

## Comment Letter #104

August 29, 2022

US EPA CASAC Ozone Review Panel Regarding Ozone NAAQS Reconsideration  
[https://casac.epa.gov/ords/sab/f?p=113:19:17031850757072:::RP.19:P19\\_ID:976](https://casac.epa.gov/ords/sab/f?p=113:19:17031850757072:::RP.19:P19_ID:976)  
<https://youtu.be/UkmVujyGsq0> (minutes 18-24)  
<http://scientificintegrityinstitute.org/OzonePanel082922.pdf>

### Dr. James Enstrom's Verbal Comment to EPA CASAC Ozone Review Panel

I am Dr. James Enstrom. I have had a long career as an epidemiologist at UCLA and I have made significant contributions to air pollution epidemiology, particularly regarding the importance of transparency and reproducibility. I have made oral public comments to CASAC on November 17, 2021 (<http://scientificintegrityinstitute.org/PMpanel121021.pdf>), February 25, 2022 (<http://scientificintegrityinstitute.org/PMpanel022522.pdf>), and June 8, 2022 (<http://scientificintegrityinstitute.org/Ozonepanel060822.pdf>) and I have submitted detailed written criticism based on these comments. My criticism is highly relevant to the PM2.5 and Ozone NAAQS. Thus far, the criticism by me and numerous other public speakers has been totally ignored by CASAC. This lack of response represents disrespect for objective science by CASAC.

I described this disrespect in my August 16, 2022 DDP talk "Politicized EPA Promotes Anti-American Pseudoscience" (<https://rumble.com/v1gvnuf-politicized-epa-promotes-anti-american-pseudoscience.html>). I pointed out that the January 20, 2021 Presidential Order Protecting Public Health directed immediate review and action to "address the promulgation of Federal regulations and other actions during the last 4 years" (<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/>). This order challenged the validity of all Federal regulations during the Trump Administration and led to the unjustified creation of the current CASAC. This order is a prime example of how regulatory science in America has become highly politicized. An ongoing Federal Lawsuit makes a strong case that the current CASAC is illegally constituted because it violates the Federal Advisory Committee Act requirements of viewpoint diversity and no conflicts of interest (<https://junkscience.com/2021/10/former-casac-chair-added-as-plaintiff-in-young-v-epa/>).

In addition, CASAC refuses to address the evidence that current average levels of human exposure to PM2.5 and ozone in the US are below the levels of known human health effects. In my office in the supposedly polluted city of Los Angeles, my ozone monitor reads about 10 parts per billion (ppb) and my PM2.5 monitor reads about 3  $\mu\text{g}/\text{m}^3$ . These levels are far below the current NAAQS (<https://www.epa.gov/criteria-air-pollutants/naaqs-table>).

Also, CASAC refuses to acknowledge the extreme publication bias against null air pollution health effects findings that I documented in my earlier comments. The 2021 EPA Policy Assessment for PM2.5 ignored at least 60 authors, including me, who have published null findings or criticized the PM2.5 NAAQS (<http://scientificintegrityinstitute.org/PMpanel121021.pdf>). Similar publication bias exists regarding the Ozone NAAQS, but even with this bias the April 2022 EPA Ozone Policy Assessment Reconsideration recommended leaving the Ozone NAAQS unchanged ([draft 2022 policy assessment](#)).

Also, CASAC refuses to support the fundamental principle of the scientific method that air pollution health effects must be based on findings that are transparent and reproducible. My 2017 and 2018 reanalysis of the ACS CPS II cohort found serious flaws in the seminal Pope 1995 article and the 2000 HEI Reanalysis and demonstrated the importance of access to underlying data (<http://scientificintegrityinstitute.org/DRPM25JEEPope052918.pdf>). However, on April 18 *Science* Editor-in-Chief Holden Thorp reinforced his strong bias against EPA transparency by personally writing to me that he will not publish any article, letter, or electronic letter that I submit to *Science* that supports “Strengthening Transparency in Regulatory Science” (<http://scientificintegrityinstitute.org/ThorpJEE041822.pdf>).

