

August 15, 2016

Jo Kay Chan Ghosh, Ph.D.
Health Effects Officer
South Coast Air Quality Management District
jghosh@aqmd.gov

Dear Dr. Ghosh,

I am writing to express serious concern that my July 26, 2016 public comments below regarding the health effects/impacts of particulate matter in the South Coast Air Basin (SCAB) are not being addressed. In particular, the August 16, 2016 PPT by Dr. Elaine Shen [Update on the Preliminary Draft Socioeconomic Report](#) claims that there will be 2,111 premature deaths due to PM2.5 in 2023. This is the same number of deaths shown in the attached July 28, 2016 PPT slide by Dr. Anthony Oliver [Preliminary Public Health Benefits of the Draft 2016 AQMP](#). This scientifically invalid claim does not provide valid public health justification for a 2016 AQMP that will impose an estimated \$38.2 billion in compliance costs on the SCAB economy.

Since 2006 I have repeatedly presented to CARB and SCAQMD strong epidemiologic evidence that there is no relationship between PM2.5 and total mortality in California. The latest version of this evidence is the attached table with 16 null results and 1 essentially null result from six different California cohorts (<http://scientificintegrityinstitute.org/NoPMDeaths081516.pdf>). Seven of the null results come from studies that were partially funded by SCAQMD. In addition, a very strong case has recently been made by nine accomplished experts, including myself, that “Particulate Matter Does Not *Cause* Premature Deaths” (https://www.nas.org/articles/nas_letter). Furthermore, I have now submitted for publication a manuscript with null findings that invalidate the positive nationwide relationship between PM2.5 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 PM2.5 premature death claims in the PPTs of Drs. Oliver and Shen.

All epidemiologic evidence relevant to the SCAB must be properly presented and summarized in the revised Draft 2016 AQMP Appendix I Health Effects (<http://www.aqmd.gov/docs/default-source/clean-air-plans/air-quality-management-plans/2016-air-quality-management-plan/DRAFT2016AQMP/appi.pdf?sfvrsn=2>). Indeed, Appendix I must be finalized in strict compliance with all provisions of California Health and Safety Code (CHSC) Section 40471 (b): “On or before December 31, 2001, and every three years thereafter, as part of the preparation of the air quality management plan revisions, 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. The south coast district board shall submit its report to the advisory council appointed pursuant to Section 40428 for review and comment. The advisory council shall undertake peer review concerning the report prior to its finalization and public release. The south coast district board shall hold public hearings concerning the report and the peer review, and shall append to the report any additional material or information that results from the peer review and public hearings.” (<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=40001-41000&file=40460-40471>).

As I have previously requested, the 2016 AQMP must present current data on the average human exposure levels for PM2.5, ozone, and NOx in the SCAB. My evidence dating back decades indicates that the actual human exposure levels are far below the EPA National Ambient Air Quality Standards (NAAQS) and well below the levels for which there are proven adverse health effects. Furthermore, the tiny health effects of air pollution must be put into perspective with all the factors that influence human health, such as, employment, and with the fact that the SCAB has 2014 age-adjusted death rates for all causes, all cancer, and all respiratory diseases that are among the lowest in the entire US. These low death rates are summarized the attached table.

The ultimate scientific and regulatory fate of the 2016 depends upon the scientists who have conducted air pollution epidemiology research and upon the SCAQMD scientists who summarize these research findings in Appendix I Health Effects. We will soon find out if the SCAQMD scientists have the honesty and integrity to state that air pollution *does not cause* premature deaths in the SCAB, that the average daily human exposures to PM2.5, ozone, and NOx in the SCAB are well below the levels that *cause* adverse health effects, and that tougher air pollution regulations in the already healthy SCAB are not justified on a public health or socioeconomic basis.

In closing, please read my attached July 19, 2016 statement to the BizFed Southern California Business Coalition “AQMD Must Reassess Its Air Quality Regulations” and the attached page summarizing my scientific credentials and academic career.

