872	(0.805-0.944)	1982-1989
McDonnell 2000 *	CA AHSMOG	~ 1.00	(0.95 – 1.05)	1977-1992
Jerrett 2005	CPS II (LA Basin Only)	1.11	(0.99 - 1.25)	1982-2000
Enstrom 2005 *	CA CPS I	0.997	(0.978-1.016)	1983-2002
Zeger 2008 *	MCAPS "West=CA+OR+WA"	0.989	(0.970-1.008)	2000-2005
Jerrett 2010	CA CPS II	~ 0.994	(0.965-1.025)	1982-2000
Krewski Jerrett 2009 (RR for CA 2010)*	CA CPS II	0.968	(0.916-1.022)	1982-2000
Lipsett Jerrett 2011	CA Teachers	1.01	(0.95 – 1.09)	2000-2005
Ostro 2011	CA Teachers	1.06	(0.96 – 1.16)	2002-2007
Ostro 2015 *	CA Teachers	1.01	(0.98 - 1.05)	2001-2007
Thurston 2016 *	CA NIH-AARP	1.02	(0.99 - 1.04)	2000-2009
Weighted Average of Latest Results (*) from Six California Cohorts		0.999	(0.988-1.010)	

From: Hohmann, Ann (HHS/OASH) <Ann.Hohmann@hhs.gov>
Sent: Wednesday, December 21, 2016 10:46 AM
To: jenstrom@ucla.edu
Cc: Garfinkel, Susan J (HHS/OASH) <Susan.Garfinkel@hhs.gov>; Trenkle, William (OS/OASH) <William.Trenkle@hhs.gov>
Subject: DIO 6351

Dear Dr. Enstrom,

As the ORI expert in biostatistics and public health, Dr. Garfinkel gave me the materials that ORI has regarding your November 7 conversation with Dr. Trenkle about the Jerrett et al. 2013 paper and your emailed materials to AskORI on November 11, 2016. I have read and reviewed all of the materials. I understand your concern about the way the data were presented in the paper and used elsewhere. Though I have no clinical training, it appears that the relative risks reported do not seem to rise to the level of clinical significance and do not provide evidence that air pollution is directly responsible for mortality. Presenting this data as such, may be a question only of bad science.

However, "bad" or sloppy science is not the same as research misconduct. ORI's regulation (42 CFR 93.103) defines research misconduct, as you know, as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." While it is true that Dr. Jerrell and colleagues did not cite all the research showing that the relative risk is very, very close to 1 and only emphasized specific numbers, they did not, as far as I can tell, change their data to get a statistically and clinically significant result. The weak results are there for all to see. Thus, there does not appear to be falsification.

To overinterpret one's data is certainly inappropriate, but would be a matter to raise with the reviewers and the journal editors, who apparently did not insist that the authors tone down their conclusions. ORI is aware that the research on the effects of air pollution is certainly not the only area of science where there is open controversy. Just this morning, *The Scientist* ran an article on the controversy regarding the effects of sugar intake (http://www.the-scientist.com/?articles.view/articleNo/47819/title/Industry-Funded-Sugar-Study--Don-t-Trust-Other-Sugar-Studies/&utm_campaign=NEWSLETTER_TS_The-Scientist-Daily_2016&utm_source=hs_email&utm_medium=email&utm_content=39616948&_hsenc=p2ANqtz-8Q5JhLgCWe4CJboPROHvuwP0x1fr3XLwxkrNXixW4tqdO_29UCNh4fj6q1IwpolH0ferca7iYMwC0oyjX7kTTvwmW8mA&_hsmi=39616948). Unfortunately, we all are aware that science loses when research is influenced by special interest groups.

The Public Health Service (PHS) regulation, under which ORI acts, is not meant to be a way to put the brakes on controversial science. The mission of our Office is to protect PHS research funds from researchers who knowingly and intentionally make up data or change them to serve their purposes. In the documents you provided, there does not appear to be evidence that Dr. Jerrell and his colleagues have done that. Without clear evidence of fabrication and/or falsification of data (and not just failing to cite contrary data), ORI is unable to further pursue your allegations. What you do and have been doing for decades – promoting your own research results – in scientific and other venues may be the best way to combat opposing viewpoints. Good luck in the future.