As my final evidence of anti-science bias, CASAC Member Christina Fuller gave a misleading presentation in the June 26 HEI Webinar “Setting Ambient Air Quality Standards—What’s Science Got to Do With It?” (<https://www.youtube.com/watch?v=XAcrlTxeiXA>). Furthermore, she has not addressed my June 30 evidence that science has nothing to do with the current NAAQS (<http://scientificintegrityinstitute.org/JEEFuller081822.pdf>). Even worse, the HEI Board of Directors Chair Richard Meserve rejected my June 30 request to initiate an independent investigation of misconduct by HEI and my July 6 request to arrange a debate on whether particulates cause premature death (<http://scientificintegrityinstitute.org/JEEMeserve072222.pdf>). These developments challenge the scientific integrity of HEI.

In conclusion, CASAC must address the extensive evidence that Americans are not being harmed by their current personal exposure to PM2.5 and ozone, but are being harmed by the regulations that are due to scientifically flawed PM2.5 and ozone NAAQS. However, regardless of what CASAC does, this evidence is being presented to the American people.

Thank you very much.

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February 25, 2022

US EPA CASAC PM Panel Webcast re PM2.5 NAAQS based on 2021 PM ISA Supp & PM PA

(<https://www.youtube.com/watch?v=ZkMsBXwyeWw>)

([https://casac.epa.gov/ords/sab/f?p=113:19:22380851460992:::RP,19:P19\\_ID:966](https://casac.epa.gov/ords/sab/f?p=113:19:22380851460992:::RP,19:P19_ID:966))

### **Dr. James Enstrom's Verbal Comment to EPA CASAC PM Panel re PM2.5 NAAQS**

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 (<http://scientificintegrityinstitute.org/pmpanel121021.pdf>).

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. 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.

Thank you.

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January 30, 2017

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Dear Dr. Ghosh,

I am writing to express my extreme disappointment with your December 8, 2016 Final Draft 2016 AQMP [Appendix I Health Effects](#). Your January 3, 2017 198-page document, [Responses to Comments on Appendix I](#), DOES NOT address the numerous critical comments that I submitted to you on [January 11, 2016](#) and [July 26, 2016](#) and [August 15, 2016](#). Below I describe six major problems with the final version of Appendix I.

1. Appendix I DOES NOT comply with [California Health and Safety Code Section 40471 \(b\)](#). Instead of satisfying the requirement “the south coast district board, in conjunction with a public health organization or agency, shall prepare a report on the health impacts of particulate matter air pollution in the South Coast Air Basin,” you stated on page 188 of your Responses document “it is not the intention of this Appendix to assess whether there is or is not an effect of a specific air pollutant on any particular health endpoint . . . .” Instead of satisfying the requirement to prepare Appendix I “in conjunction with a public health organization or agency,” you instead prepared it in conjunction with two aggressive regulatory agencies within CalEPA: OEHHA and CARB. Instead of satisfying the requirement that the “south coast district board shall hold public hearings concerning the report and the peer review,” you held four November 2016 public hearings which were conducted without the SCAQMD Board Members
2. Appendix I and your Responses document DO NOT describe the overwhelming evidence of NO relationship [relative risk (RR) = 1.00] between PM<sub>2.5</sub> and total mortality in California. The weighted average of the most recent results from six different California cohorts show RR = 0.999 (0.988-1.010), which means there are NO premature deaths caused by PM<sub>2.5</sub> in California. An appended table shows this null California evidence. This table, which is page 5 of my August 15, 2016 comments, was deliberately omitted from your Responses document.
3. Appendix I and your Responses document completely ignore this statement in my August 15, 2016 comments: “I have now submitted for publication a manuscript with null findings that invalidate the positive nationwide relationship between PM<sub>2.5</sub> and total mortality published in the seminal Pope 1995 paper, which is based on the American Cancer Society Cancer Prevention Study II (CPS II) cohort. My null CPS II cohort findings raise serious doubts about validity of the positive CPS II cohort findings in Jerrett 2005, Jerrett 2009, and Jerrett 2013, which have been used as the basis for the PM<sub>2.5</sub> premature death claims in the PPTs of Drs. Oliver and Shen.” My manuscript, entitled “Fine Particulate Matter and Total Mortality in Cancer Prevention Study II Reanalysis,” is now in press in a PubMed recognized scientific journal and should appear online in February 2017. This paper provides important new evidence that PM<sub>2.5</sub> does not cause premature deaths anywhere in the United States, including California.

