

“CARB Diesel Science, Fact or Fiction?”

James E. Enstrom, Ph.D., M.P.H.

**Epidemiologist & Physicist
Jonsson Comprehensive Cancer Center
University of California, Los Angeles**

**President
Scientific Integrity Institute
Los Angeles**

December 10, 2010

1. Understanding Good & Bad Science & Different Scientific Disciplines

Good Science: The Internet

**“The Greatest Advance in Communication
Since the Printing Press”**

Fast, Inexpensive, Comprehensive

Based on Honest Scientific Discoveries

Three Nobel Prizes That Have Made Internet Possible

1906 Discovery of Electron

1956 Discovery of the Transistor Effect

2000 Invention of the Integrated Circuit

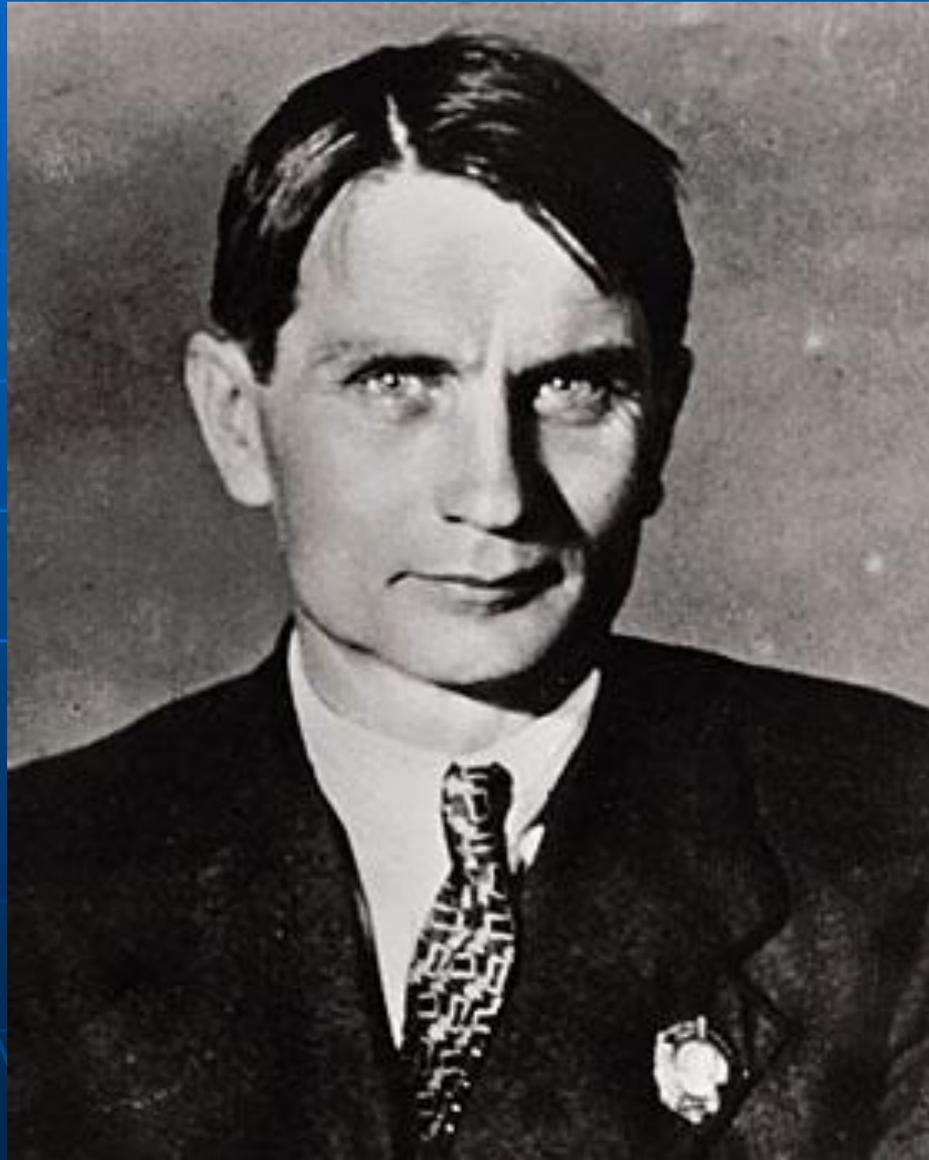
Bad Science: Unpopular Views Silenced



Nikolai Ivanovich Vavilov (1887-1943)



Trofim Denisovich Lysenko (1898-1976)



Mary Dolores Nichols, J.D.
Chair, CARB (1979-1983, July 2007→)
CARB: 1,300 employees, \$650 M budget



Lysenko Pseudoscience

**Lysenko, non scientist, gained favor of Soviet leaders
Made false crop claims & used phony plant genetics
Ignored genuine Mendelian plant genetics
Purged opposing scientists, like Vavilov
Famines resulted and Soviet citizens starved
Soviet agriculture was set back decades**

Nichols Pseudoscience

**Nichols, activist lawyer, backed by major politicians
Consistently exaggerates diesel health effects
Draconian diesel regulations adopted only in CA
Dissenting scientists ignored & never funded
CA truckers, contractors & economy hurt badly**

