

# **Does Fine Particulate Matter Kill Californians?**

## **An Epidemiologic and Regulatory Controversy**

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# Time Line of Major Events PM<sub>2.5</sub> & Diesel PM Deaths

1. Explanation of PM<sub>2.5</sub>, Diesel PM, OEHHA, SRP, CARB
2. 1988 Garshick Study on Diesel Exhaust & Lung Cancer
3. 1998 SRP and CARB Identify Diesel PM as TAC
4. 1993 Dockery & 1995 Pope Studies on PM<sub>2.5</sub> Deaths
5. 2008 CARB “Tran” Report on PM<sub>2.5</sub> Deaths in CA
6. 2000 & 2009 Krewski HEI Reports on PM<sub>2.5</sub> Deaths
7. 2011 CARB Jerrett Report on PM<sub>2.5</sub> Deaths in CA

# Fine Particulate Matter (PM<sub>2.5</sub>)

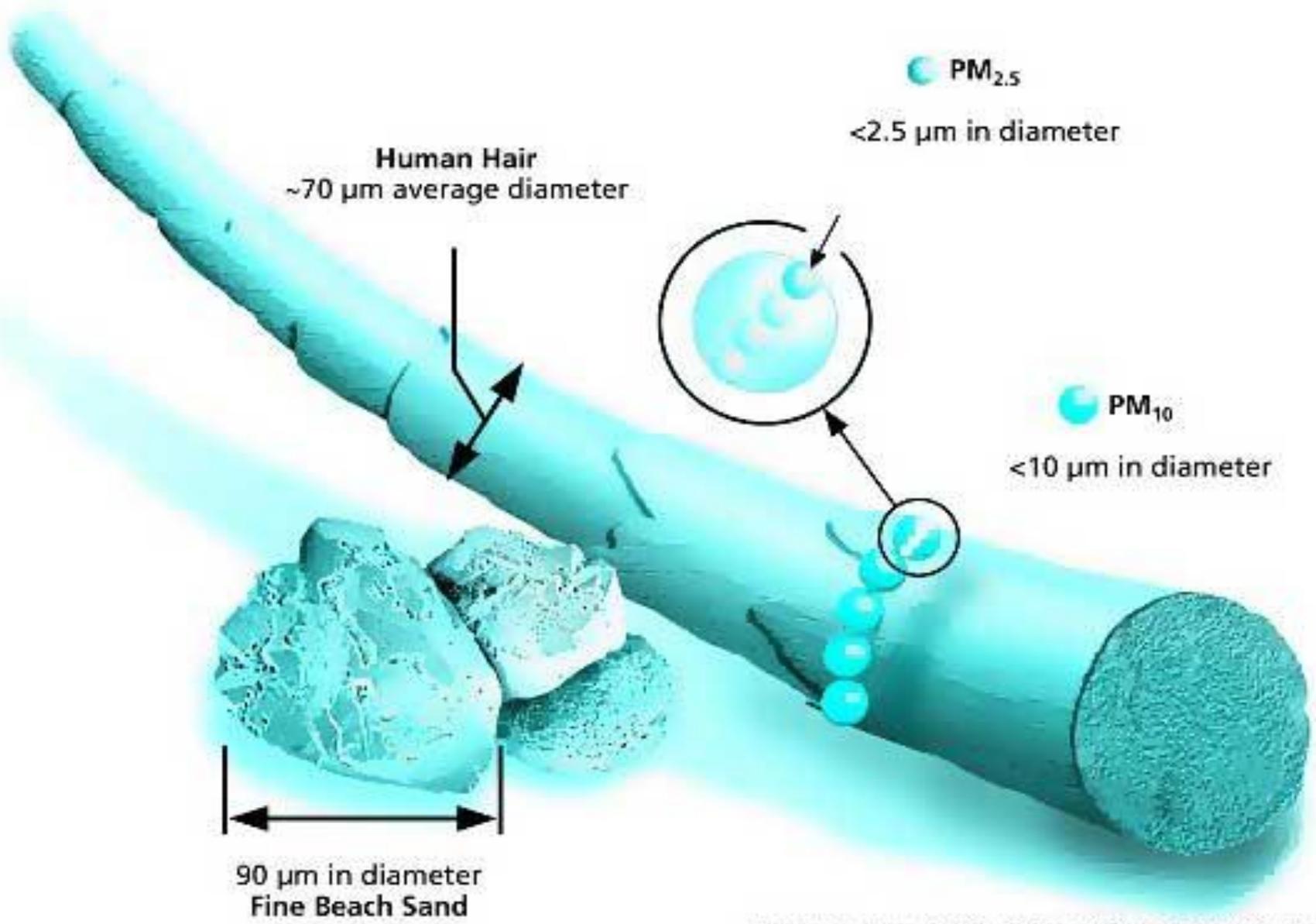
Air pollutant defined by particle size and not by chemical composition, as in the case of a gaseous air pollutant like ozone. Fine particles are generated mainly by combustion processes and their atmospheric sequelae. Main sources in California: forest fires, agricultural dust, industrial combustion, diesel engine combustion (~10% of total)

