Overestimation of PM2.5-related "Premature Deaths" by US EPA and CARB

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History of Fine Particulate Air Pollution (PM2.5) & Mortality Relationship

Dockery, Pope, et al. NEJM 1993 "**A**n association between air pollution and mortality in six U.S. cities"

Pope, Thun, et al. AJRCCM 1995 "Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults"

Wall Street Journal April 7, 1997
"Pollution study sparks debate over secret data"

SCIENCE July 25, 1997 "Showdown Over Clean Air Science" & "Researchers and Lawmakers Clash Over Access to Data"

Michael Fumento Reason Magazine August/September 1997 & 1997 AEI Press Book "Polluted Science"

Major Weaknesses of Fine Particulate Air Pollution Epidemiology

1) Ecological Fallacy: ambient PM2.5 measurements from selected monitoring stations are assumed to apply to all individual subjects within defined geographical areas

2) Confounding Variables: numerous confounding variables, including other pollutants, influence the PM2.5 mortality relationship in observational cohort studies

3) Secret Data: investigators controlling major PM2.5 databases (ACS and Harvard) refuse to allow independent analysis of these databases, in violation of Data Access Act

4) Definition of PM2.5: PM2.5 is defined as particles less than 2.5 micrometers in diameter, but its composition varies greatly, from mineral dust to diesel soot

Legal Definition of Causal Relationship

Federal Judiciary Center 2000
Reference Manual on Scientific Evidence, 2nd Ed
Reference Guide on Epidemiology

Linda A. Bailey, JD, Leon Gordis, MD, Michael Green, JD

"a relative risk of 1.0 [RR = 1.00] means that the agent has no effect on the incidence of disease. When the relative risk reaches 2.0 [RR = 2.00], the agent is responsible for an equal number of cases of disease as all other background causes. . . . A relative risk greater than 2.0 [RR > 2.00] would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. A substantial number of courts in a variety of toxic substances cases have accepted this reasoning."

"Premature Deaths" Attributed to PM2.5

A relative risk greater that 1.0 [RR > 1.00] for the relationship between PM2.5 and total (all cause) mortality is interpreted by US EPA as evidence that PM2.5 "causes" "premature deaths."

Because EPA assigns a lifetime monetary value of about $7-9 million to each "death," the health benefits of preventing these "deaths" greatly exceed the compliance costs of numerous US EPA and CARB regulations that are designed to directly or indirectly (as a co-benefit) reduce PM2.5 levels and PM2.5-related deaths.

US EPA Integrated Science Assessment for Particulate Matter

Enstrom 2005 Relative Risk [RR (95% CI)] for PM2.5 and Total (All Cause) Mortality in California

First External Review Draft Figure 7-8 December 2008 &
Second External Review Draft Figure 7-7 July 2009 &
Final Report Figure 7-7 December 2009

Enstrom 2005	CA CPS I	RR = 1.04 (1.01-1.07)	1973-1982
		RR = 1.00 (0.98-1.02)	1983-2002
		RR = 1.01 (0.99-1.03)	1973-2002

Final Report Integrative Overview Figure 2-2 December 2009 &
Mary A. Ross PPT at February 26, 2010 CARB PM Symposium, which was facilitated by CASAC Chair Jonathan M. Samet

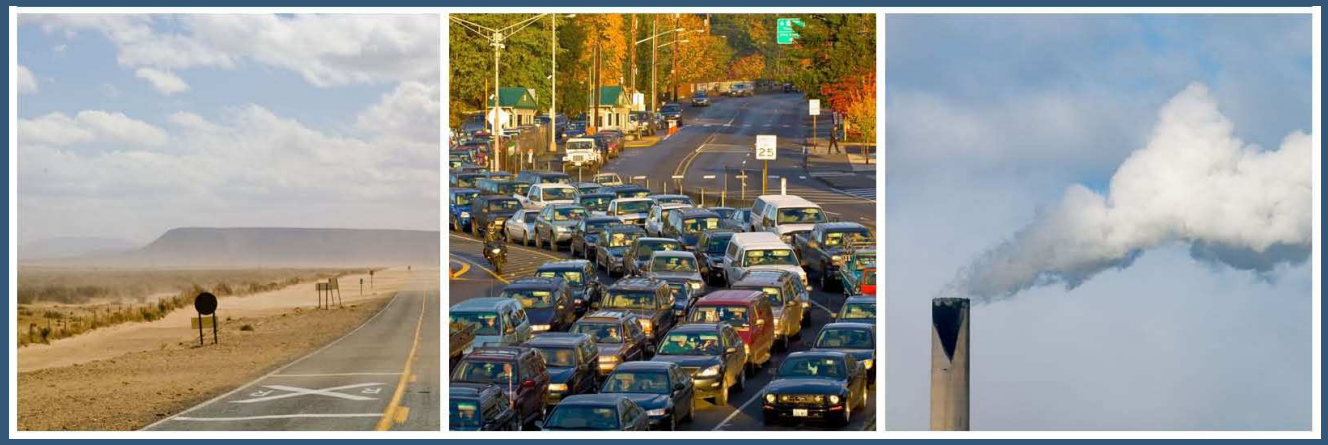
Enstrom 2005 RR = 1.04 (1.01-1.07)

