Air Resources Board

Mary D. Nichols, Chairman
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Linda S. Adams
Secretary for
Environmental Protection

Arnold Schwarzenegger
Governor

April 6, 2009

The Honorable Chuck DeVore
California State Assembly
State Capitol, Room 4102
Sacramento, California 95814

Dear Assemblymember DeVore:

This is in response to your February 17, 2009, letter to the Board Members of the California Air Resources Board (Board) requesting that we temporarily suspend our on-road and off-road diesel truck regulations. In your letter you listed scientific, legal, and economic justifications that I would like to address. Our responses to your concerns are summarized below, but additional detail is presented in the attachment.

Scientific Justification

Your first concern is that the primary scientific justification for the regulations is open to question, indicating that there is evidence from six independent sources that there is no causal relationship between fine particulate matter (PM2.5) and premature death in California. We strongly disagree. There is overwhelming evidence from several hundred studies with hundreds of thousands of individual participants that demonstrate an association between exposure to PM2.5 and increased risk of premature death. It is true that a few studies found little or no association; however, these studies are in the minority and have deficiencies, as detailed in the attachment. As our PM2.5 report documented, the weight of scientific evidence is clearly in support of an increased risk of premature death with elevated PM2.5 levels.

For our PM2.5 report, we only used scientific publications from the open peer-reviewed literature, not opinion pieces. Furthermore, the report was assessed independently and judged to be valid. The report went through four levels of independent, external peer review. Three nationally recognized scientific advisors from Harvard, Brigham Young University, and the State's Office of Environmental Health Hazard Assessment reviewed all aspects of the work. The University of California at Berkeley selected six formal peer reviewers for the report. We convened an additional panel with the U.S. Environmental Protection Agency, the World Health Organization, and internationally recognized

PM health effects experts. And at the request of the Engine Manufacturers Association, the diesel soot exposure estimates were reviewed by a professor of their choosing. All levels of review agreed with the basic conclusions of the report. Even though peer review of public comments is not required by law (Health and Safety Code section 57004), our three scientific advisors reviewed all comments and all publicly released versions of the report. In addition, we reviewed and responded to all public comments, which can be found in the appendix of the PM2.5 report.

While it is true that ambient levels of PM2.5 have decreased markedly over the last ten years, we still need to continue our efforts to attain all national and State health-based ambient air quality standards, which continue to be exceeded throughout California. There is ample evidence from many types of health studies that controlling PM2.5 mass, including diesel emissions, will reduce adverse health effects, such as illness, hospitalizations, and premature death in the general population of California. Other respected organizations, including the American Academy of Pediatrics, American Lung Association, American Heart Association, American Cancer Society, Union of Concerned Scientists, U.S. Environmental Protection Agency, and World Health Organization, have reached the same conclusion.

Legal Justification

Your second concern was on the legal justification for the regulations. You state that diesel PM was declared a toxic air contaminant by a Scientific Review Panel (SRP) that suffered irregularities in the appointment of its members. Members must be appointed from a pool of nominees created by the President of the University of California. SRP members are appointed to staggered three-year terms (Health and Safety Code Section 39671), but members need not be replaced when their three-year terms expire. Instead, SRP members, like individuals appointed to other official positions, may continue to serve until they are reappointed, resign, or are replaced (Government Code Section 1302). While it is good to cultivate new talent, automatically replacing members when their terms expire could deprive the panel of valuable expertise.

Economic Justification

The economic impact of the regulations is the third concern you raised. I want to assure you that we recognize that the approved in-use on-road diesel vehicle regulation could have a significant economic impact on California fleets. However, in approving the regulation, I also want to assure you that the Board carefully considered this impact and balanced it by providing significant flexibility to fleets to choose a compliance option that is least costly. In addition, the implementation of the regulation is phased in gradually over a 13-year period and never requires the replacement or retirement of all vehicles in

a fleet in any one year. The regulation also provides special consideration for small fleets, agricultural vehicles, low-use vehicles and vehicles used exclusively in areas of the State with cleaner air quality. For example, an independent truck owner/operator is exempt from any performance requirements until January 2014; and in many cases, they will only need to install a retrofit diesel particulate filter. Also, as fleets downsize due to the current economic downturn, a retirement provision exists that provides future credits towards compliance.