Thank you very much for your consideration.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
UCLA and Scientific Integrity Institute
jenstrom@ucla.edu
(310) 472-4274

cc: Elaine Shen <eshen@aqmd.gov>
Shah Dabirian <sdabirian@aqmd.gov>
Anthony Oliver <aoliver@aqmd.gov>
Philip M. Fine <pfine@aqmd.gov>
Wayne Nastro <wnastro@aqmd.gov>
Henry A. Roman <har@indecon.com>
George D. Thurston <George.Thurston@nyumc.org>
Kevin R. Cromar <kevin.cromar@nyu.edu>
AQMP Comment <aqmp@aqmd.gov>

July 26, 2016

Anthony Oliver, Ph.D.
SCAQMD Air Quality Specialist
aoliver@aqmd.gov

Dear Dr. Oliver,

I am an environmental epidemiologist and physicist who has had a long career at UCLA and I am an expert in the health effects of air pollution in California. I am writing regarding your planned presentation “Item #3: [Preliminary Public Health Benefits of the Draft 2016 AQMP](#)” at the July 28, 2016 SCAQMD Scientific, Technical & Modeling Peer Review Advisory Group (STMTPR) Socioeconomic Meeting (http://www.aqmd.gov/home/library/meeting-agendas-minutes/agenda?title=STMTPRSocio_072816). I challenge the validity of your “Preliminary Health Impacts – Mortality” and your selective use of Jerrett 2005, Jerrett 2009, and Jerrett 2013.

Key aspects of my prior criticism of SCAQMD STMTPR claims regarding the health impacts of PM2.5 and ozone in the South Coast Air Basin (SCAB) are contained in these three documents:

November 16, 2015 Enstrom Email to Cassmassi and SMTPR Staff re Ozone and PM in SCAB (<http://www.scientificintegrityinstitute.org/Cassmassi111615.pdf>)

November 22, 2015 Enstrom Table with 2000-2015 Results Showing NO PM2.5 Premature Deaths in CA (<http://www.scientificintegrityinstitute.org/NoPMDeaths112215.pdf>)

December 15, 2015 Enstrom Email to Roman Requesting NO IEc PM2.5 and Ozone Deaths for 2016 AQMP (<http://www.scientificintegrityinstitute.org/Roman121515.pdf>)

I strongly recommend that you carefully read all three documents, as well as all the weblinks that they contain. Then I strongly recommend that you discuss these documents with me, as well as with SCAQMD Health Effects Officer Jo Kay Chan Ghosh and IEc Principal Henry A. Roman. Finally, I strongly recommend that you announce during your presentation that several highly qualified doctoral-level scientists, including myself, are challenging the validity of your presentation, particularly your claims of “Premature Mortalities” in the SCAB.

Thank you very much for your attention to this important matter.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
UCLA and Scientific Integrity Institute
jenstrom@ucla.edu
(310) 472-4274

cc: Jo Kay Chan Ghosh <jghosh@aqmd.gov>
Henry A. Roman <har@indecon.com>
George D. Thurston <George.Thurston@nyumc.org>
Elaine Shen <eshen@aqmd.gov>
Philip M. Fine <pfine@aqmd.gov>
Wayne Nastro <wnastro@aqmd.gov>

Preliminary Health Impacts - Mortality

- Health impacts for mortality are based on the previous data and:
 - Ozone: Pooling of L.A.-specific NMMAPS and meta-analysis estimates from Bell et al. (2005).
 - PM_{2.5}: Pooling of Jerrett et al. (2005), Jerrett et al. (2013), and Kriging and LUR estimates from Krewski et al. (2009).

- No threshold effects assumed for either pollutant
 - IEC recommendation based on latest scientific evidence
 - U.S. EPA’s practice

In the absence of substantial information in the scientific literature on alternative forms of C-R functions at low O₃ concentrations, the best estimate of the C-R function is a linear, no-threshold function.

U.S. EPA, 2014 Health Risk and Exposure Assessment for Ozone

Note: Confidence intervals provided on supplementary handout.

Preliminary Health Impacts – Mortality (cont’d)

Premature Mortalities Avoided		
	2023	2031
Mortality, All Cause	2193	2563
Short-term Ozone Exposure	51	87
Los Angeles	22	40
Orange	10	14
Riverside	11	16
San Bernardino	9	15
Long-term PM_{2.5} Exposure	2111	2425
Los Angeles	1481	1707
Orange	321	356
Riverside	141	166
San Bernardino	169	197

Note: Confidence intervals provided on supplementary handout.

