

May 18, 2020

To:

Docket ID No. EPA-HQ-2018-01-0259; FRL-10004-72-ORD

Supplemental Proposed Rule “Strengthening Transparency in Regulatory Science”

<https://www.regulations.gov/comment?D=EPA-HQ-OA-2018-0259-9322>

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

From:

James E. Enstrom, Ph.D., M.P.H.

UCLA and Scientific Integrity Institute

907 Westwood Boulevard #200

Los Angeles, CA 90024

<http://www.scientificintegrityinstitute.org>

jenstrom@ucla.edu

(310) 472-4274

This Comment adds to my March 18, 2020 Comment (<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9335>) and my April 17, 2020 Comment (<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-10834>) in support of the Supplemental Proposed EPA Rule “Strengthening Transparency in Regulatory Science.” On March 18, 2020, the EPA published its [supplemental rule](#) in the Federal Register “This supplemental notice of proposed rulemaking (SNPRM) includes clarifications, modifications and additions to certain provisions in the Strengthening Transparency in Regulatory Science Proposed Rulemaking.” On April 30, 2018, the EPA published its [proposed rule](#) in the Federal Register “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.”

The 2020 Supplemental Rule improved on the 2018 Proposed Rule in three important areas: 1) it will now cover data and models, not just dose-response data and models; 2) it will cover influential scientific information and not just significant regulatory actions; and 3) it will have a “tiered approach” to data access. These improvements will increase the functionality of the Rule in increasing EPA transparency. If authors of a study provide underlying data and models to a third party, they should not block disclosure of such information to other qualified third parties. If data and models are not made public on a particular study, then this study should not be ignored but should be considered secondary to other comparable studies where data and models are made public.

In 2000, the Health Effects Institute did a [reanalysis](#) of the Harvard Six Cities Study and the American Cancer Society study, the two major studies used to justify establishment of the 1997 NAAQS for fine particulate matter (PM_{2.5}). The original investigators refused to share their data with other third

parties, but this type of refusal to share would not be allowed under the Rule. After I obtained access to an original version of the ACS data, I conducted a 2017 reanalysis that found serious flaws in both the Pope 1995 study and the HEI 2000 Reanalysis. As I have explained in my prior comments, my reanalysis reinforces the need for independent reanalysis of the underlying data for studies that are used to justify EPA regulations.

The Rule is necessary to encourage and enforce the use of the scientific method among the investigators who are conducting research, particularly epidemiologic research, that is relevant to EPA regulatory policy. My assessment is that this proposed rule has already gotten the attention of essentially all of the investigators who conduct EPA-related research on environmental factors and disease outcomes. Unfortunately, many of the investigators who find positive relationships strongly oppose the Rule and its transparency requirements. This reaction is certainly true for investigators from the Harvard TH Chan School of Public Health. These investigators have been involved with much of the US-based research relating fine particulate matter to mortality, as well as other EPA-related research. They realize that the Rule will make it very difficult for their nontransparent and irreproducible research to be used to justify future EPA regulations. This is a very positive aspect of the Rule, because nontransparent and irreproducible research should not be used to justify EPA regulations.

The importance of reproducible research in environmental science was addressed at the February 7-8, 2020 National Association of Scholars Conference at the Independent Institute in Oakland: **Fixing Science: Practical Solutions for the Irreproducibility Crisis** (<https://www.nas.org/blogs/event/fixing-science-practical-solutions-for-the-irreproducibility-crisis>). The section on reproducibility in environmental science included talks by me, EPA Science Advisory Board Member S. Stanley Young, PhD, and EPA CASAC Chair L. Anthony Cox, PhD. A brief report on the conference, slides, and videos have been posted (<https://www.nas.org/blogs/article/conference-follow-up-fixing-science>). The video for my talk “Reproducibility is Essential to Combating Environmental Lysenkoism” is here (<https://www.youtube.com/watch?v=X2f6YgA9mzM>) and the link to my slides is here (<http://www.scientificintegrityinstitute.org/NASJEE020820.pdf>).

