

December 10, 2008

California Air Resources Board
1001 "I" Street
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Sacramento, CA 95812
<http://www.arb.ca.gov/>

Re: Scientific Reasons to Postpone Adoption of Proposed STATEWIDE TRUCK AND BUS REGULATIONS (<http://www.arb.ca.gov/regact/2008/truckbus08/truckbus08.htm>)

Dear Board Members:

I am writing to describe important scientific reasons that must be addressed regarding the health effects of diesel particulate matter in California before the proposed "STATEWIDE TRUCK AND BUS REGULATIONS" are adopted.

These comments add to my previous public comments, which were submitted on April 22, 2008 (http://www.arb.ca.gov/lists/erplan08/2-carb_enstrom_comments_on_gmerp_042208.pdf), on July 11, 2008 (http://www.arb.ca.gov/research/health/pm-mort/pm-mort_supp.pdf), and on October 1, 2008 (http://www.arb.ca.gov/lists/verdev2008/33-32-carb_enstrom.pdf).

These new comments describe serious scientific deficiencies in the final October 24, 2008 CARB Staff Report "Methodology for Estimating Premature Deaths Associated with Long-Term Exposures to Fine Airborne Particulate Matter in California" (http://www.arb.ca.gov/research/health/pm-mort/pm-mort_final.pdf). This CARB Staff Report and the very similar May 22, 2008 CARB Draft Staff Report with the same title (<http://www.arb.ca.gov/research/health/pm-mort/pm-mortdraft.pdf>) have been used as a primary public health justification for reducing diesel particulate matter in California.

These reports have been prominently cited in the proposed STATEWIDE TRUCK AND BUS REGULATIONS, particularly in Appendix D: Health Impacts from On-Road Diesel Vehicles (<http://www.arb.ca.gov/regact/2008/truckbus08/appd.pdf>) and in Appendix E: Health Risk Assessment for On-Road Diesel Trucks (<http://www.arb.ca.gov/regact/2008/truckbus08/appe.pdf>). To document the serious scientific deficiencies in the CARB Staff Report, I have identified and described six specific examples of serious errors and misrepresentations.

Example 1: Scientific Qualifications of CARB Staff Report Authors

List of authors on third title page:

Project Coordinator and Lead Author
Hien T. Tran, Ph.D.
Contributing Authors

Álvaro Alvarado, Ph.D.
Cynthia Garcia
Nehzat Motallebi, Ph.D.
Lori Miyasato, Ph.D.
William Vance, Ph.D.

Response:

Because of my concerns about the unsatisfactory and unprofessional way in which the 148 pages of public comments in response to the May 22, 2008 CARB Draft Staff Report (http://www.arb.ca.gov/research/health/pm-mort/pm-mort_supp.pdf) were incorporated into the October 24, 2008 CARB Staff Report above, I have investigated the scientific qualifications of the report authors. My search of PubMed (<http://www.ncbi.nlm.nih.gov/sites/entrez/>) identified only two peer reviewed papers by lead author Hien T. Tran. Furthermore, NONE the peer reviewed papers by Tran and the five contributing authors have been on topic of their report, fine particulate matter (PM2.5) and mortality in California.

Dr. S. Stanley Young of the National Institute of Statistical Sciences wrote to Governor Arnold Schwarzenegger regarding the May 22, 2008 CARB Draft Staff Report. In response, California EPA Secretary Linda S. Adams wrote a November 4, 2008 letter to Dr. Young (<http://www.scientificintegrityinstitute.org/Adams110408.pdf>). The Adams letter makes the following statement "Regarding the professional background of the authors, the lead author and project coordinator, Hien Tran, holds a doctorate degree in statistics from the University of California at Davis"

However, I have determined from the UC Davis Office of the University Registrar and the UC Davis Department of Statistics that Hien Tran holds NO Ph.D. in statistics from UC Davis. Also, I searched ProQuest Dissertation Express (<http://disexpress.umi.com/dxweb#search>) and found NO evidence of a dissertation on any subject from any university awarded to the Hien T. Tran employed by CARB. ProQuest UMI Dissertation Publishing has been publishing dissertations and theses since 1938 and has published over 2 million graduate works from graduate schools around the world (<http://www.proquest.com/en-US/products/dissertations/>).

