Matt Malkan, Ph.D. <u>SC AQMD MATES III Comments</u> August 19, 2008

I have reluctantly come to the conclusion that the unelected members of CARB are on the verge of committing California to a radical, poorly thought-out mandate, that is likely to generate so much economic chaos it could become a threat to the health of our state's economy.

CARBs fundamental responsibility is to weigh carefully extremely complex and imperfect data on the health effects of air pollutants on Californians. But it also has an equally heavy duty to assess the costs of new environmental regulations it imposes with great care. CARB, like any powerful autonomous government agency, needs to take as its guiding principle a simple fact:

The more costly the proposed regulations, the higher the degree of certainty required. Given the lack of political oversight on some of the biggest decisions, it appears that a major re-direction of CARB leadership will be required to recover sight of this basic principle.

In the one crucial case with which I am familiar--diesel exhaust fumes--CARB is failing in its prime responsibilities to the people of California. The data on health benefits are far too uncertain to provide a sound basis for the immediate radical action it is advocating.

Is it really true, as CARB claims, that there is a correlation between fine particles (PM2.5, a few percent of which ...) and "premature deaths"? The objective, scientific answer is: **We still do not know.** There are many reasons that the current state of research cannot be considered conclusive:

1) These studies are attempting to quantify a health hazard that is smaller and weaker than almost any previously discovered ones in medical history. Footnote:(For example, the ACS and other studies found that lung cancer risk increased by 1400--2000% in smokers. The increased risk of lung cancer due to PM2.5 exposure was between 4.4 and 23%.) Since CARB is considering a possible health hazard which they believe is 60 to 900 times less dangerous than smoking, they are exploring unknown waters of public health policy. They should only draw final conclusions if they have clear-cut results from very large carefully controlled studies which accurately measure the exposure (to diesel exhaust particles) and the harm (premature death caused by these particles).

2) The studies do not in general test directly the crucial question for policy makers: can CARB's rollback of diesel emissions save lives? One of the CARB experts, Joel Schwartz, Director of the Harvard Center for Risk Analysis at the School of Public Health, explains the problem very clearly:

"But the question that CARB needs to answer in order to do an analysis of the benefits of *reducing* air pollution is what mortality reduction accompanies a reduction in exposure.

A cross-sectional analysis of mortality and air pollution does not tell us that, no matter how sophisticated the Cox Proportionate Hazard model is. It is an extrapolation to estimate change in mortality for change in pollution. However the Laden paper provides precisely that estimate that CARB needs. In that sense, it is the only relevant study." Indeed. And this Laden study found that the decreases in PM2.5 in the Harvard-6 cities did NOT lead to statistically significant decreases in cardiovascular, respiratory, or lung cancer deaths (or "other" deaths).

3) Another fundamental problem is that the studies did not compare MATCHED samples of participants in the high- and low-exposure locations. For example, poor people are more likely to live in polluted environments than are affluent people. Poor people are also more likely to suffer premature deaths. These correlations do NOT establish a causal connection. They do not show that it was the pollution, or the diesel exhaust in particular, that lead to the premature deaths.

4) None of the CARB experts has any clear idea of HOW the diesel exhaust particles are supposedly killing people "prematurely" (before age 75). The original idea was that they might be a carcinogen, which people get exposed to when they are inhaled into the lungs. However, the accumulated evidence presented by CARB does not in general support a correlation between PM2.5 and lung cancer (or any other cancers). None of the analyses of the "Harvard Six" data found a significant correlation, nor did the original ACS study, or the more detailed analysis of its 23,000 Los Angeles subjects.

With that theory shot down by the data, the researchers cast a much wider net, looking for any kind of death that might be laid at the feet of diesel exhaust. Again, the evidence failed them.

No significant correlation with respiratory-related premature deaths.

There is also no significant correlation with cystic fibrosis.

Those are the correlations that most people would be expecting to find. Most members of the public, including political leaders, have been mislead into hoping that CARB has clear evidence that deaths due to lung problems will be decreased by its rollback of diesel emissions, but it does not.

