

SCIENCE Policy Forum

The EPA Transparency Rule is Scientifically Justified and Necessary

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On April 24, 2018 the Environmental Protection Agency (EPA) issued a proposed rule “Strengthening Transparency in Regulatory Science” (Rule) designed to increase the integrity and transparency of the science that is used as the basis for EPA regulations. The latest (March 3, 2020) version of this Rule states “when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation. This includes studies with data and models that are publicly available as well as studies with restricted data and models” (1).

This Rule is completely consistent with the PUBLICATION POLICIES of *Science* Journals. The *Science* policy on “Data and Materials Availability after Publication” is “After publication, all data and materials necessary to understand, assess, and extend the conclusions of the manuscript must be available to any reader of a *Science* Journal. After publication, all reasonable requests for data, code, or materials must be fulfilled. . . . Unreasonable restrictions on data, code, or material availability may preclude publication. . . .” Instead of citing the Rule’s similarity to its own data policy, *Science* has repeatedly and harshly criticized the Rule during the past two years without acknowledging or citing important evidence that demonstrates the need for the Rule.

The criticism of the Rule by *Science* includes the March 13, 2020 Stokstad article, the January 10, 2020 Editor Thorp Editorial, the December 6, 2019 Miranda Editorial, the December 6, 2019 Editor Thorp Joint Statement, the March 21, 2019 Goldman-Dominici Policy Forum, the November 9, 2018 Wagner et al. Policy Forum, and the May 4, 2018 Editor Berg Joint Statement. In addition, *Science* has published numerous news reports criticizing the Rule, with several reports reprinted from *E&E News*, *ClimateWire*, and *Greenwire*. In addition, the AAAS CEO and *Science* Publisher Sudip Parikh issued the March 18, 2020 AAAS Statement: “EPA ‘Transparency Rule’ Weakens the Use of Science in Policymaking,” as well as a March 20, 2020 “Call to Action: Make Your Voice Heard to Protect Science and Public Health” email to AAAS members like me, “voicing opposition to the proposed rule.” I cannot find a single *Science* research article or news report that has presented evidence in support of the Rule or that has challenged the scientific validity of EPA regulations.

The Rule is addressing the fact that many EPA science assessments and regulations are based on scientific findings that cannot be independently verified because the underlying data has been kept “secret” by investigators who have generally used Federal funding to collect their data and conduct their research. In particular, the Rule has its origin in the controversial establishment by EPA of the 1997 National Ambient Air Quality Standard (NAAQS) for fine particulate matter (particles less than 2.5 microns in diameter or PM2.5), which relied upon the non-transparent results of two “secret science” studies. This controversy has been well described from three different perspectives: 1) July 25, 1997 *Science* report by news writer Jocelyn Kaiser “Showdown Over Clean Air Science” (2); 2) August 1, 1997 book “Polluted Science” by science journalist Michael Fumento (3); and 3) 2002 book “The Particular Air Pollution Controversy” by distinguished toxicologist Robert Phalen (4).

The PM2.5 NAAQS as established primarily because of the positive relationship between PM2.5 and total mortality found in the 1993 Harvard Six Cities Study (H6CS) (Dockery 1993) and the much larger 1995 American Cancer Society (ACS) Cancer Prevention Study (CPS II) (Pope 1995). The reliability of this epidemiologic relationship was scientifically challenged because there is no etiologically proven way that inhalation of a few hundred micrograms of PM2.5 per day can cause premature deaths and because the published findings were based on “secret” data that could not be independently reanalyzed in order to assess other explanations for the findings. The scientific uncertainty regarding PM2.5-related mortality and establishing the PM2.5 NAAQS was clearly expressed in the June 13, 1996 letter from the EPA Clean Air Scientific Advisory Committee (CASAC) and the Particulate Matter Review Panel (PMRP) (5). Three of the four epidemiologists who contributed to this letter, Jonathan Samet, Frank Speizer (a coauthor of H6CS), and Jan Stolwijk recommended setting NO PM2.5 annual standard. Two of the three toxicologists who contributed to the letter, Roger McClellan and Daniel Menzel, recommended setting NO PM2.5 annual standard, and the third toxicologist, Joe Mauderly, stated there was great uncertainty regarding the annual standard. CASAC Chair George Wolff opposed setting any PM2.5 standard. In addition, epidemiologists Suresh Moolgavkar and Joseph Lyon, toxicologist Robert Phalen, environmental scientist Fred Lipfert, and others challenged the PM2.5 epidemiology and the establishment of the PM2.5 standard.