Ranking of Scientific Disciplines

Physics

Rigorous experimental science with independently verifiable results, worthy of annual Nobel Prize

Chronic Disease Epidemiology

Observational public health science often involving weak and inconsistent relationships that rarely withstand independent verification

Air Pollution Epidemiology

Chronic disease epidemiology that is limited by the ecological fallacy, geographic variation, and lack of access to underlying data

2. Ethical Conduct & Scientific Integrity Regarding CARB Diesel & PM2.5 Science

University of California Standards of Ethical Conduct

“Members of the University community are expected to become familiar with the laws and regulations bearing on their areas of responsibility”

“Members of the University community engaged in research are not to . . . knowingly omit data or results to misrepresent results in the research record [falsification]”

“All those engaged in research are expected to pursue the advancement of knowledge while meeting the highest standards of honesty, accuracy and objectivity”

February 5, 2010 SCIENCE Editorial

“Ensuring Integrity in Science”

Ralph J. Cicerone

President, US National Academy of Sciences

“public opinion has moved toward the view that scientists often try to suppress alternative hypotheses and ideas and that scientists will withhold data and try to manipulate some aspects of peer review to prevent dissent”

“It is essential that the scientific community work urgently to make standards for analyzing, reporting, providing access to, and stewardship of research data operational”

APPENDIX D: HEI POLICY ON THE PROVISION OF ACCESS TO DATA UNDERLYING HEI-FUNDED STUDIES

“Access to data underlying studies of the health effects of air pollution is an important element of ensuring credibility, especially when the studies are used in controversial public policy debates”

“It is the policy of the Health Effects Institute to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and validation of the work”

3. CARB Scientific Review Panel & 1998 Identification of Diesel as TAC

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

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

39670 (b)(4): Members . . . shall be appointed from a pool of nominees submitted . . . by the President . . . University of California. The pool shall include, at a minimum, three nominees for each discipline

Key CARB SRP Members Since 1984

Toxicologist: Chair John R. Froines, UCLA
Appointed 1984; Reappointed 1988, 1991, 1994, 1997, 2000, 2003, 2006; Replaced 2010

Biostatistician: Stanton A. Glantz, UCSF
Appointed 1986; Reappointed 1987, 1990, 1993, 1996, 1999, 2002, 2005, 2008

Epidemiologist: Gary D. Friedman, Stanford
Appointed 1988; Reappointed 1991;
No appointment since 1994; Replaced 2010¹

**March 11, 1998 Scientific Review Panel Meeting
(www.arb.ca.gov/srp/mt031198.pdf, Page 240)**

**“DR. WITSCHI: I HAVE A QUESTION AND IT'S TO ERIC
THERE IS YOUR LETTER WHEN YOU CAME DOWN IN
WRITING THAT YOU OBJECT TO USING YOUR STUDIES
FOR A QUANTITATIVE RISK ASSESSMENT, AND I'M NOT
QUITE CLEAR TODAY WHERE WE STAND ON THAT ONE.
COULD YOU CLARIFY THIS FOR ME?”**

**DR. GARSHICK: WELL, I THINK THE ISSUE WAS THAT
TRYING TO HAVE ONE SLOPE DESCRIBE ALL THE DATA
AT THIS POINT . . . HAS MANY UNCERTAINTIES, AND THAT
REALLY IS THE MAJOR OBJECTION. . . . THERE
SHOULDN'T BE UNDUE EMPHASIS PUT ON THE SLOPE,
PARTICULARLY GIVEN THE DISCUSSIONS WE'RE HAVING
RIGHT NOW.”**

April 22, 1998 Scientific Review Panel Meeting (www.arb.ca.gov/srp/mt042298.htm, page 97)

“ACTING CHAIRMAN FROINES: I'm calling the meeting to order. The tension level in this room is much too low. We expected about 500 truckers here. That didn't materialize, and now everybody is so relaxed we can't move anything forward. So for better or for worse, whatever way we're headed, let's move it along.”

Questions:

- 1) What was the meeting notice and who received it?
- 2) Did 500 truckers even know about the meeting?

April 22, 1998 Scientific Review Panel Meeting

(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 [5×10^{-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.”

April 22, 1998 Scientific Review Panel Meeting

(www.arb.ca.gov/srp/mt042298.htm)

**Summary of Identification of Diesel Exhaust
as Toxic Air Contaminant (TAC)**

Portion of Transcript by Key SRP Members

Toxicologist Froines (38.0%)

Biostatistician Glantz (18.9%)

Epidemiologist Friedman (3.2%)

**Epidemiologist never discussed major limitations
of occupational studies of workers exposed to
diesel: assessment of diesel exposure and
smoking status, relevance to general California
population, and criteria for a causal relationship**

**May 27, 1998 Letter by SRP Chair Froines to
CARB identifying diesel exhaust as a toxic
air contaminant using a single unit risk
factor [3×10^{-4} per g/m³] to relate diesel
exhaust to lung cancer**

**No mention of serious limitations:
national occupational cohort studies of
railroad workers and truckers did not have
accurate assessment of diesel exposure
and smoking history;
no California-specific results were presented;
uncertain relevance to general Californians**

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 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

Legal Actions Against Diesel PM as TAC

**Apadoco, CTA, CBA, CIAQC, ATA, others
v. CARB, OEHHA, SRP (and Chairs)**

Californian Health and Safety Code 39662 (e):

“Any person may petition the state board to review a [TAC] determination made pursuant to this section.”