Although Tran is shown with a Ph.D. in the draft and final reports and in the December 7, 2007 CARB Research Division Organizational Chart (<http://www.arb.ca.gov/html/org/orgrd.htm>), most citations of Tran in documents and meetings on the CARB website identify him as Mr. Hien Tran (<http://www.arb.ca.gov/db/search/search.htm>). It is very important to have Tran clarify the actual status and nature of his alleged Ph.D. degree. This issue has direct relevance to the honesty of Tran and to the scientific integrity of the draft and final reports on which he is the lead author.

Example 2: Review Process for CARB Staff Report

Paragraph from Executive Summary:

"The methodologies and results presented in this report have been endorsed by our scientific advisors, Dr. Jonathan Levy of Harvard University, Dr. Bart Ostro of the Office of Environmental Health Hazard Assessment, and Dr. Arden

Pope of Brigham Young University. **This report underwent an external peer review by experts selected through an independent process involving the University of California at Berkeley, Institute of the Environment. The results of the peer review process have been incorporated into this report.** In addition, all public comments received on the May 22, 2008 draft version of the report have been incorporated into this staff report. Specific responses to individual comments are addressed in Appendix 5.”

Response:

Based on my November 12, 2008, 11 AM telephone conversation with Hien Tran, only the CARB Draft Staff Report underwent external peer review. This agrees with the posted CARB Peer Review Committee Background (<http://www.arb.ca.gov/research/health/pm-mort/prc.htm>). The final CARB Staff Report and the 148 pages of public comments were never shown to the external peer reviewers. Consequently, the final report does not contain all the changes that are warranted based on the public comments. Note that the Executive Summary of the final report is virtually identical to the Executive Summary of the draft report. I do not believe that the external peer reviewers would have approved the final report as written if they had seen the public comments. The final report should be sent to and fully evaluated by the external peer reviewers before it is used by CARB as public health justification for new diesel truck regulations.

Example 3: Geographic Variation of Relationship Between PM_{2.5} and Deaths in Cohort Studies

Paragraph from pages 25-26:

“Other important screening criteria include a desire for geographic appropriateness. This does not necessarily mean that only studies in California can be used for risk evaluations in California, but it means that significant factors that vary geographically should be addressed. This can occur at multiple levels. For example, a study in a developing country may not be directly applicable to the U.S., due to differences in age distributions, underlying disease patterns, pollutant composition, standard of health care, and many other factors. Within the U.S., regional differences could occur if the composition of PM_{2.5} differed significantly and more/less toxic agents could be identified, or if concentration-exposure relationships differed significantly (i.e., due to differences in air conditioning prevalence). While there are some noticeable differences between California and other states in terms of climate and concentrations of PM constituents, **there is little evidence for California’s relative risk to be differentiated from the U.S. average.** More explicitly, there is not adequate evidence at present regarding the quantitative differential toxicity of different particle constituents, and national and regional information about exposure-concentration differentials, to make any formal adjustments.”

Response:

There is substantial evidence from six different sources that there is substantial geographic variation in the relationship between PM_{2.5} and deaths within the United States and/or that there is little or no current relationship between PM_{2.5} and deaths in California:

1) Figure 21 “Fine Particles and Mortality Risk” on page 197 of the 2000 HEI Reanalysis Report by Krewski et al. shows “medium mortality” in California: “0.711<relative risk of mortality<0.919”. This finding is based the HEI analysis of 1982-1989 deaths in the ACS 1982 Cancer Prevention Study (CPS II) cohort. Figure 21 has been discussed in my April 22, 2008, July 11, 2008, and October 1, 2008 public comments cited above and in my June 1, 2006 *Inhalation Toxicology* response (<http://www.scientificintegrityinstitute.org/IT060106.pdf>).