The Board did consider the proposal from the Driving Towards a Cleaner California (DTCC) Coalition that contained less stringent requirements and delayed many of the clean up requirements of the regulation; however, the DTCC proposal would have provided roughly half of the emissions benefits that would be achieved by the regulation. Significantly delaying or lessening the requirements of the proposed regulation would result in continued poor air quality in many areas of the State and continued elevated health impacts from diesel trucks. Because of this, the Board was not able to incorporate many of the key elements of the DTCC proposal into the regulation.

I can assure you that the Board places a very high priority on the comments of those affected by the rule and is aware of the economic concerns of affected stakeholders. Staff is currently in the process of responding to all of the public comments received through its Final Statement of Reasons of Proposed Rulemaking and will be releasing this document later this year. However, because of the continued uncertainty in the California and nationwide economy, the Board directed staff to provide an update on the regulation by the end of the year, as well as to provide any appropriate recommendations regarding its provisions.

While the costs associated with the regulation are significant, we believe that its benefits are even greater. In California, among all diesel engines, trucks are the largest single source of emissions of smog-forming pollutants and diesel PM. To meet health-based clean air standards and to reduce the health impacts of air pollution caused by diesel engines, reducing emissions from trucks operating throughout the State is crucial. No other regulation considered by the Board over the last decade has provided as much of the emission reductions needed to meet federal ambient air quality standards, and failure to meet these standards places billions of dollars of federal highway funds at risk. Furthermore, with the regulation we estimate that 9,400 premature deaths statewide from diesel truck emissions will be avoided between 2011 and 2025, with a total economic valuation of $48 billion to $69 billion.

I hope that these responses have adequately addressed your concerns. Should you have any questions or would like additional information, please contact me at (916) 322-5840 or mnichols@arb.ca.gov.

Sincerely,

Mary D. Nichols
Chairman

Attachment

cc: The Honorable Lou Correa
California State Senate
State Capitol, Room 5052
Sacramento, California 95814

The Honorable Michael Villines
California State Assembly
State Capitol, Room 3104
Sacramento, California 95814

ATTACHMENT

Request for Temporary Suspension of CARB On-Road and Off-Road Diesel Truck Regulations

Response to: Scientific Justification for Suspension

"There is substantial epidemiologic evidence from six independent sources that there is no current relationship between fine particulate matter and premature deaths in California."

RESPONSE: Since these six independent sources were not named, we can only surmise that the following studies were listed as lack of evidence.

Eleven California Counties Study. Enstrom (2005) reported an analysis of about 36,000 elderly males and females in 11 California counties followed between 1973 and 2002. Countywide PM2.5 concentrations were estimated from outdoor ambient monitoring for the time period 1979–1983. For approximately the first half of the follow-up period (1973–1983) and for the time period approximately concurrent with PM2.5 monitoring, a small PM2.5-mortality association was observed. No PM2.5-mortality risk associations were observed for the later follow-up (1983–2002). For the entire follow-up period, only a small statistically insignificant association was observed. When 1979-93 pollution and mortality data were examined, a statistically significant association was observed.

While it is true that the paper is the largest study of its kind ever conducted in California, there are several factors that led to less weight being given it than some other papers. Most significant is the 40-year follow-up. At first glance, this long follow-up is an attractive idea. However, the Cox proportional hazards model is influenced by long-term trends that are not likely to remain proportional to the hazard for periods of that duration, for example, changes in health care. This is suggested by Janes et al. (2007). While it is unlikely that changes in health care, land use, demographics and other risk factors vary on the scale of a few years, they will change over 40 years, and this is not accounted for in Enstrom's study. The original American Cancer Society and Six Cities studies were less than ten years in duration, reducing the likelihood that this issue applies to them. However, as follow-up in these populations continues, this will increasingly become an issue, unless updates to model adjustments for these factors are made.