Finally, to find some significant health hazard, the researchers adopted the highly speculative hypothesis that the major cause of death--heart disease--was somehow exacerbated by diesel particles. This is the classic scientific error of "bait and switch", of completely changing the experiment after the initial design fails, to try to turn a negative result into some other weakly positive finding. So now the primary health hazard of PM2.5 is claimed to be generic "cardiopulmonary" fatalities.

5) Even if one accepts the flawed studies without considering any of their problems, they still do not provide a decisively clear answer. The possible correlation between diesel exhaust particles and "premature deaths" (mostly from heart disease) is too small to have been decisively measured in previous studies.

CARB puts the heaviest reliance on the Harvard 6-cities study (because of the quality of its data and procedures), which had a very small sample size of only 8000 subjects. The original effect was MARGINALLY significant. This study was extended for another 8 years. Although this substantially increased the total amount of data, it did NOT improve the statistical significance of the claimed effect, which was still MARGINAL.

The small sample size problem was reduced in the ACS study, but it suffers from much greater problems with data and methodology than the Harvard-6 study. It found a smaller effect than Harvard-6, but it was statistically significant because of the larger sample size. However, when the study was extended, the statistical significance dropped to MARGINAL (Pope et al 2002), and actually whisker-close to INSIGNIFICANT.

A major problem is that the exposure levels are estimated over very large areas...typically xxx20? miles

The Jerrett et al study of the LA subset of ACS data was the only one which utilized data from particle monitors (23 in the LA basin). This re-analysis found NO significant cardiopulmonary or lung cancer deaths associated with air pollution. Only by adding in ischemic heart disease deaths were Jerrett et al able to find a correlation between "All Causes" of death and PM2.5, but it was still only a MARGINAL effect, which was again very close to INSIGNIFICANT.

The evidence becomes weaker still when the other studies are included. Even by CARBs own loose standard, of the remaining 5 studies: AHSMOG, VA, 11-CA Counties, Netherlands and France, 4 found NO SIGNIFICANT EFFECT. Compared to the ACS, for example, these other independent studies have their own strengths and weaknesses. Weighing all of them is more a matter of subjective taste, than a clear scientific process. The experts in effect chose to ignore them in favoring their claim of a significant effect. Nonetheless, the results of these many studies directly contradicting that claim must raise further serious doubts in the minds of policy makers.

Footnote The "gold standard" of statistical significance in the sciences is that the measured effect be three times larger than the uncertainty. This means a "3-sigma" significance.

(In the hard sciences, 3-sigma claims are actually regarded with suspicion, and generally 4- or 5-sigma significance from multiple studies is required to produce a scientific consensus.)

However CARB has chosen to adopt only a 2-sigma threshold for it to consider a claimed effect "significant". Following the majority of working scientists who do not accept this definition, I describe 2-sigma claims as MARGINAL. 2-sigma claims might be true, or they may turn out to be wrong. They are certainly NEVER a basis for costly radical actions.

Results that are JUST 2 times the uncertainty are described as "very close to INSIGNIFICANT". This means that tiny, extremely subtle changes in the data analysis could make the entire effect DISAPPEAR. This is because, as some of the CARB experts themselves noted, the quoted uncertainties are themselves subjective and uncertain. In nearly all of these studies it is a matter of personal judgment—not scientific

fact--whether there is any effect at all. Such "results"—which are skating right on the edge of insignificance--cannot provide the justification for radical new actions.

Even if the very small claimed health hazards of diesel exhaust turn out to be real, they in no way justify CARB's draconian economy-threatening response.

CARB data show quite consistently that PM2.5 levels all across California are dropping rapidly. The Table on A-12 shows that in only 3 years, the pollution decreased by about 25%. Thus much of the problem that CARB is attacking is already fading. By 2006 the most seriously effected region, the South Coast, had PM2.5 levels which were only 50% higher than that measured in the Mojave Desert and Mountain counties (Appendix 1).

Nitric oxides are measured, but these are produced by all combustion [are diesel trucks the main source??

None of the studies was able to measure the exposure levels to diesel exhaust.).

CARB's predictions of total compliance costs--that will ultimately be borne mostly by Californians—are almost absurdly underestimated. This lack of reality is perhaps the most disturbing aspect of the proposed new regulations.

Main effect is reducing premature deaths in South Coast.

CARB needs to go after the most heavily polluting, oldest engines first.