The scientific controversy regarding the PM2.5 NAAQS that began in the mid 1990s has continued up to the present time, as described in the 2016 book “Scare Pollution” by Steve Milloy (6). This controversy has been driven by the need for access to the H6CS and CPS II data in order to independently reanalyze the findings in Dockery 1993 and Pope 1995 and the 2000 Health Effects Institute Reanalysis (HEI 2000) of those two studies. During 2011-2018 the House Science Committee (HSC) formulated the “Secret Science Reform Act” and the “HONEST Act” and issued a 2013 Subpoena as concerted efforts to gain access to the data underlying the PM2.5 NAAQS. Since 2018 the EPA Transparency Rule has been a continuation of these House Science Committee efforts. However, the HSC measures and the Rule have been strongly criticized and resisted, especially by EPA-funded researchers who oppose transparency regarding their own research.

A prime example of this criticism is the December 6, 2019 *Science* Editorial by Rice University Provost Marie Miranda, which inaccurately stated “The EPA’s proposed transparency rule does not ensure research rigor or improve transparency” and “Work by the Health Effects Institute [HEI 2000], in which an industry-government-funded partnership reanalyzed data from the Harvard Six Cities Study and the American Cancer Society Study on the link between particulate matter pollution and mortality, represents an excellent model for evaluating the validity of research pivotal to environmental health regulations without compromising confidentiality or excluding studies.” While this editorial cited the HEI 2000 Reanalysis of Pope 1995, it completely omitted the Enstrom 2017 reanalysis of Pope 1995 and

HEI 2000. My independent reanalysis of ACS CSP II data found NO robust relationship between PM2.5 and total mortality and identified major flaws in two Pope 1995 and HEI 2000. Enstrom 2017 demonstrates the importance of obtaining access to and then independently reanalyzing key data underlying EPA regulations. Enstrom 2017 did not violate subject confidentiality and is a model for the data sharing proposed by the Rule. It clearly demonstrates that data access does improve research rigor and transparency.

Furthermore, Enstrom 2017 is prime example of how *Science* has refused to publish direct evidence supporting the Rule. On July 5, 2016 I submitted for peer review my manuscript "Fine Particulate Matter and Mortality in Cancer Prevention Study Reanalysis." My Abstract stated "These findings demonstrate the importance of independent analysis of underlying data and raise serious doubts about the epidemiologic evidence supporting the PM2.5 NAAQS." On July 8, 2016 my manuscript was rejected with NO in-depth review. After I appealed the rejection, I was informed on July 11, 2016 that *Science* would not consider ANY resubmission. My July 13, 2016 submission of the same manuscript to *Science Advances* was rejected on July 30, 2016 with NO in-depth review. Enstrom 2017 was eventually published on March 28, 2017 in *Dose-Response* (7), which details the rejections. Enstrom 2017 has been further strengthened by additional CPS II reanalysis findings in Enstrom 2018 (8). My independent reanalysis was only possible because I was able to obtain an original version of the 1982-1988 CPS ACS II cohort data and documentation. Although my reanalysis strongly challenges the epidemiologic justification for the 1997 PM2.5 NAAQS and provides strong support for the Rule, it has NEVER been cited in *Science* during the past four years.

Another important aspect of the EPA Transparency Rule is that it will force EPA to produce a more transparent and accurate research record. My January 14, 2020 comment to the EPA Science Advisory Board (9) and the December 16, 2019 Letter of EPA CASAC by Chair Anthony Cox (10) provide detailed evidence that the Draft 2018 PM Integrated Science Assessment (ISA) and the Draft 2019 PM Policy Assessment (PA) seriously distort the research record in favor of the claim that PM2.5 causes premature deaths. My Comment provides documentation that the PM ISA and PM PA violate the EPA Principles of Scientific Integrity regarding "Interpreting and presenting results." I have made a very strong case against the validity of the PA PM claim 'Collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term PM2.5 exposure and total mortality.' Not only is there no causal relationship between PM2.5 and total mortality, Table 1 shows that an objective meta-analysis of published results for nine major US epidemiologic cohort studies finds NO relationship between PM2.5 and total mortality (8). In addition, Table 1 shows that the positive relationship in Pope 1995 and HEI 2000 was found to be a null relationship in Enstrom 2017.