**July 2, 1999 petition for reconsideration of diesel PM
as TAC denied by CARB on July 20, 1999**

**December 23, 1999 lawsuit challenging diesel PM
as TAC dismissed August 22, 2000**

Legal Actions Against Diesel PM as TAC

Apadoco et al. v. CARB et al.

October 10, 2000 lawsuit in Fresno County Superior Court to set aside CARB designation of diesel PM as TAC; after hearing and review of 45 volumes of Administrative Record Judge Franklin Jones ruled in favor of CARB, et al. on February 17, 2006

Ruling based on *limited review* “determining whether the agency acted within the scope of its delegated authority, whether it employed fair procedures, and whether its action is reasonable or is ‘arbitrary, capricious, or lacking in evidentiary support.’”

4. Evidence of No Relationship Between PM2.5 & Premature Deaths in CA

Line 2. Long-term exposure and mortality-- conclusions

Expanded analyses of Six-Cities and ACS cohorts → robust effect estimates.

Comparable PM-mortality effects have been observed in several other studies including:

- Infant mortality studies (Woodruff et al. 2006)
- Women's Health Initiative (Miller et al. 2004)
- Netherlands (Hoek et al. 2002)
- Hamilton, Canada (Finkelstein et al. 2004)

Mixed results have also been observed in:

- AHSMOG (McDonnell et al. 2000; Chen et al. 2005)
- French PAARC (Filleul et al. 2005)
- VA Cohort (Lipfert et al. 2000, 2003, 2006)
- 11 CA counties (Enstrom 2005)

- PM-mortality effect estimates tend to be larger when exposure estimates are based on more focused spatial resolution and/or when local sources of exposure, especially traffic sources, are accounted for.