4. Appendix I and the [2016 AQMP SES Report](#) rely heavily the PM<sub>2.5</sub>-mortality publications by Dr. Michael Jerrett and his co-authors. You have co-authored with Jerrett seven air pollution related publications during 2011-2016. This co-authorship raises serious doubts about your objectivity, particularly since you have ignored null PM<sub>2.5</sub>-mortality results and have ignored my challenges to the validity of the Jerrett publications. On November 11, 2016 I made a [US Office of Research Integrity allegation](#) that Jerrett 2013 falsified and exaggerated the relationship between PM<sub>2.5</sub> and total mortality in California. An ORI Investigator agreed that the Jerrett 2013 results “do not provide evidence that air pollution is directly responsible for mortality.” My US ORI allegation and a table showing NO PM<sub>2.5</sub>-mortality relationship in California are appended.

5. Appendix I does not describe the ACTUAL human exposures to PM<sub>2.5</sub>, ozone, and NOx in the SCAB. The human exposures to these pollutants are much lower than the ambient levels recorded at SCAQMD monitors and the average human exposures are well below the level of measurable health effects for these air pollutants. SCAQMD Board Members and SCAB residents must be informed of their actual exposures to pollutants. Furthermore, they must be informed that these levels are well below the corresponding US EPA NAAQS.

6. Appendix I provides no context regarding the impact of air pollution and other risk factors on the overall health of SCAB residents. An appended table shows low 2014 age-adjusted death rates from all causes, all cancer, and all respiratory disease in California and the SCAB. These death rates are among the lowest in the United States and the World. This table, which is page 6 of my August 15, 2016 comments, was deliberately omitted from your Responses document.

If the 2016 AQMP is approved by the SCAQMD Board on February 3, 2017, I will make a strong case to the new US EPA Administrator, the US House Science Committee, the US House Energy Committee, and the US Senate Environment Committee that the AQMP should not be implemented because it is NOT justified on a scientific or public health basis. Also, I will make a strong case to business and taxpayer groups in Southern California that the 2016 AQMP is scientifically unjustified and should not be funded. Many concerned scientists like myself are doing everything we can to stop SCAQMD from implementing new unjustified environmental regulations in Southern California, as part of a national effort to reduce unjustified regulations.

Finally, I am sending this email letter to all UCLA School of Public Health faculty members who have been involved with SCAQMD and/or with your 2011 Ph.D. in Epidemiology. I request that these faculty members assess my above comments and inform SCAQMD whether they believe the 2016 AQMP is justified on a public health basis. These faculty members are directly responsible for your training as an environmental epidemiologist and you, as a prominent public health official, are a direct reflection of the values and integrity of the School of Public Health.

Thank you for taking this message seriously, because it is a VERY SERIOUS message.

Sincerely yours,

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**Summary Table. Epidemiologic cohort studies of PM<sub>2.5</sub> and total mortality in California, 2000-2016**  
**Relative risk of death from all causes (RR and 95% CI) associated with increase of 10 µg/m<sup>3</sup> in PM<sub>2.5</sub>**  
<http://scientificintegrityinstitute.org/NoPMDeaths112215.pdf>