It is very likely that at some point across a 40-year period the risk of dying in any given year dwarfs any additional risk added by PM2.5, making additional risk related to PM2.5 undetectable. As the subjects move into the older age categories, it will become difficult to distinguish additional risk from PM2.5 from that related to age. Such is suggested by Zeger et al. (2008) as well. In fact, the Enstrom paper demonstrates this, in that the relative risk for a PM2.5 effect on death decreases

through the various measurement periods reported in the paper. It should be noted that Enstrom's relative risk for the 1973 to 1983 time period is similar to that reported by Pope et al. (1995) using the same exposure data, and when the subjects in the two groups were of similar ages.

Another concern with the Enstrom paper is the assignment of Los Angeles as the referent city, where about half of the subjects lived (N=17,340), and where PM2.5 levels were among the highest of the counties included in the analysis. The next largest group lived in Alameda County (N=4294). Several other counties had fewer than 1,000 subjects each. The effect of this is that there would be a robust estimate for the referent county due to high statistical power related to the large population, but uncertainty in comparisons between Los Angeles and the other counties would increase as the comparison population decreased due to low statistical power in the comparisons. Thus, it would be difficult to distinguish effects due to the large uncertainty ranges in many of the comparisons. Admittedly, the clustering of about half of the cohort in one county, and the non-uniform distribution of the other subjects throughout the state make it difficult to select a referent county from this group.

The table below lists the relative risks for several long-term PM2.5 exposure studies. The relative risks for a 10 $\mu g/m^3$ change in PM2.5 range from 0.3 (Lipfert et al., 2003) to 27 (Laden et al., 2005) for those studies conducted in the US. In light of this range, it is scientifically unreasonable to select a single paper's value, particularly one at the bottom of the distribution of reported risks, as the commenters urge. Consideration of the range and distribution of relative risks among the available studies led to the decision to select 10% (derived from the U.S. EPA expert elicitation results) as a reasonable value for subsequent analyses.

EPRI Veterans Cohort Studies. These studies focused on male military veterans under treatment for hypertension and who were mostly current or former smokers. Thus, the results do not directly apply to the general population. Lipfert et al. (2000, 2003) assessed the association of total mortality and air pollution in a prospective cohort of about 50,000 middle-aged, hypertensive, male patients from 32 Veterans Administration (VA) clinics followed for about 21 years. The cohort had a disproportionately large number of current or former smokers (81%) and African-Americans (35%) relative to the U.S. population or to other cohorts that have been used to study air pollution. Thus, while the results were reviewed by ARB staff (and by the experts in the US EPA elicitation), they had little direct bearing on the development of the concentration response function for the general population.

Adventist Health Study of Smog (AHSMOG) Cohort Study. This study related air pollution to 1977–1992 mortality in more than 6000 non-smoking adults living in California, predominantly from San Diego, Los Angeles, and San Francisco (Abbey et al. 1999). All-cause mortality, nonmalignant respiratory mortality, and lung cancer mortality were significantly associated with ambient PM10 concentrations in males

but not in females. Cardiopulmonary disease mortality was not significantly associated with PM10 in either males or females. However, this study did not have direct measures of PM2.5 but relied on TSP and PM10 data. In a follow-up analysis (McDonnell et al. 2000), visibility data were used to estimate PM2.5 exposure of a subset of males who lived near an airport. All-cause, lung cancer, and nonmalignant respiratory disease (either as the underlying or a contributing cause) were more strongly associated with PM2.5 than with PM10. In a recent analysis of the AHSMOG cohort, fatal coronary heart disease was significantly associated with PM among females but not among males (Chen et al. 2005).

Medicare Cohort Studies. Eftim et al. (2008) recently published a long-term PM2.5 exposure study based on a cohort retrospectively developed from the Medicare database. The cohort and PM2.5 monitoring data were from the same cities and counties as those included in the Harvard Six Cities Study (SCS: Dockery et al., 1993; Laden et al., 2006) and the ACS Cancer Prevention Study (CPS) II cohort (ACS: Pope et al., 1995; 2002; 2006) studies. The cohort included over 7.3 million people who were likely more broadly representative of the American population than the SCS and ACS cohorts in terms of demographics, including race, income, and education. However, the database has several limitations, in that it only includes people over 65 years of age, and there is no information on potential confounders and effect modifiers, such as smoking or body weight. Eftim et al. adjusted for these factors, and several socioeconomic factors on a county level based on census data. The results for the period 2000-2002 are higher than reported previously in the ACS and SCS publications.