Daniel Krewski



Richard Burnett



Arden Pope



Michael Jerrett



Doug Dockery



Francine Laden



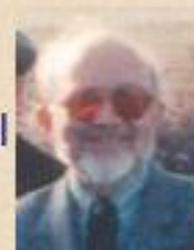
Tracey Woodruff



Joel Kaufman



Bert Brunekreef



Frederick Lipfert

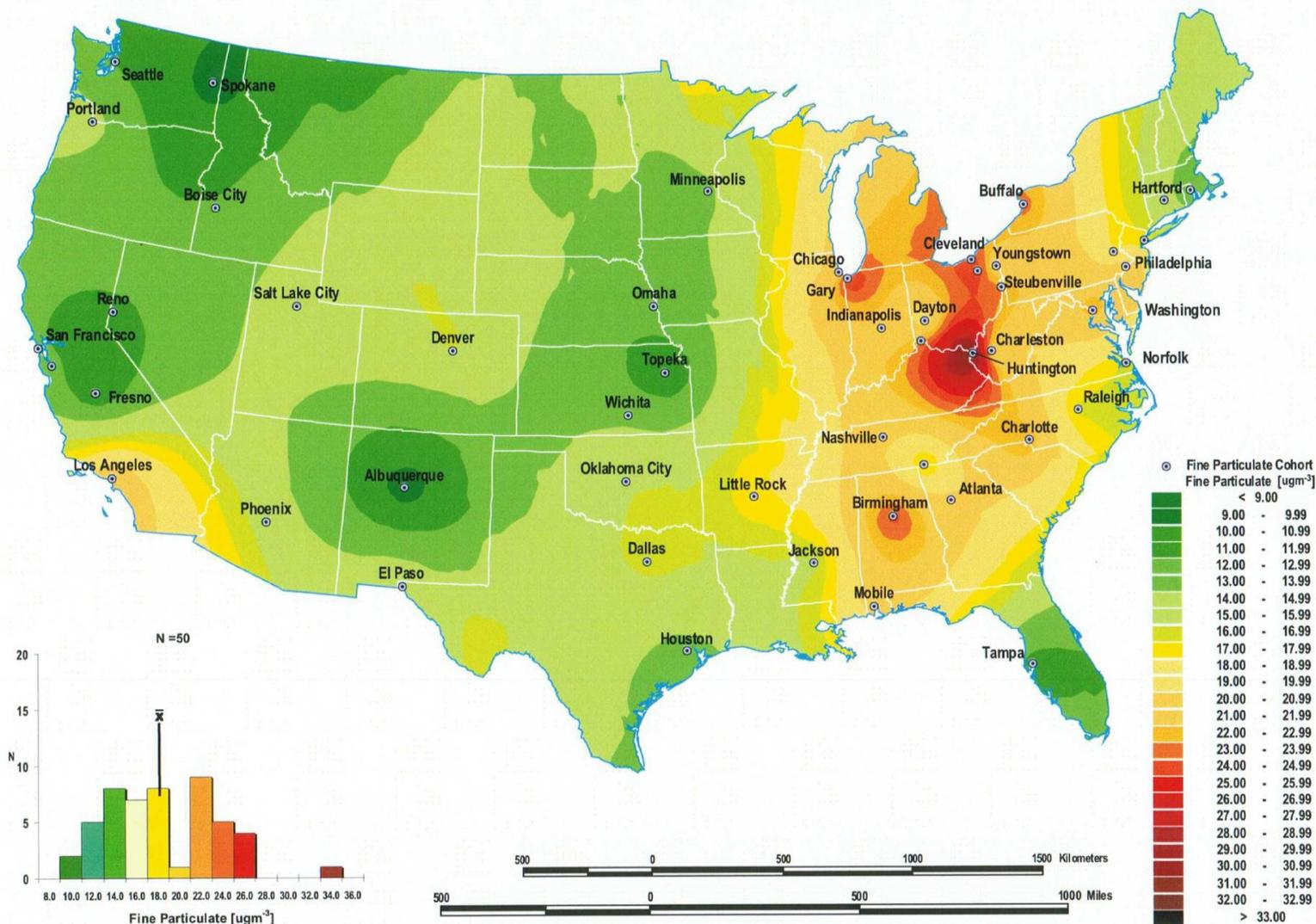


James E. Enstrom

2000 Krewski Jerrett HEI Report Figure 18

1982-1986 PM2.5 Concentration Distribution

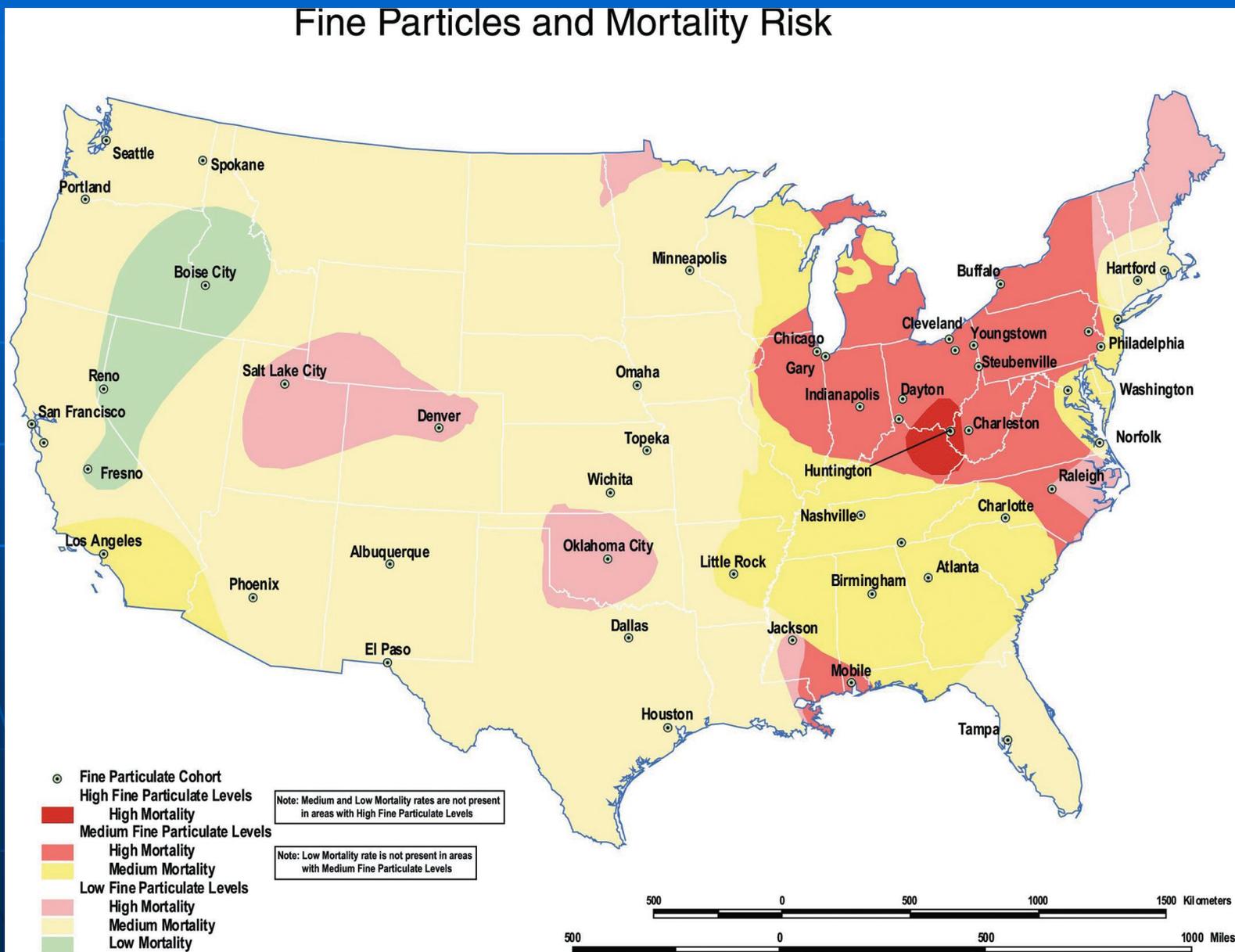
Modeled Fine Particles Surface



2000 Krewski Jerrett HEI Report Figure 21

1982-1989 CPS II PM2.5 Mortality Risk <1.0 in CA

Fine Particles and Mortality Risk



2001 EPA CASAC Slide 46 (1982-1989 CPS II)

July 11, 2008 CARB Comment by Jon Heuss

Regional Adjustment Models for NMMAPS Regions

