Comments Regarding May 22, 2008 CARB Draft 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-mortdraft.pdf)

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1) Mischaracterization of 2005 Enstrom Paper

The CARB Draft Staff Report seriously mischaracterizes my 2005 paper (*Inhalation Toxicology* 17:803-816, 2005 http://www.scientificintegrityinstitute.org/IT121505.pdf). Numerous statements on page 22 are inaccurate. The methodology used in my study is completely consistent with the methodology used in the 2002 Pope study. For instance, my study controlled for smoking at entry and presented results for never smokers. Furthermore, fully adjusted relative risks hardly differed from age-adjusted relative risks. My study used the same 1979-1983 $PM_{2.5}$ data that was used in the Pope studies and these underlying US EPA data were presented in a clear and well-defined manner. Although it is the largest and most detailed study ever published on $PM_{2.5}$ and mortality in a California population, my study was not used by CARB staff to calculate the relationship between $PM_{2.5}$ and mortality in California. CARB staff should fairly and accurately describe and use my study.

2) Omission of 2006 Enstrom Response to 2006 Brunekreef Criticism

Although the CARB Draft Staff Report cited the 2006 Brunekreef criticism of my 2005 paper, the Report completely omitted my 2006 response to Brunekreef (*Inhalation Toxicology* 18:509-514, 2006 http://www.scientificintegrityinstitute.org/IT060106.pdf). My 2006 response addressed in a detailed manner the criticism of my 2005 paper and needs to be fully considered and cited by the CARB staff in their comments about my study.

3) Failure to Respond to April 22, 2008 Enstrom Public Comments to CARB

CARB Staff and the CARB Draft Staff Report have failed to address the important points made in four pages of public comments submitted to CARB on April 22, 2008 regarding the Goods Movement Emission Reduction Plan and the health effects of diesel emissions (http://www.arb.ca.gov/lists/erplan08/2-carb_enstrom_comments_on_gmerp_042208.pdf). In particular, the CARB Draft Staff Report fails to mention the California specific epidemiologic evidence in the 2000 HEI Reanalysis Report by Krewski et al. (http://pubs.healtheffects.org/view.php?id=6, Part II, page 197). The US map of "fine particles

and mortality risk" on page 197 indicates no excess mortality risk in California due to $PM_{2.5}$ among the ACS CPS II cohort during 1982-1989. This finding that is consistent with the results in my 2005 study, which is based on the California portion of ACS CPS I (CA CPS I). All of the points in my public comments should be addressed, because they are relevant to CARB Draft Staff Report.

4) Proposed Calculation of California-specific Relative Risks in ACS CPS II Cohort

Using same ACS CPS II database and proportional hazards methodology used in Pope et al. study (*JAMA 2002;287:1132-1141* http://jama.ama-assn.org/cgi/reprint/287/9/1132), calculate all cause mortality relative risk (RR) and 95% confidence interval (CI) associated with a 10-$\mu g/m^3$ increase in PM2.5, similar to RRs shown in *JAMA* Table 2.

a) Calculate age-sex-adjusted RRs and fully adjusted RRs based on all 61 metropolitan areas for 1979-1983, 1999-2000, and average $PM_{2.5}$ related to all causes of death during three time periods: September 1, 1982 through December 31, 1998, September 1, 1982 through December 31, 1989, and January 1, 1990 through December 31, 1998 [2 x 3 x 3 = 18 RRs]. For instance, fully adjusted RR (1979-1983 $PM_{2.5}$, 1982-1998 deaths) = 1.04 (1.01-1.08).

b) Calculate age-sex-adjusted RRs and fully adjusted RRs based on the metropolitan areas in California for 1979-1983, 1999-2000, and average PM2.5 related to all causes of death for the three time periods: 1982-1998, 1982-1989, and 1990-1998 [2 x 3 x 3 = 18 RRs]. Specify the definition of the California metropolitan areas used in the *JAMA* paper and the number of CPS II subjects and deaths in each area used in the calculation of each RR.

c) Calculate age-sex-adjusted RRs and fully adjusted RRs based on the eleven California counties shown in Table A for 1979-1983, 1999-2001, and average $PM_{2.5}$ related to all causes of death for the three time periods: 1982-1998, 1982-1989, and 1990-1998 [2 x 3 x 3 = 18 RRs]. Specify the number of CPS II subjects and deaths in each county used in the calculation of each RR.

