

The PM_{2.5} Deaths Controversy: Combating Pseudoscientists

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Fine Particulate Matter (PM_{2.5}) Defined By Size ($\leq 2.5 \mu\text{m}$ Diameter), Not Composition

PM_{2.5} comes mainly from combustion (forest fires, diesel engines, manufacturing)--up to 30% in CA is from China

US EPA established the 1997 Annual National Ambient Air Quality Standard (NAAQS) for PM_{2.5} as $15 \mu\text{g}/\text{m}^3$, lowered to $12 \mu\text{g}/\text{m}^3$ in 2012, based largely on 1995 ACS “secret science” epidemiology claim that PM_{2.5} *causes* premature deaths in the CPS II cohort.

The PM_{2.5} NAAQS has been used to justify many EPA regulations that have multi-billion dollar economic impacts in US: State Implementation Plans, Air Quality Management Plans, Clean Power Plan, MATS Rule, CARB Truck and Bus Regulation, etc.

Average US Adult Now Inhales About One Gram of PM_{2.5} in 80 Years

Amount of Air Inhaled by an Adult Breathing at Rest:
~ 10,000 liters/day ~ 292 M m³/80 years

PM_{2.5} Inhaled at original NAAQS level of 15 µg/m³:
~4.38 grams/80 years = 0.88 teaspoons/80 years

PM_{2.5} Inhaled at Average 2015 Exposure:
~0.5 x US Ambient Exposure of 8.4 µg/m³
~1.2 grams/80 years

PM_{2.5} Inhaled from 100 Cigarettes ~ 4.0 grams

Reasons for NO PM_{2.5} Premature Deaths

1) No Etiologic Mechanism:

No experimental proof that 1-5 grams of PM_{2.5} causes death

2) Weak Epidemiologic Risk:

Tiny positive relative risks do not prove that PM_{2.5} causes death

3) Ecological Fallacy:

PM_{2.5} monitors are inaccurate and exaggerate human exposure

4) Enstrom Reanalysis Shows Importance of Transparency:

ACS CPS II PM_{2.5}-Deaths invalidated upon reanalysis of data

5) Totality of US Cohort Studies Shows NO Relationship:

Objective meta-analysis of US cohorts shows NO PM_{2.5}-Deaths

ACS Cancer Prevention Study (CPS II) Has Falsely Claimed PM_{2.5} Premature Deaths

1995 *AJRCCM* Article by Pope Thun

Used Selected PM_{2.5} Data and 'Secret' ACS CPS II Data

2000 HEI Reanalysis Report by Krewski Jerrett

Never Did Sensitivity CPS II Analysis Based on Best PM_{2.5} Data

2009 HEI Research Report 140 by Krewski Jerrett Pope Thun

Ignored CPS II Criticism & PM_{2.5} Risk Variation & Best PM_{2.5} Data

March 28, 2017 *Dose-Response* Reanalysis by Enstrom

NO CPS II PM_{2.5}-Deaths Based Reanalysis with Best PM_{2.5} Data

[\(<http://journals.sagepub.com/doi/10.1177/1559325817693345>\)](http://journals.sagepub.com/doi/10.1177/1559325817693345)

May 29, 2018 *Dose-Response* Reply by Enstrom

More Unrefuted Evidence of NO PM_{2.5}-Deaths in CPS II

[\(<http://journals.sagepub.com/doi/pdf/10.1177/1559325818769728>\)](http://journals.sagepub.com/doi/pdf/10.1177/1559325818769728)

Enstrom 2017 Analysis of PM_{2.5} and Total Mortality During 1982-1988 in ACS CPS II Cohort: IPN=HEIDC

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

1979-83 PM_{2.5} Subjects Relative Risk (95% CI)

Fully Adjusted for 47 Counties in Continental US

IPN [Hinton]	189,676	1.021 (0.984-1.058)
HEIDC [PM2.5 DC]	189,676	1.023 (0.984-1.064)
HEI [PM2.5 OI MD]	189,676	1.081 (1.036-1.128)

Fully Adjusted for Ohio Valley: 10 Cos IN,KY,OH,PA,WV

IPN	37,290	1.110 (0.949-1.299)
HEIDC	37,290	1.113 (0.945-1.311)
HEI	37,290	1.138 (0.941-1.376)

Fully Adjusted for Other States: 37 Cos Not Ohio Valley

IPN	152,386	0.975 (0.936-1.016)
HEIDC	152,386	0.968 (0.925-1.012)
HEI	152,386	1.025 (0.975-1.079)

