STATEMENT OF

Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis
Albuquerque, New Mexico

Before the

Senate Subcommittee on Clean Air and Nuclear Safety
Senate Environment and Public Works Committee

Hearing on EPA's Proposed Revision to the National Ambient Air Quality Standards for Ozone

July 11, 2007

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on the U.S. Environmental Protection Agency's current review of the National Ambient Air Quality Standards (NAAQS) for Ozone.

My biography is attached to this statement (Attachment 1). Since 1999, I have served as an Advisor to public and private organizations on issues related to air quality in the ambient environment and workplace drawing on more than 45 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. Prior to 1999, I provided scientific leadership for two organizations, the Chemical Industry Institute of Toxicology in Research Triangle Park, NC and the Lovelace Inhalation Toxicology Research Institute in Albuquerque, NM that earned an international reputation for developing scientific information under-girding occupational and environmental standards.

The testimony I offer today also draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA Scientific Advisory Committees from the origin of the Agency to date, including the Clean Air Scientific Advisory Committee (CASAC), which I chaired from 1988 to 1992, and on CASAC Panels that have considered all the criteria pollutants at various times. I served on the CASAC Ozone Panel that reviewed the basis for the NAAQS promulgated in 1997. I did not serve on the most recent CASAC Ozone Panel. I have followed the current NAAQS Ozone review process from its inception in September 2000. The testimony I offer today reflects my own views on that review process and the science that should inform policy judgments on any revision of the NAAQS for Ozone. In Attachment 2, I briefly review the NAAQS process as background for my comments.

I wish to make the following points:

(1) The ozone present in the ambient air arises both from Natural processes and from precursors that are of anthropogenic origin.

(2) Since promulgation of the original NAAQS for the criteria pollutants most cities in the U.S. have made remarkable progress in reducing ambient concentrations of ozone and the other criteria pollutants. As ambient concentrations of ozone are reduced the fraction of remaining ozone associated with precursors of manmade US emissions – the only part which we can control thorough policy – falls. This makes further reductions in ambient ozone a challenge in many areas.

(3) The Policy Relevant Background for Ozone used by the EPA is not a scientifically valid projection of the part of ozone that would not be controllable through policy. For one thing, it excludes the contribution of Mexico and Canada's emissions to US ozone concentrations. The projected mean and high range concentrations are unrealistically low. These scientific inadequacies result in unrealistically high mathematical projections of mortality and morbidity from low concentrations of ozone with excess risks being inappropriately attributed to ozone from anthropogenic precursors. Moreover, the failure to accurately project the upper end of the background

ozone range may result in a policy judgment to set a NAAQS that will frequently be exceeded due to ozone not arising from anthropogenic precursors. I am pleased that the "proposed rule" recognizes the shortcomings in considering the "Policy Relevant Background" (see pg 155, footnote 40 of the Proposed Rule) and intends to address this issue.

(4) Data on the potential health effects of exposure to ambient levels of ozone that should inform policy judgments on the NAAQS are from five kinds of studies; human clinical studies, three kinds of epidemiological studies and toxicological studies. I will briefly describe the evidence for each of these kinds of evidence.

(a) The human clinical studies conducted with controlled exposure of exercising human volunteers provide useful information on changes in respiratory function with extreme levels of ozone intake. There is clear evidence of functional changes with protracted exposure to ozone at concentrations of 0.08 ppm and higher. In this review EPA has re-interpreted data developed by other investigators and purport to show that exposures below 0.08 ppm cause functional changes. The validity of this re-interpretation and the significance of the functional changes is open to debate.

(b) Major long-term epidemiological studies which compare the life expectancies of groups of people living in areas with different long-term average pollutant concentrations were used to show an association between Particulate Matter and mortality have not shown ozone exposure related effects on long-term mortality.

(c) Time-series analyses consider the association between daily fluctuations in ambient ozone concentrations and day to day death rates within a particular city or other locale. These have yielded variable results, statistically significant associations with ozone concentrations have been observed in a few cities while there is no association between ambient ozone and increased short-term mortality for many cities even when the studies have been conducted using the higher ozone levels found several decades ago. (I elaborate on these issues in Attachment 4).

(d) Panel studies follow a specific group of people, often a group of children, intensively for short periods of time, measuring specific health outcomes – such as asthma symptoms – and assesses how these outcomes are correlated to an air pollution mixture that includes ozone. These too have yielded variable results. When positive effects are observed in some studies it is not apparent the effects are attributable to ozone exposure.

(e) An enlarging body of toxicological data provides a basis for hypothesizing how ozone may cause biological changes with relatively high, short-term exposures to ozone, exposures in excess of the current ozone NAAQS. This information cannot be reliably extrapolated to ozone levels currently observed across the United States.

(5) The risk assessment conducted by Abt Associates and used by EPA to inform policy judgments in setting the ozone NAAQS is seriously flawed. The assessment

depends primarily on ozone concentration-response functions derived primarily using 24-hour ozone concentrations. Only a single coefficient used in the risk assessment is based on 8-hour ozone concentrations, the averaging time of the current and proposed NAAQS. Thus, the calculated excess risk ascribed to the ozone concentrations measured in 2002, 2003 and 2004 are likely not relevant to setting a NAAQS with an 8-hour averaging time. Moreover, the calculated reductions in excess risk attributed to ozone are not realistic because of the inappropriate assumptions made about Policy Relevant Background for ozone. (I elaborate on these issues in Attachment 5).

(6) I have followed with interest the public deliberations of the CASAC Ozone Panel and carefully reviewed their letters to the Administrator. It is my opinion that the CASAC Panel did not adequately pursue critical scientific issues concerning Policy Relevant Background, the short-term mortality studies and the impact of these issues on the scientific validity of the ozone risk assessment. It is my opinion the Panel, in a "rush to judgment" offered a collective policy judgment as to the level of the NAAS for ozone. The scientific rationale for their policy judgment preference has not been articulated in the transcripts of public meetings or their letters to the Administrator.

(7) In my professional judgment, the Administrator's "proposed decision to revise the existing 8-hour O_3 primary standard by lowering the level to within a range from 0.070 to 0.075 ppm" is a policy judgment based on a flawed and inaccurate presentation of the science that should inform the policy decision. I applaud the Administrator's decision to "solicit comments on alternative levels ---- up to and including retaining the current 8-hour standard of 0.08 ppm."

Once the NAAQS are finalized, individual states have responsibility for planning and taking actions to meet the NAAQS. This includes the formal step of preparing "State Implementation Plans (SIPs). In developing strategies for meeting the NAAQS, the States can give consideration to costs in setting the pace for achieving the NAAQS. However, attainment of the NAAQS cannot be postponed indefinitely.

ATTACHMENT 1

BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary),
Dipl-ABT, Dipl-ABVT, Fellow-ATS

Advisor: Human Health Risk Analysis
Inhalation Toxicology

13701 Quaking Aspen NE
Albuquerque, NM 87111-7168, USA
Tel: (505) 296-7083
Fax: (505) 296-9573
e-mail: roger.o.mcclellan@att.net

ROGER O. McCLELLAN is currently an advisor to public and private organizations on issues concerned with inhalation toxicology and human health risk analysis. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. He is a Diplomate of the American Board of Toxicology, a Diplomate of the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences.