- 2) Pages 6-265 and 6-266 of March 2001 US EPA Second External Review Draft Air Quality Criteria for Particulate Matter Volume II (EPA 600/P-99/002bB) (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20810>) contain the following sentences: “The overlay of mortality with air pollution patterns is also of much interest. The spatial overlay of long-term PM_{2.5} and mortality (Krewski et al., 2000; Figure 21) is highest from southern Ohio to northeastern Kentucky/West Virginia, but also includes a significant association over most of the industrial midwest from Illinois to the eastern non-coastal parts of North Carolina, Virginia, Pennsylvania, and New York. . . . The apparently substantial differences in PM₁₀ and/or PM_{2.5} effect sizes across different regions should not be attributed merely to possible variations in measurement error or other statistical artifact(s). Some of these differences may reflect: real regional differences in particle composition or co-pollutant mix; differences in relative human exposures to ambient particles or other gaseous pollutants; sociodemographic differences (e.g., percent of infants or elderly in regional population); or other important, as of yet unidentified PM effect modifiers.”
- 3) Slide 46 in the July 23, 2001 EPA CASAC presentation by Dr. Lester D. Grant shows no relationship between PM_{2.5} and deaths in the “West” based on the 2000 HEI Reanalysis (ACS CPS II cohort). For further details read pages S-10 and S-11 of the July 11, 2008 public comments by Jon M. Heuss (http://www.arb.ca.gov/research/health/pm-mort/pm-mort_supp.pdf and <http://www.scientificintegrityinstitute.org/Heuss071108.pdf>) and examine the full EPA CASAC presentation by Grant (<http://www.scientificintegrityinstitute.org/Grant072301.pdf>).
- 4) My December 15, 2005 *Inhalation Toxicology* paper, “Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973-2002,” showed no relationship between PM_{2.5} and deaths in 11 California counties in the California Cancer Prevention Study (CA CPS I) cohort during 1983-1992 and 1993-2002 (<http://www.scientificintegrityinstitute.org/IT121505.pdf>).
- 5) The August 12, 2008 *Environmental Health Perspectives* paper by Drs. Scott L. Zeger, Francesca Dominici, Aidan McDermott, and Jonathan M. Samet, "Mortality in the Medicare Population and Chronic Exposure to Fine Particulate Air Pollution in Urban Centers (2000-2005)" (<http://www.ehponline.org/members/2008/11449/11449.pdf>). Page 1617 of this paper states: “A provocative finding is that the MCAPS data show no evidence of a positive association between ZIP code-level PM_{2.5} and mortality rates for the 640 urban ZIP codes in the western region. This lack of association is largely because the Los Angeles basin counties (California) have higher PM levels than other West Coast urban centers, but not higher adjusted mortality rates.” The results for the western region [California, Oregon, and Washington] are dominated by those for California, since 468 (73%) of the 640 zip codes for the western region are in California. This paper is the published version of the January 2007 Johns Hopkins University Biostatistics Working Paper 133 (<http://www.bepress.com/jhubiostat/paper133/>), which has similar findings based on 2000-2002 Medicare Cohort Air Pollution Study (MCAPS) data.
- 6) Additional results are found in the U.S. Centers for Disease Control (CDC) WONDER data base for U.S. mortality during 2000-2005 (<http://wonder.cdc.gov/cmfi-icd10.html>). This interactive national mortality data base shows that, compared with the 2000-2005 United States total age-adjusted death rate, the California rate is 9% lower and the Los Angeles County rate is 11% lower. These results are consistent with the finding in the 2008 *EHP* paper that total death rates are not higher in the Los Angeles basin counties. In addition, the relatively low total death rate for

California does not support the notion that diesel particulate matter or fine particulate matter causes premature deaths in California. California has the fourth lowest total age-adjusted death rate among all states.

