

Reproducibility is Essential to Combating Environmental Lysenkoism

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April 30, 2018 EPA Transparency Rule

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

83 Federal Register 18,768

Summary

“The proposed regulation provides that when EPA develops regulations, . . . , 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.”

<http://scientificintegrityinstitute.org/JEESAB011320.pdf>

<https://wattsupwiththat.com/2020/01/22/secret-science-under-attack-part-1/>

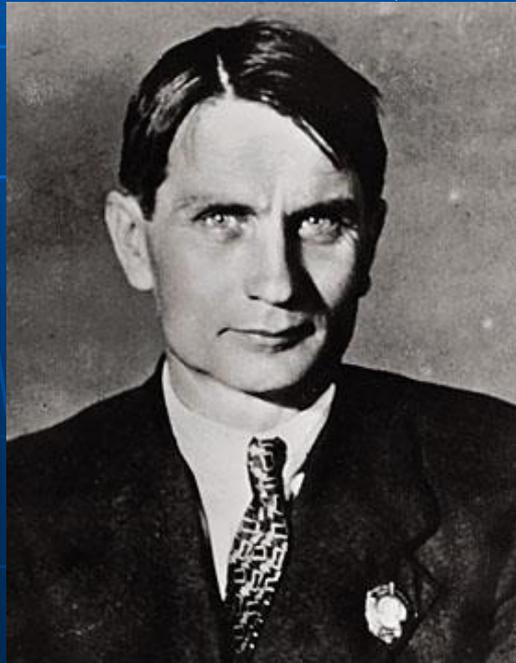
<https://wattsupwiththat.com/2020/01/23/secret-science-under-attack-part-2/>

<https://wattsupwiththat.com/2020/02/02/secret-science-under-attack-part-3/>

Trofim Denisovich Lysenko (1898-1976)

Agronomist destroyed agriculture in the Soviet Union and caused starvation by promoting false plant genetics and suppressing honest scientists with help from Joseph Stalin.

Current US Lysenkoism involves promoting PM_{2.5} deaths by misusing epidemiology, statistics, and toxicology and by suppressing honest scientists with ad hominem smears, lack of funding, lack of citation, and career termination



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 1982 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.

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) Uncontrolled Confounding Variables:

Co-pollutants, temperature, others weaken any effect of PM_{2.5}

4) Enstrom Reanalysis Reveals Irreproducibility:

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}-Deaths₅

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

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

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

1997-2000 Health Effects Institute Reanalysis

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”

Of 13 teams who responded, HEI selected 31-member Canadian team lead by Statistician Daniel Krewski, Statistician Richard Burnett, and Geographer Michael Jerrett, with only ONE Epidemiologist who was not involved with HEI 2000

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

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 [PM _{2.5} DC]	189,676	1.023 (0.984-1.064)
HEI [PM _{2.5} 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)

Enstrom 2017 Reanalysis of PM_{2.5} & 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)

Enstrom 2017 Reanalysis Done with Strict Confidentiality, Speed, No Grant, & NO ACS Help

Strong Resistance by American Cancer Society
(CEO Gary Reedy, Former EVP Res Otis Brawley,
VP Epi Susan Gapstur, Former VP Epi Michael J. Thun)

ACS Opposes EPA Transparency Rule for Invalid Reasons

ACS Disowns Enstrom 2017 & Refuses Joint Analyses of CPS II

ACS Refuses to Analyze PM_{2.5} Deaths in 1992 CPS II Nutrition Cohort (N=184,000) & 2006 CPS 3 Cohort (N=304,000)

ACS Stands by CPS II PM_{2.5} Deaths for PM_{2.5} NAAQS and Lists EPA PM_{2.5} Policies Among “Our Proudest Achievements”

August 1, 2013 House Science Committee Subpoena
produced a de-identified version of 1974 Harvard Six Cities
Study cohort data for July 2012 EHP article by Lepeule,
Laden, Dockery, and Schwartz: SAS data file in Anderson-
Gill format named “Lepeule2012_data_0713.sas7bdat”
(possessed by Harvard, HSC, Enstrom, & presumably EPA since 2013)