C. Arden Pope, III, PhD, BYU Economics

(“World’s Leading Expert on the Effects of Air Pollution on Health”)

1981 PhD in Agricultural Economics from Iowa State U

“The Dynamics of Crop Yields in the U.S. Corn Belt as
Effected by Weather and Technological Progress”

Cited Enstrom 2005 in 2006 *JAWMA* Review, but Never Again

Ignored July 11, 2008 CARB Teleconference re Null CA Results

Ignored February 26, 2010 CARB PM_{2.5} Deaths Symposium

Ignored August 1, 2013 House Science Committee Subpoena

Omitted Null CA results from Jerrett 2013 *AJRCCM* paper

Refused Enstrom’s Invitations to June 2015 ICC-10, March
2017 ICC-12, August 2017 DDP, November 2017 AFEC

Refused to Confirm or Refute 2017 *Dose-Response* Findings
Instead Stated “Study by Enstrom Does Not Contribute”

American Cancer Society Officials

(CEO Gary R. Reedy, Former EVP Res Otis W. Brawley, MD,
VP Epi Susan P. Gapstur, PhD, Analyst W. Ryan Diver,
Former VP Epi Michael J. Thun, MD)

Refuse to Correct CPS II Findings re PM_{2.5}

ACS Refused to Comply with 2013 House Subpoena and has
Released NO Current CPS II Data for Independent Analysis

ACS Refused to Collaborate with Four Qualified Ph.D.-level
PM_{2.5} Critics: Drs. Enstrom, Young, Briggs, and Malkan

ACS Continues to Falsify PM_{2.5} Death Claims in CPS II Cohort
and Will Not Correct These False Claims

CPS II Research Has Led to Unjustified EPA PM_{2.5} Regulations
But It is Still Listed Under ACS “Proudest Achievements”

Health Effects Institute

(President Daniel Greenbaum & Chief Scientist Aaron Cohen)

NEVER Conducted Proper CPS II Reanalysis

HEI Selected 31-member Canadian Reanalysis Team, mainly Statisticians and Geographers, to Reanalyze US Epidemiology

2000 HEI Reanalysis Report Never Tested Sensitivity of $PM_{2.5}$ Mortality Risk in Pope 1995 with Best $PM_{2.5}$ Data & SO_4

Since 2002 HEI has Not Provided $PM_{2.5}$ Mortality Risk for 50 Cities in Pope 1995 and HEI 2000 Figure 21

HEI Has Refused to Address Evidence of NO $PM_{2.5}$ Mortality Risk Based on 2017 Enstrom CPS II Reanalysis

Richard Burnett Presented April 30, 2018 HEI Conference Meta-Analysis Showing $RR \sim 1.10$ for $PM_{2.5}$ & Total Deaths 9

April 30, 2018 Proposed EPA RULE

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

83 FR 18,768

<https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001>

May 31, 2018

EPA Science Advisory Board Meeting

Focused on Proposed EPA RULE

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

May 30, 2018 Enstrom Comments to EPA SAB Meeting re May 29, 2018 Enstrom Dose-Response Response to December 13, 2017 Pope-ACS Dose-Response Criticism of March 28, 2017 Enstrom Dose-Response Reanalysis, which identified errors in Pope 1995, HEI 2000, HEI 2009

([https://yosemite.epa.gov/sab/sabproduct.nsf/D41456F68B9F91658525829D004DBD73/\\$File/88483770.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/D41456F68B9F91658525829D004DBD73/$File/88483770.pdf))

August 14, 2018 Enstrom Comments Supporting EPA Transparency Rule, including above three Dose-Response articles & Spring 2018 JAPS article) (<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8290>)

**August 7, 2018 34-page Harvard Letter by Wendy B. Jacobs, Esq
Co-Signed by 96 Professors Urging Withdrawal of Proposed EPA RULE
STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE**

(<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6111>)

“The proposed rule thus does not serve its stated purpose to ensure that regulatory decisions are based on ‘valid’ science.” “The rule will . . . jeopardize the health and safety of infants, children, and adults in the United States and beyond.”