Krewski 2000 & 2010	CA CPS II Cohort	N=40,408	RR = 0.872 (0.805-0.944)	1982-1989
(N=[18,000 M + 22,408 F]; 4 MSAs; 1979-1983 PM <sub>2.5</sub> ; 44 covariates)				
McDonnell 2000	CA AHSMOG Cohort	N~3,800	RR ~ 1.00 (0.95 – 1.05)	1977-1992
(N=[1,347 M + 2,422 F]; SC&SD&SF AB; M RR=1.09(0.98-1.21) & F RR~0.98(0.92-1.03))				
Jerrett 2005	CPS II Cohort in LA Basin	N=22,905	RR = 1.11 (0.99 - 1.25)	1982-2000
(N=22,905 M & F; 267 zip code areas; 1999-2000 PM <sub>2.5</sub> ; 44 cov + max confounders)				
Enstrom 2005	CA CPS I Cohort	N=35,783	RR = 1.039 (1.010-1.069)	1973-1982
(N=[15,573 M + 20,210 F]; 11 counties; 1979-1983 PM <sub>2.5</sub> )				
Enstrom 2006	CA CPS I Cohort	N=35,783	RR = 1.061 (1.017-1.106)	1973-1982
(11 counties; 1979-1983 & 1999-2001 PM <sub>2.5</sub> )				
Zeger 2008	MCAPS Cohort “West”	N=3,100,000	RR = 0.989 (0.970-1.008)	2000-2005
(N=[1.5 M M + 1.6 M F]; Medicare enrollees in CA+OR+WA (CA=73%); 2000-2005 PM <sub>2.5</sub> )				
Jerrett 2010	CA CPS II Cohort	N=77,767	RR ~ 0.994 (0.965-1.025)	1982-2000
(N=[34,367 M + 43,400 F]; 54 counties; 2000 PM <sub>2.5</sub> ; KRG ZIP; 20 ind cov+7 eco var; Slide 12)				
Krewski 2010 (2009)	CA CPS II Cohort			
(4 MSAs; 1979-1983 PM <sub>2.5</sub> ; 44 cov)		N=40,408	RR = 0.960 (0.920-1.002)	1982-2000
(7 MSAs; 1999-2000 PM <sub>2.5</sub> ; 44 cov)		N=50,930	RR = 0.968 (0.916-1.022)	1982-2000
Jerrett 2011	CA CPS II Cohort	N=73,609	RR = 0.994 (0.965-1.024)	1982-2000
(N=[32,509 M + 41,100 F]; 54 counties; 2000 PM <sub>2.5</sub> ; KRG ZIP Model; 20 ind cov+7 eco var; Table 28)				
Jerrett 2011	CA CPS II Cohort	N=73,609	RR = 1.002 (0.992-1.012)	1982-2000
(N=[32,509 M + 41,100 F]; 54 counties; 2000 PM <sub>2.5</sub> ; Nine Model Ave; 20 ic+7 ev; Fig 22 & Tab 27-32)				
Lipsett 2011	CA Teachers Cohort	N=73,489	RR = 1.01 (0.95 – 1.09)	2000-2005
(N=[73,489 F]; 2000-2005 PM <sub>2.5</sub> )				
Ostro 2011	CA Teachers Cohort	N=43,220	RR = 1.06 (0.96 – 1.16)	2002-2007
(N=[43,220 F]; 2002-2007 PM <sub>2.5</sub> )				
Jerrett 2013	CA CPS II Cohort	N=73,711	RR = 1.060 (1.003–1.120)	1982-2000
(N=[~32,550 M + ~41,161 F]; 54 counties; 2000 PM <sub>2.5</sub> ; LUR Conurb Model; 42 ind cov+7 eco var+5 metro; Table 6)				
Jerrett 2013	CA CPS II Cohort	N=73,711	RR = 1.028 (0.957-1.104)	1982-2000
(same parameters and model as above, except including co-pollutants NO <sub>2</sub> and Ozone; Table 5)				
Ostro 2015	CA Teachers Cohort	N=101,884	RR = 1.01 (0.98 -1.05)	2001-2007
(N=[101,881 F]; 2002-2007 PM <sub>2.5</sub> ) (all natural causes of death)				
Thurston 2016	CA NIH-AARP Cohort	N=160,209	RR = 1.02 (0.99 -1.04)	2000-2009
(N=[~95,965 M + ~64,245 F]; full baseline model: PM <sub>2.5</sub> by zip code; Table 3) (all natural causes of death)				
Enstrom 2016 unpub	CA NIH-AARP Cohort	N=160,368	RR = 1.001 (0.949-1.055)	2000-2009
(N=[~96,059 M + ~64,309 F]; full baseline model: 2000 PM <sub>2.5</sub> by county)				

### Allegation of Research Misconduct by Dr. Michael Jerrett and Co-Authors

James E. Enstrom, Ph.D., M.P.H.  
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November 11, 2016

I allege research misconduct (falsification) by UCLA Professor Michael Jerrett, Ph.D., and his primary co-authors C. Arden Pope, Ph.D., Daniel Krewski, Ph.D., George Thurston, Sc.D., Richard T. Burnett, Ph.D., Michael J. Thun, M.D., and Susan P. Gapstur, Ph.D., regarding their attached September 1, 2013 *AJRCCM* paper “Spatial Analysis of Air Pollution and Mortality in California” (<http://www.atsjournals.org/doi/abs/10.1164/rccm.201303-0609OC>). The authors received a portion of their funding for this research from NIEHS and CDC within DHHS. While claiming that fine particulate matter (PM<sub>2.5</sub>) was associated with mortality from all causes (total mortality) in their study, the authors omitted their own null findings and the null findings of others. These omitted findings clearly show NO association. Thus, they have engaged in falsification as defined by DHHS and the Public Health Service: “omitting data or results such that the research is not accurately represented in the research record” (Section 93.103(b) of 42 CFR 93) ([http://ori.hhs.gov/sites/default/files/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf)).