$d(\text{PM}_{2.5})$  (median aerodynamic diameter):  $\leq 2.5 \mu\text{m}$

$m(\text{PM}_{2.5})$  (typical mass per volume of air):

Annual National Ambient Air Quality Standard (EPA) =  $15 \mu\text{g}/\text{m}^3$

Annual California Standard for PM<sub>2.5</sub> (CARB) =  $12 \mu\text{g}/\text{m}^3$



*Image courtesy of EPA, Office of Research and Development*

**AB 1807 (Tanner, Davis, Hayden, . . .) 1983  
→ California Health and Safety Code 39670**

**39650(c): The Legislature finds and declares . . . It is the public policy of the state that emissions of toxic air contaminants should be controlled to levels which prevent harm to the public health.**

**39670(a): A nine-member *Scientific Review Panel on Toxic Air Contaminants* shall . . . advise the state board . . . health effects toxicity of substances**

**39670(b): The members . . . shall be highly qualified and . . . appointed . . . for a term of three years**

# **Agencies within Cal EPA Involved in Evaluating PM<sub>2.5</sub> and Diesel PM, 1989-2011**

**Office of Environmental Health Hazard Assessment (OHEEA)  
Hazard Identification & Risk Assessment Branch  
Richard J. Jackson, M.D., Chief 1990-1992**

**Scientific Review Panel on Toxic Air Contaminants (SRP)  
John R. Froines, Ph.D., Toxicologist  
Member 1984---, Chair 1998---**

**California Air Resources Board (CARB)  
Mary D. Nichols, J.D.  
Chair 1979-1983 & 2007---  
John R. Balmes, M.D.  
Member with Most PM<sub>2.5</sub> Expertise 2007---**

# Early Assessment of Diesel Exhaust as Carcinogen and Toxic Air Contaminant

- 1) 1989 IARC identifies “diesel engine exhaust” as a Group 2A carcinogen  
“probably carcinogenic to humans”
- 2) October 1, 1990 OEHHA declares “diesel engine exhaust” to be a carcinogen as per Proposition 65 (<http://www.oehha.ca.gov/prop65.html>)
- 3) OEHHA & SRP evaluate diesel exhaust as a potential TAC during 1989-1998:  
1994, 1996, 1997, 1998 Workshops

# **Primary Epidemiologic Evidence Used by OEHHA and SRP to Assess Diesel Exhaust as Toxic Air Contaminant**

## **A case-control study of lung cancer and diesel exhaust exposure in railroad workers**

Garshick E, Schenker MB, Hammond SK, Speizer FE et al.  
Am Review Resp Dis June 1987

Next of kin interviews of 1,256 male lung cancer deaths during  
1981-1982 among former railroad workers

## **A retrospective cohort study of lung cancer and diesel exhaust exposure in railroad workers**

Garshick E, Schenker MB, Hammond SK, Speizer FE et al.  
Am Review Resp Dis April 1988

1,694 lung cancer deaths during 1959-1980 among cohort of  
55,407 white male railroad workers

# **1991 Assessments of 1988 Garshick Study (Available to OEHHA & SRP in 1991 & 1994)**

## **July 1991 Report to US EPA on Independent Analysis of Diesel Emissions Risk in 1988 Garshick Study**

Kenny S. Crump, Ph.D., Tammie Lambert, Chao Chen, Ph.D.