Ann A. Hohmann, Ph.D., MPH
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2014 Age-Adjusted Death Rates by State and County and Ethnicity

Deaths per 1,000 persons (age-adjusted using 2000 U.S. Standard Population)
with 95% Confidence Interval shown in parentheses
(http://wonder.cdc.gov/ucd-icd10.html)

September 8, 2016

Location	2014 Age-Adjusted Death Rate (95% Confidence Interval)		
	All Causes	All Cancer	All Respiratory
	ICD-10=All Codes	ICD-10=C00-D48	ICD-10=J00-J98
United States (50 States + DC)	7.25 (7.24-7.26)	1.66 (1.65-1.66)	0.71 (0.71-0.71)
California (2nd lowest State)	6.06 (6.03-6.08)	1.48 (1.46-1.49)	0.57 (0.56-0.57)
South Coast Air Basin (SCAB = Los Angeles, Orange, Riverside, and San Bernardino Counties)	5.93	1.46	0.55
Hawaii (Lowest State)	5.89 (5.77-6.00)	1.44 (1.38-1.49)	0.53 (0.50-0.56)
Los Angeles County	5.71 (5.66-5.75)	1.42 (1.40-1.44)	0.53 (0.52-0.55)
Orange County	5.48 (5.40-5.56)	1.38 (1.34-1.42)	0.47 (0.45-0.49)
California Hispanics	5.02 (4.97-5.07)	1.18 (1.16-1.20)	0.39 (0.38-0.41)
SCAB Hispanics	4.96	1.19	0.39

2019 Age-Adjusted Death Rates by State and County

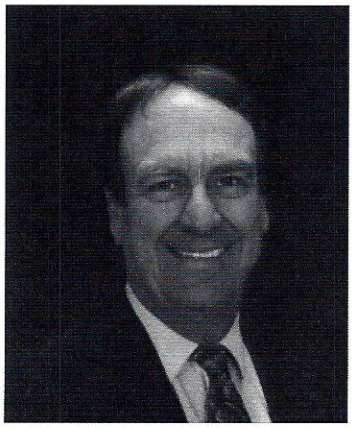
Deaths per 1,000 persons (age-adjusted using 2000 U.S. Standard Population)
with 95% Confidence Interval shown in parentheses
(http://wonder.cdc.gov/ucd-icd10.html)

James E. Enstrom, PhD, MPH
UCLA and Scientific Integrity Institute
jenstrom@ucla.edu

November 9, 2021

Location	2019 Age-Adjusted Death Rate (95% Confidence Interval)	
	All Causes	State/US Ratio
	ICD-10=All Codes	
West Virginia	9.45 (9.33-9.58)	1.3217
Mississippi	9.45 (9.35-9.56)	
Kentucky	9.11 (9.03-9.19)	
Alabama	8.98 (8.90-9.06)	
United States (50 States + DC)	7.15 (7.14-7.16)	1.0000
California (2nd lowest State)	6.02 (6.00-6.04)	
Los Angeles County	5.75 (5.70-5.79)	0.8042
Hawaii (Lowest State)	5.73 (5.62-5.84)	
California Hispanics	5.23 (5.18-5.27)	
Los Angeles Hispanics	5.07 (4.99-5.14)	0.7091

Guest Speaker: James E. Enstrom, Ph.D., M.P.H.



Dr. Enstrom is a native Californian who has lived most of his life in Los Angeles County. In 1965 He graduated co-valedictorian of his class at Harvey Mudd College in Claremont, CA, where he obtained a B.S. in physics. In 1970 Dr. Enstrom obtained his Ph.D. in experimental elementary particle physics at Stanford University from Nobel Laureate Melvin Schwartz. During 1971-1973 he worked as a physicist at the Lawrence Berkeley Laboratory in research group of Nobel Laureate Luis Alvarez. He then came to the UCLA School of Public Health as a postdoctoral fellow in cancer epidemiology and received an M.P.H. and postdoctoral certificate in 1976 from renowned public health epidemiologist Dr. Lester Breslow.