Region*	PM _{2.5} Excess Risk Estimates		PM _{2.5} and SO ₂ Excess Risk Estimates			
	Risk	Conf. Limits	PM _{2.5} Risk	Conf. Limits	SO ₂ Risk	Conf. Limits
Northeast	14	(-7, 40)	3	(-15, 24)	19	(-2, 45)
Industrial Midwest	29	(10, 56)	9	(-12, 35)	19	(4, 38)
Southeast	25	(1, 54)	9	(-8, 29)	10	(-28, 48)
West*	-9	(-29, 17)	-9	(-28, 16)	31	(1, 69)

**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 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).”

December 1, 2008 (on line August 12, 2008)

Environmental Health Perspectives

Paper by Zeger, Dominici, McDermott, Samet

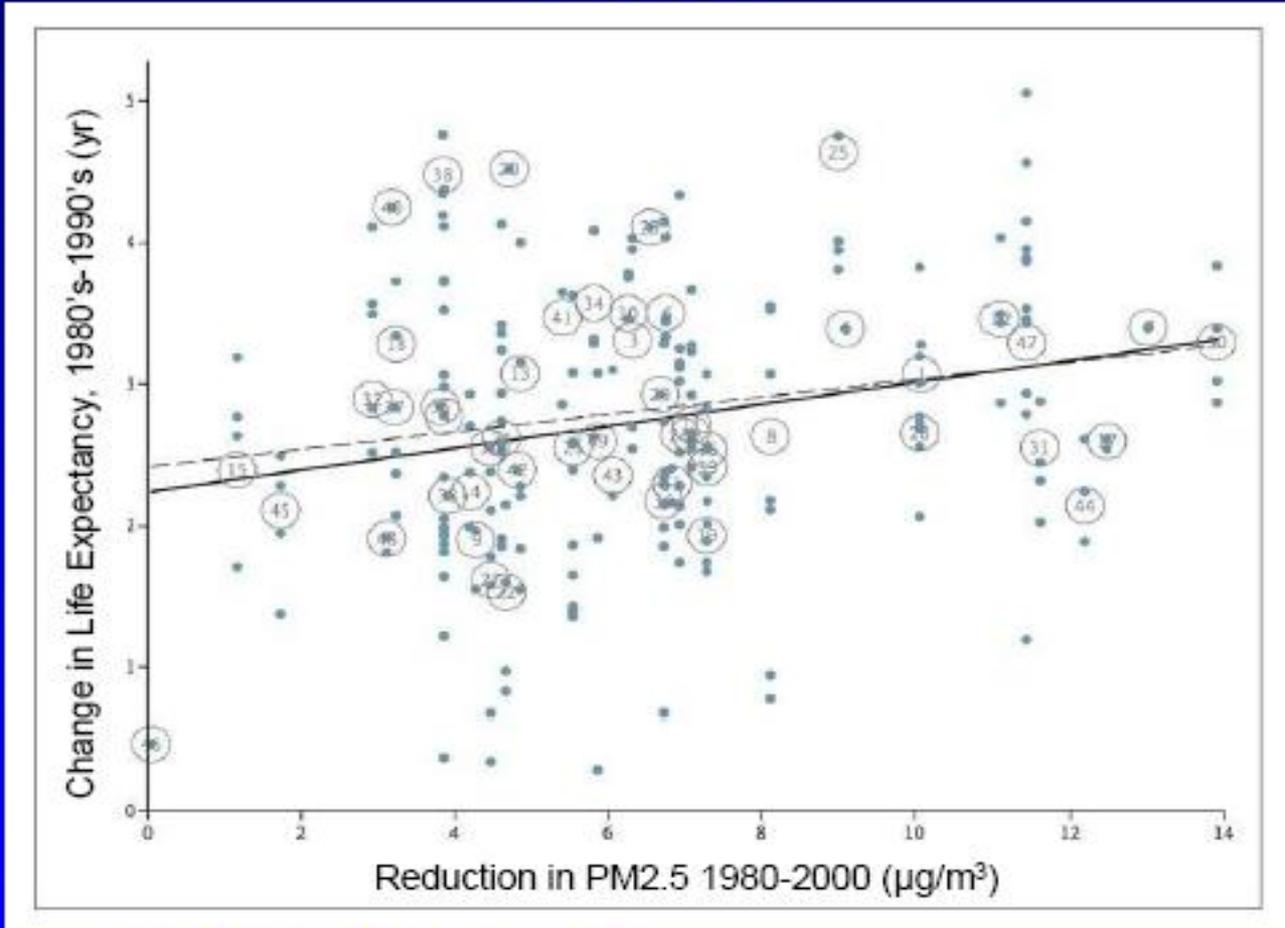
**13.2 million Medicare enrollees residing in 4,568
U.S. zip codes followed 2000-2005 (MCAPS)**