“No relationship between measures of diesel exposure and lung cancer mortality is demonstrated in this [Garshick] study”

## **August 15, 1991 Letter from Eric Garshick, M.D. to Chen**

“Furthermore, because of weaknesses in exposure ascertainment that included lack of knowledge of the exact dates of when exposure actually occurred, lack of knowledge of the changing intensities of exposure, and exposure indices that likely do not reflect true differences between exposed and unexposed groups, the nature of the exposure-response relationship could not be found in this [Garshick] study.”

**RESPONSES BY THE STAFF OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (OEHHA) TO HEALTH EFFECTS RELATED COMMENTS ON THE JUNE, 1994, DRAFT TECHNICAL SUPPORT DOCUMENT (TSD) (INCLUDING PART B, "HEALTH RISK ASSESSMENT FOR DIESEL EXHAUST") FOR IDENTIFICATION OF DIESEL EXHAUST AS A TOXIC AIR CONTAMINANT (TAC) (178 pages)**

American Mining Congress

American Trucking Associations, Inc

Association of American Railroads

California Trucking Association

Engine Manufacturers Association

Ford Motor Company

Mercedes Benz

Western States Petroleum Association

Natural Resources Defense Council

Sierra Club

# **Specific Comments from JUNE 1994 OEHHA DRAFT TECHNICAL SUPPORT DOCUMENT (TSD) (INCLUDING PART B, "HEALTH RISK ASSESSMENT FOR DIESEL EXHAUST")**

## **Dr. Werner Stoeber, Chemical Industry Institute of Technology**

“The draft TSD Part B is, by spirit and diction, a remarkable example of where something next to nothing is made into something very serious. It is one of the most biased, distorted and outdated documents the commenter has seen in a long time.”

## **Dr. Gunter Oberdoester, University of Rochester**

“The commenter's W.H.O. Review Group concluded that there are no quantitative data from the epidemiological studies suitable for estimation of human risk. The commenter mentions this because Dr. Garshick was one of the members of the group and he specifically agreed with this assessment and did not think that his data set was suitable for performing a quantitative risk assessment.”

# **January 1995 Health Effects Institute Special Report “Diesel Exhaust: Critical Analysis of Emissions, Exposure, and Health Effects”**

## **SUMMARY**

**“A wealth of information is available about the potential for diesel emissions to cause cancer. However, the lack of definitive exposure data for the occupationally exposed study populations precludes using the available epidemiologic data to develop quantitative estimates of cancer risk.”**

# August 11, 1997 Letter from Eric Garshick, M.D., to CARB, OEHHA, and SRP Regarding “Health Risk Assessment of Diesel Exhaust”

“I have been extensively involved in the reassessment of the retrospective cohort data that OEHHA has been using to form the basis for its risk assessment for diesel exhaust. . . . the relationship between lung cancer mortality and exposure cannot be summarized by a positive slope as presented by OEHHA. This means that the current results cannot be summarized using a single number relating cumulative exposure to diesel exhaust to health outcome. . . . I do not believe your current document fully expresses the uncertainty of the estimates of risk that you have presented, nor does the current retrospective cohort data allow the calculation of unit risk with confidence.”

# **April 22, 1998 Scientific Review Panel Meeting**

**Portion of Transcript by Key SRP Members  
During Meeting at Which SRP Agreed to the  
Identification of Diesel Exhaust  
as a Toxic Air Contaminant (TAC):**

**Toxicologist John R. Froines, Ph.D. (38.0%)  
Biostatistician Stanton A. Glantz, Ph.D. (18.9%)  
Epidemiologist Gary D. Friedman, M.D. (3.2%)**

**SRP members, particularly Epidemiologist, ignored important facts established during 1991-1998: no clear dose-response relationship between diesel exposure and lung cancer risk in occupational studies of workers exposed to diesel and no clear evidence that diesel exhaust levels in California were causing “harm to the public health” in California.**

# April 22, 1998 Scientific Review Panel Meeting

([www.arb.ca.gov/srp/mt042298.htm](http://www.arb.ca.gov/srp/mt042298.htm), page 193)