He served as Chief Executive Officer and President of the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from September 1988 through July 1999. The CIIT continues today as The Hamner Institute. During his tenure, the organization achieved international recognition for the development of science under-girding important environmental and occupational health regulations. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute. During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne radioactive and chemical materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). In these assignments, he was involved in conducting and managing research directed toward understanding the human health risks of internally deposited radionuclides.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science and human health risk analysis. He has authored or co-authored over 300 scientific papers and reports and edited 10 books. In addition, he frequently speaks on risk assessment and air pollution issues in the United States and

abroad. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including continuing service as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He has served on senior advisory committees for 8 federal agencies. He is past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committees on Toxicology (served as Chairman for 7 years), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine. He has recently completed a term on the Board of Scientific Councilors for the Centers for Disease Control and Prevention for Environmental Health Research and the Agency for Toxic Substances and Disease Registry. He is currently serving on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods and the National Aeronautics and Space Administration Lunar Airborne Dust Toxicity Advisory Group.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the Health Physics Society, and the American Association for the Advancement of Science. In 1998, he received the International Achievement Award of the International Society of Regulatory Toxicology and Pharmacology of standing contributions to improving the science used for decision making and the International Aerosol Fellow Award of the International Aerosol Research Assembly for outstanding contributions to aerosol science and technology. He received the Society of Toxicology 2005 Merit Award for a distinguished career in toxicology. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to the science under-girding improved air quality. In 2006 he received the New Mexico Distinguished Public Service Award. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials.

ATTACHMENT 2

Setting National Ambient Quality Standards

Each NAAQS consists of four elements: (a) an indicator (such as ozone for photochemical oxidants, (b) an averaging time (such as 8 hours), (c) a numerical level (such as 0.08 ppm ozone averaged over 8 hours), and (d) a statistical form (such as the annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years.

Under the Clean Air Act, the EPA Administrator is required to review the NAAQS for the criteria pollutants at 5-year intervals to evaluate whether or not the four elements of the NAAQS are still deemed to be acceptable based on current scientific knowledge as it applies to the assessment of public health risks. In practice the interval between reviews has been longer. The process for review and promulgation of a NAAQS, either continuation of the existing standard or establishing a new NAAQS, consists of multiple phases. The initial phase, which is obviously on-going, consists of conduct of research on the various criteria pollutants. This includes a broad spectrum of activities; understanding emissions of pollutants, transport and transformation of pollutants in the atmosphere, ambient measurements of pollutants, estimation of personal exposures to pollutants, assessment of toxic effects and mechanisms of action in cells, tissues and animals, conduct of controlled exposure studies to pollutants in human volunteers and epidemiological investigations of human populations. Most of the research is funded by the EPA, some in the Agency's own laboratories and some in academic and other laboratories, the National Institutes of Health and, to a modest extent, private industry. The dominance of federal government support of research on criteria pollutants relates to their effects being of broad societal concerns with the pollutants, by and large, having no unique industrial emission source.

The findings of this research are used by the EPA's Office of Research and Development to prepare a criteria document (CD). Each CD traditionally has been essentially an encyclopedia of everything known about a given criteria pollutant and is used as a basis of information for the preparation of a Staff Paper (SP) by the EPA's Office of Air Quality Planning and Standards. This is a Policy Assessment of Scientific and Technical Information; in short, an integration and synthesis of the information in the CD that is most relevant to setting the four elements of a NAAQS. In recent years, the Staff Papers have made substantial use of risk assessments for the criteria pollutant being considered. These risk assessments have been conducted by a single EPA Contractor organization. The various versions of the CD and SP are released to the public with an invitation to provide comments as a basis for improving the documents.

Throughout this process, a Clean Air Scientific Advisory Committee Panel, operating as an element of the EPA's Science Advisory Board, is involved in reviewing and advising on the scientific content of both the CD and the SP, including the related risk assessment. This has typically involved several revisions. Prior to the current cycle of ozone review, the CASAC Panel sent a closure letter to the EPA Administrator when

the CASAC was of the opinion that the revised documents were suitable for use by the Administrator in promulgating a NAAQS. In the current ozone review, the "closure letter" process was abandoned. Instead, the current CASAC Ozone Panel has focused on offering a consensus opinion.

At the next step, the Administrator proposes, via a Federal Register Notice, a NAAQS including specific proposals for each of the four elements of the NAAQS; the indicator, averaging times, numerical levels and statistical forms. Comments are solicited from the Public with the opportunity to submit written comments to a specific Docket. The Administrator, acting under a Consent Decree, signed a "Proposed Rule."

The next step is for the Administrator to promulgate a NAAQS consisting of the four elements discussed previously. I purposefully do not use the phrase – "final step," because the Courts may have a role in deciding whether the Administrator's proposed NAAQS for Ozone will stand. The NAAQS are to be based on the available scientific information reviewed in the CD and SP and summarized in the notice of proposed rules. The primary, health-based NAAQS are to be set at a level that will protect public health, including sensitive populations, with an adequate margin of safety. The Administrator is precluded from considering cost in the setting of the NAAQS.

At this point, I would like to emphasize that there exists no absolute and unambiguous scientific methodology that can determine which specific indicator, the precise averaging time, numerical level or statistical form that will be adequate to protect public health. The available scientific information can inform the NAAQS decisions, however, the Administrator must ultimately use policy judgment in making decisions on each of the four elements from among an array of scientifically acceptable options including consideration of their attendant scientific uncertainties. Beyond the language in the Clean Air Act, Justice Breyer in Whitman v. American Trucking Association (531 U.S. 457, 473) has given very useful guidance for the Administrator in exercising policy judgment in the setting of NAAQS (see Attachment 3).

ATTACHMENT 3

Justice Breyer on Using Policy Judgment (from Whitman v. American Trucking Association, 531 U.S. 457, 473)

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more or less stringent than necessary for these purposes. *Whitman v. American Trucking Associations*, 531 U.S. 457, 473. In establishing "requisite" primary and secondary standards, EPA may not consider the costs of implementing the standards. *Id*. At 471. As discussed by Justice Breyer in *Whitman v. American Trucking Associations*, however, "this interpretation of § 109 does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of "hurtling" industry over "the brink of ruin," or even forcing "deindustrialization." *Id*. At 494 (Breyer, J., concurring in part and concurring in judgment) (*citations omitted)*. Rather, as Justice Breyer explained:

> *"The statute, by its express terms, does not compel the elimination of all risk; and it grants the Administrator sufficient flexibility to avoid setting ambient air quality standards ruinous to industry.*
>
> *Section 109(b)(1) directs the Administrator to set standards that are "requisite to protect the public health" with "an adequate margin of safety." But these words do not describe a world that is free of all risk – an impossible and undesirable objective. (citation omitted). Nor are the words "requisite" and "public health" to be understood independent of context. We consider football equipment "safe" even if its use entails a level of risk that would make drinking water "unsafe" for consumption. And what counts as "requisite" to protecting the public health will similarly vary with background circumstances, such as the public's ordinary tolerance of the particular health risk in the particular context at issue. The Administrator can consider such background circumstances when "deciding what risks are acceptable in the world in which we live." (citation omitted).*
> *The statute also permits the Administrator to take account of comparative health risks. That is to say, she may consider whether a proposed rule promotes safety overall. A rule likely to cause more harm to health than it prevents is not a rule that is "requisite to protect the public health." For example, as the Court of Appeals held and the parties do not contest, the Administrator has the authority to determine to what extent possible health risks stemming from reductions in tropospheric ozone (which, it is claimed, helps prevent cataracts and skin cancer) should be taken into account in setting the ambient air quality standard for ozone.*

(Citation omitted)/
The statute ultimately species that the standard set must be "requisite to protect the public health" "in the judgment of the Administrator," § 109(b)(1), 84 Stat. 1680 (emphasis added), a phrase that grants the Administrator considerable discretionary standard-setting authority.