Table A. Fine particulate matter levels, $PM_{2.5}$ ($\mu g/m^3$), in 11 California counties from the 1979-1983 Inhalable Particulate Network (IPN) and 1999-2001 Aerometric Information Retrieval System (AIRS) of the EPA (Enstrom *Inhalation Toxicology* 17:803-816, 2005 http://www.scientificintegrityinstitute.org/IT121505.pdf and Enstrom *Inhalation Toxicology* 18:509-514, 2006 http://www.scientificintegrityinstitute.org/IT060106.pdf).

	$PM_{2.5}$ ($\mu g/m^3$)		
California county	1979-1983	1999-2001	Average 1979-1983/1999-2001
Santa Barbara	10.6	10.7	10.65
Contra Costa	13.9	14.0	13.95
Alameda	14.4	14.4	14.4
Butte	15.5	15.4	15.45
San Francisco	16.4	15.4	15.9
Santa Clara	17.8	17.0	17.4
Fresno	18.4	20.2	19.3
San Diego	18.9	15.2	17.05
Los Angeles	28.2	20.4	24.3
Kern	30.9	19.4	25.15
Riverside	42.0	21.1	31.55

5) July 11, 2008 Teleconference Involving Epidemiologists and CARB Staff

A July 11, 2008 teleconference was organized by Hien Tran, Ph.D., in response to concerns that I have raised in the above four points and in other forums during the past few months. This teleconference included me and several other epidemiologists and CARB staff involved with producing the May 22, 2008 Draft Staff Report. As a result of this teleconference, I have the following tentative conclusions:

a) The CARB staff indicated a willingness to revise the Draft Staff Report in order to accurately characterize my 2005 study and my 2006 response to the 2006 Brunekreef criticism. However, given the relatively low evaluation that my paper was given in Tables 2a and 2b by the twelve experts involved in the elicitation process, it is unlikely that CARB staff will actually use the California specific results in my paper in developing the final relationship between $PM_{2.5}$ and premature deaths in California.

b) The twelve experts involved in the elicitation process do not represent the full range of opinions on the epidemiologic relationship between $PM_{2.5}$ and mortality in California. Particularly troubling is the fact that many of the experts evaluated their own research. Five of the experts were co-authors on the four highest rated studies in Table 2a and on the five highest rated studies in Table 2b. Because of the heavy reliance on the opinions of these twelve experts, the Draft Staff Report does not present a fair and balanced assessment of all relevant California specific evidence.

c) Other than myself, the teleconference epidemiologists expressed great reluctance toward conducting the CPS II analyses that I proposed in point 4). These analyses would produce new California specific evidence based on the CPS II cohort. This evidence would add substantially to the California specific evidence in my 2005 paper. It is very important that these analyses be undertaken and I intend to make an effort to see that they are conducted.

d) Particularly troubling is the fact that CARB is currently funding extensive new analyses of $PM_{2.5}$ and mortality in the CPS II cohort, but not the analyses that I proposed in point 4). The analyses in point 4) involve determining the California specific results within the nationwide Pope 2002 study, which is the highest rated study in Tables 2a and 2b. Because of the economic consequences associated with the CARB assessment of the relationship between $PM_{2.5}$ and mortality in California, it is very important that CARB fund all relevant assessments of this relationship.

e) As I made clear, I am willing to work with CARB staff and the teleconference epidemiologists in conducting additional relevant analyses of my CA CPS I cohort and the ACS CPS II cohort. In the interest of determining the most accurate and reliable relationship between $PM_{2.5}$ and mortality in California, hopefully the CARB staff and teleconference epidemiologists will work with me and other epidemiologists who can provide relevant expertise on this subject.