Six key variables for last five SAS data file records are:

Cityc	rstrata	ptime	y	ypm2_5	pm2_5b	deadt
TOP	25615	1	9.8	12.3	0	
TOP	25620	0.058864	11.2	11.7	1	
TOP	25620	1	11.2	11.7	0	
TOP	25632	1	10.0	11.6	0	
TOP	25643	0.640657	8.7	12.1	0	

Chronic Exposure to Fine Particles and Mortality: An Extended Follow-up of the Harvard Six Cities Study from 1974 to 2009 (Lepeule 2012) Published Table 2 shows NO Significant PM_{2.5}-Total Deaths Relationship Since 1991

Enstrom Analysis of “Lepeule2012_data_0713.sas7bdat” Shows Exact Agreement with Key Results in Lepeule 2012

Table 2. PM_{2.5} and Total Deaths for 8,096 H6CS Subjects

Follow-up	Subjects (Person-Years)	Relative Risk (95% CI)
1974-1982	8,096 (58,798)	1.06 (0.96–1.17)
1983-1991	7,478 (63,129)	1.32 (1.16–1.50)
1992-2000	6,391 (51,800)	1.11 (0.98–1.27)
2001-2009	4,910 (38,340)	1.19 (0.91–1.55)
1974-2009	8,096 (212,067)	1.14 (1.07–1.22) ³

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.

Meta-Analyses of 8 US Cohorts and 6 CA cohorts show NO relationship between PM2.5 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 Random Effects Meta-Analysis Summary		1.014 (0.973-1.057)

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

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

EPA PM Policy Assessment Author Citations

Author Citations by AP Effects

2019 PA

2011 PA

'Positive AP Effects' Authors N=45 TOTAL	710	529
Harvard TH Chan School of Public Health N=21	291	376
Francine Dominici HTHCSPH	27	29
C. Arden Pope III BYU Economics	20	27
Jonathan M. Samet JHUSPH-USCDPM-COSPH	28	88
Joel D. Schwartz HTHCSPH	40	70
Canadian Investigators N=10	277	83
ACS & California Investigators N=14	142	70
'Null AP Effects' Authors N=50 TOTAL	10	8
EPA CASAC Members 2019-20 N=7 TOTAL	9	0

**Stanford METRICS Professor John P.A. Ioannidis’
May 3, 2018 PLoS Medicine Editorial “All science should inform policy
and regulation” states: “The Six Cities [8] and American Cancer Society
[9] studies are exemplary large-scale investigations, with . . . detailed re-
analysis of results and assessment of their robustness by entirely
independent investigators [10].”**

**Enstrom’s May 9, 2018 Email to Ioannidis states “My March 28, 2017
Dose-Response article . . . found that both the ACS CSP II study [9] and
HEI Reanalysis Report [10] are seriously flawed and do not support the
claim that fine particulate matter causes premature deaths.”**

**Ioannidis’ May 9, 2018 Reply states “I was aware of it, as well as of the
reply to your re-analysis which I found more convincing In all, I
believe that my statement in the editorial is correct.”**

Ioannidis has refused any further discussion with me on this matter.

August 7, 2018 Harvard Letter by Wendy B. Jacobs

**Co-Signed by 96 Professors Urging Withdrawal of Proposed EPA RULE
STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE**

“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 TH Chan School of Public Health &

Professors who Claim PM2.5 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 NEJM Editor-in-Chief Since September 2019

June 12, 2019 Enstrom Complaint to EPA

**Scientific Integrity Official Francesca T. Grifo, PhD,
Accuses EPA PM Assessment Lead Jason D. Sacks, MPH, of
violating EPA Scientific Integrity Policy by falsifying the research record
on PM_{2.5} deaths and making statements like: “a causal relationship
exists between long-term PM_{2.5} exposure and total mortality.”**

**September 4, 2019 Response from SIO Deputy Vincent Cogliano, PhD,
states that “falsification does not include the difference of opinions
present” and SIO “does not . . . evaluate . . . their differing opinions”**

**Thus: SIO States EPA Staff Can Write Anything Regarding
PM_{2.5} Deaths Without Violating EPA Scientific Integrity Policy**