The statute's words, then, authorize the Administrator to consider the severity of a pollutant's potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate. (citation omitted). They permit the Administrator to take account of comparative health consequences. They allow her to take account of context when determining the acceptability of small risks to health. And they give her considerable discretion when she does so.

This discretion would seem sufficient o avoid the extreme results that some of the industry parties fear. After all, the EPA, in setting standards that "protect the public health" with "an adequate margin of safety," retains discretionary authority to avoid regulating risks that it reasonably concludes are trivial in context. Nor need regulation lead to deindustrialization. Pre-industrial society, was not a very health society; hence a standard demanding the return of the Stone Age would not prove "requisite to protect the public health."

ATTACHMENT 4

Time-Series Analyses of Short-Term Mortality

The EPA places substantial reliance on the time-series analyses of short-term mortality in the Staff Paper and the associated Risk Assessment. To a large extent, results from the National Morbidity and Mortality Air Pollution (NMMAPs) studies being conducted at the Johns Hopkins University serve as a center piece of the EPA evaluation and risk assessment. The paper by Bell et al. (2004) is given considerable weight. Unfortunately, this study is founded on a very weak and dubious goal – the derivation of a national ozone concentration excess mortality coefficient. In my opinion, the heterogeneity of air pollution across the United States and the heterogeneity of the population, including morbidity and mortality in cities across the Unites States, makes it inappropriate to create a "national" concentration-response coefficient for ozone. This task, even if appropriate, is challenging because of the very weak effect of ozone, even in the cities with the highest ozone concentrations, compared to all the other factors influencing morbidity and mortality.

To help illustrate the problems involved in interpreting the Bell et al. (2004) study, I am presenting some analyses performed by my colleague, Richard Smith at the University of North Carolina-Chapel Hill, using the NMMAPs data kindly provided by the Johns Hopkins University investigators. Figure 1 was developed by Professor Smith and is essentially identical to Figure 2 in the Bell et al. (2004) paper. His reproduction of the results of Bell et al. (2004) is reassuring. You will note this figure, developed using a Bayesian statistical approach, indicates values for a percent rise in mortality per 10 ppb average 24 hour ozone that are all positive and with wide confidence intervals. What is more informative than Figure 1 is Figure 2 which shows that a substantial number of cities having negative coefficients, clearly, no effect of ozone in short-term mortality in the individual cities. Another large group of cities have positive coefficients but the confidence intervals include zero and, thus, there is no statistically significant effect of ozone on short-term mortality. Only a few cities have statistically significant associations between 24-hour average ozone and short-term mortality. At the bottom of the figure is shown a national concentration-response coefficient. It agrees well with the value of 0.52% (95% Confidence Interval, 0.27-0.77%) for the 24-hour average ozone concentration given with Bell et al. (2004) paper. I personally do not believe this national value is of much use – this is a case where one size does not fit all.

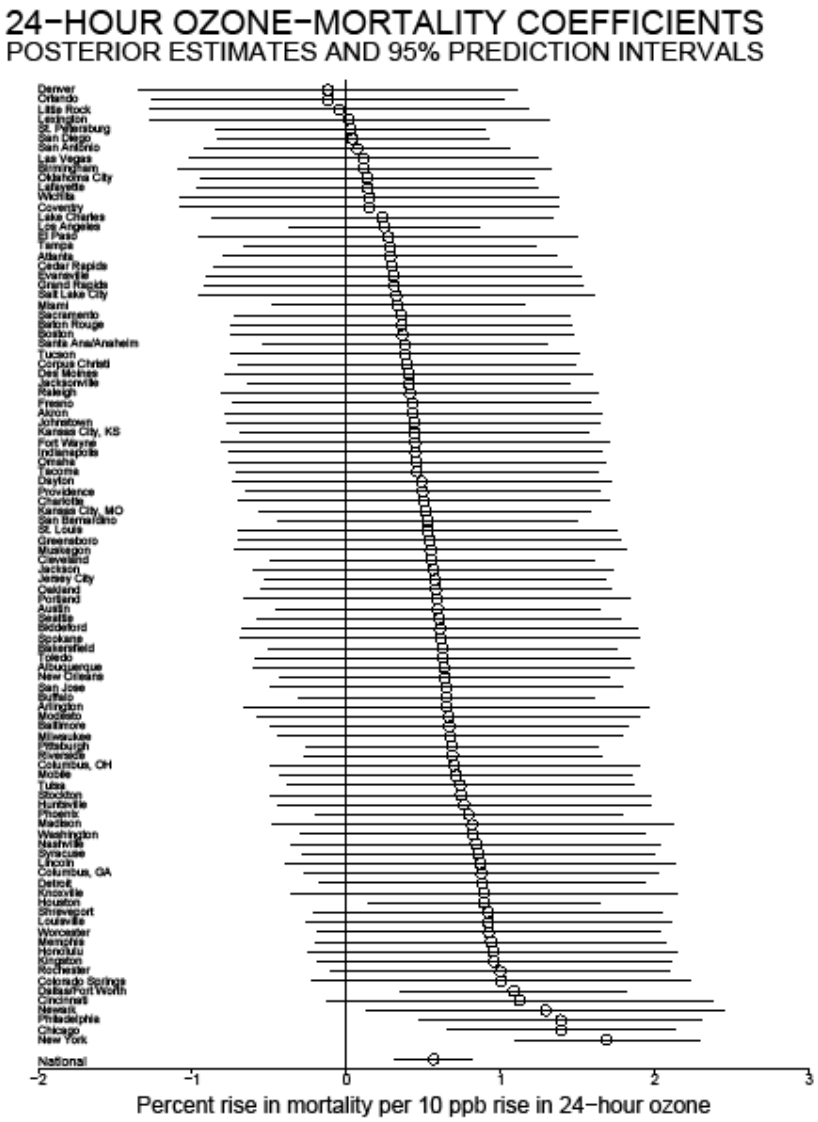
In reviewing the Bell et al. (2004) results, it is useful to recall the averaging time used for NAAQS for ozone. It is <u>not</u> the 24-hour average ozone, it is the 8-hour maximum concentration. Thus, the Bell et al. (2004) analyses as presented are not directly applicable to setting the NAAQS for ozone nor in calculating risks/benefits of alternative NAAQS. Bell et al. (2004) does give an overall national coefficient for the daily 8-hour maximum. It is 0.64% (95% Confidence Interval, 0.41%-0.86%) for a 15 ppb increase in the daily 8-hour maximum. As I have already noted, it is my view that a single national coefficient is of limited value. The results of analyses that focus on

individual city results would be more scientifically valid in evaluating potential ozone effects for any city.

The results of such analyses conducted by Professor Smith are shown in Figures 3 and 4. In Figure 3, results are presented for the individual cities in the NMMAPs database. Note that for 30 cities the values are below zero, clearly no association of increased ozone short-term mortality. I am pleased that my home town, Albuquerque, NM, is one of these cities. The results should be reassuring to our mayor. Of the remaining cities, only 10 have statistically significant associations between increases in the 8-hour concentration of ozone and increased mortality. Shown in Figure 4 are the Community-specific Bayesian estimated for the 8-hour metric, calculated in a manner similar to Bell et al. (2004). Note that now the central values all are to the right of the zero line. However, only 2 cities have positive coefficients that are statistically significant.

