

Scientific Misconduct in PM_{2.5} Epidemiology

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Major Points

1. Basics of PM_{2.5} & Premature Death Claims
2. Problems with Epidemiology of PM_{2.5} Deaths
3. ACS CPS II & PM_{2.5} Death Claims Since 1995
4. New Analysis of CPS II Finds No PM_{2.5} Deaths
5. Scientists & Journals Block Null PM_{2.5} Results
6. End 'Secret Science' & Reassess EPA NAAQS

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

PM_{2.5} is mainly from combustion: forest fires, residential burning, diesel engines, and China PM_{2.5} (up to 30% in CA)

US EPA established the 1997 Annual National Ambient Air Quality Standard (NAAQS) for PM_{2.5} as $15 \mu\text{g}/\text{m}^3$, which was lowered to $12 \mu\text{g}/\text{m}^3$ in 2012, based largely on “secret science” epidemiology

The PM_{2.5} NAAQS has been used to justify numerous EPA regulations that have multi-billion dollar economic impacts in US: State Implementation Plans, Air Quality Management Plans, CARB Truck and Bus Regulation, EPA Clean Power Plan, 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 US Ambient Exposure of 8.4 µg/m³
~1.2 grams/80 years

PM_{2.5} Inhaled from 100 Cigarettes ~ 4.0 grams

Benefit of EPA PM_{2.5} Regulations Based on Claim of 'PM_{2.5} Premature Deaths' and Assumed \$10 Million 'Value of Statistical Life' for Each Death

EPA claim that PM_{2.5} *causes* 'premature deaths' is based on invalid evidence that the relative risk (RR) between PM_{2.5} and total mortality is greater than 1.0 in US epidemiologic cohort studies

EPA uses unjustified and exaggerated assumptions to claim that the 'value of statistical life (VLS)' is \$10 million for each 'premature death'

Problems with 'PM_{2.5} Premature Deaths'

1) 'Secret Science' Invalidated by Reanalysis:

ACS CPS II PM_{2.5} studies invalidated by objective reanalysis

2) No Etiologic Mechanism:

No experimental proof that 1 gm or 5 gm of PM_{2.5} causes death

3) Weak Epidemiologic Risk:

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

4) Geographic & Temporal Variation:

Small and declining PM_{2.5}-mortality risk in most of US

5) Ecological Fallacy:

PM_{2.5} monitors exaggerate actual human exposure

6) Confounding Variables:

Co-pollutants, etc. weaken PM_{2.5}-mortality relationship

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

1995 *AJRCCM* Article by Pope Thun

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

2000 HEI Reanalysis Report by Krewski Jerrett

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

2009 HEI Research Report 140 by Krewski Jerrett Pope Thun

Totally Ignored PM_{2.5} Risk Variation and Best PM_{2.5} Data

2017 *Dose-Response* Article by Enstrom

Found NO PM_{2.5} Risk in CPS II Based on Best PM_{2.5} Data

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

<http://journals.sagepub.com/doi/10.1177/1559325817693345>

1997-2000 HEI Reanalysis Project

Co-ordinated by HEI Epidemiologist Aaron J. Cohen, DSc

July 25, 1997 Request for Qualifications

“HEI is seeking applications representing teams consisting of 2-4 epidemiologists, statisticians and air pollution exposure experts”

