QUALITY SCIENCE FOR QUALITY AIR

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY AND ENVIRONMENT

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

TUESDAY, OCTOBER 4, 2011

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Tuesday, October 4, 2011

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QUALITY SCIENCE FOR QUALITY AIR

TUESDAY, OCTOBER 4, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY AND ENVIRONMENT,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:04 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Andy Harris [Chairman of the Subcommittee] presiding.

RALPH M. HALL, TEXAS
CHAIRMAN

EDDIE BERNICE JOHNSON, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES
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Quality Science for Quality Air

Tuesday, October 4, 2011
10:00 a.m. to 12:00 p.m.
2318 Rayburn House Office Building

Witnesses:

Dr. Roger O. McClellan, Advisor, Toxicology and Human Health Risk Analysis.

Dr. George Thurston, Professor, New York University School of Medicine.

Dr. Michael Honeycutt, Chief Toxicologist, Texas Commission on Environmental Quality.

Dr. Robert F. Phalen, Professor of Medicine and Co-Director, Air Pollution Health Effects Laboratory, University of California, Irvine.

Dr. Anne E. Smith, Senior Vice President, NERA Economic Consulting.

Mr. J. Edward Cichanowicz, Consultant.

HEARING CHARTER

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON ENERGY AND ENVIRONMENT
U.S. HOUSE OF REPRESENTATIVES

Quality Science for Quality Air

TUESDAY, OCTOBER 4, 2011
10:00 A.M.–12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Tuesday, October 4, 2011, the Subcommittee on Energy and Environment of the Committee on Science, Space, and Technology held a hearing to examine the Environmental Protection Agency's (EPA) process for setting standards under the *Clean Air Act* including (1) the role of scientific advice from the Clean Air Scientific Advisory Committee (CASAC) and similar bodies, (2) the economic underpinnings of EPA's Regulatory Impact Analyses, and (3) the assumptions, models, and data used in projecting compliance, technological standards necessary to achieve compliance, and environmental benefits associated with proposed and finalized rules.

Witnesses

- **Dr. Roger O. McClellan**, Advisor, Toxicology and Human Health Risk Analysis
- **Dr. George Thurston**, Professor, New York University School of Medicine
- **Dr. Michael Honeycutt**, Chief Toxicologist, Texas Commission on Environmental Quality
- **Dr. Robert F. Phalen**, Professor of Medicine and Co-Director, Air Pollution Health Effects Laboratory, University of California, Irvine
- **Dr. Anne E. Smith**, Senior Vice President, NERA Economic Consulting
- **Mr. J. Edward Cichanowicz**, Consultant.

Background

Originally passed in 1963, the *Clean Air Act* underwent significant amendments in 1970, 1977, and 1990. The CAA provided the EPA the statutory authority to regulate air pollution to address public health and welfare concerns. Under the CAA statutory framework, the Agency is required to set goals of reducing emissions from both stationary and mobile sources.

National Ambient Air Quality Standards

The foundation of the CAA is based primarily on the concept of nationwide air quality goals and the development of individual state plans to meet those goals. EPA has identified six "criteria pollutants" that are most prevalent and necessary to the protection of public health and welfare for National Ambient Air Quality Standards (NAAQS): sulfur dioxide (SO_2), particulate matter (PM),[1] nitrogen oxides (NO_χ), carbon monoxide (CO), ozone (O_3), and lead (Pb). For each of these pollutants, EPA established a "primary" standard at a level designed to protect the public health within an "adequate margin of safety." In addition, the statute allows EPA to set a secondary NAAQS to protect public welfare. At this point, EPA has not set secondary standards at different levels than the primary standards.

The standards themselves are not directly enforceable. Rather, NAAQS establish ceilings for concentrations of criteria pollutants in ambient air. States are required to develop their own State Implementation Plans (SIPs) which outline the measures the State will take to meet the reduction required by the standard (attain) or stay in compliance with the standard (maintain). For example, a SIP may include emission limits for power plants, refineries and manufacturing facilities within the state,

[1] For the first time, during the 1997 revision of the PM NAAQS, EPA established separate standards for fine particulate matter (smaller than 2.5 micrometers or $PM_{2.5}$) and coarse particulate matter (smaller than 10 micrometers or PM_{10}).

or fuel specifications for emission reductions from mobile sources. SIPs must be approved by EPA. If EPA determines that a SIP will not be able to attain or maintain the NAAQS concentrations, EPA can require States to abide by a Federal Implementation Plan (FIP) until such time that the State develops an approvable SIP. Further, if a State fails to submit a SIP, fails to submit an adequate SIP, or fails to implement a SIP, certain sanctions may be imposed; for example, the State may be banned from receiving Federal highway grants.

Under the CAA, each NAAQS must go through a review every five years in order to ensure the standards were protecting public health according to the most recent scientific findings. After a scientific assessment and receipt of expert advice, the Administrator uses his or her own judgment to determine whether or not and to what extent an NAAQS is to be revised. Several Supreme Court cases [2] limited the ability of EPA to take cost into consideration when setting the NAAQS. However, EPA still prepares a Regulatory Impact Assessment (RIA) that details the Agency's expected costs and benefits.

Clean Air Scientific Advisory Committee

NAAQS reviews also include a scientific assessment phase in which EPA assesses the scientific and technical data and provides opportunities for public and expert review of relevant staff documents. EPA then provides these documents to the Clean Air Scientific Advisory Committee (CASAC) for review and feedback. CASAC typically provides the Administrator of the EPA with a recommended concentration range for a particular NAAQS that it believes the scientific literature justifies.

According to the EPA, CASAC "provides independent advice to the EPA Administrator on the technical bases for EPA's national ambient air quality standards. Established in 1977 under the *Clean Air Act* (CAA) Amendments of 1977 (see 42 U.S.C. § 7409(d)(2)), CASAC also addresses research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality." [3]

In providing this advice, CASAC comments on EPA staff documents and responds to charge questions from EPA staff. CASAC is comprised of seven permanent members that are supplemented by more than a dozen additional scientists that are appointed to join them for individual NAAQS reviews.

In recent months, several Members of Congress [4] have raised questions regarding the objectivity and independence of the CASAC in providing this scientific advice to EPA. [5]

Hazardous Air Pollutants

The CAA distinguishes between two types of pollutants: aforementioned criteria pollutants (e.g., NO_X, SO_2, PM, etc.) and hazardous air pollutants (HAPs). HAPs theoretically pose similar public health concerns as criteria pollutants but are much less ubiquitous; therefore, a different standard setting regime was established. The National Emission Standards for Hazardous Air Pollutants (NESHAPs) was established to deal with these nonconventional pollutants. The 1990 amendments required HAPs regulations to consider cost and technological feasibility. Further, the statute directed EPA to develop standards by industrial source category (e.g., acid gases) rather than focus on individual pollutants.

Maximum Achievable Control Technology

The mandating of NESHAPs by the 1990 CAAA set the course for the rapid development of technology-based standards for all major and industrial source categories that emit HAPs. These standards are known as Maximum Achievable Control Technologies, or MACT. MACT standards are to be based on the "maximum degree of reductions and emissions deemed achievable for the category or subcategory, the EPA administrator, taking into consideration the cost of achieving the reduction, any non-air-quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources." [6]

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[2] *Lead Industries Assn., Inc.* v. *EPA*, 647 F.2d 1130, 1148 (CADC 1980) and *Whitman* v. *American Trucking* (February 2001).

[3] *http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC.*

[4] *http://republicans.energycommerce.house.gov/Media/file/Letters/112th/030811inhofe.pdf.*

[5] *http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=d55fa42f-7c41-456e-893f-2963eb26e07e.*

[6] CAA 112(d)(2).

Scientific Inputs for Standard Setting Under the Clean Air Act

Throughout the development of both NAAQS and NESHAP standards, EPA is required to provide scientific justification for the regulations. The initial inputs include information regarding the effects of pollutants on public health and welfare. EPA must provide information that demonstrates that criteria pollutants or HAPs within the ambient air at current concentrations constitute a threat to public health. The health risk is estimated through a scientific assessment, and the public and expert advice is provided to EPA. The Court has ruled that EPA may not take cost into account when establishing NAAQS levels, though Executive Orders have required that such costs must still be analyzed through a regulatory impact assessment. For MACT, EPA must take cost into account, and may not set a standard that protects the public health to a level that has no risk of health effects. Finally, EPA is required for the MACT to conduct a technological feasibility analysis to determine if the technology to reduce emissions of pollutants is available and cost effective. Again, although EPA is not required to conduct a similar analysis in the case of NAAQS levels, the Agency still does a technical assessment when developing the regulatory impact assessment.

The results of these scientific inputs: health, risk, cost and technology, provide the basis and necessary justification for EPA to move forward with setting a standard or making an existing standard more stringent. The Science, Space, and Technology Committee will examine the process by which the quality of the scientific inputs affects the overall justification for regulation, and the importance of that process in ensuring that only appropriate and necessary rules are promulgated.

Relevant Current Proposed and Finalized (but under review) Rules

The following regulations pertain to the aforementioned *Clean Air Act* authorities:

- National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-fired Electric Utility Steam Generating Units and Standards of Performance for Electric Utility Steam Generating Units;
- National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial, and Institutional Boilers;
- National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial & Institutional Boilers and Process Heaters;
- Portland Cement Manufacturing NESHAP and NSPS;
- Review of the Primary National Ambient Air Quality Standard for Sulfur Dioxide;
- Review of the Primary National Ambient Air Quality Standard for Ozone;
- Review of the Primary National Ambient Air Quality Standard for Particulate Matter;
- Review of the Primary National Ambient Air Quality Standard for Lead;
- Cross-State Air Pollution Rule.

Chairman HARRIS. The Subcommittee on Energy and Environment will come to order.

Good morning. Welcome to today's hearing entitled "Quality Science for Quality Air." In front of you are packets containing the written testimony, biographies and Truth in Testimony disclosures for today's witness panel. I recognize myself for five minutes for an opening statement.

I thank our witnesses for being here today to provide their expertise on the process for incorporating quality science into *Clean Air Act* standards. In the debate over EPA issues, it can often seem like two ships passing in the night: one side talking about jobs, the other discussing children's health. This hearing is designed to provide context to this conversation and to examine the science and technology assumptions behind air quality standards.

It is important to note at the outset that overall air quality in the United States is excellent. By any objective metric, air quality and related human health has improved dramatically, and the levels of every major air pollutant have plummeted over the last three decades. Most of America meets increasingly stringent EPA standards.

Despite these improvements, the unprecedented pace of EPA's *Clean Air Act* agenda requires us to ask two basic questions: are we using common sense in establishing environmental standards, and how low is low enough?

Unfortunately, whether it is the Cross-State Air Pollution Rule, National Ambient Air Quality Standards for ozone or fine particulate matter, or the so-called utility MACT rules, these questions are being ignored and EPA is moving ahead promulgating major, job-destroying regulations on the basis of shaky, and often secret, science.

Now, both as a physician and the Chairman of a Subcommittee overseeing what is supposed to be science at EPA, I was alarmed to hear Administrator Lisa Jackson explain two weeks ago that particulate matter "does not make you sick. It is directly causal to dying sooner than you should" and that "if we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer."

Now two weeks ago, Assistant Administrator Gina McCarthy had a hard time explaining how the Cross-State Air Pollution Rule would avoid "up to 34,000 deaths" at a committee hearing in this room. Given the imprecise justification for those 34,000 avoided deaths, the Administrator's claim of 572,000 avoided deaths, which is the number who die from cancer each year, is patently ridiculous.

I would hope that, of all people, members of the President's Cabinet would be responsible enough to ensure any public health claims are grounded in science, not hyperbole, and if our current air is such a threat to human health that it is killing hundreds of thousands of people each year, I am very interested to review the information that the Agency relies on in establishing this relationship.

Accordingly, I have asked EPA to make the federally funded data sets and associated science upon which these health claims appear to be based publicly available. But because the EPA is not transparent with the sources of their data, from what we have seen so

far, EPA seems to rely on making statistical hay out of minor associations between pollutants and premature mortality. This is not quality science; this is press-release science in which public relations is considered more important than an honest, transparent, scientific discussion of environmental outcomes and human health.

One glaring example is the EPA's justification of these major *Clean Air Act* regulations on the basis of double-counting the health benefits of lower particulate matter levels. Without these coincidental co-benefits, none of these rules would have passed a simple cost-benefit analysis.

Just last week, EPA's Inspector General released a report highlighting the agency's inability to follow basic peer review and scientific integrity guidelines in developing its endangerment finding on carbon dioxide. I am concerned that similar problems plague EPA's Science Advisory Board and the Clean Air Scientific Advisory Committee, or CASAC. We are not seeking to denigrate the participating scientists, but there are questions raised by the IG that need to be asked about the independence of these bodies. In many cases, these panels suffer from little turnover, financial conflicts, a lack of balance and transparency, and, perhaps most importantly, panelists that are peer reviewing their own work.

There are also a number of signs that this EPA is underestimating the time and cost to install pollution control technology that is required. For example, there is no power plant in America that can meet the three requirements proposed by EPA in the Utility MACT Rule.

I am pleased that the House of Representatives has begun pushing back against this job-killing regulatory agenda through legislation like the recently passed TRAIN Act, and I hope that the recommendations of our panelists today will help guide our oversight of EPA science going forward.

[The prepared statement of Mr. Harris follows:]

PREPARED STATEMENT OF SUBCOMMITTEE CHAIRMAN ANDY HARRIS

The hearing will come to order. I thank our witnesses for being here today to provide their expertise on the process for incorporating quality science into *Clean Air Act* standards.

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I am pleased that the House of Representatives has begun pushing back against this job-killing, regulatory agenda through legislation like the recently-passed TRAIN Act, and I hope that the recommendations of our panelists today will help guide our oversight of EPA science going forward.

Chairman HARRIS. The chair now recognizes Mr. Miller for an opening statement.

Mr. MILLER. Thank you, Mr. Chairman. I appreciate your holding this hearing. The EPA does have before us the need, often court imposed, to issue new and updated regulations, and we should review what those regulations are based on and what we really get out of them, but the *Clean Air Act's* history speaks for itself. It is not just the EPA's own estimates. Those estimates have been broadly supported by public health experts, neutral experts, those who truly do not have a financial ax to grind, who are not employed by the industry, either directly or as consultants or as experts or whatever else. EPA's own estimates are that in the first 20 years of the *Clean Air Act*, the *Clean Air Act* has prevented more than 200,000 premature deaths and almost 700,000 cases of chronic bronchitis, and the benefits continue to grow and grow. The Chairman said correctly the air quality is much better in the United States. That is because we have had the *Clean Air Act* in effect for 40 years. It has not been because of the benevolence of industry. It has been because there has been an Act in place that has been enforced by the Environmental Protection Agency, in some instances, kicking and screaming, but still enforced, enforced if not by the Agency at least by the courts requiring the Agency to follow the law.

And the blame for these regulations for the effect on jobs is not really something we can attribute to the industry because there are many in the industry that support the regulations and think that they need to be tougher than they are, and many have advocated for that. But politicians have learned that there is a political value in creating a villain, creating a demon, and they have made the EPA their demon, so there is no room between their image of the EPA as a rogue agency that is enforcing the *Clean Air Act*, signed by President Nixon, later strengthened by President Bush. So demonizing the EPA by making specious claims that their regulations kill jobs also without any particularly well-grounded basis while ignoring all the benefits for public health and the economy is another cynical effort to gain votes and get Americans to vote against their own self-interest. Americans aren't buying it. Polls show that Americans understand the importance of the EPA and understand the importance of environmental protection, support clean air and water, and do not believe that pollution and damage to the public health is the price that we have to pay for prosperity.

But in this Congress we have seen an unrelenting attack on environmental protection. There have been 136 votes so far, all to ratchet back environmental protections, the most extreme example, the TRAIN Act, and nobody opposes transparency. I have pushed—for four years as Chairman of the Science Committee's Subcommittee on Oversight, I have pushed hard for transparency and we should have that, but we also know that the arguments about process are usually driven by folks who are not happy with the result of the process, and if you don't like the result, you almost never like the process.

The Inspector General did criticize, it is true, some of the processes of the EPA but also said that the EPA's processes that they did use complied with the statute, and they said that there was no reason to think that the result would have been any different if the processes had been different. I think we should continuously improve the processes. Process does matter. But the characterization of the Inspector General's report is simply not correct.

So with significant progress over the last 40 years, I think we should look at how to build on that, continuing to improve the quality of our air, recognizing the importance of that to a strong economy. Premature deaths cost our economy. People having bronchitis and not being able to go to work cost our economy. Stronger environmental protections also push industry to develop new technologies and have in fact increased jobs in various areas.

So we have proven time and again that worker productivity improves better if there is clean air. Agricultural yield is improved if there's clean air. There is a reduction in mortality and illness and other economic and public health benefits that far outweighs the cost of compliance. Of course, we should consider the costs of compliance but we should also include the effect on the public health as well.

Thank you, and I yield back.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF RANKING MEMBER BRAD MILLER

I want to thank Chairman Harris for holding a hearing to discuss the science underpinning the 40-year-old landmark legislation, the *Clean Air Act*. While I disagree with some of the opinions of my colleagues and the witnesses, I understand the timing and motivations behind this hearing. As we look forward to the EPA issuing new and updated pollution regulations, it is worth reminding ourselves of what they are based on and what we get out of them. In that regard, the *Clean Air Act's* history of protecting public health speaks for itself.

In the four decades since it was signed, the *Clean Air Act* has saved hundreds of thousands of lives. Even in its first 20 years—as emissions reductions were just beginning—EPA figures show that the *Clean Air Act* prevented more than 200,000 premature deaths and almost 700,000 cases of chronic bronchitis.

And these benefits to the public will continue to grow. The EPA projects that by 2020, the *Clean Air Act* will prevent roughly 230,000 deaths, 200,000 cases of heart disease, and 2.4 million asthma flare-ups every year. These will have a real economic effect by keeping children and adults out of the hospital and saving the nation from 22.4 million missed school and work days per year, providing upwards of $2 trillion in economic benefits by 2020. These benefits would far exceed the original costs by 30 to 1. That's not a bad investment by any standard.

The *Clean Air Act* is hardly the economy-killer that so many claim. Over the last 20 years, while emissions of the six principal air pollutants were reduced by an additional 41 percent, the Nation's Gross Domestic Product has increased by more than 64 percent. And we not only got cleaner air, but entirely new technology sectors to boot. In fact, GDP has risen by more than 200 percent since the Act was signed 40 years ago, and this is in spite of the doomsday prophesies of widespread economic disruption and industrial collapse that some said would result from environmental regulations. These claims have been proven wrong time and again, and we should expect to look back and regard the alarmism of today as no different.

To be fair, the blame for misguiding the public on the costs and benefits of regulations cannot be laid solely at the feet of industry that in the end exists to turn a profit. In fact, "industry" is hardly uniform in its regard for environmental regulations, with many industrial stakeholders clearly advocating in favor of the new regulations. It depends on how they have invested. And even those on the losing end of EPA's regulations are often complaining about the process or timeline, knowing that the eventual regulation will be the same.

Unfortunately, there is a more troubling force at play here as politicians have discovered the distinct political value of vilifying the EPA. To them, there is no middle ground, and no room for negotiation or compromise with this "rogue agency." In politicizing the issue—sometimes far beyond the comfort level of the industries they profess to champion—there also seems to be no limit to the hysterics. In a recent hearing on the EPA's transport ruIe before this Committee, a witness actuaIly stated that the rule will "jeopardize the lives of our most medically fragile citizens."

Demonizing environmental safeguards and the EPA by making specious claims that regulations kill jobs—and even people—while completely ignoring the proven positive effects they have on public health and the economy, is another cynical ploy to get Americans to vote against their own self-interest.

Thankfully, poll after poll shows that the public believes that EPA should protect their right to clean air and water more than they believe that pollution is the price they must pay for economic security.

In this Congress, it seems we have seen every assault possible on environmental protections such as the *Clean Air Act*, taking 136 anti-environmental votes in the House thus far. Before the recess, the House passed the so-called *TRAlN Act*, a piece of legislation that would derail efforts to curb emissions of dangerous pollutants such as soot, mercury, dioxins and acid gases. Of course, nobody would argue against having "transparency" in our regulatory processes, but that is not really what these bills are about. They are about politics first, and buying time for polluters who must otherwise be dragged kicking and screaming into environmental compliance, while more forward-looking firms are deprived of making a return on their investments in cleaner technology.

Efforts such as the *TRAIN Act* and the paralysis-by-analysis it would impose are themselves anything but transparent or comprehensive. It adds another layer of bureaucracy, essentially for the purpose of weighing industry' s cost of compliance, without considering the benefits for public health and the creation of new jobs. It also removes any provision to ensure that such safeguards will ever take effect, delaying them indefinitely. It is designed to ignore the overwhelming evidence that saving Americans' lives is far cheaper than saving polluters' dollars.

No regulatory process is ever going to make everyone happy because someone must always change, but we should certainly look for ways to make the processes more efficient and transparent. Instead of making doomsday claims that never hold up and scaring the American public into forgoing their own rights to a cleaner environment, we need to trust in the EPA's reliable, established scientific processes for characterizing the effects of emissions on public health and evaluating the costs and benefits of new technologies. We should acknowledge that we did not get 40 years of dramatic pollution reductions with strong economic growth because EPA's scientific processes are not tried and true. Put simply, they work.

And speaking of process, I am disappointed that we do not have before us an EPA witness nor one from the Science Advisory Board. If we're going to talk about them, they ought to be here to defend themselves. That's just fundamental fairness.

Quoting Republican President Nixon who first signed into law the 1970 *Clean Air Act*, "I think that 1970 will be known as the year of the beginning, in which we really began to move on the problems of clean air and clean water and open spaces for the future generations of America."

Although significant progress has been made in the past 40 years, it is our job now to build upon this legacy and ensure that we continue to improve our environmental quality while fostering a strong economy. This is not science fiction; it is our history. In the U.S., a healthy environment and strong economy are not mutually exclusive. Stricter pollutions limits force us to push the envelope of scientific innovation and create new technologies. And, as it has been proven many times over, improved worker productivity, increased agricultural yield, reduction in mortality and illness, and other economic and public health benefits far outweigh the costs of compliance.

Thank you, and I yield back.

Chairman HARRIS. Thank you very much, Mr. Miller.

If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

At this time I would like to introduce our witness panel. Our first witness, Dr. Roger McClellan, is an advisor to public and private organizations on issues concerned with air quality, utilizing his extensive experience in comparative medicine, toxicology, aerosol science and risk analysis. He was also formerly the Chair of EPA's Clean Air Science Advisory Committee.

Our next witness will be Dr. George Thurston, who is a Professor at the NYU School of Medicine. Dr. Thurston conducts research into the human health effects of air pollution. He has been published widely in the scientific literature and was a consultant to EPA's Clean Air Science Advisory Committee's Panel on Nitrogen Oxides.

Next, we have Dr. Michael Honeycutt, Chief Toxicologist at the Texas Commission on Environmental Quality. Dr. Honeycutt is the Director of the Toxicology Division there and an Adjunct Professor at Texas A&M University and has published numerous articles in the peer-reviewed literature.

Dr. Robert Phalen, Professor of Medicine and Co-Director of the Air Pollution Health Effects Laboratory, University of California, Irvine, will be the next witness. Dr. Phalen has over 30 years of experience with inhalation studies of hazardous materials. He is also a member of EPA's Clean Air Science Advisory Committee Panel on Particulate Matter.

Next, we have Dr. Anne Smith, Senior Vice President at NERA Economic Consulting. Dr. Smith is an economist and decision analyst specializing in energy and environmental markets and compliance planning. Before joining NERA, Dr. Smith headed the Climate and Sustainability Group at Charles River Associates.

Finally, we have Mr. J. Edward Cichanowicz, an experienced engineering consultant. He provides consulting services for utility industry clients in developing and implementing environmental control strategies to meet the mandates of the EPA and state and local regulatory agencies. Mr. Cichanowicz specializes in the technical feasibility, cost and risk of adopting both mature and evolving technologies.

Now, as our witnesses should know, spoken testimony is limited to five minutes each after which the Members of the Committee will have five minutes each to ask questions, and we do have a copy of your written testimony.

I now recognize our first witness, Dr. Roger McClellan, an advisor on toxicology and human health risk analysis. Dr. McClellan.

STATEMENT OF DR. ROGER O. MCCLELLAN, ADVISOR, TOXICOLOGY AND HUMAN HEALTH RISK ANALYSIS

Dr. MCCLELLAN. Good morning, distinguished Members of the Subcommittee. Thank you for the invitation to present my views and the role of science in informing policy judgments on the setting of National Ambient Air Quality Standards. I ask that my written testimony be entered in the record as though read in its entirety. Let me summarize it.

What I hope my comments will convey is how low is low enough requires context. It is not an abstract question. For more than five decades, I have been contributing to the development of the science needed to address important societal issues concerned with air quality. I am proud to have served on many EPA advisory committees under the Administrations of both parties. I have served on numerous Clean Air Scientific Advisory Committee panels and chaired CASAC from 1988 to 1992. I served on the panels that advised on the 1997 ozone standard, the 2006 particulate matter standard. I did not serve on the ozone panel that advised on the 2008 ozone standard. However, I did offer comments to the Administrator and CASAC.

In March 2008, then-Administrator Johnson revised the ozone standard using the policy judgment exclusively delegated to the EPA Administrator in the *Clean Air Act*. He retained ozone as an indicator, the averaging time of eight hours, the statistical form, the standard attained when the fourth highest eight-hour average is less than the numerical level of the standard, and he reduced the concentration allowed from 84 to 75 parts per billion. In announcing his decision, he noted that he depended on the science to inform his decision and noted that the advice provided by the Clean Air Scientific Advisory Committee was in fact a blend of science and the committee's own personal policy preferences.