## Discussion of unit risk factor relating diesel exhaust to lung cancer:

**“DR. GLANTZ:** If it comes out 5 times 10 to the minus 4 [ $5 \times 10^{-4}$ ], I'm happy. I just --

**ACTING CHAIRMAN FROINES:** None of it's correct anyway.

**DR. GLANTZ:** Well, don't say that.

**ACTING CHAIRMAN FROINES:** It's a risk assessment.

**DR. GLANTZ:** I know, but, thanks, you just got yourself sued.

**ACTING CHAIRMAN FROINES:** None of this is real.”

# May 27, 1998 Letter by SRP Chair Froines to CARB identifying diesel exhaust as a TAC using a single unit risk factor [ $3 \times 10^{-4}$ per $\text{g}/\text{m}^3$ ] to relate diesel exhaust to lung cancer risk

“The data, developed and reviewed by OEHHA and ARB, in the scientific risk assessment on exposure to diesel exhaust (Part A) and its health effects (Part B), are extensive and scientifically sound. . . . Development of this report began in 1989, and this compound has the most human epidemiological studies (over 30). . . . These studies have investigated the relationship between occupational diesel exhaust exposure and lung cancer, and the epidemiological evidence indicates exposure to diesel exhaust increases the risk of lung cancer. It is noted that in 1990 the State of California, pursuant to Proposition 65, identified diesel exhaust as a chemical ‘known to the State to cause cancer.’ ”

**July 29, 1998 CARB meeting was highly contentious and a delay in declaring diesel exhaust to be a TAC was supported by 66 legislators, California Trucking Association, and other industry groups.**

- 1) Questioned effects of diesel on the general public**
- 2) Noted that diesel engines since 1988 emit only 10% of the PM of unregulated diesel engines**
- 3) Concerned about potential financial liability regarding diesel-related diseases like lung cancer**
- 4) Concerned about the economic impact of future regulations on diesel-related businesses**

**August 27, 1998 CARB meeting was also highly contentious, but a compromise was reached whereby diesel particulate matter (PM), not diesel exhaust as a whole, was declared by CARB to be a TAC. Diesel PM was something more specific to control than all diesel exhaust.**

**The primary health concern in 1998 was the SRP conclusion that diesel exhaust could be causing 14,000 cases of lung cancer in California, a highly controversial estimate that was not based on general population samples.**

**Engine clean up was rapid and 1998 trucks had only 10% of the diesel emissions of 1988 trucks<sup>18</sup>**

# History of Fine Particulate Matter (PM<sub>2.5</sub>) & Mortality Relationship

**Dockery, Pope, et al. NEJM 1993** “An 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 Matter Epidemiology

- 1) **Ecological Fallacy:** ambient  $PM_{2.5}$  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  $PM_{2.5}$  mortality relationship in observational cohort studies
- 3) **Secret Data:** investigators controlling major  $PM_{2.5}$  databases (ACS and Harvard) refuse to allow independent analysis of these databases, in violation of Data Access Act
- 4) **Definition of  $PM_{2.5}$ :**  $PM_{2.5}$  is defined as particles less than 2.5 micrometers in diameter, but its composition varies greatly, from mineral dust to diesel soot

# **“Premature Deaths” Attributed to PM<sub>2.5</sub>**

**A relative risk greater than 1.0 [RR > 1.00] for the relationship between PM<sub>2.5</sub> and total (all cause) mortality is interpreted by US EPA and CARB as evidence that PM<sub>2.5</sub> “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 the US EPA and CARB regulations that are designed to reduce PM<sub>2.5</sub> levels and PM<sub>2.5</sub>-related deaths.**

**Without PM<sub>2.5</sub>-related “premature deaths” the US EPA and CARB regulations are not justified<sup>1</sup>**

**December 15, 2005 *Inhalation Toxicology*  
Paper by James E Enstrom**

**49,975 elderly Californians in 11 counties followed during 1973-2002 in California Cancer Prevention Study (CA CPS I)**

**“For the initial period, 1973–1982, a small positive risk was found: RR was 1.04 (1.01–1.07) for a 10- $\mu\text{g}/\text{m}^3$  increase in  $\text{PM}_{2.5}$ .**