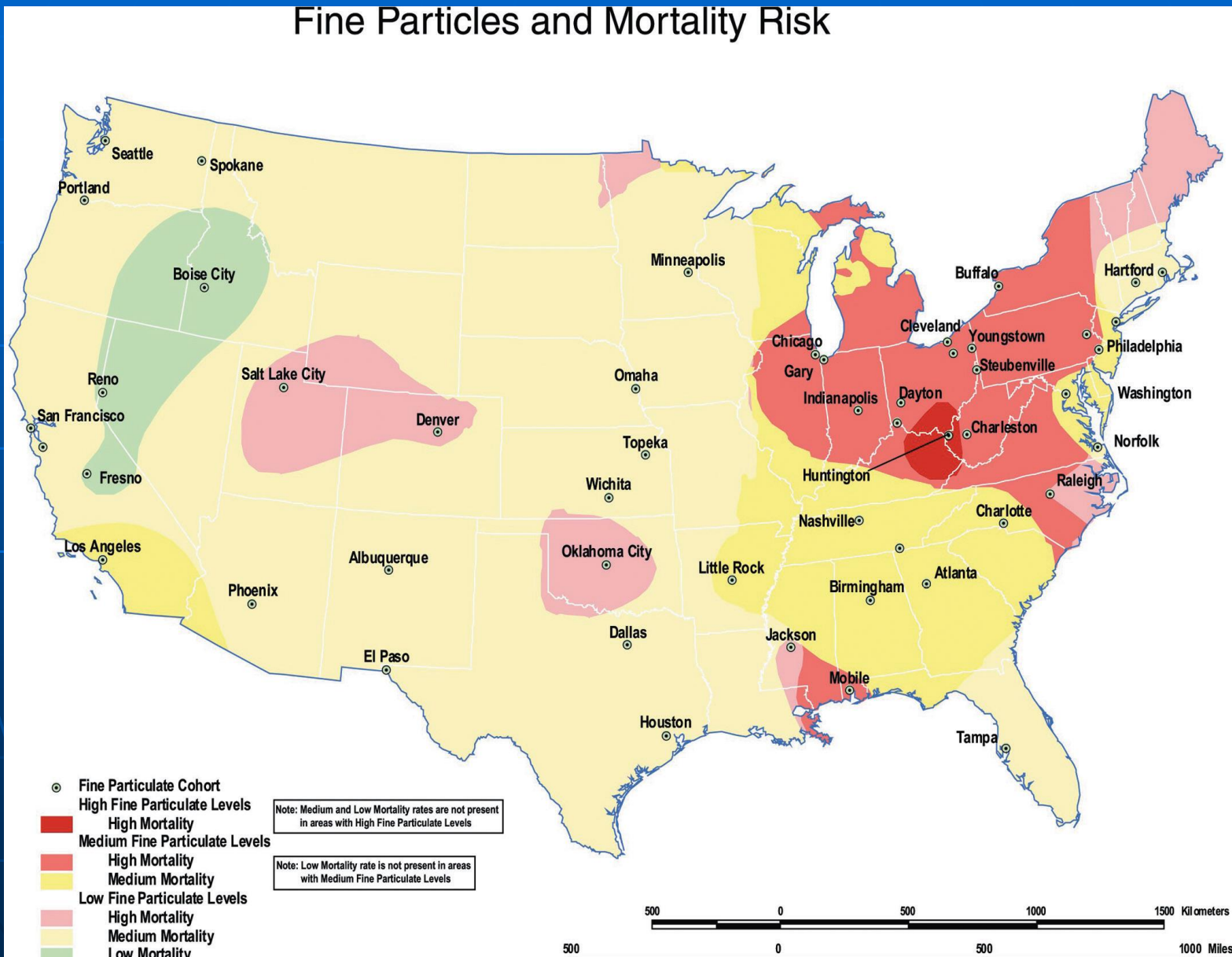
“Objectives and Scope: 2) Conduct sensitivity analyses to test the robustness of the original findings and interpretations to alternative analytic approaches”

Of 13 teams who responded, HEI selected 31-member foreign team of Statistician Daniel Krewski, based at U Ottawa. It included Geographer Michael Jerrett and Statistician Richard Burnett, but had only one Epidemiologist, Yue Chen, MD, PhD (Shanghai Med U), not a co-author on HEI 2000 or HEI 2009

2000 Krewski HEI Reanalysis Report Figure 21

1982-1989 CPS II PM_{2.5} Mortality Risk Varies in US

Fine Particles and Mortality Risk



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

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

Fully Adjusted for 50 Counties in Continental US

IPN [Hinton]	195,215	1.025 (0.990-1.061)
HEIDC [PM _{2.5} DC]	216,897	1.024 (0.987-1.061)
HEI [PM _{2.5} OI MD]	195,215	1.082 (1.039-1.128)