He then joined the UCLA School of Public Health faculty as a Research Professor / Researcher and he held that position for 36 years until June 2012. He currently retains a similar affiliation with UCLA, although he is now drawing retirement. He has been a Fellow of the American College of Epidemiology since 1981, he has been listed in Who's Who in America since 1990, and he has been President of the Scientific Integrity Institute in Los Angeles since 2005.

During his long career, he has explored many important epidemiological issues, particularly focusing on California. A major theme of his research has been identifying healthy lifestyles. He has shown that it is possible to reduce mortality risk from cancer and heart disease by 70% in the middle age range and to increase longevity by as much as 10 years. Examples of healthy populations that he has examined include religiously active California Mormons, California Cancer Prevention Study subjects, California PREVENTION Magazine Readers, and California and national samples of adults adhering to good health practices.

He has also examined the influence of environmental factors on mortality. In December 2005 he published a major paper on fine particulate matter and mortality in California and he has numerous other fm. Since then he has conclusively documented that fine particulate matter does not cause premature death in California. Since 2013, following the lead of the US House Science Committee, he has been involved with efforts to obtain the access to the "secret science" data that EPA has used to justify its fine particulate and ozone air pollution regulations in California and the United States. These efforts include the August 1, 2013 House subpoena of EPA, as well as the Secret Science Reform Acts of 2014 and 2015.

He is currently conducting important new air pollution epidemiology research that is relevant to the EPA, CARB, and SCAQMD regulations. More information can be found at his Scientific Integrity Institute website (http://www.scientificintegrityinstitute.org/).

South Coast
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April 15, 2022

The Honorable Michael S. Regan, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (Mail Code 1101A)
Washington, D.C. 20460
Sent via certified mail, return receipt requested

RE: Notice of Intent to Sue Pursuant to Section 304(b)(2) of the Clean Air Act; State Implementation Plan Submissions from California; South Coast Air Quality Management District

Dear Administrator Regan:

I am writing on behalf of South Coast Air Quality Management District (South Coast AQMD) to notify you of ongoing violations of the federal Clean Air Act by the U.S. Environmental Protection Agency (EPA) for failing to timely act on a State Implementation Plan (SIP) submittal on contingency measures submitted by the South Coast AQMD on December 31, 2019. EPA action on this SIP submittal is due according to the mandatory deadlines assigned by Section 110(k)(2) of the Clean Air Act (CAA), 42 U.S.C. § 7410(k)(2). More specifically, EPA has failed to timely act on a contingency measures plan adopted December 6, 2019 that was submitted through the California Air Resources Board (CARB) on December 31, 2019 for EPA approval in addressing the provisions of CAA Section 182(e)(5). EPA was required to act on the plan by June 30, 2021. Section 110(k)(2) directs action in accordance with Section 110(k)(3) on "Full and partial approval and disapproval," but in this case, EPA must under Section 110(k)(3) only approve, and not disapprove, this SIP submittal. Congress intended for EPA to regulate federal sources[1] as necessary to allow all areas, and in particular the South Coast Air Basin, to attain the air quality standards. Any action to disapprove the SIP on the basis that it relies on the federal government to take actions would be subject to challenge because the South Coast region simply cannot attain without massive reductions from federal sources. Accordingly, we submit

[1] Federal sources, as used in this notice, refers to federally regulated sources for which neither South Coast AQMD nor the State (i.e., CARB) can set emission standards. EPA has previously employed this terminology, for example, in recognizing EPA's need to deliver "fair share reductions of federal sources" to South Coast. *See, e.g.*, 64 Fed. Reg. 39923, 39924 (July 23, 1999).

that the SIP must be approved, and EPA must develop a regulatory strategy and find sufficient funding to reduce federal emissions to meet the health-based National Ambient Air Quality Standards.

