

December 6, 2024

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Re: Flawed ACS CPS II Research and Bad EPA Regulations

Dear ACS Leadership,

We represent major California business organizations that have been harmed by US Environmental Protection Agency (EPA) and California Air Resources Board (CARB) air pollution regulations that are largely based on very flawed research findings involving the 1982 ACS Cancer Prevention Study (CPS II). This flawed research has had and continues to have multibillion dollar adverse economic consequences on our businesses. Thus, we request that ACS immediately address the extensive evidence that, contrary to the claims ACS has made since 1995, fine particulate matter (PM2.5) is NOT related to increased risk of death from all cancer and all causes in the CPS II cohort. Furthermore, we request that ACS address the evidence that the use of CPS II data for air pollution epidemiology violates the cancer prevention mission and enrollment criteria of CPS II. Below we summarize the controversy, the evidence of flawed CPS II research, and the evidence of the adverse impact of scientifically unjustified PM2.5 regulations on California businesses. Retired UCLA Research Professor James E. Enstrom (Enstrom) has assisted us in the preparation of this summary. Enstrom's relationship with ACS dates back to 1973 and he has published peer-reviewed evidence that there is NO relationship between PM2.5 and total mortality in CPS II, based on his unique access to CPS II data. Enstrom possesses detailed evidence supporting misconduct by ACS.

ACS became involved in the PM2.5 controversy with the publication of the March 1, 1995 *AJRCCM* article "Particulate Air Pollution [PM2.5] as a Predictor of Mortality in a Prospective Study of U.S. Adults [CPS II]" with lead authors C. Arden Pope of BYU and Michael J. Thun of ACS [Pope 1995] (http://www.scientificintegrityinstitute.org/Pope1995.pdf). This article was immediately challenged because EPA used the weak positive relationship between PM2.5 and total mortality found in the CPS II cohort as a primary justification to propose and implement the 1997 PM2.5 National Ambient Air Quality Standard (NAAQS). Detailed criticism of EPA's action in this regard is contained in the August/September 1997 Reason.com article "Polluted Science" (https://reason.com/1997/08/01/polluted-science/) or (https://www.scientificintegrityinstitute.org/Fumento080997.pdf). One particularly appropriate quote in this article is "We've just arbitrarily decided PM2.5 is the villain This comes as close to witchcraft as anything I've seen. This isn't science."

Because of the intense scientific controversy and the multi-billion dollar economic impact of the 1997 PM2.5 NAAQS, the Health Effects Institute (HEI) issued a July 25, 1997 "REQUEST FOR QUALIFICATIONS [RFQ]: Epidemiologists and Statisticians to Participate in a Reanalysis of Cohort Studies of Long-term Mortality and Particulate Air Pollution" (http://www.scientificintegrityinstitute.org/HEIRFQ072597.pdf). Some key sentences in the RFQ are: "Two recent prospective cohort studies, the American Cancer Society (ACS) Study [Pope 1995] and the Six Cities Study [Dockery 1993] have reported estimated increases in annual average total mortality associated with fine particles (PM2.5).... The findings of these studies are controversial; the possibility that the magnitude of the observed associations may have been estimated inaccurately due to uncontrolled confounding and/or errors in the measurement of exposure remains a persistent concern. . . . The U.S. EPA has relied, in part, on the results of the Six-Cities and American Cancer Society studies to support a new, more stringent, air quality standard for fine particles. Although these studies were reviewed by the EPA's Clean Air Scientific Advisory Committee (CASAC) as part of the PM Criteria Document process which preceded the promulgation of the new fine particle standard, representatives of industry, members of Congress, and other scientists have urged Harvard University, the American Cancer Society, and the EPA to make the original data from these studies available to other analysts. . . ."

The subsequent 2000 HEI Reanalysis (HEI 2000) was conducted by a team of Canadian statisticians led by Daniel Krewski and Michael Jerrett, who were granted limited access to the CPS II data. HEI 2000 confirmed the findings in Pope 1995, but it did not explore alternative explanations for the findings as required in the RFQ. The 1997 PM2.5 NAAQS was implemented in California in 2008 in the form of severe diesel vehicle regulations (the 2008 CARB Statewide Truck and Bus Regulation) in an effort to reduce the alleged deaths due to diesel PM2.5. Enstrom's December 10, 2008 CARB Public Comment contained detailed evidence that PM2.5 and diesel PM2.5 do not cause deaths in California (http://www.scientificintegrityinstitute.org/CARBPC121008.pdf). The January 2009 California Transportation News, published by Western States Trucking Association, reprinted Enstrom's entire CARB Public Comment (http://www.scientificintegrityinstitute.org/CTN010109.pdf). CARB ignored the null evidence of Enstrom and several others. Press accounts critical of CARB diesel science and its diesel PM regulations are shown in 175 pages (http://www.scientificintegrityinstitute.org/CriticalPress010910.pdf).

Largely because of Enstrom's evidence of CARB research misconduct regarding PM2.5 deaths, a February 26, 2010 "CARB Symposium: Estimating Premature Deaths from Long-term Exposure to PM2.5" was held in Sacramento (https://cal-span.org/meeting/carb 20100226/). Enstrom presented extensive evidence of NO PM2.5 deaths in California. Jerrett presented CPS II evidence that also showed no PM2.5 deaths in California. Five other leading PM2.5 investigators raised doubts about the validity of PM2.5 deaths. Also, Enstrom prepared an October 28, 2011 Compilation of Criticism of the CARB-ACS Jerrett Report on CA PM2.5 Deaths in CPS II (CARB Contract No. 06-332) and this criticism showed that there were NO PM2.5 Deaths in CA in CPS II (http://www.scientificintegrityinstitute.org/JerrettCriticism102811.pdf).

