Statement of Deborah Shprentz
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on the Second Draft OAQPS Staff Paper on the
Review of National Ambient Air Quality Standards for Particulate Matter
Clean Air Scientific Advisory Committee (CASAC)
April 6, 2005

Good Morning. I am Deborah Shprentz, a consultant to the American Lung Association on the review of the National Ambient Air Quality Standards (NAAQS).

The American Lung Association is extremely pleased with the considerable effort that has gone into the preparation of the second draft Staff Paper and the associated technical analyses. This version represents a major improvement over the earlier preliminary and first draft Staff Papers issued for public and CASAC review and comment.

Under the Clean Air Act, revisions to the NAAQS must be based on scientific criteria including evidence of adverse effects of the pollutant.

The conclusions of the final Criteria Document -- after undergoing six rounds of review by the CASAC -- make plain that adverse health effects including asthma exacerbations, emergency room visits, increased cardiac risk, and premature deaths are occurring at concentrations below the current NAAQS for fine particles. EPA's limited risk assessment conservatively estimates that 3,500 premature deaths would occur each year in five cities, even after these areas attain the current standards. The national impacts are of course many times greater.

EPA staff scientists are compelled by the plain evidence in the Criteria Document to propose strengthened air quality standards for fine particles.

The EPA staff scientists' recommendations to strengthen the level and form of the fine particle standards are well supported by the scientific evidence. The rationale used to derive recommended levels for the fine particle standards from the scientific studies are sound, and the analyses of the air quality monitoring data support more protective forms of the standards.

This committee should not bow to industry demands to raise the upper end of the ranges for the annual average or 24-hour fine particle standards. To do so would allow the Administrator to promulgate "status quo" standards that do not satisfy the requirements of the Clean Air Act to protect public health, including the health of children, seniors, and people with heart or lung disease, with an adequate margin of safety. As illustrated on the attached chart, EPA's risk analysis shows that the least protective option analyzed, a combined annual/24-hour standard of 15 $\mu g/m^3$/40 $\mu g/m^3$ 98th percentile, does not reduce the mortality remaining under the current standards.

The American Lung Association strongly supports lowering both the annual average and the 24-hour fine particle standards, while tightening the way compliance with the standards is measured.

Specifically, we favor an annual average $PM_{2.5}$ standard of at least 12 $\mu g/m^3$ with no monitor averaging, and a 24-hour standard of at least 25 $\mu g/m^3$, 99th percentile.

EPA's ranges should be modified to accommodate this option.

Use of Hypothetical "Thresholds" in Risk Assessment

The American Lung Association would like to raise serious objections to the use of alternative hypothetical thresholds in the risk assessment. There is no scientific evidence of a threshold at exposures that have been studied. Several studies that have been specifically designed to identify a threshold have not been able to find one.

The long-term epidemiological studies found effects down to the lowest level studied -- which was lower than the levels of 10 and 12 micrograms chosen by EPA for use in the sensitivity analysis. EPA also inappropriately uses phony thresholds of 10, 15, and 20 micrograms in the analysis of short-term morality and morbidity risks. The NMMAPS study specifically explored the thresholds question for the 20 largest U.S. cities and concluded that for total mortality and mortality from cardiovascular-respiratory causes, there was no evidence of a threshold down to daily ambient concentrations of PM_{10} as low as 10 $\mu g/m^3$.

A recent European study within the APHEA Multicity Project specifically assessed the hypothesis of thresholds in a very large dataset.[1] This study explored a variety of hypothetical thresholds in their data, including several tried in the draft Staff Paper (20 and 10 $\mu g/m^3$), and discovered that in all cases the linear models gave a better fit. This large dataset, incorporating data from 30 cities across Europe, failed to give any support to the hypothesis that a threshold may exist.

The results of the sensitivity analyses using these fabricated threshold levels are given undue prominence in the risk assessment chapter of the Staff Paper. Worse yet -- these hypothetical results are highlighted in the discussion of policy alternatives. The pseudo-threshold risk assessments should be stripped from the Staff Paper, and the risk assessment should restrict itself to the linear or log linear model that numerous studies conclude are appropriate for assessing the effects of air pollution.