In January 2010, EPA Administrator Jackson formally announced a fast-track reconsideration proposal to set the standard in the range of 70 to 60 PPB. This in my opinion was the beginning of a serious misadventure and waste of resources. In my opinion, her decision was discretionary, arbitrary, capricious and without precedent. With the decision, she was expressing a personal opinion. If I had been in office 22 months earlier, I would have made a different policy choice. She wrapped herself in the cloak of science saying I will follow the advice of CASAC. In taking this

course, she abdicated the specific and exclusive authority delegated to the EPA Administrator by the *Clean Air Act*.

In January 2011, she asked CASAC to elaborate on the basis of their recommended range. CASAC Chair Jonathan Samet wisely noted the decision as to an adequate margin of safety to protect public health was inherently a blend of science and policy.

After repeatedly missing self-imposed deadlines, Administrator Jackson sent a proposed final rule to OMB in mid-summer. On September 2, 2011, Administrator Cass Sunstein of the OMB Office of Information and Regulatory Affairs advised Administrator Jackson her proposed rule was not mandatory, said it was discretionary, it would produce needless uncertainty and was being offered even while the next five-year review cycle was proceeding in an orderly fashion to conclude in March 2013, and he noted that her rule was not based on the latest science as called for by the *Clean Air Act*, and most importantly, the President had indicated he has made it clear he does not support finalizing the rule at this time.

I applaud the common sense decision of Administrator Sunstein and President Obama. It is unfortunate that the President and his appointees did not have a discussion in 2009 that could have avoided this serious misadventure.

Looking to the current review, I urge EPA and CASAC to carefully heed the thoughtful advice of Supreme Court Justice Stephen Breyer, who offered the view that a comparative health view was appropriate in setting the standards. I urge the Administrator to recognize that even when all U.S. manmade precursor emissions are eliminated, ambient ozone concentrations expressed as the maximum eight-hour average are just below 60 PPB. These background levels should be considered in making policy judgments on setting the standard.

I think the Administrator and CASAC should be cognizant of the very weak signal for air pollution impacting public health currently. We have made great progress. And keep in mind, the substantial adverse health signal associated with socioeconomic status. Employment and jobs do matter.

Frequently we hear about the relative risks associated with air pollution expressed as a few percent over a baseline. My view is, we ought to be concerned more with the science of the baseline. What can we do to drive down those baseline risks? Future research should focus on that, and keep in mind, a big number in terms of relative risk, the relative risk of unemployment, lower socioeconomic status. That is not a couple of percent, that is 100 percent looking at the lowest quartile versus the upper quartile.

Thank you for the opportunity to testify, and I look forward to addressing your questions later, including the process used by CASAC.

[The prepared statement of Dr. McClellan follows:]

PREPARED STATEMENT OF DR. ROGER O. MCCLELLAN, ADVISOR, TOXICOLOGY AND HUMAN HEALTH RISK ANALYSIS

Major Points of Testimony of Roger O. McClellan—October 4, 2011

- *Clean Air Act* is primary National Statute governing air quality issues in the U.S.A. The CAA requires the Administrator of the U.S. EPA to establish primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards for six criteria pollutants with science-based criteria to be reviewed every five years.
- Primary NAAQS are to be established by the EPA Administrator based on the "latest scientific knowledge" at levels "requisite to protect public health" while "allowing an adequate margin of safety" without considering the cost of implementing the standard.
- In March 2008, then-Administrator Stephen Johnson revised the Ozone NAAQS as required by the CAA using the scientific record based largely on papers published in 2005 and earlier to inform his policy judgments. He retained (a) ozone as the indicator for photochemical oxidants, (b) the averaging time of eight hours, (c) the statistical form (the standard is attained when the fourth highest eight-hour average value over a three-year period does not exceed the numerical level of the standard, and (d) reduced the level from 84 ppb to 75 ppb. In announcing his decision he noted that the Clean Air Scientific Advisory Committee had recommended the standard be set in the range of 60 to 70 ppb, advice based on a blend of science and their policy judgment.
- In January 2010, Administrator Lisa Jackson announced that she was going to "reconsider" Administrator Johnson's policy decision and set the standard in the range of 60 to 70 ppb. She based this discretionary, arbitrary and capricious action on (a) her personal opinion that if she had been in office 22 months earlier she would have made a different policy choice, and (b) wrapped herself in a "cloak of science" saying I will follow the advice of CASAC. With this proposal she abdicated the specific and exclusive authority delegated to the EPA Administrator to make the policy judgments inherent in setting the NAAQS.
- On September 2, 2011, Administrator Cass Sunstein of the Office of Information and Regulatory Affairs/OMB advised Administrator Jackson that her proposed final rule was: (a) not mandatory, produced needless uncertainty, and that her Agency was already proceeding with five-year review cycle set to conclude in March 2013, (b) that her proposed final rule was not based on the latest science, and (c) the President had instructed Mr. Sunstein to return the rule to her—"He has made it clear that he does not support finalizing the rule at this time."
- I applaud the actions of Administrator Sunstein and the President. My only regret is they did not have this "common sense" discussion with Administrator Jackson in early 2009. It would have avoided the misuse of the substantial EPA resources spent on this misadventure during 2009–2011.
- Building on recent experience in revising the NAAQS for Ozone and $PM_{2.5}$, I will comment on the NAAQS setting process and the role of CASAC.
- I will emphasize that the language of the CAA and the efforts of narrowly focused advocacy groups may not be promoting, but rather damaging, public health.
- I urge the Congress to refocus the Nation's effort on public health revising the *Clean Air Act*, to allow consideration of costs in setting NAAQS, as part of an omnibus legislative package—"Promoting Public Health" that recognizes a healthy economy with people employed is the cornerstone of a healthy population.

Good morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on the role of science in informing policy judgments on the setting of National Ambient Air Quality Standards.

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 50 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 (1988–1999) in Research Triangle Park, NC, and the Lovelace Inhalation Toxicology Research Institute (1966–1988) in Albuquerque, NM. Both organizations, under my leadership, earned an international reputation for developing scientific information undergirding occupational and environmental health 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, 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 Panel that advised on the 2006 revision of the Particulate Matter MAAQS. 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. However, I closely followed the current NAAQS Ozone review process from its inception in September 2000 to present. The testimony I offer today reflects my own views on that review process and the science used to inform the policy judgments made in revising the NAAQS for Ozone. Attachment 2 is a reprint of a recent paper I authored entitled "Role of Science and Judgment in Setting National Ambient Air Quality Standards: How low is low enough?", *Air Quality and Atmospheric Health* (published online: 01 June 2011).

EPA Administrator Johnson's March 2008 Decision

This morning I would like to comment on the role of science and judgment in the "Final Rule for the National Ambient Air Quality Standard for Ozone" announced on March 12, 2008, by EPA Administrator Stephen Johnson. That Final Rule revises the 1997 Standard and concludes a process begun in September 2000. Throughout the review process, there was debate over the numerical level of a revised standard. In my view, much of the debate was premature and focused on the outcome desired by various parties—a lowering of the ozone standard—even before the review of the science was complete. That resulted in a blurring of the boundary between the role of science and judgment in the setting of the standard.

As I will discuss later, Administrator Lisa Jackson took advantage of the CASAC's blended science and policy advice to initiate in January 2010 reconsideration of the March 2008 decision of then-Administrator Johnson.

As required by a Court Decree, the EPA published a Proposed Rule on July 11, 2007, and requested public comments on anticipated action in issuing a Final Rule for the ozone standard. Release of the Proposed Rule intensified the debate over the numerical level of the standard and continued to blur the distinction between science and judgment in the setting of the standard. Numerous comments were submitted to the official ozone docket. I submitted my personal comments to the ozone docket and also joined with nine of my scientific colleagues in submitting a document—"Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone" to the Docket. The debate over the numerical level of the standard continues even today as evidenced by this Hearing.

Much of the debate failed to acknowledge that the setting of the standard involves policy judgments informed by science. The debate has included repeated reference to the Clean Air Scientific Advisory Committee (CASAC) Ozone Panel recommendation that the primary standard be set within a specific narrow numerical range, i.e., 0.060–0.070 ppm. In my opinion, the CASAC Ozone Panel moved from the science arena into the policy arena in advocating an upper bright line value of 0.070 ppm for the primary standard. That value represents the personal judgment of the Ozone Panel Members, not just their interpretation of the science. It is my opinion, the CASAC Ozone Panel never adequately communicated the extent to which the recommendations they communicated to the Administrator represented both their interpretation of the science and their personal policy judgments on the numerical level of the standard.

The EPA Administrator, under the authority of the *Clean Air Act*, has the *exclusive responsibility and authority* for making policy judgments, informed by science, in setting the ozone standard. Supreme Court Justice Stephen Breyer, in the landmark case *Whitman* v. *American Trucking Association* (531 U.S. 457, 2001), offered "common sense" guidance for setting the standards for criteria pollutants such as ozone (Attachment 3). Justice Breyer expressed the opinion that while the Administrator cannot consider cost in setting air quality standards for the criteria pollutants, the EPA Administrator need not set standards at zero risk. He advised the Administrator to use judgment in a "comparative health" context when "deciding what risks are acceptable in the world in which we live."

In short, Justice Breyer recognized that everyday life carries with it a variety of risks. Justice Breyer's opinion provides "common sense" guidance for deciding how low is low enough in setting air quality standards—the numerical level of the standard and the associated acceptable risk level, even if not specifically articulated, are policy judgments that should be informed by science. In my opinion, the Administrator could have made a policy judgment, informed by science, with selection of a numerical value for the ozone primary standard as high as the 1997 primary stand-

ard of 0.08 ppm. His selection of a lower value was consistent with the original advice of his own staff—0.075 ppm up to a level slightly below the current standard.

In my own comments to the Ozone Docket, I reviewed the science available on the health effects of ozone. In my comments, I noted the substantial uncertainty and variability in the findings of an increase in common health effects with ozone exposure in the range of the current standard and below. These scientific uncertainties were also detailed in the comments I and nine of my colleagues submitted to the Docket. Both sets of comments also emphasized that the selection of any specific numerical standard is a policy judgment informed by science.

The CASAC Ozone Panel, in proposing a bright line upper limit of 0.070 ppm, offered their collective judgment on, in the words of Justice Breyer—"what risks are acceptable in the world in which we live." The CASAC was advancing their collective policy choice; it should not be postured as being exclusively science based. Science alone can never provide a basis for deciding how low is low enough; policy judgments are always required in deciding "what risks are acceptable." Any specific numerical value for the Standard has an associated implied "acceptable risk value," even if the level of acceptable risk has not been explicitly stated.

The CASAC Ozone Panel's letter to the Administrator dated April 7, 2008, commenting on the Final Rule, continues to suggest that somehow science and scientists alone can establish the appropriate numerical level of the NAAQS for ozone. In that letter, the CASAC Ozone Panel again failed to clarify the distinction between their interpretations of the science *and* their policy judgment in offering an opinion on the numerical level of the ozone standard. The Panel should have clearly acknowledged that the numerical level they have advocated reflects their personal policy preferences. Likewise, in arguing for "further lowering the national ambient ozone standards," the Panel fails to acknowledge that this is a collective wish that goes well beyond considering just the available scientific information. How low is low enough for the ozone standard is ultimately a policy judgment informed by scientific information and analysis. The *Clean Air Act* clearly specifies that the EPA Administrator has the exclusive authority and responsibility for using judgment in the setting of the standard.

Without question, the Administrator, in setting the standard, should consider scientific advice received from many parties, including the special advice provided by the Clean Air Scientific Advisory Committee. However, it is clear that the *Clean Air Act* calls for an Advisory Committee and not a Clean Air *Standard Setting* Committee. This places a special responsibility on the Committee to distinguish between their scientific advice and their personal policy judgments as to the numerical level of the Standard.

It is noteworthy that the March 2008 Final Rule states—"the Administrator observes that he reaches a different policy judgment than the CASAC Panel based on apparently placing different weight in two areas:—" The Final Rule goes on to detail these differences. The Rule goes on to state—"and fully considering the scientific and policy views of CASAC, the Administrator has decided to revise the level of the primary eight-hour O_3 standard to 0.075 ppm." Without question, the Final Rule clearly acknowledges that the CASAC Ozone Panel offered both their scientific and policy views. It is unfortunate that the CASAC Ozone Panel did not make this important distinction in its communications to the Administrator in their public statements on the Final Rule.

Administrator Jackson's Misadventure

During 2009 there were rumors that the President Obama/Administrator Lisa Jackson Administration was going to "fast track" a "reconsideration" of the March 2008 Ozone NAAQS issued by then-Administrator Stephen Johnson. Thus, it was not surprising when Administrator Jackson on January 19, 2010, announced a proposed "reconsideration" Ozone NAAQS to be based on the record used to set the standard in March 2008. This included the science used for the March 2008 policy decisions, scientific papers which had been published primarily in 2005 or earlier. By initiating the "reconsideration" action, Administrator Jackson was in essence saying—"if I had been in office in March 2008 (nearly a year before being appointed and confirmed), I would have made a different policy judgment call." In my opinion, Administrator Jackson's action was totally discretionary, arbitrary, capricious and without precedent. I know of many NAAQS that have been revised by EPA Administrators in accordance with the *Clean Air Act* and using EPA's now well-established formal rulemaking process. I know of no NAAQS established by a previous Administrator that has been "reconsidered" by a new Administrator based on the old and aging record.

In announcing the "reconsideration" proposal (EPA, 2010) Administrator Jackson put on the "cloak of science" and said that she would set the "reconsideration" standard in the range of 60 to 70 ppb following the advice of the CASAC Ozone Panel. In taking this course, she ignored the documented record of previous Administrator Johnson who noted that the advice of the CASAC Panel was a blend of science and policy. In the fall of 2008, the EPA was already initiating action on the next review of the Ozone NAAQS (Martin, 2008). In initiating the next review, it was noted that the CASAC advice on the previous review was "a mixture of scientific and policy considerations." By proceeding with the "reconsideration" proposal based exclusively on the advice of the CASAC Panel, Administrator Jackson abdicated her responsibilities under the *Clean Air Act* to use her judgment in the setting of NAAQS.

The "fast track" reconsideration proposal turned out to be on a slow track with the target date for release of the final rule repeatedly revised. My suspicion was that Administrator Jackson and her senior advisors were continually spinning the "Ozone Science Kaleidoscope" in an attempt to have the science justify a specific numerical level. Indeed, in January 2011, Administrator Jackson went back to CASAC and asked for yet another opinion on the setting of the ozone NAAQS. The CASAC Panel had a difficult time dealing with this serious question for several reasons.

First, the CASAC members found it difficult to offer an opinion on the old science since many of them were already involved in reviewing the new science that would inform policy judgments on potential revision of an Ozone NAAQS in March 2013. Second, the CASAC Panel meetings were actually teleconferences. With about 20 "official" participants such teleconferences are much like a "Tower of Babylon." The third issue was the challenge of separating the Panel members' views of the science from their personal policy preferences. The CASAC Chair, Dr. Jonathan Samet, wisely offered the following summary comment to Administrator Jackson in his letter dated March 30, 2011. Dr. Samet wisely noted that establishing a margin of safety was apparently a blend of science and policy. I offered comments to Administrator Jackson on Comments on EPA-CASAC-11-004 Clean Air Scientific Advisory Committee (CASAC) Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standards (Attachment 4).

Apparently Administrator Jackson and her senior advisors spun the "Ozone Science Kaleidoscope" without a firm endorsement of CASAC and in mid-summer sent forward a final rule for review by OMB's Office of Information and Regulatory Affairs. Administrator Jackson has testified that she had proposed 70 ppb. I have seen no indication as to specifics of a revised Secondary Standard. It is important to recognize that the CASAC Ozone Panel (Henderson, 2008) in a letter dated April 7, 2008, based on a meeting scheduled even before then Administrator Johnson had issued a final rule protested both the Primary and Secondary Standard. They also expressed their displeasure with the involvement of then-President Bush and Susan Dudley, who then headed OMB's Office of Information and Regulatory Affairs. Such involvement was not a surprise to students of the history of the NAAQS process. President Clinton conferred with the EPA Administrator Carol Browner on the Ozone and Particulate Matter NAAQS revisions in 1997.

The misadventure of Administrator Jackson with the "reconsideration" Ozone NAAQS was brought to a close on September 2, 2011. The legal basis for the decision to abandon the "reconsideration" proposal is contained in a memo from Cass Sunstein, Administrator of the Office of Information and Regulating Affairs within OMB (Sunstein, 2011) (Attachment 5). In his memo, he notes the proposed final rule was (a) not mandatory and produced needless uncertainty and that his Agency was already proceeding with the next review that should be concluded in March 2013, (b) her proposed final rule was not based on the latest science, recall the record is largely based on pre-2006 scientific publications, and (c) the President had advised Mr. Sunstein to return the proposal to Administrator Jackson—"He has made it clear that he does not support finalizing the rule at this time."

I applaud the actions of Mr. Sunstein and President Obama for making a sound common sense decision. My only regret is that the key parties had not conferred in early 2009 and never have launched this misadventure that wasted valuable EPA resources and those of many other interested parties. In this time of crisis, the scarce resources could have been used better on other endeavors. The really good news is that a potential precedent setting actions did not take place. It is hard to imagine the uncertainty and chaos that would occur if every change in Presidential Administration were to be accompanied by a new EPA Administrator that would "reconsider" the policy judgments of the previous EPA Administrator.

The Wrong Scientific and Policy Focus

Remarkable progress has been made in improving air quality in the United States during the last four decades using the various regulatory tools provided by the *Clean Air Act* including the establishment of NAAQS. Clean air is automatically equated with better health. Every lowering of a NAAQS for each of the criteria pollutants has been justified on the basis of health benefits.

It has been argued by some that a linear relationship, without a threshold, exists between ambient concentrations of criteria pollutants and increased risk of morbidity and mortality over and above the baseline morbidity or mortality rate. Some scientists have argued that the absence of a threshold and a linear concentration-response relationship extends to background concentrations. Using that logic, which I do not necessarily agree with, it can be argued that health benefits result from every reduction in concentration, even reductions in background. With this flawed logic and a prohibition in considering cost in setting NAAQS the answer to how low is low enough becomes zero. That is hardly realistic and certainly does not meet the common sense comparative health approach advanced by Supreme Court Justice Breyer.

In my view, the USA is reaching a point of diminishing returns in setting the NAAQS at lower and lower concentrations with each review and treating each reduction as a success story for public health. In examining this viewpoint, it is important to remember that each NAAQS is *a federal goal*. The achievement of the goals is by and large left to the States through the development of State Implementation Plans and their actual implementation and, finally, to actions on the part of private firms and the public.

In my opinion, this approach is flawed in that it fails to recognize any untoward consequences of setting lower standards and attempting to attain them. I submit the untoward consequences may be substantial. Let me illustrate by discussing health impacts using a common metric-all-cause mortality. Major population studies have suggested that a 1 $\mu g/m^3$ increase in particulate matter—2.5 micron size causes a 0.5% increase in mortality. You may not recognize the 0.5% value because it is usually expressed as 2.5% increase per 5 $\mu g/m^3$ of $PM_{2.5}$. In reality, 5 to 10 $\mu g/m^3$ is the background level for PM2.5 in most areas in the U.S.A. Does it make sense to talk about a 5 $\mu g/m^3$ change in PM2.5? In my opinion, *No*! Thus, I use a more realistic 1 $\mu g/m^3$ change.

Some population studies suggest a 0.24% change in mortality for a 5 ppb change in eight-hour ozone concentration. Again, you may not recognize the value because it has frequently been presented as 3.6% for a 75 ppb change in eight-hour ozone. This is hardly a realistic presentation recognizing background levels for the eight-hour highest ozone concentrations approaches 60 ppb, the level simulated by models when all man-made ozone precursors are shut off. I view a 5 ppb shift in ozone as being more realistic.

Let me now turn to a real risk factor—socioeconomic status (SES). The ratio of the mortality rate for all-cause mortality for men in the lowest quartile of SES over the top quartile was found to be 2.02 by Steenland et al. (2004). In other words, a doubling of the mortality rate by dropping from the top quartile to the bottom quartile. Put another way, moving to the second quartile from the lowest quartile reduced the ratio to 1.69 and a move from the second to the third quartile reduced the ratio to 1.25. Socioeconomic status matters—employment and jobs matter. If the U.S. wants to improve the health of the Americans, we need to create employment—JOBS.

Setting aside the issue of socioeconomic status, does it make sense to keep pursuing risk factors that only contribute marginally to our overall burden of disease? I think the answer is *No*! Recognizing the small estimated burden of disease attributed to air pollution, it would appear to make more sense to pursue what are the major factors that contribute to the baseline incidence of disease. For example, there is appropriate increasing concern for rising asthma rates. However, when it is recognized that air pollution decreased substantially while asthma rates increased, it would appear that the focus on air pollution and asthma is misdirected.

A Path Forward

I am increasingly concerned that our policy for advancing public health is being driven by advocacy groups with narrow interests. Perhaps it is time for all the advocacy groups to step back and ask what can be done to further improve the health of all Americans. A starting point is to recognize that the steady progress made in improving the health of Americans over the last half century has been driven by a strong economy that provided jobs and improving income. Perhaps the answer to

the question of how low is low enough for each of the NAAQS is low enough for now. I suggest it is appropriate for time out on moving the goal posts.

I urge the Congress to refocus the nation's effort on public health revising the *Clean Air Act*, to allow consideration of costs in setting NAAQS, as part of an omnibus legislative package—"Promoting Public Health" that recognizes a healthy economy with people employed is the cornerstone of a healthy population.

References

McClellan, R. O. Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, *Federal Register*, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818–37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.

Brauer, M., Frampton, M.W., Koutrakis, P., McClellan, R.O., McDonnell, W.F., Moolgavkar, S., North, D. W., Smith, A.E., Smith, R.L., Utell, M.J. Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone. Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, *Federal Register*, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818–37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.

McClellan, R.O., "Written Statement for Consideration by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel" at the Panel's Teleconference Meeting on February 18, 2011 (Prepared on February 7, 2011).

Chairman HARRIS. Thank you very much, Dr. McClellan.

I now recognize our second witness, Dr. George Thurston, a Professor at New York University School of Medicine. Dr. Thurston.

STATEMENT OF DR. GEORGE THURSTON, PROFESSOR, NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Dr. THURSTON. Good morning.

The evidence is clear, as Mr. Miller was saying, the adverse health consequences of breathing polluted air are well documented in the published medical and scientific literature, even at levels we experience today. This human evidence includes impacts revealed by epidemiologic studies, natural experiments and controlled chamber exposure experiments, also including consistent associations between air pollution exposure and increases in risk of adverse health impacts across a wide range of human health outcomes including illness and death.

These effects of air pollution include decreased lung function, the ability of a person to breathe air in and out freely, more frequent asthma symptoms, increased numbers of asthma and heart attacks, more frequent emergency department visits, additional hospital admissions, and increased numbers of premature deaths, which, by the way, all have a huge economic impact.

One of the air pollutants most carefully studied is fine particulate matter, or $PM_{2.5}$, which are particles that are so small that they can become lodged deep in the lung when they are breathed in and they can cause a variety of health problems. For example, two of the larger cohort studies of air pollution and death, the Harvard Six Cities study and the American Cancer Society study, both of which I was involved in, have demonstrated greater risk of premature death in more polluted cities as compared to studies with cleaner air as demonstrated in figure one of my testimony that I submitted.

Another major air pollution health threat is ozone, as Mr. McClellan was discussing. Ozone is a highly irritant gas that is formed in our atmosphere in the presence of sunlight and other precursor air pollutants such as nitrogen oxides and hydrocarbons

that come from trucks and buses and cars and power plants and various pollution sources. In my own research, I found that ozone air pollution is associated with increased numbers of respiratory hospital admissions and death. But these effects of ozone are only the tip of the iceberg of adverse health effects associated with this pollutant. Ozone is especially a problem for children with asthma. My own asthma camp study results have shown that children have more asthma attacks on higher ozone air pollution days in the summer. The air pollution health effects associated indicated by epidemiological studies are supported by a large body of data from controlled human exposure studies giving consistent results and demonstrating pathways by which air pollution can damage the human body when it is breathed.

It has also been well shown that reducing pollution in the air can result in health benefits for the public. For example, Arden Pope conducted a compelling study of the period during the winter of 1986 and 1987 when the Geneva steel mill in Utah Valley shut down during a strike. The PM levels dropped dramatically and the hospital admissions in the valley showed the same pattern as the air pollution, decreasing dramatically during the strike as shown again in my written testimony. When pollution levels diminish, the health of the general public improves.

A recent follow-up analysis of a Harvard Six Cities study has also shown that mortality is decreased as $PM_{2.5}$ pollution decreases over time, as shown in figure three of my written testimony. Thus, recent research shows lowering of air pollution levels in the air is an effective way to improve public health.

As to the role of CASAC, the setting of the National Ambient Air Quality Standards, or NAAQS, is an essential mandate of the *Clean Air Act*. The Clean Air Science Advisory Committee was authorized by Congress to provide the EPA Administrator with independent advice on the setting of the NAAQS. This process has worked well and has led to the application of sound science to the setting of the U.S. NAAQS standards to protect the health of the American people.

In conclusion, the science is sound and the results are clear. Cleaning our air reduces air pollution and health impacts, lowers our health care costs and saves lives. With the independent advice of CASAC, the EPA's regulatory control of ambient air pollution has led to reductions in both air pollutant exposures and health risks to the American people. This has caused the public to enjoy associated health benefits including decreased asthma attacks, fewer hospital admissions, fewer heart attacks, and increased length and quality of life.

Thank you for this opportunity to testify on this important issue.

[The prepared statement of Dr. Thurston follows:]

PREPARED STATEMENT OF DR. GEORGE THURSTON,
PROFESSOR, NEW YORK UNIVERSITY SCHOOL OF MEDICINE

I am George Thurston, a tenured Professor of Environmental Medicine at the New York University (NYU) School of Medicine. My scientific research involves investigations of the human health effects of air pollution. I have served on the U.S. EPA's Clean Air Science Advisory Committee (CASAC) Panel, and have been a contributing author to EPA's Integrated Science Assessment (ISA) documents.

I am also a member of the National Institute of Environmental Health Sciences' (NIEHS) Center at the NYU Institute of Environmental Medicine. One goal of this Center is to provide an impartial scientific resource on environmental health issues to the public and decision makers, and that is my purpose in speaking to you at this hearing.