Table 1. An objective meta-analysis of the relationship between PM2.5 and total mortality in nine US cohort studies is given in the September 28, 2018 Intrepid Insight (II) article Table B3 [“Statistical Review of Competing Findings in Fine Particulate Matter and Total Mortality Studies”](#)(8).

Nine US Cohorts That Analyzed Fine Particulate Matter (PM2.5) and Total (All-cause) Mortality Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 µg/m³ in PM2.5

US Cohort Studies	HTHCSPH	Author Year	RR Table	F-U Years	RR	95%CI(L)	95%CI(U)
Veterans Study		Lipfert 2000	T6	1986-1996	0.890	0.850	0.950
Medicare (MCAPS) Eastern US	H	Zeger 2008	T3	2000-2005	1.068	1.049	1.087
Medicare (MCAPS) Central US	H	Zeger 2008	T3	2000-2005	1.132	1.095	1.169
Medicare (MCAPS) Western US	H	Zeger 2008	T3	2000-2005	0.989	0.970	1.008
ACS Cancer Prev Study (CPS II)	H	HEI RR140 2009	T34	1982-2000	1.028	1.014	1.043
Nurses Health Study	H	Puett 2009	T3	1992-2002	1.260	1.020	1.540
Health Professionals FU Study	H	Puett 2011	T2	1989-2002	0.860	0.720	1.020
Harvard Six Cities Study (H6CS)	H	Lepeule 2012	T2	1974-2009	1.140	1.070	1.220
Agricultural Health Study		Weichenthal 2015	T2	1993-2009	0.950	0.760	1.200
NIH-AAPR Diet and Health Study	H	Thurston 2016	T2 F3	2000-2009	1.025	1.000	1.049
National Health Interview Survey		Parker 2018	Corr T3	1997-2011	1.016	0.979	1.054
Intrepid Insight Random Effects Meta-Analysis Summary RR					1.031	0.997 - 1.066	

Q Test Statistic = 109.5100704 I² 90.87%

Cochrane's Q Test for Homogeneity of Studies (Null Hypothesis: Studies are Homogenous)

P-Value = 6.69843E-19 → Since Studies fail Test for Homogeneity, Random Effects Meta-Analysis

Yields Summary RR = 1.031 (0.997-1.066), which is statistically consistent with 1.000 (NO relationship)

Comparison of Pope 1995 with Two Reanalyzes: HEI 2000 (see HEI RR140 2009) and Enstrom 2017

CPS II Original Analysis (50 cities)	Pope 1995			1982-1989	1.07	1.04	1.10
CPS II Reanalysis #1 (50 cities)	HEI RR140 2009	T34		1982-1989	1.067	1.037	1.099
CPS II Reanalysis #2 (50 cities)	Enstrom 2017	T2		1982-1988	1.025	0.990	1.061

The EPA Transparency Rule will also force EPA to correct the imbalance that exists in the research record regarding the 'positive findings' and the 'null findings.' Table 2 documents that the Draft 2019 PM PA and Final 2011 PM PA almost exclusively cite the research of 'positive authors,' investigators who publish positive relationships emphasizing the adverse health effects of PM2.5. These PM PAs essentially omitted the 'null authors,' investigators who publish evidence of no health effects of PM2.5 and/or who criticize the PM2.5 health effects findings. To document the magnitude of this bias, I tabulated the names of the first authors of the publications cited in the 2019 PM PA and the 2011 PM PA. Table 2 shows the citations of 45 'positive authors' separated into: Group 1) 21 authors associated with the Harvard TH Chan School of Public Health (HTHCSPH) and/or other northeastern universities; Group 2) 11 Canadian authors; and Group 3) 13 authors associated with the American Cancer Society or California universities. Group 1 authors are cited 291 times, Group 2 authors are cited 329 times, and Group 3 authors are cited 90 times. Thus, the 45 'positive authors' are cited a grand total of 710 times in the 2019 PM PA and 529 times in the 2011 PM PA. By contrast, 50 'null authors' were cited only 10 times in the 2019 PM PA and 8 times in the 2011 PM PA. These 'null authors' include CASAC members, CASAC consultants, myself, and dozens of other distinguished MDs and PhDs dating back more than 30 years. Full details regarding Tables 1 and 2 are contained in my EPA comment (9).

