Pseudoscientific Aspects of Fine Particulate Matter Epidemiology, 1993-2012

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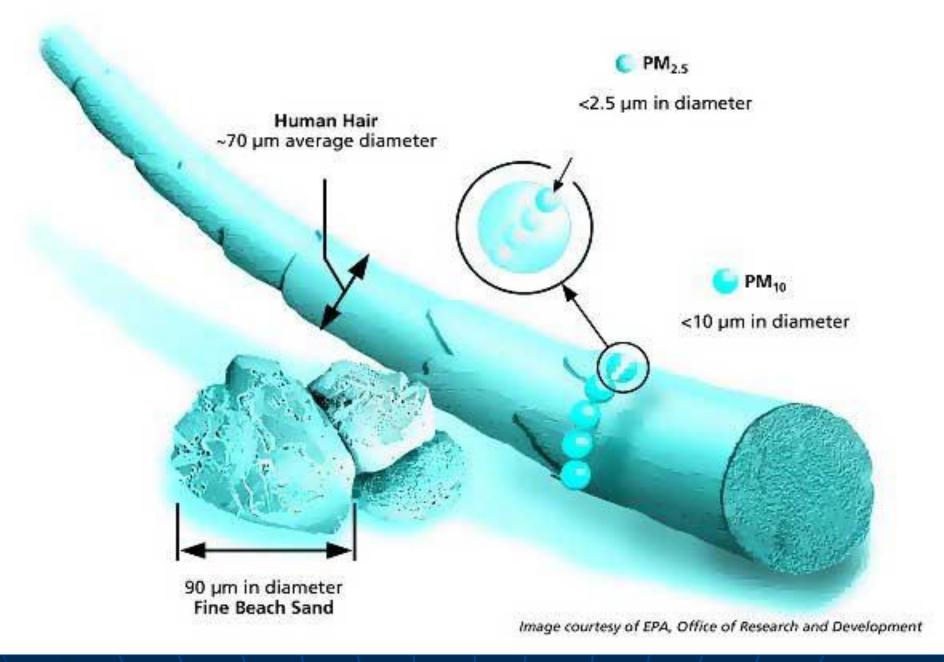
## Fine Particulate Matter (PM<sub>2.5</sub>)

 $PM_{2.5}$  is defined by particle size ( $\leq 2.5 \mu$ m in diameter) and not by chemical composition, as in the case of a gaseous air pollutant like ozone.  $PM_{2.5}$  is generated mainly by combustion processes. The major sources of  $PM_{2.5}$  are forest fires, agricultural dust, industrial combustion, and diesel engines and these sources vary across the US

 $PM_{2.5}$  epidemiology has been used to set two major standards:

1) In 1997 US EPA established the current Annual National Ambient Air Quality Standard (NAAQS) for  $PM_{2.5}$  at 15  $\mu$ g/m<sup>3</sup>

2) In 2002 CARB established the current Annual California Ambient Air Quality Standard (CAAQS) for  $PM_{2.5}$  at 12  $\mu$ g/m<sup>3</sup>



# PM<sub>2.5</sub> & Mortality Relationship: First Two Studies & Resulting Criticism

**Dockery, Pope, et al. NEJM 1993** "An association between air pollution and mortality in six U.S. cities" (H6CS)

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

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 1997 "Polluted Science" Reason & AEI Press
Robert Phalen 2002 "The Particulate Air Pollution Controversy"

## "Premature Deaths" Attributed to PM<sub>2.5</sub>

An increased relative risk [RR > 1.00], based on increase in total (all cause) mortality risk for 10  $\mu$ g/m<sup>3</sup> increase in PM<sub>2.5</sub> level, 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" exceed the compliance costs of the EPA and CARB regulations that are designed to reduce PM<sub>2.5</sub> levels and PM<sub>2.5</sub>-related "premature deaths"

Without PM<sub>2.5</sub>-related "premature deaths" the EPA and CARB regulations are not justified on a cost-benefit basis

# Major Reasons for Lack of Proof that PM<sub>2.5</sub> "Causes" "Premature Deaths"

 Small Variable Effect: the relative risk of death due to PM<sub>2.5</sub> is small (RR ~ 1.10), varies by time and place, and there is no consistent dose-response relationship

2) Confounding Variables: confounders, including other pollutants, often reduce PM<sub>2.5</sub> effect to zero (RR ~ 1.00)

3) Ecological Fallacy: PM<sub>2.5</sub> measurements made at selected monitoring stations are imputed to individuals

4) Variable PM<sub>2.5</sub>: PM<sub>2.5</sub> is defined by specific particle size, but its composition varies greatly across the US

5) Secret Data: major PM<sub>2.5</sub> studies (H6CS & ACS) cannot be independently analyzed, violating Data Access Act 6

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

(http://www.arb.ca.gov/planning/gmerp/dec1plan/gmerp\_comments/enstrom.pdf)