Annual Average $PM_{2.5}$ Standards

[1] Samoli E, Analitis A, et al. Estimating the exposure-response relationships between particulate matter and mortality within the APHEA multicity project. *Environ Health Perspect* 2005;113;88-95

The evidence of long-term effects of fine particles is strong and even more compelling than it was 8 years ago when the first $PM_{2.5}$ standards were established. The major cohort studies have been audited, replicated, reanalyzed, and extended and new long term studies such as the California Children's Health Study have been completed. Long-term exposure to $PM_{2.5}$ causes decreased lung function growth in children, and mortality from cardiopulmonary diseases and lung cancer. The studies show increased risk down to the lowest levels studied, suggesting that an annual average $PM_{2.5}$ standard below 12 $\mu g/m^3$ may be warranted.

The EPA staff's methodology of setting the standard well below the average of the long-term concentrations across the cities in the long-term studies to provide for a margin of safety is the same reasoning that led California to adopt an annual average $PM_{2.5}$ standard of 12 $\mu g/m^3$ in 2002. The risk assessment shows that lowering the annual average $PM_{2.5}$ standard to 12 $\mu g/m^3$ would reduce mortality risk in the five cities studied by half, compared to the current standard. Clearly, this is not sufficient to protect public health and must be supplemented by a stringent 24-hour standard to further reduce exposures.

Furthermore, the long-term mean $PM_{2.5}$ concentrations in ten of the short-term studies examined in the Ross & Langstaff memo indicate mean concentrations less than 15 $\mu g/m^3$, providing additional support for an annual average standard of 12 $\mu g/m^3$ or below.

The Lung Association supports the recommendation in the Staff Paper to eliminate spatial averaging for the annual average standard because it is wrong to allow an area with high monitored concentrations to average its way out of nonattainment.

<u>24-Hour $PM_{2.5}$ Standards</u>

Hundreds of studies from around the world have now demonstrated that short-term exposure to fine particle pollution causes mortality from cardiopulmonary diseases, hospitalization and emergency room visits for cardiopulmonary diseases, increased respiratory symptoms, decreased lung function, and cardiac effects. That is, as air pollution rises, it is followed by an increase in adverse effects the next day, or over several days. An annual standard alone is not sufficient to protect against these effects, nor the effects of more acute, sub-daily exposures. This is particularly true in areas that experience high daily concentrations relative to the annual average due to seasonal sources.

Of the 10 short-term North American studies with annual mean $PM_{2.5}$ concentrations less than 15 $\mu g/m^3$ reviewed in the Ross & Langstaff memo, 95th percentile concentrations ranged from 20 - 43 $\mu g/m^3$, with most values in the upper-20's, suggesting that the 24-hour standard should be set at 25 $\mu g/m^3$ or below. This is similar to the reasoning that led California to propose a 24-hour $PM_{2.5}$ standard of 25 $\mu g/m^3$ in 2002.

The risk assessment demonstrates that lowering the 24-hour $PM_{2.5}$ standard to 25 $\mu g/m^3$, in conjunction with an annual average standard of 12 $\mu g/m^3$, eliminates residual long-term mortality risks in 2 of the 5 cities studied and greatly reduces it in the other 3 cities.

However, there is considerable long-term residual risk. Further, the analysis shows short-term mortality and morbidity risk remaining in all five cities even with a combined standard of 12 $\mu g/m^3$ annual average, 25 $\mu g/m^3$ 24-hour, suggesting that standards should be set below these levels to protect public health with an adequate margin of safety.

For a standard designed to limit high 24-hour concentrations, the 98th percentile form simply allows too many high pollution days to go unregulated -- 18 days over a three year period. The 99th percentile form is a big improvement, and EPA's analysis shows that it would provide substantial additional health protection in every city analyzed.

$PM_{10-2.5}$ Standards

With respect to the thoracic coarse particle standard, the American Lung Association believes that the staff suggested range falls short of what is needed to protect public health.

It appears that EPA has tortured its interpretation of the Detroit study to propose ranges for a 24-hour that are equivalent to the 1987 PM_{10} standard of 150 µg/m3. It is not credible to establish such a weak standard as proposed by EPA in light of the hundreds of studies reporting positive associations between much lower concentrations of PM_{10} and morbidity and mortality that have been published since 1987.

The key coarse particle studies that reported positive associations with respiratory- and cardiac-related hospital admissions reported 98th percentile concentrations between 30-36 $\mu g/m^3$. This suggests that a range of 25-30 $\mu g/m^3$, 99th percentile is needed to provide a margin of safety.

