

March 28, 2023

To:

Docket ID No. **EPA-HQ-OAR-2015-0072-1543**

[Reconsideration of the National Ambient Air Quality Standards for Particulate Matter](#)

<https://www.regulations.gov/document/EPA-HQ-OAR-2015-0072-1543>

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

From:

James E. Enstrom, PhD, MPH, FFACE

Retired UCLA Research Professor (Epidemiology)

President, Scientific Integrity Institute

907 Westwood Boulevard #200

Los Angeles, CA 90024

<http://www.scientificintegrityinstitute.org>

<http://www.scientificintegrityinstitute.org/PM25Block032823>

[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)

(310) 472-4274

Re: Comment Supporting Current PM NAAQS Based on My Criticism of ACS and HTHCSPH Being Blocked

EPA is proposing to revise the primary (health-based) annual PM<sub>2.5</sub> standard from its current level of 12.0 µg/m<sup>3</sup> to within the range of 9.0 to 10.0 µg/m<sup>3</sup>. EPA is proposing not to change the current primary and secondary 24-hour PM<sub>2.5</sub> standards, primary and secondary PM<sub>10</sub> standards, and secondary (welfare-based) annual PM<sub>2.5</sub> standard. My February 23, 2023 verbal comment to EPA opposing the PM<sub>2.5</sub> NAAQS Reconsideration is printed below and can be viewed during minutes 3:03:40-3:08:27 of the February 23, 2023 EPA Public Comment Webcast (<https://youtube.com/live/GlfHXXeiVew>).

"I am Dr. James Enstrom. I appreciate the opportunity to give public comments. I have had a 50-year epidemiology career at UCLA and I have made significant contributions to PM<sub>2.5</sub> epidemiology. I have presented verbal and written evidence at the EPA CASAC PM Panel Meetings that there is NO relationship between PM<sub>2.5</sub> and total mortality in the US. My March 2017 Dose-Response reanalysis of the ACS CPS II cohort found NO relationship and challenges the validity of the 1995 Pope study that provided the primary basis for establishing the 1997 PM<sub>2.5</sub> NAAQS. The 2021 analysis presented by UNC Statistics Professor Richard Smith found NO relationship below 12 µg/m<sup>3</sup> in the Medicare cohort. These null findings and many others are not cited in the 2022 ISA or Policy Assessment. The EPA has greatly exaggerated the US evidence of PM<sub>2.5</sub> deaths, particularly PM<sub>2.5</sub> deaths below 12 µg/m<sup>3</sup>.

This exaggeration is due to four major biases against null findings: investigator bias, funding bias, publication bias, and citation bias. For instance, foreign investigator bias exists in the more than 80 Medicare-based studies from the Harvard Chan School of Public Health. This School has received \$350 million from a Chinese businessman. The principal investigator is Italian biostatistician Francesca Dominici, who has trained at least 30 Chinese doctoral students to misuse of Medicare records. Dominici and her trainees refuse to respond to my evidence of their misconduct. Medicare records, which contain NO data on air pollution, have been used without the knowledge or permission of Americans in order to inappropriately claim that there are PM<sub>2.5</sub> deaths below 12 µg/m<sup>3</sup>.

EPA needs to follow the 2020 recommendation of the prior CASAC and the prior EPA Administrator and leave the PM2.5 NAAQS unchanged. Furthermore, EPA needs explain that that average personal exposure to PM2.5 in the US is below the level of known human health effects. This is because Americans are mostly exposed to indoor air, not ambient outdoor air. Inside my Los Angeles office, my PM2.5 monitor reads 3  $\mu\text{g}/\text{m}^3$ . Thus, a typical American inhales only about one gram of PM2.5 in a lifetime. The current average ambient level in the US of 7.7  $\mu\text{g}/\text{m}^3$  is close to the lowest level in the entire world. This level is virtually impossible to reduce because polluted air comes into the US from other countries like China, which has a level of 48  $\mu\text{g}/\text{m}^3$ .

In conclusion, the PM2.5 NAAQS must remain unchanged. Finally, I ask the Panel to indicate now whether EPA will read and properly cite the null evidence by Professor Smith and me. Thank you.”

The three EPA Panel Members who listened to my comment (Darryl Weatherhead, Erin Cowder, and James Kelly) refused to indicate whether EPA will read and properly cite the null PM2.5 deaths evidence by Professor Smith and me.

In support of my verbal comment I present below 45 pages of email messages and related material that documents the refusal of scientific experts and organizations that support the EPA regulatory agenda to address the null evidence that I have submitted to them. I have made strong cases that ACS CPS II data and Medicare data analyzed at the Harvard TH Chan School of Public Health, as well as the traditional rules of epidemiology, have been misused in order to promote the scientifically unjustified claim that there is a “significant” positive relationship between PM2.5 and total mortality in California and the US. I provide extensive unrefuted details that CASAC PM Panel members, EPA-funded scientists, and EPA staff have deliberated exaggerated the adverse health effects of PM2.5, particularly regarding the claim that PM2.5 **causes** premature deaths in the US. The 45 pages of evidence is divided into the sections shown below and my Scientific Integrity Institute weblink is included for each section.

Comment Sections:

Pages 4-19: February 16, 2023 Enstrom Email to ACS Board of Directors and CEO re EPA Misuse of CPS II for PM2.5 Deaths and ACS Rejection (<http://www.scientificintegrityinstitute.org/ACSEPA021623.pdf>)

Pages 20-23: July 22, 2022 Enstrom Email to HEI Board Chair Meserve re HEI Misconduct on PM2.5 Deaths and Meserve Rejection (<http://www.scientificintegrityinstitute.org/JEEMeserve072222.pdf>)

Pages 24-27: April 18, 2022 Science Editor Holden Thorp Rejects Enstrom Request to Publish Any Form of Evidence re PM2.5 Transparency (<http://www.scientificintegrityinstitute.org/ThorpJEE041822.pdf>)

Pages 28-30: March 3, 2022 Enstrom Allegations to CSU Research Integrity Officer Regarding Epidemiologic Misconduct by CASAC PM Panel Member Jennifer Peel  
Pages 31-32: March 10, 2022 Geoffrey Kabat Allegations to CSU Research Integrity Officer Regarding Epidemiologic Misconduct by CASAC PM Panel Member Jennifer Peel  
Pages 33-34: March 11, 2022 CSU Research Integrity Officer Refusal to Address Enstrom and Kabat Allegations About Peel and Refusal to Connect Us with Peel  
(<http://www.scientificintegrityinstitute.org/CSURIOPeel031122.pdf>)

Page 35-36: February 2, 2022 Enstrom Email to HTHCSPH Graduate Xiao Wu re Misconduct in Using Medicare Records to Make Unjustified PM2.5 Death Claims  
(<http://www.scientificintegrityinstitute.org/JEEWu020222.pdf>)

Page 37-38: January 4, 2022 Enstrom Email to HTHCSPH Biostat Chair Quackenbush with Misconduct Complaint Against Francesca Dominici for Misusing Medicare Records to Make PM2.5 Death Claims  
(<http://www.scientificintegrityinstitute.org/JEEDominici010422.pdf>)

Pages 39-40: September 15, 2021 Enstrom Case for Removing Dominici from NASEM NAAQS Committee for Violation of FACA and for Misusing Medicare Records to Make PM2.5 Death Claims  
(<http://www.scientificintegrityinstitute.org/NASEMDominici091521.pdf>)

Pages 41-42: August 30, 2021, Enstrom Email to Emory SPH Dean Curran re Misuse of Medicare Records by HTHCSPH Graduate Lihua Shi (<http://www.scientificintegrityinstitute.org/CurranJEE083021.pdf>)

Pages 43-47: July 8, 2021 Enstrom Detailed Critical Review of ES&T Manuscript by Lihua Shi That Claims PM2.5 Medicare Deaths (<http://www.scientificintegrityinstitute.org/ESTJEEAdd070821.pdf>)

Page 48: World Map of 2019 Annual Average PM2.5 Level by Country Showing VERY LOW Level in US  
(<https://www.stateofglobalair.org/air/pm>)

From: **James E. Enstrom** <jenstrom@ucla.edu>

Date: Thu, Feb 16, 2023 at 12:00 PM

Subject: ACS and EPA Misuse CPS II to Claim PM2.5 Causes Death

To: Katie A. Eccles <keccles@rqn.com>

Cc: Karen E. Knudsen <karen.knudsen@cancer.org>, Alpa V. Patel <alpa.patel@cancer.org>, W. Ryan Diver <ryan.diver@cancer.org>

February 16, 2023

Katie A. Eccles, Esq.

Secretary-Treasurer, Board of Directors

American Cancer Society

<https://www.cancer.org/about-us/>

[keccles@rqn.com](mailto:keccles@rqn.com)

Re: ACS and EPA Misuse CPS II Data to Claim That PM2.5 Causes Death

Dear Secretary-Treasurer Eccles,

I am writing to you because my requests to other ACS officials have failed. Since 1993 ACS has misused 1982 CPS II cohort data in order to promote the claim that fine particulate matter (PM2.5) "**causes**" premature death. These CPS II findings were used by EPA to create a new National Ambient Air Quality Standard (NAAQS) for PM2.5 in 1997 and subsequent multi-billion-dollar PM2.5 regulations. This misuse of CPS II data is wrong for at least three reasons: 1) it violates the ACS Mission Statement because PM2.5 deaths and costly EPA regulations have nothing to do with cancer; 2) it violates the scientific method because ACS refuses to support full transparency and reproducibility regarding CPS II data and refuses to acknowledge that my 2017 independent reanalysis of CPS II data found NO relationship between PM2.5 and total mortality; and 3) ACS has politicized its CPS II research by helping the Clinton EPA establish the 1997 PM2.5 NAAQS, by helping the Obama EPA tighten the PM2.5 NAAQS in 2012, and by allowing the Biden EPA to use contested CPS II findings in its current effort to further tighten the PM2.5 NAAQS. My key ACS correspondence and evidence on the flawed CPS II findings dating back to 2013 are provided in the attached 18-page "ACS & EPA Misuse CPS II to Claim PM2.5 Deaths 021623" PDF (<http://scientificintegrityinstitute.org/ACSEPA021623.pdf>). To further understand this complex controversy, please watch the February 21-23, 2023 EPA Public Hearing on the PM2.5 NAAQS (<https://www.epa.gov/pm-pollution/public-hearing-notice-proposal-national-ambient-air-quality-standards>). Based on ALL relevant evidence, there is no scientific, public health, or economic justification for the Biden EPA to further tighten the PM2.5 NAAQS.

Please assist me in getting a response from ACS CEO Karen E. Knudsen, ACS Senior Vice President Alpa V. Patel, and/or ACS Data Analysis Director W. Ryan Diver. Until ACS acknowledges and stops the misuse of CPS II data, I will continue to make the case that ACS is violating its Mission Statement, violating the scientific method, and politicizing its research. Worst of all, at this time of intense national division on most major policy issues, CPS II data continues to be misused for unjustified EPA regulations that hurt America, especially California, and give a competitive advantage to Communist China.

Thank you very much for your assistance with this important issue.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE

Retired UCLA Research Professor (Epidemiology)

President, Scientific Integrity Institute

<http://scientificintegrityinstitute.org/>

[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)

(310) 472-4274

From: **Timothy Phillips** <timothy.phillips@cancer.org>  
Date: Fri, Jan 27, 2023 at 11:22 AM PT  
Subject: RE: Request re CPS II  
To: James E. Enstrom <jenstrom@ucla.edu>  
Cc: Karen E. Knudsen <karen.knudsen@cancer.org>, William Dahut <bill.dahut@cancer.org>

Dr. Enstrom,

Please consider this communication as the ACS response to your requests, both written and verbal, for ACS to engage in what you described to me as an active “30 year controversy,” related to the EPA’s regulatory activity. The ACS is an independent, evidenced-based organization dedicated to improving the lives of people with cancer and their families. We do not engage in regulatory controversies; rather, we support research and science that reduces the unnecessary burden of cancer. Thus, we respectfully decline your request to engage.

I appreciate your patience, but please consider this matter closed.