The *AJRCCM* paper claims there is a positive relationship between PM<sub>2.5</sub> and mortality from all causes in California because their “conurbation” land use regression (LUR) model yielded a slightly positive relative risk of RR=1.060 (1.003-1.120), as shown in Table 6. However, complete study results are in the October 28, 2011 Jerrett CARB Final Report “Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort: Final Report” (<http://www.arb.ca.gov/research/apr/past/06-332.pdf>). The eight entirely null models, shown in the attached Report Table 22, were omitted from the paper. The results for all nine models are shown in my Summary Table on the next page. The weighted average relative risk for all nine models is RR=1.002 (0.992-1.012), which means NO relationship.

Furthermore, the *AJRCCM* paper does not cite any of the null California PM<sub>2.5</sub>-mortality results from other papers and reports dating back to 2000, including earlier findings by Dr. Jerrett. These results are shown on the next page, as well as on the attached August 15, 2016 Summary Table that I presented to SCAQMD (<http://www.aqmd.gov/home/library/clean-air-plans/air-quality-mgt-plan/Draft2016AQMP/2016-aqmp-appendix-i-comment-letter> (letter #7)). The weighted average relative risk for the most recent result from each of the six different California cohorts is RR=0.999 (0.988-1.010), which means NO relationship.

I contend that the falsification in the paper was deliberate because it was done after extensive criticism of the June 9, 2011 Draft Report and the October 28, 2011 Final Report. This criticism was presented to the authors via CARB by myself, William M. Briggs, Ph.D., John D. Dunn, M.D., S. Stanley Young, Ph.D., Gordon Fulks, Ph.D., and Frederick W. Lipfert, Ph.D. A compilation of all criticism of the 2011 Report is attached (<http://www.scientificintegrityinstitute.org/JerrettCriticism102811.pdf>). Detailed criticism of the *AJRCCM* paper, including its misrepresentation of the results contained in the CARB Report, was given by Dr. Briggs in his statistical blogs of August 6, 2013 (<http://wmbriggs.com/blog/?p=8720>), September 11, 2013 (<http://wmbriggs.com/blog/?p=8990>), and September 25, 2013 (<http://wmbriggs.com/blog/?p=9241>).

In conclusion, Dr. Jerrett and his co-authors falsified the relationship between PM<sub>2.5</sub> and total mortality in California in their *AJRCCM* paper by deliberately omitting their own null evidence and the null evidence of others. This is quite disturbing because PM<sub>2.5</sub>-mortality claims in the paper are being used as public health justification for the very costly SCAQMD 2016 Air Quality Management Plan (<http://www.aqmd.gov/>).



**Summary Table.** Epidemiologic cohort studies of PM<sub>2.5</sub> and total mortality in California, 2000-2016  
Relative risk of death from all causes (RR and 95% CI) associated with increase of 10 µg/m<sup>3</sup> (IQR=10) in PM<sub>2.5</sub>