The adverse health consequences of breathing polluted air are well documented in the published medical and scientific literature. During the past decades, medical research examining air pollution and public health has shown that air pollution causes a host of serious adverse human health effects. The human evidence includes impacts revealed by epidemiologic studies, natural experiments and controlled chamber exposures, all showing consistent associations between air pollution and increases in adverse health impacts across a wide range of human health outcomes, including illness and death.

Epidemiological Evidence of Air Pollution Effects on Health

Observational epidemiology studies provide the most compelling and consistent evidence of the adverse effects of air pollution. "Epidemiology" is literally "the study of epidemics," but includes all statistical investigations of human health and potentially causal factors of good or ill health. In the case of air pollution, such studies follow people as they undergo varying real-life exposures to pollution over time, or from one place to another, and then statistically intercompare the health impacts that occur in these populations when higher (versus lower) exposures to pollution are experienced. In such studies, risks are often reported in terms of a Relative Risk (RR) of illness, wherein a RR=1.0 is an indication of no change in risk after exposure, while a RR>1.0 indicates an increase in health problems after pollution exposure, and that such exposure is damaging to health.

These epidemiological investigations are of two types: (1) population-based studies, in which an entire city's population might be considered in the analysis; and (2) cohort studies, in which selected individuals, such as a group of asthmatics, are considered. Both of these types of epidemiologic studies have confirmed associations between air pollution exposures and increasing numbers of adverse impacts, including:

- decreased lung function (a measure of our ability to breathe freely);
- more frequent asthma symptoms;
- increased numbers of asthma and heart attacks;
- more frequent emergency department visits;
- additional hospital admissions; and
- increased numbers of premature deaths.

The fact that the effects of air pollution have been shown so consistently for so many health endpoints, and in so many places, indicates these associations to be causal.

Particulate Matter Air Pollution

One of the air pollutants most carefully studied is particulate matter (PM). Fine particles ($PM_{2.5}$), such as those that result from power plants and diesel trucks, defeat the defensive mechanisms of the lung, and can become lodged deep in the lung where they can cause a variety of health problems. New evidence indicates that short-term exposures to air pollution cause both respiratory and cardiac effects, including more heart attacks. In addition, my own research indicates that long-term exposure to fine particles increases premature mortality, and such exposures in the general population have been estimated to take years from the life expectancy of people living in our most polluted cities, relative to those living in cleaner cities (e.g., see Brunekreef, 1997).

$PM_{2.5}$ air pollution may be emitted directly from tailpipes and smokestacks (known as "primary" particulate matter), but much $PM_{2.5}$ that we breathe comes from the conversion of gaseous pollution emissions, such as sulfur dioxide, in the atmosphere to form "secondary" $PM_{2.5}$.

The hazards of PM air pollution have become particularly clear in the past two decades of research. Two of the largest studies on air pollution and death, the Harvard Six Cities Study, published in 1993, followed by the American Cancer Society (ACS) Study report in 1995, have demonstrated greater risk of premature death in higher PM cities compared to cities with cleaner air. The Harvard Six Cities study monitored air pollution and tracked mortality in six U.S. cities and discovered a 25 percent increased risk of death in the most polluted city (Dockery *et al*., 1993). Simi-

larly, the ACS study examined half a million people in over 150 metropolitan areas throughout the United States and found a 17 percent increase in risk of mortality between the city with the least PM and the city with the highest levels of this pollution (Pope *et al*., 1995). The results of these two landmark studies were challenged by industry, resulting in an independent reanalysis by the Health Effects Institute (HEI)-funded by industry and EPA. HEI found the results to be robust, and confirmed the relationships documented by the original investigators (Krewski *et al*., 2002).

More recent follow-up analyses of the Harvard and ACS studies have now considered longer records of time, and have confirmed and extended the conclusions from these two major studies. Indeed, a recent National Institute of Environmental Health Sciences (NIEHS)-funded extension of the ACS study, of which I was Principal Investigator, strengthens the original conclusions of the ACS study and, importantly, now links increased risk of lung cancer to long-term exposure to particulate matter (Pope *et al*., 2002), as shown in Figure 1.

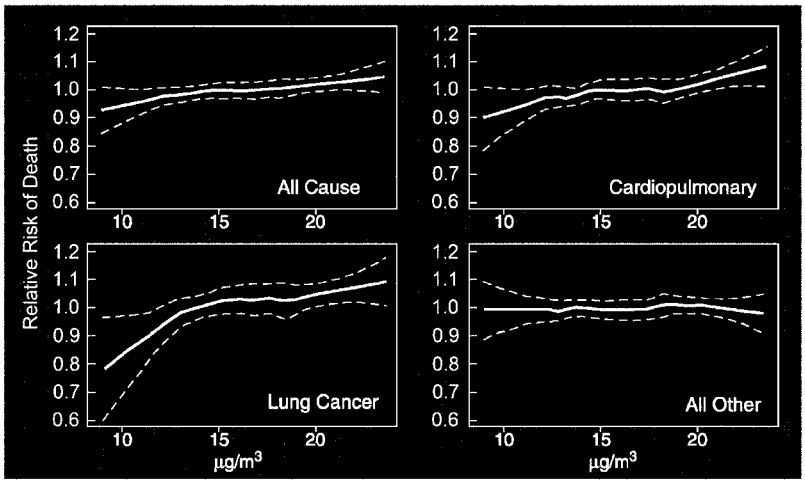

Figure 1. Results from the extended ACS *JAMA* Study showing increased risk of All Cause, Cardiopulmonary, and Lung Cancer Death with rising $PM_{2.5}$ air pollution. (adapted from Pope et al, 2002).

Ozone Air Pollution

Another major air pollution health threat, ozone (O_3), is a highly irritant gas that is formed in our atmosphere in the presence of sunlight from other "precursor" air pollutants, including nitrogen oxides and hydrocarbons. These precursor pollutants are emitted by pollution sources including automobiles, electric power plants, and industry.

In my own research, I have found that ozone air pollution is associated with increased numbers of respiratory hospital admissions in U.S. and Canadian cities. But these effects of ozone are only the "tip of the iceberg" of adverse effects associated with this pollutant, and they are best viewed as indicators of the much broader spectrum of adverse health effects being experienced by the public today as a result of air pollution exposures, such as more restricted activity days and doctors' visits.

Airway inflammation induced by ozone is especially a problem for children and adults with asthma, as it makes them more susceptible to having asthma attacks. My own asthma camp results have shown that children have more asthma attacks on high ozone days in the summer (Thurston *et al*., 1997). In addition, recent controlled human studies have indicated that prior exposure to ozone enhances the reactivity of asthmatics to aeroallergens, such as pollens, which can trigger asthma attacks. In addition, the increased inflammation and diminished immune system

ozone effects in the lung can make the elderly more susceptible to pneumonia, a major cause of illness and death in this age group.

Controlled Exposure Studies

The air pollution—health effects associations indicated by epidemiologic studies are supported by a large body of data from controlled exposure studies giving consistent and/or supportive results, and demonstrating pathways by which ozone can damage the human body when it is breathed. For example, clinical studies have demonstrated ozone-related decreases in lung function, increased frequencies of respiratory symptoms, heightened airway hyper-responsiveness, and cellular and biochemical evidence of lung inflammation in healthy exercising adults exposed to ozone. Similarly, animal exposures to combustion-related $PM_{2.5}$ have been shown to have significant adverse effects on the lung, including diminished respiratory defense mechanisms, opening the lung to illness from other causes.

The Benefits of Cleaner Air

Most published studies evaluate whether rising air pollution levels worsen health, but it has also been shown that reducing pollution in the air can result in health benefits to the public. For example, Pope (1989) conducted a compelling study clearly showing that, when pollution levels diminish, the health of the general public improves. He investigated a period during the winter of 1986–87 when the Geneva Steel mill in the Utah Valley shut down during a strike. The PM levels dropped dramatically in that strike-year winter, as opposed to the winters preceding and following when the steel mill was in operation. As shown in Figure 2 below, hospital admissions in the valley showed the same pattern as the PM air pollution, decreasing dramatically during the strike. As a control, Pope also examined the pollution and hospital admissions records in nearby Cache Valley, where the mill's pollution was not a factor, and no such drop in respiratory admissions was seen, showing that the drop in admissions in the Utah Valley was not due to some cause other than the reduction in the air pollution levels.

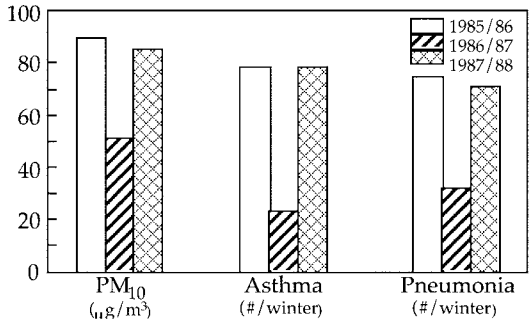

Figure 2. Decreasing PM pollution lowered the number of children's hospital admissions (Source: Pope, 1989).

A more recent study considers a broadly relevant case showing the benefits of cleaner air. During the Atlanta Summer Olympics of 1996, traffic-related ozone and PM declined significantly as a result of the alternative mass transportation strategy implemented to reduce road traffic during the Games (Friedman et al., 2001). These improvements were correlated with changes in the rate of children's hospital admissions. Compared to a baseline period, traffic-related ozone and PM levels declined by 28% and 16%, respectively. Concentrations of both PM and ozone also rose noticeably after the end of the Olympics. The study showed a significant reduction in asthma events associated with these pollution improvements. This study indicates that improvements in acute air pollution can provide immediate public health benefits.

Furthermore, a recent follow-up analysis of the Harvard Six Cities Study discussed earlier (Dockery *et al.*, 1993) has shown that mortality was decreased by lowering pollution (Laden *et al.*, 2006). An extended analysis of the Harvard Six Cities Study (to include follow-up through 1990) has now shown that reductions in long-

term ambient PM pollution results in concomitant reductions in the health risks associated with PM. As shown in Figure 3, large reductions in PM at Harvard study cities have resulted in likewise large reductions in the relative risk (RR) of mortality in those cities: Steubenville, OH (S), Harriman, TN (H), St. Louis, MO (L), and Watertown, MA (W). The authors found that, for each decrease of 1 $\mu g/m^3$ in averge $PM_{2.5}$, the overall death rate from causes such as cardiovascular disease, respiratory illness and lung cancer decreased by some 3 percent, while also extending the lives of study subjects. Thus, although we still carry very large health risks in the United States from our present levels of air pollution, amounting to tens of thousands of premature deaths per year, recent research shows that the lowering of air pollution levels in the air is an effective way to improve public health.

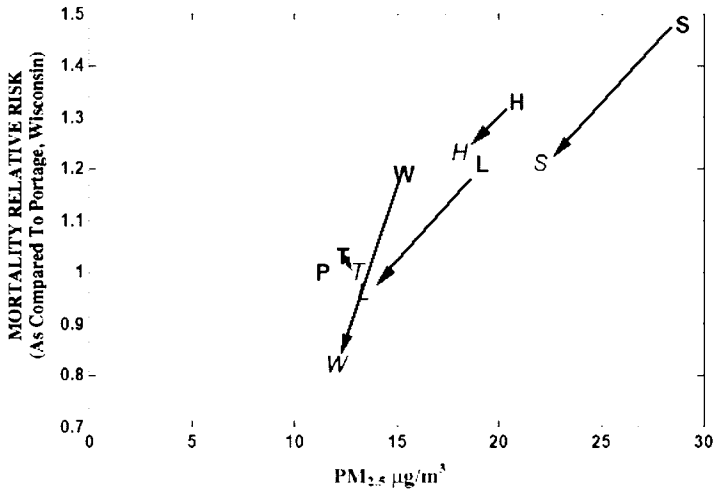

Figure 3. Reducing long-term PM exposure reduces mortality risk
(adapted from Laden et al., 2006)

The evidence is clear and consistent: air pollution is adversely affecting the health and lives of Americans across our Nation. There is a coherence between the epidemiologic study associations and experimental study results, validating that there is indeed a cause-effect relationship between air pollution and adverse human health effects. The importance of these health effects relationships is made all the more imperative by the fact that virtually every American is directly impacted by this pollution. Cleaning the air causes improvements in public health, saving lives and improving the quality of life of all Americans.

The Role of CASAC

The setting of the National Ambient Air Quality Standards (NAAQS) is an essential mandate of the *Clean Air Act*. These NAAQS apply to "criteria" air pollutants that, in the words of the legislation, "endanger public health or welfare." At present, six pollutants are designated as criteria pollutants. The Clean Air Science Advisory Committee (CASAC) was authorized by the Congress in 1977 to aid the EPA Administrator in the setting of these NAAQS. Its members are derived largely from academia and from private sector research institutes, and are appointed by the EPA Administrator. CASAC's role is primarily to review the agency's work in the process of setting each NAAQS, which are each reviewed on an every-five-year schedule, and then to provide the EPA Administrator with independent advice on the interpretation of agency documents for the setting of the NAAQS. Most notably, CASAC reviews the agency's Integrated Science Assessment (ISA) and the Risk and Exposure Assessment (REA) that summarize the science and the policy analyses, respectively. The assessment of these pollutants individually during the CAAA approach, potentially missing effects of synergisms among the various air pollutants, combined

with the fact that not all potential health impacts can be quantified in the REA process, has likely caused the EPA to underestimate the total benefits of pollution reductions when viewed on an individual pollutant-by-pollutant basis. Despite these facts, the EPA's REA and RIA (Regulatory Impact Analysis) analyses have consistently indicated that the valuation of the health benefits of cleaner air, such as fewer hospital admissions and deaths, far outweigh the costs of applying emission controls to reduce air pollution.

Based upon the EPA ISAs, REAs, and CASAC independent expert advice on the setting of the NAAQS (usually provided as a range of possible standards), the EPA Administrator proposes an updated standard for each pollutant that can be the same, more stringent, or less stringent than the existing NAAQS standard for a criteria air pollutant. This process has generally worked well in the past, and has led to the application of sound science to the setting of the U.S. NAAQS standards to protect the health of the American public.

Conclusions

- The science is sound and the results are clear: cleaning our air reduces air pollution health impacts, lowers our health care costs, and saves lives.
- With the independent advice of CASAC, as stipulated by the Congress, the EPA's regulatory control of ambient air pollutants has led to reductions in both air pollutant exposures and health risks to the American people. This has caused the public to enjoy associated health benefits, including decreased asthma attacks, fewer hospital admissions, fewer heart attacks, and increased length and quality of life.

Thank you for the opportunity to testify on this important issue.

References

Brunekreef B. (1997) Air pollution and life expectancy: is there a relation? *Occup Environ Med*. Nov; 54(11): 781–4.

Dockery DW, Pope CA 3rd, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG Jr, Speizer FE. (1993) An association between air pollution and mortality in six U.S. cities. *N Engl J Med*. Dec 9; 329(24):1753–9.

Krewski, D. et al. (2000) Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality: Investigators' Report Part I: Replication and Validation. Health Effects Institute, Cambridge, MA.

Laden F, Schwartz J, Speizer FE, Dockery DW. (2006) Reduction in fine particulate air pollution and mortality: Extended follow-up of the Harvard Six Cities study. *Am J Respir Crit Care Med*., Mar 15; 173(6):667–72.

Pope CA 3rd. (1989). Respiratory disease associated with community air pollution and a steelmill, Utah Valley. *Am J Public Health*. 1989 May; 79(5):623–8.

Pope CA 3rd, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, Speizer FE, Heath CW Jr. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. *Am JRespir Crit Care Med*. 1995 Mar; 151(3 Pt 1): 669–74.

Pope CA III, Burnett RT, Thun MJ, Calle EE, Krewski D, Ito K, and Thurston, GD. (2002). Lung Cancer, Cardiopulmonary Mortality and Long-Term Exposure to Fine Particulate Air Pollution. *Journal of the American Medical Association (JAMA)*. March 6, 2002, Vol. 287, No. 9, pp. 1132–1141.

Thurston, G. D., Lippmann, M., Scott, M.B., and; Fine, J.M. Summertime haze air pollution and children with asthma. *Am. J. Respir. and Crit. Care Med*. 155:654–660 (1997).

Chairman HARRIS. Thank you very much, Dr. Thurston.

I now recognize our next witnesses, Dr. Michael Honeycutt, Chief Toxicologist for the Texas Commission on Environmental Quality. Dr. Honeycutt.

STATEMENT OF DR. MICHAEL HONEYCUTT, CHIEF TOXICOLOGIST, TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Dr. HONEYCUTT. Good morning, Mr. Chairman and Members of the Committee. I have submitted more detailed written comments on the science behind the ozone and PM NAAQS and the Utility MACT, but I will touch on the highlights right now.

Regarding ozone, I would first like to talk about the concept of personal exposure. As regulators, we set health protective standards for chemicals in outdoor air and we measure those pollutants at outdoor monitors. However, it is a well-established fact that we are not exposed to ozone concentrations at concentrations measured at outdoor monitors. This is because Americans spend on average 90 percent of our time indoors, especially on hot days when ozone levels are at their highest. Because ozone is formed in sunlight, ozone concentrations are always much lower indoors than outdoors and in fact are practically zero in air conditioned buildings. Keeping that in mind, I want to talk briefly about the ecological epidemiology studies that EPA is using as the primary basis for the ozone NAAQS.

Ecological epidemiology studies are exploratory studies designed to look for correlations. They are supposed to be followed up by more rigorous epidemiology studies to see if the correlations are real. These studies are not supposed to be used quantitatively and they are certainly not rigorous enough to set environmental policy. Statisticians can run data through elegant models to try to find statistically significant correlations but the output of those models is only as good as the input, and any researcher worth their salt will tell you that correlation is not causation.

With the ozone NAAQS, EPA has set environmental policy based on these ecological epidemiology studies. Specifically, the studies gathered death certificates for people who died from non-accidental causes including cancer, liver disease or any other disease. The assumption is that breathing ozone made them die earlier than they would have otherwise. The researchers correlated the outdoor ozone levels, usually from the highest monitor in the city, with various time periods just before the time of death for these thousands of people. Using the highest monitor or even an average value in the city is not scientific since ozone levels can vary tremendously across a city. These studies did not look at whether the people who died were actually outdoors for eight hours just prior to their death to actually breathe that ozone. Even if we assume that these ill people spent eight hours outdoors just before they died, were they near the monitor the EPA assumed they were? Were they exposed to other pollutants during the day? Did they take their medications that day? There are a whole host of common sense questions that go unanswered in these studies. Simply put, these studies cannot tell us if ozone caused these deaths or if these people died prematurely, much less tell us what level of ozone caused their premature death.

EPA also used clinical studies conducted by Professor William Adams, formerly from USC, in setting the ozone NAAQS. EPA reanalyzed his data inappropriately and called the mild effects he observed adverse.

Turning to the Utility MACT, EPA themselves determined that the rule will not have an effect on mercury levels in fish in America's watersheds. EPA continues to overstate the health risk of lower IQ and heart disease from mercury while ignoring the very well-demonstrated health benefits of eating seafood. EPA used a study known as the Faroe Island study to set their safe level for mercury where the mothers ate whale meat and blubber contaminated with PCBs in addition to eating the fish. The Faroe Island infants ingested 600 times EPA safe dose of PCBs. I will say it again: 600 times EPA safe level. The effects EPA attributed to mercury can more justifiably be attributed to the PCBs. A similar study in the Seychelles Islands that did not include PCB exposures was essentially negative. EPA ignores the fact that Japanese eat 10 times more fish than Americans do and have higher levels of mercury in their blood but they have lower rates of coronary heart disease and they have high scores on their IQ tests. Methyl mercury is a toxic chemical but scientific data overwhelmingly do not support EPA's position on the risk of mercury. In fact, EPA may have the most conservative safe level for mercury in the world. The FDA, the ATSDR, the World Health Organization and Canada all have set a higher safe level for mercury, and EPA still uses decade-old data whenever they say that six percent of the women in the United States have unsafe levels of mercury in their blood. Newer data time and time again clearly shows this isn't the case.

Thank you for the opportunity to testify.

[The prepared statement of Mr. Honeycutt follows:]

PREPARED STATEMENT OF DR. MICHAEL HONEYCUTT,
CHIEF TOXICOLOGIST, TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Main Conclusions

On behalf of the Texas Commission on Environmental Quality (TCEQ), I disagree with the United States Environmental Protection Agency's (EPA) proposed range of values for the eight-hour ozone and PM standards because of uncertainties relating ambient concentrations to personal exposures and limitations of the epidemiological and clinical studies used as the basis of the revisions. The TCEQ strongly recommends that EPA use robust scientific data as the basis for the ozone and PM standards and Utility MACT, and more meaningful consideration of risk management issues in its final policy decisions.

The roles of uncertainty and bias in EPA's assessments have been severely downplayed and should be reexamined. This is particularly true in EPA's analysis of personal exposure. For ozone, EPA relies on studies that estimate personal exposure (the amount of ozone a person actually breathes) by using ambient monitoring data, which oversimplifies personal exposure by assuming that ambient monitoring data accurately reflects personal exposure. Further, EPA doesn't acknowledge or account for this potential overestimate in their standard calculations. Also, it is essential that EPA clearly discuss the uncertainties associated with adverse health effects reported in both ecological epidemiology and clinical studies. These uncertainties should also be clearly communicated in publicly accessible documents in consideration of new standards.

EPA should be more critical and conscientious in its selection of studies they use to calculate proposed numerical standards. Specifically, EPA should consider ecological epidemiology studies in a more broad, supportive context, rather than as the primary basis for calculating air quality standards. Ecological epidemiology studies are not scientifically rigorous enough to draw conclusions about the cause of health effects identified in the studies for ozone or any other pollutant and are not suitable for policy decisions. As with all observational studies, the results may provide valid areas for further inquiry and be informative, but should not be considered conclusory. EPA's criteria for the selection of key studies should emphasize not only statistical significance but also biological significance of the observed adverse health ef-

fects Furthermore, EPA should focus on the entire weight of evidence of more robust epidemiology and toxicology studies for the basis of its policy decisions.

Finally, EPA should avoid unnecessary regulation that will not improve human health. EPA's own analysis demonstrates that the Utility MACT will not have an effect on mercury levels in fish in U.S. watersheds. EPA's claims of mercury causing lower IQ and heart disease scares the public into avoiding seafood. EPA ignores the fact that Japanese eat 10 times more fish than Americans do and have higher levels of mercury in their blood, but have lower rates of coronary heart disease and high scores on their IQ tests. To claim that a policy decision is "based on the science" without putting those decisions in appropriate context with real world implications is not just a misuse of science but causes harm to the public. It is a disservice to her citizens when government exaggerates, misstates or misleads the public about the "real" risk of environmental effects.

Ozone NAAQS

Ecological Epidemiology Studies

EPA used ecological epidemiology studies, also known as time-series analyses, as the primary basis of the most recent proposed ozone standard. Ecological epidemiology studies are observational studies designed to look for correlations. To accomplish this they examine the relationships between exposure and disease at a population level rather than on an individual level. These types of studies are intended to be followed up by more rigorous epidemiology studies to determine if the correlations are real. While ecological epidemiology studies are useful in evaluating potential associations between health effects and ambient exposures to environmental pollutants, they are severely limited due to their study design. Policy conclusions should not be based on ecological epidemiology studies for the following reasons:

- 1. *Ecological epidemiology studies are not designed to determine if ozone caused the health effects evaluated*. The assumption that ozone caused all evaluated health effects, including aggravation of asthma and premature mortality, in ecological epidemiology studies is not well-grounded in science. Ecological epidemiology studies do not collect data on when, how long, and how much exposure occurred; if exposure occurred before the health effects; or if it makes biological sense that the chemical could cause the effect. In other words, the study designs are incomplete. Scientists agree that the incomplete study design does not provide enough information to determine the actual cause of studied effects. Ecological epidemiology studies are not supposed to be used quantitatively and they certainly are not rigorous enough to set environmental policy.
- 2. *Lack of personal exposure data severely limits the utility of ecological epidemiology studies*. The issue of limited or entire absence of personal exposure data is significant. Personal exposure is a measurement of the amount of an air pollutant that a person actually breathes. In the case of air pollutants like ozone, ecological epidemiology studies rely on ambient monitoring data as a surrogate for personal exposure for percentages of people with a health issue in an area (i.e., census tract, county, or state). However, it is very unlikely that people would ever be exposed to those pollutants at concentrations measured at outdoor monitors for very long. This is partly because the average American spends 90% of his/her time indoors, especially during the heat of the summer when ozone concentrations tend to be at their highest. Ozone concentrations in most buildings are characteristically low, due to the reactive nature of ozone, the tendency of ozone to deposit on surfaces, and the ventilation systems inside buildings (McClellan et al., 2009). Other additional factors such as time spent outdoors, outdoor activity level, and weather (especially temperature and relative humidity) can dramatically change the potential for ozone exposure and the resultant estimate of risk. Therefore, ambient ozone concentrations alone do not adequately characterize, and easily overestimate, personal exposures (Sarnat et al., 2006). This position is shared by the National Academies of Science (NAS 2008) and the Clean Air Science Advisory Committee (CASAC 2006). That ecological epidemiology studies continue to derive inconsistent and vastly differing conclusions about the adverse effects of ozone is perhaps evidence of this fact.
- 3. *Ecological epidemiology studies frequently do not take into account the heterogeneity of regional air pollution and oversimplify their exposure analysis by re-*

lating health effects to only ozone. In most ecological epidemiology studies,[1] exposure is estimated to be either some statistical representation (e.g., average or weighted average) of several air monitors or concentrations at the monitor with the highest readings. This assumption oversimplifies outdoor exposure because concentrations vary across a given area. [2] Moreover, few studies fully account for simultaneous exposure to multiple other pollutants, such as particulate matter, nitrogen dioxide, and sulfur dioxide. The ratios of these pollutants can vary tremendously from region to region, making it difficult to determine which effects are related to which pollutants. This complication blurs the association between health effects and ozone exposure, as documented in recent studies. Furthermore, it has been documented in studies that the association between ozone and health effects is confounded by temperature and relative humidity (which alone can cause physical stress), and population characteristics, such as age, health status, socioeconomic status, and exercise.