Very respectfully,

Tim Phillips

**Timothy Phillips**

Chief Legal and Risk Officer

404.327.6423 | m: 404.759.7617 | f: 404.417.5808

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Kennesaw, GA 30144

[cancer.org](http://cancer.org) | 1.800.227.2345

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
**Sent:** Friday, January 27, 2023 2:02 PM ET (11:02 AM PT)  
**To:** Timothy Phillips <[timothy.phillips@cancer.org](mailto:timothy.phillips@cancer.org)>  
**Cc:** Karen E. Knudsen <[karen.knudsen@cancer.org](mailto:karen.knudsen@cancer.org)>; William Dahut <[bill.dahut@cancer.org](mailto:bill.dahut@cancer.org)>  
**Subject:** Re: Request re CPS II

Dear Tim,

I am writing regarding my concerns about the use of ACS CPS II cohort data for EPA PM2.5 regulations, which we discussed during our January 19 Zoom Meeting . I have not received any response from Dr. William Dahut, as per our agreement that he would respond to my concerns. I want to emphasize the urgency of my concerns by alerting you to the January 27 Federal Register Notice below which describes the current intention of EPA to tighten the PM2.5 NAAQS. The important role of ACS CPS II findings regarding the PM2.5 NAAQS is cited on page 24 of the 162-page PDF. Unfortunately, EPA has ignored the large body of evidence that tightening the PM2.5 NAAQS is unjustified. Tightening the PM2.5 NAAQS will have a particularly devastating impact on California. Thus, it is very important that I receive a response from Dr. Dahut within the next few days. Alternatively, I want to receive a timely response from Dr. Alpa Patel or Mr. Ryan Diver.

Thank you very much for your assistance with this important request.

Best regards,

Jim Enstrom  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

## Reconsideration of the National Ambient Air Quality Standards for Particulate Matter

**FR Document:** [2023-00269](#)

[PDF](#) Pages 5558-5719 (162 pages)

**Citation:** 88 FR 5558

[Permalink](#)

**Abstract:** Based on the Environmental Protection Agency's (EPA's) reconsideration of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA proposes to revise the primary annual PM<sub>2.5</sub> standard by lowering the level. The Agency proposes to retain the current primary 24-hour PM<sub>2.5</sub> standard and the primary 24-hour PM<sub>10</sub> standard. The Agency also proposes not to change the secondary 24-hour PM<sub>2.5</sub>...

On Tue, Dec 20, 2022 at 1:23 PM PT Timothy Phillips <[timothy.phillips@cancer.org](mailto:timothy.phillips@cancer.org)> wrote:

Dear Dr. Enstrom-

Thank you for the outreach and inquiry. As a data-driven organization, we value the integrity of the scientific process. We stand behind the data and interpretation of all ACS-authored publications surrounding CPS II, and are unable to identify concerns therein. While we have no insight into your findings, we look forward to assessing after peer review.

I would ask that any future correspondence related to this matter be directed solely to my attention.

Wishing you and your family a safe and healthy holiday season.

Tim Phillips

### Timothy Phillips

Chief Legal and Risk Officer

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From: **James E. Enstrom** <jenstrom@ucla.edu>  
Date: Mon, Nov 28, 2022 at 11:30 AM  
Subject: Request re ACS CPS II Reanalysis & PM2.5 NAAQS  
To: Karen E. Knudsen <karen.knudsen@cancer.org>  
Cc: William L. Dahut <bill.dahut@cancer.org>, Alpa V. Patel, PhD <alpa.patel@cancer.org>

November 28, 2022

Karen E. Knudsen, PhD, MBA  
American Cancer Society CEO  
3380 Chastain Meadows Parkway NW, Suite 200  
Kennesaw, GA 30144  
[karen.knudsen@cancer.org](mailto:karen.knudsen@cancer.org)

Dear Dr. Knudsen,

I am writing to request your assistance regarding use of the 1982 ACS Cancer Prevention Study (CPS II) cohort since 1995 to claim that fine particulate air pollution (PM2.5) causes premature deaths. Former ACS Vice President of Epidemiology Susan M. Gapstur and former ACS CEO Gary M. Reedy refused to address my concerns that CPS II data have been misused (<http://scientificintegrityinstitute.org/Reedy081717.pdf>). My March 28, 2017 peer-reviewed reanalysis of the CPS II cohort found NO significant relationship between PM2.5 and mortality (<http://journals.sagepub.com/doi/10.1177/1559325817693345>). In addition, on December 10, 2021 I presented an even more compelling case to the EPA CASAC PM Panel that PM2.5 DOES NOT cause deaths (<http://scientificintegrityinstitute.org/PMPanel121021.pdf>). This matter is highly relevant to both epidemiologic integrity and the US economy. The EPA CASAC has proposed tightening the National Ambient Air Quality Standard (NAAQS) for PM2.5 based largely on the claim that the low levels of PM2.5 in the US cause deaths. Such tightening could occur as soon as March 2023 and this would result in new multi-billion dollar EPA PM2.5 regulations that are scientifically and economically unjustified (<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2060-AV52>).

Thus, I request that ACS Senior Vice President of Population Science Alpa V. Patel and/or ACS Chief Scientific Officer William L. Dahut review my 2017 CPS II reanalysis and then produce transparent results that either confirm or refute my CPS II evidence. This review can be done very rapidly if ACS epidemiologists will simply perform the same calculations that are in my reanalysis. CPS II results played the major role in EPA's 1997 establishment of and 2012 tightening of the PM2.5 NAAQS. The PM2.5 NAAQS has been highly controversial since it was established and many experts like myself believe that PM2.5 regulations are not scientifically justified. The ACS has an obligation to conduct transparent and reproducible scientific findings, especially when these findings have national policy implications. Finally, ACS should focus on its stated Mission "to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer." The relationship between PM2.5 and mortality has NOTHING to do with cancer risk.

Thank you very much for your consideration and assistance.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
907 Westwood Boulevard #200  
Los Angeles, CA 90024  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

cc: Alpa V. Patel, PhD <[alpa.patel@cancer.org](mailto:alpa.patel@cancer.org)>  
William L. Dahut, MD <[bill.dahut@cancer.org](mailto:bill.dahut@cancer.org)>



**From:** James E. Enstrom [mailto:jenstrom@ucla.edu]

**Sent:** Friday, October 13, 2017 1:00 PM

**To:** 'Gary M. Reedy' <kelly.hicks@cancer.org>

**Cc:** 'W. Ryan Diver' <ryan.diver@cancer.org>; 'Susan P. Gapstur' <susan.gapstur@cancer.org>; 'C. Arden Pope III' <cap3@byu.edu>

**Subject:** Repeat Request for Analysis of PM2.5 & Mortality in CPS II

October 13, 2017

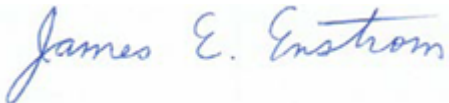
Dear Mr. Reedy,

I am writing you again on this special day because I have not received a response to my August 17 email message below. I repeat my request for a response from Mr. W. Ryan Diver and/or Dr. Susan P. Gapstur confirming or refuting my March 28 *Dose-Response* findings of NO relationship between fine particulate matter (PM2.5) and total mortality in the ACS CPS II cohort. In addition, I invite them and BYU Professor C. Arden Pope, III, to present any evidence that challenges the validity of my CPS II findings at the November 9 America First Energy Conference in Houston, Texas (<http://americafirstenergy.org/about/>). I will present my March 28 findings, as well as additional new evidence, showing NO relationship between PM2.5 and total mortality in the CPS II cohort and I will give them an opportunity to present any contradictory evidence.

If I receive no response to this message, then I will assume that this matter does not concern you or the leadership of ACS.

Thank you very much for your consideration.

Sincerely yours,

A handwritten signature in blue ink that reads "James E. Enstrom". The signature is written in a cursive style and is contained within a thin black rectangular border.

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

**From:** James E. Enstrom [mailto:jenstrom@ucla.edu]  
**Sent:** Thursday, August 17, 2017 8:30 AM  
**To:** 'Gary M. Reedy' <kelly.hicks@cancer.org>  
**Subject:** Request for Analysis of PM2.5 & Mortality in CPS II

August 17, 2017

Gary M. Reedy, CEO  
American Cancer Society  
250 Williams Street, Suite 600  
Atlanta, GA 30303-1002  
c/o Kelly Hicks, Senior EA  
[kelly.hicks@cancer.org](mailto:kelly.hicks@cancer.org)

Dear Mr. Reedy,

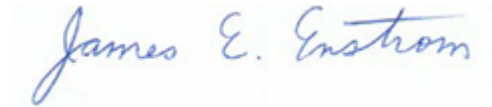
I am writing you regarding a very important epidemiologic issue that involves the 1982 ACS Cancer Prevention Study (CPS II) cohort. I request your assistance because I have received no cooperation from Vice President of Epidemiology Susan M. Gapstur or Epidemiology Data Analysis Core Director W. Ryan Diver. On March 23 I made a compelling case that there is no causal relationship between fine particulate matter (PM2.5) and total mortality (<http://climateconferences.heartland.org/james-enstrom-iccc10-panel-8/>). My case is based largely on my independent analysis of the CPS II cohort, which was published on March 28 in a peer-reviewed journal (<http://journals.sagepub.com/doi/10.1177/1559325817693345>). During the past five months, Dr. Gapstur and Mr. Diver have continuously refused to confirm or refute my null CPS II evidence. They did not accept my invitation to participate in my August 12 presentation, where I showed that CPS II data has been used since 1995 to deliberately exaggerate and misrepresent the PM2.5-mortality relationship (<http://www.ddponline.org/>).

Thus, I request that you and/or an appropriate ACS official review my March 28 *Dose-Response* article, including all 27 references, and then produce transparent results that either confirm or refute my CPS II evidence. This can be done in a few days if ACS epidemiologists will simply perform the appropriate calculations and report their results. CPS II results have played major roles in the establishment and tightening of the US EPA National Ambient Air Quality Standard (NAAQS) for PM2.5. In turn, the PM2.5 NAAQS has been used to justify many multi-billion dollar regulations that many experts like myself believe are not scientifically justified. We want these regulations immediately reassessed as per Presidential Executive Order 13777 (<https://www.epa.gov/laws-regulations/regulatory-reform>) and the HONEST Act (<https://www.govtrack.us/congress/bills/115/hr1430>).

Please let me know if you need any clarification of my request or additional information. Because of the national significance of this matter, I have informed several scientific colleagues, as well as several appropriate Congressional staff members and US EPA officials of this message.

Thank you very much for your cooperation and assistance.

Sincerely yours,

A handwritten signature in blue ink that reads "James E. Enstrom". The signature is written in a cursive style and is contained within a thin black rectangular border.

James E. Enstrom, Ph.D., M.P.H.  
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# The EPA's Game of Secret Science

Smith, Lamar.

**Wall Street Journal, Eastern edition** 30 July 2013: A.15.

Virtually every major EPA air-quality regulation under President Obama has been justified by citing two sets of decades-old data from the Harvard Six Cities Study and the American Cancer Society's Cancer Prevention Study II. The agency is also poised to use the data to justify its expensive new ozone standards -- the EPA's Regulatory Impact Analysis estimated that lowering the ozone standard to 60-70 parts per billion would cost up to \$90 billion per year in compliance costs.

As the Environmental Protection Agency moves forward with some of the most costly regulations in history, there needs to be greater transparency about the claimed benefits from these actions. Unfortunately, President Obama and the EPA have been unwilling to reveal to the American people the data they use to justify their multibillion-dollar regulatory agenda.

To cite a few examples of where the EPA would like to take the country, the agency is moving forward with strict new limits on ozone that by its own estimates will cost taxpayers \$90 billion per year, which would make the regulation the most costly in history. Other examples include a Mercury and Air Toxics Standard for power plants (previously known as "Utility MACT") that the EPA estimates could cost up to \$10 billion a year. Yet more than 99% of the EPA's health-based justifications for the rule are derived from scientific research that the EPA won't reveal. Taxpayers are supposed to take on faith that EPA policy is backed by good science.

We know this much: Virtually every major EPA air-quality regulation under President Obama has been justified by citing two sets of decades-old data from the Harvard Six Cities Study and the American Cancer Society's Cancer Prevention Study II. The EPA uses the data to establish an association between fine-particulate emissions and mortality.

For two years, the House Science, Space and Technology Committee, of which I am the chairman, has sought to make this information available to the public. But the EPA has obstructed the committee's request at every step. To date, the committee has sent six letters to the EPA and other top administration officials seeking the data's release.

In September 2011, the EPA's then-Assistant Administrator Gina McCarthy committed to provide these data sets to the committee. But the data still remain out of sight. Ms. McCarthy was recently confirmed by the Senate as administrator of the EPA. Now that she leads the agency, Ms. McCarthy has no excuse not to make these taxpayer-funded studies public.

Simple transparency is not the only reason this information should be released. The costs of these rules will be borne by American families. They deserve to know what they are paying for. Time is almost up. If the administration does not provide this data by the end of July, the science committee will force its release through a subpoena.

The federal government has no business justifying regulations with secret information. This principle has been supported by two of the president's own science and technology advisers, John Holdren and Deborah Swackhamer. "The data on which regulatory decisions and other decisions are based should be made available to the committee and should be made public," said Dr. Holdren in testimony before the committee last year. Executive-branch rules dating to the Clinton administration require that federally funded research data be made publicly available, especially if it is used for regulatory purposes.