**“Chronic exposure to PM_{2.5} was associated with
mortality in the eastern and central regions,
but not in the western United States.”**

**“This lack of association is largely because
the Los Angeles basin counties (California) have
higher PM levels than other West Coast urban
centers, but not higher adjusted mortality rates.”³²**

2009 Pope NEJM 11-page paper (peer reviewed by Balmes) did not address Enstrom concerns about geographic variation

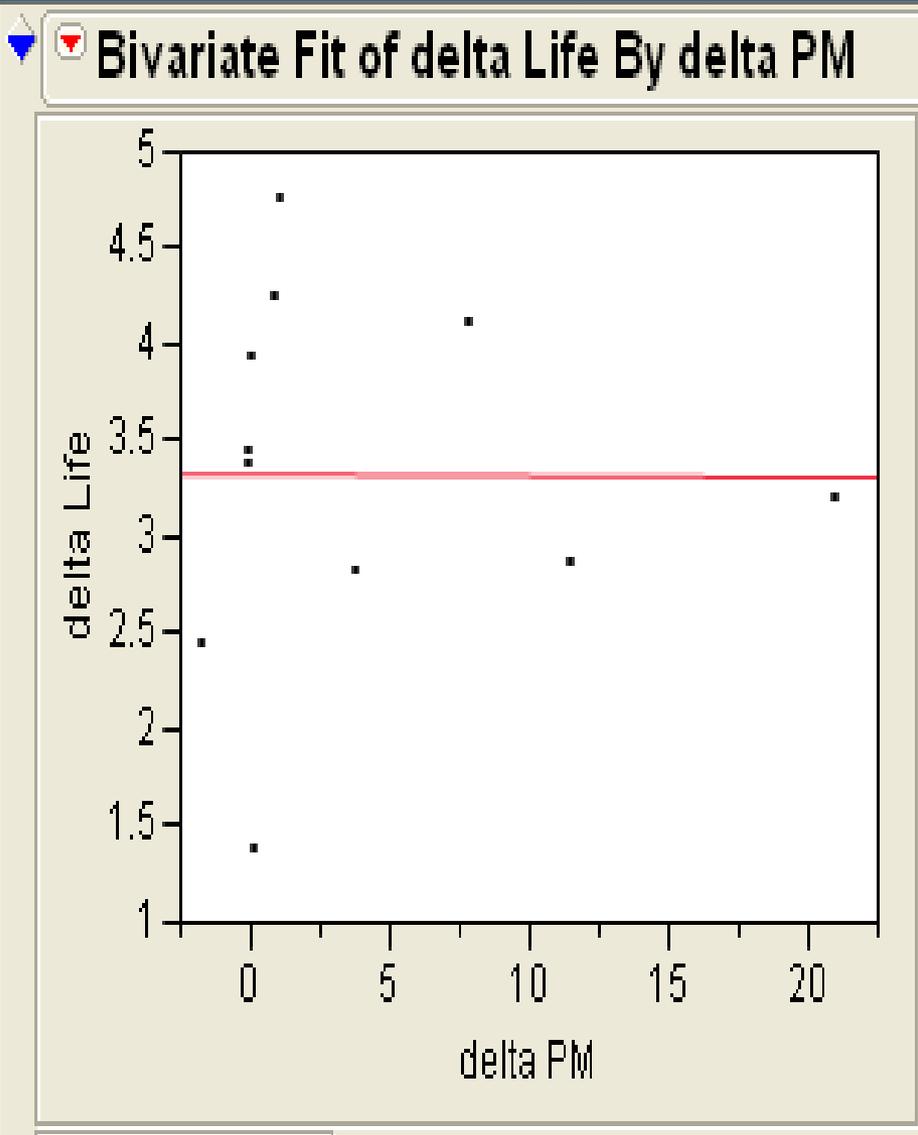
Changes in Life Expectancy and PM2.5 1980-2000



Pope C et al. N Engl J Med 2009;360:376-386

February 2009 Enstrom letter re Pope NEJM paper: PM2.5 and life expectancy changes not related in CA

	County	delta PM	delta Life
1	Santa Barbar	-0.1	3.45
2	Contra Cost	-0.1	3.38
3	Alameda	0	3.94
4	Butte	0.1	1.37
5	San Francisc	1	4.76
6	Santa Clara	0.8	4.25
7	Fresno	-1.8	2.45
8	San Diego	3.7	2.83
9	Los Angeles	7.8	4.11
10	Kern	11.5	2.87
11	Riverside	20.9	3.2



June 3, 2009 HEI Report 140: Extended Follow-up and Spatial Analysis of Fine Particulate Air Pollution and Mortality (1982-2000 CPS II) Table 33 (same as May 21, 2008 HEI PPT)

Daniel Krewski, Michael Jerrett, C Arden Pope III,
Michael J Thun, others

<u>Author-year Reference</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)
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)