United States Environmental Protection Agency

Integrated Science Assessment for Particulate Matter

Mary A. Ross, Ph.D

Briefing for California Air Resources Board



Office of Research and Development
National Center for Environmental Assessment, Research Triangle Park, NC

26 February 2010

NAAQS Review Process

United States Environmental Protection Agency

Integrated Science Assessment:
Concise evaluation and synthesis of most policy-relevant studies including epidemiology, human clinical, animal toxicology, human exposure, and atmospheric science

1st Draft *2nd Draft* *Final*

Integrated Review Plan

Identify key policy-relevant issues that will frame the science, risk, and policy assessments

Draft *Final*

Policy Assessment

Staff views on scientific basis for considering adequacy of current standard and alternative policy options, drawing from most policy-relevant science and risk/exposure assessments

1st Draft *2nd Draft* *Final*

Rulemaking Notices:

Agency decision making
Interagency review
Proposed Rule

Public hearings/comment
Agency decision making
Interagency review
Final Rule

Risk/exposure Assessment Reports

Concise quantitative risk/exposure assessments

Plan *1st Draft* *2nd Draft* *Final*

Public workshop
CASAC/public consultation
Early guidance from Agency management

CASAC review and public comment on all draft science, risk/exposure, and policy assessment documents

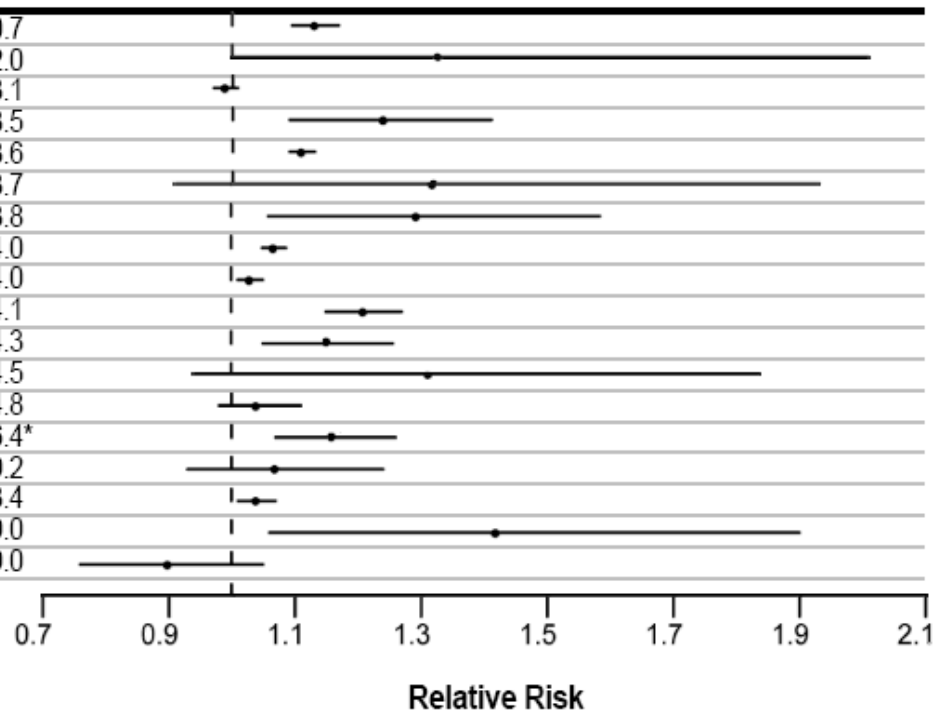
Opportunity for CASAC and public comment on final assessment documents

Causality Determinations for Long-Term Exposures to PM

Size Fraction	Outcome	Causality Determination
$PM_{2.5}$	Cardiovascular Effects	Causal
	Respiratory Effects	Likely to be Causal
	Reproductive and Developmental	Suggestive
	Cancer	Suggestive
	Mortality	Causal
$PM_{10-2.5}$	Cardiovascular Effects	Inadequate
	Respiratory Effects	Inadequate
	Reproductive and Developmental	Inadequate
	Cancer	Inadequate
	Mortality	Inadequate
Ultrafine PM	All Outcomes	Inadequate