- 4. *Ecological epidemiology studies have considerable uncertainty in their identification of health effects*. To determine prevalence of a health issue, epidemiologists frequently use readily available information, including hospital admissions records and death certificates, or participant surveys. In some of the ecological epidemiology studies EPA used for the proposed ozone standard, death certificates for thousands of people who died at a hospital from any non-accidental cause were compared to outdoor ozone levels from up to three days before the person died. Because of the broad selection criteria, it is highly likely that many of these people died due to non-respiratory health issues unrelated to ozone exposure. This problem is compounded when paired with the lack of personal exposure data, making it impossible to know if decedents were actually well enough to be outdoors in the days preceding their deaths. In this case, patient history records from physicians would be more reliable than hospital admission records or death certificates for determining the presence and severity of any health effects potentially caused or aggravated by ozone exposure. EPA could better serve the public trust to recognize the limitations on the information and data used and to fully consider these limitations when making policy decisions.
- 5. *Additional statistical analysis (time-series and multi-city time-series studies) further complicates the interpretation of ecological epidemiology studies*. The shortcomings of ecological epidemiology studies are compounded when researchers perform time-series studies, which try to correlate health effects collected from epidemiology studies and ambient ozone concentrations measured during the hours and days leading up to their hospital visit or death. Some studies compare even broader sets of data from multiple cities averaged over multiple years. In addition to the issues regarding uncertainty in the original ecological epidemiology study discussed previously, this additional analysis fails to take into account:

- The high degree of variability between cities, seasons, and years;
- The effect of other pollutants that contribute or cause the same effects;
- The inconsistent ambient air sample collection period between cities;
- Socioeconomic factors such as age, access to health care, etc., and
- Mortality differences among cities.

In addition, further analysis of time-series data indicates the studies are highly influenced by the type of statistical model used (often, the model showing the most health effects) and publication bias (studies showing effects are more likely to get published than those showing no effects). Due to the substantial uncertainty in these studies, policy decisions should not be based on these studies and EPA should revise its study selection criteria to use studies of higher scientific quality.

- 6. *Results of ecological epidemiology studies are inconsistent and it remains unclear if ozone is truly related to increased health effects*. Ecological epidemiology studies have provided vastly different conclusions regarding the effects of ozone on the population, with studies showing significant adverse effects, no effects, or even protective effects of ozone. In particular, one reanalysis of an ecological

[1] Many ecological epidemiology studies do not look at the area immediately around a monitor but rather at a conglomeration of several cities. For example, Bell and Dominici (2008) looked at communities, which they defined as a county or contiguous counties.

[2] EPA acknowledges the variance in ozone concentrations across a region within its state implementation planning (SIP) process by its requirements to have multiple monitors within a populated region and its requirement to further analyze unmonitored areas during the planning process.

epidemiology study frequently cited by EPA identified only six out of 95 cities evaluated with a significant correlation of mortality and ozone (Smith et al., 2009). Furthermore, although it has been repeatedly hypothesized that ozone is a potent inducer of asthma attacks, Texas Inpatient Hospital Discharge data on the numbers of hospital visits for asthma between 1999 and 2001 actually showed that people were more likely to visit the hospital for asthma during winter when ozone is at its lowest than they were in the summer when ozone concentrations are high. In a relative risk sense, cold weather and pet dander are more potent inducers of asthma hospital visits than ozone. Furthermore, results from a four-year (2000–2003) air quality study conducted by Texas A&M University and Driscoll Children's Hospital indicate hospital admissions to be weakly correlated with ambient daily maximum ozone levels.

Clinical Studies

Clinical studies expose humans to a known concentration of ozone for a known period of time and monitor their health. Although these studies do not have the significant limitations of ecological epidemiology studies, there is confusion among scientists and regulators about whether subtle clinical changes documented in the studies represent adverse effects. In its ozone reassessment, EPA failed to consider key recommendations regarding this issue and conducted a reanalysis of clinical data that was not scientifically appropriate.

- 1. *EPA should rely on biological, not just statistical, significance in identifying an adverse health effect in clinical studies*. Ambiguity exists in defining what constitutes an adverse effect on exposure to air pollution. Clinical studies evaluating health effects due to ozone exposure have mainly focused on decreases in lung function as measured by forced expiratory volume in one second (FEV1) [3] and other similar measures. Daily normal activities, exercise, and diurnal variations can themselves cause changes in the FEV1. Within a single day, FEV1 in normal subjects can vary by over 5% (Pellegrino et al., 2005) and be as high as 17.6% (Medarov et al., 2008). Therefore, controlled exposure studies must properly account for normal changes by including filtered air (FA) exposures and a range of concentrations and exposure durations. The American Thoracic Society (ATS) recommends a comprehensive description of "adverse" effects by combining the loss of lung function in conjunction with respiratory symptoms, such as cough and discomfort while breathing (ATS 2000). Further, OEHHA, the TCEQ, and jointly the ATS and the European Respiratory Society (ERS) consider decrements in FEV1 of $\leq$ % as "mild," not "adverse." However, in its reevaluation of the Adams (2006) study, EPA identified FEV1 decrements of only 2.8% to be adverse effects. According to the sources listed previously and Adams himself, the decrements in the Adams (2006) study at 0.06 ppm are not of biological significance, even though they may be of statistical significance. Therefore, it is also prudent that the EPA justify the importance of key study results to indicate not just statistical significance, but also biological significance before labeling the result as an adverse effect.
- 2. *EPA's reanalysis of Adams (2006) data is not scientifically appropriate and should not be included as part of the final ozone policy decision*. In addition to the issue of whether or not the decrease in FEV1 was adverse, the EPA also conducted a highly contentious statistical reanalysis of the Adams (2006) data to show statistical significance in the absence of the effect (Brown 2007, Brown 2008). Dr. Adams himself disagreed with the EPA's reanalysis and statistical reinterpretation of his study during a teleconference on March 5, 2007, and in written comments to the EPA during the 2007 comment period. EPA's reanalysis was also criticized by other statisticians and scientists, as stated in comments submitted to EPA by Drs. RL Smith and JE Goodman. The TCEQ concurs with Dr. Adams' peer-reviewed results.
- 3. *EPA should consider more recent studies as part of the ozone weight of evidence*. Recent clinical studies (Kim et al., 2011; Schelegle et al., 2009) of ozone exposure at concentrations lower than 0.08 ppm have further confirmed the Adams (2006) results, showing no adverse effects at 0.06 ppm. When compared to filtered air, Schelegle et al. (2009) reported statistically significant mean per-

[3] FEV1 is a measure of the forced expiratory volume during the first second of an active exhalation. This measurement is used to assess lung function and is often used in epidemiological or controlled clinical studies. The measurement is accomplished by having a subject inhale deeply and then exhale quickly. A significant reduction in FEV1 may be indicative of impaired ventilation.

cent change in FEV1 at 0.07 ppm (5.34%) and Kim et al. (2001) reported statistically significant mean percent change in FEV1 at 0.06 ppm (1.71%), these are not only within in the range of intra-individual variability but are also substantially less than the 20% decrease identified as adverse.

- 4. *EPA needs to emphasize the importance of having realistic controls for clinical studies*. Many of the clinical studies use filtered air (no ozone) for the control groups (Schelegle et al., 2009; Kim et al., 2011), which creates an unrealistic scenario as the natural background ozone concentration in the atmosphere is around 0.04 ppm (Last et al., 2010). In its analysis of the clinical studies, EPA has not adjusted for this background factor and has not provided any justification for not doing so. Not adjusting for background can result in overestimating the severity of the observed effects as "adverse effects," when in fact the effects were "not adverse." Based on the clinical studies, it can be inferred that the weight of evidence at the lower range of exposure levels (i.e, 0.06–0.07 ppm) is weak and inconclusive. Thus, I can conclude that the clinical studies used to justify the lower end of the proposed range do not support lowering the ozone standard below the present NAAQS of 0.075 ppm (Adams 2002 and 2006; Schelegle et al., 2009; Kim et al., 2011). Further, these studies are conservative since they do not consider personal exposure.

Differing Roles of Policy and Science

EPA's recent attempts at using science to justify policy decisions are particularly troubling. In its reconsideration of the ozone standard, EPA attempts to establish a health basis as the need for a new, reduced standard. However, the assumption that the reduced standard would prevent up to 12,000 deaths is based on dubious studies and the use of such an analysis signals an unfortunate shift in the roles of scientists and risk managers.

- 1. *The basis of the theoretical number of lives saved is meaningless and unrealistic.* EPA relied on studies that took mortality data from ecological epidemiology studies to calculate the number of theoretical deaths that would be avoided with a lower standard. Not only do these studies suffer from the severe limitations described above, but theoretical lives saved estimates are also meaningless from a scientific and practical standpoint. It is not possible to verify either the current number of deaths due to ozone exposure or the future change in deaths if the standard is lowered because there is still no conclusive evidence that ozone causes mortality at ambient concentrations. [4] There is no guarantee of increased life expectancy or degree of confidence in this estimation, since some degree of risk is present in all aspects of daily life.
- 2. *EPA misuses scientific studies to justify policy decisions. Scientific studies should be just one aspect of responsible policymaking*. Rigorous scientific studies focus on expanding the knowledge of how a chemical interacts with the body at different tested doses. However, even the most extensive studies are not able to define an acceptably safe level of a chemical. In the specific case of ozone, scientific studies have still been unable to clearly identify human risk at current ambient levels and have certainly not shown if 0.065 ppm ozone is substantially more protective than 0.08 ppm. Determining what level of risk is acceptable is and should remain a decision for risk managers, not scientists.

Responsible risk managers and policymakers consider science as one of many aspects to be considered in setting policy. Science cannot determine practical issues, such as the feasibility of implementation and to what extent society would accept the trade-offs associated with the standard. For example, an overly restrictive health-based standard might be more detrimental to public health if it forces an industry out of business due to the cost of compliance and its employees are unable to find work to support their families. Studies have consistently indicated that poverty is a much better predictor for premature mortality than exposure to environmental pollutants. Public officials with a broader perspective of potential policy implications are better equipped to evaluate these important aspects.

[4] In fact, EPA has provided no data to illustrate lives saved under previous standards. All estimates of lives saved are projections, not factual.

PM NAAQS

The Proposed PM Standard

EPA has proposed a new particulate matter (PM) standard that is twice as stringent as the current standard. Attainability of the proposed standard, especially in rural and agricultural areas, is impractical and even EPA staff acknowledges that the available scientific evidence supports the effectiveness of the current standard in protecting public health. There is no scientific basis supporting a reduction in the current standard, let alone a two-fold reduction.

- 1. *EPA based the proposed PM standard on an ecological epidemiology study*. EPA used a study by Zanobetti and Schwartz (2009), which is an ecological epidemiology study, as a basis for the proposed PM standard. This ecological epidemiology study concludes that exposure to coarse PM is "suggestive" of a causal relationship with adverse effects. As stated above, ecological epidemiology studies are incomplete studies plagued with limitations and should not be used as the basis for policy conclusions.
- 2. *EPA assumes all PM composition is equal*. Not all PM is created equally; however, EPA makes the assumption that it is. Coarse PM is produced by surface abrasion or suspension of biological material and fragments of living things. Because of this, PM in urban and industrial areas is likely to be vastly different from PM in rural and agricultural areas. Urban and industrial PM is expected to be enriched with pollutants; pollutants that are inherently more toxic than the dust predominantly found in agricultural operations and arid rural areas. EPA didn't take this scientific fact into consideration when they developed their proposed PM standard. When they assume all PM composition is the same, they ignore the fact that agricultural and rural areas will likely exceed the standard due to natural occurrences rather than man-made sources.
- 3. *PM composition varies greatly by geographic regions*. The PM data EPA used in their assessment for the proposed PM standard were not uniformly distributed across the United States or even within counties. Therefore, potential differences in PM composition may be reflected in the EPA estimates. Geographic variability is also strongly influenced by region-specific sources, meteorology (e.g., wind speed and direction), and topographical conditions (e.g., trees, mountains). When PM composition differs geographically, the conclusions drawn may not apply equally to all parts of a geographic region.

Utility MACT

Mercury and the Utility MACT

EPA has proposed a National Emission Standards for Hazardous Air Pollutants (NESHAP) rule for coal- and oil-fired electric utility steam generating units (EGU). This proposed NESHAP rule (the Utility MACT) would establish maximum achievable control technology (MACT) emission limits for certain hazardous air pollutants (HAP), including mercury. In EPA's analysis for mercury, they state "if U.S. EGU impacts to watersheds included in the risk assessment were zeroed out, for a significant majority of those watersheds, total exposure would still exceed (and in most cases, significantly exceed) the RfD [Reference Dose]." In EPA's own words they are admitting control of U.S. EGU mercury emissions will not have an effect on mercury levels in fish in U.S. watersheds; however, they still insist on the necessity to require these controls. Concurrent with the Utility MACT, the EPA's National-Scale Mercury Risk Assessment Supporting the Appropriate and Necessary Finding for EGUs (mercury risk assessment) was released for public comment and review by EPA's Science Advisory Board Mercury Review Panel. Currently, the Mercury Review Panel's support for the mercury risk assessment is contingent upon development of a revised document that addresses numerous issues. The Panel's comments to EPA on the mercury risk assessment were finalized in September 2011, illustrating the limited time allowed for review and revisions of such an important document whose purpose was to determine whether a public health hazard is associated with U.S. EGU emissions. One could easily conclude that the Panel's input was merely a formality and was not intended to be seriously considered, much like EPA treats input from the States.

- *The EPA 2000 appropriate and necessary finding estimates were inaccurate.*[5] The risk analysis estimates of hazard quotients due to U.S. EGU-attributable emissions of mercury have already decreased significantly between the 2005 and 2016 scenarios, mainly due to PM controls. In fact, 2010 levels of mercury emissions are already at levels predicted for 2016. In addition, the 2000 appropriate and necessary finding was based on estimates that U.S. utility mercury emissions would increase from 46 tons in 1990 to approximately 60 tons in 2010. In reality, emissions were reduced to 29 tons in 2010.
- *U.S. EGU mercury emissions are insignificant compared to other sources*. The Utility MACT preamble states that on average, U.S. EGUs are estimated to contribute only 2% to total mercury deposition in the U.S. Therefore, any health benefits related to mercury reductions would pose an insignificant change in the overall risk from mercury from all sources. Only in combinations of the worst-case watersheds with fish consumption rates (e.g., 95th and 99th percentile fish consumption rates paired with the 95th and 99th percentile watersheds) did estimates of U.S. EGU-attributable hazard quotients (HQs) exceed 1.5 (EPA considered an HQ>1.5 to represent a potential public health hazard). U.S. EGUs contributed insignificantly to the total risks posed by other sources of mercury; thus, regardless of this regulation, risk from mercury deposition will remain from sources other than U.S. EGUs.

Mercury is a global pollutant. It travels beyond boundaries of states and continents. EPA modeling estimates that, on average, 83% of the mercury deposited in the U.S. originates from international sources, excluding Canada; the remaining 17% comes from U.S. and Canadian sources. As such, control strategies related to EGUs may not affect change in fish tissue concentrations of mercury. According to EPA (2007), "The mix of long-distance and local sources makes it difficult in some water bodies to achieve water quality standards for mercury."

- *EPA uses a worst-case scenario for risk and does not characterize risk for realistic U.S. populations*. EPA should have characterized risk for the more realistic general recreational angler population to provide perspective and information to that population. Instead, the EPA's mercury assessment is essentially a worst-case scenario that focuses on subsistence fishing populations and may overestimate risk for the majority of the U.S. population. EPA's own Science Advisory Board Mercury Review Panel states "There is scant evidence documenting the prevalence or extent of subsistence fishing in the United States."
- *EPA states that about seven percent of women of child-bearing age are exposed to mercury at a level capable of causing adverse effects in the developing fetus*. Several well-conducted studies examining effects of mercury on children have been conducted, including the Seychelles Child Development Study (Seychelles) and the Faroe Island Study (Faroe). A blood mercury No Effect Level (NEL) of 85 parts per billion (ppb) was observed in the Seychelles study. Interestingly, this study also observed positive improvements on IQ as mercury levels increased; a phenomenon likely due to nutrients such as omega-3 fatty acids and selenium from high fish consumption. A blood mercury NEL of 58 ppb was observed in the Faroe study; however, these residents also consumed large quantities of whale meat and blubber that contained unsafe (according to EPA) levels of polychlorinated biphenyls (PCBs). Since neither study found effects below 58 ppb blood mercury levels, one would only expect to find health effects in children whose mothers had mercury levels higher than 58 ppb in their blood. EPA's safe level (the RfD) is set to prevent blood mercury levels exceeding 5.8 ppb, 10 times lower than the NEL of 58 ppb from the Faroe study.

Data from the Centers for Disease Control's (CDC's) National Health and Nutrition Examination Survey (NHANES), 2003–2008, show the mean blood mercury level for pregnant women is 0.69 ppb (well below EPA's safe blood mercury level)

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[5] In December 2000, EPA issued a "regulatory determination" under the *Clean Air Act* (CAA) that it is "apppropriate and necessary" to regulate mercury emissions from coal-based power plants and nickel emissions from oil-based power plants. This regulatory determination listed coal- and oil-based EGUs as a source category under section 112(c) of the CAA, the first step to setting MACT standards. On January 30, 2004, EPA proposed to remove EGUs from the 112 list based on a finding that it was neither appropriate nor necessary to regulate EGUs under this section of the CAA. On March 29, 2005, EPA issued a final revision of the appropriate and necessary finding for coal- and oil-fired EGUs and removed such units from the 112 list. The removal of EGUs from the 112 list was challeneged in court. On February 8, 2008, the court determined that EPA violated the CAA by removing EGUs from the 112 list. As a result, EGUs remain a CAA section 112(C) listed source category according to EPA. The basis of the court ruling was that EPA did not follow the requirements of 112(C)(9) in removing EGUs from the 112 list. As such, the court did not reach a determination on the merits of the case.

(Jones et al., 2010). Although some individuals have blood mercury levels greater than EPA's safe blood mercury level, none have blood mercury levels above the Faroe study NEL of 58 ppb, and therefore adverse health effects would not be expected in their children. A 2005 study conducted by Texas Department of State Health Services (DSHS 2005) determined that even when subsistence fishers are eating fish from Caddo Lake with elevated mercury, women of child-bearing years did not have blood mercury levels greater than the EPA's safe blood mercury level.

On comparing U.S. blood mercury levels to other countries, both the United Kingdom (UK) and Japan median blood mercury levels are higher. Using EPA's RfD to describe Japan's data, 66% of Japanese women are exposed to levels above EPA's safe blood level. From this the claim could be made (falsely) that 66% of Japanese children are born at risk for adverse effects. On the contrary, the Japanese population consumes 10 times more fish than the U.S. population but only shows positive outcomes; they have lower rates of coronary heart disease and high IQ scores. EPA is causing unnecessary alarm in the public with their assertions that 7% of women of child-bearing age are exposed to mercury at a level capable of causing adverse effects in the developing fetus when the evidence clearly shows this statement to be false and misleading.

- *EPA uses an RfD that is more conservative than most other Agencies (U.S. and World).* The Agency for Toxic Substances and Disease Registry (ATSDR) and the U.S. Food and Drug Administration (FDA) both have established safe levels three-fold higher than EPA's conservative RfD. The World Health Organization (WHO) recommends a level that is two times higher than EPA's RfD; Health Canada uses a value similar to the WHO recommended value. The TCEQ agrees with ATSDR and FDA that it is more appropriate to use a study that reflects U.S. fish consumption (e.g., saltwater fish such as tuna) rather than a study based entirely on consumption of saltwater fish and mammals (e.g., whale).

References

Adams, WC. 2002. Comparison of chamber and face-mask 6.6-hour exposures to ozone on pulmonary function and symptoms responses. *Inhal. Toxicol*. 14(7): 745–764.

Adams, WC. 2003. Comparison of chamber and face mask 6.6-hour exposure to 0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhal. Toxicol*. 15: 265–281.

Adams, WC. 2006. Comparison of chamber 6.6-h exposures to 0.04–0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhal. Toxicol*. 18(2): 127–136.

Adams, WC. 2007. Public Comment to CASAC Ozone Review Panel Teleconference. University of California, Davis, CA, 2p., March 5.

Agency for Toxic Substances and Disease Registry, Minimum Risk Level for Mercury, *www.atsdr.cdc.gov/toxprofiles/tp46-a.pdf*.

American Thoracic Society (ATS). 2000. What constitutes an adverse health effect of air pollution? *Am. J. Respir. Crit. Care Med*. 161: 665–673.

American Thoracic Society and European Respiratory Society. 2008. Outcomes for COPD pharmacological trials: from lung function to biomarkers. Available online at *http://erj.ersjournals.com/content/31/2/416.full#sec-149*.

Bell, ML; Dominici, F. 2008. Effect modification by community characteristics on the short-term effects of ozone exposure and mortality in 98 U.S. communities. *Am J Epidemiol*. 167(8): 986.997.

Brown, JS. [U.S. EPA]. 2007. Memo to Ozone NAAQS Review Docket (OAR-2005-0172) re: The effects of ozone on lung function at 0.06 ppm in healthy adults. 8p., June 14.

Brown, JS; Bateson, TF; McDonnell, WF. 2008. Effects of exposure to 0.06 ppm ozone on FEV1 in humans: A secondary analysis of existing data. *Environ. Health Perspect*. 116(8): 1023–1026.

California Environmental Protection Agency (California EPA). 2008. Technical support document for the derivation of noncancer reference exposure levels, Oakland, California.

Daniels, JL; Longnecker, MP; Rowland, AS; and Golding, J. (2004). Fish intake during pregnancy and early cognitive development of offspring. *Epidemiology*. 15(4): 394–402.

Davidson, P; Myers, G; Cox, C; et al. (1995) Longitudinal neurodevelopmental study of Seychellois children following in utero exposure to methylmercury from maternal fish ingestion: outcomes at 19 and 29 months. *NeuroToxicology* 16:677–688.

Davidson, PW; Myers, GJ; Cox, C; et al. (1998) Effects of prenatal and postnatal methylmercury exposure from fish consumption on neurodevelopment: outcomes at 66 months of age in the Seychelles child development study. *JAMA* 280:701–707.

Dourson, ML; Wullenweber, AE; Poirier, KA. (2001) Uncertainties in the Reference Dose for Methylmercury, *NeuroToxicology* 22 (5) (2001) pp. 677–689.

EPA. 1997. Mercury Study Report to Congress: Volume VII: Characterization of Human Health and Wildlife Risks from Mercury Exposure in the United States. EPA-452/R-97-009. Available online at *http://www.epa.gov/ttn/oarpg/t3/reports/volume7.pdf*.

EPA. 2007. Memorandum on Listing Waters Impaired by Atmospheric Mercury Under Clean Water Act Section 303(d): Voluntary Subcategory 5m. March 8. Available online at *http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/mercury5mfactsheet.cfm*.

EPA Notice of Regulatory Finding, 65 Fed. Reg. 79,825, 79,830 (Dec. 20, 2000). Available online at: *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=00-32395-filed.pdf*.

Goodman, JE; Prueitt, RL. 2010. Comments on U.S. EPA's Health Effects Draft Materials for the Ozone Integrated Science Assessment (ISA). Gradient, Report to American Petroleum Institute, 49 p., September 9.

Grandjean, P; Weihe, P; White, R; et al. (1997) Cognitive deficit in 7-year-old children with prenatal exposure to methylmercury. *Neurotoxicol Teratol* 20:1–12.

Henderson, R. 2006. Letter from CASAC Chairman Rogene Henderson to EPA Administrator Stephen Johnson, June 5, 2006, EPA-CASAC-06-007.

Jones , L, Parker, JD, and Mendola, P. 2010. Blood lead and mercury levels in pregnant women in the United States, 2003–2008. NCHS data brief no 52. Hyattsville, MD: National Center for Health Statistics. Available online at: *http://www.cdc.gov/nchs/data/databriefs/db52.pdf*.

Kim, CS; Alexis, NE; Rappold, AG; Kehrl, H; Hazucha, MJ; Lay, JC; Schmitt, MT; Case, M; Devlin, RB; Peden, DB; Diaz-Sanchez, D. 2011. Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. *Am. J. Respir. Crit. Care Med*. 183: 1215–1221.

Kjellstrom, T; Kennedy, P; Wallis, S; et al. (1986) Physical and mental development of children with prenatal exposure to mercury from fish. Stage 1: Preliminary test at age 4. Natl Swed Environ Protec Bd, Rpt 3080 (Solna, Sweden).

Kjellstrom, T; Kennedy, P; Wallis, S; et al. (1989) Physical and mental development of children with prenatal exposure to mercury from fish. Stage 2: Interviews and psychological tests at age 6. Natl Swed Environ Prot Bd, Rpt 3642 (Solna, Sweden).

Last, JA; Hyde, DM, and Schelegle, E.S. 2010. Ozone and Ozone Toxicity. *Comprehensive Toxicology (Second Edition)* 8: 261–275.

McClellan, RO; Frampton, MW; Koutrakis, P; McDonnell, WF; Moolgavkar S, North, DW; Smith, AE, Smith, RL; Utell, MJ. 2009. Critical considerations in evaluating scientific evidence of health effects of ambient ozone: a conference report. *Inhal. Toxicol*. Sept 21 Suppl. 2: 1–36.

Myers, GJ; Marsh, DO; Cox, C; et al. (1995a) A pilot neurodevelopmental study of Seychellois children following in utero exposure to methylmercury from a maternal fish diet. *Neurotoxicology* 16(4):629–638.

Myers, GJ; Marsh, DO; Davidson, PW. (1995b) Main neurodevelopmental study of Seychellois children following in utero exposure to methylmercury from a maternal fish diet: outcome at six months. *Neurotoxicology* 16(4):653–664.

Myers, GJ; Davidson, PW; Cox, C; et al. (1995c) Neurodevelopmetnal outcomes of Seychellois children sixty-six months after in utero exposure to methylmercury from a maternal fish diet: pilot study. *Neurotoxicology* 16(4):639–652.