**For the subsequent period, 1983–2002, this risk was no longer present: RR was 1.00 (0.98–1.02).**

**For the entire follow-up period, RR was 1.01 (0.99–1.03).”**

**May 22, 2008 Draft CARB Report on  
PM<sub>2.5</sub> & Premature Deaths in California  
Hien T. Tran, “Ph.D.”, Lead Author  
C. Arden Pope III, Scientific Advisor**

**June 4, 2008 Enstrom testimony at Nichols  
confirmation before Senate Rules Committee  
because “Tran” Report ignored Enstrom 2005**

**July 11, 2008 Tran Teleconference with Enstrom and  
epidemiologists Pope, Jerrett, Burnett, and others**

**July 11, 2008 148 pages of mostly critical public  
comments by Enstrom and others on Draft CARB  
Report---these comments were largely ignored in  
the October 24, 2008 Final CARB Report**

**October 24, 2008 Final CARB Report on  
PM<sub>2.5</sub> & Premature Deaths in California  
Hien T. Tran, “Ph.D.”, Lead Author  
C. Arden Pope III, Scientific Advisor**

**18,000 Premature Deaths Due to All PM<sub>2.5</sub>  
3,500 Premature Deaths Due to Diesel PM**

**Based primarily on:**

**Harvard Six Cities Study Cohort (Dockery 1993,  
Krewski 2000, Laden 2006)—cities in midwest/east**

**ACS CPS II Cohort (Pope 1995 , Krewski 2000,  
Pope 2002, Pope 2004)—nationwide results**

**ACS CPS II Cohort (Jerrett 2005)—LA basin**

**August 31, 2010 Revised CARB Report on  
PM<sub>2.5</sub> & Premature Deaths in California  
No Authors Listed**

**9,200 Premature Deaths Due to All PM<sub>2.5</sub>  
2,000 Premature Deaths Due to Diesel PM**

**Based entirely on:**

**December 2009 US EPA Integrated Science  
Assessment of Particulate Matter, which relied  
upon 2009 HEI Research Report 140  
(Krewski, Jerrett, Burnett, Pope, Thurston, Thun,  
et al.), which contained nationwide results from  
the 1982-2000 follow-up of ACS CPS II Cohort**

# 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.

<u>Results shown in Table</u>	<u>Follow-up</u>	<u>RR (95% CI)</u>
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)
<u>Enstrom analysis of Table</u>	<u>Follow-up</u>	<u>RR (95% CI)</u>
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)

# **2010 Estimates of PM<sub>2.5</sub>–Related Premature Deaths That Will Be Prevented by CARB Diesel Regulations**

**Based on 2009 Krewski HEI nationwide 1982-2000 results,  
CARB estimates that off-road diesel regulations will  
prevent 25 premature deaths per year in California**