The South Coast AQMD intends to file a lawsuit seeking to address EPA's failure to timely act as required by 42 U.S.C. § 7410(k)(2) and (3), 60 days from the date of this letter under CAA Section 304, 42 U.S.C. § 7604. This notice is submitted in accordance with 40 C.F.R Section 54.3. The following case information supports our position.

I. The South Coast Air Basin Cannot Attain the 1997 Eight-Hour Ozone Standard Without Massive Emission Reductions From Federally Regulated Sources

The South Coast Air Basin cannot attain the 1997 8-hour ozone standard without massive emission reductions from federal sources. Even considering only emissions from ships, locomotives, and aircraft, the region needs an additional 46 tons per day (tpd) of NOx reductions by 2023 to attain the standard in a timely manner.[2] When also considering the emissions from on-road heavy-duty trucks that are subject to federal authority, the region needs a total of 67-69 tpd of NOx reductions from federal sources.[3]

Unfortunately, the federal government does not currently have plans to secure these reductions as specific commitments and a regulatory agenda were noticeably absent in the Fiscal Year 2022-2026 EPA Strategic Plan released on March 28, 2022. While total NOx emissions in the South Coast Air Basin will have been reduced by almost 50% between 2012 and 2023, almost all these reductions will come from sources under CARB or South Coast AQMD authority. For example, over this time, NOx emissions from light duty vehicles will have been reduced by over 70%. CARB and the South Coast AQMD are doing our part. In contrast, NOx emissions from aircraft, locomotives, and ocean-going vessels will *increase* by almost 10% over the same period.[4]

It would be impossible to attain the standard without the required reductions from these federal sources. Reaching attainment solely with emission reductions from South Coast AQMD and CARB regulated sources would require eliminating all emissions from *virtually all* such sources. According to the CARB 2018 updates to the California SIP, baseline emissions of NOx in 2023 in the South Coast Air Basin will total 269 tpd. *See* Summary Table for 2023 NOx Emissions, appended to this letter. To attain the 1997 ozone standard, these emissions must be reduced to a

[2] Revised Proposed 2016 State Strategy for the State Implementation Plan (March 7, 2017), p.32. *available at* https://ww3.arb.ca.gov/planning/sip/2016sip/rev2016statesip.pdf.
[3] Final Contingency Measure Plan, December 2019, Table 2-1, p. 39, *available at* https://www.aqmd.gov/docs/default-source/clean-air-plans/air-quality-management-plans/2016-air-quality-management-plan/1997-ozone-contingency-measure-plan/1997-8-hour-ozone-draft-contingency-measure-plan---120619.pdf?sfvrsn=10.
[4] Final Contingency Measure Plan, December 2019, p. 58.

carrying capacity of 141 tons per day by 2023.[5] Thus, the region must reduce expected 2023 emissions by 128 tpd (the difference between the baseline of 269 tpd and the carrying capacity of 141 tpd). If no further reductions come from federal sources, all 128 tons of reductions would need to come from state and locally regulated sources. This would mean, for example, completely eliminating all emissions from stationary and area sources (49 tpd), all emissions from California-regulated on-road vehicles (69 tpd), and 10 tpd of California-regulated off-road sources such as larger farm and construction equipment (about 20% of the total of off road sources).

It is not yet possible to completely eliminate all emissions from on-road, stationary, and area sources of NOx in the South Coast Air Basin. Nor is it realistic to expect that all such sources would be entirely zero-emissions in the near future. Therefore, it is imperative that significant emission reductions come from federal sources. And it would be manifestly unfair to penalize the South Coast AQMD and the State by disapproving the Contingency Measure Plan and triggering sanctions based on emissions under federal control.