In my view, the community-specific estimates are highly relevant to the setting of the NAAQS. That can be illustrated in part by reviewing the data in Attachment 6. This attachment is based on EPA data and shows the 8-hour design values for individual cities. A review of the list of Core-Base Statistical Areas and their associated 8-hour design values will reveal that the cities shown to have positive associations between increases in 8-hour maximum ozone and increases in short-term mortality are near the top of the list. These cities are out of compliance with the current NAAQS for ozone, 0.084 ppm using conventional rounding techniques for the NAAQS set at 0.080 ppm. What is equally important is to recognize that many cities shown in Figures 3 and 4 to have no association between increases in 8-hour design values in the range of 0.060 ppm to 0.084 ppm for which the Administrator has solicited comments on alternative numerical standards. Indeed, many cities such as Albuquerque are in the range of 0.075 ppm (the upper end of the proposed range in the proposed rule) and 0.084 ppm. It is my view that these data provide the kind of context that Justice Breyer has indicated is a part of considerable discretionary standard-setting authority granted to the Administrator. As a citizen of Albuquerque, NM, with an 8-hour design value of 0.077 ppm, I would have great difficulty explaining to my mayor the scientific basis for having to attain a standard set at 0.075 ppm, if that were the numerical level set for the NAAQS for ozone in the final rule.

Figure 1


24−HOUR OZONE−MORTALITY COEFFICIENTS
POSTERIOR ESTIMATES AND 95% PREDICTION INTERVALS
Denver
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Little Rock
Lexington
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San Antonio
Las Vegas
Birmingham
Oklahoma City
Lafayette
Wichita
Coventry
Lake Charles
Los Angeles
El Paso
Tampa
Atlanta
Cedar Rapids
Evansville
Grand Rapids
Salt Lake City
Miami
Sacramento
Baton Rouge
Boston
Santa Ana/Anaheim
Tucson
Corpus Christi
Des Moines
Jacksonville
Raleigh
Fresno
Akron
Johnstown
Kansas City, KS
Fort Wayne
Indianapolis
Omaha
Tacoma
Dayton
Providence
Charlotte
Kansas City, MO
San Bernardino
St. Louis
Greensboro
Muskegon
Cleveland
Jackson
Jersey City
Oakland
Portland
Austin
Seattle
Bedeford
Spokane
Bakersfield
Toledo
Albuquerque
New Orleans
San Jose
Buffalo
Arlington
Modesto
Baltimore
Milwaukee
Pittsburgh
Riverside
Columbus, OH
Mobile
Tulsa
Stockton
Huntsville
Phoenix
Madison
Washington
Nashville
Syracuse
Lincoln
Columbus, GA
Detroit
Knoxville
Houston
Shreveport
Louisville
Worcester
Memphis
Honolulu
Kingston
Rochester
Colorado Springs
Dallas/Fort Worth
Cincinnati
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Philadelphia
Chicago
New York
National
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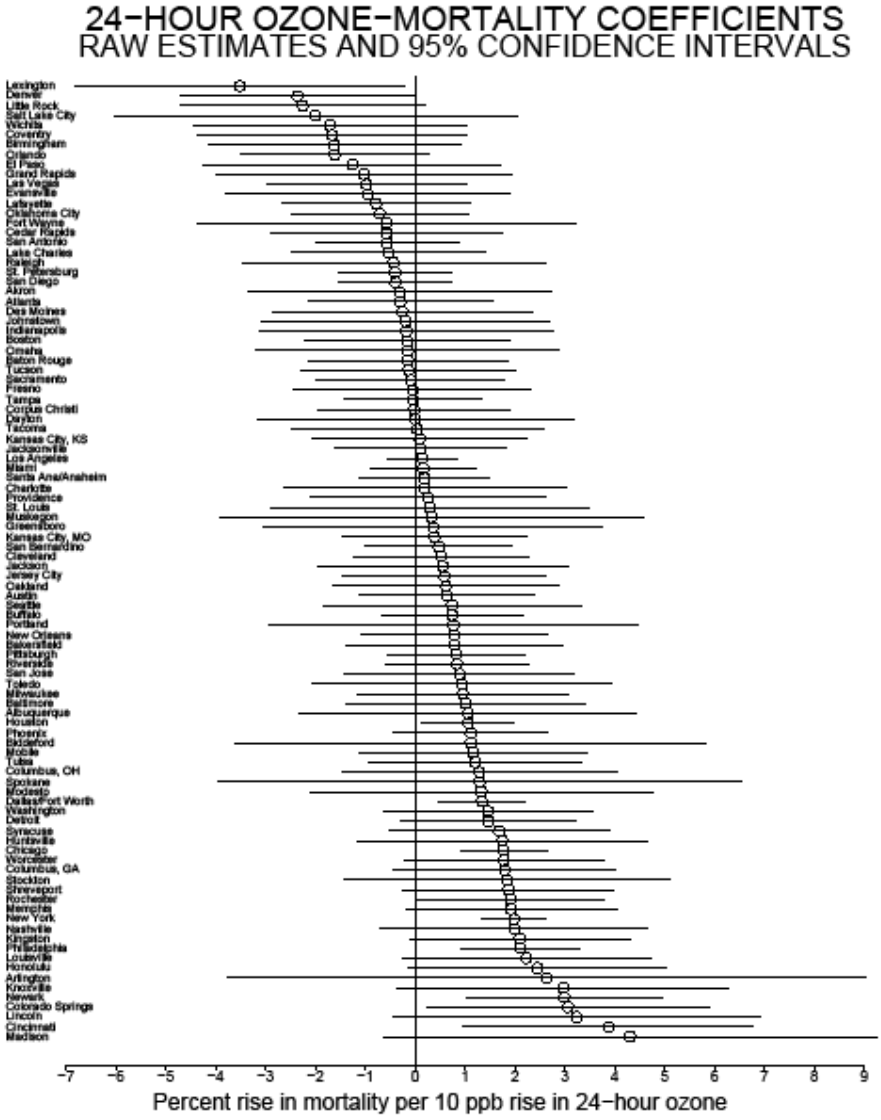
3
Percent rise in mortality per 10 ppb rise in 24−hour ozone

