

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

3380 Chastain Meadows Pkwy NW Suite 200

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

[404.327.6423](tel:404.327.6423) | m: [404.759.7617](tel:404.759.7617) | f: [404.417.5808](tel:404.417.5808)

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

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

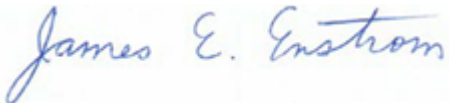
Dear Mr. Reedy,

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,

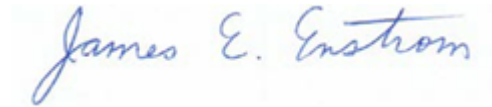
I am writing you regarding a very important epidemiologic issue that involves the 1982 ACS Cancer Prevention Study (CPS II) cohort. I request your assistance because I have received no cooperation from Vice President of Epidemiology Susan M. Gapstur or Epidemiology Data Analysis Core Director W. Ryan 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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# Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis

Dose-Response:  
An International Journal  
January-March 2017:1-12  
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sagepub.com/journalsPermissions.nav  
DOI: 10.1177/1559325817693345  
journals.sagepub.com/home/dos



James E. Enstrom<sup>1</sup>

## Abstract

**Background:** In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter (PM<sub>2.5</sub>), largely because of its positive relationship to total mortality in the 1982 American Cancer Society Cancer Prevention Study (CPS II) cohort. Subsequently, EPA has used this relationship as the primary justification for many costly regulations, most recently the Clean Power Plan. An independent analysis of the CPS II data was conducted in order to test the validity of this relationship.

**Methods:** The original CPS II questionnaire data, including 1982 to 1988 mortality follow-up, were analyzed using Cox proportional hazards regression. Results were obtained for 292 277 participants in 85 counties with 1979-1983 EPA Inhalable Particulate Network PM<sub>2.5</sub> measurements, as well as for 212 370 participants in the 50 counties used in the original 1995 analysis.

**Results:** The 1982 to 1988 relative risk (RR) of death from all causes and 95% confidence interval adjusted for age, sex, race, education, and smoking status was 1.023 (0.997-1.049) for a 10 µg/m<sup>3</sup> increase in PM<sub>2.5</sub> in 85 counties and 1.025 (0.990-1.061) in the 50 original counties. The fully adjusted RR was null in the western and eastern portions of the United States, including in areas with somewhat higher PM<sub>2.5</sub> levels, particularly 5 Ohio Valley states and California.

**Conclusion:** No significant relationship between PM<sub>2.5</sub> and total mortality in the CPS II cohort was found when the best available PM<sub>2.5</sub> data were used. The original 1995 analysis found a positive relationship by selective use of CPS II and PM<sub>2.5</sub> data. This independent analysis of underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the PM<sub>2.5</sub> NAAQS. These findings provide strong justification for further independent analysis of the CPS II data.

## Keywords

epidemiology, PM<sub>2.5</sub>, deaths, CPS II, reanalysis

## Introduction

In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter (PM<sub>2.5</sub>), largely because of its positive relationship to total mortality in the 1982 American Cancer Society (ACS) Cancer Prevention Study (CPS II) cohort, as published in 1995 by Pope et al.<sup>1</sup> The EPA uses this positive relationship to claim that PM<sub>2.5</sub> causes premature deaths. However, the validity of this finding was immediately challenged with detailed and well-reasoned criticism.<sup>2-4</sup> The relationship still remains contested and much of the original criticism has never been properly addressed, particularly the need for truly independent analysis of the CPS II data.

The EPA claim that PM<sub>2.5</sub> causes premature deaths is implausible because no etiologic mechanism has ever been established and because it involves the lifetime inhalation of

only about 5 g of particles that are less than 2.5 µm in diameter.<sup>5</sup> The PM<sub>2.5</sub> mortality relationship has been further challenged because the small increased risk could be due to well-known epidemiological biases, such as, the ecological fallacy, inaccurate exposure measurements, and confounding variables like copollutants. In addition, there is extensive evidence of spatial and temporal variation in PM<sub>2.5</sub> mortality risk (MR) that does not support 1 national standard for PM<sub>2.5</sub>.

<sup>1</sup> University of California, Los Angeles and Scientific Integrity Institute, Los Angeles, CA, USA

## Corresponding Author:

James E. Enstrom, University of California, Los Angeles and Scientific Integrity Institute, 907 Westwood Boulevard #200, Los Angeles, CA 90024, USA.  
Email: jenstrom@ucla.edu



In spite of these serious problems, EPA and the major PM<sub>2.5</sub> investigators continue to assert that their positive findings are sufficient proof that PM<sub>2.5</sub> causes premature deaths. Their premature death claim has been used to justify many costly EPA regulations, most recently, the Clean Power Plan.<sup>6</sup> Indeed, 85% of the total estimated benefits of all EPA regulations have been attributed to reductions in PM<sub>2.5</sub>-related premature deaths. With the assumed benefits of PM<sub>2.5</sub> reductions playing such a major role in EPA regulatory policy, it is essential that the relationship of PM<sub>2.5</sub> to mortality be independently verified with transparent data and reproducible findings.

In 1998, the Health Effects Institute (HEI) in Boston was commissioned to conduct a detailed reanalysis of the original Pope 1995 findings. The July 2000 HEI Reanalysis Report (HEI 2000) included "PART I: REPLICATION AND VALIDATION" and "PART II: SENSITIVITY ANALYSES."<sup>7</sup> The HEI Reanalysis Team lead by Daniel Krewski successfully replicated and validated the 1995 CPS II findings, but they did not analyze the CPS II data in ways that would determine whether the original results remained robust using different sources of air pollution data. For instance, none of their models used the best available PM<sub>2.5</sub> measurements as of 1995.