Fully Adjusted for Ohio Valley (IN,KY,OH,PA,WV)

IPN	42,174	1.050 (0.918-1.201)
HEIDC	43,945	1.048 (0.922-1.191)
HEI	42,174	1.111 (0.983-1.256)

Fully Adjusted for States Other Than Ohio Valley

IPN	153,041	0.975 (0.936-1.051)
HEIDC	172,952	0.960 (0.919-1.003)
HEI	153,041	1.025 (0.975-1.078)

CA NM WV Counties with PM_{2.5} Values Used in Pope 1995, HEI 2000, HEI 2009, Enstrom 2017

<u>State</u>	<u>ACS</u>	<u>County</u>	<u>1979-83 PM_{2.5} (µg/m³)</u>		
			<u>IPN</u>	<u>HEIDC</u>	<u>HEI</u>
	<u>Div-Unit</u>		(N=85)	(N=63)	(N=50)
CA	06001	Alameda	14.3882		
CA	06002	Butte	15.4525		
CA	06003	Contra Costa	13.9197		
CA	06004	Fresno	18.3731	10.3	10.3
CA	06008	Kern	30.8628		
CA	06051	Los Angeles	28.2239	26.8	21.8
CA	06019	Riverside	42.0117		
CA	06020	San Diego	18.9189	18.9	
CA	06021	San Francisco	16.3522	16.4	12.2
CA	06025	Santa Barbara	10.6277		
CA	06026	Santa Clara	17.7884	17.8	12.4
NM	34201	Bernalillo	12.8865	12.9	9.0
WV	58117	Ohio	23.9840		[33.4]

Enstrom 2017 Analysis of PM_{2.5} and Total Mortality During 1982-1988 in California ACS CPS II Cohort Compared with Krewski 2010 HEI Special Analysis

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

Enstrom 2017 Fully Adjusted For 1982-1988 Deaths

IPN (4 Counties) 36,201 0.879 (0.805-0.960)

HEI (4 Counties) 36,201 0.870 (0.788-0.960)

Krewski 2010 Fully Adjusted For 1982-1989 Deaths

“Same” Standard Cox Model

HEI (4 Counties) 40,408 0.872 (0.805-0.944)

“Different” Standard Cox Model

HEI (4 Counties) 38,925 0.893 (0.823-0.969)

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

<u>Author & Year</u>	<u>CA Cohort</u>	<u>Relative Risk (95% CI)</u>
McDonnell 2000	AHSMOG	RR ~ 1.03 (0.95-1.12)
Enstrom 2005	CA CPS I	RR = 1.00 (0.98-1.02)
Zeger 2008	MCAPS “West”	RR = 0.99 (0.97-1.01)
Jerrett 2011 9 RRs	CA CPS II	RR = 1.00 (0.99-1.01)
Ostro 2015	CA Teachers	RR = 1.01 (0.98-1.05)
Thurston 2016	CA NIH AARP	RR = 1.02 (0.99-1.04)
Weighted Average (Six Cohorts)		RR = 1.00 (0.99-1.01)

(<http://scientificintegrityinstitute.org/ORI111116.pdf>)

**PM_{2.5} and Total Mortality in US and California:
Enstrom 2017 re 1982-1988 ACS CPS II Cohort
Thurston 2016 re 2000-2009 NIH AARP Cohort**

<u>Geographic Area</u>	<u>Subjects</u>	<u>Relative Risk (95% CI)</u>
<u>United States</u>		
Enstrom Analysis Fully Adjusted for 1982-1988 Deaths 85 Counties	269,766	1.023 (0.997-1.049)
Thurston Analysis Fully Adjusted for 2000-2009 Deaths 6 States & 2 Cities	517,041	~1.025 (1.000-1.049)
<u>California</u>		
Enstrom Analysis Fully Adjusted for 1982-1988 Deaths 11 Counties	60,521	0.992 (0.954-1.032)
Thurston Analysis Fully Adjusted for 2000-2009 Deaths 58 Counties	160,209	~1.017 (0.990-1.040)