Myers, GJ; Davidson, PW; Shamlaye, CF; et al. (1997) Effects of prenatal methylmercury exposure from a high fish diet on developmental milestones in the Seychelles Child Development Study. *Neurotoxicology* 18(3):819–830.

National Academy of Science, Toxicological Effects of Methylmercury (2000).

National Academy Sciences (NAS) 2008. Committee on Estimating Mortality Risk Reduction Benefits from Decreasing Tropospheric Ozone Exposure, National Re-

search Council Copyright National Academy of Sciences. Available online at *http://www.nap.edu/catalog.php?record_id=12198#description*.

Pellegrino, R; Viegi, G; Brusasco, V; Crapo, RO; Burgos, F; Casaburi, R; Coates, A; van der Grinten, CP; Gustafsson, P; Hankinson, J; Jensen, R; Johnson, DC; MacIntyre, N; McKay, R; Miller, MR; Navajas, D; Pedersen, OF; Wanger, J. 2005. Interpretative strategies for lung function tests. *Eur. Respir. J*. 26(5): 948–968.

Sarnat, SE; Coull, BA; Schwartz, J; Gold, DR; Suh, HH. 2006. Factors affecting the association between ambient concentrations and personal exposures to particles and gases. Environ. Health Perspect. 114: 649–654.

Schelegle, ES; Morales, CA; Walby, WF; Marion, S; Allen, RP. 2009. 6.6-Hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans. *Am. J. Respir. Crit. Care Med*. 180(3): 265–272.

Smith, RL; Xu, B; Switzer, P. 2009. Reassessing the relationship between ozone and short-term mortality in U.S. urban communities. *Inhal. Toxicol. 21(Suppl. 2)*: 37–61.

Texas A&M University and Driscoll Children's Hospital Report—Hamilton, M. J. ; Banks, J. M; Ricard, J. R. No Date. Air Quality, Ozone Level, Respiratory Response and Acute Pediatric Hospital Admissions.

Texas Commission on Environmental Quality (TCEQ). 2011. Proposed Guidelines to Develop Inhalation and Oral Cancer and Non-Cancer Toxicity Factors. Chief Engineer's Office. Available online at *http://www.tera.org/peer/tceqesl/*.

Texas Department of State Health Services (DSHS). Health Consultation: Mercury Exposure Investigation Caddo Lake Area—Harrison County Texas. Agency for Toxic Substances and Disease Registry (2005). Available online at: *http://www.atsdr.cdc.gov/HAC/pha/CaddoLake/CaddoLakeHC.pdf*.

Weil, M, Bressler, J, Parsons, P, Bolla, K, Glass, T, and Schwartz, B 2005. Blood Mercury Levels and Neurobehavioral Function. *JAMA*. 2005;293(15):1875–1882.

Zanobetti A, Schwartz J (2009). The effect of fine and coarse particulate air pollution on mortality: A national analysis. *Environ Health Perspect*., 117: 1–40.

Chairman HARRIS. Thank you very much, Dr. Honeycutt.

I now recognize Dr. Robert Phalen, Professor of Medicine, and Co-Director of the Air Pollution Health Effects Laboratory, for five minutes to present his testimony. Dr. Phalen.

STATEMENT OF DR. ROBERT F. PHALEN, PROFESSOR OF MEDICINE, AND CO-DIRECTOR, AIR POLLUTION HEALTH EFFECTS LABORATORY, UNIVERSITY OF CALIFORNIA, IRVINE

Dr. PHALEN. Chairman Harris, Mr. Miller, thank you for this opportunity.

My participation in the Clean Air Scientific Advisory Committee on Particulate Matter was interesting and stimulating. Everyone involved—the members of CASAC, the EPA staff and public presenters—was qualified, efficient and dedicated. But we are here to find, and I think all of us agree, to find possible ways to improve the CASAC process of incorporating good science. Therefore, I will present seven points for you to consider that are my observations as a result of my participation in the CASAC Particulate Matter subcommittee.

One, the EPA mandate is too restrictive. It does not allow the full competence of the EPA to be used in protecting public health. They are required to evaluate pollutants one by one, and pushing one pollutant way down can raise the risks from other factors, including unemployment. The EPA also has to err on the side of increased safety, and if you overdo this, you actually increase the overall risk to public health.

Two, linear incrementalism. This is where CASAC is only allowed to comment on questions that are supplied by EPA, and each of these comments seems to lead step by step to an inevitable conclusion. Therefore, the committee can't really express their concerns and their doubts along the way.

Three, the definition of particulate matter just by weighing it, and not taking the composition into account, to me is very poor science mainly because some areas of the country have more toxic particulate matter than others. And by setting one standard nationwide that adequately protects maybe two or three cities, you are punishing major industries, including agriculture, and you are punishing areas where the particulate matter has a different, less toxic composition.

Four, the current risk assessment process is very seriously flawed, as it is based on "individual pollutants." In 2009, the National Academy of Sciences at EPA's request looked at risk assessment and said in reality the risks are not the just risks of the pollutant, the risks are the risks of the "decision" about that pollutant. For example, if you lower a particle standard, it is going to affect agriculture, it is going to affect the price of gas, and it is going to affect small businesses in particular. The National Academy said the risk assessment has to be on the decision itself because that is what the public lives with. So the decision itself and all of its important health consequences have to be taken into account in the risk assessment.

Five, the public commenters that make presentations to CASAC were eloquent and well reasoned in their presentations, but CASAC did not even discuss them or weigh their comments and that was a shame. So the feedback from industry, interested scientists, and the American Lung Association, for example, were not effectively taken into account by CASAC.

Six, the subcommittee that I was on did not adequately inform the Administrator on the pitfalls, the scientific limitations, and even the adverse health consequences that would flow from a more stringent regulation. Not understanding the feasibility of compliance, the economic hardships and unintended adverse consequences places the Administrator in an embarrassing position of possibly having to issue a standard that might do more harm than good to public health.

Number seven, the final, and I think this is the most important, the public is not going to be adequately informed about the adverse effects (i.e., unintended consequences) associated with new standards. They (the public) are informed about the benefits but not the adverse side of the coin. "Informed consent" is a fundamental ethical principle that has to be applied when you make decisions that will affect people's lives. Informed consent must include, and elucidate, the adverse consequences that flow from a standard or decision. CASAC was not allowed to discuss any of the adverse consequences associated with setting new standards. But the public must live with all the consequences of the new standard.

In sum, the current process is very elegant, it is very highly evolved, and it is very efficient for getting scientists involved. But in my opinion, it is seriously flawed, it is narrowly focused, and it is even ethically questionable.

It is important to reiterate that no one is really to blame because all of the people that were involved, in my opinion, performed their tasks enthusiastically and competently. Thank you.

[The prepared statement of Dr. Phalen follows:]

PREPARED STATEMENT OF DR. ROBERT F. PHALEN,
PROFESSOR OF MEDICINE, AND CO-DIRECTOR,
AIR POLLUTION HEALTH EFFECTS LABORATORY,
UNIVERSITY OF CALIFORNIA, IRVINE

My participation in the CASAC subcommittee on Particulate Matter (CASAC-PM) was stimulating and enlightening. Everyone involved, committee members, EPA staff, and public presenters, were well-qualified, efficient, and dedicated. But we are here, in part, to explore possible improvements in the process, so I will summarize some of my personal observations to that end. Many of the problems arose from the outdated mandate that the U.S. EPA had to follow.

- 1. The mandate is too restrictive, and does not allow the full competence of the EPA to be used in protecting public health. Evaluating air pollutants one by one can lead to air standards that do not make sense given the complexities of air chemistry (e.g., suppression of one pollutant can cause the mixture to have increased toxicity). The mandate to err on the side of increased safety can also be a disservice to public health. And the policy to set nationwide standards can place unreasonable burdens on some industries and some regions of the U.S.
- 2. Linear incrementalism, in which CASAC only comments on each step in a long process, can lead to conclusions that do not pass a "common-sense criterion." The questions posed to CASAC-PM appeared to be restrictive, carefully crafted, and led to inevitable conclusions.
- 3. Defining particulate matter by aerodynamic mass fractions, with composition not taken into account, is poor science in my opinion, and it punishes some regions and industries. Furthermore, it does not apply to ultrafine particles (the count can be quite large without having any appreciable mass).
- 4. The current risk assessment process is seriously flawed. It is based on individual mass fractions and can lead to regulations that do not serve public health. The 2009 National Academy of Sciences Report (National Research Council, "Science and Decisions: Advancing Risk Assessment," *The National Academy Press*, Washington, DC, 2009) advises that the "decision" to set a standard, not the "pollutant," is what must undergo risk assessment. The public must live with all of the relevant consequences of an air standard, not just selected effects of the substance under consideration (the general economy, jobs, and costs of goods and services have dominant impacts on public health, but they are not even considered by CASAC).
- 5. The public comments were not weighed and discussed by CASAC-PM in spite of the fact that most were well-reasoned and relevant. If the agenda included time for discussion of public comments and formal acceptance or rejection of their recommendations, the process might be improved.
- 6. The CASAC-PM subcommittee did not adequately inform the EPA Administrator on the pitfalls, scientific limitations, and even the range of adverse health consequences associated with the recommended PM standards. Not understanding the feasibility, economic hardships, and unintended adverse health consequences can place the Administrator in the embarassing position of issuing a standard that may harm public health.
- 7. The public will not be adequately informed about the adverse effects associated with new standards. "Informed consent" is a fundamental ethical principle that should be applied to mandates, including air standards. Informed consent must include, and elucidate, the adverse consequences that flow from a decision. CASAC-PM was not allowed to adequately discuss the adverse consequences associated with air standards.

In sum, the current process, although elegant and efficient, in my opinion is flawed, narrow, and possibly ethically questionable.

It is important to reiterate that all of the people involved performed their tasks enthusiastically and competently. Thank you for this opportunity to provide what I hope are constructive comments.

Chairman HARRIS. Thank you very much, Dr. Phalen.

I now recognize Dr. Anne Smith, Senior Vice President at NERA Economic Consulting, for five minutes. Dr. Smith.

STATEMENT OF DR. ANNE E. SMITH,
SENIOR VICE PRESIDENT, NERA ECONOMIC CONSULTING

Dr. SMITH. Mr. Chairman, Members of the Committee, thank you for inviting me. I am Anne Smith. My statements today reflect my own opinions and not those of my company, NERA Economic Consulting.

EPA is relying on benefit estimates, the so-called co-benefits from ambient $PM_{2.5}$ reductions to claim that the rules that are not intended to address $PM_{2.5}$ at all have benefits larger than their costs. For instance, for the ozone reconsideration, up to 91 percent of the estimated benefits were not from reductions in ozone risk but from EPA's predictions of coincidental $PM_{2.5}$ reductions under that rule. Ozone benefits alone always fell short of their costs by tens of billions of dollars per year.

For the Ozone Utility MACT Rule, EPA claims this air toxics rule will save up to 17,000 lives per year and many other respiratory and heart ailments but all of those purported benefits are due to $PM_{2.5}$, not to air toxics. Over 99.99 percent of the Utility MACT Rule's estimated benefits are due to $PM_{2.5}$ co-benefits and not the air toxics that are its purpose.

EPA has developed a habit since 1996 of relying on $PM_{2.5}$ co-benefits to create a benefit-cost case for its non-PM rulemakings. $PM_{2.5}$ co-benefits were the driving factor in all but two of the 24 non-PM air rules which EPA quantified any benefits for at all as you can see listed here in this figure with the Xs in the first column, and EPA's co-benefits habit has really taken over since 2009. Claims of $PM_{2.5}$ mortality co-benefits now account for over 99.9 percent of the benefits in all of the RIAs since 2009 except the ozone reconsideration, as you can see in the last column of the table.

Where did all these PM co-benefits come from? How could they be increasing in importance even though ambient 2.5 is declining to the levels that EPA deems safe? This is how. In 2009, EPA changed the assumption that in one fell swoop nearly quadrupled its estimates of the number of U.S. deaths due to $PM_{2.5}$. EPA decided to calculate risks from $PM_{2.5}$ exposures that occur far below the level it deems safe under the $PM_{2.5}$ NAAQS. Prior to this change, EPA was assuming that less than four percent of all current U.S. deaths were due to $PM_{2.5}$, and after this change it is assuming that 13 percent of all current deaths in the United States are due to $PM_{2.5}$. All of these newly calculated $PM_{2.5}$ risks come from the most non-credible source of risk calculation. By assuming that a unit of exposure to $PM_{2.5}$ at concentrations well below any epidemiological studies will increase your risk of death by just as much as a unit of exposure at the much higher $PM_{2.5}$ levels that statisticians have observed correlations for. This new assumption is scientifically dubious but its lack of realism shows in how it has driven the underlying estimate of PM-related deaths in the United States to implausible levels. EPA's new PM risk estimates now imply that 25 percent of all deaths nationwide were due to $PM_{2.5}$ as recently as 1980, 25 percent. EPA projects $PM_{2.5}$ will be almost entirely in the safe range, that is, in attainment with the PM

NAAQS, after the Cross-State Air Pollution Rule is implemented in 2014. But EPA is also assuming there will still be about 250,000 deaths per year due to $PM_{2.5}$ after that and it keeps tapping into this implausible estimate of a reservoir of PM benefits to come up with the very large co-benefits estimates for its new rules, and the Utility MACT is a shining example. The 17,000 lives that EPA claims it would save in 2016 are taken from that highly dubious pool. Effectively, all of those 17,000 deaths are from exposures to PM that according to the EPA ambient standard are safe. About 4,000 of those 17,000 deaths, if believed to really exist, will be prevented anyway if EPA tightens its $PM_{2.5}$ standard down to 11 micrograms per cubic meter as it appears to be poised to do this year. The Utility MACT should not be credited with those benefits. They belong on the PM NAAQS benefits ledger. But the remaining 13,000 of those deaths should not be counted at all because they are from exposures that are already below 11 micrograms per cubic meter, which EPA does not consider to be risks that are believable enough to set a PM NAAQS standard that would stop them. So in sum, EPA's use of highly dubious co-benefits gives it a shield to justify a complex web of rules.

The fact that EPA does not just use its streamlined regulatory option, which is to set a $PM_{2.5}$ NAAQS, hints at the degree to which it realizes that those co-benefits calculations do not reflect true public health risk but also it is just bad policy. A complex web of non-PM rules cannot possibly be a cost-effective path to addressing a nation's clean air needs, and no one disputes that these rules do have significant costs that need to be streamlined to the maximum extent possible.

Thank you very much.

[The prepared statement of Dr. Smith follows:]

PREPARED STATEMENT OF DR. ANNE E. SMITH,
SENIOR VICE PRESIDENT, NERA ECONOMIC CONSULTING

Mr. Chairman and Members of the Committee, thank you for your invitation to participate in today's hearing. I am Anne E. Smith, and I am a Senior Vice President of NERA Economic Consulting. I am a specialist in environmental risk assessment and integrated assessment to support environmental policy decisions, which was a core element of my Ph.D. thesis at Stanford University in economics and decision sciences. I have performed work in the area of air quality cost and benefits analysis and risk assessment over the past 30 years, including as an economist in the USEPA's Office of Policy, Planning, and Evaluation, as a consultant to the USEPA Air Office, and in many consulting engagements since then for government and private sector clients globally. I have also served as a member of several committees of the National Academy of Sciences focusing on risk assessment and risk-based decision making. I have been deeply involved in assessment of the evidence on risks from ambient fine particulate matter ($PM_{2.5}$) since EPA first turned to the task of identifying an appropriate National Ambient Air Quality Standard (NAAQS) for $PM_{2.5}$ over 15 years ago. I have also analyzed costs, risks and benefits of many other key U.S. air policies, including ozone, regional haze, mercury and other air toxics, NO_2, SO_2, and greenhouse gases. I thank you for the opportunity to share my perspective today on the economic underpinnings of EPA's policy analyses for setting air quality standards. My written and oral testimonies reflect my own opinions, and do not represent any position of my company, NERA Economic Consulting.

The Chairman has asked me to describe my work analyzing major *Clean Air Act* regulations including National Ambient Air Quality Standards (NAAQS) and National Emission Standards for Hazardous Air Pollutants (NESHAPs), and to discuss any trends I have identified in EPA's analyses of such regulations. Although I have worked on these issues for over 30 years, I would like to focus my testimony today on analyses and research that I have done during 2011. In the past several months,

I have reviewed and commented on the costs and benefits in EPA's Regulatory Impact Analysis (RIA) for the reconsideration of the ozone NAAQS. I have also prepared technical comments on the RIA for the proposed NESHAP for electric generating units, which was proposed in May 2011. That rule is commonly called the "Utility MACT" rule because it would impose maximum achievable control technology (MACT) standards on several categories of air toxics emitted by electricity generators. I am presently in the process of reviewing the entire body of RIAs that EPA has produced for air quality regulations, to trace the history of some troubling patterns that I found in EPA's ozone and utility MACT RIAs.

My key findings, which I will explain in more detail below, are:

- EPA is relying to an extreme degree on coincidental "co-benefits" from $PM_{2.5}$ reductions to create the impression of benefit-cost justification for many air regulations that are not intended to address $PM_{2.5}$.
- In 2009, EPA vastly increased the levels of mortality risks that it attributes to $PM_{2.5}$ simply by starting to assign risks to levels of $PM_{2.5}$ down to zero exposure, thus "creating" risks from ambient exposures that are well within the safe range established by the $PM_{2.5}$ NAAQS.
- This single change nearly quadrupled the pool of purported U.S. deaths due to $PM_{2.5}$ that RIAs can now count as "saved" by minor incremental reductions in already-low ambient $PM_{2.5}$ levels projected under new rules.
- This additional pool of $PM_{2.5}$-related mortality consists of the most non-credible sort of risk estimate, as it is derived from an assumption that a unit of exposure at $PM_{2.5}$ levels well below any observed in the epidemiological studies poses just as much risk as a unit of exposure at the higher $PM_{2.5}$ levels where associations have been detected.
- With this change, EPA is now assuming that 13% to 22% of all deaths in the Eastern U.S. were due to $PM_{2.5}$ in 2005, and that 25% of all deaths nationwide were due to $PM_{2.5}$ as recently as 1980.
- The decision to inflate the $PM_{2.5}$ risk estimates by presuming risks continue down to zero has its greatest impact on co-benefits estimates because—for rules that do not address $PM_{2.5}$ directly—a much greater share of their incremental reduction of $PM_{2.5}$ will occur in areas that are already in attainment with the $PM_{2.5}$ NAAQS (and thus that have $PM_{2.5}$ levels that EPA has deemed safe). Yet, EPA now attributes about 200,000 more $PM_{2.5}$-related deaths per year to exposures in those areas.
- If it were viewed as credible that such large effects exist below the level of the $PM_{2.5}$ NAAQS, the appropriate policy remedy would be to tighten the $PM_{2.5}$ standard, and not to regulate something else altogether in order to obtain those benefits through "coincidence."
- Co-benefits from a pollutant that EPA already can and does regulate should not be allowed to serve as the predominant benefit in RIA's for rules that target a different public health concern.
- Otherwise, RIAs will only help drive our nation towards regulatory complexity by creating the false appearance of a benefit-cost justification for regulations that are very costly compared to their own benefits.

EPA is relying to an extreme degree on coincidental "co-benefits" from $PM_{2.5}$ reductions to justify air regulations that are not intended to address $PM_{2.5}$.

As EPA releases each of its proposed and final air quality rules, it typically emphasizes that the rule will generate health benefits that exceed its costs. However, close inspection of the associated RIAs reveals that a majority of those benefits—sometimes *all* of them—are not from reductions in the pollutant(s) being targeted by the new regulation, especially in the case of air regulations that are targeting clean air objectives other than $PM_{2.5}$. For many of those, the bulk of the benefits estimates in their RIAs are attributable to reductions in already-low concentrations of ambient $PM_{2.5}$ that EPA has predicted will occur *coincidentally* as a result of regulation of those non-PM pollutant(s).

For example:

- In the Ozone Reconsideration RIA, up to 91% of EPA's benefits estimate for its preferred standard was due to EPA's predictions of coincidental $PM_{2.5}$ reduc-

tions rather than to reductions in ozone risks that were the target of the rule.[1] Not a single one of EPA's benefits estimates in that RIA exceeded its costs unless $PM_{2.5}$-mortality co-benefits were added in. By EPA's own calculations, all of the alternative ozone standards had ozone benefits that fell short of their costs by billions of dollars per year.[2]

- EPA has widely claimed that the Utility MACT rule, which targets air toxics, will save up to 17,000 lives per year, 11,000 heart attacks, and numerous other respiratory and cardiovascular ailments. But *all* of those purported health benefits are due to EPA's predictions of coincidental reductions of $PM_{2.5}$—which is not an air toxic. Of all the air toxics targeted by this rule, EPA has estimated benefits for only one—mercury—and EPA's highest estimate of those mercury benefits is only $6 million per year, compared to EPA's estimate of $10.9 billion in costs per year. In the Utility MACT's RIA, over 99.99% of the benefits that EPA has attributed to the rule are due to $PM_{2.5}$ co-benefits rather than to the air toxics that are its purpose.[3]

In my ongoing review of all air regulation RIAs, I have identified 28 RIAs released since 1996 that were for rules not targeting $PM_{2.5}$-related health risks. These are listed in Table 1 in chronological order.

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[1] The preferred standard that EPA had forwarded to OMB for the Ozone Reconsideration was 70 ppb.

[2] A copy of my full review of the ozone RIA is available at *http://www.nera.com/67_7390.htm*. Parts of it are excerpted in the Appendix of this testimony.

[3] A copy of my full review of the Utility MACT RIA is available at *http://www.nera.com/67_7412.htm*. Parts of it are excerpted in the Appendix of this testimony.

Table 1. Summary of Use of Co-Benefits in 28 RIAs for Air Rules Not Targeting Ambient $PM_{2.5}$

Year	RIAs for Rules Not Targeting Ambient PM2.5	$PM_{2.5}$ Co-Benefits Are Majority of Total Benefits	Co-Benefits Are Only Benefits Quantified
1996	Ozone NAAQS (.12 1hr=>.08 8hr)	X	
1997	Pulp & Paper NESHAP		
1999	Regional Haze Rule	X	
1998	NOx SIP Call & Section 126 Petitions	X	
1999	Final Section 126 Petition Rule	X	X
2003	Stationary Reciprocating Internal Combustion Engine NESHAP	X	X
2004	Plywood & Composite Wood Products NESHAP	(no health benefits quantified)	
2004	Automobile & Light-Duty Vehicle Manufacturing NESHAP	(no health benefits quantified)	
2004	Industrial Boilers & Process Heaters NESHAP	X	X
2005	Clean Air Mercury Rule	X	
2005	Clean Air Visibility Rule/BART Guidelines	X	
2006	Stationary Compression Ignition Internal Combustion Engine NSPS		
2008	Ozone NAAQS (.08 8hr =>.075 8hr)	X	
2008	Petroleum Refineries NSPS	X	
2008	Lead (Pb) NAAQS	X	
2009	Portland Cement Manufacturing NESHAP	X	X
2010	Ozone Reconsideration	X	
2010	NO2 NAAQS	X	X
2010	Existing Stationary Compression Ignition Engine NESHAP	X	X
2010	Indus'l, Comm'l & Institutional I Boilers & Process Heaters NESHAP	X	X
2010	Greenhouse Gases PSD and Tailoring Rule	(no health benefits quantified)	
2010	SO2 NAAQS (==> 1-hr 75 ppb)	X	>99.9%
2010	Portland Cement Manuf'g NSPS & NESHAP Amendment	X	X
2011	Sewage Sludge Incineration Units NSPS & Emission Guidelines	X	X
2011	Comm'l & Indus'l Solid Waste Incineration Units NSPS and Emission Guidelines	X	X
2011	Utility Boiler MACT NESHAP	X	>99.9%
2011	Mercury Cell Chlor Alkali Plant Mercury Emissions NESHAP	X	X
2011	Oil & Natural Gas Industry NSPS & NESHAP Amendment	(no health benefits quantified)	

Table 1 shows that in 22 of those 28 RIAs, I found that a majority of the total benefits were due to $PM_{2.5}$ mortality co-benefits. In fact, $PM_{2.5}$ co-benefits were the only benefits, or accounted for more than 99.9% of the quantified benefits in 13 of those 22. Of the remaining six, four did not quantify health benefits at all (yet most of those discussed $PM_{2.5}$ co-benefits qualitatively as well as direct benefits of the rule's targeted pollutants). This leaves just two of the 28 RIAs that were not specifically targeting ambient $PM_{2.5}$ yet did not find that most or all of the quantified benefits were actually co-benefits due to $PM_{2.5}$. Overall:

- $PM_{2.5}$ health-related co-benefits have been relied on to create the benefit-cost case for regulations that were actually intended to address mercury, a host of other air toxics, ozone, regional haze, lead, NO_2, and SO_2.
- The trend towards almost complete reliance on $PM_{2.5}$-related health co-benefits has grown over time.

In 2009, EPA changed its RIA calculations to vastly increase the levels of $PM_{2.5}$ co-benefits that it can attribute to non-$PM_{2.5}$ rules.

As noted above, EPA has been increasingly relying on $PM_{2.5}$ co-benefits to produce a benefit-cost case for a host of non-$PM_{2.5}$ rules. However, in my review of RIAs, I also realized that EPA made a move in 2009 that greatly increased those co-benefits estimates —and did so in a way that I consider to have no scientific credibility. The co-benefits that EPA estimates for rules that are not targeting ambient $PM_{2.5}$ are calculated from very small changes in $PM_{2.5}$ concentrations that are already well below the safe level established by the $PM_{2.5}$ NAAQS. This is because those co-benefits are supposed to be computed only for incremental improvements beyond existing regulations, such as the existing $PM_{2.5}$ NAAQS. The $PM_{2.5}$ NAAQS imposes a maximum annual average ambient concentration of 15 $\mu g/m^3$, which the EPA Administrator deemed to protect the public health with an adequate margin of safety in 2006. That NAAQS is under review now, and EPA staff (with CASAC's concurrence) has stated that the lowest level that it may be revised to is 11 $\mu g/m^3$.[4] Nevertheless, in 2009, EPA suddenly started to calculate $PM_{2.5}$ risks in its RIAs down to the lowest level its air quality models predict, which can be as low as 4 or 5 $\mu g/m^3$. This results in risks being attributed to exposures that are far below the level of $PM_{2.5}$ deemed safe. As I will show, those increased risk estimates are very large. EPA is using those greatly inflated risk estimates to justify a wide range of regulations other than $PM_{2.5}$, even though it is not prepared to argue that those risks are credible enough to justify action in the form of an even-tighter $PM_{2.5}$ NAAQS.