The data in question have not been subjected to scrutiny and analysis by independent scientists. And

the EPA does not subject its cost-benefit claims to peer review. This means we have no way of evaluating the quality of the science being used to justify the agency's claims.

The withholding of information is troubling -- and not just because it is being done by "the most transparent administration in history," as the president boasted in February. The National Academy of Sciences declared in 2004 that the data the EPA is using is of "little use for decision-making." Similarly, President Obama's Office of Management and Budget recently acknowledged that "significant uncertainty remains" about the EPA's claims based on its data sets, saying that the claims "may be misleading" and should be treated with caution.

Yet the EPA presses on: The same data are used to justify the agency's claims about the health benefits of recent proposals to limit emissions for refineries and vehicles. The agency is also poised to use the data to justify its expensive new ozone standards -- the EPA's Regulatory Impact Analysis estimated that lowering the ozone standard to 60-70 parts per billion would cost up to \$90 billion per year in compliance costs. The regulation could force large areas of the country into non-attainment, a designation that would drastically limit economic growth. Inevitably, the costs would be borne by working families and would include higher gasoline and electricity prices.

The administration's reliance on secret science doesn't stop there. President Obama's ambitious and costly new climate agenda is backed by a finding from a federal interagency working group regarding the "social cost of carbon." How that "social cost" was determined remains unclear. This new justification for economy-wide regulations was developed without public comment or peer review.

The U.S. saw dramatic improvements in air quality well before the Obama administration came to Washington, yet the White House has upped the ante, launching an aggressive anti-fossil-fuel, regulatory assault on affordable energy -- while refusing to reveal the scientific basis for the campaign. The EPA should reveal the research it uses and let the American people decide whether the agency's costly regulations are justified.

Rep. Lamar Smith represents the 21st District of Texas and is chairman of the House Committee on Science, Space and Technology.

# Congress of the United States

## House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371  
www.science.house.gov

June 12, 2013

The Honorable Robert Perciasepe  
Acting Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

Dear Acting Administrator Perciasepe:

On March 4, 2013, a letter was sent from this Committee to Gina McCarthy, Assistant Administrator for the Office of Air and Radiation at the Environmental Protection Agency (EPA), requesting that EPA take immediate steps in accordance with current law and Administration policy to obtain and release the underlying research data from specific PM<sub>2.5</sub> studies that EPA has relied on to support multiple rulemakings. In this same letter, we also requested that EPA obtain and immediately release the underlying data supporting a critical ozone study (Jerrett 2009) that relies on these same datasets and that EPA has referenced 18 times in its Integrated Scientific Assessment (ISA) in preparation for the upcoming ozone rulemaking.

The Agency's April 10, 2013, response to that letter acknowledges that the previously released information is "not sufficient" to allow replication of the study results. In the three months that have passed since our most recent request, we have yet to receive any commitment from the Agency that, in the case of Jerrett 2009, it will discontinue the use of this data or in the case of the most recent PM<sub>2.5</sub> long term cohort studies, immediately obtain and release that data. In May, EPA proposed new Tier III Vehicle Emission and Fuel Standards that depend on these same datasets to provide a majority of the claimed benefits. EPA's response also shows a general lack of understanding of Administration policy and the nature of the requested data:

- While EPA is correct in noting that the responses to the personal interview questionnaires collected 30 years ago include confidential information, the electronic input and output files used in the actual analysis for these studies are unlikely to contain confidential data. This was confirmed by Health Effects Institute (HEI) in 2000 when it conducted a reanalysis of the studies.<sup>1</sup>

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<sup>1</sup> Krewski et al. 2000, *Part I: Replication and Validation*; (p 42). The HEI Report confirms that an electronic data file ("Mort6C.file") containing a copy of the Harvard Six cities database "did not contain any information that could be used to identify the individual study participants."

- EPA's proffered excuse for not obtaining the data because the studies "received funding from a number of different sources, including the EPA, other federal agencies, and non-federal sources" conflicts with OMB policy which clearly states that funding Agencies retain the right to obtain all data developed from mixed funding sources.<sup>2</sup>
- EPA's response also incorrectly states that NDI data cannot be released, ignoring the fact referenced in its own attachment on page 3 that Harvard University had released (and EPA transmitted) coded NDI data in 2011.

We also remain deeply concerned that EPA continues to rely on this data, even while the National Research Council has cautioned against using them in its 2004 report.<sup>3</sup> In that report, the NRC concluded that updates of these two cohorts alone would be of "little use for decisionmaking" due to the outdated nature of the information and dwindling relevance to today's population and risk profile. The full NRC discussion on this point is attached for review. For example, since the time the data were initially collected, smoking rates have declined from 40 to 20 percent, while education levels (used as a surrogate for socioeconomic status in air pollution studies) have increased. A number of other factors affecting the surveyed population's health status have also changed, including improved treatments for hypertension and cholesterol that have contributed to reductions in the cardiovascular mortality rates in the U.S. Because the American Cancer Society and Harvard Six City cohorts have not been updated, there is a clear concern that the health benefits attributed to reduced PM<sub>2.5</sub> and ozone levels over the past 30 years could in fact be incorrect due to other changes affecting the health status of the surveyed individuals that may have a much greater bearing.

EPA's recent clarification about which studies it relies upon fails to acknowledge this central point. Indeed, the fact that EPA has chosen not to rely on two studies using this outdated cohort information (Pope 2002 and Laden 2006) in the Regulatory Impact Assessment for the Tier III rulemaking but instead to use Krewski 2009 and Lepeule 2012 does not address this weakness but rather exacerbates the problem since both of these more recent studies use more recent and lower air pollution data but continue to rely on the same outdated cohort information.

Throughout this process, EPA has responded to our questions in a cavalier manner, hoping perhaps we were not reading the NRC reports carefully or were simply unaware of the law or guidance governing data access. The opposite is true. Our examination has underscored two central points:

- EPA must immediately refrain from relying on and citing studies that continue to use 30-year old cohort data. This includes all PM<sub>2.5</sub> and ozone studies that rely on the American Cancer Society and the Harvard Six Cities cohorts. The NRC's main criticism in 2004 is even more relevant today, nine years later.

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<sup>2</sup> *Federal Register*, Vol. 64, No. 195 (Friday, October 8, 1999). See section G: Projects Funded From Multiple Sources.

<sup>3</sup> National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (2004), Board on Environmental Studies and Toxicology (BEST), p 135.

- EPA must immediately obtain all of the underlying research data supporting the previously requested PM<sub>2.5</sub> and ozone studies, and release all non-confidential data in accordance with current law and Administration guidance. EPA must also take steps to determine whether confidential data sets can be de-identified to help ensure transparency in its decision making.

Current law and OMB guidance are clear in requiring EPA to obtain and release the data. To confirm there are no confidential data in the electronic input and output files and whether de-identification procedures can be applied, EPA must first obtain the data – which it openly admits to not having. The EPA's continued refusal to comply with this Committee's oversight request undermines the credibility of its regulations.

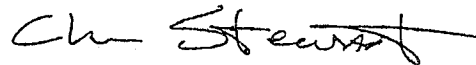
EPA officials should justify their agenda through an open and transparent process that is based on good science, if they can. EPA has projected that its upcoming ozone standard will be the most costly environmental regulation in U.S. history. Working families will bear these costs. They have a right to know what scientific data supports EPA's claims.

EPA must respect the law and the public's right to this information. In order to avoid formal action by this Committee to obtain the requested information, we urge you to comply with our request by July 8, 2013.

Sincerely,



Lamar Smith  
Chairman  
House Science, Space and Technology



Chris Stewart  
Chairman  
Environment Subcommittee

cc: Rep. Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology  
Ms. Gina McCarthy, Assistant EPA Administrator  
Dr. Glenn Paulson, Science Advisor to the EPA Administrator  
Dr. Ken Olden, NCEA Director  
Dr. John Holdren, Director, OSTP  
Ms. Sylvia Mathews Burwell, Director, Office of Management and Budget



## References

Jerrett et al. "Spatial analysis of air pollution and mortality in Los Angeles." *Epidemiology* 16(2005): 727-736.

Jerrett et al. "Long-term ozone exposure and mortality." *N Engl Med* 360 (2009): 1085-1095

Krewski et al. "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality." Special Report to the Health Effects Institute, Cambridge MA. (2000) <http://pubs.healtheffects.org/getfile.php?u=274>

Krewski et al. "Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality." *HEI Research Report, 140*, Health Effects Institute, (2009) Boston, MA

Laden et al. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine*. 173 (2006): 667-672

Lipfert et al. "PM<sub>2.5</sub> constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans." *Inhal. Toxicol.* 18 (2006): 41-72.

Lepeule et al. "Chronic Exposure to Fine Particles and Mortality; An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009." *Environ Health Perspect.* Jul; 120(7) (2012): 965-70

Pope et al. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287 (2002): 1132-1141.

Pope et al. "Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults." *Am. J. Respir. Crit. Care Med* 151 (1995): 669-674.

Attachment A:

**Excerpt from the National Research Council's 2004 report, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress***

**INVESTIGATING THE HEALTH EFFECTS OF LONG-TERM EXPOSURE TO AIR POLLUTION**

**Epidemiological Approaches**

The striking findings of the Harvard Six Cities Study (Dockery et al. 1993), which linked chronic exposure to increased mortality, provided a strong impetus for reevaluating the PM NAAQS, particularly after their confirmation in the 1995 publication based in the American Cancer Society's Cancer Prevention Study 2 (CPS 2) (Pope et al. 1995). The findings on increased mortality associated with longer-term exposures to higher concentrations of particles suggested that the associations observed in the time-series studies did not reflect only a slight advancement of the timing of death for frail individuals. The findings of the two studies were confirmed with an extensive reanalysis (Krewski et al. 2000) and on further follow-up of the CPS 2 cohort (Pope et al. 2002). Findings from several other cohort studies have also been reported (Abbey et al. 1999; Lipfert et al. 2000; Hoek et al. 2002). Although these cohorts have provided critical evidence for long-term effects, evidence from further follow-up of these two U.S. cohorts alone will have little use for decisionmaking. The cohorts were established decades ago, and some critical data items, including residence history and potential confounding and modifying factors, have not been comprehensively updated. Consequently, an increasing degree of exposure misclassification can be anticipated as the participants move from their original residences. And, most important, characterization of current air quality cannot recreate the complex air environments in which the individuals and populations lived and worked in the many years for which data are not available. Long-term studies are likely to remain central, however, in assessing the public health burden caused by air pollution. For quantitative risk assessment and cost-benefit analysis, estimates of the disease burden associated with exposure to particles are needed. These estimates could come from a new generation of studies with more complete information on short- and long-term exposures to PM, its components, and exposures to other pollutants.

Recognizing both the limitations of these studies and the need for ongoing information on long-term exposure to air pollution and health, the committee recommends that research approaches continue to be developed on the basis of existing and new cohorts. Mechanisms are needed for enrollment and tracking of cohorts over time to provide an ongoing characterization of any impact on health of long-term exposure to air pollution. Without substantial commitment of personnel and funds, studies, such as the Six Cities Study and the CPS 2 cohorts, cannot be readily and feasibly undertaken. Rather, such studies might be based on cohorts routinely enrolled for other purposes, for example, investigating cardiovascular diseases (Atherosclerosis Risk in Communities [ARIC 2004] and the Cardiovascular Health Study [CHS 2003]), Medicare participants, and cohorts assembled by the National Center for Health Statistics. However, even such studies will require substantial funding, and their value must be compared with data collection specifically designed as long-term studies of health effects of air pollution. Medicare has a large cohort under follow-up that is maintained with replacement sampling. The Veterans'

Administration also has a large cohort under follow-up. In addition, there might be other opportunities for adding a component related to air pollution and health; the anticipated National Children's Study (2004) is one example. That study might provide insights into air pollution and childhood asthma or lung development, for example. New cohort studies of persons having informative patterns of exposure or heightened susceptibility may also be warranted.

Studies of effects of long-term exposure to PM, based on residence location and other information, need to include large numbers of participants and to incorporate exposure estimates. With information on residence location, the EPA's monitoring data, captured in the Air Quality System (AQS) database (EPA 2004), could be used to estimate exposures. However, these data might not be optimal for health studies, and additional data collection or model data would be needed to better capture population exposure (see Chapter 6). For example, the spatial detail within communities might be better captured with focused monitoring and use of population exposure models. As the AQS data are increased from the new speciation sites and other data-collection efforts, it should become possible to develop estimates for exposures beyond particle mass alone. It is critically important that future monitoring strategies go beyond currently regulated pollutants to allow the testing of a broader range of epidemiological hypotheses.