2017 Enstrom Requests to Confirm/Refute NO PM_{2.5} Deaths in CPS II in *Dose-Response*

March 10 Email to HEI Pres Greenbaum & Scientist Cohen

April 10 Email to Lead Authors Pope & Krewski

May 12 Email to HEI Board Chair Richard Celeste

May 26 Email to HEI 2009 Co-Author Michelle Turner

June 15 Repeat Email to HEI Reanalysis Scientist Cohen

July 4 Email to ACS Data Core Director Ryan Diver

August 4 Email Invitation to Diver, Gapstur, Pope

(<http://scientificintegrityinstitute.org/DR073117.pdf>)

Evasive Responses to 2017 Enstrom Requests re NO PM_{2.5} Deaths in CPS II

May 9 Letter to Editor of *Dose-Response* by Pope-Krewski-Gapstur-Turner-Jerrett-Burnett

Did Not Confirm or Refute Any Enstrom Evidence of NO PM_{2.5} Deaths in CPS II & Made False Statements Like:

“The assertion regarding selective use of the CPS-II and PM_{2.5} data is false”

“It is not clear how or why his ‘IPN’ PM_{2.5} data differ from the ‘HEI’ PM_{2.5} data”

“the study by Enstrom does not contribute to the larger body of evidence on the health effects of PM_{2.5}”

<http://scientificintegrityinstitute.org/DR073117.pdf>

C. Arden Pope, III, Ph.D., BYU Economics

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

1981 Ph.D. 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 Many Null CA results from Jerrett 2013 *AJRCCM* paper

Ignored Enstrom Invitation to Attend June 11, 2015 ICC-10

Ignored Several Requests to Challenge 2017 *Dose-Response*

Ignored Enstrom Invitation to Attend August 12, 2017 DDP

(<http://scientificintegrityinstitute.org/Pope041017.pdf>)

Michael L. Jerrett, Ph.D., USC, UCB, UCLA

(PM_{2.5} 'Expert' Who Never Cites His or Others' Null Evidence)

1996 Ph.D. in Geography from U Toronto

“Green cost, red ink: An environmental accounting of the defensive expenditures made by municipal governments in Ontario”

2013 AJRCCM Jerrett Krewski Thun Pope: PM_{2.5} & CA Deaths

Browns Filed 2014 Claim with UCLA re Jerrett 2013 Paper:
Claim Ignored by UCLA Chancellor Block & Provost Waugh

Enstrom Refiled Browns' Claim with UCLA in 2015:
Claim Dismissed by UCLA Research Integrity Officer Goldberg

Enstrom Filed 2016 Detailed Claim with UCLA re Jerrett 2013:
Claim & Null Findings Dismissed by UCLA RIO Karagozian

Enstrom Filed 2016 Detailed Claim with US ORI re Jerrett 2013:
ORI Officer Concluded Jerrett 2013 shows NO PM_{2.5} Deaths

(<http://scientificintegrityinstitute.org/ORI111116.pdf>)

(<http://www.scientificintegrityinstitute.org/Hohmann122116.pdf>)

American Cancer Society Officials

(Otis Brawley, M.D., Susan Gapstur, Ph.D.,
Michael Thun, M.D., Alpa Patel, Ph.D., and W. Ryan Diver)

Refuse to Clarify CPS II Findings re PM_{2.5}

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

ACS Refused to Cooperate with Qualified Ph.D.-level PM_{2.5}
Critics, including Drs. Enstrom, Young, and Briggs

ACS Violated CPS II Subject Confidentiality by Allowing
Home Addresses for Use in Jerrett 2013 AJRCCM Paper

ACS Continues to Participate in Falsification of PM_{2.5} Deaths
in CPS II Cohort and WILL NOT Respond to Critics

(<http://scientificintegrityinstitute.org/GapsturEns092013.pdf>)