February 26, 2010 CARB Symposium

Estimating Premature Deaths From Long-term Exposure to PM2.5

**Michael Jerrett
(co-authors Daniel Krewski, C Arden Pope III,
Michael J Thun, others)**

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

Based on ~95,000 CA CPS II subjects in ~ 50 CA Counties

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

**Special Analysis of California Subjects
in 2000 HEI Reanalysis Report
(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 29, 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**

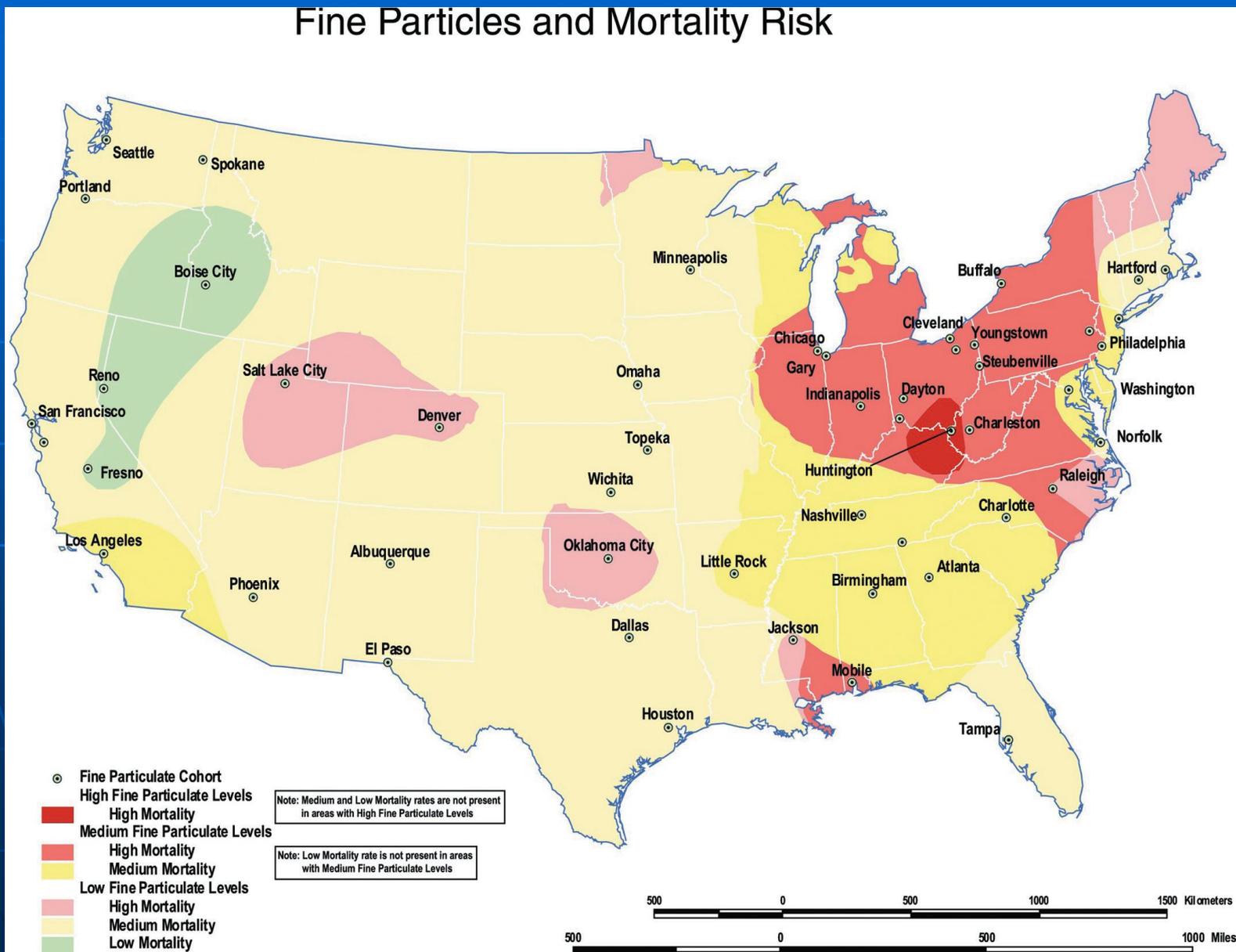
**Fresno had 2nd Lowest MR of the 49 cities
Los Angeles had 5th Lowest MR of the 49 cities**

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

2000 Krewski Jerrett HEI Report Figure 21

1982-1989 CPS II PM2.5 Mortality Risk <1.0 in CA

Fine Particles and Mortality Risk



Enstrom Conclusion

Based on the findings revealed in 2010, largely because of pressure applied on UC and HEI, Krewski, Jerrett, Pope, and Thun have known since 2000 that there is NO relationship between PM2.5 and premature deaths in California and they have gone out of their way to obfuscate this California-specific finding until this year.

5. Falsification & Conflicts of Interests Associated with CARB Tran Report

October 24, 2008 CARB Staff Report Methodology for Estimating Premature Deaths Associated with Long-term Exposure to Fine Airborne Particulate Matter in California

Project Coordinator and Lead Author
Hien T. Tran, Ph.D.