Signers Include:

Harvard President & Dean of Harvard T.H. Chan School of Public Health &

Professors who Claim PM_{2.5} Deaths in Six Cities and Medicare Studies

Francine Laden ScD (Laden 2006, Lepeule 2012)

Douglas Dockery ScD (Dockery 1993, Laden 2006, Lepeule 2012)

Francesca Dominici PhD (Zeger 2008, Di 2017, Di 2017)

Joel Schwartz PhD (Pope 1992, Laden 2006, Lepeule 2012, Di 2017, Di 2017)

Eric J. Rubin MD PhD New September 2019 NEJM Editor-in-Chief

September 28, 2018

Intrepid Insight

“Statistical Review of Competing Findings in Fine Particulate Matter and Total Mortality Studies”

Intrepid Insight Statistical Review Done in Response to April 30, 2018 HEI Burnett Meta-Analysis Claiming RR ~ 1.10

Intrepid Insight Statement of Support for Data Transparency: all nine of Intrepid Insight’s directors and contributors voted to support data transparency as a principle (in this case and in all others). Because the Pope 1995 paper is used to support public policies, there is an even greater justification for releasing the underlying data.

https://www.intrepidinsight.com/pm25_statreview/

Meta-Analyses of 8 US Cohorts and 6 CA cohorts show NO relationship between PM_{2.5} and total deaths. Contested Medicare Cohort Study from Harvard was omitted because Zeger 2008 results are inconsistent with Di 2017 results and authors have not addressed extensive criticism.

PM_{2.5} and Total Mortality in US: Eight Cohorts

([https://www.intrepidinsight.com/pm25_statreview/ Table B4](https://www.intrepidinsight.com/pm25_statreview/Table B4))

<u>Author & Year</u>	<u>US Cohort</u>	<u>Relative Risk (95% CI)</u>
Lipfert 2000	Veterans 42 Cities	0.890 (0.850-0.950)
Krewski HEI 2009	CA CPS II 50 Metro Areas	1.028 (1.014-1.043)
Puett 2009	HSPH Nurses NE MW	1.260 (1.020-1.540)
Puett 2011	HSPH Health Profs NE MW	0.860 (0.720-1.020)
Lepeule 2012	HSPH Six Cities NE MW	1.140 (1.070-1.022)
Weichenthal 2015	Ag Health NC & IA	0.950 (0.760-1.200)
Thurston 2016	NIH AARP 6 States+2 Cities	1.025 (1.000-1.049)
Parker 2018	NHIS US Sample Corrected	1.016 (0.979-1.054)
II Fixed Effects Meta-Analysis		1.023 (1.012-1.035)
II Random Effects Meta-Analysis (correct M-A)		1.014 (0.973-1.057)

PM_{2.5} and Total Mortality in California: Six Cohorts

(https://www.intrepidinsight.com/pm25_statreview/ Table B7)

<u>Author & Year</u>	<u>CA Cohort</u>	<u>Relative Risk (95% CI)</u>
McDonnell 2000	AHSMOG	~1.000 (0.950-1.100)
Enstrom 2005	CA CPS I	0.997 (0.978-1.016)
Zeger 2008	MCAPS “West”	0.989 (0.970-1.008)
Krewski HEI 2010	CA CPS II	0.968 (0.916-1.022)
Ostro 2015	CA Teachers	1.010 (0.980-1.050)
Thurston 2016	CA NIH AARP	1.017 (0.990-1.040)
II Fixed Effects Meta-Analysis		0.999 (0.988-1.009)
II Random Effects Meta-Analysis		0.999 (0.988-1.009)

USC Preventive Medicine Professors Misrepresent Air Pollution Health Effects in Southern California

February 15, 2019 Provost Quick Unwilling to Discuss
February 13, 2019 Enstrom Request re USC Preventive
Medicine Professors Support of SB 732 Sales Tax for
Unjustified SCAQMD AQMP Regulations.

NO Response to January 3, 2019 Enstrom Request to
Prof Thomas re Strong Evidence of NO US $PM_{2.5}$ Deaths
After NO Response to June 27, 2018 Enstrom Request to
Prof Berhane Who Organized April 30, 2018 HEI Meta
Analysis by Richard Burnett Which Found a 'Strong'
Relationship (RR~1.10) between $PM_{2.5}$ and Total Mortality

<http://scientificintegrityinstitute.org/USCEmails021519.pdf>

**April 16, 2019 California Globe
Expose by Katy Grimes
“A Totally Different USC Scandal”**

(<https://californiaglobe.com/legislature/a-totally-different-usc-scandal/>)

During the past 25 years key USC Preventive Medicine Professors have used several hundred thousand Federal research dollars to deliberately exaggerate the adverse health effects of air pollution in Southern California. Their research has been used by SCAQMD and CARB to implement and enforce multi-billion dollar regulations that are not justified on a scientific, public health, or economic basis. The USC Professors have not refuted the strong evidence presented in expose.