An additional concern in any cohort study is the availability of information on potential confounding and modifying factors. Life styles and the associated frequency of chronic diseases, particularly heart and lung diseases, are variable across the country. There is a potential for a varying profile of susceptibility to PM across the country and for confounding as well. Some approaches based on population-level data can be identified that might be used to characterize potential confounding and modifying factors. Population-level data are available on tobacco sales, although they are a poor surrogate for actual smoking rates within the cohorts; available data on prevalence of tobacco use and mortality provide an index of the underlying rates of chronic heart and lung disease, particularly coronary heart disease and chronic obstructive pulmonary disease. Population sampling might be done to augment those data resources. However, such population-level data are inherently imperfect measures of individual-level exposures. Some health-system-based cohorts, such as Medicare, include information on diagnoses leading to outpatient visits and hospitalizations. Those data could be used to identify susceptible groups.

The development of new approaches to carrying out these cohort studies will be challenging and time-consuming and should be supported by EPA or other agencies. In 2001 and again in 2003, EPA sought new cohorts for studies of long-term effects through its Science to Achieve Results (STAR) grant mechanism, but it should also support an ongoing planning effort. Although a request has been initiated by EPA to establish a long term cohort to follow up cardiovascular events, it is important for EPA to recognize the need for continued and substantial financial support necessary for these types of studies. At the same time, it will be important for EPA to continue to support additional alternative approaches. The spectrum of human health effects has expanded over the past several years (see Table 5-1). Because each of these effects has the potential to result in substantial economic and social consequences, as well as significant health impairment, it is important that continued work be undertaken to quantify as much as possible the degree to which PM contributes to these conditions.

From: **James E. Enstrom** <jenstrom@ucla.edu>  
Date: Fri, Jul 22, 2022 at 11:00 AM  
Subject: Re: Scientific Misconduct by the Health Effects Institute  
To: Richard Meserve <rmeserve@carnegiescience.edu>  
Cc: William Happer <happer@princeton.edu>

July 22, 2022

Dear Dr. Meserve,

I appreciate your response. However, I still believe that there is GREAT value in having an OPEN and BALANCED debate on whether particulates (PM2.5) *cause* premature death. I have followed the NASEM NAAQS Committee since it held its first (secret) meeting on April 30, 2021. Its most recent (secret) meeting was on January 14, 2022 and the date of a future meeting and/or the date of a final report have not been announced. In this regard, I filed a January 4, 2022 Scientific Misconduct Complaint against Harvard TH Chan School of Public Health Professor Francesca Dominici (<http://scientificintegrityinstitute.org/JEEDominici010422.pdf>). She is a prominent member of the NASEM NAAQS Committee and a prominent HEI-funded investigator. She has refused to address my detailed nine-point complaint and she has not responded to any of my requests since 2008. Please give me your opinion of my complaint. Finally, please reconsider my July 6, 2022 request for a Zoom debate.

Thank you very much.

Best regards,

James  
James E. Enstrom, PhD, MPH  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

----- Forwarded message -----

From: **Richard Meserve** <rmeserve@carnegiescience.edu>  
Date: Mon, Jul 18, 2022 at 2:04 PM  
Subject: Re: Scientific Misconduct by the Health Effects Institute  
To: James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
Cc: William Happer <[happer@princeton.edu](mailto:happer@princeton.edu)>

Dear Dr. Enstrom –

I don't agree that there would be much value in arranging a debate on whether particulates cause premature death. There is a current NASEM committee that is exploring exactly that issue: <https://www.nationalacademies.org/our-work/assessing-causality-from-a-multidisciplinary-evidence-base-for-national-ambient-air-quality-standards>

Best regards.

Richard

Richard A. Meserve  
President Emeritus  
Carnegie Institution for Science

From: **James E. Enstrom** <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
Date: Wed, Jul 6, 2022 at 2:15 PM  
Subject: Re: Scientific Misconduct by the Health Effects Institute  
To: Richard Meserve <[rmeserve@carnegiescience.edu](mailto:rmeserve@carnegiescience.edu)>  
Cc: William Happer <[happer@princeton.edu](mailto:happer@princeton.edu)>

July 6, 2022

Richard A. Meserve, PhD, JD  
President Emeritus  
Carnegie Institution for Science  
[rmeserve@carnegiescience.edu](mailto:rmeserve@carnegiescience.edu)

Dear Dr. Meserve,

Thank you very much for your July 5 response to my allegation of scientific misconduct by HEI. Unfortunately, based on my dealings with them since 2002, the HEI staff DOES NOT take allegations of scientific misconduct seriously. Thus, I strongly request that you examine ALL of my evidence of misconduct and evasion by HEI dating from August 9, 2002 to June 26, 2022. Most of this evidence is posted on my website (<http://scientificintegrityinstitute.org/>). I can summarize this evidence over the phone if you are willing to call me.

Alternatively, you could organize a Zoom Session to debate the scientific validity of the EPA PM2.5 NAAQS, particularly the claim that PM2.5 *causes* premature deaths. Support for PM2.5 death claim could be presented by the three scientists primarily responsible for the establishment of the PM2.5 NAAQS: BYU Professor of Economics C. Arden Pope, III, Harvard Professor Emeritus of Environmental Health Douglas W. Dockery, and Retired American Cancer Society Vice President of Epidemiology Michael J. Thun. Opposition to the PM2.5 death claim could be presented by 2018-2020 EPA CASAC Chair L. Anthony Cox, Jr., UNC Professor of Statistics Richard L. Smith, and myself.

After examining all of my HEI evidence or watching a debate about the claim that PM2.5 *causes* premature deaths, you could decide whether or not to initiate an independent (of HEI) investigation of evidence of scientific misconduct by HEI.

Thank you very much for your additional consideration of this important issue.

Sincerely yours,

James E. Enstrom, PhD, MPH  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

From: **Richard Meserve** <[rmeserve@carnegiescience.edu](mailto:rmeserve@carnegiescience.edu)>  
Date: Tue, Jul 5, 2022 at 8:13 AM  
Subject: Fwd: FW: Scientific Misconduct by the Health Effects Institute  
To: <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
Cc: William Happer <[happer@princeton.edu](mailto:happer@princeton.edu)>

Dear Dr. Enstrom:

I am writing in response to your email to me of June 30, 2022, in which you raise an allegation of scientific misconduct by HEI in connection with the analysis of the health effects associated with air emissions of fine particulate matter. My response is guided by the link you provided to various papers on the website of the Scientific Integrity Institute.

I note that you published a reanalysis of the HEI 2000 report in early 2017 and that a response to your claims was published later that year. Your claims ripened into an allegation of scientific misconduct by HEI in another publication in early 2018. This was a very public scientific dispute in which the issues were raised over four years ago. I am mindful in this connection that it is my understanding that considerable additional data and analysis about the effects of fine particulate matter have been collected beyond the original HEI analysis and data set that provides the foundation for your claims, and that established scientific review panels (including the Clean Air Scientific Advisory Committee in 2020) have drawn conclusions on this broader data.

Both I and the HEI take issues of scientific misconduct very seriously. But in my view there is no reason to open up an old dispute yet again.

Richard A. Meserve  
President Emeritus  
Carnegie Institution for Science

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
**Sent:** Thursday, June 30, 2022 4:01 PM  
**To:** Meserve, Richard <[rmeserve@cov.com](mailto:rmeserve@cov.com)>  
**Cc:** William Happer <[happer@princeton.edu](mailto:happer@princeton.edu)>  
**Subject:** Scientific Misconduct by the Health Effects Institute

**[EXTERNAL]**

June 30, 2022

Richard A. Meserve, PhD, JD

Senior Of Counsel  
Covington & Burling LLP  
[rmeserve@cov.com](mailto:rmeserve@cov.com)  
[\(202\) 662-5304](tel:(202)662-5304)

Re: Scientific Misconduct by the Health Effects Institute

Dear Dr. Meserve,

I am writing because you are Chair of the Health Effects Institute (HEI) Board of Directors (<https://healtheffects.org/about/board/richard-meserve>). I am an accomplished environmental epidemiologist who has conducted and published seminal peer-reviewed evidence that contradicts the HEI claim the fine particulate matter (PM2.5) *causes* premature deaths in the US. In addition, I have extensive evidence dating back to 2002 of scientific misconduct in HEI-sponsored air pollution health effects research.

Thus, I request that you initiate an independent (of HEI) investigation of evidence of scientific misconduct by HEI, such as, the evidence contained in my 2017 Reanalysis of the ACS CPS II cohort, which challenges the validity of the 2000 HEI Reanalysis of the ACS CPS II cohort and the related EPA PM2.5 NAAQS (<http://scientificintegrityinstitute.org/DRPM25JEEPope052918.pdf>). My evidence involves serious violations of the scientific method that have profound scientific and economic implications for the US. Because both of us have doctoral-level training in science (physics), Princeton Professor Emeritus of Physics William Happer has agreed to confirm the legitimacy of my request. Please let me know if you are willing to discuss my request with me and/or Professor Happer.

Thank you very much for your consideration.

Sincerely yours,

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

cc: William Happer <[happer@princeton.edu](mailto:happer@princeton.edu)>

## Slightly Reformatted Emails With Cell Numbers Removed

From: **Holden Thorp** <[hthorp@aaas.org](mailto:hthorp@aaas.org)>  
Date: Mon, Apr 18, 2022 at 7:24 AM  
Subject: Re: Request to Discuss February 8 UNC Forum "Science and Democracy" & Science  
To: James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>

James,

Thanks again for catching up about this. I have reviewed all of the files and discussed with the editors. We have decided not to do anything further on this. I know that is not the answer you hoped for, but at least you got a response. I realize you may state publicly that we did not engage. Thanks for thinking of us.

Holden

Holden Thorp  
Editor-in-Chief, Science Family of Journals  
1200 New York Ave NW  
Washington, DC 20005  
Cell:  
[hthorp@aaas.org](mailto:hthorp@aaas.org)

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
**Date:** Friday, April 1, 2022 at 1:00 PM  
**To:** Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)>  
**Subject:** Re: Request to Discuss February 8 UNC Forum "Science and Democracy" & Science

**[EXTERNAL EMAIL]**

April 1, 2022

Dear Holden,

Thank you very much for speaking with me today about the EPA Transparency Rule. Please examine the following two links on my Scientific Integrity Institute website and the Richard Smith Public Comment to EPA. Please let me know how you decide to proceed on this matter, particularly whether you will consider a Policy Forum, Letter, or eLetter from me on this subject.

Best regards,

Jim Enstrom  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310)



March 27, 2020 Enstrom Science Policy Forum Manuscript "The EPA Transparency Rule is Scientifically Justified and Necessary", which was immediately rejected by Brad Wible:  
(<http://www.scientificintegrityinstitute.org/EPATransJEE041720.pdf>)

December 10, 2021 36-page Enstrom Comment to EPA CASAC PM Panel on PM2.5 NAAQS, including UNC Professor Richard Smith's November 17, 2021 Public Comment on pages 22-25:  
(<http://www.scientificintegrityinstitute.org/PMPanel121021.pdf>)

November 17, 2021 29-page Richard Smith Public Comment on PM2.5 NAAQS and Full Unpublished Manuscript on PM2.5 Deaths:  
([https://casac.epa.gov/ords/sab/f?p=105:19:15763176931927:::RP,19:P19\\_ID:962](https://casac.epa.gov/ords/sab/f?p=105:19:15763176931927:::RP,19:P19_ID:962)) or  
([https://casac.epa.gov/ords/sab/apex\\_util.get\\_blob?s=10004505678157&a=105&c=7666875007252584&p=19&k1=5853&k2=&ck=u1N01nl6P-tYhVGR2\\_XKHJD54iPDaELf7GnCJaolkVJmsaqw\\_X6LawinH9Pvj7pdfyB4llBPT7qr-llzE3iAwQ&rt=IR](https://casac.epa.gov/ords/sab/apex_util.get_blob?s=10004505678157&a=105&c=7666875007252584&p=19&k1=5853&k2=&ck=u1N01nl6P-tYhVGR2_XKHJD54iPDaELf7GnCJaolkVJmsaqw_X6LawinH9Pvj7pdfyB4llBPT7qr-llzE3iAwQ&rt=IR))

On Tue, Mar 29, 2022 at 5:30 AM Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)> wrote:

Talk to you then.

Holden

Holden Thorp  
Editor-in-Chief, Science Family of Journals  
1200 New York Ave NW  
Washington, DC 20005  
Cell:  
[hthorp@aaas.org](mailto:hthorp@aaas.org)

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>

**Date:** Monday, March 28, 2022 at 5:43 PM

**To:** Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)>

**Subject:** Re: Request to Discuss February 8 UNC Forum "Science and Democracy" & Science

[EXTERNAL EMAIL]

Dear Holden,

Thank you very much for your positive response. Please call my cell on Friday at 12 Noon ET (9 AM PT).