<u>Study (Year)</u>	<u>Cohort</u>	<u>RR</u>	<u>95% CI</u>	<u>F-U Years</u>
Jerrett 2013 (AJRCCM Table 6 Model)	CA CPS II	1.060	(1.003–1.120)	1982-2000
Jerrett 2011 (CARB Report Figure 22)	CA CPS II			
KRG IND Model (Table 30, IQR=8.52902→10.0)		0.992	(0.965-1.020)	1982-2000
KRG ZIP Model (Table 28, IQR=8.4735→10.0)		0.993	(0.964-1.023)	1982-2000
KRG IND+O3 Model (Figure 22 extrapolated, IQR=10.0)		1.020	(0.980-1.060)	1982-2000
IDW IND Model (Table 29, IQR=8.74→10.0)		1.003	(0.978-1.028)	1982-2000
IDW ZIP Model (Table 27, IQR=9.37→10.0)		0.995	(0.967-1.025)	1982-2000
BME IND Model (Figure 22 extrapolated, IQR=10.0)		1.000	(0.975-1.025)	1982-2000
LUR IND Model (Table 31, IQR=5.35→10.0)		1.009	(0.980-1.039)	1982-2000
LUR IND+5 Metro Model (Abstract Table 1, IQR=10.0) [Jerrett 2013 Model]		1.080	(1.000-1.150)	1982-2000
RS IND Model (Table 32, IQR= 5.39→10.0)		0.998	(0.968-1.029)	1982-2000
Weighted Average of All Nine Models		1.002	(0.992-1.012)	1982-2000
Other Results by Jerrett and Other Investigators				
Krewski Jerrett 2000 (RR for CA 2010)	CA CPS II	0.872	(0.805-0.944)	1982-1989
McDonnell 2000 *	CA AHSMOG	~ 1.00	(0.95 – 1.05)	1977-1992
Jerrett 2005	CPS II (LA Basin Only)	1.11	(0.99 - 1.25)	1982-2000
Enstrom 2005 *	CA CPS I	0.997	(0.978-1.016)	1983-2002
Zeger 2008 *	MCAPS “West=CA+OR+WA”	0.989	(0.970-1.008)	2000-2005
Jerrett 2010	CA CPS II	~ 0.994	(0.965-1.025)	1982-2000
Krewski Jerrett 2009 (RR for CA 2010)*	CA CPS II	0.968	(0.916-1.022)	1982-2000
Lipsett Jerrett 2011	CA Teachers	1.01	(0.95 – 1.09)	2000-2005
Ostro 2011	CA Teachers	1.06	(0.96 – 1.16)	2002-2007
Ostro 2015 *	CA Teachers	1.01	(0.98 - 1.05)	2001-2007
Thurston 2016 *	CA NIH-AARP	1.02	(0.99 - 1.04)	2000-2009
Weighted Average of Latest Results (*) from Six California Cohorts		0.999	(0.988-1.010)	

**From:** Hohmann, Ann (HHS/OASH) <Ann.Hohmann@hhs.gov>  
**Sent:** Wednesday, December 21, 2016 10:46 AM  
**To:** jenstrom@ucla.edu  
**Cc:** Garfinkel, Susan J (HHS/OASH) <Susan.Garfinkel@hhs.gov>; Trenkle, William (OS/OASH) <William.Trenkle@hhs.gov>  
**Subject:** DIO 6351

Dear Dr. Enstrom,

As the ORI expert in biostatistics and public health, Dr. Garfinkel gave me the materials that ORI has regarding your November 7 conversation with Dr. Trenkle about the Jerrett et al. 2013 paper and your emailed materials to AskORI on November 11, 2016. I have read and reviewed all of the materials. I understand your concern about the way the data were presented in the paper and used elsewhere. Though I have no clinical training, it appears that the relative risks reported do not seem to rise to the level of clinical significance and do not provide evidence that air pollution is directly responsible for mortality. Presenting this data as such, may be a question only of bad science.

However, “bad” or sloppy science is not the same as research misconduct. ORI’s regulation (42 CFR 93.103) defines research misconduct, as you know, as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” While it is true that Dr. Jerrell and colleagues did not cite all the research showing that the relative risk is very, very close to 1 and only emphasized specific numbers, they did not, as far as I can tell, change their data to get a statistically and clinically significant result. The weak results are there for all to see. Thus, there does not appear to be falsification.

To overinterpret one’s data is certainly inappropriate, but would be a matter to raise with the reviewers and the journal editors, who apparently did not insist that the authors tone down their conclusions. ORI is aware that the research on the effects of air pollution is certainly not the only area of science where there is open controversy. Just this morning, *The Scientist* ran an article on the controversy regarding the effects of sugar intake ([http://www.the-scientist.com/?articles.view/articleNo/47819/title/Industry-Funded-Sugar-Study--Don-t-Trust-Other-Sugar-Studies/&utm\\_campaign=NEWSLETTER\\_TS\\_The-Scientist-Daily\\_2016&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=39616948&\\_hsenc=p2ANqtz-8Q5JhLgCWe4CJboPROHvuwP0x1fr3XLwxkrNXixW4tqdO\\_29UCNh4fj6q1IwpolH0ferca7iYMwC0oyjX7kTTvwmW8mA&\\_hsmi=39616948](http://www.the-scientist.com/?articles.view/articleNo/47819/title/Industry-Funded-Sugar-Study--Don-t-Trust-Other-Sugar-Studies/&utm_campaign=NEWSLETTER_TS_The-Scientist-Daily_2016&utm_source=hs_email&utm_medium=email&utm_content=39616948&_hsenc=p2ANqtz-8Q5JhLgCWe4CJboPROHvuwP0x1fr3XLwxkrNXixW4tqdO_29UCNh4fj6q1IwpolH0ferca7iYMwC0oyjX7kTTvwmW8mA&_hsmi=39616948)). Unfortunately, we all are aware that science loses when research is influenced by special interest groups.