Epidemiologic Effect Estimates for Long-Term Exposures to $PM_{2.5}$

Study	Outcome	Mean+
Zeger et al. (2008, 191951)	All-Cause Mortality, Central U.S.	10.7
Kim et al. (2004, 087383)	Bronchitis (Children)	12.0
Zeger et al. (2008, 191951)	All-Cause Mortality, Western U.S.	13.1
Miller et al. (2007, 090130)	CVD Morbidity or Mortality	13.5
Eftim et al. (2008, 099104)	All-Cause Mortality, ACS Sites	13.6
Goss et al. (2004, 055624)	All-Cause Mortality	13.7
McConnell et al. (2003, 049490)	Bronchitis (Children)	13.8
Zeger et al. (2008, 191951)	All-Cause Mortality, Eastern U.S.	14.0
Krewski et al. (2009, 191193)	All-Cause Mortality	14.0
Eftim et al. (2008, 099104)	All-Cause Mortality, Harv 6-Cities	14.1
Lipfert et al. (2006, 088756)	All-Cause Mortality	14.3
Dockery et al. (1996, 046219)	Bronchitis (Children)	14.5
Woodruff et al. (2008, 098386)	Infant Mortality (Respiratory)	14.8
Laden et al. (2006, 087605)	All-Cause Mortality	16.4*
Woodruff et al. (2008, 098386)	Infant Mortality (Respiratory)	19.2
Enstrom (2005, 087356)	All-Cause Mortality	23.4
Chen et al. (2005, 087942)	CHD Mortality, Females	29.0
	CHD Mortality, Males	29.0



* Mean estimated from data in study
\+ $\mu g/m^3$

Figure 2-2. **Summary of effect estimates (per 10 $\mu g/m^3$) by increasing concentration from U.S. studies examining the association between long-term exposure to $PM_{2.5}$ and cardiovascular and respiratory effects, and mortality.**

US EPA Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards Enstrom 2005 Relative Risk [RR (95% CI)] for PM2.5 and Total (All Cause) Mortality in California

First External Review Draft Figure 2-1 March 2010
Enstrom 2005 RR = 1.04 (1.01-1.07)

Second External Review Draft Figure 2-4 June 2010
Enstrom 2005 Entirely Omitted
Reviewed by August 25, 2010 CASAC Teleconference:
Enstrom gave verbal & written comments on omission

Final Report Figure 2-4 April 18, 2011
Enstrom 2005 Entirely Omitted—NO Change

PM2.5 and Total Mortality in California: RR (95% CI)

(http://scientificintegrityinstitute.org/Enstrom081111.pdf)

McDonnell 2000	AHSMOG	RR ~ 1.03 (0.95-1.12)	1976-1992
Krewski 2000 (4 MSAs)	CA CPS II	RR = 0.87 (0.81-0.94)	1982-1989
Enstrom 2005	CA CPS I	RR = 1.04 (1.01-1.07)	1973-1982
		RR = 1.00 (0.98-1.02)	1983-2002
Zeger 2008 (CA,OR,WA)	MCAPS "West"	RR = 0.99 (0.97-1.01)	2000-2005
Krewski 2010 (7 MSAs)	CA CPS II	RR = 0.97 (0.92-1.02)	1982-2000
Jerrett 2010-11 (~50 Cos, Nine Model Average)	CA CPS II	RR = 1.00 (0.99-1.01)	1982-2000
Lipsett 2011	CA Teachers	RR = 1.01 (0.95-1.09)	2000-2005

Table 33 in 2009 HEI Research Report 140: Extended Follow-up and Spatial Analysis of Fine Particulate Air Pollution and Mortality (1982-2000 ACS CPS II Cohort)

Daniel Krewski, Michael Jerrett, Richard T. Burnett, C. Arden Pope III, George Thurston, Michael J. Thun, et al.

Results shown in Table	Follow-up	RR (95% CI)
Pope 1995 equivalent	1982-1989	1.048 (1.022 - 1.076)
Pope 2002 equivalent	1982-1998	1.031 (1.015 - 1.047)
Krewski 2009	1982-2000	1.028 (1.014 - 1.043)

Enstrom analysis of Table	Follow-up	RR (95% CI)
Pope 1995 equivalent	1982-1989	1.048 (1.022 - 1.076)
Pope 2002 latest years	1990-1998	1.021 (1.002 - 1.041)
Krewski 2009 latest years	1999-2000	1.014 (0.980 - 1.049)