In 2016 an ACS-related source provided Enstrom with a 1989 version of the 1982-1988 CPS II data and documentation, which made possible his March 28, 2017 *Dose-Response* article "Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis" (DOI: 10.1177/1559325817693345). Contrary to the findings in Pope 1995, HEI 2000, and HEI 2009, Enstrom published "Conclusion: No significant relationship between PM2.5 and total mortality in the CPS II cohort was found when the best available PM2.5 data were used. The original 1995 analysis found a positive relationship by selective use of CPS II and PM2.5 data. This independent analysis of underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the PM2.5 NAAQS. These findings provide strong justification for further independent analysis of the CPS II data."

Pope, Jerrett, Krewski, and ACS tried to minimize the significance of Enstrom 2017, but they did not identify any errors in his reanalysis. Enstrom published a May 29, 2018 *Dose-Response* letter that refuted their criticism (DOI: 10.1177/1559325818769728). "Conclusions: My findings of no PM2.5-related deaths during 1982 to 1988 in the CPS II cohort, which are based on my peer-reviewed reanalysis of the CPS II data, stand unchallenged. In addition, my null findings challenge the positive findings in 3 seminal publications [Pope 1995, HEI 2000, and HEI 2009] as not robust and not supportive of the claim that PM2.5 causes premature deaths." (https://junkscience.com/2018/05/pope-fails-to-find-error-inenstroms-2017-reanalysis-of-pope-1995-pm2-5-study/).

Enstrom presented detailed evidence of NO PM2.5 deaths in California or the US in his July 20, 2019 DDP talk "The PM2.5 Deaths Controversy" (http://www.scientificintegrityinstitute.org/DDPPPT072019.pdf) and (https://youtu.be/8j3a4MBUU40). Then he presented detailed evidence that ACS misused CPS II data for a purpose that had nothing to do with cancer prevention and he proposed an explanation for ACS involvement with EPA and its air regulations. See his July 8, 2023 DDP Talk "Corruption of Science by the American Cancer Society" (https://www.scientificintegrityinstitute.org/DDPACSJEE070823.pdf) and (https://www.youtube.com/watch?v=GNjR4ft3xG4).

A new, more restrictive PM2.5 NAAQS was adopted by the Biden EPA in 2024 following an inappropriately accelerated and legally challenged review process during 2021-2023. This new PM2.5 NAAQS will have a devastating economic impact on the US, particularly California, as explained in a February 28, 2024 letter signed by 32 US Senators who oppose the new regulation (https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-tuberville-demand-epa-rescind-job-killing-air-quality-standards/). One indication of its vast regulatory impact on California is the December 5, 2024 CARB Public Workshop (https://content.govdelivery.com/accounts/CARB/bulletins/3c2d9de), which explains that about 80% of Californians live in areas that are out of attainment with the new PM2.5 NAAQS. Finally, we have added below the unanswered October 21, 2024 Enstrom letter to ACS regarding their recent CA article on cancer risk factors that does not mention air pollution (PM2.5) as a risk factor (DOI: 10.3322/caac.21858). This article agrees with Enstrom 2017 and not with Pope 1995.

Thank you for your consideration and timely response.

Sincerely yours,

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

Date: Mon, Oct 21, 2024 at 11:11 AM

Subject: Request to Examine Risk Factors in ACS CPS II

To: Farhad Islami <farhad.islami@cancer.org>

Cc: Alpa V. Patel <alpa.patel@cancer.org>, Karen E. Knudsen <karen.knudsen@cancer.org>

October 21, 2024

Farhad Islami, MD, PhD
Senior Scientific Director, Cancer Disparity Research
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Dear Dr. Islami,

I request your assistance regarding the 1982 ACS Cancer Prevention Study (CPS II). CPS II has been used since 1995 by ACS epidemiologists Michael J. Thun, MD, and Susan M. Gapstur, PhD, to publish extensive epidemiologic research indicating that fine particulate matter (PM2.5) is an important risk factor for death from cancer and all causes. However, your recent CA article on potentially modifiable cancer risk factors makes no mention of PM2.5 as a risk factor (DOI: 10.3322/caac.21858).

Because of the ongoing controversy regarding PM2.5 deaths, I request that you examine my 2017 peer-reviewed reanalysis of the CPS II cohort, which does not support the significant relationship between PM2.5 and mortality found in the 1995 ACS analysis (DOI: 10.1177/1559325817693345). ACS Senior Vice President for Population Science Alpa V. Patel, PhD, could assist you with an examination because she has used CPS II extensively and has been with ACS during the entire time of this controversy. Also, this matter was explained in detail to ACS COE Karen E. Knudsen in my November 22, 2022 email letter (http://www.scientificintegrityinstitute.org/Knudsen112822.pdf).

This is an urgent request because PM2.5 death claims, originating with the 1995 CPS II analysis, have been used by EPA to establish and repeatedly tighten the PM2.5 National Ambient Air Quality Standard (NAAQS). The newest PM2.5 NAAQS will have a devastating economic impact on the US, particularly California. In their February 28, 2024 letter, 32 US Senators explain their strong opposition to forthcoming new PM2.5 regulations (https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-tuberville-demand-epa-rescind-job-killing-air-quality-standards/). Please examine the above web links and send me a timely response.

Thank you very much for your consideration of my request.

Sincerely yours,

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