I close by documenting my difficulty in having the 1984-1997 Dean of the Harvard TH Chan School of Public Health, **Harvey V. Fineberg, MD, PhD**, state the value of the EPA Transparency Rule, as explained in detail below in my rejected March 10, 2020 *JAMA* letter.

From: <leted@jamanetwork.org>
Date: Mon, Mar 23, 2020 at 1:47 AM
Subject: JAMA20-3152 Decision Letter
To: <jenstrom@ucla.edu>

March 23, 2020

Dr James E Enstrom
UCLA and Scientific Integrity Institute

Re: EPA Transparency Rule is Scientifically Justified

Dear Dr Enstrom:

Thank you for your recent letter to the editor. Unfortunately, because of the many submissions we receive and our space limitations in the Letters section, we are unable to publish your letter in JAMA.

[Email Edited and Paragraphs Deleted to Comply with JAMA Privacy Statement]

Sincerely yours,

Jody W. Zylke, MD
Deputy Editor, JAMA
Letters Section Editor

EPA Transparency Rule is Scientifically Justified

Letter to the Editor re

Fineberg HV, Allison DB. The Use and Misuse of Transparency in Research. *JAMA*. 2020;323(7):605-606

James E. Enstrom, PhD, MPH, FFACE
UCLA and Scientific Integrity Institute
jenstrom@ucla.edu

March 10, 2020

Word Count = 400

In their February 18 JAMA Viewpoint opposing the proposed EPA Transparency Rule (1), Drs. Fineberg and Allison misrepresent the scientific justification for the Rule and are not transparent regarding their own conflicts of interest. Contrary to their conclusion that the Rule will “jeopardize public health,” it will increase scientific rigor, transparency, and honesty in the research findings used to justify EPA regulations by requiring independent access to the key data underlying EPA regulations. The March 3

Supplement to the Rule addresses concerns about confidential data by proposing tiered access to such data (2).

The authors mischaracterize the repeated requests for the data relating fine particulate matter (PM_{2.5}) to mortality in the Harvard Six Cities Study (Dockery-Pope 1993) and the 1995 American Cancer Society (ACS) Cancer Prevention Study (CPS II) (Pope-Thun 1995). These requests were primarily driven by strong scientific challenges to the etiologically implausible and still unproven claim that inhaling a few hundred micrograms of PM_{2.5} per day causes premature deaths, not by industry complaints about the costs of complying with EPA PM_{2.5} regulations. The June 13, 1996 EPA CASAC letter illustrates the scientific uncertainty regarding PM_{2.5} causing deaths (3). While the authors twice cite the value of the 2000 Health Effects Institute (HEI) reanalysis, they completely ignore the 2017 Enstrom ACS CPS II reanalysis (4). Enstrom 2017 found NO robust relationship between PM_{2.5} and total mortality and identified major flaws in Pope-Thun 1995 and HEI 2000. Furthermore, 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.

Finally, the authors are not transparent about Dr. Fineberg's conflicts on this issue due to his influential leadership and oversight of the Harvard TH Chan School of Public Health (HTHCSPH). He was HTHCSHP Dean from 1984 to 1997 and Harvard University Provost from 1997 to 2002. During these years, five prominent investigators with HTHCSPH associations were primarily responsible for the epidemiologic evidence on PM_{2.5} deaths that resulted in 1997 EPA PM_{2.5} regulations. Drs. Arden Pope III, Jonathan Samet, and Michael Thun received graduate training at HTHCSPH, and Drs. Douglas Dockery and Joel Schwartz were professors. Drs. Fineberg and Allison have no scientific basis for opposing transparency in EPA regulatory science when data access and independent reanalysis currently challenge the validity of EPA PM_{2.5} regulations (5).