August 31, 2010 Letter from Daniel Krewski to HEI President Greenbaum

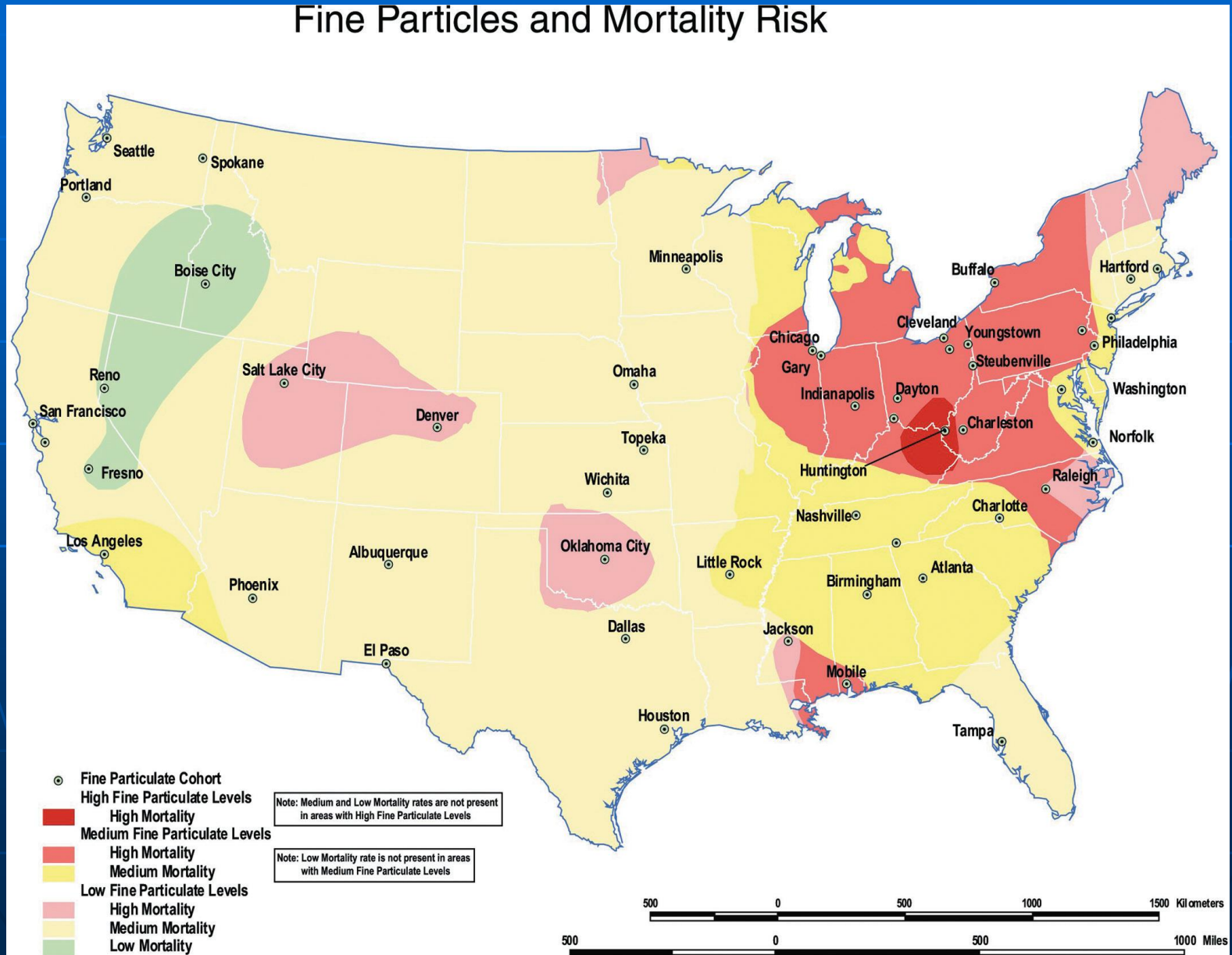
Special Analysis of California Subjects in Krewski 2009 HEI Research Report 140 (resulting from repeated requests to HEI by Ad Hoc Trucking Group during 2010)

RR = 0.872 (0.805 – 0.944) during 1982-1989

RR = 0.960 (0.920 – 1.002) during 1982-2000

Based on 40,408 CPS II subjects in 4 CA Metro Areas (MSAs)

2000 Krewski Jerrett HEI Report Figure 21
1982-1989 CPS II PM2.5 Mortality Risk <1.0 in CA



Analysis of Relative Risk (RR) by City Associated with PM2.5 Level in 2000 HEI Reanalysis Report Based on Figures 5 and 21 and Appendix D: Cities Sorted by US Region & CA