Scientific Advisors (3)

Clive Arden Pope, III, Ph.D., Brigham Young University

Reviewers (4)

Melanie Marty, Ph.D., Environmental Health Hazard Assessment

Peer Reviewers (6)

Mark D. Eisner, M.D., M.P.H., UC San Francisco
Alan Hubbard, Ph.D., UC Berkeley

THE REGENTS OF

Thornhill University

UPON THE NOMINATION OF THE COUNCIL OF THE POSTGRADUATE DIVISION
OF THE SCHOOL OF BUSINESS AND ADMINISTRATION
HEREBY CONFER UPON

Hien Thanh Tran

HAVING DEMONSTRATED ABILITY BY GENERAL SCHOLARSHIP

Magna cum Laude

THE DEGREE

Philosophiae Doctor in Applied Statistics

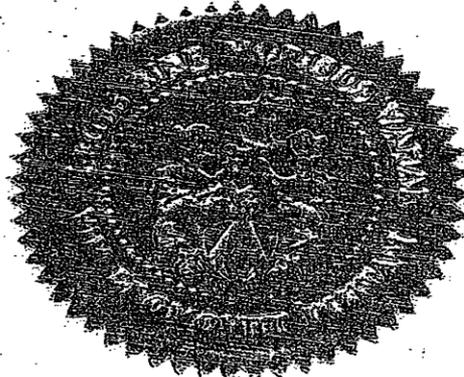
WITH ALL THE RIGHTS AND PRIVILEGES THERETO PERTAINING

GIVEN THIS TWENTY-EIGHTH DAY OF JUNE IN THE YEAR

TWO THOUSAND SEVEN

Carol Anderson

PRESIDENT OF THE REGENTS



John McAllagh

PRESIDENT OF THE UNIVERSITY

Jonathan Korn

DEAN OF THE UNIVERSITY

Ronald K. Bourvent

CHANCELLOR



COEH Faculty

John R. Balmes, Director---CARB Member

Paul D. Blanc---SRP Member

Mark D. Eisner---Tran Report Peer Reviewer

S. Katharine Hammond---SRP Member

Irva Hertz-Picciotto---RSC Member

Alan E. Hubbard---Tran Report Peer Reviewer



Environmental Health Sciences Faculty

S. Katharine Hammond, Chair—SRP Member

Alan E. Hubbard—Tran Report Peer Reviewer

Michael L. Jerrett—Author of Studies in Tran Report

John R. Balmes—CARB Member

**June 3, 2009 HEI Report 140: Extended Follow-up
and Spatial Analysis of Fine Particulate Air
Pollution and Mortality (1982-2000 CPS II)
(May 21, 2008 PPT→available for Tran Report)**

Authors Jerrett, Pope, and Burnett participated in
July 11, 2008 CARB teleconference with Enstrom

Falsification (failure to respond to Enstrom requests
and other misrepresentations of research record):

Enstrom 2005 paper not cited

Zeger Samet et al. 2008 paper not cited

PM2.5 Risk Map for US (like Figure 21) omitted

CA-specific PM2.5 risks not addressed in text

November 29, 2009 San Diego Union-Tribune Letter

Air board: shameful or ‘most competent’?

CARB members John R. Balmes and Daniel Sperling

[Response to November 22, 2009 Editorial “The air board’s shame / Staff never revealed internal scandal before crucial vote” following November 19, 2009 statement by CARB member John G. Telles regarding Hien T. Tran and 2008 Tran Report]

“there was no abuse, manipulation or dishonesty of any type”

“No one has questioned the accuracy or integrity of the report”

“there is no evidence to question the regulation^s, the supporting studies or board ARB management”

2010 Summary of Evidence on PM2.5 and Premature Deaths in California

CARB estimates that off-road diesel regulations will prevent 25 premature deaths per year in California

CARB estimates that on-road diesel regulations will prevent 233 premature deaths per year in California

Based on all California-specific epidemiologic evidence, CARB off-road and on-road diesel regulations will most likely prevent NO premature deaths in California

October 2004 Paper

“The Particulate Air Pollution Controversy”

Robert F. Phalen, Ph.D., UC Irvine

“Today, we are at an important crossroad with respect to the future of air-pollutant regulation. One road involves performing the needed research and making decisions on the basis of the science, with full consideration of the many trade-offs associated with new regulations. The other road involves adopting regulations driven by public fear, politics, and pressure groups. The first road is obviously the more beneficial one for protecting human health. . . . The second approach promises uncontrolled, chaotic, and rapidly changing rules. A great deal is at stake. Will science and reason, or expediency, fear, and ignorance, be the determinants of public health decisions?”

6. California is Very Healthy State

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

7. Recommended Actions Based on Above Findings

Objectively reassess relationship of PM2.5 and diesel PM to premature death in CA with independent reviewers not connected to CARB

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

CARB & HEI need to fund all legitimate researchers, including critics, in order to show commitment to objective air pollution epidemiology

Conduct independent investigation of entire process leading to CARB diesel regulations that are scientifically, legally, and economically unjustified