Figure 2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Baton Rouge
Tucson
Sacramento
Fresno
Tampa
Corpus Christi
Dayton
Tacoma
Kansas City, KS
Jacksonville
Los Angeles
Miami
Santa Ana/Anaheim
Charlotte
Providence
St. Louis
Muskegon
Greensboro
Kansas City, MO
San Bernardino
Cleveland
Jackson
Jersey City
Oakland
Austin
Seattle
Buffalo
Portland
New Orleans
Bakersfield
Pittsburgh
Riverside
San Jose
Toledo
Milwaukee
Baltimore
Albuquerque
Houston
Phoenix
Biddeford
Mobile
Tulsa
Columbus, OH
Spokane
Modesto
Dallas/Fort Worth
Washington
Detroit
Syracuse
Huntsville
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Stockton
Shreveport
Rochester
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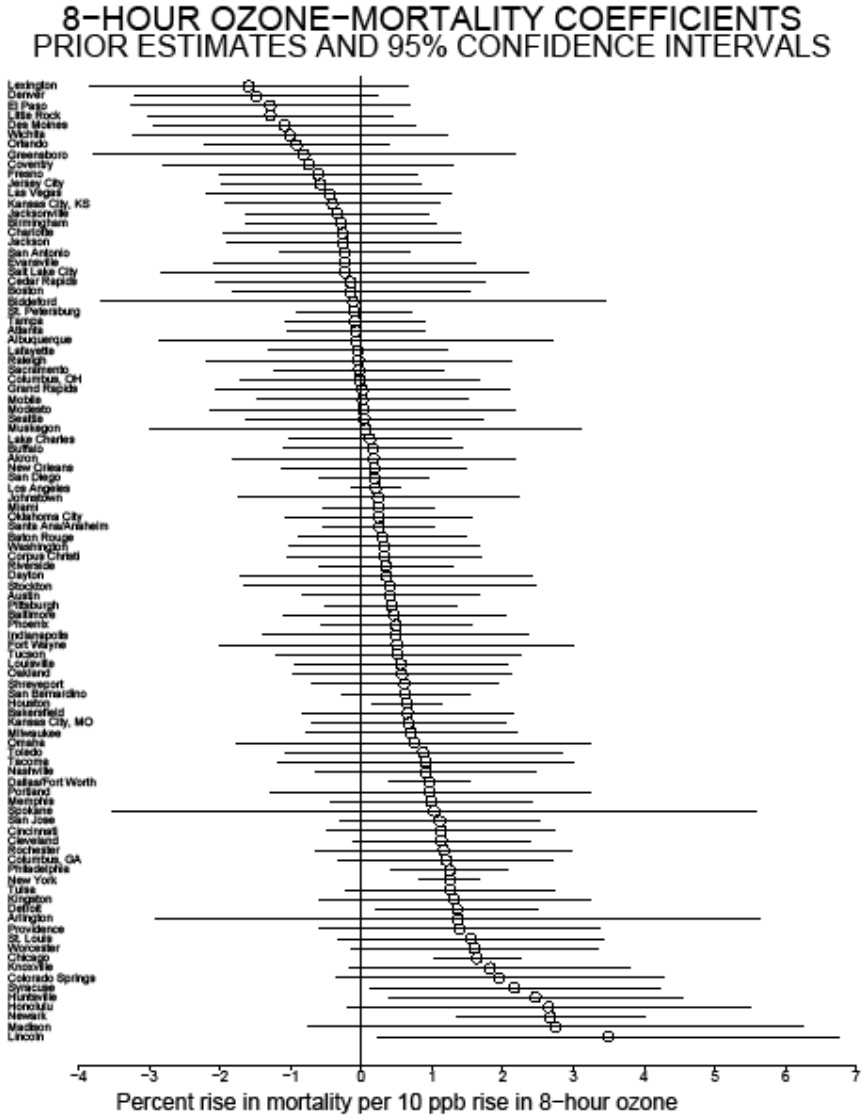
New York
Nashville
Kingston
Philadelphia
Louisville
Honolulu
Arlington
Knoxville
Newark
Colorado Springs
Lincoln
Cincinnati
Madison
-7 -6 -5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8 9
Percent rise in mortality per 10 ppb rise in 24-hour ozone

Figure 3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Albuquerque
Lafayette
Raleigh
Sacramento
Columbus, OH
Grand Rapids
Mobile
Modesto
Seattle
Muskegon
Lake Charles
Buffalo
Akron
New Orleans
San Diego
Los Angeles
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Miami
Oklahoma City
Santa Ana/Anaheim
Baton Rouge
Washington
Corpus Christi
Riverside
Dayton
Stockton
Austin
Pittsburgh
Baltimore
Phoenix
Indianapolis
Fort Wayne
Tucson
Louisville
Oakland
Shreveport
San Bernardino
Houston
Bakersfield
Kansas City, MO
Milwaukee
Omaha
Toledo
Tacoma
Nashville
Dallas/Fort Worth
Portland
Memphis
Spokane
San Jose
Cincinnati
Cleveland
Rochester
Columbus, GA
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Kingston
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Huntsville
Honolulu
Newark
Madison
Lincoln
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7
Percent rise in mortality per 10 ppb rise in 8-hour ozone

Figure 4

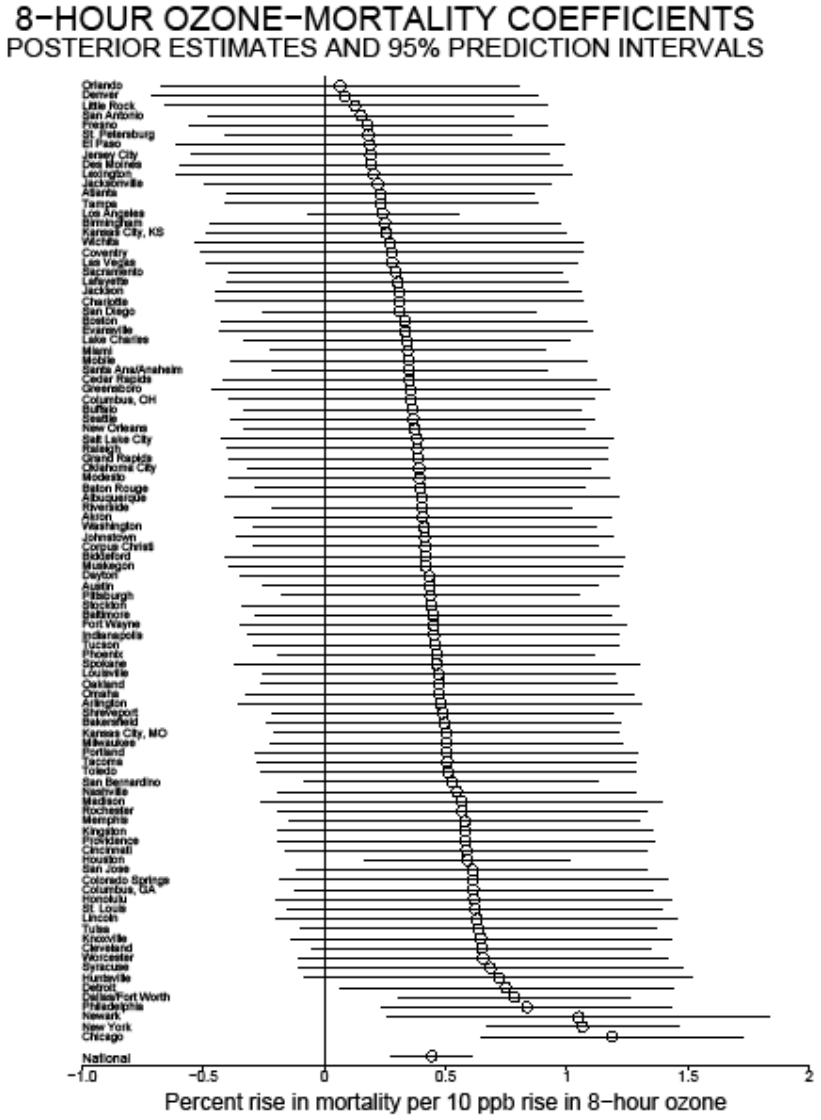
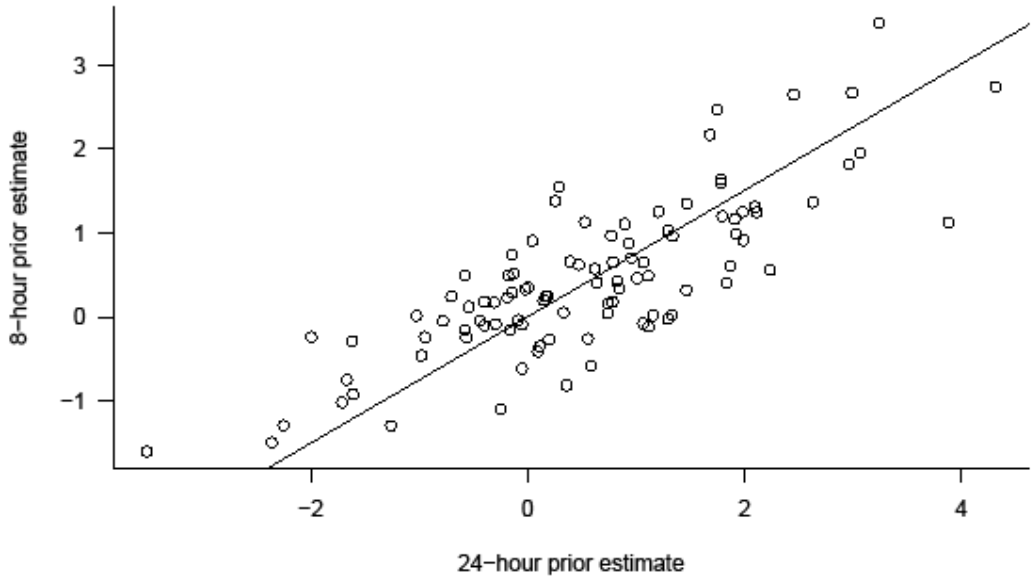
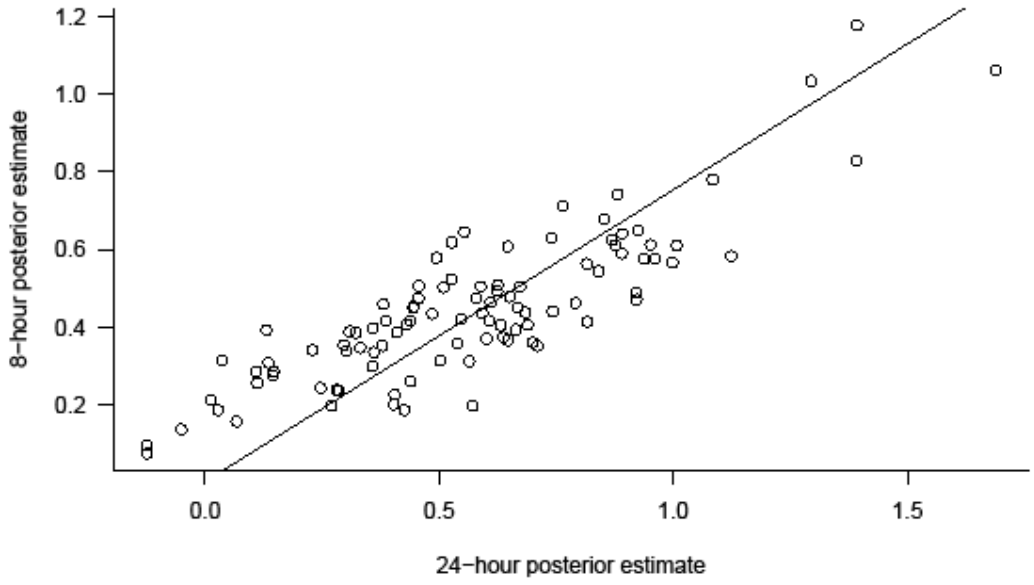