PM2.5 Level Rank	Table D.1 City Number	Table D.1 City	Table D.1 State	Table D.1 PM2.5 Level (Annual µg/m³)	Appendix D US Region	Figure 5 RR (Ruler Measure)	Figure 21 PM2.5 Rank (Low,Med,High)	Figure 21 RR Rank (Low,Med,High)	RR Level Rank
				PM2.5		**RR**			
3	8	Fresno	CA	10.3	W/CA	0.680	L	L	2
8	13	San Francisco	CA	12.2	W/CA	0.890	L	M	25
9	14	San Jose	CA	12.4	W/CA	0.885	L	M	24
39	9	Los Angeles	CA	21.8	W/CA	0.760	M	M	5
1	83	Albuquerque	NM	9.0	W	0.710	L	M	4
2	150	Spokane	WA	9.4	W	0.810	L	M	8
4	44	Topeka	KS	10.3	W	0.830	L	M	11
6	85	Reno	NV	11.8	W	0.670	L	L	1
7	149	Seattle	WA	11.9	W	0.780	L	M	7
11	70	Omaha	NB	13.1	W	0.880	L	M	23
12	138	Houston	TX	13.4	W	0.700	L	M-->L	3
13	45	Wichita	KS	13.6	W	0.890	L	M	27
15	109	Portland	OR	14.7	W	0.830	L	M	12
17	5	Phoenix	AZ	15.2	W	0.855	L	M	21
18	144	Salt Lake City	UT	15.4	W	1.025	L	H	46
19	136	El Paso	TX	15.7	W	0.910	L	M	28
21	107	Oklahoma City	OK	15.9	W	0.985	L	H	40
22	16	Denver	CO	16.1	W	0.925	L	H	31
23	135	Dallas	TX	16.5	W	0.850	L	M	19
				PM2.5		**RR**			
10	124	Providence	RI	12.9	OV/NE	0.890	L	M	26
16	21	Hartford	CT	14.8	OV/NE	0.845	L	M	17
27	79	Jersey City	NJ	17.3	OV/NE	0.810	M	M	9
29	110	Allentown	PA	17.9	OV/NE	1.005	M	H	43
30	100	Dayton	OH	18.8	OV/NE	0.980	M	H	37
31	157	Charleston	WV	20.1	OV/NE	1.005	M	H	44
32	106	Youngstown	OH	20.2	OV/NE	1.060	M	H	47
37	37	Indianapolis	IN	21.1	OV/NE	0.970	M	H	36
38	117	Philadephia	PA	21.4	OV/NE	0.910	M	H	30
42	97	Cincinnati	OH	23.1	OV/NE	0.980	M	H	38
43	104	Steubenville	OH	23.1	OV/NE	1.145	M	H	49
44	87	Buffalo	NY	23.5	OV/NE	0.960	M	H	35
46	95	Akron	OH	24.6	OV/NE	1.060	M	H	48
47	98	Cleveland	OH	24.6	OV/NE	0.980	M	H	39
48	36	Gary	IN	25.2	OV/NE	0.995	H	H	41
49	158	Huntington	WV	33.4	OV/NE	1.020	H	H	45
5	28	Tampa	FL	11.4	E	0.845	L	M	16
14	63	Minneapolis	MN	13.7	E	0.815	L	M	10
20	66	Jackson	MS	15.7	E	0.930	L	H	32
24	129	Chattanooga	TN	16.6	E	0.840	L	M	14
25	73	Raleigh	NC	16.8	E	1.000	L	H	42
26	146	Norfolk	VA	16.9	E	0.910	L	M	29
28	4	Little Rock	AR	17.8	E	0.870	M	M	22
33	29	Atlanta	GA	20.3	E	0.840	M	M	15
34	132	Nashville	TN	20.5	E	0.845	M	M	18
35	3	Mobile	AL	20.9	E	0.950	M	H	34
36	33	Chicago	IL	21.0	E	0.945	M	H	33
40	23	Washington	DC	22.5	E	0.850	M	M	20
41	71	Charlotte	NC	22.6	E	0.835	M	M	13
45	1	Brimingham	AL	24.5	E	0.760	M	M	6

September 30, 2010
Analysis by James E. Enstrom, Ph.D., M.P.H.

	Table D.1 PM2.5 Level (Annual µg/m³)	Appendix D US Region	Figure 5 RR (Ruler Measure)	Excel Least Squares Regression RR = Intercept + Coefficent * PM2.5 Intercept	Coefficent	95% CI	95% CI LL	95% CI UL
Average for 4 California Cities (Fresno, LA, SF, San Jose)	14.175	CA Average	0.804	0.834	-0.00210	(-0.061,0.058)	-0.06183	0.05763
Average for 16 Cities in Western States (see Appendix D)	13.616	West Average	0.835	0.674	0.01177	(-0.004,0.027)	-0.00369	0.02724
Average for 19 Cities in Ohio Valley States (see Appendix D)	21.375	OV/NE Average	0.976					
Average for 14 Cities in Eastern States (see Appendix D)	18.657	East Average	0.874					
	20.107	AllEast=East+OV/NE	0.928	0.766	0.00808	(0.001,0.015)	0.00093	0.01523
Average for all 49 US Cities	17.590	Total Average	0.892	0.697	0.01108	(0.006,0.016)	0.00606	0.01610
Median for all 49 US Cities (City 25)	16.800	Median City	0.890					
Average for 13 Cities west of and including Denver, CO		West (Denver) Ave	0.825					
Average for 36 Cities east of Denver, CO		East (Denver) Ave	0.916					