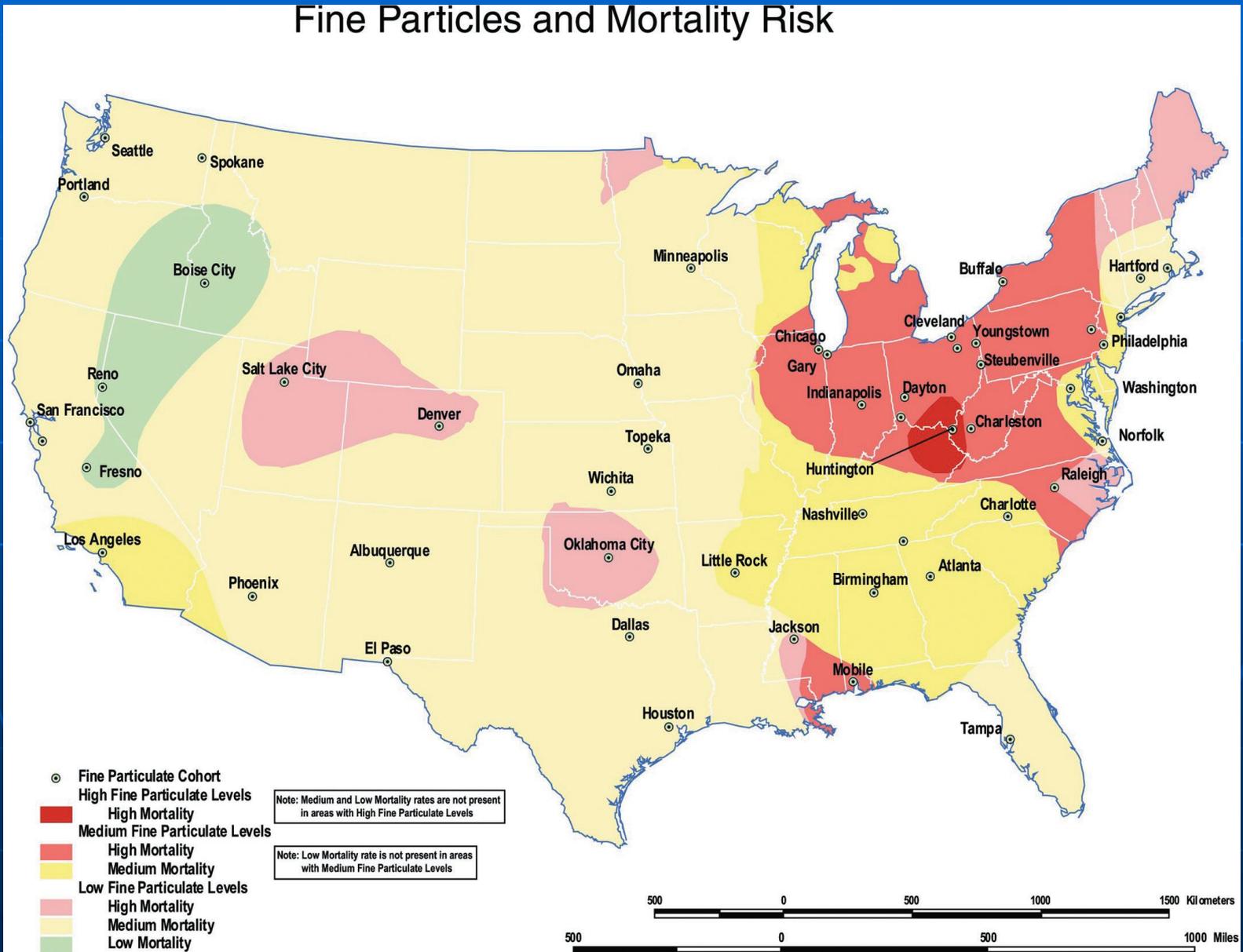
**Based on 2009 Krewski HEI nationwide 1982-2000 results,  
CARB estimates that on-road diesel regulations will  
prevent 233 premature deaths per year in California**

**~ 235,000 total deaths per year in California**

# 2000 Krewski Jerrett HEI Report Figure 21

## 1982-1989 CPS II PM<sub>2.5</sub> Mortality Risk <1.0 in CA

Fine Particles and Mortality Risk



# **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)**

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

**(<http://scientificintegrityinstitute.org/Enstrom093010.pdf>)**

**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 2<sup>nd</sup> Lowest MR of the 49 cities  
Los Angeles had 5<sup>th</sup> 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**

# **Jerrett Project (Begun January 2007)**

**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 + Others  
Total Budget of \$750,000 for Three Year Project  
Funded by CARB and SC AQMD**

