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 (≤2.5 μm 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 μg/m^3, lowered to 12 μg/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 $PM_{2.5}$-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

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

State	ACS Div-Unit	County	1979-83 $PM_{2.5}$ ($\mu g/m^3$) IPN (N=85)	HEIDC (N=63)	HEI (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 [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)

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	ypm2_5	y	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)

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

https://www.intrepidinsight.com/pm25_statreview/ Table B4

Author & Year	US Cohort	Relative Risk (95% CI)
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

Author & Year	CA Cohort	Relative Risk (95% CI)
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

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/m^3 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/m^3 increase in $PM_{2.5}$

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