(<http://scientificintegrityinstitute.org/Patel112513.pdf>)

Health Effects Institute President Daniel W. Greenbaum and Chief Scientist Aaron J. Cohen Have Never Clarified 2000 HEI Reanalysis Findings re CPS II

HEI 2000 Reanalysis Never Tested Sensitivity of
PM_{2.5} Mortality Risk in Pope 1995 with best PM_{2.5} Data

Since 2002 HEI has not provided PM_{2.5} Mortality Risk
for 50 Cities in Pope 1995 and HEI 2000 Figures 5 and 21

Krewski 2010 HEI Analysis: No PM_{2.5} Deaths in CA CPS II

HEI Has Not Conducted Requested Analysis of PM_{2.5}
Mortality Risk in CPS II for Ohio Valley and Other States

Greenbaum Accepted June 21, 2017 “nobel prize” from
CARB for “sustained leadership on air pollution health science”
(<http://scientificintegrityinstitute.org/Greenbaum031017.pdf>)

2007 Jerrett *SERRA* Figure 3 NO 1982-2000 CPS II PM_{2.5} Mortality Risk by Period

Stoch Environ Res Risk Assess (2007) 21:511–522

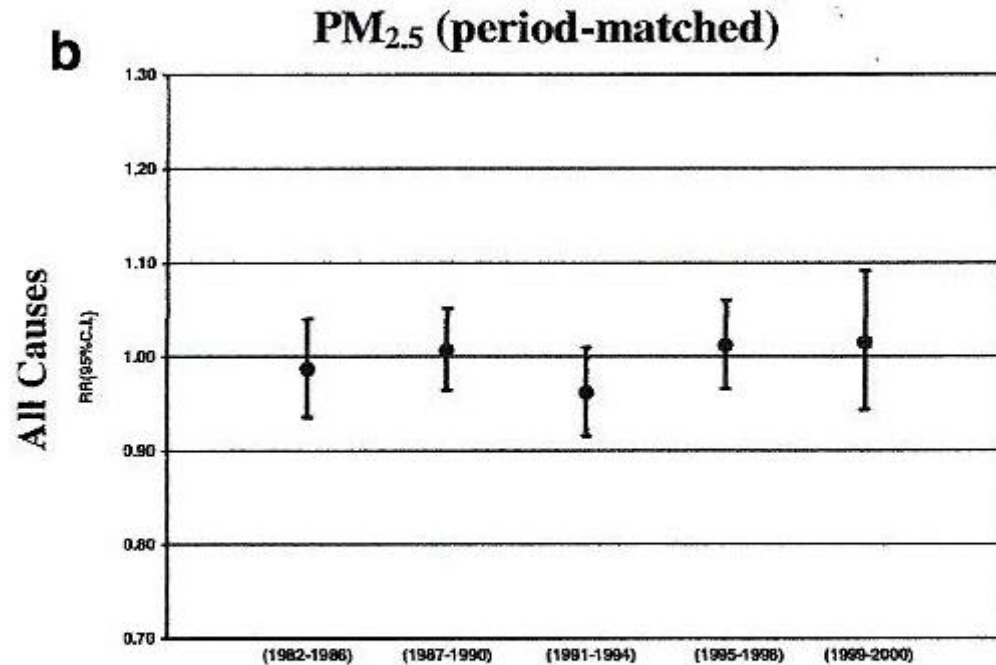


Fig. 3 a Relative risks for all-cause, cardiopulmonary and lung cancer deaths estimated for five time periods of the follow-up (1982–1986, 1987–1990, 1991–1994, 1995–1998, and 1999–2000) with measured exposures. **b** Relative risks for all-cause, cardiopulmonary