8-HOUR OZONE-MORTALITY COEFFICIENTS
POSTERIOR ESTIMATES AND 95% PREDICTION INTERVALS
Orlando
Denver
Little Rock
San Antonio
Fresno
St. Petersburg
El Paso
Jersey City
Des Moines
Lexington
Jacksonville
Atlanta
Tampa
Los Angeles
Birmingham
Kansas City, KS
Wichita
Coventry
Las Vegas
Sacramento
Lafayette
Jackson
Charlotte
San Diego
Boston
Evansville
Lake Charles
Miami
Mobile
Santa Ana/Anaheim
Cedar Rapids
Greensboro
Columbus, OH
Buffalo
Seattle
New Orleans
Salt Lake City
Raleigh
Grand Rapids
Oklahoma City
Modesto
Baton Rouge
Albuquerque
Riverside
Akron
Washington
Johnstown
Corpus Christi
Biddeford
Muskegon
Dayton
Austin
Pittsburgh
Stockton
Baltimore
Fort Wayne
Indianapolis
Tucson
Phoenix
Spokane
Louisville
Oakland
Omaha
Arlington
Shreveport
Bakersfield
Kansas City, MO
Milwaukee
Portland
Tacoma
Toledo
San Bernardino
Nashville
Madison
Rochester
Memphis
Kingston
Providence
Cincinnati
Houston
San Jose
Colorado Springs
Columbus, GA
Honolulu
St. Louis
Lincoln
Tulsa
Knoxville
Cleveland
Worcester
Syracuse
Huntsville
Detroit
Dallas/Fort Worth
Philadelphia
Newark
New York
Chicago
National
-1.0
-0.5
0
0.5
1
1.5
2
Percent rise in mortality per 10 ppb rise in 8-hour ozone

Figure 5a (above) and 5b (below)





ATTACHMENT 5

EPA/Abt Risk Assessment

The "Ozone Health Risk Assessment for Selected Urban Areas" conducted by Abt Associates for the EPA provides key information to inform the Administrator's policy judgments in setting the NAAQS for ozone. Substantial use is made of the risk assessment in the Staff Paper and in the Proposed Rule.

There are serious problems with the present risk assessment which I will briefly comment on. Key elements of the risk assessment are: (a) the cities selected for evaluation, (b) the historical population morbidity and mortality data for these cities, (c) the estimated ambient concentrations of ozone projected for these cities, and (d) the ambient ozone concentration-response coefficients used in estimating excess risk for the identified populations.

The risk assessment and its appendices are turgid with detailed information. Unfortunately, it is not presented in a manner that is easy to grasp. It is especially noteworthy that the presentation does not provide the kind of contextual information that is needed by the Administrator to make policy judgments on setting the NAAQS for ozone. A reading of Justice Breyer's opinions referenced earlier and contained in Attachment 2 emphasize that any calculated risk attributed to ozone needs to be placed in context relative to other risks commonly encountered by the populace. That kind of information is not made clear in the risk assessment or the Staff Paper with side-by-side comparison of the size of the population and historical data on common morbidity and mortality indices. The use of percentage values common in the risk assessment is not a substitute for the starkness of absolute numbers to inform policy judgments.

A major shortcoming of the risk assessment is the failure to directly link the analysis to the 8-hour averaging time used in the current and projected NAAQS for ozone. A quick reading of the risk assessment would lead one to assume that a 24-hour averaging time was to be used for the NAAQS for ozone. Table B.1 of the Risk Assessment lists the study specific information used. This table lists 96 exposure metrics used in the risk assessment; 80 are for 24-hour average, 14 for the 1 hour maximum and only 2 for 8-hour maximum. This leaves open the question of what the risk analysis would have revealed if an 8-hour maximum metric had been used. As discussed earlier, there is data available for the 8-hour maximum metric.

The fallacy of assuming there are some national metrics that can be used for converting from the 24-hour daily average to the 8-hour maximum values is illustrated in Figure 5a and b which plots the ratio of the coefficients derived using an 8-hour maximum versus 24-hour daily average for both the prior and posterior (Bayesian) estimates for individual cities. The straight lines represent the ratio commonly used to convert from one metric to the other. Again, it is apparent that a national one size fits all approach is not scientifically valid. For a few cities the ratio values fall close to the line and indicates that a national conversion value is acceptable. In many cases, 24-hour daily

average metric is a poor surrogate for the 8-hours maximum metric. In my view, it is crucial to use city-specific 8-hour maximum coefficients if the NAAQS for ozone is to be set with an 8-hour averaging time.