We also recommend that more serious consideration be given to establishment of an annual average coarse particle standard, and note that in 2002, California lowered their annual average PM_{10} standard from 30 $\mu g/m^3$ to 20 $\mu g/m^3$ to protect against chronic effects.

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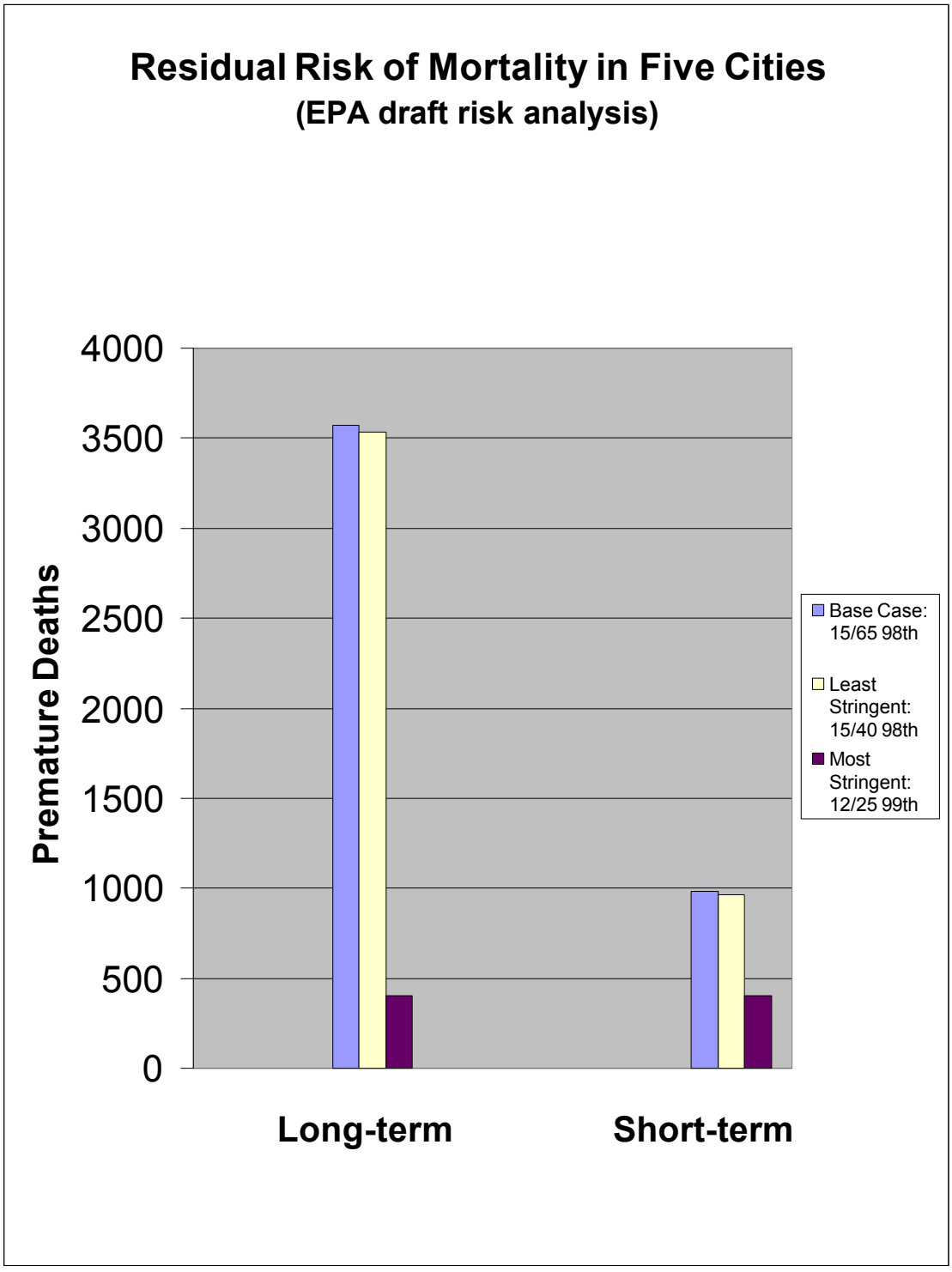
We remind you that this is the third version of the Staff Paper that has come before CASAC for review. We urge you to reach closure on the Staff Paper at this time, while recommending the suggested changes we have outlined.