**June 25, 2008 CARB Quarterly Progress Report**

**No mention of a relationship between  $PM_{2.5}$  & total deaths**

**Detailed 18-month Progress Report Never Submitted**

**Results could have influenced October 2008 “Tran” Report**

**February 26, 2010 CARB PM Symposium**

**RR ~ 0.994 (0.965 – 1.025) during 1982-2000**

# June 9, 2011 Jerrett Draft Final Report

**Major Results for PM<sub>2.5</sub> and Total Mortality in CA (Figure 22)**

**RR = 1.002 (0.992-1.012) Nine Model Average**

**RR = 1.08 (1.00-1.15) New “Conurbation” Model**

**Critical Comments Submitted on June 9 by  
Drs. Enstrom, Malkan, and Dunn, and Mr. Brown**

**CARB Research Screening Committee Tabled Draft Report  
and Requested Revisions from Investigators**

**Additional Comments Submitted after June 9 by Drs.  
Enstrom, Malkan, Dunn, Lipfert, Briggs, and Fulks**

**All Comments and Meeting Records Compiled**

**(<http://scientificintegrityinstitute.org/JerrettCriticism102811.pdf>)**

# October 28, 2011 Jerrett Revised Final Report

**Major Results for PM<sub>2.5</sub> and Total Mortality in CA (Figure 22)**

**RR = 1.002 (0.992-1.012) Nine Model Average**

**RR = 1.08 (1.00-1.15) New “Conurbation” Model**

**CONCLUSION “We conclude that combustion-source air pollution is significantly associated with premature death in this large cohort of Californians”**

**Results and CONCLUSION Unchanged from June Draft & CONCLUSION Does Not Reflect Findings in the Report**

**CARB Research Screening Committee Approved Revised Final Report by 8-0 Vote in Spite of 53 Pages of Detailed Criticism from Six Doctoral Level Scientists**

# Conclusions About PM<sub>2.5</sub> & Mortality in CA and US in ACS CPS II Cohort

Based on findings revealed in 2010 and 2011, Enstrom concludes that Krewski, Jerrett, Pope, Burnett, Thurston, and Thun have known for years (likely as far back as 2000) that within the ACS CPS II Cohort:

- 1) there is NO significant relationship between PM<sub>2.5</sub> and total mortality in California &
- 2) the national relationship between PM<sub>2.5</sub> and total mortality was weaker in the 1990s than in the 1980s (no mortality follow-up since 2000).

# PM<sub>2.5</sub> and Total Mortality in California: RR (95% CI)

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

McDonnell 2000	AHSMOG (9 air sheds)	RR ~ 1.03 (0.95-1.12)	1976-1992
Krewski 2000 (reported in 2010)	CA CPS II (4 MSAs)	RR = 0.87 (0.81-0.94)	1982-1989
Enstrom 2005	CA CPS I (11 Cos)	RR = 1.04 (1.01-1.07)	1973-1982
		RR = 1.00 (0.98-1.02)	1983-2002
Zeger 2008	MCAPS "West" (CA,OR,WA)	RR = 0.99 (0.97-1.01)	2000-2005
Krewski 2010	CA CPS II (7 MSAs)	RR = 0.97 (0.92-1.02)	1982-2000
Jerrett 2010-11	CA CPS II (54 Cos, Nine Model Average)	RR = 1.00 (0.99-1.01)	1982-2000
Lipsett 2011	CA Teachers	RR = 1.01 (0.95-1.09)	2000-2005

# 2005 Age-Adjusted Total Death Rate (x 10\*\*5) and Life Expectancy at Birth (years) (CDC)

<u>State</u>	<u>Death Rate</u>	<u>Life Expectancy</u>
Hawaii	630	81.7
Minnesota	693	80.5
North Dakota	715	79.8
California	719	79.7
Connecticut	728	80.1
Massachusetts	735	79.8
United States	801	78.0

# Recommendations

**Objectively reassess relationship of PM<sub>2.5</sub> and diesel PM to premature death in CA using expert reviewers with not ties to CARB or US EPA**

**Reassess designation of diesel PM as a TAC and the need for CARB diesel regulations**

**Conduct independent investigation of entire 22-year process leading to CARB diesel regulations**

**Suspend CARB off-road and on-road diesel regulations pending outcome of above investigations**

# **Congressional Letters re US EPA and PM<sub>2.5</sub>**

**June 30, 2011 Senators Vitter and Inhofe Letter to  
US EPA Administrator Jackson re Bad Science**

**August 4, 2011 Senator Inhofe Letter to US EPA  
re CASAC Conflicts of Interest**

**September 19, 2011 Congressman Latta Letter to President  
Obama re Cost / Benefit Ratio of US EPA Regulations**

**September 22, 2011 Congressman Harris Letter to  
US EPA McCarthy re Transparency in EPA Health Data**

**October 18, 2011 Senators Vitter, Inhofe, Issa Letter to  
Science Advisor Holdren re Federal Agency Science**

**November 15, 2011 Congressmen Harris and Broun  
Letter to Sunstein re flaws in PM<sub>2.5</sub> science**