Risk Estimates Have Been Nearly Quadrupled. This decision by EPA to calculate risks down to the lowest level that its models project, rather than just to the lowest measured level (LML) in the epidemiological study that serves as the basis for its risk relationship greatly increased EPA's estimates of $PM_{2.5}$ co-benefits in its RIAs. This large inflationary effect can be observed just by comparing EPA's baseline 2005 risk estimates in its 2010 $PM_{2.5}$ Quantitative Health Risk Assessment for $PM_{2.5}$—which does not extrapolate below the LML—to those in its post-2009 RIAs which do extrapolate below the LML. The former is being used the current review of the $PM_{2.5}$ NAAQS mentioned above, and in it, EPA estimates 88,000 deaths were due to $PM_{2.5}$ in 2005 based on an epidemiological study by Laden *et al.*[5] In its concurrent RIAs, however, EPA estimates fully 320,000 deaths due to $PM_{2.5}$ for the same year, the same estimated air quality, and using the same Laden *et al.* study.[6] The former is 4% of total annual U.S. deaths of 2.4 million and the latter is 13% of 2.4 million annual U.S. deaths. *Notably, EPA is now using both of these contradictory estimates of baseline $PM_{2.5}$-related deaths simultaneously in different regulatory proceedings*—EPA is using the smaller number of baseline deaths in its CASAC-reviewed risk analyses for the $PM_{2.5}$ NAAQS review, and it is using the larger number of baseline deaths in its RIAs that are generating the large co-benefits for non-$PM_{2.5}$

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[4] EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards*. EPA-452/R-11-003. Office of Air Quality Planning and Standards, Research Triangle Park, N.C., April 2011, p. 2–106. (Available at: *http://www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf.*)

[5] EPA, *Quantitative Health Risk Assessment for Particulate Matter*. EPA-452/R-10-005. Office of Air Quality Planning and Standards, Research Triangle Park, N.C., June 2010, p. G–2. (Available at: *http://www.epa.gov/ttn/naaqs/standards/pm/data/PM_RA_FINAL_June_2010.pdf.*)

[6] EPA, *Regulatory Impact Analysis (RIA) for the Final Transport Rule*, Docket ID No. EPA-HQ-OAR≥2009-0491, p. 3. (Available at *http://www.epa.gov/airtransport/pdfs/FinalRIA.pdf.*)

regulations, such as for air toxics regulations and for non-PM NAAQS, such as ozone.

Thus, with this single change in its RIA calculations, EPA has caused the estimate of total $PM_{2.5}$-related deaths to nearly quadruple, from 88,000 to 320,000. In effect, in 2009, EPA quietly "created" an additional reservoir of 232,000 $PM_{2.5}$-related deaths that it could continue to tap into in its future RIAs as co-benefits for the many non-PM clean air regulations that it will be proposing and promulgating in the future. The RIAs for the proposed Utility MACT and the Ozone Reconsideration are recent RIAs that benefited from the dramatic inflation of EPA's estimates of total $PM_{2.5}$ risks, as I will show next.

Inflated Co-Benefits Estimates Are Being Calculated for Small Changes in Exposure to $PM_{2.5}$ *that EPA Deems Safe*. The Cross-State Air Pollution Rule (CSAPR) that was promulgated in July 2011 is intended to help bring the nation into compliance with the present $PM_{2.5}$ NAAQS. The RIA for the CSAPR reports that in 2014 it will save up to 34,000 lives that would otherwise end prematurely due to $PM_{2.5}$ exposures, as compared to premature deaths in a baseline that did not even include CAIR.[7] One can think of this as a reduction from the 320,000 underlying deaths associated with 2005 levels of $PM_{2.5}$. Even if we assume that control measures between 2005 and 2014 additional to those of CSAPR would double the estimated lives saved that EPA attributes to CSAPR alone, EPA is estimating that there still will remain some 250,000 deaths due to $PM_{2.5}$ even after CSAPR has been implemented in 2014. It is from this remaining reservoir of "premature deaths" (still nearly 10% of all U.S. deaths per year!) that EPA finds the 17,000 lives that it purports would be "saved" as a co-benefit of the Utility MACT, when it comes into effect in 2015 and mandates reductions of acid gases.[8] When placed in the context of such a huge pool of lives that still "could be saved" if $PM_{2.5}$ were to be 100% eradicated, it becomes apparent that the 17,000 lives of "co-benefits" is a small percentage change that reflects the small difference in $PM_{2.5}$ exposures offered by the Utility MACT. The RIA for the Utility MACT confirms that it provides not only a small percentage risk reduction, but that its comes from very low exposures, as Figure 1, copied from Figure 6-15 of the Utility MACT RIA, shows.

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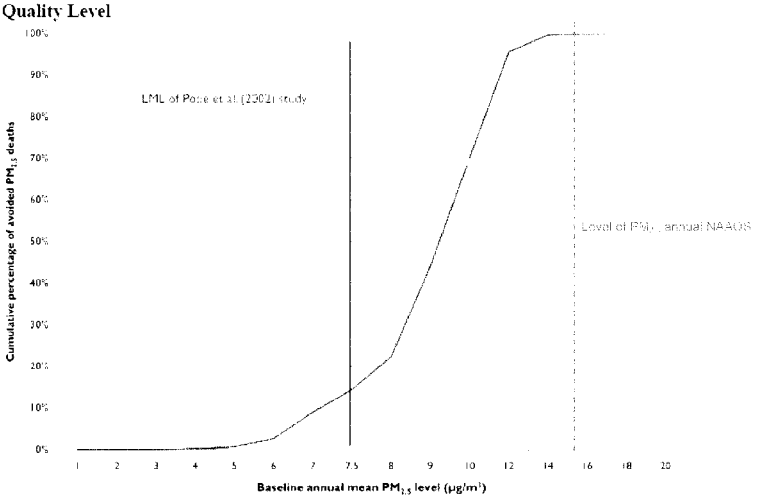
[7] EPA, *Regulatory Impact Analysis (RIA) for the Final Transport Rule*, Docket ID No. EPA-HQ-OAR-2009-0491, p. 1. (Available at *http://www.epa.gov/airtransport/pdfs/FinalRIA.pdf.*)

[8] The benefits of the Utility MACT rule are calculated after having modeled full implementation of the proposed Clean Air Transport Rule, which was the proposed version of the final CSAPR. It is thus fairly similar to an analysis of benefits after accounting for the reductions expected from CSAPR.

Figure 1. Copy of Figure 6-15 from the Utility MACT RIA[9]
(The dotted red vertical line has been added to identify the level of the current annual $PM_{2.5}$ NAAQS)

Figure 6-15. Cumulative Percentage of Total PM-Related Mortalities Avoided by Baseline Air Quality Level



Of the total PM-related deaths avoided:
86% occur among population exposed to PM levels at or above the LML of the **Pope et al.** study.
occur among population exposed to PM levels at or above the LML of the study.

[9] EPA, *Regulatory Impact Analysis of the Proposed Toxics Rule,* Final Report, March 2011 (the "Utility MACT RIA"). (Available at: http://www.epa.gov/ttnecas1/regdata/RIAs/ToxicsRuleRIA.pdf.)

Figure 1 shows that effectively all of the Utility MACT's purported $PM_{2.5}$ co-benefits are due to reductions in exposures to $PM_{2.5}$ that are already below the annual NAAQS standard of 15 µg/m³. This fact can be inferred from the figure in the following way. The blue S-shaped curve in Figure 1 indicates on the vertical axis the percent of the RIA's $PM_{2.5}$ co-benefits estimate that is attributable to baseline $PM_{2.5}$ exposures at or below the $PM_{2.5}$ concentration on the horizontal axis. This is known as a "cumulative distribution." The point on the horizontal axis where the S-shaped curve just reaches 100% indicates the level of baseline $PM_{2.5}$ at or below which all (i.e., "100%") of the estimated $PM_{2.5}$ co-benefits occur. I have added a vertical dotted red line to Figure 1 at the level of the current annual NAAQS (i.e., at 15 µg/m³ on the horizontal axis). As one can see, the vertical reading on the blue S-shaped curve is about 100% at 15 µg/m³, which means that about 100% of EPA's estimated $PM_{2.5}$ co-benefits from the Utility MACT would be based on reductions in annual average $PM_{2.5}$ exposures that are already below the health-protective level of the current standard. Not only are most of the benefits occurring at very low $PM_{2.5}$ exposures to start with, but RIA also tells us that they are due to very small exposure changes. The changes in exposure are only 0.7 µg/m³ on average, and do not exceed 1.49 µg/m³ in any location.[10]

EPA is presently considering whether to tighten the $PM_{2.5}$ NAAQS, with a Proposed Rule expected later in 2011. EPA is considering a range of possible alternative annual standards that extends as low as 11 µg/m³. If EPA revises the NAAQS to the lowest of those levels, the RIA's figure also tells us that 20% of the co-benefits being attributed to the Utility MACT (i.e., those that occur in locations where pre-rule $PM_{2.5}$ is above 11 µg/m³) are going to occur anyway, as a result of NAAQS attainment.[11] They therefore are inappropriate to count as co-benefits of the Proposed

[10] See Utility MACT RIA, p. 4–5, (at *http://www.epa.gov/ttnecas1/regdata/RIAs/ToxicsRuleRIA.pdf.*)

[11] 11 Some might argue that these $PM_{2.5}$ benefits will appear sooner because the Proposed Utility MACT Rule will be fully implemented by 2016, while full implementation of a tightened

Rule for air toxics—they should be counted as the direct benefits of the new $PM_{2.5}$ standard. Moreover, the remaining 80% of the Utility MACT's $PM_{2.5}$ co-benefits are for reductions in $PM_{2.5}$ exposures that will still be deemed safe by EPA.

The Additional $PM_{2.5}$ Benefits Estimates Are Not Scientifically Credible. The significant inflation in $PM_{2.5}$ health benefits that EPA has introduced into its RIA calculations since 2009 is accomplished by adding in benefits of the least credible sort because most of that increase is due to benefits estimates below—often far below—the levels of $PM_{2.5}$ that have been observed in the scientific studies that form the basis of the $PM_{2.5}$ health effects literature. Thus, overnight in 2009, in the course of preparing RIAs that are not subject to public peer review, EPA dramatically escalated its estimates of benefits for all of its RIAs. This had the most profound impact on its estimates of benefits in the vast swath of the U.S. that has $PM_{2.5}$ concentrations below 10μg/m^3: small changes in modeled $PM_{2.5}$ in these areas used to contribute nothing to the total estimated benefits of a regulation, but they now contribute as much as 70% of the co-benefits estimates (as can be seen in the case of the co-benefits in the Utility MACT RIA from Figure 1). EPA accomplished this enormous benefits inflation without changing the epidemiological studies it relies on, but by altering a much more obscure assumption in its risk analysis calculations, the use of the "LML."

One associated and interesting effect of this benefits inflation, however, is the degree to which it makes the total number of deaths attributed to $PM_{2.5}$ implausible. EPA's presumption that fully 320,000 deaths in the U.S. were "due to $PM_{2.5}$" in 2005 represents over 13% of all deaths in the U.S. *on average*. And behind that average is the presumption that in large expanses of the Eastern U.S., between 16% and 22% of all deaths in 2005 were "due to $PM_{2.5}$." By extension (although EPA has not reported this calculation), EPA's estimates imply that about 25% of all deaths nationwide were due to $PM_{2.5}$ as recently as 1980.[12] These fundamental assumptions that underpin EPA's co-benefits calculations stretch the bounds of credibility, and thus undercut the credibility of all the co-benefits estimates themselves.

The simple reason why these new baseline risks are so large—implausibly large in my view—is that EPA assumes in its risk analysis calculations that there is no tapering off of relative risk as $PM_{2.5}$ exposure approaches zero. For years there has been a debate about whether the concentration-response relationship can truly be linear down to zero, but this debate has been focused on questions of statistical power and on basic principles of toxicology. The implication of the linear-to-zero/no-threshold assumption has never been debated in terms of its implication that an implausible proportion of total deaths in the U.S. would be due to $PM_{2.5}$—but perhaps now it should be debated that way too.

The decision to inflate the $PM_{2.5}$ risks by presuming risks continue down to zero has its greatest impact on co-benefits estimates.

The vast increase in total deaths that EPA now attributes to $PM_{2.5}$ exposures (i.e., the increase from 88,000 to 320,000 for the year 2005) has a greater inflationary effect on estimates of co-benefits from rules that do not address $PM_{2.5}$ risks directly than it does on the direct benefits of rules to steer ambient $PM_{2.5}$ into attainment of its NAAQS. In rules not targeting ambient $PM_{2.5}$ directly, the changes in $PM_{2.5}$ are only coincidental and presumably incremental to attainment of the $PM_{2.5}$ NAAQS. Such changes are most likely to occur in areas that are either already in attainment or will be pushed into attainment by rules implementing the $PM_{2.5}$ NAAQS. In fact, coincidental and incremental reductions of $PM_{2.5}$ that could qualify as co-benefits from a non-PM rule must occur in locations that are already in attainment with the $PM_{2.5}$ NAAQS, or else those benefits are being double-counted, because they have already or soon will be counted as the direct benefits of the $PM_{2.5}$ NAAQS itself. Hence, by inflating its $PM_{2.5}$ benefits estimates with additional risk estimates of the least credible form, EPA has enhanced its ability to justify *non-$PM_{2.5}$* regulations through $PM_{2.5}$ co-benefits. The practice of basing the benefit-cost case for new rules almost solely on co-benefits rather than on direct benefits is troubling to start with, but this recent change in EPA's RIA benefits estimation methods

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$PM_{2.5}$ NAAQS will be several years later. However, that difference is only temporary, and many have argued that the accelerated time frame for implementation of the Utility MACT rule will be far more disruptive than EPA's cost analysis indicates due to its exceedingly rapid implementation. Thus, making a point that these could be considered valid temporary co-benefits for the years 2016 through perhaps 2020 only raises the question of whether that accelerated time frame is reasonable and justifiable.

[12] See pp. 14–16 of my technical comments on the Utility MACT (at: *http://www.nera.com/67_7412.htm*).

now causes the bulk of the co-benefits that it estimates to be quite suspect from a scientific basis.

If it were viewed as credible that such large effects exist below the level of the $PM_{2.5}$ NAAQS, the appropriate policy remedy would be to tighten the $PM_{2.5}$ standard, and not to regulate something else altogether in order to obtain those benefits through "coincidence."

There remain many reasons to continue to have doubts about the causality in the presumed relationship between ambient $PM_{2.5}$ and mortality. These calculations continue to rely solely on statistical associations with little to no clinical evidence to support the causal interpretation of these correlations. Despite many efforts to provide statistical controls, the ability to tease out other explanations based on phenomena that are correlated with variations in ambient $PM_{2.5}$ levels remains elusive. Alternative explanatory factors may include traffic, noise, and even socioeconomic conditions that have not been possible to characterize fully with statistically useful data. Tighter controls on $PM_{2.5}$ may therefore not produce the benefits that EPA calculates even for reductions from levels of $PM_{2.5}$ that are in the ranges of concentrations that have been measured in the epidemiological studies. But to also assume that the presumed causal relationship remains in effect with equivalent potency down to essentially zero concentration levels is simply inappropriate scientifically. [13]

EPA and CASAC have not shown any willingness to argue for setting a $PM_{2.5}$ standard at those very low levels that have not yet been studied, even though there is a complete and thoroughly effective mechanism in the *Clean Air Act* that gives the Administrator the ability to protect the public health from such exposures if they really do pose risks as large as EPA assumes in its RIAs. EPA therefore should not continue its practice of reporting that regulations that do not address ambient $PM_{2.5}$ will have benefits that exceed their costs based on estimates of $PM_{2.5}$ risks that EPA is not prepared to directly reduce through the $PM_{2.5}$ NAAQS.

Co-benefits from a pollutant that EPA already regulates should not be allowed to serve as the predominant benefit in an RIA for a rule that targets a different public health concern.

EPA's use of co-benefits in its RIAs scares the public into believing that people would be dying in droves were it not for implementation of new rules on pollutants for which EPA has not actually identified any current public health risk. It gives EPA a shield to justify building a complex web of many different rules, when EPA could provide almost all of those purported health-protective benefits with just a single rule: the $PM_{2.5}$ NAAQS. That EPA does not take this simple, streamlined approach hints at the degree to which it realizes that its co-benefits calculations do not reflect true public health risks. But also, it is just bad policy to promote the goal of further $PM_{2.5}$ risk reductions by way of expanding MACT rules for mercury, acid gases, metallic air toxics and by way of striving to attain tighter NAAQS for ozone, lead, SO_2 and NO_χ. This cannot possibly result in a cost-effective path to addressing a nation's clean air needs.

Appendix

More Details From My Technical Comments on the Utility MACT and Ozone RIAs

I have described and discussed the key trends of concern that I have observed in my review of many RIAs, but I also would like to also provide the summaries of the specific issues that I found in the two RIAs for which I have written full technical comments. I believe that a recap of my summaries for those two individual RIAs may help illustrate the depth of the problems that are created by EPA's reliance on $PM_{2.5}$ co-benefits as the central feature of its benefits analyses for clean air rules that are not purposefully reducing $PM_{2.5}$-related health risks.

Summary of Key Findings From My Review of the Proposed Utility MACT Rule

This section is excerpted from my *Technical Comments on the Regulatory Impact Analysis Supporting EPA's Proposed Rule for Utility MACT and Revised NSPS (76 FR 24976)* which was entered into the Utility MACT docket as part of comments

[13] 13 For a more complete discussion of these points, see my technical comments on the Utility MACT RIA, pp. 19–20, pp. 35–36, and Appendix C, available at *http://www.nera.com/67_7412.htm*.

submitted by the Utility Air Regulatory Group (UARG). The full comments can be downloaded from *http://www.nera.com/67_7412.htm*.

- Although EPA reports that the Proposed Rule will produce annual benefits ranging from $53 billion to $140 billion, *these benefits have nothing to do with air toxics at all*.
- EPA's estimates of the direct benefits due to reduction of the air toxics that are the specific purpose of this rulemaking range from only $0.0005 billion to $0.006 billion per year [14]—less than .01% of EPA's total benefits estimate—and this is due to reduction of just one of the HAPs, mercury (Hg). EPA concluded it had no basis for estimating benefits from reduction of any of the other EGU HAPs.
- Effectively all of the $53 billion to $140 billion of estimated benefits is due to "co-benefits" from coincidental reductions of fine particulate matter ($PM_{2.5}$), a pollutant that is separately and independently regulated under the *Clean Air Act* (CAA) as a criteria pollutant.
- The $PM_{2.5}$ co-benefits lack credibility because almost all of that dollar value comes from exposures that are so low that EPA deems them safe and is expected to continue to deem them safe after completing its review of the current $PM_{2.5}$ health standard this year. Further, the reductions in exposure levels are very small, averaging only 0.7 $\mu g/m^3$ in annual average concentrations. [15]
- The $PM_{2.5}$ co-benefits also lack credibility because of a long list of well-documented technical problems with the way EPA chooses to calculate actual health risks from statistical associations that have not been reliably shown to reflect causal relationships. These causality questions are particularly pronounced with respect to individual $PM_{2.5}$ constituents such as sulfate, which is almost the only constituent accounting for the Proposed Rule's co-benefits.
- *Prima facie* evidence of the non-credibility of EPA's co-benefits estimates exists in EPA's baseline estimates of risk in this RIA: deaths that were "due to" ambient $PM_{2.5}$ exposures exceeded 20% in areas of the U.S. in 2005. These co-benefits assumptions also imply that over 40% of deaths were due to $PM_{2.5}$ in parts of the U.S. during the period 1979–1983 when $PM_{2.5}$ concentrations were approximately double those for 2005. These surprisingly high assumptions about baseline risk, which in my opinion stretch the bounds of plausibility, are the result of a single assumption change in 2009 in EPA's RIAs to extrapolate risks below the ambient $PM_{2.5}$ levels that have been studied, to as low as background (i.e., nearly zero).
- RIAs are not subject to peer review by EPA's Clean Air Scientific Advisory Committee (CASAC) or to a public comment period.
- EPA has not made this assumption change in any of the risk analyses supporting its current review of the $PM_{2.5}$ health standard, which are subject to CASAC review.
- The $PM_{2.5}$ co-benefits estimates are virtually all tied to attainment of the Proposed Rule's MACT for acid gases, which is the one MACT category in this Proposed Rule for which EPA has not offered any evidence of health risk.
- Given that almost all of the co-benefits are solely attributable to the acid gas MACT portion of the Proposed Rule, there is no cost-benefit case for the remainder of the HAPs control requirements in the rule, whether their estimated co-benefits are included or not.

In light of the above points, which are further elaborated in the rest of my comments, I conclude that *the lower bound of the $PM_{2.5}$ co-benefits should be zero, and that EPA's upper bound $PM_{2.5}$ co-benefits estimate is just not credible*. EPA has not even quantified any benefits for the HAPs themselves, other than a tiny benefit from Hg reduction.

More importantly, I conclude that *EPA's argument that there is a strong cost-benefit justification for the Proposed Rule is inappropriate because it is based solely on a preponderance of co-benefits from a pollutant that is already regulated, and not*

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[14] Stated in a more readable format, the range of benefits estimated for the air toxics is $500,000 per year to $6 million per year. The Utility MACT RIA's summary Table 1-3 incorrectly states the lower bound, and I am reporting the values from RIA Chapter 5 (Table 5-7), and in the Proposed Rule (at 24979).

[15] 15 Utility MACT RIA, p. 4–5. To put this in context, the annual average standard (i.e., the level protective of public health with an adequate margin of safety) is 15 $\mu g/m^3$, about 20 times larger. Even the maximum decrease in $PM_{2.5}$ projected under the Proposed Utility MACT Rule is only 1.49 $\mu g/m^3$ (*ibid*.).

an air toxic. Moreover, the estimate is almost entirely derived from changes in very low concentrations that EPA has deemed adequately protect the public health. In the meantime, EPA has not been able to quantify, or even clearly identify, any meaningful amount of direct benefits from the reductions in air toxics that this rule mandates. The maximum ratio of direct benefits to costs for all three MACT groupings is 0.0006-to-1, with a net *loss* of about $10.9 billion per year. Each individual MACT grouping appears to impose a net benefit-cost loss on the basis of its direct benefits only, and two of those groupings appear to impose net losses even if their share of the upper bound estimates of co-benefits is included in the net benefit calculation.

Summary of Key Findings From My Review of the Ozone Reconsideration RIA

This section contains excerpts from the beginning and end of my report, "Summary and Critique of the Benefits Estimates in the RIA for the Ozone NAAQS Reconsideration," which was prepared for the American Petroleum Institute. The full report can be downloaded from *http://www.nera.com/67_7390.htm*.

The excerpts below have been modified to fit the current document's figure numbering.

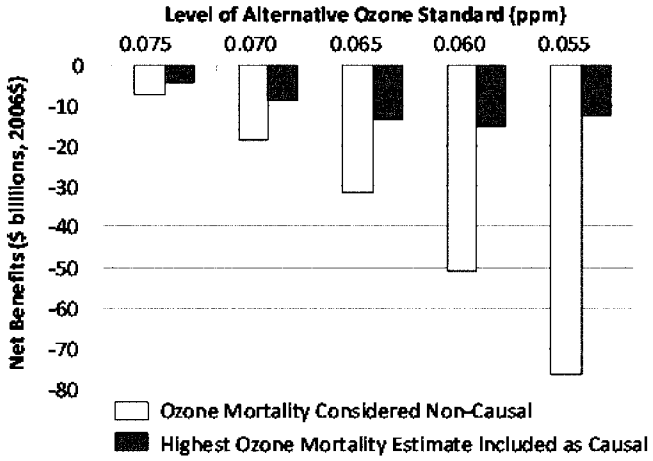
EPA's statements on health benefits from lowering the Ozone NAAQS grossly misrepresent what EPA is actually estimating as the potential benefits of reducing public exposures to ozone. If based on ozone benefits alone, not one of EPA's estimates of the benefits of reducing ozone to a tighter alternative ozone standard is as large as the costs of attaining that respective ozone standard—all cost more than the ozone benefits they might provide.

EPA's estimates of ozone benefits are less than their costs despite the fact that EPA has now escalated those benefits by always including benefits due to ozone-related mortality. EPA's science advisors (CASAC) found no "causal" link established between ozone and mortality during their deliberations, but EPA now presumes, as part of the reconsideration, a causal link between ozone and mortality risk. Despite this change that is unsupported by CASAC, EPA's net benefits estimates for ozone standards tighter than 0.075 ppm are all still deeply negative.

The only way EPA finds benefits greater than costs for a tighter ozone standard is to add in health gains from concomitant reductions in $PM_{2.5}$ that may occur while reducing ozone precursors—"co-benefits" that have nothing to do with ozone exposures. Thus, EPA's claim that tightening the Ozone NAAQS has greater benefits than costs has nothing to do with reducing risks from ozone. EPA also has inflated the magnitude of these co-benefits as part of the reconsideration through several specious assumption changes. The Agency's inflated co-benefits assumptions during this reconsideration represent a change compared to those assumed in the original Ozone NAAQS review ending in 2008. Even with both ozone mortality benefits and $PM_{2.5}$ mortality co-benefits, a large fraction of EPA's net benefits estimates are negative.