Residual Risk of Mortality in Five Cities
(EPA draft risk analysis)
Premature Deaths
4000
3500
3000
2500
2000
1500
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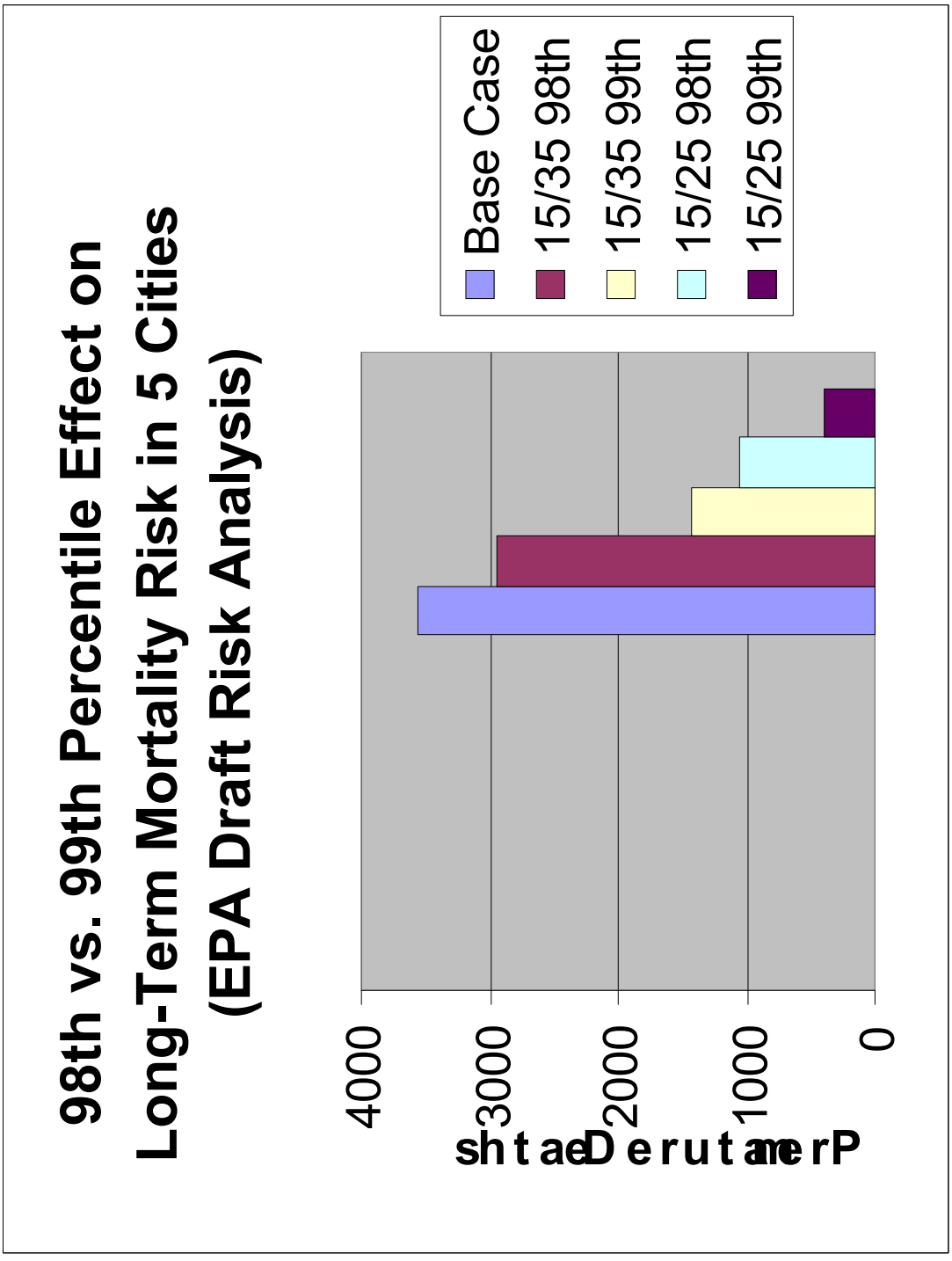
Long-term
Short-term
Base Case: 15/65 98th
Least Stringent: 15/40 98th
Most Stringent: 12/25 99th