Zeger et al. (2008) expanded on Eftim et al's. (2008) study to include over 13 million Medicare enrollees and a five year exposure assessment (2000 – 2005). The study employed methods similar to Eftim et al. (2008), although it also included secondary analyses on a regional basis (Eastern, Central and Western United States), and based on age (65 to 74, 75 to 84, and over 85 years of age). The results showed a decrease in effect with advancing age, such that there was no effect in persons over 85 years of age, consistent with the results of Enstrom (2005) and Laden et al. (2006).

Several factors could influence the differences between Eftim's and Zeger's results and those from the ACS and SCS studies. The size of the exposure aggregation units in larger metropolitan areas could lead to underestimated effect estimates. The Medicare cohort was generally older than the SCS and ACS cohorts, and several papers have suggested that the influence of PM2.5 on mortality decreases in the oldest age groups (Enstrom, 2005; Laden et al., 2006).

In Zeger et al. (2008), the statistically significant results for eastern and central United States are in general agreement with previous publications. However, Zeger et al. (2008) found no significant effect of PM2.5 on mortality in the western United States. This result may be due to lack of control for individual level covariates in the analysis.

These covariates may include body mass index, diet, lifestyle, or other factors that differentiate the Los Angeles basin from other counties in the West. Further, "the West" was defined as urban areas of California, Oregon, and Washington. Thus, in the stratified analysis, the authors effectively compared the Los Angeles basin with other parts of the region. The authors recognize that the Los Angeles basin counties have higher PM levels than other West Coast urban centers, but lower adjusted mortality rates. Therefore, the result for the West can be significantly biased by the lack of control for individual-level lifestyle factors.

"The evidence that CARB relies upon is not sufficient to establish a true causal relationship in California"

RESPONSE: Below is a summary of the key studies that have provided evidence for the PM2.5 mortality relationship (Table 1). These studies contain results from hundreds of US cities and hundreds of thousands of individual participants.