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

Key Author of Harvard Six Cities Study (Dockery 1993) and
ACS CPS II (Pope 1995) Used to Justify 1997 PM_{2.5} NAAQS

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

Refused Enstrom’s Repeated Invitations Since 2008 to
Objectively Assess PM_{2.5} Deaths in CA and US

Refuses to Confirm or Refute 2017 *Dose-Response* Reanalysis

Pope Analyses of PM_{2.5} & Total Mortality in NHIS since 2017 Do Not Cite Pope 1995, HEI 2000, Enstrom 2017

C. Arden Pope III, et al. *Air Quality, Atmosphere & Health* (1 Apr 2018)

C. Arden Pope III, et al. *Enviro Health Perspect* (24 Jul 2019)

Jacob S. Lefler, Pope, et al. *Environmental Health* (21 Nov 2019)

UC Berkeley Ag Econ PhD Student Jacob S. Lefler, former BYU student, falsified research record and made apparent error in analysis of NHIS, RR=1.10 (1.07-1.13) per 10 µg/m³ increase in PM_{2.5},

Compared with Parker 2018 Corrected Analysis of NHIS, which found RR=1.02 (0.98-1.06) per 10 µg/m³ increase in PM_{2.5}

BMJ Corruption of PM2.5 Peer Review Process

BMJ and BMJ Open Immediately Rejected Enstrom CPS II Reanalysis Without Peer Review in June 2016

In January 2019 Dr. Sophie Cook, *BMJ* UK Research Editor, asked me to peer review Manuscript BMJ-2018-048424 by Wang, Wei, Dominici, Schwartz, et al. “Air pollution and cause specific risks and costs of hospital admissions” from Harvard TH Chan School of Public Health.

In many emails up to April 1, 2019, I explained my unsuccessful attempts to upload my January 24, 2019 Review recommending Unequivocal Rejection of Manuscript. On April 18, 2019, Dr. Elisabeth Loder stated “Recently, I asked you to review Manuscript ID BMJ-2018-048424 It has since become apparent that I will not need you to review at this time.”

This Manuscript was published in November 27, 2019 *BMJ* with NO reference to January 24, 2019 Enstrom Review.

December 13, 2019 Enstrom eLetter to *Science*

Criticizes the Opposition to the EPA Transparency Rule and Omission of my March 28, 2017 *Dose-Response* Reanalysis in

December 6, 2019 *Science* Editorial “Getting the EPA back on track” by Rice Provost Marie Lynn Miranda and

“Joint statement on EPA proposed rule and public availability of data” by *Science* Editor-in-Chief H. Holden Thorp and five other journal editors

Enstrom Reanalysis and All Other Criticism of PM_{2.5} Deaths since 2015 have been Immediately Rejected without Peer Review by *Science*

Harvey Fineberg Has Conflicts re EPA Transparency

January 23, 2020 JAMA Viewpoint by Harvey Fineberg & David Allison

“The Use and Misuse of Transparency in Research:
Science and Rulemaking at the Environmental Protection Agency”

Citation of HEI 2000 Reanalysis but NO citation of Enstrom 2017
Reanalysis, just strong opposition to EPA Transparency Rule

Moore Foundation President Harvey Fineberg Has Conflicts of Interest
re Harvard TH Chan School of Public Health Undisclosed to JAMA

Professor before and since 1984

Dean 1984-1997

Provost 1997-2001

Negotiated 1997-2000 HEI Reanalysis of H6CS

Current Courtesy Appointment

Actions to Strengthen Reproducibility in Science

Focused on Environmental Epidemiology and EPA

Promote-Approve-Implement EPA Transparency Rule

Reanalyze All (N~10) US Cohort Studies on PM_{2.5} Deaths

Seek Cooperation from Authors of US PM_{2.5} Death Studies

Obtain Peer Review Comments for US PM_{2.5} Death Studies

Demand Scientific Integrity of EPA PM ISA and PM PA Staff

Reject Draft PM ISA & Draft PM PA Until Objective/Accurate

Request Funding for Reanalysis from Moore Foundation