References

1. Fineberg HV, Allison DB. The Use and Misuse of Transparency in Research: Science and Rulemaking at the Environmental Protection Agency. JAMA. 2020;323(7):605-606. doi:10.1001/jama.2019.22026
2. EPA 40 CFR Part 30 [EPA-HQ-OA-2018-0259; FRL-10004-72-ORD] RIN 2080-AA14 Strengthening Transparency in Regulatory Science: Supplemental notice of proposed rulemaking. March 3, 2020 https://www.epa.gov/sites/production/files/2020-03/documents/supplemental_notice_of_strengthening_transparency_in_regulatory_science.pdf
3. EPA CASAC Letter EPA-SAB-CASAC-LTR-96-008 Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter. June 13, 1996 [https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/\\$File/casI9608.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/$File/casI9608.pdf)
4. Enstrom JE. Fine particulate matter and total mortality in Cancer Prevention Study cohort reanalysis. Dose-Response 2017 Mar 28;15(1):1559325817693345. doi: 10.1177/1559325817693345
5. Enstrom JE. Scientific Support for EPA Proposed Rule Strengthening Transparency in Regulatory Science. January 14, 2020 Public Comment to EPA Science Advisory Board [https://yosemite.epa.gov/sab/sabproduct.nsf//6F178C790030BEA3852584F00052DED0/\\$File/Enstrom+Comment+to+SAB+Supporting+EPA+Transparency+Rule+011420.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//6F178C790030BEA3852584F00052DED0/$File/Enstrom+Comment+to+SAB+Supporting+EPA+Transparency+Rule+011420.pdf)

Reproducibility is Essential to Combating Environmental Lysenkoism

James E. Enstrom, PhD, MPH, FFACE

National Association of Scholars “Fixing Science” Conference

Independent Institute, Oakland, CA

February 8, 2020

Slide 20

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**

Gordon and Betty 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

From: James E. Enstrom <jenstrom@ucla.edu>
Sent: Wednesday, January 29, 2020 12:31 PM
To: Harvey V. Fineberg <harvey.fineberg@moore.org>
Cc: David B. Allison, PhD <allison@iu.edu>
Subject: January 23 JAMA Viewpoint Misrepresents EPA Transparency Rule

January 29, 2020

Harvey V. Fineberg, MD, PhD
President, Gordon and Betty Moore Foundation
<https://www.moore.org/people-detail?personUrl=harveyf>
<https://www.hsph.harvard.edu/harvey-fineberg/>
<https://chinamedicalboard.org/people/harvey-v-fineberg>
harvey.fineberg@moore.org

Dear Dr. Fineberg,

I am writing to inform you of a major omission in your January 23, 2020 *JAMA* Viewpoint “The Use and Misuse of Transparency in Research: Science and Rulemaking at the Environmental Protection Agency” (<https://jamanetwork.com/journals/jama/fullarticle/2759410>). Regarding the HEI 2000 Reanalysis (Reference 6) of Pope 1995 (Reference 5), you do not cite my March 28, 2017 *Dose-Response* Reanalysis (<http://scientificintegrityinstitute.org/EPATransJEE081418.pdf>), which found serious flaws in both Pope 1995 and HEI 2000. Also, the concluding sentence in your Viewpoint misrepresents the proposed EPA Transparency Rule. For strong evidence supporting the EPA Transparency Rule, please read the 22-page Comment that I prepared for the January 17, 2020 EPA SAB Meeting (<http://www.scientificintegrityinstitute.org/JEESAB011420.pdf>).

In order to better understand this issue, I invite you or another Moore Foundation scientist to attend the February 7-8, 2020 National Association of Scholars Conference In Oakland: **Fixing Science: Practical Solutions for the Irreproducibility Crisis** (<https://www.nas.org/blogs/event/fixing-science-practical-solutions-for-the-irreproducibility-crisis>). I would like to personally speak with you or another Moore scientist.

Thank you very much for your consideration.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE
UCLA and Scientific Integrity Institute
[http://scientificintegrityinstitute.org/
jenstrom@ucla.edu](http://scientificintegrityinstitute.org/jenstrom@ucla.edu)
(310) 472-4274