Particularly troubling is the fact that EPA and the major PM<sub>2.5</sub> investigators have ignored multiple null findings on the relationship between PM<sub>2.5</sub> and mortality in California. These null findings include my 2005 paper,<sup>8</sup> 2006 clarification,<sup>9</sup> 2012 American Statistical Society Joint Statistical Meeting Proceedings paper,<sup>10</sup> and 2015 International Conference on Climate Change presentation about the Clean Power Plan and PM<sub>2.5</sub>-related cobenefits.<sup>6</sup> There is now overwhelming evidence of a null PM<sub>2.5</sub> mortality relationship in California dating back to 2000. The problems with the PM<sub>2.5</sub> mortality relationship have generated substantial scientific and political concern.

During 2011 to 2013, the US House Science, Space, and Technology Committee (HSSTC) repeatedly requested that EPA provide access to the underlying CPS II data, particularly since substantial Federal funding has been used for CPS II PM<sub>2.5</sub> mortality research and publications. On July 22, 2013, the HSSTC made a particularly detailed request to EPA that included 49 pages of letters dating back to September 22, 2011.<sup>11</sup> When EPA failed to provide the requested data, the HSSTC issued an August 1, 2013 subpoena to EPA for the CPS II data.<sup>12</sup> The ACS refused to comply with the HSSTC subpoena, as explained in an August 19, 2013 letter to EPA by Chief Medical Officer Otis W. Brawley.<sup>13</sup> Then, following the subpoena, ACS has refused to work with me and 3 other highly qualified investigators regarding collaborative analysis of the CPS II data.<sup>14</sup> Finally, HEI has refused to conduct my proposed CPS II analyses.<sup>15</sup> However, my recent acquisition of an original version of the CPS II data has made possible this first truly independent analysis.

## Methods

Computer files containing the original 1982 ACS CPS II deidentified questionnaire data and 6-year follow-up data on deaths from September 1, 1982 through August 31, 1988, along

with detailed documentation, were obtained from a source with appropriate access to these data, as explained in the "Acknowledgments." This article presents my initial analysis of the CPS II cohort and it is subject to the limitations of data and documentation that is not as complete and current as the data and documentation possessed by ACS.

The research described below is exempt from human participants or ethics approval because it involved only statistical analysis of existing deidentified data. Human participants' approval was obtained by ACS in 1982 when each individual enrolled in CPS II. Because of the epidemiologic importance of this analysis, an effort will be made to post on my Scientific Integrity Institute website a version of the CPS II data that fully preserves the confidentiality of all of participants and that contains enough information to verify my findings.

Of the 1.2 million total CPS II participants, analysis has been done on 297 592 participants residing in 85 counties in the continental United States with 1979 to 1983 EPA Inhalable Particulate Network (IPN) PM<sub>2.5</sub> measurements.<sup>16,17</sup> Among these participants, there were 18 612 total deaths from September 1, 1982 through August 31, 1988; 17 329 of these deaths (93.1%) had a known date of death. Of the 297 592 participants, 292 277 had age at entry of 30 to 99 years and sex of male [1] or female [2]. Of the 292 277 participants, 269 766 had race of white [1,2,5] or black [3,4]; education level of no or some high school [1,2], high school graduate [3], some college [4,5], college graduate [6], or graduate school [7]; and smoking status of never [1], former [5-8 for males and 3 for females], or current [2-4 for males and 2 for females]. Those participants reported to be dead [D, G, K] but without an exact date of death have been assumed to be alive in this analysis. The unconfirmed deaths were randomly distributed and did not impact relative comparisons of death in a systematic way. The computer codes for the above variables are shown in brackets.

CPS II participants were entered into the master data file geographically. Since this deidentified data file does not contain home addresses, the Division number and Unit number assigned by ACS to each CPS II participant have been used to define their county of residence. For instance, ACS Division 39 represents the state of Ohio and its Unit 041 represents Jefferson County, which includes the city of Steubenville, where the IPN PM<sub>2.5</sub> measurements were made. In other words, most of the 575 participants in Unit 041 lived in Jefferson County as of September 1, 1982. The IPN PM<sub>2.5</sub> value of 29.6739 µg/m<sup>3</sup>, based on measurements made in Steubenville, was assigned to all CPS II participants in Unit 041. This PM<sub>2.5</sub> value is a weighted average of 53 measurements (mean of 33.9260 µg/m<sup>3</sup>) and 31 measurements (mean of 29.4884 µg/m<sup>3</sup>) made during 1979 to 1982<sup>16</sup> and 53 measurements (mean of 27.2473 µg/m<sup>3</sup>) and 54 measurements (mean of 28.0676 µg/m<sup>3</sup>) made during 1983.<sup>17</sup> The IPN PM<sub>2.5</sub> data were collected only during 1979 to 1983, although some other IPN air pollution data were collected through 1984. The values for each county that includes a city with CPS II participants and IPN PM<sub>2.5</sub> measurements are shown in Appendix Table A1.

# 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

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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.

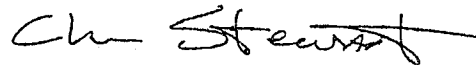
EPA officials should justify their agenda through an open and transparent process that is based on good science, if they can. EPA has projected that its upcoming ozone standard will be the most costly environmental regulation in U.S. history. Working families will bear these costs. They have a right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

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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.