II. The Legislative History Demonstrates that Congress Intended EPA to Regulate Federal Sources as Needed to Enable All Areas of the Nation to Attain the National Ambient Air Quality Standards

In the 1990 Amendments to the CAA, Congress preempted the states from establishing emission standards for locomotives, farm and construction equipment, and other nonroad engines, which includes marine vessels. CAA Section 209(e).[6] And for decades, states have been preempted from regulating new motor vehicles, with California allowed to adopt its own standards with a waiver from EPA. CAA Section 209(a) and (b); 42 U.S.C. §§ 7543(a), (b).

As Congress debated the 1990 Amendments, Members of Congress from California stated that unless EPA regulates these sources, the South Coast region would be prevented from attaining the ozone standards. Representative Carlos Moorhead (R-CA) stated that it will be impossible for Los Angeles to attain the NAAQS if EPA fails to regulate federal sources.[7] Senator Pete Wilson (R-CA) also explained that if federal sources are not controlled, California will not be able to comply.[8] In response to these concerns, Senator John Chafee (R-RI), the lead co-sponsor of the Senate Bill, assured the California delegation that Congress intended that EPA would regulate federal sources as necessary so that all areas could attain the standards. In response to a question from Senator Wilson regarding the Amendments, Senator Chafee explained that "EPA has the obligation…to adopt control measure[s] for sources which it exclusively controls when these

[5] Final Contingency Measure Plan, December 2019, p. 2.
[6] 42 U.S.C. § 7453(e). The CAA also preempts state and local governments from setting emission standards for aircraft. CAA Section 233; 42 U.S.C. § 7573.
[7] Congressional Research Service, A Legislative History of the Clean Air Act Amendments of 1990, (Leg. History), p. 2613.
[8] Leg. History, p. 1125-26.

controls are necessary to attain national [ambient air quality] standards."[9] Finally, when Congress enacted section 213 of the CAA, 42 U.S.C. § 7547, which obligated EPA to regulate nonroad sources, it stated in the Conference Report: "We expect EPA to carry out this mandate in a fashion which assures that states which are preempted will not suffer any additional [e]missions beyond what they themselves would have allowed."[10] This Conference Report reflects the views of the Members from both the House and Senate. Thus, Congress intended for EPA to regulate federal sources as necessary to allow all areas to attain the standards.

III. EPA Has Previously Recognized the Need for Significant Reductions From Federal Sources and Approved the 1994 South Coast Ozone SIP Which Relied on Such Reductions and EPA Must Do So Again

As demonstrated above, under the CAA, EPA has the responsibility to regulate federal sources where necessary to allow all areas to attain the standards. EPA itself has recognized that responsibility in the past. In approving the 1994 1-hour ozone SIP for the South Coast Air Basin, EPA recognized that "massive further reductions are needed for attainment in the South Coast and that attainment may be either very costly and disruptive or impossible if further reductions are not achieved from national or international sources."[11] While EPA noted it did not think states have authority to assign responsibilities to the Federal Government under the Clean Air Act, it also said it believed EPA should help speed cleaning the air in California and nationally.[12] Accordingly, EPA made an "enforceable commitment" to adopt federal measures that it determined were EPA's responsibility.[13] On this basis, EPA was able to approve a SIP submittal that relied on federal measures. Therefore, EPA has established precedent of doing the right thing and approving a plan that relies on federal measures, recognizing the federal responsibility to regulate where necessary to allow the region to attain the standard.[14] EPA must take a similar approach to acting on the 2019 Contingency Measure Plan, since as discussed below, a disapproval, which inevitably triggers sanctions, would be unlawful.

IV. Disapproval of the Contingency Measure Plan Would Lead to Sanctions that Congress Did Not Intend

If EPA were to disapprove the contingency measure plan on the basis that it relies on federal measures, such disapproval would trigger sanctions. The sanctions include greatly increasing the cost and difficulty of issuing permits as well as cutting off federal highway funds. CAA Section 179; 42 U.S.C. Section 7509. Sanctions can be avoided if the basis for the disapproval is corrected. *Id.* However, in this case it is not possible to eliminate the plan's reliance on federal