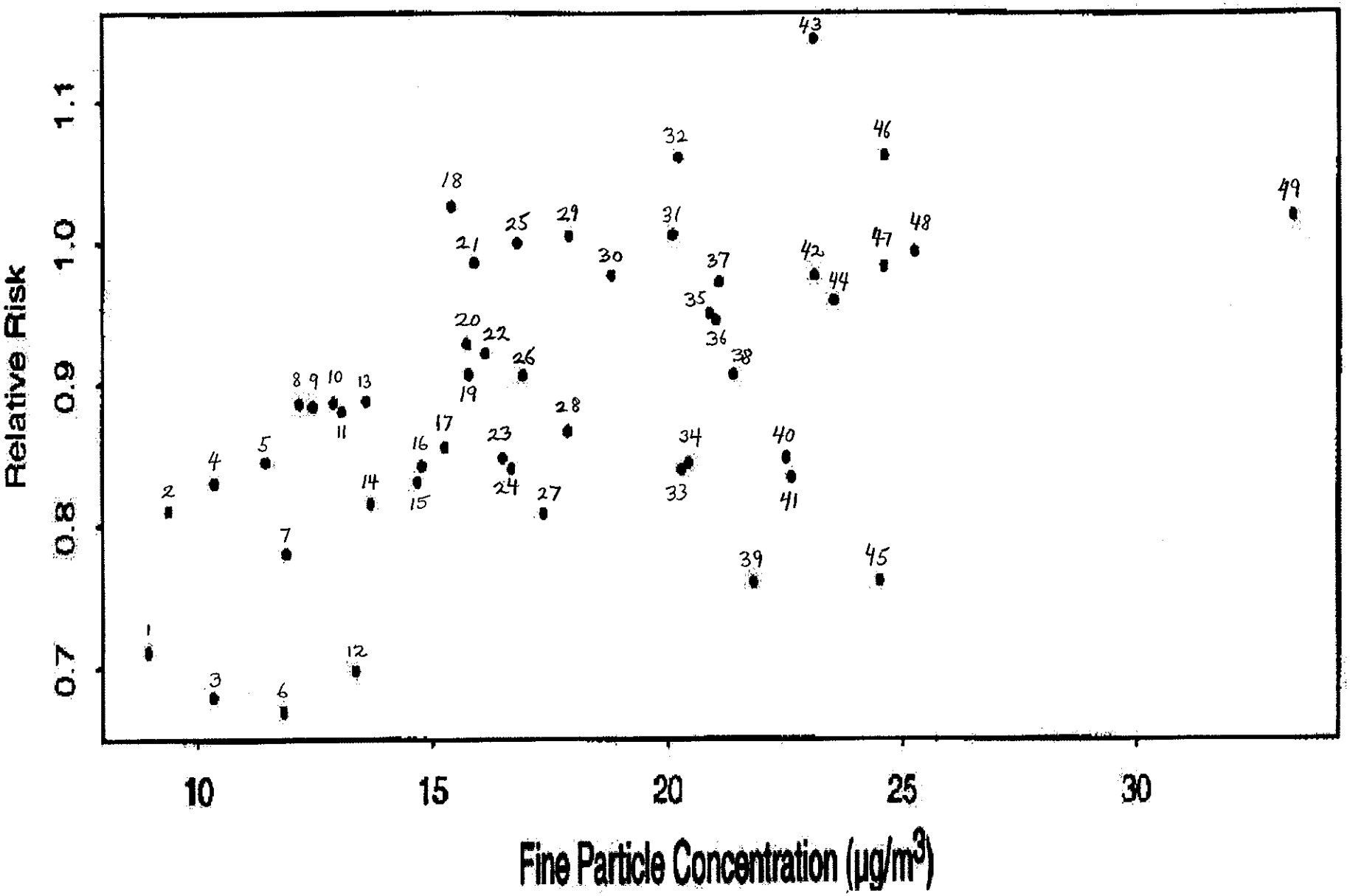
Figure 21 Definition of Levels of Fine Particles (PM2.5 in µg/m³) and Relative Risk of Mortality (RR)