98th vs. 99th Percentile Effect on
Long-Term Mortality Risk in 5 Cities
(EPA Draft Risk Analysis)
Base Case
15/35 98th
15/35 99th
15/25 98th
15/25 99th
4000
3000
2000
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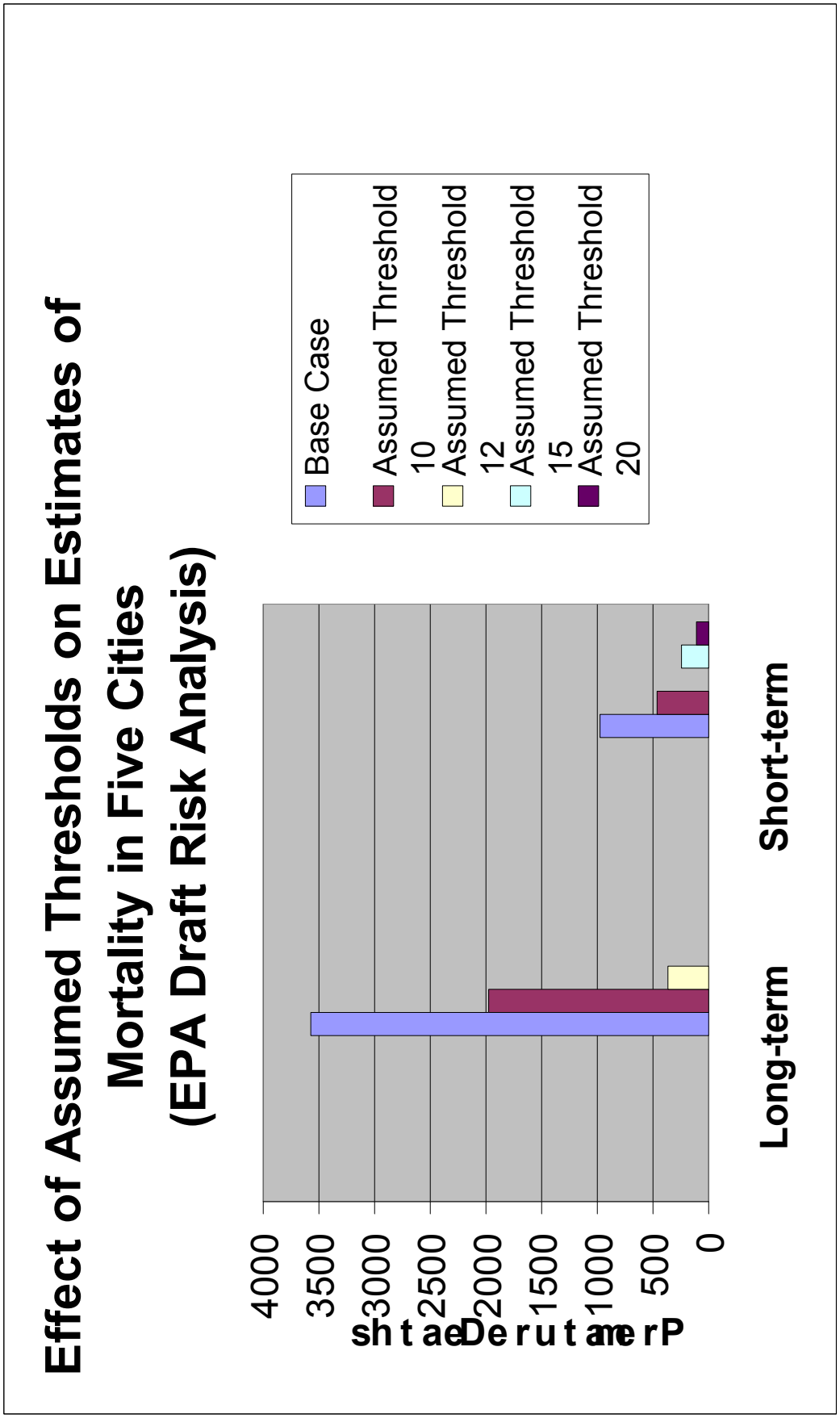
Effect of Assumed Thresholds on Estimates of Mortality in Five Cities (EPA Draft Risk Analysis)
Base Case
Assumed Threshold 10
Assumed Threshold 12
Assumed Threshold 15
Assumed Threshold 20
Premature Deaths
4000
3500
3000
2500
2000
1500
1000
500
0
Long-term
Short-term