[9] Leg. History, p. 1127.
[10] Leg. History, p. 1021
[11] Approval and Promulgation of Implementation Plans; California—Ozone, 62 Fed. Reg. 1150, 1152 col.3---1153 col. 1 (Jan. 8, 1997).
[12] 62 Fed. Reg. 1150, 1151 col. 2.
[13] 62 Fed. Reg. 1150, 1154 col. 1.
[14] *See* 40 CFR § 52.238 ("Commitment to undertake rulemaking").

measures, because CARB and South Coast AQMD lack adequate authority to obtain necessary emission reductions from federal sources. Therefore, the region has no ability to avoid sanctions. But Congress did not intend sanctions to be imposed where the area being sanctioned does not have adequate authority to correct the alleged deficiency.

The legislative history of the 1990 Amendments to the Clean Air Act shows that Congress did not intend sanctions to be imposed where the state and local governments lack sufficient authority to remedy the deficiency, which in this case is because the CAA preempts state and local governments from setting emission standards for federal sources. On May 23, 1990, during the House debate on the CAA, Representative Norm Mineta (D-CA) stated that "Under the sanctions provisions, the EPA Administrator is required to establish criteria for exercising his or her authority to impose sanctions on political subdivisions that have adequate authority to correct an air quality deficiency."[15] In this case, the South Coast AQMD does not have adequate authority to correct the supposed deficiency, since it is impossible to devise a plan that does not rely on emission reductions from federal sources for which EPA has the authority to set emission standards. This principle was repeated during the House debate on the Conference Report on October 26, 1990. Representative Glenn Anderson (D-CA) stated: "This provision will ensure that available sanctions are applied to the geographical areas under the control of the government agency principally responsible for failure to comply with the Clean Air Act and with the authority to remedy the deficiency."[16] While this discussion pertains directly to CAA Section 110(m), which prohibits statewide sanctions for 24 months if the failure is primarily due to a political subdivision, it clearly shows that Congress did not intend for sanctions to be imposed on an area that may be unable to correct the deficiency.

Moreover, Congress did not intend for a state to be penalized where an inability to demonstrate attainment is due to emissions from federal sources. The Clean Air Act recognizes that such a result would be highly unfair. Section 179B of the CAA [42 U.S.C. § 7509a] requires EPA to approve an attainment demonstration where the state shows it would attain the standard "but for emissions emanating from outside of the United States." The legislative history of this section makes it clear that it was adopted precisely because it would be unfair to hold a state responsible for emissions over which it has no control. The amendment was sponsored by Senator Phil Gramm (R-TX), who explained: "it is unfair to hold El Paso accountable for pollution that is generated in a foreign country that they have no control over."[17] Senator Max Baucus (D-MT), the sponsor of the Senate bill, spoke in support of the provision, noting that border areas "do not have control of their own destiny themselves."[18] Thus, Congress did not intend to penalize areas that have no control over the sources causing nonattainment. By the same token, Congress would not have intended to penalize areas where nonattainment is due to federal sources. Congress did not see a need to specifically discuss this possibility because it had already made it clear that

[15] Congressional Research Service, *A Legislative History of the Clean Air Act Amendments of 1990,* (Leg. History) Committee Print, p. 2658
[16] Leg. History, p. 1200.
[17] Leg. History, p. 5741.
[18] Leg. History, p. 5742.

EPA was expected to regulate federal sources as needed to allow all areas, and specifically the South Coast Air Basin, to attain the standards, as discussed in Part III above. Therefore, Congress did not anticipate that areas would fail to attain due to emissions from federal sources.