Major long-term PM<sub>2.5</sub> death study with null results: 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  $10-\mu$ g/m<sup>3</sup> increase in PM<sub>2.5</sub>. 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 "Tran" Report on PM<sub>2.5</sub> & Premature Deaths in California Hien T. Tran, "Ph.D.", Lead Author (http://www.scientificintegrityinstitute.org/CARBPMDraft052208.pdf)

June 4, 2008 Enstrom testimony at confirmation hearing of CARB Chair Mary Nichols because "Tran" Report ignored Enstrom 2005

July 11, 2008 Tran Teleconference with Enstrom and PM<sub>2.5</sub> experts Pope, Jerrett, Burnett, and others

July 11, 2008 148 pages of mostly critical public comments by Enstrom and others on Draft "Tran" Report---these comments were largely ignored

#### October 24, 2008 Final CARB "Tran" Report (http://www.scientificintegrityinstitute.org/CARBPMFinal102408.pdf)

#### **Conclusions for California:**

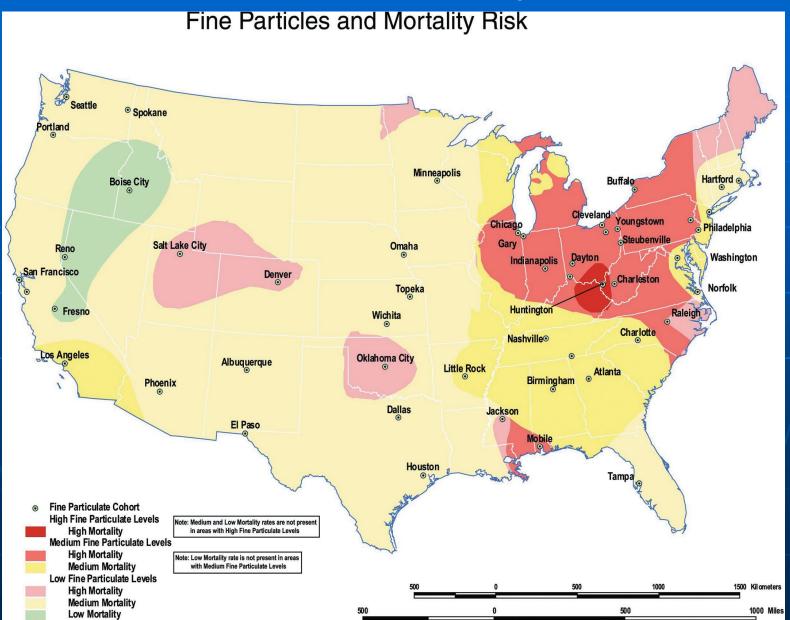
18,000 Annual Premature Deaths Due to All PM<sub>2.5</sub> 3,500 Annual Premature Deaths Due to Diesel PM

US Results Used, Not CA-specific Results: 1) Harvard Six Cities Study (Dockery 1993, Krewski 2000, Laden 2006)—KS,MA,MO,OH,TN,WI

2) ACS CPS II Cohort (Pope 1995, Krewski 2000, Pope 2002, Pope 2004)—nationwide results & (Jerrett 2005)—Los Angeles basin

Report Rejected Because Tran had Phony "Ph.D." → February 26, 2010 CARB PM Symposium

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



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September 30, 2010 Special Analysis by Enstrom of Figures 5 and 21 in 2000 HEI Reanalysis Report (http://scientificintegrityinstitute.org/HEIFigure5093010.pdf)

Mortality Risk (MR) during 1982-1989 in 49 cities was determined by manual analysis using Figures 5 and 21 and Appendix D (Original Request for MRs Made to HEI in 2002)

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

MR (4 CA cities) ~ 90% MR (all 49 cities) MR (4 CA cities) Not Related to PM<sub>2.5</sub> Level 11 August 31, 2010 Letter from Krewski to HEI President Greenbaum (http://www.arb.ca.gov/research/health/pmmort/HEI\_Correspondence.pdf)

Special Analysis of California Subjects in Krewski 2009 HEI Research Report 140 (direct result of 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)

#### Jerrett Project (Begun January 2007) (http://www.scientificintegrityinstitute.org/Jerrett012510.pdf)

Spatiotemporal Analysis of Air Pollution and Mortality in California Based on ACS CPS II Cohort Jerrett, Burnett, Pope, Krewski, Thurston, Thun + Others (Three-Year Budget of \$750,000 from CARB and SC AQMD)

Major Progress Report, due July 2008, was not submitted, but June 25, 2008 CARB Quarterly Progress Report made NO mention of a relationship between PM<sub>2.5</sub> & total deaths

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

These null results should have been included in the 2008 "Tran" Report but they were delayed until 2010

## June 9, 2011 Jerrett Draft Final Report

Major Results for PM<sub>2.5</sub> and Total Mortality in CA (Figure 22) RR = 1.08 (1.00-1.15) New "Conurbation" Model RR = 1.002 (0.992-1.012) Nine Model Average