Figure 2 illustrates the *Supplemental RIA*'s estimates of the net benefits of each of the alternative ozone standards (relative to the standard of 0.084 ppm) when no $PM_{2.5}$ co-benefits are included. Even using the highest estimate of ozone mortality benefit in the RIA combined with the lowest EPA cost estimate, the estimated net benefits of the 0.075 ppm standard are about −$4.5 billion relative to the 0.084 ppm standard while the yet-tighter alternative standards (*i.e.*, 0.070 through 0.055 ppm) have estimated net benefits ranging from −$8.8 billion to −$12.7 billion. If one treats the ozone-mortality association as non-causal, EPA estimates that the current ozone standard of 0.075 ppm would have net benefits of −$7.5 billion and the yet-tighter alternative standards of 0.070 through 0.055 ppm would range from −$18.8 billion to −$76.7 billion. In fact, if there is no causal relationship between ozone and mortality risk, the net benefits estimates for standards tighter than 0.075 ppm remain negative even with the inclusion of the *highest* of EPA's $PM_{2.5}$ mortality and morbidity co-benefits and using the low end of its cost range.

Figure 2. Summary of Net Benefits of Each Alternative Ozone Standard Relative to Standard of 0.084 ppm for Ozone-Related Benefits Only (All Are Negative).



Chairman HARRIS. Thank you, Dr. Smith.

And I now recognize our final witness, Mr. J. Edward Cichanowicz, for five minutes to present his testimony. Mr. Cichanowicz.

STATEMENT OF MR. J. EDWARD CICHANOWICZ, CONSULTANT

Mr. CICHANOWICZ. Thank you. Good morning, Mr. Chairman, Members of the Committee. This morning I would like to summarize my opinion on the time that it takes to design and install environmental controls, and then I would also like to present a few graphics that convey the size of this equipment and how it fits into a power plant.

I will discuss three types of equipment: flue gas desulfurization scrubbers that remove sulfur dioxide, catalytic converters that remove nitrogen oxides, and a fabric filter, or baghouse, that removes particulate matter. Experience with this equipment in the last 10 years demonstrates that the timeline for most projects starting all the way from conceptual design including permitting and picking the right contractor and through commercial operation is more than 40 months for scrubbers and catalytic converters. Fabric filters will require less time.

The mandates of the Cross-State Air Pollution Rule and the Utility MACT are based on EPA's assumption of a much shorter time frame, less than 30 months. Notably, others within EPA agree with the estimates of near 40 months. Specifically, in a rulemaking addressing the retrofit of best available control technology to reduce NOx at a power station in New Mexico, EPA staff conducted their own survey and concluded that 37 months on average was required to retrofit catalytic converters. In summary, the mandates for the

Cross-State Air Pollution Rule and the Utility MACT presume an installation time that is not supported by recent experience.

If I could ask you to turn your attention to the graphics, I would like to show first a power station. This is a satellite image from a power station that is in Georgia. The reason why it is important is that they have already retrofit or are in the process of retrofitting the controls that we have just talked about. They have done it in response to a state mandate, and what we are going to do is look at the layout of the equipment as originally designed, and then we are going to walk around the unit and see what kinds of things have been put in and where they have been put. First, I will call your attention to the original equipment as designed, and that is denoted by the blue callouts. On the top, you see the boiler house and below it the initial original particulate collectors. The boiler house is indicated by the red rectangle and it contains, as you would guess, the boiler and the steam turbine and a lot of the fuel handling equipment. Right below it is the original particulate control device, and you will see it has its own stack. The first thing we will do is look and see what happens when we install a catalytic converter. This station is so big that it actually has two parallel flow paths so it is kind of like having two environmental control systems on one site, and what you see in the green is one of the two catalytic reactors being retrofit. At the time of the image, that construction was almost complete on one and was starting on the second. It is important to know that these catalytic converters are basically hung off the back of the boiler house so they are a couple hundred feet in the air. They are quite large devices.

As you continue to walk around the station, we see first one of the fabric filters that has been retrofit. Now, the good news for this site is that there is actually room to put one. The bad news is, it is not real close to the original equipment so you can see the fair amount of ductwork that had to be configured to tie it into the existing equipment.

As we continue to walk around, we see the location for the scrubber. It is being constructed within the green circle, and again, there is space for it, it just isn't very close to the balance of plant equipment and you need the additional ductwork. Also please note, there is an additional stack that is being constructed. For the type of scrubbers that most people prefer, they essentially saturate the gas with water, and what that means is that when the gas goes up the stack, it basically rains inside the stack and so you kind of have to build a new stack to tolerate those set of conditions. And then finally, the second of the two fabric filters is shoehorned in, and again, there is space for it, it just has to be configured within the site.

The next graphic or the only other graphic I will show is an absorber tower for a scrubber. First, I will call your attention to the red circle in the lower right. That is the standard reference person, and it gives you an idea of how large the equipment is. The gas enters on the lower right, proceeds vertically upward and then exits through the top to the left. The reason why these devices are so big is that the speed of the gas has to be slowed down to about anywhere from four to seven miles per hour. We have to mix other chemicals with it and we also have to make sure there is enough

residence time for the reactions to take place. If you will note on the top of the tower, there is a series of nozzles that spray an alkaline material.

Let me give you an idea of how much water is there. If you were to, say, stumble into a monsoon on the Pacific Rim, you might have a rainfall of 15 to 20 inches of rain per hour. Within that scrubber, it is generated 80 to 100 inches of rain per hour. So the point is, it is a very powerful spray and it sets up an engineered set of really perfect conditions that are intended to annihilate almost anything coming out in the gas, and for many cases, they do so.

So in summary, the reason why these devices take the time that they do is that they are complex, engineered systems. Their design needs to be thought out and they need to be constructed with precision.

Thank you.

[The prepared statement of Mr. Cichanowicz follows:]

PREPARED STATEMENT OF MR. J. EDWARD CICHANOWICZ, CONSULTANT

Summary

The U.S. Environmental Protection Agency (EPA) states that planning, designing, and constructing state-of-the-art emission control systems can be accomplished in less than 30 months. EPA made such claims when publishing its Cross State Air Pollution Rule (CSAPR) this summer and when proposing National Emissions Standards for Hazardous Air Pollutants for electric generating units (the Utility MACT proposal) last spring.

Contrary to EPA's claims, however, the "start to finish" times for this equipment—flue gas desulfurization (FGD) "scrubbers" to reduce sulfur dioxide (SO_2); selective catalytic reduction (SCR) catalytic reactors to reduce nitrogen oxides (NO_χ); and fabric filters to remove particulate matter—will be much more than 30 months. The most recent experience shows retrofits of FGD and SCR systems will typically take between 40 and 50 months.

There are two key reasons why it takes this long to plan, permit, fabricate, and install these control systems. First, the equipment is large and must be configured to fit into often-crowded plant sites. Second, these are not off-the-shelf designs; each must be custom-tailored to the site and coal. The problems are compounded when several control technologies are retrofit simultaneously at one plant site. For example, in order to comply with the CSAPR and the Utility MACT rule as proposed, owners may need to install FGD scrubbers and SCR catalytic converters at their plant sites at about the same time they are installing fabric filters to reduce mercury and other pollutants targeted by the proposed Utility MACT rule.

Few "short cuts" are available to significantly reduce this schedule by more than a few months. I do not concur with EPA's statement in the CSAPR rulemaking that years can be carved off the "start-to-finish" times of FGD and SCR systems by fast tracking design and procurement processes. And there is a downside to fast tracking these kinds of projects: it could compromise the quality of design or construction of the equipment, forcing plant operators for decades to use control systems that are ill-suited or otherwise not optimal for their sites.

Similarly, EPA has no basis to predicate the feasibility of its very tight Utility MACT compliance deadlines on principally one methodology: injecting specially prepared powders or sorbents into power plant gas streams to remove mercury and other pollutants such as hydrogen chloride. These sorbents will work in some instances, but not across the board as envisioned by EPA to achieve the targeted reductions. And where the use of sorbents does not achieve the very low emission limits proposed by EPA, owners will have to retrofit fabric filters to meet the proposed Utility MACT rule. EPA predicts as much as half of the generating inventory in the U.S. will have to do so. Under the best of circumstances, it would be difficult (if not impossible) to retrofit fabric filter controls at so many sites in the short MACT compliance timeframe. The challenge becomes even greater, though, if owners must install fabric filters at roughly the same time they are installing FGD and SCR systems to comply with the CSAPR.

Introduction

Chairman Hall, Ranking Member Johnson, and Members of the Subcommittee, thank you for the opportunity to speak with you today. I will provide an overview of the factors that affect the retrofit of environmental control technologies to coal-fired power stations for the purpose of meeting the mandates of the Cross State Air Pollution Rule (CSAPR) and the National Emissions Standards for Hazardous Air Pollutants (i.e., Utility MACT), particularly factors that influence the timing of installation.

The power industry in the last 10 years has successfully retrofit state-of-the-art environmental controls to a large fraction of generating units. Consequently, much of the power delivered into today's markets is generated by units equipped with effective environmental controls. The industry will continue to strive to meet future environmental mandates. However, as I will describe, the type of equipment that must be retrofit is exceedingly large in size, can be very complex, and can require special engineering and preparation tasks. To do this right simply takes time. Further, we have learned from experience what happens when the design or fabrication of a control technology is rushed, or is not optimized or properly designed for a given site and fuel. The outcome is never good.

Based on my years of experience advising power generation equipment owners in the retrofit of environmental control technology, I believe that typically between 40 and 50 months will be required to retrofit control options to meet the mandates of the CSAPR and the Utility MACT. It may be possible to reduce a few months from the schedule by fast tracking design and procurement, and using so-called "lean" construction methods, but in general it will not be possible to achieve this outcome in less than 30 months. Further, a result of fast tracking these duties could be a compromise in the quality of design or construction of this equipment. Operators would be forced for decades to use equipment that is not optimal for the site, orotherwise ill-suited.

Description of Environmental Controls

The industry selects from a suite of environmental controls those appropriate for a given task: removing sulfur dioxide (SO_2), nitrogen oxides (NO_χ), particulate matter, and trace species commonly referred to as hazardous air pollutants (HAPS). HAPS include mercury and acid gases such as hydrogen chloride. There are two distinguishing features of environmental controls for power plant effluent gases—first, the equipment is very large, and second, there is no one-size-fits-all design. Most equipment represents a custom design tailored to the characteristics of a particular site, and coal.

Exhibits 1–3 depict three of the key control technologies utilized. Exhibit 1 depicts a flue gas desulfurization (FGD) process that removes SO_2. Exhibit 2 depicts a selective catalytic reduction (SCR) module to reduce NO_χ; this module is basically a catalytic converter for a power station. Exhibit 3 depicts a fabric filter or baghouse, which filters out particulate matter. As will be discussed subsequently, the fabric filter device is important not only to control particulate matter, but also to contribute to limiting emissions of HAPS. Each of Exhibits 1–3 is meant to convey the large equipment size that is necessary to process the volume of gaseous combustion products. The equipment must be of large flow cross-section to reduce the velocity or speed of the gas to very low levels, to allow mixing of chemical reagents, and to provide time for reactions to take place to completion. For example, the speed of the gas in the FGD absorber tower is typically 5–10 feet per second—or about 3–7 mph—necessitating a large reactor.

The vessel size becomes problematic when it must be fit into an existing crowded site. It is the challenge of fitting these vessels into crowded sites, all of which differ in almost limitless ways, which can require a protracted design and installation effort. Exhibit 4 presents a plant layout—in my opinion of intermediate difficulty—containing this equipment, showing how environmental controls can be arranged. Some sites can be open and offer less challenge, but a notable number of units will face space limits.

In summary, the retrofit of environmental controls—all utilizing large vessels or reaction chambers, some with chemical and byproduct support plants—requires custom design, shop fabrication, and installation that take a lot of time.

Timeline for Equipment Installation

The "start-to-end" time line to install these control systems includes many steps above and beyond just the work to prepare a detailed design and install the equipment. A discussion of the key steps required and a summary of recent experience

is insightful. A detailed description of the key steps and recent relevant experience is presented in a report submitted to EPA on October 1, 2010 (a copy of which is attached to these comments), as part of comments to the rulemaking process. I'll summarize both topics.

Ten Steps: Project Initiation to Completion

The complete scope of activities to retrofit environmental controls can require as many as 10 separate steps, each of which will vary by project. Several of these steps can be conducted in parallel, but most require some sequence—at least some portion of one activity must be completed before the next is started. The 10 steps, including the range of time (in months) for execution, are:

- Conceptual Design and Preparing a Specification. What you want to build must be described in a way bidders can use to derive a design (6–12 months).
- Identification of Qualified Bidders. Potential contractors are to be identified; this process is typically conducted in parallel with the preceding (one month).
- Solicitation and Review of Bids and Contractor Selection. Onsite "walkdowns" are essential to acquaint bidders with the project. Evaluating capabilities is key; cost alone is not the determining factor in contractor selection (3–5 months).
- Negotiating Contract Terms and Conditions. Acceptable terms and conditions for labor and material, including escalation, are negotiated in advance (1–5 months).
- Securing Construction, Operating Permits. Permits—issued by local regulatory agencies and public utilities commissions—are required before construction can begin. Some preliminary design must be completed to define equipment and estimate emissions. Opening a storage site for byproduct material is most challenging (4 months–4 years).
- Finalizing Design. Producing engineering drawings is key, with detailed estimates of media emissions, to enable equipment purchase and fabrication (15–45 months).
- Mobilizing the Workforce. Identifying and securing the services of the mobile, specialized workforce has been rate-limiting for some projects (1–3 months).
- Construction. Includes soil, foundation, and structural preparatory work; fabricating, transporting, and erecting equipment. This is the most protracted onsite activity (25–40 months).
- Process Tie-In (1–3 months) and Process Start-Up (1–3 months) are the final steps.

Each of these steps is essential, although some can be expeditiously conducted depending on the site. For example, where an owner has negotiated a long-term strategic agreement with one supplier, the steps of contractor selection, evaluation, and contract negotiation for any project may take less time. However, getting the long-term agreement in place at the start is a lengthy process.

Projected time lines that do not consider each of these steps may not reflect the true "start" date, and will not be accurate.

Recent Experience and Lessons Learned

The power industry, working with the community of equipment suppliers, has extensive experience retrofitting environmental control technology to generating units. Most recently, a significant fraction of the generating inventory was retrofit with FGD scrubbers and SCR catalytic converters over the time period of 2008 through 2010. Specifically, a total of 123 generating units were retrofit with FGD, and a total of 40 units were retrofit with SCR catalytic converters from 2008 through 2010.

During the past two years, I have been involved with or had the opportunity to review retrofit projects for 22 FGD scrubbers and 14 SCR catalytic converters. As I described in the previously referenced October 1, 2010, report that was submitted to EPA, the time required to execute each retrofit—from "start-to-finish"—varied between units and sites. For FGD retrofits, completing all duties for the least complex projects—those that retrofit a single FGD process at a single site—took from 40 to 64 months, with the average of projects being 48 months. The shortest of these schedules—40 months—was incurred for a unit that applied the process design from a near-identical "sister" unit, and was able to construct several critical facilities in

parallel. The retrofit of multiple FGD equipment to more complex sites can require more time.

For SCR catalytic converters, the complete scope of duties for the least complex projects required from 28 to 46 months, with an intermediate project taking 40 months. The shortest of these schedules—28 months—was achieved as the subject unit was on the "end" of a row, providing improved access for cranes and other heavy fabrication equipment. Similar to FGD, the retrofit of SCR equipment to more complex sites with multiple units requires more time, up to 60 months.

Some within EPA appear to agree it will typically take more than 21 (or even 30) months to install SCR. In an unrelated rulemaking to establish Best Available Retrofit Technology (BART) to limit NO_χ emissions from the San Juan Generating Station (SJGS) in New Mexico, EPA determined recently (on August 22, 2011), that on average it takes 37 months to retrofit an SCR system on an existing unit. And EPA determined that it would be reasonable for the owners of SJGS to have five years to undertake and complete the SCR retrofit at SJGS.

In summary, under the best conditions, an FGD scrubber will require at least 40 months to retrofit, with most applications between 40 and 50 months. For SCR, under the best conditions an SCR catalytic reactor will require 28 months, with most applications averaging 44 months.

Compliance Timing: "Logjam" of Events 2012 to 2015

The emissions reductions provisions of the CSAPR and the Utility MACT require control technologies to be installed and operational at almost the same time—January 1 of 2014 for the CSAPR, and January 1 of 2015 for the Utility MACT rule. Given the time required to prudently design and install control equipment, it is not possible for operators affected by these regulations to meet these deadlines. This becomes clear with a further elaboration of the needs of each mandate.

2014 Mandates of the Cross State Air Pollutant Rule (CSAPR)

The CSAPR requires affected companies in the so-called "Group 1" states to achieve the mandated SO_2 reductions by January 1 of 2014. The amount of generating capacity, and the number of FGD scrubbers that need to be installed to achieve this compliance, has been projected by EPA as part of the Agency's analysis in support of the rule.

EPA's initial estimates of technology retrofit for the CSAPR, as first published in 2010, projected that 85 units generating 25 GW of capacity would retrofit FGD to comply with the 2014 mandate. In the final proposal for the CSAPR in July of 2011, EPA revised downward the estimates of FGD to 39 units generating 17.4 GW of capacity. The basis of EPA's downward revision appears to be a consequence of altering the modeling details and lowering the projected load growth. Based on the typical FGD "start-to-finish" scope discussed of 40 to 50 months, any owners that must comply would already have had to start—and in fact should be more than one year into these efforts. Given the date of the final release of the CSAPR—less than 60 days ago on July 7 of 2010—the timing presumes owners started engineering well in advance of finalizing EPA's rule.

EPA's rationale in proposing the 2014 date is not only that a 27-month time line is typical for FGD, but also that owners can start work without risk prior to the promulgation of a final regulation. This is not the case. Historically, there have been instances where owners have quickly and proactively responded to a pending rule, only to witness the rule being changed or delayed. As a result, construction is terminated, or acquired SO_2 allowances cannot be utilized. The owner must absorb any "sunk" costs for equipment or allowance purchase.

2015 Mandates of the Utility MACT Rule

Perhaps more challenging is the schedule presented by the National Emissions Standards for Hazardous Air Pollutants (NESCHAPS)—the Utility MACT mandate. Compliance strategies for this proposed rule—scheduled to be finalized by the end of this year—are uncertain. The control technologies discussed in this testimony so far—the FGD scrubber, the SCR catalytic converter, and the fabric filter—can contribute in ways both large and small to MACT compliance. Owners of generating units are investigating how to best utilize these technologies for MACT, recognizing the degree of control required for both mercury and hydrogen chloride is at or beyond the capabilities of these controls in most applications.

However, EPA is predicating success—timely compliance with the MACT—based principally on one methodology. This method entails injecting into the gas one or more specialty powder(s), referred to as sorbents, to remove mercury and hydrogen

chloride. One class of sorbents, known as activated carbon, is intended to remove mercury from combustion products. A second class of sorbents—actually a family of materials derived from the mineral trona—is intended to remove acid gases, such as hydrogen chloride. EPA believes any shortcomings in sorbent performance can be compensated by retrofitting fabric filters to 166 GW of capacity—more than half of the national inventory of units in 2015.

Regarding mercury, experience with activated carbon in demonstration tests suggests this sorbent will be successful on many units. However, as noted in an August 2011 report addressing mercury control technology (a copy of which is attached to this testimony) for the proposed Utility MACT rule, there may be an equal population of units that will not meet the targeted mercury limit. There may also be units where the carbon sorbent induces operating problems, or increases the emissions of particulate matter.

Regarding control of "acid gases" such as hydrogen chloride, the uncertainty is far greater. EPA, to its credit, developed an extensive database of emissions of HAPS species from power generation equipment. Regrettably, certain elements of the database were either ignored or not properly utilized. EPA's proposed hydrogen chloride limits presume that sodium sorbents can be a sole means to comply—despite the fact that of the 11 units in EPA's database using this approach, there are only two units with data suggesting such success. EPA predicted in a March 17, 2011, document that 56 GW of capacity would deploy this sodium-based sorbent approach. It is hard to believe the design for so many commercial systems can be successfully scaled, and equipment installed, on such limited experience.

For both the mercury and hydrogen chloride MACT mandates, EPA's "backstop" approach is broad application of fabric filters to 166 GW of capacity. Again, it is hard to believe that such capacity can be retrofit with both sorbent injection systems and fabric filters, and successfully operate as predicted, in slightly more than three years. Furthermore, the proposed fabric filter retrofits are to be achieved at the same time the technologies for CSAPR are being deployed. Such a schedule would stretch supply sources in 2013 and, in my opinion, well into 2014 as the FGD units are delayed. Although the task of installing any single fabric filter collector may be less onerous than a FGD or a SCR catalytic converter, many of the steps are still the same.

Review of Key Uncertainties

In summary, several key uncertainties behind the proposed mandates in 2014 and 2015 should be considered:

Equipment Installation Timeline: EPA's assumed time line for equipment installation—based on experience gathered from 2008 through 2010—is unrealistic. The FGD and SCR installations completed prior to 2010 were mandated five years prior to the compliance date. As EPA hasnoted in CSAPR rulemaking documents, some large system owners initiated work prior to 2005, but in response to incentives to acquire SO_2 allowances. Owners had a financial incentive to deploy technology early—and not a disincentive of putting capital at risk, which is the present case.

Capability of Sorbent Injection for Hg Control. The use of activated carbon sorbent to remove mercury has been demonstrated to meet the proposed MACT mercury limit for several categories of generating units. However, an equal number of generating units could be at risk to meet the proposed MACT limit using activated carbon sorbents, unless a fabric filter is retrofit.

Capability of Sodium-Based Sorbents to Remove Hydrogen Chloride to the MACT Limit. Sodium-derived sorbents have been used to remove acid gases such as hydrogen chloride, but there is limited experience in achieving the low levels mandated by the MACT. At this time there are only two operating units with data suggesting this option can potentially meet the proposed Utility MACT rule.

Capability to Broadly Retrofit Fabric Filters. EPA's analysis of complying with the MACT is predicated on the ability to successfully retrofit 166 GW of generating capacity with fabric filter controls by January of 2015. As noted in an analysis that I co-authored and submitted in July of 2011 as comments to MACT (a copy of which is attached to this testimony), it is unlikely this amount of fabric filter control technology can be retrofit by January of 2015. Successfully retrofitting fabric filters to this capacity alone would be a challenge, much less conducting this work contemporaneous with FGD scrubber retrofit for the CSAPR.

EXHIBIT 1

Perspective Drawing of Wet Flue Gas Desulfurization (FGD) or Scrubber Process
(Source: Babcock Power, Inc.)

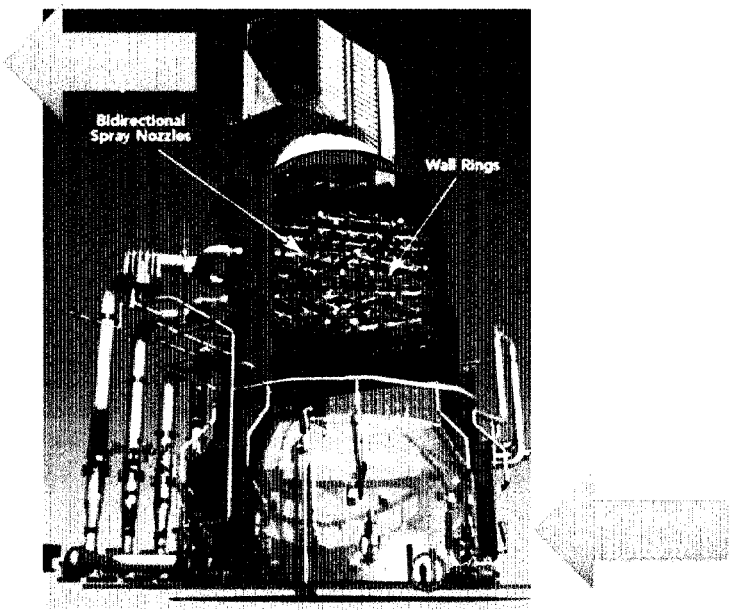


EXHIBIT 2

Selective Catalytic Reduction (SCR) Catalytic Reactor
(Source: Babcock & Wilcox)

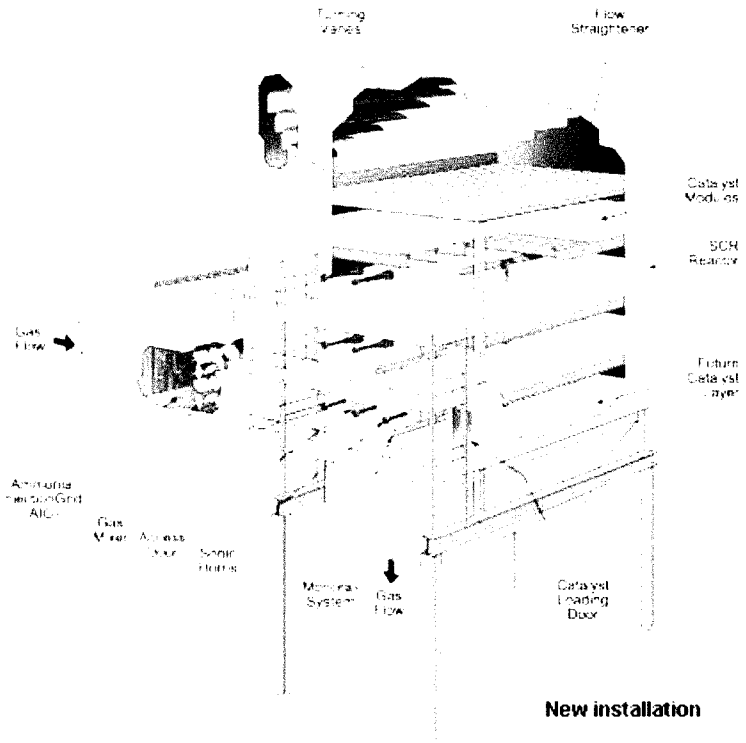


EXHIBIT 3

Fabric Filter Particulate Collector
(Source: Babcock & Wilcox)

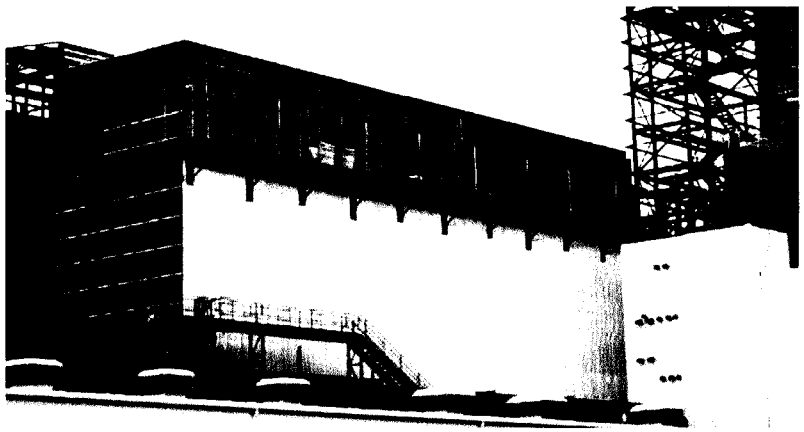
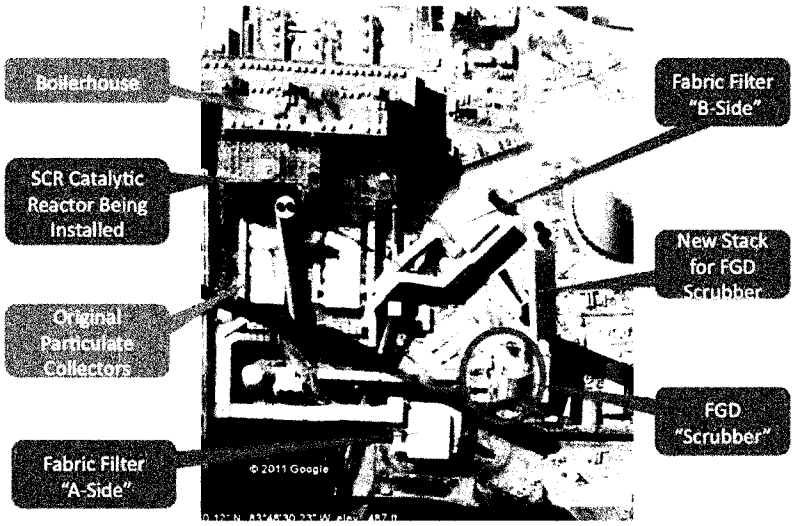


EXHIBIT 4

Large Generating Plant Layout Depicting Location of Environmental Control Equipment
(Source: Satellite Image)



Chairman HARRIS. Thank you very much, Mr. Cichanowicz.