Example 4: Geographic Variation of Relationship Between PM_{2.5} and Deaths in Time Series Studies

Paragraph from page 26:

“National-scale epidemiological studies addressing short-term effects of PM exposure using time-series analyses do not demonstrate an appreciable difference between California and other states or regions in relative risks. For example, in a publication on 91 U.S. cities addressed by the National Mortality Morbidity Air Pollution Study, **Dominici et al. (2005)** showed that the southern California relative risk was slightly higher than the national average, while that of the Northwest (which included northern California as well as Oregon, Washington) was slightly lower than the national average. A simple average of the southern California and Northwest relative risks gives a value almost identical to the national average. A recent publication investigating PM_{2.5} mortality in 27 large communities around the U.S. (**Franklin et al. 2007**) found that the C-R function was above the national average for San Diego and Sacramento but below the national average and insignificant for Riverside and Los Angeles. It should be noted that the cohort study by Jerrett et al. (2005a) did find a statistically significant effect for the Los Angeles metropolitan area, once exposure was estimated with more geographic precision. Thus, the available evidence does not provide any rationale for excluding relative risks derived from studies across the U.S. to California.”

Response:

The results of the two time series studies cited are inaccurately described. Dominici et al. (2005) presented only PM₁₀ results and made no mention of PM_{2.5} in California or elsewhere in the U.S. (<http://www.scientificintegrityinstitute.org/JTEH2005.pdf>). It is entirely inappropriate and misleading to cite this study as being relevant to PM_{2.5} relationships throughout the U.S. The Franklin et al. (2007) relative risks (RR) are described inappropriately. A properly weighted average of results for the 5 counties in California yields RR = 1.0009 (0.9972-1.0046), where as the results for all 27 U.S. counties analyzed in the paper showed RR=1.0121 (1.0029-1.0214) (<http://www.scientificintegrityinstitute.org/JESEE2005.pdf>). Thus, the results of Franklin et al (2007) support the above evidence of geographic variation in the relationship between PM_{2.5} and deaths in the U.S., with no current relationship in California.

Example 5: Misrepresentation of July 11, 2008 CARB Teleconference Organized by Hien Tran

Pages A-95 and A-96 of

“Appendix 5 (Public Comments and Staff Responses)

In this appendix, we summarize the key comments received from the public on the May 22, 2008 draft report, and our responses to them.”

“1. **Choice of studies for draft report** - Draft report emphasized positive studies and omits consideration of negative chronic mortality studies (i.e. Veteran’s study and Enstrom (2005)). In addition, many of the studies chosen were not California-centric. . . .

Some commenters suggested that CARB put greater emphasis on the Enstrom (2006) study. CARB staff convened a teleconference with Dr. Enstrom and several prominent epidemiologists to discuss his findings. We amended that portion of the report to reflect the discussion, **which focused on two main issues: the time of follow-up since initial enrollment of the cohort, and the age of the cohort.**”

Response:

The above statement totally misrepresents the July 11, 2008 teleconference, which focused on the full July 11, 2008 agenda that I prepared in advance of the teleconference (<http://www.scientificintegrityinstitute.org/AgendaFull071108.pdf>). While the age of the CA CPS I cohort used in my 2005 paper was noted during the discussion, the long follow-up period of my study was not discussed. Although my study used an elderly cohort, it is important to note that about 75% of all California deaths occur among residents 65+ years of age. The primary purpose of the teleconference was to correct the mischaracterization by CARB of my 2005 paper, to address the points made in my 2006 response to criticism of my 2005 paper, to address my April 22, 2008 CARB public comments, and to discuss my proposed calculation of California-specific relative risks in ACS CPS II cohort, the cohort used in the studies rated highest in the CARB Staff Report. The full text of my public comments submitted just after the teleconference are available on pages S-139 to S-141 of the complete July 11, 2007 CARB public comments (http://www.arb.ca.gov/research/health/pm-mort/pm-mort_supp.pdf and <http://www.scientificintegrityinstitute.org/PMDeathsEnstrom071108.pdf>).