Study	Primary Source	Exposure Increment	All Cause	Cardio-pulmonary	Lung Cancer
Harvard Six Cities, original	Dockery et al. 1993	10 μg/m^3 PM2.5	13 (4.2, 23)	18 (6.0, 32)	18 (-11, 57)
Harvard Six Cities, HEI reanalysis	Krewski et al. 2000	10 μg/m^3 PM2.5	14 (5.4, 23)	19 (6.5, 33)	21 (-8.4, 60)
Harvard Six Cities, extended analysis	Laden et al. 2006	10 μg/m^3 PM2.5	16 (7, 26)	28 (13, 44)[a]	27 (-4, 69)
Harvard Six Cities, extended analysis between periods	Laden et al. 2006	10 μg/m^3 PM2.5	27 (5, 43)	31 (-1, 54)	6 (-57, 162)
Harvard Six Cities, extended analysis, linearity explored	Schwartz et al. 2008	10 μg/m^3 PM2.5	10 (0, 21)†		
ACS, original	Pope et al. 1995	10 μg/m^3 PM2.5	6.6 (3.5, 9.8)	12 (6.7,17)	1.2 (-8.7, 12)
ACS, HEI reanalysis	Krewski et al. 2000	10 μg/m^3 PM2.5	7.0 (3.9, 10)	12 (7.4, 17)	0.8 (-8.7, 11)
ACS, extended analysis	Pope et al. 2002 Pope et al. 2004	10 μg/m^3 PM2.5	6.2 (1.6, 11)	9.3 (3.3, 16) 12 (8, 15)[a]	13.5 (4.4, 23)
ACS adjusted using various education weighting schemes	Dockery et al. 1993 Pope et al. 2002 Krewski et al. 2000	10 μg/m^3 PM2.5	8–11	12–14	3–24
ACS intrametro Los Angeles	Jerrett et al. 2005a	10 μg/m^3 PM2.5	17 (5, 30)	12 (_3, 30)	44 (-2, 211)
Postneonatal infant mortality, U.S	Woodruff et al. 1997	20 μg/m^3 PM10	8.0 (4, 14)	–	–
Postneonatal infant mortality, CA	Woodruff et al. 2006	10 μg/m^3 PM2.5	7.0 (-7, 24)	113 (12, 305)[c]	–
AHSMOG[b]	Abbey et al. 1999	20 μg/m^3 PM10	2.1 (-4.5, 9.2)	0.6 (-7.8, 10)	81 (14, 186)
AHSMOG, males only	McDonnell et al. 2000	10 μg/m^3 PM2.5	8.5 (-2.3, 21)	23 (-3, 55)	39 (-21, 150)
AHSMOG, females only	Chen et al. 2005	10 μg/m^3 PM2.5	–	42 (6, 90)[a]	–
Women's Health Initiative	Miller et al. 2004	10 μg/m^3 PM2.5	–	32 (1, 73)[a]	
Women's Health Initiative	Miller et al. 2007	10 μg/m^3 PM2.5	–	76 (25, 147)[a]	
VA, preliminary	Lipfert et al. 2000, 2003	10 μg/m^3 PM2.5	0.3 (NS)[d]	–	–
VA, extended	Lipfert et al. 2006a	10 μg/m^3 PM2.5	15 (5, 26)[e]	–	–
11 CA counties, elderly	Enstrom 2005	10 μg/m^3 PM2.5	1 (-0.6, 2.6)	–	–
Netherlands	Hoek et al. 2002	10 μg/m^3 BS	17 (-24, 78)	34 (-32, 164)	–
Netherlands	Hoek et al. 2002	Near major road	41 (-6, 112)	95 (9, 251)	–
Netherlands, extended analysis	Beelen et al. 2008	10 μg/m^3 BS		22 (-1, 50)[c]	3 (-12, 20)
Netherlands, extended analysis	Beelen et al. 2008	10 μg/m^3 PM2.5		4 (-10, 21)[c]	6 (-18, 38)
Hamilton, Ontario, Canada	Finkelstein et al. 2004	Near major road	18 (2, 38)	–	–
French PAARC	Filleul et al. 2005	10 μg/m^3 BS	7 (3, 10)[f]	5 (-2,12)[f]	3 (-8,15)[f]
Cystic fibrosis	Goss et al. 2004	10 μg/m^3 PM2.5	32 (-9, 93)	–	–
Medicare Cohort in ACS locations	Eftim et al. 2008	10 μg/m^3 PM2.5	10.9 (9, 12.8)	–	–
Medicare Cohort in Harvard Six Cities Study locations	Eftim et al. 2008	10 μg/m^3 PM2.5	20.8 (14.8, 27.1)	–	–
Medicare Cohort in eastern U.S.	Zeger et al. 2008	10 μg/m^3 PM2.5	6.8 (4.9, 8.7)	–	–
Medicare Cohort in central U.S.	Zeger et al. 2008	10 μg/m^3 PM2.5	13.2 (9.5, 16.9)	–	–
Medicare Cohort in western U.S.	Zeger et al. 2008	10 μg/m^3 PM2.5	-1.1 (-3.0, 0.8)	–	–

Table 1. From "Methodology for Estimating Premature Deaths Associated with Long-term Exposure to Fine Airborne Particulate Matter in California", CARB Staff Report (2008) http://www.arb.ca.gov/research/health/pm-mort/pm-mort_final.pdf

Regarding the suggestion to use only certain publications as the source for the PM2.5 concentration-response function, it should be noted that the scientific method and the development of science-based public policy require consideration of all relevant available data. Standard scientific practice is to consider the range of data reported in the literature, along with its uncertainty, and draw the most reasonable conclusion possible. When multiple studies exist, standard scientific practice does not support reliance on only one study.

"Serious doubts have been raised about the professional qualifications of the CARB staff members who prepared the key report on PM2.5 and premature deaths"

RESPONSE: The report underwent several levels of review and did not rely solely on any particular staff member's analysis. The review process is summarized here.