Interval Classifications for Fine Particles (PM2.5 in µg/m³): Low (L) = 8.99 - 17.03; Medium (M) = 17.03 - 25.07; High (H) = 25.07 - 33 [or 33.4]
Interval Classifications for Relative Risk of Mortality (RR): Low (L) = 0.502 - 0.711; Medium (M) = 0.711- 0.919; High (H) = 0.919-1.128 [or 1.145]

Appendix D Definition of US Regions: West (W), East (E), Ohio Valley/Northeast (OV/NE)
Note: California (CA or W/CA) is one state within the West

We then divided the United States into three regions corresponding to the cities used in the artifact adjustment analysis: West – Washington, Oregon, California, Montana, Utah, New Mexico, Nevada, Arizona, Colorado, North Dakota, Nebraska, Kansas, Oklahoma, Texas; East – Minnesota, Wisconsin, Illinois, Iowa, Missouri, Arkansas, Louisiana, Alabama, Mississippi, Georgia, Florida, South Carolina, North Carolina, Kentucky, Tennessee, Virginia, Maryland, DC, New Hampshire, Maine; Ohio Valley/Northeast – Indiana, Ohio, Pennsylvania, West Virginia, New York, Rode Island, Connecticut, New Jersey, and Massachusetts. We adjusted the sulfate data from the high-volume samplers using three

All Cause Mortality (Excluding Boise City, Idaho)