The Public Health Service (PHS) regulation, under which ORI acts, is not meant to be a way to put the brakes on controversial science. The mission of our Office is to protect PHS research funds from researchers who knowingly and intentionally make up data or change them to serve their purposes. In the documents you provided, there does not appear to be evidence that Dr. Jerrell and his colleagues have done that. Without clear evidence of fabrication and/or falsification of data (and not just failing to cite contrary data), ORI is unable to further pursue your allegations. What you do and have been doing for decades – promoting your own research results – in scientific and other venues may be the best way to combat opposing viewpoints. Good luck in the future.

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## 2014 Age-Adjusted Death Rates by State and County and Ethnicity

Deaths per 1,000 persons (age-adjusted using 2000 U.S. Standard Population)  
with 95% Confidence Interval shown in parentheses  
(<http://wonder.cdc.gov/ucd-icd10.html>)

September 8, 2016

<u>Location</u>	<u>2014 Age-Adjusted Death Rate (95% Confidence Interval)</u>		
	<u>All Causes</u> ICD-10=All Codes	<u>All Cancer</u> ICD-10=C00-D48	<u>All Respiratory</u> ICD-10=J00-J98
United States (50 States + DC)	7.25 (7.24-7.26)	1.66 (1.65-1.66)	0.71 (0.71-0.71)
California (2 <sup>nd</sup> lowest State)	6.06 (6.03-6.08)	1.48 (1.46-1.49)	0.57 (0.56-0.57)
South Coast Air Basin (SCAB = Los Angeles, Orange, Riverside, and San Bernardino Counties)	5.93	1.46	0.55
Hawaii (Lowest State)	5.89 (5.77-6.00)	1.44 (1.38-1.49)	0.53 (0.50-0.56)
Los Angeles County	5.71 (5.66-5.75)	1.42 (1.40-1.44)	0.53 (0.52-0.55)
Orange County	5.48 (5.40-5.56)	1.38 (1.34-1.42)	0.47 (0.45-0.49)
California Hispanics	5.02 (4.97-5.07)	1.18 (1.16-1.20)	0.39 (0.38-0.41)
SCAB Hispanics	4.96	1.19	0.39

**Guest Speaker: James E. Enstrom, Ph.D., M.P.H.**



Dr. Enstrom is a native Californian who has lived most of his life in Los Angeles County. In 1965 He graduated co-valedictorian of his class at Harvey Mudd College in Claremont, CA, where he obtained a B.S. in physics. In 1970 Dr. Enstrom obtained his Ph.D. in experimental elementary particle physics at Stanford University from Nobel Laureate Melvin Schwartz. During 1971-1973 he worked as a physicist at the Lawrence Berkeley Laboratory in research group of Nobel Laureate Luis Alvarez. He then came to the UCLA School of Public Health as a postdoctoral fellow in cancer epidemiology and received an M.P.H. and postdoctoral certificate in 1976 from renowned public health epidemiologist Dr. Lester Breslow.

He then joined the UCLA School of Public Health faculty as a Research Professor / Researcher and he held that position for 36 years until June 2012. He currently retains a similar affiliation with UCLA, although he is now drawing retirement. He has been a Fellow of the American College of Epidemiology since 1981, he has been listed in Who's Who in America since 1990, and he has been President of the Scientific Integrity Institute in Los Angeles since 2005.

During his long career, he has explored many important epidemiological issues, particularly focusing on California. A major theme of his research has been identifying healthy lifestyles. He has shown that it is possible to reduce mortality risk from cancer and heart disease by 70% in the middle age range and to increase longevity by as much as 10 years. Examples of healthy populations that he has examined include religiously active California Mormons, California Cancer Prevention Study subjects, California PREVENTION Magazine Readers, and California and national samples of adults adhering to good health practices.