This evidence has been sent to USC President, USC Provost, and USC Vice President of Research, and USC has not acknowledged doing anything inappropriate.

April 24, 2019
American Lung Association
“State of the Air 2019”

(<https://www.lung.org/our-initiatives/healthy-air/sota/>)

“43.3% of Americans live in counties that have monitored unhealthy ozone and/or particle pollution”

“Breathing particle pollution may trigger illness, hospitalization and premature death”

“U.S. could prevent approximately 34,000 premature deaths a year if the nation could lower annual levels of particle pollution by 1 $\mu\text{g}/\text{m}^3$ ”

8 of 10 Most Polluted Annual $\text{PM}_{2.5}$ Counties are in California
10 of 10 Most Ozone Polluted Counties are in California

American Lung Association “State of the Air”

Authors with Most Citations	2019	2010
Richard T. Burnett Health Canada	7	4
Douglas W. Dockery Harvard TH Chan SPH	8	3
Francine Dominici Harvard TH Chan SPH	12	6
C. Arden Pope III BYU Economics	11	12
Joel D. Schwartz Harvard TH Chan SPH	37	13
Annette Zanobetti Harvard TH Chan SPH	18	9
Top 15 Non-USC Investigators	138	69
Edward L. Avol USC Prev Med	7	3
Kiros T. Berhane USC Prev Med	6	1
W. James Gauderman USC Prev Med	9	6
Frank D. Gilliland USC Prev Med	7	3
Michael Jerrett USC Prev Med→UCLA SPH	8	3
Rob S. McConnell USC Prev Med	7	2
Jonathan M. Samet USC→CO SPH & ALA SOTA	9	5
Duncan C. Thomas Statistics USC Prev Med	4	0
Top 22 Current & Former USC Investigators	81	26
Citations of 37 Promoters of AP Effects	219	95
Citations of 30 Critics of AP Effects	0	0

April 25, 2019 Nature Editorial

“Stop denying the risks of air pollution:

**Research linking fine particulate pollution and premature deaths
is under attack in the United States and other countries.”**

(<https://www.nature.com/articles/d41586-019-01234-2>)

Responses by Louis Anthony Cox, Jr., Chair EPA CASAC

Letter Submitted to Nature: “sound science entails use of clear definitions, explicit derivations of conclusions, reproducible tests of predictions against observations, and careful qualification of causal interpretations and conclusions to acknowledge remaining ambiguities or conflicts in evidence. . . . My hope and expectation is that the present CASAC will continue to use scientific analysis of evidence to inform policy, rather than letting policy preferences and judgments inform interpretation of evidence.”

April 27, 2019 Cox Global Epidemiology Article:

“Communicating more clearly about deaths caused by air pollution”

(<https://doi.org/10.1016/j.gloepi.2019.100003>)

**June 12, 2019 Enstrom Complaint to
EPA Scientific Integrity Official
Francesca T. Grifo, PhD
Against 2018 EPA PM Integrated Science
Assessment Lead Jason D. Sacks, MPH**

**In spite of overwhelming NULL US evidence since 2009,
2018 Draft EPA PM ISA falsely states: ‘Overall, recent
epidemiologic studies build upon and further reaffirm the
conclusions of the 2009 PM ISA for total mortality,’ and
‘Collectively, this body of evidence is sufficient to
conclude that a causal relationship exists between
long-term PM_{2.5} exposure and total mortality.’**

(<http://scientificintegrityinstitute.org/SIOGrifo061219.pdf>)

Conclusions

- 1) Strong Evidence from Eight Major US Cohorts That $PM_{2.5}$ Does Not *Cause* Premature Deaths
- 2) Strong Evidence That Lead Researchers, EPA, and HEI Have Falsified $PM_{2.5}$ Deaths in the US
- 3) EPA Must Adopt and Implement Proposed RULE “Strengthening Transparency in Regulatory Science”
- 4) EPA Must Use This RULE in Integrated Science Assessments of $PM_{2.5}$ NAAQS and Ozone NAAQS
- 5) Aggressive Campaign is Needed Against All Air Pollution Pseudoscientists in the US