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

Dr. Matt Briggs Posts Three Blogs Critical of Jerrett Report (http://wmbriggs.com/blog/?p=4587) <sup>14</sup> October 28, 2011 Jerrett Final Report (http://scientificintegrityinstitute.org/JerrettCriticism102811.pdf)

Major Results for PM<sub>2.5</sub> and Total Mortality in CA (Figure 22) RR = 1.08 (1.00-1.15) New "Conurbation" Model RR = 1.002 (0.992-1.012) Nine Model Average

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 <sup>15</sup>

## Experts Who Have Refused to Debate PM<sub>2.5</sub> Epidemiology with Enstrom (Yellow = Involved with 2008 CARB "Tran" Report)

June 2011 North Am Congress of Epidemiology Symposium on PM<sub>2.5</sub> Epi Ethics (Cancelled) Burnett (Health Canada), Dockery (Harvard), Hopke (Clarkson), Jerrett (UC Berkeley), Krewski (Ottawa), Pope (BYU), Samet (USC), Schwartz (Harvard), Speizer (Harvard), Thun (ACS), Thurston (NYU); Cohen (HEI), Lippmann (NYU), Miller (former US EPA), Pekar (US EPA), Puett (USoCar), Ross (US EPA)

April 24, 2012 Dose-Response Conference Levy (BU), Cohen (HEI), Greenbaum (HEI)

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

Based on 2010-2011 findings and their failure to dispute my interpretation or debate me, Enstrom concludes that Pope & Thun (1995) and Krewski & Jerrett & Burnett (2000) have known since 2000 that within the ACS CPS II Cohort:

 there is NO significant relationship between PM<sub>2.5</sub> and total mortality in California &
there is substantial geographic variation nationally (West vs East) in the dose-response relationship between PM<sub>2.5</sub> and total mortality <sup>17</sup> PM2.5 & Total Mortality in California: RR (95% CI) (http://scientificintegrityinstitute.org/Enstrom081111.pdf)

McDonnell 2000 AHSMOG RR ~ 1.03 (0.95-1.12) 1976-1992 (9 air sheds) Krewski 2000 CA CPS II RR = 0.87 (0.81-0.94) 1982-1989 (reported in 2010) (4 MSAs) Enstrom 2005 CA CPS I RR = 1.04 (1.01-1.07) 1973-1982 (11 Cos) RR = 1.00 (0.98-1.02) 1983-2002

Zeger 2008 MCAPS "West" RR = 0.99 (0.97-1.01) 2000-2005 (CA,OR,WA) Krewski 2010 CA CPS II RR = 0.97 (0.92-1.02) 1982-2000 (7 MSAs) Jerrett 2010-11 CA CPS II RR = 1.00 (0.99-1.01) 1982-2000 (54 Cos, Nine Model Average) Lipsett 2011 CA Teachers RR = 1.01 (0.95-1.09) 2000-2005

**Key Documents Since 2000 that Misrepresent Relationship Between** PM<sub>25</sub> & Total Mortality in California 2001-2003 Establishment of PM<sub>2.5</sub> Standard in CA 2002 Pope et al JAMA Paper on PM<sub>2.5</sub> Deaths in US 2004 US EPA Air Quality Criteria for PM<sub>25</sub> 2008 CARB "Tran" Report on PM<sub>2.5</sub> Deaths in CA 2009 Krewski HEI Report 140 on PM<sub>25</sub> Deaths 2009 US EPA Science Assessment for PM<sub>2.5</sub> <sup>19</sup>

April 12, 2012 SC AQMD Retreat: PM Health Effects Talk by Ospital re 2012 Air Quality Management Plan (http://www.aqmd.gov/aqmp/2012aqmp/index.htm)

Harvard Six Cities Study Update: 1974-2009 Deaths March 28, 2012 EHP by Lepeule Dockery Schwartz RR = 1.14 (1.07–1.22) All Causes RR = 1.26 (1.14–1.40) CVD RR = 1.37 (1.07–1.75) Lung Cancer

*"Conclusion:* relationship between chronic exposure to PM2.5 and all cause, cardiovascular and lung cancer mortality was found to be linear without a threshold."

Nothing on 2011AQMD Jerrett & Lipsett Studies or 2011 Enstrom Summary of PM<sub>2.5</sub> & Mortality<sup>20</sup>

### **Overall Conclusions**

There is now overwhelming evidence that PM<sub>2.5</sub> does not cause "premature deaths" in California and that USEPA, CARB, and SC AQMD, are obfuscating and ignoring this evidence.

Independent investigators need to conduct new national PM<sub>2.5</sub> epidemiologic studies that involve recent mortality follow-up and verifiable databases

There should be no further regulation of PM<sub>2.5</sub> until there is strong evidence of a positive dose-response relationship with mortality that satisfies accepted causality criteria

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### Recent Letters Critical of US EPA re 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 Members Conflicts of Interest

September 19, 2011 Congressman Latta Letter to President 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<sup>22</sup>