The MATESIII technical experts have done an impressive job trying to estimate the details of air pollutants in Southern California. But when it comes to fine particulate matter, PM2.5, from diesel exhaust, I'm very concerned about the *larger questions* of estimating benefits and costs that AQMD is using to guide its policy. The stakes have become too high for AQMD to rely uncritically on conclusions from the California Air Resources Board, which CARB is basing on a selected set of results with alarmingly low statistical significance.

CARB is imposing new regulations on diesel exhaust that go far beyond what any of the other 49 states, or the federal government has adopted. The claimed toxic effects of PM2.5 are hundreds of times smaller than, for example, the increased risk of lung cancer caused by cigarette smoking. These possible effects are so small, the actual exposure levels of human subjects are so difficult to estimate, and there are so many confounding health factors that are hard or impossible to control, that all of the studies need to be scrutinized with more caution than is shown in the Draft Final Report.

I've tried to take an objective look at the scientific question: Is fine particulate matter in diesel exhaust causing cancer and premature deaths of a measurable number of Southern Californians? The short answer is that we do not yet know. But whichever way the answer eventually turns out will have no effect whatever on my career, or my grant funding. I don't stand to gain any power to control any sectors of the economy. I'm just looking for a clear scientific answer, which gives me a big advantage. I'm just a 30-year L.A. resident, but I do use the same statistical tools (like Cox Proportional Hazard tests) in my own astrophysics research.

CARB's original justification for targeting PM2.5 was that it caused lung cancers. This claim has not been confirmed by subsequent research. In fact the research that CARB relies on has failed to find any statistically significant increased risk of ANY form of cancer, or other lung diseases associated with fine particles. In a classic "bait and switch", CARB then sought new correlations with the far larger, amorphous category of deaths due to heart disease, without a clear medical model of how this might be

caused by fine particles. Even in the studies CARB experts chose to weight most heavily (the ones they tend to be co-authors on), the claimed associations between PM2.5 and "premature" deaths of almost any kind range from insignificant to barely "significant" at the 95% confidence level. In the physical sciences, you can't get a result published unless it passes the higher 99% significance level. I don't think any of the studies of mortality risks of fine particles has that level of statistical confidence.

As the studies grow in size and in time coverage, the desperately low statistical significance of the claimed hazards of PM2.5 has not improved. I'm also alarmed by the growing number of other studies that FAILED TO DETECT ANY MEASURABLE LIFE-THREATENING RISKS ASSOCIATED WITH FINE PARTICLES. We still cannot confidently rule out the possibility that diesel exhaust is statistically associated with ZERO premature deaths. From the policy point of view, it does not help if your painstaking estimates of elemental carbon, PM2.5 etc may be quite accurate, since you are then multiply them by a Unit Risk Factor which might possibly be zero. The science is still not solid enough to justify an all-out crash program to eliminate fine particle emission.

Even if it eventually turns out that fine particles are associated with a very small increased risk of life-threatening disease, AQMD has a serious obligation to analyze carefully the most cost-effective means of reducing our exposure to PM2.5 over the coming decades. Disturbingly little thought appears to have gone into the real-world tradeoffs of various regulations and timetables. It seems likely that a program to retrofit or gradually retire the dirtiest diesel trucks first could cut PM2.5 emissions by half or maybe even 2/3 over the next decade, at a TINY FACTION OF THE COST of the radical measures that are being proposed. The true costs of the extreme proposed rules seem to have been grossly underestimated. Every epidEmiologist knows there is an inescapable trade-off that cannot be ignored: if new regulations make us tens of billions of dollars (maybe a hundred) poorer, that is also associated with statistically poorer health. That amount of money could otherwise have saved and prolonged many lives. Dumping these costs primarily on small independent truckers could cripple the competitiveness of the entire industry. Shifting to other modes of transport, or to less regulated ports in Mexico could actually INCREASE the total health hazards.

BEFORE you sign on to some unprecedented PM2.5 controls which may impose enormous costs, in pursuit of terribly uncertain health benefits, AQMD's technical advisors need to think harder to understand both sides of the equation. Otherwise a lot of very smart people—it doesn't matter what your paygrade is--could miss seeing the forest for the trees.