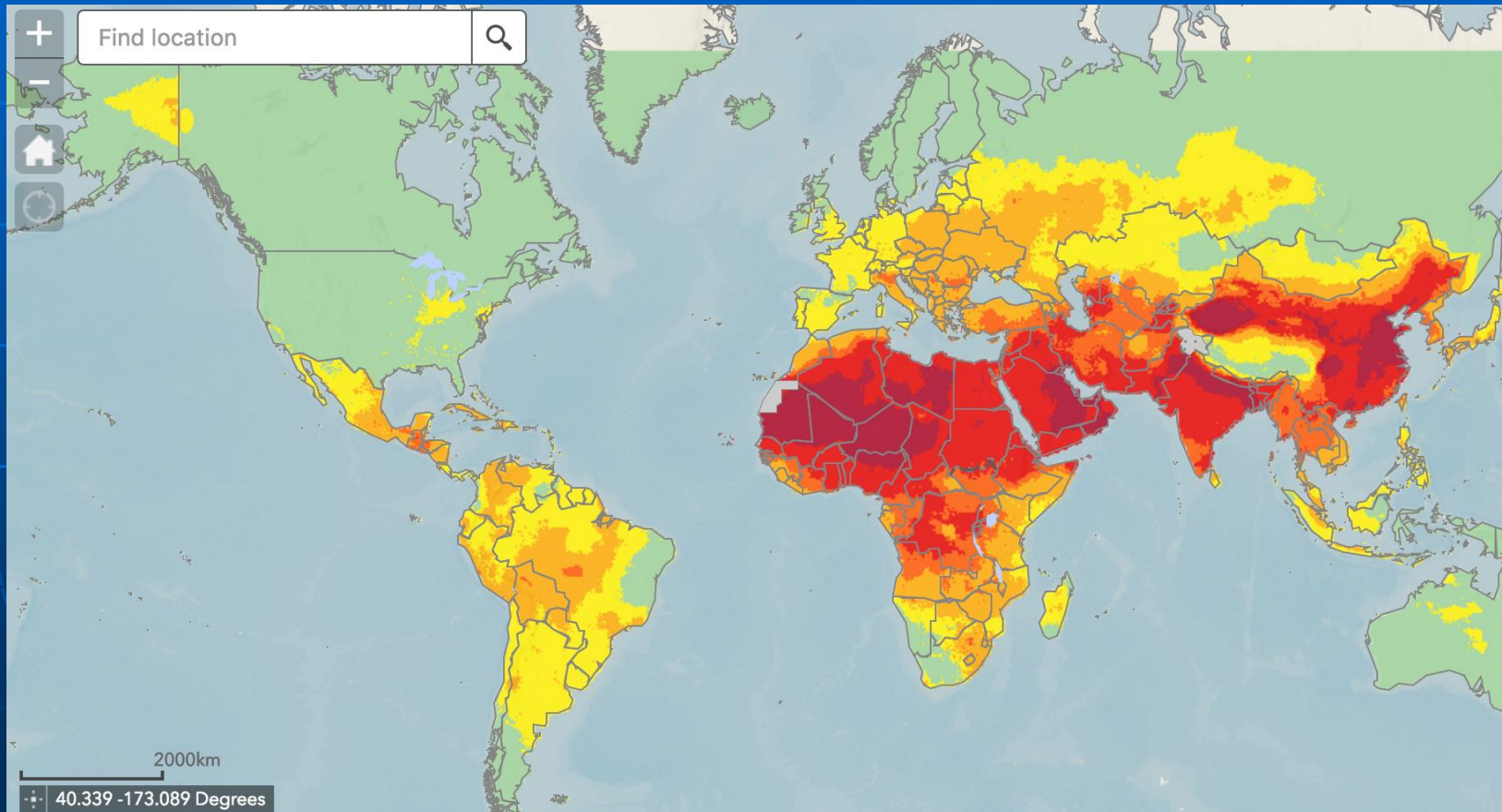
May 13, 2017 (on line April 10, 2017) *Lancet* 'Global Burden of Disease' by Cohen & Pope

2015 Deaths Attributed to PM_{2.5}

Table 2

<u>Country</u>	<u>Deaths</u>	<u>Death Rate</u> (per 100,000)	<u>Mean PM_{2.5}</u> ($\mu\text{g}/\text{m}^3$)
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} ($\mu\text{g}/\text{m}^3$)