V. EPA Action to Disapprove the South Coast 2019 Contingency Measure Plan Would Violate the Doctrines of Impossibility and Absurd Results

As discussed in Part I above, it is impossible for the South Coast Air Basin to attain the 1997 8-hour ozone standard without massive further emissions reductions from federal sources. Therefore, if EPA were to disapprove the 2019 Contingency Measure plan because it relies on federal action, it would be impossible for the South Coast AQMD to submit a plan that eliminated that reliance. Thus, the South Coast AQMD would never be able to correct the alleged deficiency in the plan and would be subject to sanctions which it has no ability to avoid. These sanctions would likely lead to the South Coast AQMD being unable to issue permits for new or modified major stationary sources, because the 2-to-1 offset ratio would require offsets that simply are not available in the region. Moreover, the sanction of withholding highway transportation funds would likely affect billions of dollars in economic activity as infrastructure projects are waylaid creating ramifications for the largest container Ports complex in the nation with no way to ever correct the deficiency and have the transportation sanctions lifted. Since disapproval of the 2019 Contingency Measure Plan would lead to a requirement that the South Coast AQMD do the impossible, it would be unlawful. "The law does not require impossibilities of any person, natural or artificial…" *Dist. of Columbia v. Woodbury*, 136 U.S. 450, 464 (1890). And as stated in California Civil Code Section 3531, "[t]he law never requires impossibilities." So EPA cannot by a disapproval require the South Coast and California to do the impossible.

In addition, the doctrine of "absurd results" prevents EPA from disapproving the Plan. Any action which would impose sanctions on a region for a failure caused by sources over which it has no control would create absurd results. The Supreme Court has long held that when the literal language of a statute "has led to absurd or futile results…this Court has looked beyond the words to the purpose of the act. Frequently, however, even when the plain meaning did not produce absurd results but merely an unreasonable one plainly at variance with the policy of the legislation as a whole this Court has followed that purpose rather than the literal words." *U.S. v. American Trucking Ass'ns.,* 310 U.S. 534, 543 (1940) (cleaned up). The Supreme Court reiterated this language in *Perry v. Commerce Loan Co.,* 383 U.S. 392, 400 (1966). Penalizing the South Coast with an action that causes sanctions because of emissions over which the state and local agencies lack the ability to set emission standards creates absurd results and is plainly at variance with the purpose of the statute as a whole, which is not to penalize states for sources outside their control.

VI. Imposing Sanctions on An Area that Cannot Attain the Standard Because of Emissions from Federal Sources Would Violate the 10th Amendment and Principles of the Spending Clause

In 2012, the U.S. Supreme Court struck down provisions of the Affordable Care Act on the ground that the conditions placed on the receipt of federal funds were so coercive as to violate the limits of the Spending Power. *Nat'l Federation of Independent Business v. Sibelius*, 567 U.S. 519 (2012). Since the 1990 Amendments, certain states have challenged the CAA as violating the 10th Amendment and the Spending Clause of the U.S. Constitution. These cases have been unsuccessful, based on the conclusion that the CAA sanctions were not so coercive that the state had no choice but to comply with the Act's demands. *Mississippi Commission on Environmental Quality v. EPA*, 790 F. 3d. 138 (D.C. Cir. 2015); *Com. of Virginia v. Browner*, 80 F. 3d 869 (4th Cir. 1996). However, in the present case, an action that results in sanctions would violate the 10th Amendment and the Spending Clause, because the state and local government have no choice, and no ability, to avoid sanctions.

The principles under which the Supreme Court has upheld exercises of the Spending Power depends on the element of choice. Congress may "offer States the choice of regulating the activity according to federal standards or having state law preempted by federal regulation." *New York v. U.S.*, 505 U.S. 144 167 (1992). Moreover, a valid exercise of the Spending Power requires that the state have a choice whether to regulate as the federal law directs or to lose federal funding. *See New York*, 505 U.S. at 173. Here, the state and South Coast AQMD have no choice whether to lose federal funding or suffer other sanctions because they lack the ability to set emission standards for federal sources, and thus no ability to comply with what would be required if EPA disapproves the Plan. Thus, an action to disapprove the Plan, which triggers sanctions the region has no ability to avoid, would violate the 10th Amendment and the Spending Clause.

