



P.O. Box 277517, Sacramento, CA 95827
Phone (916) 364-0292 FAX (916) 364-7641

June 9, 2011

California Air Resources Board
1001 I Street
P.O. Box 2815
Sacramento, CA 95812

Attn: Research Screening Committee

RE: Draft Final Report for Contract No. 06-332 "Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort"

Dear Committee Members,

A review of the recently released study by Dr. Michael Jerrett and many co-authors that was posted on June 6, 2011 finds significant evidence that proves once again that California is a very healthy state.

- All 9 studies used show the confidence intervals meeting or crossing 1.0, confirming that there is of NO EFFECT of all cause premature death from PM2.5
- When you have 9 studies chosen by the researchers that include 95% confidence intervals that include 1.0, which means the authors have shown that toxic causation of mortality from PM2.5 is non-existent in California as defined by the results.

However, the conclusion from this referenced study states: "We conclude that combustion-source air pollution, especially from traffic, is significantly associated with premature death in this large cohort of Californians." How could the authors use words like "conclude" or "significantly associated" when they have **nothing** in the study to support the assertion?

Observational studies must show a strong Relative Risk (RR) (Hazard Ratio) in order to suggest causation because they are not randomized or controlled and subject to many confounders. Extensive research by the Observational Medical Outcomes Partnership strongly suggests a RR of 3-5 to reduce the uncertainties created by these confounders. Under the Federal *Reference Manual on Scientific Evidence*, Chapter on Epidemiology (written by Leon Gordis, an internationally known epidemiologist with two equally prominent co-authors, Mical Freedman and Michael Greene) on page 384 they describe proof of causation of disease or death must, as a **minimum**, have a relative risk (RR) of 2 (100% increase in effect).¹

The singular cited study showing an association of a HR (RR) =1.08 is not strong enough to show cause for regulation when 1.0 is within the confidence interval (RR1.00 is no effect in an observational study). This weak association could be caused by any number (up to 50) of

¹ Reference Manual on Scientific Evidence, Pg 375-384 (2nd ed., Federal Judicial Center, 2000)

confounders or biases which epidemiologists should consider. The medical literature reports that observational study assertions of causation and effects are not replicated in over 50 percent of cases and in some studies as high as 90 percent.² A scientific study that cannot be replicated has to be considered null. None of the studies referenced by the authors are randomized and controlled as they are all observational and subject to the unreliability outlined here.

Just a few of the potential confounders are listed below:

- Statistical power of the study
- Level of statistical significance
- False positive report probability
- Multiple modeling bias
- Uneven placement of air monitors making the “dose” unknown
- Data “mining” or “dredging”
- Analysis and publication bias.

While it is difficult for this lay person to understand some of these confounders and the more sophisticated epidemiological concepts, it is not difficult at all to comprehend analysis and publication bias. This amounts to “manipulation in the analysis or reporting of findings”.³ The authors of this document were paid (handsomely) for this report by the California Air Resources Board. **Any reasonable adult understands the influence of \$750,000 for research to confirm the already committed policy decisions of the agency that provided the funding.** If the report cannot claim there are “significant associations” to people dying, then there is no need for more studies to be funded and future funding for additional studies is over. But while the study’s own results fail to show any associations, the author(s) still claim significance! **What else were the authors supposed to say when the regulations were already being implemented before the report was completed?** An impartial and objective analysis of this study takes us back to the February, 2010 admission by Dr. Jarrett that his research agreed with Dr. James Enstrom’s that California citizens do not suffer premature deaths from small particles in the air.

The CARB needs studies showing premature death to justify regulation, thus maintaining their sinecure. The “scientists” need funding. There is and has been an extensive track record of certain scientists promoting “premature death from small particle (including diesel) PM2.5”, necessitating funding of studies (for these same scientists in some cases) who then justify the past and continued funding by claiming “associations” that prove to be nothing more than a scare tactic that CARB can use to claim necessity of regulations. For a detailed description of this, visit my “CARB’s House of Cards” letter to CARB dated February 17, 2010.

Two corollaries discussed in his paper on the unreliability of observational studies by Dr. Ioannidis⁴ are “The greater the financial and other interests and prejudices in a scientific field, the less likely the research findings are to be true”, and “The hotter a scientific field (with more scientific teams involved), the less likely the research findings are to be true”. This field (observational studies on premature death by small particles, including diesel PM) is filled with conflicts of interest and prejudice, both of which increase bias. When papers are co-authored

² Young National Institute of Statistical Sciences,
www.niss.org/sites/default/files/Young_Safety_June_2008.pdf

³ Ioannidis JPA (2005) Why Most Published Research Findings are False. PLoS Med 2(8); e124.doi:10.1371/journal.pmed.0020124

⁴ *ibid*

repeatedly by a small group of researchers (who are often picked as the “peer reviewer” of their own papers⁵), conflicts can arise from personal relationships and long time associations that can reduce objectivity and increase bias.

Additionally, when you review the number of co-investigators (the “who’s who” list of fund recipients in the air pollution field), it is not a reach to suggest that this is a “hot scientific field”, especially when conflicted with a public agency or agencies needing “confirmation” that the human health effects justifies their regulatory regime. Air quality research will remain “hot” as long as agencies distribute generous grants and research funds or awards for work to the recognized and reliable researchers who will confirm the Agency Policy Agenda. More money flows when a public agency such as CARB is forced to justify its regulatory regimes, enforcement actions, releases of public information, or for that matter, its very existence.

But even in light of these corollaries and the fact that the regulations preceded the very “California Specific” study necessary to advance the exigency, these 14 researchers working for 4-½ years, could not show one study that approaches proof of small particle toxic causation of morbidity or mortality. In fact, 100% of their work proves NO EFFECT by the rules of epidemiological studies.

The Research Screening Committee (RSC) should accept this California specific study as confirmation that the 2005 study by Dr. James Enstrom has been validated. There is NO PREMATURE DEATH EFFECT FROM SMALL PARTICLES (THAT INCLUDES DIESEL PM2.5 IN CALIFORNIA). Every study since the debunked Initial Statement of Reasons (Tran report) used by CARB has been nothing more than FACTOIDS (something fictitious or unsubstantiated that is presented as fact, devised especially to gain publicity and accepted because of constant repetition).

This study drives the stake in the very heart of the phantom menace PM2.5 as promoted by CARB.

The RSC should reject the abstract discussion and conclusion stated as unfounded, baseless and deceptive. These statements should be aligned with the actual findings of the report itself. This report confirms that there is no need for small particle (including diesel particles) regulations and the RSC should recommend to the Board to stop the implementation thereof.

Sincerely,



Skip Brown
Owner

Cc: Air Resources Board

⁵ Delta Letter “CARB’s House of Cards” dated February 17, 2010