Example 6: Repeated Failure to Obtain California-specific Results from ACS CPS II Cohort

Page A-104 of **“Appendix 5 (Public Comments and Staff Responses)**

“12. Pope/American Cancer Society (ACS) study

Some comments are focused on Figure 21, page 197 of Krewski et al. (2000) suggest a misunderstanding of the figure. The figure is a visual overlay of the mortality and the PM2.5 surfaces as spatially modeled in one of the ACS sensitivity analyses. The figure shows that in California, the majority of the most populous regions have low to medium levels of PM2.5, and medium mortality. The exception is the Fresno area, and moving east into the Sierra Nevada Mountains. The description of the figure is on page 198, and states: “For the medium levels of pollution, intersections exist (referring to the two spatial surfaces) for high and medium mortality rates, but not for low mortality rates. Only the low fine particle category intersects with the low mortality rate category.” The point of the figure was to investigate the spatial concordance between high PM2.5 and high mortality areas, not to make a statement as to specific risk in any area of the country.

We appreciate the commenter’s suggestion for calculation of California-specific relative risks using the ACS CPS II cohort data. However, **CARB staff does not own or have access to this data, and consequently can not perform the requested calculations. While CARB has funded projects that use the CPS II data, the agency has no role in obtaining the necessary data.** In terms of studies on the relationship between long-term exposure to PM2.5 and mortality, recent research (Jerrett et al., 2005a) into spatial variability in PM2.5 concentrations across regions, for example the Los Angeles area, shows that exposure assessments based on county level monitoring, as used in Enstrom (2005) and the various Pope et al. papers (1995, 2002, 2004), do not adequately represent population exposure, and introduce a bias toward the null. Consequently, we question the utility of an analysis that relies on what is not currently viewed as the best exposure estimation methodology.”

Response:

As discussed points 1-3 in Example 3, there is no “misunderstanding” of Figure 21 from the HEI Reanalysis. Figure 21 shows clear geographic variation with RR below 1.00 in California. Slide

46 in the Grant EPA presentation confirms the geographic variation found in the ACS CPS II cohort, with RR = 0.91 (0.71-1.17) in the West (PM2.5 Excess Risk = -9%) (<http://www.scientificintegrityinstitute.org/Heuss071108.pdf>).

Based information obtained from Hien T. Tran and the July 21, 2008 letter to me by CARB Chair Mary D. Nichols (<http://www.scientificintegrityinstitute.org/Nichols072108.pdf>), CARB has an ongoing contract involving Dr. Michael Jerrett of UC Berkeley, Dr. C. Arden Pope of Brigham Young University, and Dr. Michael J. Thun of ACS to fully analyze the relationship of PM2.5 to deaths in California. The Pope 1995, Pope 2002, and Jerrett 2005 epidemiologic studies are all based on the ACS CPS II cohort and are the primary studies that have been used in the CARB Staff Report to estimate the relationship of PM2.5 to deaths in California. Thus, it is important that the ongoing analyses examine the relationship in several ways, including those that I proposed on July 11, 2008 in my teleconference involving Tran, Jerrett, and Pope (<http://www.scientificintegrityinstitute.org/AgendaFull071108.pdf>).

Unfortunately, Pope has not responded to my August 20, 2008 email request to conduct my proposed analyses and Thun has not responded to my December 1, 2008 request to conduct these analyses. In the best interest of all Californians, particularly those impacted by CARB regulations, CARB should make public its ongoing contract with Jerrett, Pope, and Thun and should require that all analyses of the ACS CPS II cohort data are conducted in a complete and transparent manner. Although "CARB staff does not own or have access to this data," CARB can require that the requested analyses be completed as part of their contract.

The serious errors and misrepresentations that exist in the CARB Staff Report, as illustrated by the six examples above, raise serious doubts about the honesty of the lead author, Hien T. Tran, and the scientific integrity of this report. The major issues described above must be satisfactorily addressed before this report is used as a primary public health justification for the proposed Statewide Truck and Bus Regulations. Given the extensive evidence that diesel particulate matter and fine particulate matter are not currently causing premature deaths in California, these proposed regulations should be postponed until the above issues are fully addressed.

Thank you very much for your consideration of my public comments above.

Sincerely yours,

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