He has also examined the influence of environmental factors on mortality. In December 2005 he published a major paper on fine particulate matter and mortality in California and he has numerous other fm. Since then he has conclusively documented that fine particulate matter does not cause premature death in California. Since 2013, following the lead of the US House Science Committee, he has been involved with efforts to obtain the access to the "secret science" data that EPA has used to justify its fine particulate and ozone air pollution regulations in California and the United States. These efforts include the August 1, 2013 House subpoena of EPA, as well as the Secret Science Reform Acts of 2014 and 2015.

He is currently conducting important new air pollution epidemiology research that is relevant to the EPA, CARB, and SCAQMD regulations. More information can be found at his Scientific Integrity Institute website (<http://www.scientificintegrityinstitute.org/>).

<http://www.dailynews.com/opinion/20170203/in-air-quality-talks-haziest-thing-may-be-the-facts-susan-shelley>

## Los Angeles Daily News February 5, 2017

### In air-quality talks, haziest thing may be the facts: Susan Shelley



A clear-air day in downtown Los Angeles, with snow-capped mountains in the background. (Getty Images)

By [Susan Shelley](#), LA Daily News

Posted: 02/03/17, 2:00 PM PST | Updated: 1 week, 4 days ago

Suppose it was 1650 and you were accused of being a witch. Would you prefer trial by water or hanging?

If you choose trial by water, the people in charge of things will throw you into the nearest lake, river or ocean and wait to see if you sink or float.

If you sink, you're innocent, for all the good that does you.

So you may as well choose hanging. With any luck, it will take a good long time before the people in charge of things can agree on where to build the gallows.

That's exactly the choice the business community in Southern California has faced for the past four years, as the South Coast Air Quality Management District worked up its next four-year plan for air quality management.

In this version of trial by water, businesses are commanded to spend fortunes trying to meet ever-tightening emissions standards, and they are fined to death when they cannot comply.

With hanging, the businesses are offered incentives to walk up the 13 steps and put their own necks in the noose.

The South Coast Air Quality Management District, a powerful regulatory agency with authority over businesses in four counties, held a public meeting Friday to consider its brand new 2016 Air Quality Management Plan, 5,300 pages long.

The plan is part of a complex federal and state regulatory apparatus that's attempting to achieve "attainment" of federal air quality standards. Unfortunately, the standards are so tough that we wouldn't meet them even if every source of emissions regulated by the SCAQMD shut down completely.

Business groups support the 2016 AQMP because it relies on incentives to cut emissions, not "command and control" rule-making from regulators. The money for the incentives would likely come from raising your taxes.

Groups with "environmental justice" in their names joined the Sierra Club at the public hearing to denounce the incentive-based plan. They believe that tougher regulations will save lives but not cost jobs.

Everybody should believe in something.

This is a witch trial because businesses have been judged guilty of killing people with invisible particles, and nobody in government wants to hear from legitimate scientists who have done studies demonstrating that this is not true.

That's because regulations have to meet a standard of cost-effectiveness, and only the value of a human life can justify the crazy-expensive cost of replacing so much equipment over and over again. At Friday's meeting, an AQMD staffer claimed 1,600 lives are lost per year in the South Coast Air Basin to the health effects of air pollution.

But in letters written in response to the air quality management plan's appendix on health effects, reputable and accomplished people in the fields of science, statistics, physics and medicine cite evidence that the number of deaths caused by air pollution in California is zero.

What if they're right?

The 2016 AQMP is wildly expensive. It may lead to higher taxes to pay for incentives to further clean up something that has already been cleaned up. We may see higher prices as a result of higher shipping and energy costs. Even the price of a water heater could shoot up if gas-fired appliances are banned.

Shouldn't we know for certain whether any of that is really necessary for public health?

Maybe the new EPA administrator in Washington would like to hold hearings. It would be a nice change from witch trials.

115TH CONGRESS  
1ST SESSION

# H. R. 861

To terminate the Environmental Protection Agency.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 2017

Mr. GAETZ (for himself, Mr. MASSIE, Mr. PALAZZO, and Mr. LOUDERMILK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Agriculture, Transportation and Infrastructure, and Science, Space, and Technology, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To terminate the Environmental Protection Agency.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. TERMINATION OF THE ENVIRONMENTAL PRO-**  
4 **TECTION AGENCY.**

5 The Environmental Protection Agency shall termi-  
6 nate on December 31, 2018.

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