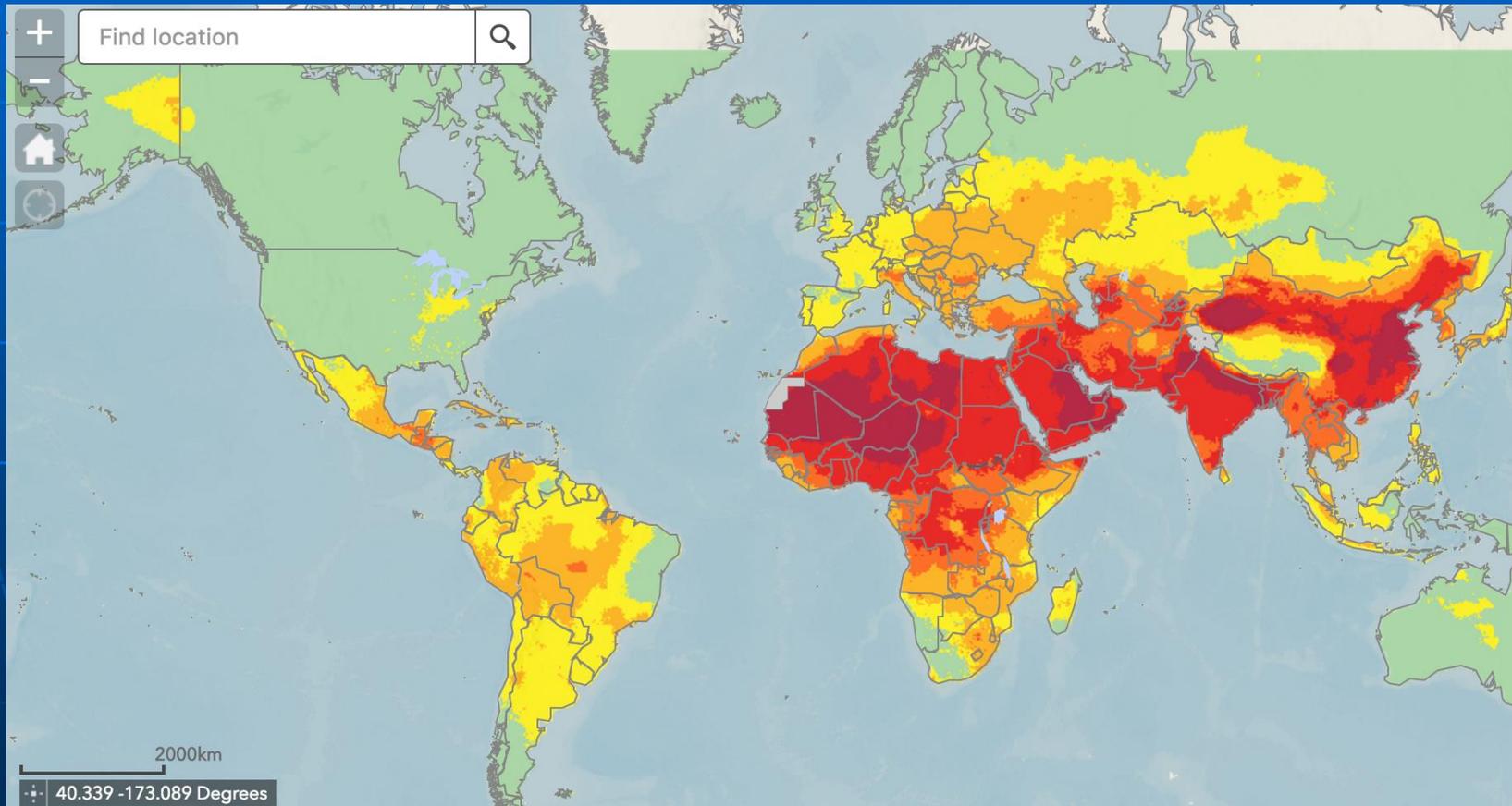
**May 13, 2017 *Lancet* 'Global Burden of Disease'
by HEI Aaron Cohen & BYU C. Arden Pope, III
(using flawed PM_{2.5} deaths methodology)**

Table 2. 2015 Deaths Attributed to PM_{2.5}

<u>Country</u>	<u>Deaths</u>	<u>Death Rate</u> (per 100,000)	<u>Mean PM_{2.5}</u> (μg/m³)
USA	88,400	18.5	8.4
China	1,108,100	84.3	58.4
India	1,090,400	133.5	74.3
Pakistan	135,100	136.3	65.0
Bangladesh	122,400	133.2	89.4
World	4,200,000		

World Health Organization Map 2015 Annual Mean Ambient PM_{2.5} (µg/m³)

<http://www.who.int/airpollution/en/>



Xi Jinping

President of the People's Republic of China