James

On Mon, Mar 28, 2022 at 1:43 PM Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)> wrote:

James,

Sure. How's Friday afternoon, say noon or 1 my time?

Holden

Holden Thorp  
Editor-in-Chief, Science Family of Journals  
1200 New York Ave NW  
Washington, DC 20005  
Cell:  
[hthorp@aaas.org](mailto:hthorp@aaas.org)

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
**Date:** Monday, March 28, 2022 at 3:55 PM  
**To:** Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)>  
**Subject:** Request to Discuss February 8 UNC Forum "Science and Democracy" & Science

**[EXTERNAL EMAIL]**

March 28, 2022

H. Holden Thorp, PhD  
Editor-in-Chief, *Science*  
[hthorp@aaas.org](mailto:hthorp@aaas.org)

Dear Dr. Thorp,

I have been an AAAS member since 1976. I want to discuss certain aspects of the February 8 UNC Program for Public Discourse "Science and Democracy" featuring Drs. Clemens, Thorp, and Maroja: <https://cpb-us-w2.wpmucdn.com/blogs.baylor.edu/dist/1/10923/files/2022/01/Science-and-Democracy-1.pdf>. This Program can be viewed here: [https://www.youtube.com/watch?v=Rlsr\\_VmsZq8](https://www.youtube.com/watch?v=Rlsr_VmsZq8). Also, I want to discuss how Science magazine is not following the Scientific Method, particularly regarding Transparency and Reproducibility. Based on your February 28, 2020 email message below, which I just found, and your response to me today, please propose a convenient time(s) when you can speak with me.

Thank you very much for your time and consideration.

Best regards,

James E. Enstrom, PhD, MPH  
Retired UCLA Research Professor (Epidemiology)  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274  
(310) (cell)

Begin forwarded message:

**From:** Holden Thorp <[hthorp@aaas.org](mailto:hthorp@aaas.org)>  
**Date:** February 28, 2020 at 12:59:32 PM PST  
**To:** [jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
**Subject:** Your messages

James,

Thanks for your messages. Crazy times here with coronavirus and other things. Happy to catch up next week. Send me a few good times.

Thanks,

Holden

Holden Thorp  
Editor-in-Chief  
*Science* Family of Journals  
American Association for the Advancement of Science  
1200 New York Ave NW  
Washington, DC. 20005  
Landline: 202-326-6505  
Cell:  
[hthorp@aaas.org](mailto:hthorp@aaas.org)

**From:** James E. Enstrom <[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)>  
**Sent:** Thursday, March 3, 2022 1:45 PM  
**To:** Kimberly Cox-York <[Kimberly.Cox-York@colostate.edu](mailto:Kimberly.Cox-York@colostate.edu)>  
**Cc:** Jennifer L. Peel <[Jennifer.Peel@ColoState.EDU](mailto:Jennifer.Peel@ColoState.EDU)>  
**Subject:** Allegation of Research Misconduct by CSU Professor Jennifer L. Peel

March 3, 2022

Kimberly Cox-York, PhD  
Research Integrity Officer (RIO)  
Colorado State University (CSU)  
<https://www.research.colostate.edu/ricro/rcr/research-misconduct/kimberly.cox-york@colostate.edu>  
(970) 491-5241

Re: Allegation of Research Misconduct by CSU Professor Jennifer L. Peel

Dear Research Integrity Officer Cox-York,

I alleging Research Misconduct and Research-Related Misconduct by CSU Professor of Epidemiology Jennifer L. Peel (Peel) (<https://vetmedbiosci.colostate.edu/erhs/directory/member/?id=3558>) based on the CSU **Research Misconduct & Research-related Misconduct Policy** (<http://policylibrary.colostate.edu/policy.aspx?id=587>). This letter will focus on my allegation of Research-Related Misconduct, which involves “**reviewing research** or reporting research results while **6. Failing to promptly disclose (a) actual or potential . . . conflicts of interest**”. Separately, I will present details on my allegation of Research Misconduct (Falsification), which involves “**omitting data or results such that the . . . data or results are not accurately represented in the research record.**”

My allegation of Research-Related Misconduct is Peel’s failure to disclose actual or potential conflicts of interest in connection with her current service on the Biden EPA CASAC Particulate Matter (PM) Panel ([https://casac.epa.gov/ords/sab/f?p=105:14:15824296385893:::14:P14\\_COMMITTEEON:2021%20CASA%20PM%20Panel](https://casac.epa.gov/ords/sab/f?p=105:14:15824296385893:::14:P14_COMMITTEEON:2021%20CASA%20PM%20Panel)). Peel has received EPA funding since 2002 ([https://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/display.investigatorInfo/investigator/6877](https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.investigatorInfo/investigator/6877)) . Peel has co-authored five PM2.5-related articles since 1994 with Biden EPA CASAC Chair Lianne Sheppard (<https://pubmed.ncbi.nlm.nih.gov/?term=sheppard+peel>). Peel is a member of the Health Effects Institute (HEI) Review Committee (<https://www.healtheffects.org/about/review-committee>), which reviewed and approved the January 26, 2022 HEI Research Report 211, which claims that PM2.5 likely *causes* death ([https://www.healtheffects.org/system/files/dominici-rr-211-report\\_1.pdf](https://www.healtheffects.org/system/files/dominici-rr-211-report_1.pdf)). Peel has received NIEHS funding and is an Associate Editor of the NIEHS Journal *Environmental Health Perspectives* (EHP) (<https://ehp.niehs.nih.gov/about-ehp/editorial-boards/associate>). EHP refuses to publish null findings regarding PM2.5 deaths, including my own findings. Additional details on Peel’s conflicts of interest can be provided.

Peel’s service on the CASAC PM Panel is severely impaired because her conflicts of interest have made it impossible for her to objectively assess the research record relevant to the PM2.5 NAAQS, an air pollution standard that underlies several multi-billion dollar EPA regulations. Her lack of objectivity became obvious as of the November 17, 2021-December 2, 2021 CASAC PM Panel Public Meetings

(<https://casac.epa.gov/ords/sab/f?p=105:19:15763176931927::RP,19:P19 ID:962>). Peel totally ignored the November 17, 2021 verbal criticism of the 2021 EPA PM Integrated Science Assessment (ISA) Supplement and PM Policy Assessment (PA) by me and others ([https://www.youtube.com/watch?v=P6OhZaaexv8&ab\\_channel=SamuelDelk](https://www.youtube.com/watch?v=P6OhZaaexv8&ab_channel=SamuelDelk)). Also, Peel totally ignored my 36-pages of December 10, 2021 written evidence that there is NO proof that PM2.5 *causes* death and NO scientific or public health justification for tightening the PM2.5 NAAQS (<http://scientificintegrityinstitute.org/PMPanel121021.pdf>). Instead of addressing the evidence by me and others, Peel voted to tighten the annual PM2.5 NAAQS from 12  $\mu\text{g}/\text{m}^3$  to 8-10  $\mu\text{g}/\text{m}^3$ .

Furthermore, Peel did not recommend that EPA make changes in the PM ISA Supplement and the PM PA in response to public criticism. Instead, the February 4, 2022 EPA CASAC PM Panel Letter supported the PM PA and Peel made the following statement on page A-76, lines 32-36: “Based on a robust and comprehensive evaluation of the literature, the draft PA presents a clear evaluation of relationship between new concentrations reported in epidemiologic and the annual PM2.5 design values. Section 3.3 presents the relevant evidence regarding the entire body of literature of the health effects of PM2.5 relevant for this consideration.”

([https://casac.epa.gov/ords/sab/apex\\_util.get\\_blob?s=5062483298491&a=105&c=13113392902739068&p=19&k1=399&k2=&ck=vFCIf\\_cof\\_5DD5\\_O0mXUCn6fYA2E1U-NQeoFIOPXkq-zv0H3wipteWBg4twM0ejB5Z51hvsQ8ubE05PJuel9sQ&rt=IR](https://casac.epa.gov/ords/sab/apex_util.get_blob?s=5062483298491&a=105&c=13113392902739068&p=19&k1=399&k2=&ck=vFCIf_cof_5DD5_O0mXUCn6fYA2E1U-NQeoFIOPXkq-zv0H3wipteWBg4twM0ejB5Z51hvsQ8ubE05PJuel9sQ&rt=IR)). Apparently, Peel does not acknowledge the massive evidence that the PM PA is NOT “a robust and comprehensive evaluation of the literature.”

At the February 25, 2022-March 4, 2022 CASAC PM Panel Public Meetings (<https://casac.epa.gov/ords/sab/f?p=105:19:5062483298491::RP,19:P19 ID:966>), I made the following February 25, 2022 verbal comment: “I have 50 years of experience in conducting epidemiologic cohort studies and I have published important peer-reviewed PM2.5 death findings based on ACS CPS I and CPS II cohort data. The February 4 PM Panel letters do not address the detailed public criticism of the 2021 PM ISA Supplement and PM PA. The EPA staff has made NO changes in these documents in response to this criticism. In particular, they ignored Richard Smith’s evidence of NO PM2.5 deaths below 12  $\mu\text{g}/\text{m}^3$  and my 36 pages of evidence that PM2.5 DOES NOT *cause* premature deaths in the US. The recommendations of the PM Panel and EPA staff to tighten the PM2.5 NAAQS are based on a deliberately falsified research record regarding PM2.5-related deaths. Falsification is serious scientific misconduct as defined in the January 11 White House OSTP Scientific Integrity Task Force Report (<https://www.whitehouse.gov/ostp/news-updates/2022/01/11/white-house-office-of-science-technology-policy-releases-scientific-integrity-task-force-report/>). Thus, I request that Jennifer Peel, with a PhD in Epidemiology, confirm that the PM PA is “a robust and comprehensive evaluation of the epidemiologic literature” and that public comments like mine do not alter her evaluation. There is NO scientific or public health justification for tightening the PM2.5 NAAQS because there is no etiologic mechanism by which inhaling about 100  $\mu\text{g}$  of PM2.5 per day can cause death and the US already has a very low average PM2.5 level of 7  $\mu\text{g}/\text{m}^3$  whereas our competitor China has a very high level of 48  $\mu\text{g}/\text{m}^3$ . Indeed, there are adverse public health, welfare, social, economic, and energy effects associated with tightening the PM2.5 NAAQS. This tightening will hurt America at a time when it is facing military and economic dangers from Russia and China, as well as rapidly increasing energy costs. Finally, I strongly support the ongoing Young and Cox v. EPA lawsuit because the Biden CASAC and its PM Panel are illegally constituted and in gross violation of the Federal Advisory Committee Act. The current misguided effort to tighten the PM2.5 NAAQS must be stopped.”

All twenty of the February 25, 2022 public comments can be viewed at the beginning of the EPA CASAC Webcast YouTube (<https://www.youtube.com/watch?v=ZkMsBXwyenw>). My comment begins at

minute 17 and the last comment ends at minute 83. The PM Panel had NO response to any of the public comments and it appeared that they did not even listen to the comments. In particular, Peel did not respond to my request that she confirm that the PM PA is “a robust and comprehensive evaluation of the epidemiologic literature” and that public comments like mine do not alter her evaluation. A response from Peel is particularly important because she is the only one of the 22 panel members who has a PhD degree in epidemiology, the public health discipline most relevant to the PM2.5 death evidence under review. Presumably, she understands the methodology, limitations, and ethics of epidemiology better than the other PM Panel Members.

Before I file a formal Research Misconduct complaint against Peel, I request that you ask her to participate in a Zoom Meeting with you and me in order to address my above allegations. Ideally, I would like to include former EPA SAB Member S. Stanley Young, PhD, and former EPA CASAC Chair L. Anthony Cox, PhD, in this Zoom Meeting. Drs. Young and Cox are Plaintiffs in an ongoing lawsuit against EPA CASAC and its PM Panel because of its violation of the Federal Advisory Committee Act (FACA) (<https://junkscience.com/2021/10/former-casac-chair-added-as-plaintiff-in-young-v-epa/>). FACA has two fundamental requirements for an advisory committee: (1) membership must be “fairly balanced in terms of the points of view represented” and (2) the agency [EPA] must adopt “appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority [EPA] or by any special interest, but will instead be the result of the advisory committee’s independent judgment.”