A comparison of 5a (the prior estimates) with 5b (the Bayesian posterior estimates) indicates how the Bayesian estimates are "shrunk" toward a common central value. It is my opinion that for most cities the prior estimates are sufficiently robust based on observations over 14 years in cities with populations usually exceeding 500 thousand that it is not necessary to use Bayesian techniques to bolster statistically confidence in the values. If Bayesian techniques were to be used, the results might have more validity if the focus was on regional estimates rather than the creation of national concentration-response coefficients. In my opinion, there is need for respecting the underlying heterogeneity.

As already noted, the risk assessment is seriously flawed in that inappropriate estimates have been used of the Policy Relevant Background. A review of the transcripts of the CASAC meetings and CASAC letters reveals that CASAC recognized that the "Policy Relevant Background" issue was not resolved. Unfortunately, CASAC did not adequately pursue this issue and especially the impact on the risk assessment. I am pleased that the EPA (see page 155, footnote 40 of the proposed rule) recognizes this matter needs more attention by calling for additional sensitivity analyses related to Policy Relevant Background. It is my opinion that this matter is of sufficient importance that it requires the development of amendments to the Criteria Document, Staff Paper and Risk Assessments with associated public meetings for review and comment. Indeed, it is my understanding that material germane to this issue has already been prepared by EPA contractors and was excluded by Administrative decisions from the final documentation used in the ozone NAAQS review.

By using estimates of the Policy Relevant Background developed by low resolution modeling in calculating excess risk, the risk assessment inappropriately attributes risks to anthropogenic origin ozone that in fact is a part of the background.

ATTACHMENT 6

Ozone 8-Hour Design Values for 2002-2004

(Extracted from Memo of Lance McCluney, USEPA, Office of Air Quality Planning and Standards, January 18, 2007)

Core-Base Statistical Areas (CBSA)	Ozone 8-Hour Design Value
Riverside-San Bernardino-Ontario, CA	0.127
Los Angeles-Long Beach-Santa Ana, CA	0.125
Bakersfield, CA	0.116
Visalia-Porterville, CA	0.105
Fresno, CA	0.104
Merced, CA	0.102
Sacramento--Arden-Arcade--Roseville, CA	0.102
Houston-Sugar Land-Baytown, TX	0.101
New York-Northern New Jersey-Long Island, NY-NJ-PA	0.099
Dallas-Fort Worth-Arlington, TX	0.098
Truckee-Grass Valley, CA	0.097
Washington-Arlington-Alexandria, DC-VA-MD-WV	0.096
Baltimore-Towson, MD	0.095
Bridgeport-Stamford-Norwalk, CT	0.095
Cleveland-Elyria-Mentor, OH	0.095
New Haven-Milford, CT	0.095
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	0.095
Ashtabula, OH	0.094
Chicago-Naperville-Joliet, IL-IN-WI	0.094
Modesto, CA	0.094
Oxnard-Thousand Oaks-Ventura, CA	0.094
Salisbury, NC	0.094
Allegan, MI	0.093
Atlanta-Sandy Springs-Marietta, GA	0.093
Hanford-Corcoran, CA	0.093
Jamestown-Dunkirk-Fredonia, NY	0.093
Beaumont-Port Arthur, TX	0.092
Charlotte-Gastonia-Concord, NC-SC	0.092
Detroit-Warren-Livonia, MI	0.092
Hartford-West Hartford-East Hartford, CT	0.092
Indianapolis-Carmel, IN	0.092
Sheboygan, WI	0.092
Boston-Cambridge-Quincy, MA-NH	0.091

Buffalo-Niagra Falls, NY Metropolitan Sta	0.091
Cincinnati-Middletown, OH-KY-IN	0.091
Columbus, OH	0.091
Knoxville, TN	0.091
San Antonio, TX	0.091
Trenton-Ewing, NJ	0.091
Wilmington, OH	0.091
Youngstown-Warren-Boardman, OH-PA	0.091
Pittsburgh, PA	0.09
Providence-New Bedford-Fall River, RI-MA	0.09
Richmond, VA	0.09
Springfield, MA	0.09
Yuba City, CA Metropolitan Statistical	0.09
Akron, OH	0.089
Anderson, IN	0.089
Baton Rouge, LA	0.089
Madera, CA	0.089
Poughkeepsie-Newburgh-Middletown, NY	0.089
San Diego-Carlsbad-San Marcos, CA	0.089
South Bend-Mishawaka, IN-MI	0.089
St. Louis, MO-IL	0.089
Toledo, OH	0.089
Torrington, CT	0.089
Vineland-Millville-Bridgeton, NJ	0.089
Allentown-Bethlehem-Easton, PA-NJ	0.088
Barnstable Town, MA	0.088
Chico, CA	0.088
Louisville-Jefferson County, KY-IN	0.088
Milwaukee-Waukesha-West Allis, WI	0.088
Norwich-New London, CT	0.088
Raleigh-Cary, NC	0.088
Dayton, OH	0.087
Durham, NC	0.087
Elkhart-Goshen, IN	0.087
Erie, PA	0.087
Green Bay, WI	0.087
Lancaster, PA	0.087
Lima, OH	0.087
Memphis, TN-MS-AR	0.087
Morristown, TN	0.087
Racine, WI	0.087
Sevierville, TN	0.087
Springfield, OH	0.087

Winston-Salem, NC	0.087
Albany-Schenectady-Troy, NY	0.086
Canton-Massillon, OH	0.086
Columbia, SC	0.086
Huntington-Ashland, WV-KY-OH	0.086
Lincolnton, NC	0.086
Macon, GA	0.086
Michigan City-La Porte, IN	0.086
Muskegon-Norton Shores, MI	0.086
Niles-Benton Harbor, MI	0.086
Virginia Beach-Norfolk-Newport News, VA-NC	0.086
Watertown-Fort Drum, NY	0.086
York-Hanover, PA	0.086
Austin-Round Rock, TX	0.085
Birmingham-Hoover, AL	0.085
Chambersburg, PA	0.085
Chattanooga, TN-GA	0.085
DuBois, PA	0.085
El Centro, CA	0.085
Flint, MI	0.085
Fort Wayne, IN	0.085
Las Vegas-Paradise, NV	0.085
Phoenix-Mesa-Scottsdale, AZ	0.085
Red Bluff, CA	0.085
Rocky Mount, NC	0.085
Seaford, DE	0.085
Ann Arbor, MI	0.084
Atlantic City, NJ	0.084
Bloomington, IN	0.084
Denver-Aurora, CO	0.084
Dover, DE	0.084
Fayetteville, NC	0.084
Grand Rapids-Wyoming, MI	0.084
Greensboro-High Point, NC	0.084
Holland-Grand Haven, MI	0.084
Kingsport-Bristol-Bristol, TN-VA	0.084
Manchester-Nashua, NH	0.084
Parkersburg-Marietta, WV-OH	0.084
Phoenix Lake-Cedar Ridge, CA	0.084
Portland-South Portland-Biddeford, ME	0.084
San Jose-Sunnyvale-Santa Clara, CA	0.084
Spartanburg, SC	0.084
State College, PA	0.084