Summary Table. Epidemiologic cohort studies of PM_{2.5} and total mortality in California, 2000-2016
Relative risk of death from all causes (RR and 95% CI) associated with increase of 10 µg/m³ in PM_{2.5}
<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 _{2.5} ; 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_{2.5}; 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 _{2.5})				
			RR = 0.997 (0.978-1.016)	1983-2002
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 _{2.5})				
			RR = 0.995 (0.968-1.024)	1983-2002
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 _{2.5})				
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 _{2.5} ; KRG ZIP; 20 ind cov+7 eco var; Slide 12)				
Krewski 2010 (2009)	CA CPS II Cohort			
(4 MSAs; 1979-1983 PM_{2.5}; 44 cov)		N=40,408	RR = 0.960 (0.920-1.002)	1982-2000
(7 MSAs; 1999-2000 PM_{2.5}; 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 _{2.5} ; 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 _{2.5} ; 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 _{2.5})				
Ostro 2011	CA Teachers Cohort	N=43,220	RR = 1.06 (0.96 – 1.16)	2002-2007
(N=[43,220 F]; 2002-2007 PM _{2.5})				
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_{2.5}; 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 NO₂ 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 _{2.5}) (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 _{2.5} 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 _{2.5} by county)				

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>	<u>All Cancer</u>	<u>All Respiratory</u>
	ICD-10=All Codes	ICD-10=C00-D48	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 nd 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

“AQMD Must Reassess Its Air Quality Regulations”

James E. Enstrom, Ph.D., M.P.H.
UCLA and Scientific Integrity Institute
jenstrom@ucla.edu

July 19, 2016

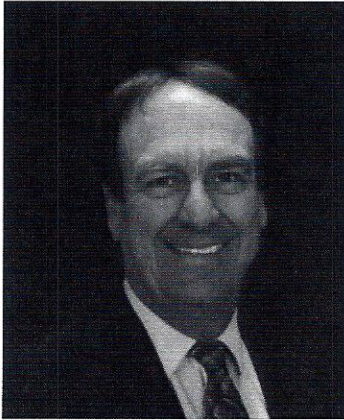
The South Coast Air Quality Management District (AQMD), one of the most powerful regulatory agencies in the United States, has just proposed tightening its regulations. During the past 40 years it has implemented strong air quality regulations in the 11,000 square-mile South Coast Air Basin (SCAB), which includes the 17 million people who live in the populated areas of Los Angeles, Orange, Riverside, and San Bernardino counties. These increasingly aggressive and costly regulations have impacted all sectors of the economy, from utility power plants, oil refineries, the ports, and all manufacturers to restaurants, dry cleaners, printers, and auto repair shops. While these regulations have improved air quality substantially, they have been excessive and have contributed to the loss of more than half of the manufacturing jobs in Southern California.

The regulation of fine particulate matter (PM_{2.5}), ozone (O₃), and nitrogen oxides (NO_x) has been largely justified on a cost-benefit basis by the claim that air pollution causes 5,000 premature deaths per year in the SCAB. This claim relies on the implausible and unproven hypothesis that inhalation over a lifetime of about one teaspoon of PM_{2.5} (particles less than 2.5 microns in diameter) causes premature death. For perspective, inhaling this amount of PM_{2.5} is roughly equivalent to smoking two cigarettes a year, certainly not a lethal dose. Moreover, there is overwhelming epidemiological evidence, including two large 2011 AQMD-funded epidemiological studies, that air pollution does not cause any premature deaths in California. Furthermore, the SCAB has an age-adjusted total death rate that is lower than the death rate in every state except Hawaii. It has a similarly low total cancer death rate.

Regarding exposures, the average ambient levels of 8-hour ozone and 24-hour PM_{2.5} in the SCAB, as measured by AQMD monitors, are below the current Environmental Protection Agency (EPA) National Ambient Air Quality Standards (NAAQS) for ozone and PM_{2.5}. Furthermore, the average personal exposures to ozone and PM_{2.5} among SCAB residents are much lower than the ambient levels measured by AQMD monitors. These average personal exposure levels are far below the levels associated with adverse health effects. Air pollutants are now at record low levels and close to natural background levels. The last Stage 3 smog alert was in 1974 and the last Stage 2 smog alert was in 1988. Much of the remaining SCAB pollution comes across the Pacific Ocean from China, which ignores air pollution regulations and which does much of the manufacturing that used to be done here.