Thank you very much for your timely consideration and assistance regarding this important matter.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
<http://scientificintegrityinstitute.org/>  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

cc: Jennifer L. Peel, PhD <[jennifer.peel@colostate.edu](mailto:jennifer.peel@colostate.edu)>

March 10, 2022

Kimberly Cox-York, PhD  
Research Integrity Officer (RIO)  
Colorado State University (CSU)

Re: Allegation of Research Misconduct by CSU Professor Jennifer L. Peel

Dear Dr. Cox-York,

I am an epidemiologist and have been on the faculty of the Albert Einstein College of Medicine and the Stony Brook School of Medicine as well as holding other positions. (I am retired as of 2018). In addition to over [150 peer-reviewed articles](#), I written for the general public regarding questions involving putative health risks and how to assess the relevant scientific evidence in venues including Forbes, Slate, Issues in Science and Technology, and the Genetic Literacy Project. I have also written two books published by Columbia University Press about environmental health risks ([here](#) and [here](#)) and how, on certain prominent questions, epidemiology has been used to make erroneous claims that various environmental factors play an important role in specific diseases. Most recently, I have published [numerous popular articles](#) on glyphosate as well as [a peer-reviewed meta-analysis](#) showing in detail how this useful herbicide has been subjected to an “availability cascade” which highlights the results of selected low-quality studies, while ignoring the results of the highest-quality studies, as well as the fact that, [17 national and international health agencies have found the product to be safe and not carcinogenic](#).

I am writing to support Dr. James E. Enstrom’s March 3, 2022 Allegation of Research Misconduct by CSU Professor Jennifer L. Peel. I have been an epidemiologic colleague of Dr. Enstrom for at least 40 years and believe that there is tremendous merit in his allegation, which I have carefully read. I have also read the CSU Research Misconduct & Research-Related Misconduct Policy. Dr. Enstrom has documented that Dr. Peel has many serious conflicts-of-interest regarding her service on the current EPA CASAC PM Panel. These serious conflicts should have disqualified her for service on the PM Panel as per the requirements of the Federal Advisory Committee Act and the CSU Research-Related Misconduct Policy. Indeed, there is an ongoing Federal lawsuit that the current EPA CASAC and its PM Panel are not legally constituted because of violations of the Federal Advisory Committee Act.

In addition, Dr. Enstrom has fully documented that Dr. Peel does not acknowledge the massive evidence that the 2021 EPA Particulate Matter Policy Assessment is NOT “a robust and comprehensive evaluation of the literature.” In particular, Dr. Peel does not acknowledge the detailed evidence in Dr. Enstrom’s December 10, 2021 written comments to the EPA CASAC PM Panel that PM2.5 does not cause death and that there is no scientific or public health justification for tightening the PM2.5 NAAQS. Indeed, the prior EPA CASAC and prior EPA Administrator as of December 2020 concluded that PM2.5 NAAQS should not be tightened.

Finally, I believe that Dr. Peel's research integrity is compromised because she has been a close colleague of the current EPA CASAC Chair Lianne Sheppard since 1994. I have challenged the research integrity and objectivity of Dr. Sheppard regarding her research relating glyphosate to cancer. Please examine my detailed evidence challenging the integrity of Dr. Sheppard: particularly, [here](#), [here](#), and [here](#). Both Dr. Peel and Dr. Sheppard are distorting the health risks of PM2.5 and are hurting the research integrity of epidemiology.

Please let me know if you want additional details from me in support of Dr. Enstrom's Allegation of Research Misconduct by Dr. Peel.

Thank you very much for your consideration.

Sincerely,

Geoffrey Kabat, Ph.D., M.S.  
16 Bon Air Avenue  
New Rochelle NY 10804

Mobile: 914-471-5388





Research Integrity Office  
200 University Services Center – Campus Delivery 2011  
Fort Collins, CO 80523-2011  
TEL: (970) 491-5241  
FAX: (970) 491-2293

March 11, 2022

Dear Dr. Enstrom.

Thank you for contacting the Colorado State University (CSU) Research Integrity Office with your concerns about Dr. Peel's service on the Environmental Protective Agency Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Panel. It is important that scientists and citizens alike engage in public discourse about these important matters, and CSU takes seriously our part in that discourse.

Per the CSU Research Misconduct and Research-related Misconduct Policy, the Research Integrity Officer will assess allegations of Research Misconduct and Research-related Misconduct determine whether or not they fit the definitions outlined, to merit progression into the pre-inquiry phase. As defined in our policy, Research Misconduct and Research-related Misconduct 'does not include honest error or difference of opinion'. Therefore, my assessment of your concerns and the conditions surrounding Dr. Peel's research and her service on the CASAC, is that **your allegation does not meet the definition of Research Misconduct or Research-related Misconduct.**

As I'm sure you are aware, panelists on EPA committees are selected for their expertise and undergo special ethics training and detailed vetting for any real or perceived conflicts of interest. Dr. Peel went through these processes and was cleared for her service on the CASAC.

#### **Colorado State University Policies:**

It is important and expected for academic scientists to participate in public service. Indeed, it is the mission of CSU and land-grant institutions writ large to engage in this type of activity. This expectation is documented in the CSU Faculty Manual, and it is in this capacity that Dr. Peel serves on the CASAC Panel.

##### **E.12.3.6 Other Types of Service**

3. Public service. As faculty members advance through the professorial ranks, they are expected to exhibit an increasing record of service in their dossier of performance. Recognition is given to service that fulfills the public mission of the University, such as involvement in community organizations and service to governmental agencies at the local, state and national level, and to professional associations at the local, national, and international level.

While I offered the potential of facilitating a meeting between you and Dr. Peel, I am declining to do so, based on my assessment of your concerns. While I believe open dialog is important in general, in this instance, your concerns are not appropriately directed toward a single investigator. The CSU Faculty Manual outlines the academic freedoms afforded our faculty members and the role of administration in promoting and preserving these freedoms of faculty, per the excerpts below. There are several other ways to engage in this discourse, including public comment periods, scientific conferences, scientific journals and the like.

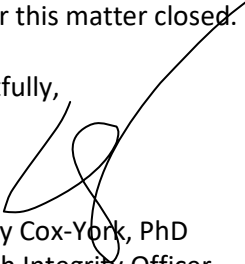
The faculty member is entitled to freedom of research within the confines of the stated conditions or agreements with the institution and/or contract or proposal parameters, if applicable. This freedom extends to publication of results.

The freedoms granted by the First Amendment to the Constitution of the United States are applicable to the faculty member, both as an academician and as a citizen.

The major purpose of the University Administration is to provide an atmosphere conducive to teaching, research, extension, and service. Administrators, therefore, must protect, defend, and promote academic freedom as a necessary prelude to the free search for and exposition of truth and understanding.

Thank you for raising your concerns with the Colorado State University Research Integrity Office. We consider this matter closed.

Respectfully,



Kimberly Cox-York, PhD  
Research Integrity Officer  
Colorado State University

From: **James E. Enstrom** <jenstrom@ucla.edu>  
Date: Wed, Feb 2, 2022 at 4:15 PM  
Subject: Request to Discuss PM2.5 Deaths and PM2.5 NAAQS  
To: Xiao Wu <xiao\_wu@mail.harvard.edu>  
Cc: Xiao Wu <wuxiao@stanford.edu>

February 2, 2022

Xiao Wu, PhD  
Biostatistics Researcher  
Harvard TH Chan School of Public Health  
[xiao\\_wu@mail.harvard.edu](mailto:xiao_wu@mail.harvard.edu)  
Postdoctoral Scholar  
Stanford Department of Statistics  
<https://profiles.stanford.edu/271313>  
[wuxiao@stanford.edu](mailto:wuxiao@stanford.edu)

Dear Dr. Wu,

I am writing because I have strong evidence that two publications co-authored by you contain FALSE statements. The July 17, 2020 *Sciences Advances* article “Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly” by Xiao Wu, Danielle Braun, Joel Schwartz, Marianthi-Anna Kioumourtzoglou, and Francesca Dominici ([DOI: 10.1126/sciadv.aba5692](https://doi.org/10.1126/sciadv.aba5692)) claims “Leveraging 16 years of data—68.5 million Medicare enrollees—we provide strong evidence of the *causal* link between long-term PM2.5 exposure and mortality under a set of causal inference assumptions.” The January 26, 2022 Health Effects Institute Research Report 211 (HEI RR 211) “Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Implementation of Causal Inference Methods” by Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Danielle Braun, Ben Sabath, and Xiao Wu ([https://www.healtheffects.org/system/files/dominici-rr-211-report\\_1.pdf](https://www.healtheffects.org/system/files/dominici-rr-211-report_1.pdf)) claims “The consistency of the associations across methods provides stronger support than past studies for what is likely a *causal* effect between long-term exposure to PM2.5 and mortality” (page 21) and “collectively our results indicate that long-term PM2.5 exposure is likely to be *causally* related to mortality” (page 51).

These two EPA-funded publications are part of a long-running campaign by senior author Dominici to make unjustified claims that are currently being used by the Biden EPA to justify tightening the PM2.5 NAAQS. A recent New York Times article about HEI RR 211 is an example of the Dominici campaign (<https://www.nytimes.com/2022/01/26/climate/air-pollution-study-epa.html>): “The findings come as the Biden administration is considering whether to strengthen the national standard for PM 2.5, which is currently set at a yearly average of 12 micrograms per cubic meter, a level higher than that recommended by the World Health Organization. Researchers concluded that 143,257 deaths could have been prevented between 2006 and 2016 if the standard had been tightened to 10 micrograms per cubic meter. ‘If we were to reduce PM 2.5, we would be saving a substantial amount of lives,’ said Francesca Dominici, a professor of biostatistics at Harvard who led the study, which took four years to complete. ‘It’s highly significant.’ ‘This is important evidence for E.P.A. to consider,’ Dr. Dominici added.”

Because Harvard Biostatistics Professor Dominici (<https://www.hsph.harvard.edu/francesca-dominici/>) has made MANY FALSE statements about health effects of PM2.5 during the past 15 years, I have filed a formal complaint of scientific misconduct against her. My complaint consists of the following nine points that challenge the scientific validity of her claims that fine particulate matter (PM2.5) *causes* premature deaths in the US:

1. Her **deliberate falsification** of the research record on PM2.5 deaths obscures the many NULL findings
2. Her **opposition to transparency** in EPA research hinders reproducibility of all PM2.5 death findings
3. **Enstrom 2017 challenges** the validity of PM2.5 NAAQS and her findings of Medicare PM2.5 deaths
4. **Smith 2021 reanalysis** of Di JAMA 2017 challenges her findings of PM2.5 deaths below 12 µg/m<sup>3</sup>
5. Her service on the EPA-funded NASEM NAAQS Committee **violates** NASEM conflict of interest policy
6. Her advocacy for tightening the PM2.5 NAAQS is erroneous given the existing **low US PM2.5 levels**
7. She **misuses Medicare records** for weak ecological epidemiology and unjustified causal conclusions
8. Her access to confidential Medicare records is **without the informed consent** of 69 million Americans
9. Her **30+ Chinese co-authors** are a concern for HIPAA violation of Medicare records confidentiality

Because you are part of the Dominici campaign, I request the opportunity to discuss with you my evidence that there is NO proof that PM2.5 *causes* death and NO scientific or public health justification for tightening the PM2.5 NAAQS (<http://scientificintegrityinstitute.org/PMPanel121021.pdf>). Please respond to me via email or telephone by February 7, 2022.

Thank you very much for your consideration.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
<http://scientificintegrityinstitute.org/>  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

From: James E. Enstrom <jenstrom@ucla.edu>  
Date: Tue, Jan 4, 2022 at 10:00 AM  
Subject: Scientific Misconduct by HTHCSPH Professor Francesca Dominici  
To: John Quackenbush <johnq@hsph.harvard.edu>  
Cc: Clifford S. Duke <cduke@nas.edu>

January 4, 2022

John Quackenbush, PhD  
Professor and Chair, Department of Biostatistics  
Harvard TH Chan School of Public Health (HTHCSPH)  
[johnq@hsph.harvard.edu](mailto:johnq@hsph.harvard.edu)

Re: Scientific Misconduct by HTHCSPH Professor Francesca Dominici

Dear Dr. Quackenbush,

I am herewith submitting to you a formal complaint of scientific misconduct against Francesca Dominici, PhD, Clarence James Gamble Professor of Biostatistics, Population and Data Science at the HTHCSPH (<https://www.hsph.harvard.edu/francesca-dominici/>). My complaint consists of the following nine points that challenge the scientific validity of her EPA-funded claims that inhaling about 100 µg of fine particulate matter (PM2.5) per day **causes** premature deaths without any proven **causal** mechanism:

1. Her deliberate falsification of the research record on PM2.5 deaths obscures the many NULL findings
2. Her opposition to transparency in EPA research hinders reproducibility of all PM2.5 death findings
3. Enstrom 2017 challenges the validity of PM2.5 NAAQS and her findings of Medicare PM2.5 deaths
4. Smith 2021 reanalysis of Di JAMA 2017 challenges her findings of PM2.5 deaths below 12 µg/m<sup>3</sup>
5. Her service on the EPA-funded NASEM NAAQS Committee violates NASEM conflict of interest policy
6. Her advocacy for tightening the PM2.5 NAAQS is erroneous given the existing low US PM2.5 levels
7. She misuses Medicare records for weak ecological epidemiology and unjustified **causal** conclusions
8. Her access to confidential Medicare records is without the informed consent of 69 million Americans
9. Her 30+ Chinese co-authors are a concern for HIPAA violation of Medicare records confidentiality

I have very strong evidence to support all nine of the above points, such as, my 36-page December 10, 2021 Comments to EPA CASAC (<http://scientificintegrityinstitute.org/PMPanel121021.pdf>) and my September 15, 2021 request to remove Dr. Dominici from the NASEM NAAQS Committee (<http://scientificintegrityinstitute.org/NASEMDominici091521.pdf>). I can submit additional evidence once you agree to examine my complaint.