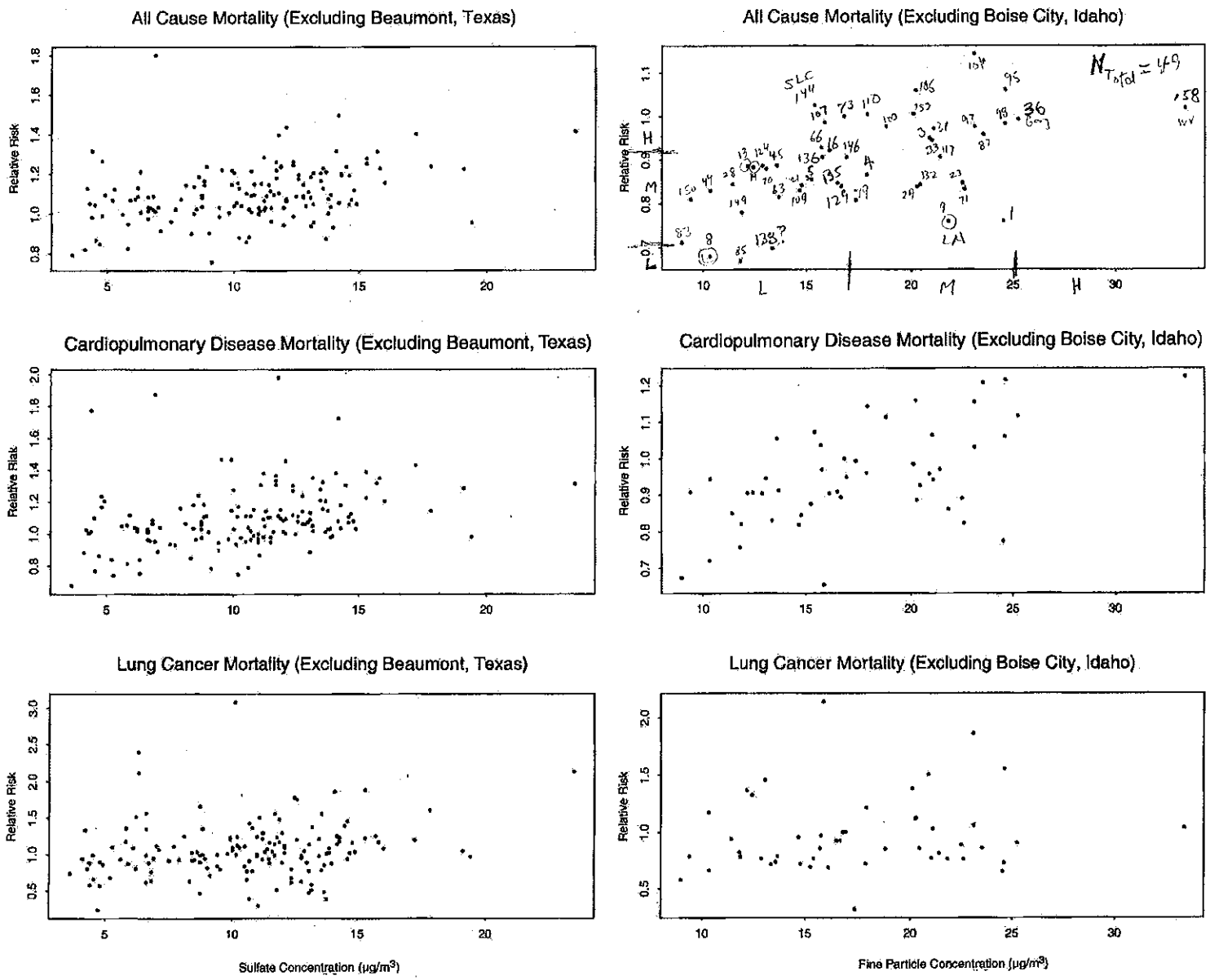


Figure 5. Shape of concentration-response function (relative risks) in the ACS Study. Relative risks of mortality from all causes, cardiopulmonary disease, and lung cancer by ambient concentrations of sulfate (linear-quadratic model) or fine particles (linear-quadratic-cubic model) for the reanalysis of the ACS Study. Based on the Extended Model and calendar year as the time axis. Relative risk scaled to unity at minimum concentration. Baseline hazard function stratified by 1-year age groups, gender, and race.

September 30, 2010 Special Analysis by James Enstrom of Figures 5 and 21 in 2000 HEI Reanalysis Report

Mortality Risk from all causes of death (MR) during 1982-1989 among CPS II subjects in 49 cities was determined by manual analysis using Figures 5 and 21 and Appendix D

Fresno had 2nd Lowest MR of the 49 cities
Los Angeles had 5th Lowest MR of the 49 cities

The average MR for the 4 CA cities in CPS II was 90% of the average MR for the 49 cities

June 9, 2011 CARB Draft Final Report

Spatiotemporal Analysis of Air Pollution and Mortality in California Based on ACS Cohort

Michael Jerrett, Richard T. Burnett, C. Arden Pope III, Daniel Krewski, George Thurston, Michael Thun, MD + 8 Others

(http://scientificintegrityinstitute.org/Enstrom060911.pdf)

(http://wmbriggs.com/blog/?p=4353)

June 25, 2008 CARB Quarterly Progress Report
No mention of a relationship between PM2.5 & total deaths

February 26, 2010 CARB PM Symposium
RR ~ 0.994 (0.965 – 1.025) during 1982-2000

June 9, 2011 CARB Draft Final Report
RR = 1.002 (0.992-1.012) Nine Model Average
RR = 1.08 (1.00-1.15) New "Conurbation" Model

US EPA Shows Geographic Variation in PM2.5 “Premature Deaths”

US EPA Regulatory Impact Analysis of the Proposed Toxics Rule: Final Report March 2011

Table 1-2 (page 1-4) shows only 1.7% of the total US "premature deaths" are in the Western US (CA, OR, WA, AZ, NV, UT, ID, NM, CO, WY, MT)

PM-Related Endpoint of “Premature Death” Based on:

Pope 2002	120 in Western US	6,700 in Eastern US
Laden 2006	300 in Western US	17,000 in Eastern US

Conclusions About PM2.5 & Mortality in CA and US in ACS CPS II Cohort

Based on findings revealed directly to and by them in 2010 and 2011, Enstrom concludes that Krewski, Jerrett, Pope, Burnett, Thurston, and Thun have known since February 26, 2010 or earlier that within the ACS CPS II Cohort:

1) **there is NO significant relationship between PM2.5 and total mortality in California &**
2) **the national relationship between PM2.5 and total mortality was weaker in the 1990s than in the 1980s, with no mortality follow-up since 2000.**

Investigation Finds Lack of Impartiality, Financial Conflicts of Interest in US EPA Science Boards

August 4, 2011 Letter from US Senator James Inhofe to US EPA Inspector General Arthur A. Elkins: EPA Report due September 19, 2011

- ***Lack of Impartiality***: EPA has violated its own Peer Review Handbook
- ***Failure to Balance Perspectives***: EPA has violated the requirements of the Federal Advisory Committee Act
- ***Failure to Rotate Members***: EPA has disregarded Administration policy to rotate membership on panels
- ***Financial Conflict of Interest***: EPA has repeatedly selected panel members with EPA research grants

Evidence for Overestimation of PM2.5-related "Premature Deaths"

1) Reliance on results from investigators who do not share underlying databases (ACS & HSCS) and who publish only selected results
2) US EPA emphasizes "positive" results from some publications and does not clearly address geographic variation and time trends in results
3) CARB bases California PM2.5-related premature deaths on national ACS results in 2009 US EPA PM ISA instead of null California-specific results
4) CASAC Chair and members have conflicts of interest that impair their objectivity

Recommendations

1) US EPA should conduct new, accurate, objective ISA of PM and eliminate errors and omissions

2) US EPA should withhold all regulations justified by PM2.5-related "premature deaths" until an accurate and objective reassessment is done

3) CASAC members should have minimal conflicts of interest and should serve limited terms

4) US EPA & CARB need to fund all legitimate researchers, including critics, and need to commit to objective air pollution epidemiology