Unfortunately, the AQMD staff, led since 1997 by Executive Officer Barry R. Wallerstein, has ignored the extremely positive air quality evidence above. Instead of acting in the best public health and socioeconomic interest of the SCAB residents, AQMD staff has implemented scientifically unjustified regulations in conjunction with the EPA, the California Air Resources Board, and powerful environmental activist groups (like Coalition for Clean Air, American Lung Association, Natural Resources Defense Council, and Sierra Club). The AQMD Board justifiably fired Wallerstein on March 4. There is now an opportunity for the remaining AQMD staff to work with numerous qualified experts like myself in order to reassess the scientific validity of all their regulations. The REgional CLean Air Incentives Market (RECLAIM), the Multiple Air Toxics Exposure Study (MATES), and the 2012 Air Quality Management Plan (AQMP) all need to be reassessed. These reassessments must be made before the 2016 AQMP is finalized and, if they are not made, the AQMD Board should not approve the 2016 AQMP. It is time to stop unjustified regulations in Southern California and to bring manufacturing jobs back.

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/>).

August 26, 2016

Jo Kay Ghosh, PhD
Health Effects Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Subject: Comments on Appendix I Draft 2016 Air Quality Management Plan

Dear Dr. Ghosh:

I appreciate the opportunity to represent the Home Rule Advisory Group (HRAG) on the Advisory Council and submitting comments on the draft Health Effects Appendix. My comments are focused primarily on Ozone (O₃) and PM_{2.5}, as they are set forth in Appendix I of the 2016 Draft Air Quality Management Plan (AQMP). Speaking on behalf of the HRAG, we understand that the AQMP promises to have significant impacts on all who are participating in the process and applaud the time and effort required to produce a science-based and economically feasible plan.

Following are my comments:

Notwithstanding Staff's admonition for the Council to focus our review and comments solely on health effects, as reported in Appendix I, I found it too much of a challenge to ignore such important elements as the cost and practicality of basing the likelihood of meeting the emission reduction commitments in the AQMP based solely on the findings in the draft Appendix. Recognizing that the total implementation costs of the Draft 2016 AQMP are projected to be:

SCAQMD Stationary Source	\$ 8.0	(billions of 2015 dollars)
SCAQMD Mobile Sources	\$ 1.5	(billions of 2015 dollars)
CARB Mobile Source	<u>\$28.7</u>	(billions of 2015 dollars)
Total:	\$38.2	(billions of 2015 dollars)

and accepting the fact that the District and the sources it regulates will be held accountable for achieving the emission reductions commitments associated with these costs, I strongly urge Staff to seriously consider these constructive remarks and recommendations:

▪ **HEALTH EFFECTS OF AIR POLLUTION**

- In the recent three AQMPs (2007, 2012, 2016), as well as the 1997 AQMP, Staff has asserted that ambient air pollution is a major cause of public health concern. And most would agree. It is confusing - to me at least - that while Staff has added

Table I-1 in the current Appendix I, to support the addition of a few more recent review articles discussing the health impacts of Ozone, PM_{2.5}, NO₂, and SO₂, on the Southern California population, that the weight of evidence descriptors for causal determination of [adverse] health effects seems to call in to question the reliability of the findings and conclusions reported in these research papers. For example, most of the determinations made by U.S. EPA regarding the causality of air pollution health effects, is that there is “**likely** to be a causal relationship,” “**suggestive** of a causal relationship,” “**not likely** to be a causal relationship” or “**inadequate to infer** a causal relationship.” On its face, the degree to which important uncertainties seem to permeate the research cited in Appendix I, strongly suggests that **more definitive research is urgently needed, especially in an AQMP that is projected to cost regulated sources \$38.2 billion dollars, reduce health impacts, and improve air quality.**

▪ **OZONE**

- In the process of updating Appendix I, I commend the Staff for including EPA’s lowering the 8-hour ozone standard to 0.070 ppm.
- In reviewing Table I-2, Summary of Causal Determinations for Short-Term Exposures to Ozone, I observed similar uncertainty in the assignment of causal determinations for the following health categories:
 - ✓ Cardiovascular Effects – **Likely** to be a causal relationship
 - ✓ Central Nervous System Effects – **Suggestive** of a causal relationship
 - ✓ Effects on Liver and Xenobiotic Metabolism – **Inadequate** to infer a causal relationship
 - ✓ Effects on Cutaneous and Ocular Tissues – **Inadequate** to infer a causal relationship, and most important.....
 - ✓ Mortality – **Likely** to be a causal relationship

Again, it strongly suggests that **more research is urgently needed**, especially in an AQMP that is projected to cost regulated sources \$38.2 billion dollars, reduce health impacts, and improve air quality.