I commend you for expressing strong support for transparent and reproducible scientific research by co-authoring the October 14, 2020 *Nature* commentary “Transparency and reproducibility in artificial intelligence” (doi: [10.1038/s41586-020-2766-y](https://doi.org/10.1038/s41586-020-2766-y)). Transparency and reproducibility are urgently needed in PM2.5 epidemiology.

Time is of the essence regarding my complaint because the EPA CASAC and its PM Panel are now preparing to formally recommend tightening the PM2.5 NAAQS and the NASEM NAAQS Committee is preparing (via secret meetings) a report on **causality** that is highly relevant to the PM2.5 NAAQS. Also, my complaint is relevant to the Federal lawsuit challenging the composition and legality of the current EPA CASAC (<https://junkscience.com/2021/12/wall-street-journal-editorializes-on-young-v-epa/>).

The scientific misconduct of Dr. Dominici is one example of “The Ideological Corruption of Science: in American laboratories and universities, the spirit of Trofim Lysenko has suddenly been woke.” This corruption is described by renowned theoretical physicist Lawrence Krauss in his July 13, 2020 Wall Street Journal Op-Ed (<https://www.wsj.com/articles/the-ideological-corruption-of-science-11594572501>). Dr. Krauss has appropriately noted that “Whenever science has been corrupted by falling prey to ideology, scientific progress suffers. This was the case in Nazi Germany, the Soviet Union . . .”

Thank you very much for your consideration of my complaint.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
<http://scientificintegrityinstitute.org/>  
[jenstrom@ucla.edu](mailto:jenstrom@ucla.edu)  
(310) 472-4274

cc: NASEM BEST Director Clifford S. Duke, PhD

Comment to NASEM DELS-BEST NAAQS Committee

“Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards”

<https://www.nationalacademies.org/our-work/assessing-causality-from-a-multidisciplinary-evidence-base-for-national-ambient-air-quality-standards>

<https://www8.nationalacademies.org/pa/feedback.aspx?type=project&key=DELS-BEST-20-06>

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
[http://scientificintegrityinstitute.org/  
jenstrom@ucla.edu](http://scientificintegrityinstitute.org/jenstrom@ucla.edu)

September 15, 2021

**The Case for Removing Harvard TH Chan School of Public Health Professor of Biostatistics  
Francesca Dominici (Dominici) from the NASEM DEL-BEST NAAQS Committee**

Dominici should be removed from this NASEM Committee for the five reasons presented below. These reasons provide strong evidence that she cannot honestly and objectively contribute to the Committee goal to “consider frameworks to assess causality of health and welfare effects of air pollutants in EPA’s Integrated Science Assessments (ISAs) conducted as part of EPA reviews of National Ambient Air Quality Standards (NAAQS).”

1. Dominici has been using detailed US Medicare records since 2006 to conduct ecological epidemiology research and to publish etiologically flawed links between air pollution and various health conditions, particularly death. In spite of repeated efforts, I have been unable to confirm that Dominici and her collaborators have proper access to Medicare records on 69 million Americans who represent about 95% of all Americans aged 65+ years since 2000. Individual Medicare recipients, including myself and my relatives and scientific colleagues, NEVER granted permission to Dominici to have our Medicare records used for ecological epidemiology, which Dominici is using to advocate for more restrictive NAAQS. Dominici possesses so much information on individual Medicare recipients that I believe she can identify many of these individuals even if she does not possess their name and street address. The information she possesses can be linked with other databases that contain full name, full address, and age or date of birth. Thus, I want to determine if Dominici has been violating Medicare patient confidentiality. Because I have been unable to get any response from Dominici, I have directed my efforts to one of her former graduate students, Lihua Shi, ScD (Shi) of Emory University, who also has access to these Medicare records. Since July 8, 2021 I have requested that Shi release to me the de-identified Medicare records that she possesses for about 500 residents of a particular zip code (<http://scientificintegrityinstitute.org/estjeeadd070821.pdf>). Because Shi has not responded to me, I have directed my request to several top officials at Emory University as of August 30, 2021 (<http://www.scientificintegrityinstitute.org/CurranJEE083021.pdf>). Since none of these officials have responded to me, I am expanding my efforts to stop the epidemiologic misuse of Medicare records.

2. A September 6, 2021 PubMed.gov search of “Dominici Medicare” yielded 83 ecological epidemiology articles by Dominici during 2006-2021 that are based on Medicare records. Of these, 46 presented positive associations of PM2.5 with disease or death in the US. They contain aggressive conclusions like the one in her July 2021 Epidemiology article (doi: 10.1097/EDE.0000000000001354): “We estimated that reducing PM2.5 and O3 concentrations to levels below current standards [NAAQS] would increase life expectancy by substantial amounts compared with the recent increase of life expectancy at age 65 of 0.7 years in a decade.” I contend that all these articles are based on improper use of Medicare records and are meant to improperly influence the EPA ISA and NAAQS for PM2.5. Obviously, these articles will overwhelm the ISA literature review and will obscure the small number of important articles that do not support the claim that PM2.5 causes premature deaths in the US.

3. Dominici’s articles falsify the research record on PM2.5 and mortality because they ignore the extensive evidence that there is NO significant relationship between PM2.5 and total mortality in the US. In particular, Dominici has NEVER cited Enstrom 2005, Enstrom 2017, or other articles that find NO relationship. This NULL evidence directly contradicts Dominici’s Medicare results, as detailed in my 31-page July 8, 2021 Review of a similar manuscript by Shi (<http://scientificintegrityinstitute.org/estjeeadd070821.pdf>). Furthermore, Dominici never mentions the extensive evidence that the Linear No Threshold (LNT) Model is severely flawed (<https://doi.org/10.1016/j.envres.2021.111025>). This evidence on LNT contradicts her claims of causality in low-level air pollutant health effects. Finally, Dominici never mentions the intense controversy that has existed for about 30 years regarding PM2.5 deaths, as summarized in my Review.

4. Dominici fails to acknowledge in her publications that there is NO public health benefit in lowering the annual EPA PM2.5 NAAQS of 12  $\mu\text{g}/\text{m}^3$  because as of 2019 the average population-weighted PM2.5 level in the US was 7.7  $\mu\text{g}/\text{m}^3$ , as per the 2019 State of Global Air Map (<https://www.stateofglobalair.org/data/#/air/map>). The US level is among lowest in the world, where as the Chinese level of 48  $\mu\text{g}/\text{m}^3$  is among the highest in the world. It is worth noting that Dominici’s Medicare articles have a total of 34 Chinese co-authors, like Shi, and Shi now has her own Emory University research group (<https://www.liuhuashi.com/people/>), which includes 12 Chinese graduate students. It is amazing that NONE of Dominici’s articles mention China. If Dominici and her Chinese co-authors really cared about PM2.5 health effects, they would focus on the very high PM2.5 level in China rather than on the very low PM2.5 level in the US.

5. Based on Dominici’s biased articles emphasizing adverse air pollution health effects in the US and her falsification of the complete research record on air pollution health effects in the US, a strong case can be made that she is contributing to what has been described by renowned physicist Lawrence Krauss as “The Ideological Corruption of Science” (<https://www.wsj.com/articles/the-ideological-corruption-of-science-11594572501>). If Dominici remains on the NASEM DEL-BEST NAAQS Committee she will certainly damage its objectivity and credibility.



From: **James E. Enstrom** <jenstrom@ucla.edu>

Date: Mon, Aug 30, 2021 at 9:00 AM

Subject: Emory Gangarosa Investigators Misuse US Medicare Records

To: James W. Curran <jcurran@emory.edu>

Cc: Liuhua Shi <liuhua.shi@emory.edu>, Rebecca Rousselle <rebecca.rousselle@emory.edu>, Nelson Kyle Steenland <nsteenl@sph.emory.edu>, Timothy L. Lash <tlash@emory.edu>, Ravi V. Bellamkonda <provost@emory.edu>, Gregory L. Fenves <president@emory.edu>

August 30, 2021

James W. Curran, MD, MPH  
Dean and Professor of Epidemiology  
Emory University Rollins School of Public Health  
[jcurran@emory.edu](mailto:jcurran@emory.edu)

Re: Emory Gangarosa Investigators Misuse US Medicare Records

Dear Dean Curran,

I have strong evidence that Gangarosa Department of Environmental Health investigators in the Rollins School of Public Health, particularly The Environment and Seniors Health Research Group (<https://www.liuhuashi.com/>), are misusing confidential Medicare records in order to publish scientifically unjustified claims about air pollution health effects in the US.

These investigators possess detailed personal and medical data on at least 69 million US Medicare beneficiaries aged 65 years and above, including myself. They never obtained permission from me or the other beneficiaries for their use of this confidential medical information. In spite of repeated requests since June 28, 2021, the Emory Institutional Review Board (<http://www.irb.emory.edu/>) has not confirmed the validity of the investigators' claims "This study was approved by the Institutional Review Board of Emory University and a waiver of informed consent was granted" and "Written informed consent of individuals was not required due to the nature of the study."

Thus, please provide the justification for these claims and please explain how these investigators obtained access to Medicare data on 69 million Americans. Furthermore, please ask the investigators to release to me all the de-identified data that they possess on about 500 Medicare beneficiaries in one zip code that I will specify. I want to demonstrate that many of these beneficiaries can be individually identified, in violation of the Medicare privacy policy (<https://www.medicare.gov/privacy-policy>).

My grave concerns about epidemiologic misuse of Medicare records are contained in my July 8, 2021 detailed peer-review of the now rejected Environmental Science & Technology (ES&T) manuscript "Low-concentration air pollution and mortality in American older adults: A national cohort analysis (2001-2017)" by Dr. Liuhua Shi and other Emory investigators (<http://scientificintegrityinstitute.org/ESTJEEAdd070821.pdf>). I expressed similar concerns in a July 27, 2021 email message to Nature (<http://www.scientificintegrityinstitute.org/NatureJEE072721.pdf>) regarding a Dr. Shi, et al. manuscript submitted to a Nature Portfolio Journal: "Long-term air pollution exposure and incident dementia in American elderly population: a national cohort study (2000-2018)" (<https://www.researchsquare.com/article/rs-514522/v1>).

The ES&T manuscript is filled with aggressive and misleading claims like “In conclusion, long-term exposures to PM2.5, NO2, and O3 were significantly associated with an increased risk of all-cause mortality, particularly at levels below the current NAAQS standards, suggesting that implementing more stringent regulations in air quality may yield substantial health benefits.” Furthermore, the manuscript ignores the severe flaws of ecological epidemiology and falsifies the research record by not citing the strong evidence that there is NO relationship between air pollution and all-cause mortality in the US and that the linear no threshold (LNT) theory is invalid. Finally, there is NO public health justification for this study because the US already has extremely low levels of air pollution that will not be influenced by more stringent regulations, as explained in my review.

Please ask Dr. Shi to respond to my above concerns in a timely manner. Thus far, she has ignored my requests for a response. I have copied this message to other Emory University officials who should be aware of the misuse of Medicare records.

Thank you very much for your consideration and assistance.

Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE  
Retired UCLA Research Professor (Epidemiology)  
President, Scientific Integrity Institute  
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# Review of *Environmental Science & Technology* Manuscript ID es-2021-03653z

James E. Enstrom, PhD, MPH, FFACE

July 8, 2021

## Low-concentration air pollution and mortality in American older adults: A national cohort analysis (2001-2017)

Liuhua Shi\*<sup>1</sup>, ScD, Andrew Rosenberg\*<sup>1</sup>, MPH, Pengfei Liu<sup>2</sup>, PhD, Mahdieh Danesh Yazdi<sup>3</sup>, PhD, Weeberb Réquia<sup>4</sup>, PhD, Kyle Steenland<sup>1</sup>, PhD, Howard Chang<sup>5</sup>, PhD, Jeremy A. Sarnat<sup>1</sup>, ScD, Yang Liu<sup>1</sup>, PhD, Kuo Zhang<sup>1,6</sup>, MPH, Jingxuan Zhao<sup>7</sup>, MPH, Joel Schwartz<sup>3,8</sup>, PhD

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### Lack of Epidemiologic Qualifications of Authors

Lead co-author Dr. Liuhua Shi is Emory University Research Assistant Professor of Environmental Health (<https://sph.emory.edu/faculty/profile/index.php?FID=liuhua-shi-10928>). She has a 2016 ScD in Environmental Health from Harvard TH Chan School of Public Health (HTHCSPH) and a 2009 BS and 2012 MS in Geography from Beijing Normal University in China. Her 2016 ScD Dissertation, “Estimating Health Effects of Temperature and pm2.5 Using Satellite-Retrieved High-Resolution Exposures,” was apparently obtained under the direction of Senior Author and HTHCSPH Professor Joel D. Schwartz. She states “My research focuses on employing massive datasets, including satellite-retrieved high resolution exposures and health data of all Medicare beneficiaries, to investigate how climate change and air pollution influence seniors' health.” However, she lists no formal training in Epidemiology, the discipline most relevant to the above manuscript.

Lead co-author Mr. Andrew Rosenberg has a 2021 MPH in Environmental Health from Emory University and is a “Master Student” member of Dr. Shi’s “The Environment and Seniors’ Health Research Group” (<https://www.liuhuashi.com/people/>). He lists no formal training in Epidemiology. The stated goal of this Group “is to leverage massive nationwide datasets, including satellite-retrieved high-resolution environmental exposure data and individual-level longitudinal health records, to better understand the influence of environmental risk factors on older adults’ health and better frame environmental policy.” The Group website does not cite any of the severe flaws of ecological epidemiology used in the Group publications (<https://www.liuhuashi.com/publications/>).

Based on an initial examination of backgrounds of the ten other authors, they have little or no formal training in epidemiology.

## **Lack of Public Health Basis for Study Because Current Air Pollution Levels in the US are Very Low**

There is NO public health basis for this study because the US already has very low levels of air pollution. Indeed, several of these levels are not much higher than natural background levels. In recent years, the US has had far lower PM2.5 than most other countries. At present, PM2.5 levels in the US are about one-sixth the global average, one-seventh of the China average, and one half of the continental Europe average, as per the 2019 State of Global Air Map (<https://www.stateofglobalair.org/data/#/air/map>), which is shown on page 30 of this review. In 2019, the average annual population-weighted PM2.5 level was **7.7 µg/m<sup>3</sup> in the US** and **48 µg/m<sup>3</sup> in China**. The lowest PM2.5 level anywhere in the world was about 6 µg/m<sup>3</sup>, which must be considered as a realistic minimum level.

## **Specific Criticism of Manuscript**

1. The Abstract makes unjustified scientific and policy claims about air pollution.

Abstract Claims (Line 45): “There was strong evidence of linearity in concentration-response relationships for PM2.5 and NO2 at levels below the current NAAQS, suggesting that no safe threshold exists for health-harmful pollution levels. For O3, the concentration-response relationship shows an increasingly positive association at levels above 30-ppb. In conclusion, long-term exposures to PM2.5, NO2, and O3 were significantly associated with an increased risk of all-cause mortality, particularly at levels below the current NAAQS standards, suggesting that implementing more stringent regulations in air quality may yield substantial health benefits.”

There is extensive peer-reviewed evidence that does not support the validity of the EPA NAAQS and the authors have not cited any of this evidence. Instead, the authors suggest “implementing more stringent regulations in air quality” based on their selective and biased analysis of Medicare data that was never intended for this type of analysis. The manuscript completely ignores 30+ years of severe criticism of the ecologic epidemiology used to relate air pollution to mortality. The Senior Author Joel Schwartz is WELL AWARE of this criticism and he continues to deliberately ignore it. A sample of the criticism is shown on pages 6-29 of this review: the classic 1988 AJE “The Ecological Fallacy” (doi:10.1093/oxfordjournals.aje.a114892); the 2002 RTP critique of the PM2.5 NAAQS by Green and Lash (doi:10.1006/rtp.2002.1548); the 2017 and 2018 D-R Reanalysis articles by Enstrom, and the June 29, 2020 Enstrom Comment to EPA on the PM2.5 NAAQS (Enstrom 2020) (<http://www.scientificintegrityinstitute.org/EPAPM25JEE062920.pdf>).

Note that the 2002 RTP critique, co-authored by Dr. Timothy Lash, current Chair of the Emory University Department of Epidemiology, states: “Associations between airborne concentrations of fine particulate matter (PM2.5) and mortality rates have been investigated primarily by ecologic or semiecologic epidemiology studies. Many investigators and regulatory agencies have inferred that the weak, positive association often observed is causal, that it applies to all forms of airborne PM2.5, and that current ambient levels of PM2.5 require reduction. Before implementing stringent regulations of ambient PM2.5, analysts should pause to consider whether the accumulated evidence is sufficient, and sufficiently detailed, to support the PM2.5 National Ambient Air Quality Standard. . . . Taken together, the toxicologic evidence and lessons learned from analogous epidemiologic associations should encourage further investigation of the association between particulate matter and mortality rates before additional regulation is implemented, and certainly before the association is characterized as causal and applicable to all PM2.5.” The PM2.5 death associations have been continuously challenged

since the PM2.5 NAAQS was established in 1997, as documented in Enstrom 2020 (pages 10-29 of this review).

## 2. The Introduction falsifies the research record regarding PM2.5 and mortality in the US

Introduction Claims (Line 62): “Increasing epidemiological evidence has documented the associations between long-term exposure to fine particulate matter (particles with a mass aerodynamic diameter below 2.5  $\mu\text{m}$  (PM2.5) and reduced life expectancy among adults.(3-7)” References 3 to 7 do not objectively describe the existing US evidence on PM2.5 deaths. Reference 3 (Wu 2020, line 373), Reference 4 (Di 2017, line 376), Reference 7 (Wang 2020, line 384) cite other PM2.5 death findings by Senior Author Schwartz based on Medicare records. These various overlapping findings involve tiny relative risks that do not establish a causal connection between PM2.5 and mortality. The claims of PM2.5 deaths in the ACS CPS II cohort in Reference 5 (Krewski 2009, line 379) were shown to be seriously flawed by Enstrom 2017 and Enstrom 2018. Reference 6 (Ostro 2015, line 381) actually found NO relationship between PM2.5 and total mortality in the CTA cohort, as shown in Enstrom 2017. Enstrom 2020 presents strong evidence that there is NO significant relationship between PM2.5 and total mortality in the US. Furthermore, this current review challenges the validity of all claims of a causal relation between PM2.5 and total deaths based on the multiple ecological epidemiologic analyses of Medicare records by these authors.

## 3. The Materials *Study Population* section involves likely violations of NIH Human Subjects Research Regulations

Line 98: “Health data were obtained from the Centers for Medicare and Medicaid Services (CMS), including all [68.7 million] Medicare beneficiaries, aged 65 years or older, in the contiguous United States from 2001-2017. We extracted data including age and year of Medicare entry, sex, race, Medicaid eligibility (a proxy for SES), the date of death, and ZIP code of residence **for each beneficiary**. Medicaid eligibility and ZIP code were updated annually. We constructed an open, full cohort containing all Medicare beneficiaries who were alive on January 1 of the year following enrollment into Medicare, through each calendar year of follow-up, with all-cause mortality as the outcome of interest.”

I contend that the authors of this manuscript have made unethical use of personal and medical data on 68.7 million Medicare beneficiaries. These beneficiaries include me, many of my extended family members, and many of my scientific colleagues. Consent was never given my me or my family members or my scientific colleagues to have our personal Medicare data used for ecologic epidemiology that I am explaining in this review is bad science. The age and year of Medicare entry, sex, race, Zip code of residence, and date of death is sufficient to identify many beneficiaries, even without their name or exact address. I can identify specific beneficiaries if the investigators produce the deidentified Medicare records for beneficiaries who died during 2001-2005 in a Zip Code that I specify. If the investigators refuse to produce the requested Medicare records, I will use their refusal as evidence that they do not support transparent and reproducible research.

I contend that this NIEHS-funded research violates NIH Human Subjects Research Regulations (<https://grants.nih.gov/policy/humansubjects.htm>). This research does not satisfy NIH Human Subjects

Exemption Categories ([https://grants.nih.gov/sites/default/files/exemption\\_infographic\\_v8\\_508c\\_1-15-2020.pdf](https://grants.nih.gov/sites/default/files/exemption_infographic_v8_508c_1-15-2020.pdf)) and does not satisfy the NIH Requirements for Waiver of Informed Consent (<https://policymanual.nih.gov/3014-301>). Exemption Categories are shown on page 31 of this review. Thus, the authors must provide the evidence that substantiates their claim (Line 110) “This study was approved by the Institutional Review Board of Emory University and a waiver of informed consent was granted.” Because of the seriousness of these violations, I am currently pursuing the matter with the appropriate officials at Emory University and the Centers for Medicare and Medicaid Services.

4. The Results section misrepresents full analysis of PM2.5 and deaths in Medicare cohort

Line 208: “Our findings indicate that long-term exposure to PM2.5, NO2, and O3 was significantly associated with an increased risk of all-cause mortality, particularly at levels below the current NAAQS standards for each pollutant (Fig. 2). Line 213: “Assessing each pollutant individually in the full cohort analysis, a 10-µg/m3 increase in PM2.5 . . . was associated with an increase in mortality rate (i.e., HR-1) ranging between 5-7% . . . . In contrast, the low exposure analysis yielded larger effect estimates, with corresponding increases in mortality rate ranging between 10-13% . . . .”

The focus in the Results and the Abstract is on the “low exposure” Medicare beneficiaries, where the HR for PM2.5 has a maximum value of 1.13. But for the full cohort, the HR for PM2.5 averages 1.06 for single-pollutant models and 1.02 for the three-pollutant models, as shown in Figure 2 (Line 253). These HRs are etiologically insignificant and the most likely reason that they are slightly positive is because of selective analysis, the ecological fallacy, and lack of proper control of confounders.

In addition, the authors have not mentioned the large geographic variation found in the first major analysis of Medicare data, the 2008 *EHP* article “Mortality in the Medicare Population and Chronic Exposure to Fine Particulate Air Pollution in Urban Centers (2000–2005)” (doi:[10.1289/ehp.11449](https://doi.org/10.1289/ehp.11449)). Table 3 of the *EHP* article shows large unexplained geographic variation in PM2.5 mortality risk in the Eastern, Central, and Western portions of the US. There was NO relationship in the Western US (mainly CA) and CA is the state which has been subjected to the most restrictive PM2.5 regulations.

The geographic variation in HR (RR) from the *EHP* Table 3 is shown below.

	Eastern US	Central US	Western US	Total US
Age-adjusted HR:	1.155 (1.130-1.180)	1.178 (1.133-1.222)	1.003 (0.981-1.025)	1.091 (1.076-1.107)
Age+SES-adjusted HR:	1.105 (1.084-1.125)	1.089 (1.052-1.125)	0.997 (0.978-1.016)	1.056 (1.043-1.069)
Age+SES+COPD-adjusted HR:	1.068 (1.049-1.087)	1.132 (1.095-1.169)	0.989 (0.970-1.008)	1.044 (1.032-1.057)

The authors must acknowledge this large unexplained geographic variation in their current manuscript. Indeed, the authors must acknowledge that the US HR in the total Medicare cohort may be NULL if it could be fully and properly adjusted on the individual level to account for sex, race, cigarette smoking, education level, co-pollutants, and other relevant confounders. Enstrom 2020 documents that the HR is NULL for nine US cohorts, including the 2008 Medicare cohort, as shown on page 14 of this review.

5. Conclusion is not justified because of all criticisms in this review.

Line 346: “Using a large nationwide cohort and robust epidemiological analyses, we provide strong evidence that long-term exposure to PM2.5, NO2, and O3, at levels below the current national standards, is significantly and independently associated with increased mortality. Amending national standards in the future may pose substantial public health benefits.”

This Conclusion is a complete distortion of their own analysis of the Medicare cohort, for the reasons described throughout this entire review. The authors provide NO evidence that “Amending national standards in the future may pose substantial public health benefits.”

**Manuscript Decision: Unequivocally, do not publish this manuscript .**

Potential Alternative: A point-counterpoint on the air pollution epidemiology, where Enstrom makes the point criticizing air pollution epidemiology and Schwartz makes the counterpoint promoting air pollution epidemiology.

# Average Annual Population-Weighted PM2.5 Concentrations in 2019