Finally, it is important to realize that investigators associated with the Harvard TH Chan School of Public Health (HTHCSPH) have been responsible for a large portion of the PM2.5 deaths claims, including authorship of six of the nine cohort studies in Table 1. The epidemiologic evidence on PM2.5 deaths used to establish the 1997 EPA PM2.5 regulations came primarily from three of these investigators, known as the 'Particle Hunter Triumvirate': Arden Pope III received graduate training at HTHCSPH and Douglas Dockery and Joel Schwartz have been long-time professors at HTHCSPH. Much of the evidence on PM2.5 deaths is based on misusing epidemiology and statistics, falsifying the research record, failing to identify a causal mechanism, ignoring the damage that air pollution regulations have done to sectors of the US economy, ignoring evidence that air pollution levels are very low in the US, but very high in China, India, and Africa. It is time that EPA regulations are based on a complete and transparent assessment of all the evidence from investigators who rigorously practice the scientific method, particularly as it involves epidemiology, statistics, and toxicology.

AAAS CEO Parikh is correct regarding the Rule in the respect that "this policy would fundamentally change the way science is used to inform regulations and policies that aim to protect public and the environment." This change is necessary and appropriate when one considers that current policy has been distorted by scientifically unjustified regulations on PM2.5 based on 'secret science'. *Science* should not oppose transparency and data access and should not oppose correcting EPA regulations that are scientifically unjustified. *Science* should not oppose honest and transparent science and should allow supporters of the EPA Transparency Rule to make their case to the readers. The EPA Transparency Rule puts the credibility of *Science* on the line.

Table 2. Citations of ‘Positive Authors’ and ‘Null Authors’ in the 2011 Final and 2019 Draft EPA Particulate Matter Policy Assessments (PM PA). Harvard TH Chan School of Public Health (HTHCSPH) Training and/or Position is Indicated. Citations are shown for twelve of the most prolific ‘Positive Authors.’ ‘Null Authors’ include Critics of PM2.5 Death Claims.

		EPA Particulate Matter Policy Assessment	
		Draft 2019	Final 2011
Group 1) 21 HTHCSPH Related & Other NE ‘Positive Authors’			
Michelle L Bell	Yale U	25	39
Douglas W Dockery	HTHCSPH (1979 ScD Env Health HTHCSPH)	7	20
Francine Dominici	JHBSPH→HTHCSPH	27	29
Francine Laden	HTHCSPH (1998 ScD Env Health HTHCSPH)	14	18
C Arden Pope III	BYU→HTHCSPH→BYU (1992-1993 IPH Env Health at HTHCSPH)	20	27
Jonathan M Samet	JHBSPH→USC DPM→CO SPH (1977 MS Epi HTHCSPH)	28	88
Joel D Schwartz	USEPA→HTHCSPH	40	70
George D Thurston	NYU (1983 ScD Env Health Sci HTHCSPH)	16	9
Annette Zanobetti	HTHCSPH	24	51
Total Citations for Group 1 ‘Positive Authors’		291	376
Group 2) 10 Canadian ‘Positive Authors’			
Richard T. Burnett	Health Canada, Ottawa	38	33
Daniel Krewski	U Ottawa	19	34
Total Citations for Group 2 ‘Positive Authors’		277	88
Group 3) 14 American Cancer Society and California ‘Positive Authors’			
Michael Jerrett	CN→USC DPM→UCB SPH→UCLA SPH	52	5
Total Citations for Group 3 ‘Positive Authors’		90	65
Grand Total Citations for 45 ‘Positive Authors’		710	529
Grand Total Citations for 50 ‘Null Authors’		10	8

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