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Response to Invited Commentary

Dominici et al. Respond to ''Heterogeneity of Particulate Matter Health Risks''

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Tolbert (1) highlights issues that we also found to be complex as we interpreted the results of our analyses (2). We analyzed data from a 14-year interval over which particulate matter levels dropped substantially across the United States. We applied methods developed as part of the National Morbidity, Mortality, and Air Pollution Study for evaluating change in the short-term effect of particulate matter $\leq$10 μm in aerodynamic diameter over a period of increasingly stringent regulation that might have changed the chemical composition and toxicity of particulate matter. The decline in particulate matter concentrations over a span with uniformly collected particulate matter measurements and mortality provided an opportunity to assess whether the health of the public had benefited from the decline. Our work can be categorized as accountability assessment, that is, evaluating whether regulations have had an impact on harmful exposures and the occurrence of health effects (3). There is an increasing call for such evaluations, given the cost of some environmental regulations, including the National Ambient Air Quality Standard for particulate matter.

For two of the ''criteria pollutants'' with specific biomarkers—lead (blood lead level) and carbon monoxide (level of carboxyhemoglobin in blood)—declines in levels in population samples were readily linked to specific events, including the removal of lead from gasoline (4). For airborne particulate matter, a heterogeneous mixture with many sources, accountability assessment is far more challenging, as noted by Tolbert (1). In meeting the National Ambient Air Quality Standard for particulate matter, strategies in nonattainment areas typically focus on the controllable sources delivering the greatest emission load, and not necessarily the most toxic particles since we are still uncertain as to the toxicity-determining characteristics of particulate matter. Of necessity, our analyses were descriptive, seeking to identify whether there was an indication of a change in the risk of health events associated with particulate matter, beyond that associated with a decline in overall particulate matter mass concentration.

As noted by Tolbert (1), the evidence for a decline in toxicity is suggestive, but far from conclusive. Tolbert lists alternative explanations for the findings. One possible explanation is the play of chance, given the imprecision with which possible effect modification was estimated. The sample size, of course, is fixed, because we used most of the data available. Our estimates could be interpreted as at least bounding the magnitude of any change in risk. The imprecision associated with the temporal changes in the short-term effect of particulate matter $\leq$10 μm in aerodynamic diameter, even when estimated from 14 years of data for 100 cities, shows one challenge of accountability assessment, particularly given the graded implementation over time of measures affecting particulate matter concentrations and characteristics.

We view accountability assessment as a form of surveillance that will provide some understanding of the consequences of regulations or of other measures that may affect the public health consequences of air pollution. Causal interpretation of findings will also be guarded, except in those circumstances leading to an abrupt change in an exposure. As shown by our findings (2), however, analyses intended to address questions of accountability and of surveillance can be carried out. For the future, with regard to the National Ambient Air Quality Standard pollutants, approaches for accountability assessment based on time-series analyses will have limited power because of the relatively substantial declines in pollutant levels to date. For particulate matter, given

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current concentrations, we cannot anticipate a relative decline as large as that achieved over the period 1987–2000. Consequently, more complex analyses will be necessary that will incorporate temporal changes in the characteristics of particulate matter. The needed data are now being collected (5).

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