We only used scientific publications from the open peer-reviewed literature. We considered 78 peer-reviewed scientific journal articles and eight reports from the National Academies of Science, the U.S. Environmental Protection Agency and the World Health Organization. We did not include secondary literature, such as books or opinion pieces.

Three nationally recognized scientific advisors from BYU, Harvard and OEHHA reviewed all aspects of our work, including all publicly released versions of the report. We received comments throughout the process from our three advisors: Dr. Jonathon Levy from Harvard, Dr. Arden Pope from Brigham Young University and Dr. Bart Ostro from the Office of Environmental Health Hazard Assessment. They publish frequently in the areas of air pollution and statistical relationships with premature death, the main subject of our report, and concurred with our finding.

The UC Berkeley Institute of the Environment selected six peer reviewers for the report. Our draft report was reviewed following the Cal/EPA external scientific peer review guidelines for independent review. In this process the UC Berkeley Institute of the Environment selects the peer reviewers without input from staff. Staff was only allowed to submit a list of individual who may have a conflict of interest and so could not participate. Furthermore, candidates were accepted as reviewers only if the disclosure information showed they had no conflict of interest related to the report. The six reviewers identified by UC Berkeley and selected by the Cal/EPA Project Director to review the proposed methodology in the PM2.5 Mortality staff report are: Dr. Jeff Brook from Environment Canada, Professor Mark D. Eisner of UC San Francisco, Professor Richard C. Flagan of the California Institute of Technology, Professor Alan Hubbard of UC Berkeley, Professor Joel Kaufman of University of Washington and Professor Joel Schwartz of Harvard University. Collectively, their expertise is based on research in the areas of chronic obstructive pulmonary disease related to air pollution, statistical analysis of epidemiological data, particle formation and measurements in air, air quality risk management, air pollution and daily mortality associations, and epidemiology. They all concurred with our basic conclusions.

The report went through an additional informal, independent peer review. At the request of Board Chairman Mary Nichols, ARB staff convened a panel of worldwide PM health effects experts. Participants included U.S. EPA, Environment Canada, the World Health Organization, the Chairs of Cal/EPA's Air Quality Advisory Committee and Scientific Review Panel, the Health Effects Institute and several internally recognized academic researchers. There was general concurrence on the basic

conclusions of the report.

Other organizations are coming into alignment with our methodology. U.S. EPA is transitioning to using a range of 6% to 16% (versus our 10%) increase in all-cause mortality for a 10 $\mu g/m^3$ increase in PM2.5). Also a 2007 peer-reviewed elicitation of European experts also concluded 6% is too low.

"The final version of this report and relevant public comments were never shown to outside peer reviewers and required by state law"

RESPONSE: A role for public comments does not appear in the H & S code section 57004 on peer review. Also, the Cal/EPA external scientific peer review guidelines do not include consideration of public comment as part of the peer review process. Overall, the peer reviewers overall agreed with our assessment.

"There is substantial evidence that the appointments of the nine members of the SRP as of 1998 were not made in accord with all relevant provisions in Sections 39670-39671 of the California Health and Safety Code and the original legislative bills that reacted the SRP"

RESPONSE: The Secretary of the California Environmental Protection Agency and the Legislature appoint members to the Scientific Review Panel on Toxic Air Contaminants (Health and Safety Code section 39670). The Secretary appoints five members; one must be a pathologist, one an oncologist, one an epidemiologist, one an atmospheric scientist, and the last a scientist with relevant experience who is also experienced in the operation of scientific review or advisory bodies. The Senate Rules Committee appoints two members, one of whom must be qualified as a biostatistician and one of whom is a physician or scientist specializing in occupational medicine. The Speaker of the Assembly also appoints two members, one of whom must be a toxicologist and the other a biochemist or molecular biologist. Members must be appointed from a pool of nominees created by the President of the University of California, must be highly qualified and professionally active or engaged in the conduct of scientific research, and must hold, or have held, academic or equivalent appointments at universities and their affiliates in California.

SRP members are appointed to staggered three-year terms (Health and Safety Code section 39671), but members need not be replaced when their three-year terms expire. Instead, SRP members, like individuals appointed to other official positions, may continue to serve until they are reappointed, resign, or are replaced (Government Code section 1302).

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