***NEJM* Rejection of Enstrom on PM_{2.5} Deaths**

Editor-in-Chief Jeffrey Drazen Rejected:

October 2004 Manuscript Showing NO Relationship Between PM_{2.5} & Total Mortality in California ACS CPS I in Spite of One Positive Review for This Major Cohort Study

September 2015 Manuscript “Particulate Matter Does Not Cause Premature Deaths” Without Peer Review

June 2016 Manuscript on First Independent Analysis of PM_{2.5} and Total Mortality in CPS II in Spite of One Positive Review

June 2016 Request for Reconsideration of June 2016 Decision

July 2017 Letter Criticizing June 2017 NEJM Article on PM_{2.5} Deaths in Medicare Cohort (pending)

***Science* Rejection of PM_{2.5} Deaths Papers**

Editor Marcia McNutt Rejected June 2015 Letter re Falsification
in Jerrett 2013 and Need for Secret Science Reform Act

July 2015 Policy Forum on PM_{2.5} Rejected Without Review

August 2015 Perspective on PM_{2.5} Rejected Without Review

June 2016 PM_{2.5} Deaths CPS II Paper Rejected Without Review

Enstrom 2017 Findings That PM_{2.5} Does Not Cause Deaths
and Other Evidence Shows Publication Bias of *Science*

https://www.nas.org/articles/nas_letter

March 9, 2017 US House Science Committee

H.R. 1430 “Honest and Open New EPA Science Treatment (HONEST) Act of 2017”

“To prohibit the Environmental Protection Agency from proposing, finalizing, and disseminating regulations or assessments based upon science that is not transparent or reproducible.”

H.R. 1431 “EPA Science Advisory Board Reform Act of 2017”

“the scientific and technical points of view represented on and the functions to be performed by the Board are fairly balanced among the members of the Board”

‘Science Has Taken A Turn Toward Darkness’

Lancet Comment by Editor Richard Horton

April 11, 2015 The Lancet Vol 385 Page 1380

“‘A lot of what is published is incorrect.’ . . . one of the most sensitive issues in science today: the idea that something has gone fundamentally wrong with one of our greatest human creations.

The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness.”

‘Scientists Who Cheat’

June 1, 2015 New York Times Editorial

“Cheating in scientific and academic papers is a longstanding problem, but it is hard to read recent headlines and not conclude that it has gotten worse.

The scientific community clearly needs to build a better safety net.

It can start by ensuring that scientists, especially peer reviewers, are allowed to see the underlying data of a paper, which researchers are typically reluctant to share.”

Nikolai I. Vavilov (1887-1943)



Trofim D. Lysenko (1898-1976)



Lysenko Pseudoscience

Lysenko, non scientist, gained favor of Stalin
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

Particulate Matter Pseudoscience

A few activist scientists publish most major papers
Dissenting scientists are poorly funded & ignored
ACS 'secret science' findings cannot be checked
Activists from ALA, UCS, NRDC file demand lawsuits
EPA, CARB, local agencies exaggerate health effects
Unproven 'PM_{2.5} Premature Deaths' used to justify
strict EPA regulations which hurt general public

Elmer Gantry 1927

by Nobel Laureate Sinclair Lewis



Conclusions

- 1) Strong Evidence from Two Major US Cohorts That $PM_{2.5}$ Does Not *Cause* Premature Deaths
- 2) Strong Evidence That EPA, HEI, and Lead $PM_{2.5}$ Researchers Have Falsified the $PM_{2.5}$ and Total Mortality Relationship Since 1995
- 3) H.R. 1430 and H.R. 1431 Must Become Law and There Must Be Complete Reassessment of EPA NAAQS as per Those Laws
- 4) California Waivers (Clear Air Act Section 209) Must No Longer Be Granted
- 5) Aggressive Campaign Needed Against US Researchers Who Conduct $PM_{2.5}$ Pseudoscience