- In reviewing Table I-3, Summary of Causal Determinations for Long-Term Exposures to Ozone, I observed even more **uncertainty in the assignment of causal determinations** for the following health categories:
 - ✓ Respiratory Effects – **Likely** to be a causal relationship
 - ✓ Cardiovascular Effects – **Suggestive** of a causal relationship
 - ✓ Reproductive and Developmental Effects – **Suggestive** of a causal relationship
 - ✓ Central Nervous System Effects – **Suggestive** of a causal relationship

Once again, it strongly suggests that **more research is urgently needed**, especially in an AQMP that is projected to cost regulated sources \$38.2 billion dollars, reduce health impacts, and improve air quality.

- Finally, among the **scientific studies** cited in the paragraph entitled: Long-Term Effects of Ozone; many of which or all were **conducted at locations other than California/Southern California**, we were glad to see an almost imperceptible reference to smoking as one of a number of behavioral and demographic factors accounting for increased risk of all-cause, cardiovascular, and respiratory mortality. Curiously, **the causal relationship between smoking and morbidity and mortality are far more conclusive than the causal relationship between ozone and the health categories mentioned previously.**

According to the CENTER FOR DISEASE CONTROL:

- ✓ 16 million Americans are living with a disease caused by smoking.
- ✓ For every person who dies because of smoking, at least 30 people live with a serious smoking-related illness.
- ✓ Smoking causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease.
- ✓ **Cigarettes are responsible for more than 480,000 deaths per year in the U.S.**
- ✓ **42,000 people die annually from second-hand smoke.**
- ✓ Smokers die, on average, 10 years earlier than non-smokers.

(CDC Statistics as of 2015)

▪ **PARTICULATE MATTER**

- I commend Staff for acknowledging that in spite of U.S. EPA setting standards for PM_{2.5} in 1997, lowering them in 2006 to 35 ug/m³ for a 24-hour average and reaffirming 15 ug/m³ for annual average standard, and again revising the average annual standard in 2012 to 12.0 ug/m³, **there continues to be considerable controversy and debate surrounding the review of particulate matter health effects and the consideration of ambient air quality standards.** Staff also mentions that: *“numerous studies have been published and some of the key studies were closely scrutinized and the data reanalyzed by additional investigators.”* Staff goes on to write: *“The reanalyses confirmed the original findings, and there are now additional data confirming and extending the range of the adverse health effects of PM_{2.5} exposures.”*

▪ **SHORT-TERM EXPOSURE EFFECTS OF PM**

- While we commend Staff for citing some recent epidemiological studies on morbidity and mortality, on Page I-19 of the Appendix, they appear to be on PM₁₀, and involve populations in Europe, Asia, and South America. Apparently

there was also a study “... *involving communities across the U.S.*,” but **it isn’t clear that any of these communities were located in Southern California, and that the findings are applicable to our local population.**

