Comments on EPA Ozone Regulations by S. Stanley Young, PhD, FASA, FAAAS

Three points. Data access. There is no effect of air quality on mortality in western US. There are geographic, and other inconsistencies that call into question regulatory reliance on current data and methods. In summary of the three points given below, the EPA is seeking to impose a "one size fits all" regulation that will not improve health in well over one half of the country (all of the US west of Chicago) while costing enormous sums of money that, since the US Treasury is running a deficit, we do not in fact have.

Point 1: Data Access

There is no public access to most the data sets in the papers that the EPA is relying on. As the EPA does not have most of the data either, the EPA is relying on "Trust Me" science, which is to say, not science at all.

Board on Life Sciences, *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences* (National Academies Press, Washington, DC, 2003)
see www.nap.edu/books/0309088593/html/

Community standards for sharing publication-related data and materials should flow from the general principle that the publication of scientific information is intended to move science forward. More specifically, the act of publishing is a *quid pro quo* in which authors receive credit and acknowledgment in exchange for disclosure of their scientific findings. An author's obligation is not only to release data and materials to enable others to verify or replicate published findings (as journals already implicitly or explicitly require) but also to provide them in a form on which other scientists can build with further research. All members of the scientific community—whether working in academia, government, or a commercial enterprise—have equal responsibility for upholding community standards as participants in the publication system, and all should be equally able to derive benefits from it.

Roger D. Peng, Francesca Dominici, and Scott L. Zeger Reproducible epidemiologic research *Am. J. Epidemiol. (1 May 2006) 163 (9): 783-789.*
http://aje.oxfordjournals.org/content/163/9/783

The replication of important findings by multiple independent investigators is fundamental to the accumulation of scientific evidence. Researchers in the biologic and physical sciences expect results to be replicated by independent data, analytical methods, laboratories, and instruments. Epidemiologic studies are commonly used to quantify small health effects of important, but subtle, risk factors, and replication is of critical importance where results can inform substantial policy decisions. However, because of the time, expense, and opportunism of many current epidemiologic studies, it is often impossible to fully replicate their findings. An attainable minimum standard is ''reproducibility,'' which calls for data sets and software to be made available for verifying published findings and conducting alternative analyses. The authors outline a

standard for reproducibility and evaluate the reproducibility of current epidemiologic research. They also propose methods for reproducible research and implement them by use of a case study in air pollution and health.

Point 2: There is no effect of air quality on mortality in western US.

Using a data set from Pope et al. (2009) and dividing the data geographically, there was no effect of PM2.5 on mortality in the western US. When the data set is divided at Chicago, there is a very small effect in the eastern US and no effect in the West. It is improper to impose a one size fits all across the US when any effects are localized. In statistical terms, there is a "geography by air quality interaction" so it is not proper to rely on average effects. No effect is observed in western US by multiple research groups using multiple data sets, e.g. Smith et al. 2009 below.

Pope CA III, Ezzati E, Dockery DW. 2009. Fine-particulate air pollution and life expectancy in the United States. *N Engl J Med* **360**:376-86.

Point 3. Geographic, and other inconsistencies

"In summary, it is our view that estimates of the association between ozone and mortality, based on time-series epidemiologic analyses of daily data from multiple cities, reveal important still-unexplained inconsistencies and show sensitivity to modeling choices and data selection. These inconsistencies and sensitivities contribute to serious uncertainties when epidemiological results are used to discern the nature and magnitude of possible ozone-mortality relationships or are applied to risk assessment."

Richard L. Smith, Baowei Xu, and Paul Switzer. Reassessing the relationship between ozone and short-term mortality in U.S. urban communities. Inhalation Toxicology, 2009; 29(S2): 37–61.