Adrian, Ml	0.083
Augusta-Richmond County, GA-SC	0.083
Dalton, GA	0.083
Evansville, IN-KY	0.083
Hagerstown-Martinsburg, MD-WV	0.083
Longview, TX	0.083
Manitowoc, WI	0.083
Mount Vernon, OH	0.083
Muncie, IN	0.083
Nashville-Davidson--Murfreesboro, TN	0.083
Reading, PA	0.083
San Francisco-Oakland-Fremont, CA	0.083
Terre Haute, IN	0.083
Traverse City, MI	0.083
Weirton-Steubenville, WV-OH	0.083
Anderson, SC	0.082
Asheville, NC	0.082
Clarksville, TN-KY	0.082
Fort Collins-Loveland, CO	0.082
Harrisburg-Carlisle, PA	0.082
Hickory-Lenoir-Morganton, NC	0.082
Kansas City, MO-KS	0.082
Lafayette, IN	0.082
New Orleans-Metairie-Kenner, LA	0.082
Santa Barbara-Santa Maria, CA	0.082
Seneca, SC	0.082
Williamsport, PA	0.082
Altoona, PA	0.081
Charleston, WV	0.081
Granbury, TX	0.081
Greenville, NC	0.081
Kalamazoo-Portage, MI	0.081
Marshall, TX	0.081
Rochester, NY	0.081
Rockland, ME	0.081
Scranton--Wilkes-Barre, PA	0.081
Stockton, CA	0.081
Tyler, TX	0.081
Bishop, CA	0.08
Chester, SC	0.08
Corpus Christi, TX	0.08
Decatur, AL	0.08
Florence, SC	0.08

Gaffney, SC	0.08
Gettysburg, PA	0.08
Greenville, SC	0.08
Gulfport-Biloxi, MS	0.08
Huntington, IN	0.08
Johnstown, PA	0.08
Kingston, N	0.08
Lake Charles, LA	0.08
Lansing-East Lansing, MI	0.08
Owensboro, KY	0.08
Paducah, KY-IL	0.08
Pensacola-Ferry Pass-Brent, FL	0.08
Seymour, IN	0.08
Lafayette, LA	0.079
Middlesborough, KY	0.079
Mobile, AL	0.079
Mount Vernon, IL	0.079
Ogden-Clearfield, UT	0.079
Oklahoma City, OK	0.079
Roanoke, VA	0.079
Salt Lake City, UT	0.079
Tulsa, OK	0.079
Victoria, TX	0.079
Athens-Clarke County, GA	0.078
Bennington, VT	0.078
Bowling Green, KY	0.078
El Paso, TX	0.078
Huntsville, AL	0.078
Janesville, WI	0.078
Kinston, NC	0.078
Little Rock-North Little Rock, AR	0.078
Miami, OK	0.078
Panama City-Lynn Haven, FL	0.078
Pascagoula, MS	0.078
Union, SC	0.078
Utica-Rome, NY	0.078
Wheeling, WV-OH	0.078
Whitewater, WI	0.078
Winchester, VA-WV	0.078
Albuquerque, NM	0.077
Beaver Dam, WI	0.077
Claremont, NH	0.077
Elmira, NY	0.077

Greeley, CO	0.077
Las Cruces, NM	0.077
Mayfield, KY	0.077
Monroe, LA	0.077
New Castle, PA	0.077
Prescott, AZ	0.077
Sarasota-Bradenton-Venice, FL	0.077
Syracuse, NY	0.077
Tampa-St. Petersburg-Clearwater, FL	0.077
Watertown-Fort Atkinson, WI	0.077
Augusta-Waterville, ME	0.076
Boise City-Nampa, ID	0.076
Boulder, CO	0.076
Brigham City, UT	0.076
Burlington-South Burlington, VT	0.076
Cadillac, MI	0.076
Daphne-Fairhope, AL	0.076
Harrison, AR	0.076
Houma-Bayou Cane-Thibodaux, LA	0.076
Lawrenceburg, TN	0.076
Lawton, OK	0.076
Morgantown, WV	0.076
Natchez, MS-LA	0.076
Provo-Orem, UT	0.076
Shreveport-Bossier City, LA	0.076
Tucson, AZ	0.076
Bangor, ME	0.075
Bloomington-Normal, IL	0.075
Concord, NH	0.075
Davenport-Moline-Rock Island, IA-IL	0.075
Elizabethtown, KY	0.075
Fond du Lac, WI	0.075
Gadsden, AL	0.075
Laconia, NH	0.075
Orlando, FL	0.075
Peoria, IL	0.075
Tupelo, MS	0.075
Walterboro, SC	0.075
Wichita, KS	0.075
Wilmington, NC	0.075
Flagstaff, AZ	0.074
Jacksonville, FL	0.074
Keene, NH	0.074

Madison, WI	0.074
Montgomery, AL	0.074
Ocala, FL	0.074
Omaha-Council Bluffs, NE-IA	0.074
Reno-Sparks, NV	0.074
Seattle-Tacoma-Bellevue, WA	0.074
Somerset, KY	0.074
Tallahassee, FL	0.074
Alexandria, LA	0.073
Appleton, WI	0.073
Champaign-Urbana, IL	0.073
Charleston-North Charleston, SC	0.073
Cleveland, MS	0.073
Clinton, IA	0.073
Colorado Springs, CO	0.073
De Ridder, LA	0.073
Decatur, IL	0.073
Farmington, NM	0.073
Jackson, MS	0.073
Lakeland, FL Metropolitan Statistical	0.073
Lexington-Fayette, KY	0.073
McAlester, OK	0.073
Medford, OR	0.073
Morgan City, LA	0.073
Rockford, IL	0.073
San Luis Obispo-Paso Robles, CA	0.073
Spokane, WA	0.073
Springfield, IL	0.073
Tuscaloosa, AL	0.073
Brunswick, GA	0.072
Columbus, GA-AL	0.072
Effingham, IL	0.072
Gainesville, FL	0.072
Lebanon, NH-VT	0.072
McAllen-Edinburg-Mission, TX	0.072
Quincy, IL-MO	0.072
Sierra Vista-Douglas, AZ	0.072
Meridian, MS	0.071
Monroe, WI	0.071
Redding, CA	0.071
Vallejo-Fairfleld, CA	0.071
Americus, GA	0.07
Baraboo, WI	0.07

Cape Coral-Fort Myers, FL	0.07
Eugene-Springfield, OR	0.07
Gillette, WY	0.07
Lake City, FL	0.07
Springfield, MO	0.07
Wausau, WI	0.07
Deltona-Daytona Beach-Ormond Beach, FL	0.069
Minneapolis-St. Paul-Bloomington, MN-WI	0.069
Palm Bay-Melbourne-Titusville, FL	0.069
Sebring, FL	0.069
Vicksburg, MS	0.069
Logan, UT-ID	0.068
Naples-Marco Island, FL	0.068
Portland-Vancouver-Beaverton, OR-WA	0.068
Rapid City, SD	0.068
Salinas, CA	0.068
Savannah, GA	0.068
Brownsville-Harlingen, TX	0.067
Carson City, NV	0.067
Cedar Rapids, IA	0.067
Waterloo-Cedar Falls, IA	0.067
Miami-Fort Lauderdale-Miami Beach, FL	0.066
Mountain Home, ID	0.066
Napa, CA	0.066
Port St. Lucie-Fort Pierce, FL	0.066
Santa Cruz-Watsonville, CA	0.066
Clearlake, CA	0.065
Iron Mountain, MI-WI	0.065
Olympia, WA	0.065
Salem, OR	0.065
Duluth, MN-WI	0.064
Gardnerville Ranchos, NV	0.064
Laredo, TX	0.064
Jackson, WY-ID	0.063
Durango, CO	0.061
Fargo, ND-MN	0.061
Santa Rosa-Petaluma, CA	0.061
Ames, IA	0.058
Shelton, WA	0.058
Ukiah, CA	0.058
Bellingham, WA	0.057
Des Moines-West Des Moines, IA	0.057
Lincoln, NE	0.056

Kalispell, MT	0.055
Mount Vernon-Anacortes, WA	0.052
Port Angeles, WA	0.044
Honolulu, HI	0.042