- On Pages I-20 – I-21 of the Appendix, Staff cites a National Morbidity, Mortality, and Air Pollution study of 20 of the largest U.S. cities. It is reported that the findings determined a combined risk estimate of about a 0.5% increase in total mortality for a 10 ug/m³ increase in PM₁₀ (Samet et al 2000a). A further reading of the conclusions reached by Samet reveals that there were a number of confounding findings with regard to the extent by which PM₁₀ contributes to mortality rates. Samet attributes some of the confusion to a software package with inappropriate default settings. Curiously, in a reanalysis of the 90 city study (Dominici et al 2002L Health Effects Institute 2003), where the estimates were recalculated, **the estimate changed from 0.41% increase in mortality for a 10 ug/m³ increase in PM₁₀ to a 0.27% increase.**
- On Page I-23 of the Appendix, Staff writes that: “*The relative importance of both PM_{2.5} and PM_{10-2.5} may vary in different regions depending on the relative concentrations and components, which can also vary by season.*” “*A major knowledge gap is the relative paucity of direct measurements of PM_{2.5-10}.*” To their credit, Staff goes on to write: “***More research is needed better access the relative effects of coarse (PM_{10-2.5}) fractions of particulate matter.***” This is exactly what we are advocating throughout these comments.
- Finally, on Page I-25 of the Appendix, Staff writes: “*Some studies have examined the health effects of short-term exposures to specific PM constituents and sources (Lippman 2014; Basagana et al 2015; Atkinson et al 2016). While there is some evidence suggesting possible links with specific constituents or sources, such as diesel exhaust, sulfates (related to coal combustion), and certain metals, the U.S. EPA determined there were not enough studies evaluating the short-term constituents of source-specific exposures at the time of previous Integrated Science Assessment to be able to make a causal determination (U.S. EPA 2009).*”

■ LONG-TERM PARTICULATE MATTER EXPOSURES AND MORTALITY

- Our review of this part of Appendix I revealed more controversy and debate over the association of and exposures to PM_{2.5} (Page I-26). **While a number of studies are cited, and a few claim to include some Southern California cities, most studies seem to involve cohorts in other regions of the U.S, like the Harvard Six Cities Study, and there seems to be an abundance of strong scientific opinions that contradict each other.**

■ SUMMARY - PARTICULATE MATTER HEALTH EFFECTS

- Our reading of this segment of Appendix I (Page I-41), suggests that **Staff may be experiencing some of the frustration that those in the business community have long felt.** While Staff seems to favor the body of epidemiological studies that point to PM as causing thousands of deaths per year, and thousands more hospitalizations for a variety of diseases, they do concede that

coexisting pollutants contribute to increases in cases of morbidity and mortality in the community. This should be another clarion call for more and balanced research before the business community is presented with a bill for \$38.2 billion dollars. which

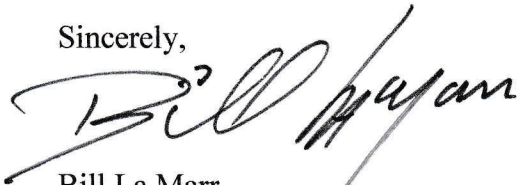
At the meeting of the Advisory Council, Staff presented us with some materials from **Dr. James E. Enstrom, a renowned and respected epidemiologist. We also had the opportunity to hear some of his theories and conclusions about the health effects of PM which contradict those made by Staff.** And while his remarks were made in haste, due to time constraints imposed by the Staff, it was clear to me at least that **his research has been acknowledged by scores of reputable scientists across the U.S.** In view of the controversy that exists over the health effects of PM, and the **highly suspicious methodology that Staff insists on using to factor the value of a human life and the price that society is willing to pay to avoid cancer, I strongly recommend that an opportunity be given for all stakeholders to actually hear and evaluate the scientific findings by Dr. Enstrom and some other scientists before the 2016 AQMP is adopted.**

To add emphasis to this request, **I have attached a comment letter by Jonathan M. Samet, MD, MS - Professor and Flora L. Thornton Chair, Dept. of Preventive Medicine, Keck School of Medicine of USC, and Director, USC Institute for Global Health.** The letter was written in response to a request by Dr. Jean Ospital, former AQMD Health Effects Officer, wherein Dr. Samet was invited to critique Appendix I of the 2012 AQMP. To avoid any confusion, I have attached only the letter and transmittal form. Originally, Dr. Samet attached his comments on a complete copy of the Appendix. I have assumed that Staff has a copy of the complete document on file. If not, I will be happy to transmit it to you.

You will note that while **Dr. Samet agrees that coverage of criteria pollutants, ultrafine particulates, and toxic air contaminants are appropriate to the development of the AQMP, he questions the degree to which the District is able to act impartially when presenting ALL scientific conclusions.**

In closing, I want to express my sincere appreciation for inviting me to serve once again on the AQMP Advisory Council, and comment on this important Appendix to the 2016 AQMP

Sincerely,



Bill La Marr
Executive Director
California Small Business Alliance

Keck School of Medicine of USC

Department of Preventive Medicine
Jonathan M. Samet, MD, MS
Professor and Flora L. Thornton Chair
Director, USC Institute of Global Health

September 25, 2012

Jean Ospital, MPH, PhD
Health Effects Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Dear Jean,

As you requested, I attach comments concerning the Health Effects Appendix of the District's draft Air Quality Management Plan. Please do not hesitate to contact me if you have questions with regard to these comments.