VII. Notice of Intent to Sue

A. Failure to Perform Nondiscretionary Duties

The contingency measure plan submitted to meet CAA Section 182(e)(5) is subject to the SIP processing requirements of CAA Section 110. *See* 42 U.S.C. §§ 7410, 7511a(e)(5). The Clean Air Act further requires the Administrator to fully or partially approve or disapprove a plan submission within twelve (12) months after such submission has been deemed complete, either by the Administrator or as a matter of law. *See* 42 U.S.C. Section 7410(k)(2). If the EPA does not make a completeness finding, plan submissions are deemed complete by operation of law six (6) months after submission. *See* 42 U.S.C. Section 7410(k)(1)(B). Therefore, at most, EPA had eighteen (18) months within which to take final action to approve, disapprove, or partially approve the plan submission. As of the date of this letter, EPA has failed to fully or partially approve or disapprove the SIP submittal. As explained, in this case, the only lawful exercise of the Administrator's duties would be to approve the SIP submittal in acting under 42 U.S.C. § 7410(k)(3). Because EPA has failed to take required action by the statutory deadline, EPA is now in violation of CAA Section 110(k)(2) and (3); 42 U.S.C. § 7410(k)(2) and (3). After the expiration of sixty (60) days from the date of this notice of intent to sue, South Coast AQMD intends to file suit against EPA in federal court for the failure to act in accordance with, or fulfill, the duties described in this letter.

B. Identity of Persons Giving Notice and Their Counsel

As required by 40 C.F.R Section 54.3, the name and address of South Coast AQMD, the noticing party, is as follows:

South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765
Tel: 909-396-3535

Legal contacts and counsel representing South Coast AQMD on this matter will include the following:

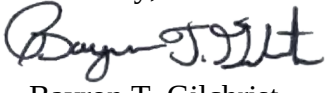
Bayron T. Gilchrist, General Counsel
Barbara Baird, Chief Deputy Counsel
Brian Tomasovic, Principal Deputy District Counsel
Tel: 909.396.3400
Fax: 909.396.2961
Email: bgilchrist@aqmd.gov; bbaird@aqmd.gov; btomasovic@aqmd.gov

C. Offer to Negotiate

During the sixty (60) day notice period, South Coast AQMD is willing to discuss effective measures to correct EPA's failure to comply with nondiscretionary duties and to discuss any information bearing upon this notice. We sincerely hope that we can engage in productive and meaningful discussions with EPA that results in a regulatory strategy and finds sufficient funding to reduce federal emissions to meet the health-based National Ambient Air Quality Standards. We do not, however, intend to delay the filing of a complaint in federal court if the discussions fail to resolve these matters within the sixty (60) day notice period, and intend to seek all appropriate relief, including injunctive relief and all costs of litigation, including, but not limited to, attorneys fees, expert witness fees, and other costs. We believe this notice provides information sufficient for EPA to determine the mandatory duty we allege it has failed to perform. If, however, there are any questions, please feel free to contact us for clarification.

We look forward to working with you on this important issue.

Sincerely,



Bayron T. Gilchrist
General Counsel

BTG/lal

Michael S. Regan, Administrator
United States Environmental Protection Agency
April 15, 2022

Appendix.
Summary Table for 2023 NOx Emissions.

Source Category	**2023 NOx Emissions**	**References**
Stationary and Area Sources	49 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161
CA Vehicles (on-road)	68.5 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161 EMFAC 2014 https://arb.ca.gov/emfac/2014/
CA off-road mobile	54.2 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161 California Emission Projection Analysis Model (CEPAM) Version 1.05 https://www.arb.ca.gov/app/emsinv/fcemssumcat/fcemssumcat2016.php
Federal Vehicles (on-road)	20.3 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161 EMFAC 2014 https://arb.ca.gov/emfac/2014/
Federal off-road	7.2 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161 California Emission Projection Analysis Model (CEPAM) Version 1.05 https://www.arb.ca.gov/app/emsinv/fcemssumcat/fcemssumcat2016.php
Federal planes trains and ships	69.7 tpd	2018 SIP Update https://ww3.arb.ca.gov/planning/sip/2018sipupdate/2018update.pdf?_ga=2.203433616.1202062696.1609860434-773042855.1578434161
TOTAL	269 tpd	