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I assert with confidence that the Chair of the CASAC, Jon Samet has performed and published research that is dispositive on the question of ozone air pollution.

The research can be found in the New England Journal of Medicine December 14, 2000 at:
www.nejm.org/doi/full/10.1056/NEJM200012143432401

In a comprehensive effort to replicate the Pope and Six Cities studies that, in the 1990s, were claimed by the EPA to justify Ozone regulations, Samet studied human death effects of various elements of air pollution in 20 cities to find premature death effects. He and his group of 5 from Johns Hopkins looked at effects from Nitrous Oxide, Sulfur Dioxide, Carbon Monoxide, PM 10 (as a surrogate for PM 2.5, since PM 2.5 monitoring was not available) and Ozone and their findings appeared in the *New England Journal of Medicine*.

I assert that the methodology and the data analysis of the Samet study replicates what was relied on in the past 15 years by the EPA to justify its aggressive regulatory efforts on Ozone. The Samet study results do not, however, justify any Ozone regulations at all, considering current ambient urban Ozone and ozone precursor levels.

Quoting from the Samet study “Fine particulate matter air pollution and mortality in 20 U.S. Cities 1987-1994,” on page 1742 “The estimated increase in the relative rate of death from cardiovascular and respiratory causes was 0.68% for each increase in the PM 10 of 10 micrograms per cubic meter.” (That’s a relative risk of 1.007 rounded off); and on page 1747 “We did not find an effect of ozone levels on the overall rate of death. . . “

Unless Dr. Samet wishes to refute his own study and criticize his own conclusions, I would suggest the EPA and its Clean Air Scientific Advisory Committee and the EPA consider that the research on human health effects has been poisoned by bias and political agendas when it asserts that the evidence shows reliable evidence of ozone toxicity. The EPA and the CASAC would also be well advised to reconsider the question of reliability of epidemiology on air pollution.

I assert that the observational population studies on toxicity of air pollutants are not proof of anything and should not be relied on as justifying air pollution regulations that would modify current United States ambient levels. My criticisms are directed at the studies by Pope, Dockery, Krewski, Jarrett, and Schwartz and others relied on by the EPA.

My criticisms of the research studies relied on by the EPA are based on the following:

1. Toxicology requires establishing a biologically plausible explanation before an assertion of effect can be made—none of the studies are anything more than data dredges for short term premature deaths associated with air monitor increases.
2. Toxicology also requires establishing some reasonable relationship between the proposed toxic exposure and the mechanism of death. The mere presence of a premature death increase must be scientifically and plausibly related to a known time lag for causation. If air pollution causes premature deaths, it certainly doesn't cause sudden death or short term death in the ambient levels of the studies referenced above.
3. In no way can the historic black smoke smog events, and the acute respiratory illness and deaths caused by those events be plausibly connected to deaths from current ambient air pollutant levels.
4. The data on premature deaths, if allowed to stand as evidence even after the arguments of 1-3, must establish an effect that complies with the accepted rules for observational population studies, rules that at least mitigate the uncertainties of uncontrolled studies. No study referenced by EPA can come close to the minimum effect of a Relative Risk of 2 (100% increase in premature deaths) and so all, ALL of the studies relied on by the EPA on Ozone or other air pollution are inadequate to prove anything.
5. If one ignores arguments 1-4 and assumes that Jon Samet's study of 2001 as an example of the studies used to justify EPA ozone regulations, one cannot ignore the finding of the Samet study that Samet could identify only one air pollutant that caused a small effect on premature deaths—small particles.
6. Even if one accepts the risible argument that a few days of lag from air pollution increase to premature death makes sense, Dr. Samet is still stuck with a claim based death effects much less than 10 percent, well below the threshold of acceptable evidence of proof of toxicity.
7. Substituting the precautionary principle, a non scientific concept, or dose response trends in the non proof range doesn't cure the problem of inadequate toxic effects with Relative Risks less than acceptable for proof.

Even if the EPA and the CASAC refuse to accept the rules of epidemiology as set out above and on pages 375 and 384 of the *Reference Manual on Scientific Evidence* 2nd Ed., published by the Federal Judicial Center, with chapters written by renowned scientists, found at

<http://www.air.fjc.gov/public/fjcweb.nsf/pages/16>

and even if the arguments about the flawed nature of these studies is unsuccessful; and even if one ignores the limits of the studies, the uncertainty of the claims, the CASAC and EPA must admit that Samet's 2000 study that shows no ozone human health effect refutes any claims of the EPA that Ozone is a pollutant that must be regulated.

For any reader or listener who might hold the delusion that multiple small effects studies such as cited above, overcome the arguments, it is a well known rule of scientific inquiry that one study that disproves or falsifies a theory is dispositive. "Me too" studies are too often the result of the problem of politically and economically or even socially driven "consensus" thinking, data dredging for an effect, and

publication bias. Torturing data for an outcome is symptomatic of political and economic biases, certainly a consideration in cases of research sponsored by millions of dollars from the EPA or federal agencies that are surrogates for the EPA.

This new proposal to grind down the ozone standard cannot be justified.

The research of the Chair of the CASAC is exhibit one. The *Reference Manual* is exhibit two.

This problem of irresponsible epidemiologic toxicology claims by EPA sponsored researchers must be brought under control, since the hinge for all the EPA regulatory regimes is the claim that EPA is saving lives. Data dredged lives on the desks of well paid researchers, paid by the EPA to find toxicities and toxic effects, is no way to protect the interests of the public. Regulatory compliance is costly and has a negative economic and human welfare effect. Expensive and burdensome regulations for imagined toxic threats can cause harm and shorten lives.

Cordially,

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