Yours sincerely,



Jonathan M. Samet, MD, MS
Professor and Flora L. Thornton Chair
Department of Preventive Medicine
Director, USC Institute for Global Health



**Review: Health Effects Appendix
South Coast Air Quality Management District
Jonathan M. Samet, MD, MS**

General Comments:

This relatively brief document provides an overview of the health effects of various air pollutants, giving emphasis to pollution by airborne particulate matter. The document also covers other "criteria pollutants" as well as ultrafine particulate matter and toxic air contaminants. This range of topics is appropriate to the development of an Air Quality Management Plan.

As presented, the document represents a summary, and an apparent updating of an earlier report. It is necessarily selective in its coverage and relies to an extent on the review documents prepared by the US Environmental Protection Agency for the "criteria" pollutants. I have the following general comments:

- Preparation of reviews of the health effects of air pollution is a daunting task, given the extensive data available and its continuing and rapid accrual. The South Coast Air Quality Management District is not well positioned to prepare a comprehensive and up-to-date review. Consequently, there are deficiencies of this review related to its scope and timeliness. The basis for the document's development is provided in the last paragraph on page I-2. While the statement is clear, the methods are not fully transparent. In particular, several older reviews are mentioned, along with more recent documents from the US Environmental Protection Agency and several prepared by the California EPA. I suggest that more careful attention be given to describing the basis for this review and to consideration of its methodology. For example, given the complexity and scope of the literature, the developers of the review might rely solely on summary documents or to also summarize documents and research published based on studies in California. In the present version, I could not readily identify why particular studies were included.
- I understand that the South Coast Air Quality Management District is required to provide a review in support of its air quality management plan. As stated, the California Health and Safety Code Section 40471(b) requires the preparation of report on "the health impacts of particulate matter in the South Coast Air Basin (SCAB) in conjunction with the preparation of the Air Quality Management Plan revisions." This document does not directly address the health impacts, if some quantification of burden is implicit in the requirement. The identification of health effects and selected of examples of risks from the literature represents a starting point in estimating the health impact. As noted in my next comment, the review might have establishing the relevance of the broad body of evidence to the South Coast Air Quality Management District as one objective.

- There is an extensive literature on airborne particulate matter and health, as well as on the risks of various other air pollutants. One question that might be reasonably addressed in this report is the generalizability of findings from this broad literature to California. Here, a careful review of studies in California might be of benefit. Additionally, considerations might be given to the mixture of pollutants in the South Coast Air Basin to support conclusions about the generalizability of findings.
- The document needs further editing in part to improve clarity and in part to bring in some of the most recent and relevant references. Additionally, if the most recent US EPA documents are to be used as the basis of the report, some updating is needed.

Specific comments:

See attached.



Daniel W Nebert, MD, Professor
Department of Environmental Health
College of Medicine
University of Cincinnati Medical Center
P.O. Box 670056
Cincinnati, OH 45267-0056

Phone 503-694-8482
503-815-1977
Fax 513-558-4397

dan.nebert@uc.edu

13 August 2016

Anthony Oliver, PhD aoliver@aqmd.gov
SCAQMD Air Quality Specialist

Dear Dr. Oliver and All Others Concerned:

I have been asked by Professor James E. Enstrom (UCLA) to express my opinion to you-all concerning “particulate matter of the size 2.5 micrometers in diameter (**PM2.5**) as being “*unequivocally the direct cause* of at least 2,100 deaths per year in Southern California”.

By way of introduction, I am author/coauthor of more than 650 peer-reviewed scientific publications and among the “640 most-cited authors of all time” by my peers—as determined by **Google Scholar** parameters. My fields of research interest as a physician-scientist include genetics, comparative and evolutionary genomics, gene nomenclature, drug metabolism, pharmacogenetics, adverse drug reactions, personalized medicine, environmental contaminants and disease, pediatrics, developmental biology, teratogenesis, neurobiology, endocrinology and cancer. I am board-qualified in both California and Ohio in the practice of medicine and have been Principal Investigator (PI) on numerous basic science and clinical research projects, some of which are still in preparation for publication. At the University of Cincinnati, I was Founder of the **Center for Environmental Genetics** (1992-98), which is still going strong today in its 25th year (current PI is Professor Shuk-mei Ho); I continue to participate in CEG’s Community Outreach and Education Program (COEP) directed by Dr. Erin Haynes. I also have spearheaded the worldwide standardized nomenclature system (based in London) for all genes and gene families in all living organisms.

Particulate matter has been studied extensively—by many scientists, including by one of the leaders in this field, **Joel Schwartz**, who applied longitudinal data analysis to environmental health. There was a controversy about his work on PM10 and mortality; these findings were therefore re-analyzed twice by the Health Effects Institute (funded 50% from the US EPA and 50% from automotive manufacturers). Whereas the magnitude of the effect was somewhat diminished on this re-analysis, “a small effect” was still seen, although statistically not significant [<http://pubs.healtheffects.org/getfile.php?u=21>]. Most disturbingly, the variability among and between studies was very substantial. Explanations for this variability were suggested to include “the degree of temporal smoothing used in the original analyses, number of smoothed terms in the models, and degree of nonlinear collinearity (concurvity) among the smoothed terms.” The relative importance of these and other explanations remains highly equivocal.

Joel Schwartz also used these methods to examine the relationship of PM2.5 with mortality. He and others have estimated an association to be “a ~10% increase in mortality for every 10 $\mu\text{g}/\text{meter}^3$ —**above** (but not below) 10 $\mu\text{g}/\text{meter}^3$. At 20 $\mu\text{g}/\text{meter}^3$, it was possible to measure a slight increase in mortality in a study of 10,000 deaths. However, at levels in the range of 10–15 $\mu\text{g}/\text{meter}^3$, the study would require a very large cohort in order to gain sufficient statistical power to detect “an unequivocal effect”.




The PM2.5 relationship was assessed considerably before the 21st century, when several cities (e.g. Allegheny County, Pittsburgh) suffered from levels above 20 µg/meter³. **However, these levels of air pollution no longer exist, anywhere in the United States today.** This is mainly because many of the antiquated power plants have been converted to natural gas or have shut down. Thus, I do not believe that particulate matter air pollution is a major problem any longer in this country—although it remains a challenge in certain cities of China and India.

In conclusion, existing evidence on “the relationship between PM2.5 and total mortality in California” (and indeed, nationally) is **absolutely underwhelming** for SCAQMD to claim that “PM2.5 **causes** 2,100+ deaths per year in the South Coast Air Basin”. It is categorically unethical to use that claim as the primary public health justification for a 2016 Air Quality Management Plan that **imposes a burden of \$38.2 billion in additional compliance costs** on the Southern California taxpayers and their economy.

This is yet-another glaring example of “public policy being pushed forward—despite any solid scientific evidence supporting the proposed policy.” As a physician-scientist who is proud of scientific integrity in all his published research for more than five decades, I find this behavior despicable and I denounce it. I urge you to take these comments seriously.

Sincerely,



Daniel W Nebert, BA [biochem], MS [biophys], MD [pediatrics], Professor Emeritus
Department of Environmental Medicine and Center for Environmental Genetics
University of Cincinnati College of Medicine, Cincinnati, OH 45267
Department of Pediatrics & Molecular Developmental Biology, Division of Human Genetics
Cincinnati Children's Hospital, Cincinnati, OH 45229
Affiliate Faculty, Department of Environmental & Molecular Toxicology, Oregon State University,
Corvallis, OR 97331
Consultant, Department of Environmental Health Sciences, Yale University School of Public Health,
New Haven, CT 06520

cc:

Jo Kay Chan Ghosh jghosh@aqmd.gov
Henry A. Roman har@indecon.com
George D. Thurston george.thurston@nyumc.org
Elaine Shen eshen@aqmd.gov
Philip M. Fine pfine@aqmd.gov
Wayne Natri wnatri@aqmd.gov
Eula Bingham, Professor Emeritus, Undersecretary-of-Labor, 1977-81 eula.bingham@uc.edu