And what we will do now is, we will start with five minutes of questions, a five-minute round of questions, and I recognize myself for the first five minutes.

Dr. Phalen, let me just ask you a question just to elaborate a little bit about your testimony because what you imply is that the decisions made by CASAC are made—or I should say the advice is not made as to the entirety of the decisions and the other potential ramifications of that decision. Rather, it goes to a very specific question that is asked without taking the entire context. Is that correct?

Dr. PHALEN. Yes, sir, that is correct. And when you look at such isolation of an issue, it causes trouble everywhere else.

Chairman HARRIS. Sure, so that when you have—for instance, there is a study from Stony Brook University earlier this year that found that people who experienced a period of unemployment were more than 60 percent more likely to experience premature mortality. So you have some co-factor there, and in this case, everybody agrees, I think that if you lose your health insurance, you are more likely to have premature mortality. I mean, I think probably there is uniform agreement on that. If you don't have a job, you are more likely not to have health insurance. Therefore, you can connect something that reduces the number of jobs to actually an adverse health effect. Is that what you are talking about when you are saying that the panel should be allowed to make statements regarding the entirety of a decision?

Dr. PHALEN. Affirmative, Mr. Chairman.

Chairman HARRIS. Okay. Thank you very much.

Dr. McClellan, you stated in your testimony that CASAC specifically said that it was a science and policy judgment when these standards are being suggested. Now, I am a little puzzled by that. How are you making policy judgments without science? I mean, is that what is happening at EPA, that in fact, you are infusing policy into these decisions that are not based on science or without a scientific background?

Dr. MCCLELLAN. In the CASAC review of the science in the two recent cases, the $PM_{2.5}$ and then the ozone, they chose to set a bright line. They said in the case of the $PM_{2.5}$ that the Administrator should set the annual standard and higher than 14 micrograms per cubic meter. The Administrator renewed it at 15 and they stamped their feet and said you didn't follow our advice. Anybody knows that 14 is one integer less than 15 but to suggest that the science was so compelling that 14 was acceptable, 15 was not, that is a blending of policy and science. In the case of ozone, they said 60 to 70 PPb. They tried to sort of justify it by saying well, we gave you a range. I don't presume to say that they would have stamped their feet if you had gone below 60 but they stamped their feet when the Administrator set it at 75 PPb. They actually had scheduled a meeting before the formal rule was announced, and at that meeting protested and said no, we told you 70 PPb, you set it at 75 PPb. Their advice was a blend of science and their personal policy preferences. There is no scientific methodology that can tell you this is where the standard should be set. That represents a policy choice exclusively delegated to the Administrator of EPA.

Chairman HARRIS. Thank you. Thank you very much.

Dr. THURSTON. I would like to respond to that.

Chairman HARRIS. Well, I have a question for you, Dr. Thurston, because I only have about a minute left. Dr. Thurston, two questions. One is, one of your graphs kind of presumes that there are linear effects and some of the science assumes that there is a linear effect of increasing and decreasing exposure but we know from carcinogens, for instance, specifically that is likely not true, that at some low levels, you know, an effect seeing a reducing carcinogens at a higher level may not have the same effect on mortality as reducing the amounts at a lower level. So would you agree that the science about linearity of effect of air pollutants is not clear?

Dr. THURSTON. Well, I would say the evidence we have is consistent, or certainly not inconsistent with a linear effect, and I think that, you know——

Chairman HARRIS. Right. Okay. Thanks. I just need a very simple answer because I have one more question.

Dr. THURSTON. But you mentioned figure one does show the association going down to seven micrograms per cubic meter, well below the standard.

Chairman HARRIS. I know, and it has a bunch of lines. I understand that.

Dr. THURSTON. But in response to Dr. Smith's comment——

Chairman HARRIS. I have to ask this question because this puzzles me.

Dr. THURSTON. Go look at figure one.

Chairman HARRIS. In the past 20 years, and I have observed this being a physician even in the operating room, the incidence of asthma has clearly increased. The incidence and prevalence of asthma in the population has clearly increased in the past several decades. Would you agree with that?

Dr. THURSTON. Yes. It is a multifactoral disease.

Chairman HARRIS. Has air pollution clearly decreased significantly in the past several decades?

Dr. THURSTON. Yes, but it is not the only cause of asthma.

Chairman HARRIS. These are very complicated interactions; aren't you afraid that we simplify them too much when we make statements as were made by the Assistant Air Quality Administrator here that hundreds of thousands of asthma episodes are going to be avoided if we change these standards when in fact there are hundreds of thousands more episodes since the last time we changed these standards?

Dr. THURSTON. I think it raises a good point, that there is a whole pyramid of effects that are not measured by the system. In other words, I can't answer that question because we don't have good records of those hospital—you know, the asthma exacerbations, and that is not considered by the process, so we are really underestimating the benefits of clean air and the process the EPA is using today, and that is a good example.

Chairman HARRIS. Thank you. And Dr. Thurston, by the same logic, I would say we may be overestimating the benefits by the very same example of the poor data we have.

Anyway, I recognize Mr. Miller for five minutes.

Mr. MILLER. Thank you, Mr. Chairman. This hearing is about process, but the process of the Committee I think also bears some scrutiny. It is very strange for the EPA's processes to be the subject of this Committee's hearing and for the EPA not to be present. I think most Americans understand fundamental fairness is that if you are going to be criticized in public, that you should be there to defend yourself, but the EPA has not been invited today, and in past hearings when they have been criticized, they have not been called to testify.

There was a book about a famous singer of the last generation. I will not say his name although all of you know who I am talking about, because I think he denied this and his family denied this, but according to the book, the singer as a young man would go to bars, have too much to drink, get in fights, but then after he became famous and as a middle-aged man he would continue to go to bars and get in fights but the fights would be different. He would have his bodyguards hold the person he was in the fight with so he could punch them. This hearing does seem like one of those fights. The EPA is being punched and cannot punch back. Fundamental fairness does require that they be here and they are not.

Also, the Chairman used the term "financial conflicts" to describe those involved in EPA decision-making, and I think that is something we should be concerned about. I think members of this Committee and the American people are entitled to know what financial interest anyone has who is involved in any process of government. That is why I criticize the Committee's change in rules at

the beginning of this Congress to require much less in financial disclosure; the Truth in Testimony forms require all that a witness disclose is that they are being paid to testify at the hearing without any other disclosure of what their financial interests are, and we have had again and again witnesses whose entire livelihood comes from the industries whose interests are very much the subject of Committee hearings, and all we see on the financial disclosure forms are that they are not being paid to attend, they are simply public-spirited citizens.

Just to pick on one of you, Mr. Cichanowicz, your information available on the Internet about you does say that you—and actually in the introduction it says that you do primarily work for utility industry clients. It does appear from the Internet that your clients have included Edison Electric, Midwest Ozone Group, American Coalition for Clean Coal Electricity, American Public Power Association, the National Rural Electric Cooperative Association. Mr. Cichanowicz, what percentage of your income comes from the utility industry?

Mr. CICHANOWICZ. Probably 75 percent.

Mr. MILLER. Okay. Do you not think the American people and the members of this Committee ought to know that in evaluating your testimony?

Mr. CICHANOWICZ. It is evident, isn't it? I mean, in my resume——

Mr. MILLER. Well, we had to ask about it. It was not available in the regular course of things. It is something that I have had to use my time to ask about today.

Dr. Thurston, it seems like you could barely get a word out in response to Dr. McClellan's statements and the questioning. Do you want to elaborate upon what you said earlier?

Dr. THURSTON. Well, you know, I did want to just point out that first of all, I don't remember any foot stamping in the CASAC process. But the fact is that the reason why there was a problem, this was the first time that the Administrator in many years of CASAC, that I know of, that the Administrator did not follow the advice of CASAC, and that is really what this whole problem was about, and that is why, of course, Administrator Jackson then went ahead and she said well, okay, the last Administrator wouldn't follow CASAC, but I will go back to the tradition of following CASAC, and that is really in a nutshell what happened there.

Mr. MILLER. Okay. I will yield back the little bit of time I have left.

Chairman HARRIS. Thank you.

I recognize the gentleman from California, Mr. Rohrabacher, for five minutes.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman.

Let me just note that the personal attack on our witness was obnoxious and not reflective of higher standards that I have had here and you have also had, to my colleague from North Carolina. This type of personal attack is not acceptable. The fact is, every witness we ever have has some contact with the people that they are expert with.

Mr. MILLER. Will the gentleman yield?

Mr. ROHRABACHER. No, not yet. The fact is, is that people who are expert tend to have worked in the industry in which they are expert, and the fact is that when you confront someone's arguments, you confront someone's arguments with better arguments or you challenge what they are saying by suggesting there is another explanation. That is totally within the area of acceptability with these kind of hearings. Just simply trying to dismiss someone on a personal level because of the way he has earned his living is just absolutely unacceptable to me. Anyway, let me go on with my questions now.

Mr. MILLER. Will the gentleman now yield?

Mr. ROHRABACHER. Yes, I will. Go right ahead.

Mr. MILLER. Okay. Mr. Rohrabacher, do you not think the American people are entitled to know if a witness has financial interest, if they are employed by an industry whose interests are at stake in the hearing? I did not attack him personally but I said that——

Mr. ROHRABACHER. Let me just——

Mr. MILLER. And those were the questions I asked at our organizational meeting, why does our form not require the same law as it has in the past.

Mr. ROHRABACHER. Reclaiming my time. The fact is, is that this witness's background, his financial background is open in his resume. He stated that very clearly, and he is not hiding anything, and your line of questioning, which I might add, questioning the process rather than the arguments, which called into question our Chairman's integrity was unacceptable as well, and this is just the type of thing that we see time and time again. It is the global warming approach as well, dismiss your opponents, do not confront their arguments, challenge them on their integrity rather than challenging the positions that they have taken. This is not acceptable, and that is one of the reasons we are having this hearing today is because the EPA may be suffering from that same type of mindset which is not consistent with good science and is not consistent with finding the truth.

Dr. Thurston, you had some things you wanted to say, you wanted to confront, I would be happy to grant you time—you didn't feel you had the time to confront some of the things, the points the Chairman was making. Go right ahead.

Dr. THURSTON. Well, thank you. Well, I did get a few of those comments in anyway, but I was trying to refer to Dr. Smith's testimony saying that, well, below the ambient—the NAAQS standards, that there is probably no proof that there were any benefits. But figure one of my testimony is from a study that I was principal investigator of, and there is the indications that the benefits do keep going down well below the standard to levels about seven micrograms per meter cubed. And the only reason probably we can't show below that is we have no place in the country that is cleaner than that, that has a metropolitan area with enough people to study.

Mr. ROHRABACHER. Thank you very much.

Dr. McClellan, do you have something to say about that?

Dr. MCCLELLAN. Well, again, that is a failure to place the science in context. If we examine the Thurston graph very closely, it shows confidence intervals around each one of those curves, and I think

you would be very hard pressed to suggest that there is even statistical significance in terms of those effects as we go down at that lower portion of the curve. What you are arguing, Dr. Thurston, is that the answer to how low is low enough is zero. I am saying that you have to have context in terms of making those decisions. I look forward to having an Administrator of the EPA who will make those policy judgments and not rely exclusively upon scientists who draw a bright line.

Mr. ROHRABACHER. And Dr. Phalen, did you have something to comment on that as well?

Dr. PHALEN. No, sir.

Mr. ROHRABACHER. Okay. Thank you very much.

I would just like to note, Dr. Phalen does come from the University of California at Irvine and we are very proud of the work that you do there and very proud of the work that the university is engaged in.

Dr. PHALEN. We are very proud of you as well.

Mr. ROHRABACHER. Thank you. God bless.

Chairman HARRIS. Thank you very much, Mr. Rohrabacher.

I now recognize the gentleman from California, Mr. McNerney.

Mr. MCNERNEY. Thank you, Mr. Chairman, and I thank the witnesses for coming in today.

Dr. Honeycutt, I was pretty intrigued by your quote that correlation is not causation. There is some truth to that.

My question is going to be directed to Dr. Thurston. Dr. Thurston, how do scientists, in your opinion, determine causal relationships between pollution and adverse health effects? What is the right way to go about doing that?

Dr. THURSTON. Well, as you pointed out, correlation does not necessarily mean cause and effect, but when you start to look at a broad-based knowledge base, you know, as I pointed out in my testimony, and basically we use the principles of Austin Hill that he developed to look at cigarette smoke. Back in the 1960s there were many of those who said well, really you can't prove that cigarettes cause lung cancer, and so we went through many decades before people really accepted the fact that cigarette smoke and smoking cigarettes causes lung cancer. Believe it or not, people denied that for decades, and based on these same arguments that sometimes you hear about air pollution. So then he developed a whole series of things where you look for coherence between different endpoints, you look for a time sequence, you look for natural experiments like Dr. Pope's experiment, well, study, where he followed the fact that when there was a strike and the pollution levels went down, the hospital admissions for children also went down, and then when the pollution—when the plant started up again, the pollution went up, the hospital admissions went back up again the following year.

Mr. MCNERNEY. So, I mean, there is no yellow brick road for science. You have to look at it——

Dr. THURSTON. Well, you have to look at all the evidence, and one study is not enough, and you need to look at many studies and many different types of studies, and we have done that, and the evidence is clear that air pollution, increasing pollution causes increased adverse health effects. And decreasing pollution causes decreased health impacts and better public health.

Mr. MCNERNEY. I agree, but that is not what I hear from all the witnesses here.

Dr. Honeycutt, do you think that the *Clean Air Act* is worth enforcing, and if so, who should enforce it?

Dr. HONEYCUTT. Excellent question, sir. It goes back to what Dr. McClellan said. It is how low is low enough. What Dr. Thurston is saying is absolutely correct. But those levels that they were talking about are extremely high levels. There is no doubt that, you know, getting air pollution out of the milligram-per-cubic-meter range into the microgram-per-cubic-meter range has been a great benefit. But now we have reached the point of diminishing returns. You know, lowering the standard a microgram per cubic meter or two or a part per billion or two, that is in the statistical noise of health effects. You are not going to be able to see to measure those health effects, but they are going to cost billions of dollars to get. So the question now flips back to you. I mean, do you think that is worth the investment? It is not up to me as a scientist to make that call.

Mr. MCNERNEY. Well, I don't have enough scientific knowledge to understand how much one or two micromeasurements is going to make a difference. Is that within the realm, Dr. Thurston, of causality? Can we make determinations on those small differences?

Dr. THURSTON. Well, sure. You know, I think that we do studies where we look at different places and look at the same place over time and are able to discern those differences. You need enough power, which is one of the quandaries we have is that the places where the people live tend to be the more polluted places, and the less polluted places don't have as many people, so then it becomes more difficult to study at the lower levels.

But I did want to pick up on something that Dr. Phalen pointed out, which is that the components of the pollution are important, and in fact, the most recent studies are showing that if you look at the components, like from traffic and from coal plants and from oil plants, and start looking at the various pieces and adding them up, you actually see larger effects than just looking at particulate matter in general where you just weigh it, and our studies have started to show this, and some of them we have published doing work for the Health Effects Institute and right now——

Mr. MCNERNEY. So there is room for more science here?

Dr. THURSTON. There is, but what I am saying is, we are probably underestimating the benefits of clean air, and perhaps we should be looking at these—and I am agreeing with Bob here that we should be starting to look at more of the constituents, the way we did with lead. We looked at lead in particulate matter and controlled that. Maybe we have to start looking at the components because right now we are underestimating, I think, the benefits of clean air.

Mr. MCNERNEY. Thank you. I didn't expect you to end that quickly.

I just spoke to a friend of mine from Iowa who I grew up with who has COPD and he said that just goes with being a farmer in Iowa, the dust that you breathe in, and so Dr. Smith mentioned, well, what is in the particles makes a difference, and I agree with that. I mean, if the dust particle has plutonium in it, that is a lot different than just having dust, but just the size of the particle by

itself makes a difference and has to be taken into consideration if we want people to remain healthy and don't want to have to pay continually increasing health costs for our seniors.

I yield back.

Dr. THURSTON. But I don't think that COPD should be a part of doing a job. I remember in the past people used to say well, when they smelled pollution, that was the smell of money, and you know, in reality, we have been able to run our businesses and clean up the air and, you know, our GNP has been rising at the same time the pollution levels were going down, so they are not really as closely linked as you might have been led to believe today. There are health benefits and also economic benefits of cleaning the air. I am guessing here, and one should never guess, but I am guessing that some of the equipment that was put on those plants were made right here in America, and we can have a lot of jobs and make a lot of money selling that pollution control equipment, saving lives around the world and making money, creating jobs cleaning the air. So I think that, you know, you have to look at the whole picture.

Mr. MCNERNEY. Thank you.

Chairman HARRIS. Thank you very much. I couldn't agree more, you have to look at the whole picture.

I recognize the distinguished gentleman from Florida, the Chairman, Mr. Hall—I am sorry, from Texas.

Chairman HALL. I will move anytime.

Mr. Harris, I won't ask any questions. I just want to make a comment here that I probably shouldn't make. You offered me the chance to ask three EPA witnesses a couple of weeks ago or so, and I said I wouldn't believe any of them under oath, and I was with one of them later at a party and I wished I hadn't said that. So I might say some things that I want to take back, but when Gina McCarthy came before our Committee and remarked about people that were out of work, she said "We are not in the business of creating jobs." I think that is an insult to every person and every breadwinner that has been a breadwinner and had to look into the face of his children and tell them why he couldn't and his wife and tell her why he couldn't send her children back to school next year because he didn't have a job. He had no job, very little hope and a whole lot of heartbreak. I think that is the kind of testimony we are getting from them. She didn't use any science when she gave us that really smart aleck remark that hurt a lot of people.

And Mr. Miller, the great lawyer who came here, I think, because he is a great attorney, but I understand he had the right to ask for a witness. I don't know if he did or not but if he didn't, he could always appeal to me, and of course, I would have told him to go back to you. I think he had an opportunity to have a witness if he wanted, and he threw the skunk into the jury box and then left. I didn't get a chance to tell him that in person.

Chairman HARRIS. Would the Chairman yield?

Chairman HALL. I have high regard for Mr. Miller, a minimum high regard for him.

Chairman HARRIS. Thank you. Would the Chairman yield?

Chairman HALL. Yes, I yield the rest of my time to you.

Chairman HARRIS. Thank you very much, Mr. Chairman.

Yes, I would like to respond to that. As you know, Mr. Chairman, the minority always has the opportunity to invite any witness they would like. They clearly could have invited someone from EPA. We extended an invitation to the current Chair of CASAC and they weren't able to attend. I mean, the bottom line is, we tried. You know, we can't drag them in, as you know, Mr. Chairman, but we tried.

In response to the consults don't disclose enough information, this was an astounding line of attack on this panel of witnesses. Every expert in the field has financial paths back somewhere, everyone. Look, I was an expert on obstetric anesthesiology and fetal physiology. I got money from the NIH. Clearly, I had an interest in that research being done because I got funding, supported my salary. I suspect Dr. Thurston gets funding for it. I suspect that you could easily presume all that from reading anyone's biography that is submitted to this panel. I just wanted to point for the record those biographies are part of the record. They are made part of the record. They were supplied to the minority. Nothing was hidden at all, just so we clear the air on that, if you pardon the pun.

Now, Dr. Thurston, I have got to ask you a question here, because, you know, it is always comfortable to assume well, you know, if you got a little bit of something that is bad, then if you have more, it must be worse, and if you have less, it must be better. Let us take mercury because I think Dr. Honeycutt—I mean, the science behind mercury is fascinating because I had read this but had forgot about it years ago, that, you know, the EPA's blood level for safety is 10 times less than what the Faroe study showed is safe based on epidemiology, and in fact there is evidence that as you increase exposure to mercury because you also increase exposure to the other fatty acids that are obtained in those same fish that in fact you could have an improvement in neurologic development. Now, that flies in the face of examining mercury by itself and saying well, you know, 58 is good, 5.8 must be better. Well, that is not true. That is just not what the scientific—so although it is attractive to say that—I mean, would you agree that that is one of the stories of the mercury standards?

Dr. THURSTON. Well, I can't profess to be an expert on the toxicity of mercury.

Chairman HARRIS. Do you disagree with Dr. Honeycutt's testimony? I mean, you are—I don't know. I guess—so you are not an expert in other air pollutants besides particulate matter?

Dr. THURSTON. Well, no, but mercury is a toxic metal, and I have not spent my time studying it, but it is true, you know, when you look at metals, each one is unique and you really have to look at that one. Like fluoride is——

Chairman HARRIS. Sure. Let me just—and I hate to interrupt you but——

Dr. THURSTON [continuing]. Is a nutrient at low levels, and toxic at high levels.

Chairman HARRIS. So just like when we look at particulate matter, $PM_{2.5}$, I mean, there are numerous different things that can be a particulate matter of that size, some of which may be less toxic, some of which may be much more toxic, but the EPA doesn't distinguish, does it? It says this is the level for any particle of that size.

Dr. THURSTON. It has been a process. They started out originally collecting all particles in the air, total suspended particulate matter, and then we moved to $PM_{2.5}$, which are particles small enough to pass the trachea. In other words, they said with the particles that you can't even breathe, we are not going to monitor those, and then now we have gone to $PM_{2.5}$, which are very fine particles that get deepest in the lung, and we monitor that most closely, although we are still looking at the other particles that can get into other parts of the lung, the $PM_{2.5}$ minus $PM_{2.5}$ or the coarse particles, that is something that is being investigated and indirectly can be controlled through $PM_{2.5}$ standards. But that is under consideration by CASAC and EPA what the coarse particle standards should be.

But then the next step is to, as you say, to go to what the composition is, and what I am telling you is, when we have started doing that, what we are finding is, the sum of the parts is greater than that whole. So it is not an exact measure of the toxic pollutant but by being so we have uncertainty and the estimates, therefore it is reducing.

But I did want to comment——

Chairman HARRIS. Dr. Thurston, we are way, way over.

Dr. THURSTON. I know, but you brought my name up——

Chairman HARRIS. If we have a second round, you will get it, okay?

Dr. THURSTON [continuing]. Vested interest. I have never taken money from vested interests. That is an important distinction here.

Chairman HARRIS. You don't consider government funding a vested interest? I think the American public would disagree with you.

Chairman HALL. Mr. Chairman, my time is expired.

Chairman HARRIS. Thank you for yielding back the balance of your time, Mr. Chairman.

I recognize the gentlewoman from California, Ms. Woolsey, for five minutes, and you can take extra.

Ms. WOOLSEY. Thank you, thank you.

Mr. Cichanowicz, I was going to call you witness number six until I realized I could say your name. I was taken by your graph chart picture of how difficult you thought it was for the utilities to put in control devices. Do you have any kind of picture or graph or comparison that tracks the results of not taking care of our clean air, of what happens when our air is poor, when our kids are getting asthma, when our workers are unproductive because they have got respiratory disease, because of the cumulative impact of not just your industry but all industries and cars and people and airplanes, the effect this is having and the cost to our health care system? How does that compare with putting some control devices into some of the utilities? Do you have anything like that?

Mr. CICHANOWICZ. Those issues are out of my skill set.

Ms. WOOLSEY. Well, see, we ought to have that because the check and the balance of this whole thing is not just about an industry, it is about the people and the costs of keeping people healthy in the United States of America, and clean air is a huge, huge part of that. So I just wanted to say that.

So Dr. Thurston, okay, CASAC got a lot of criticism. As I was coming in I heard a lot of CASAC this, CASAC that. You were part of CASAC?

Dr. THURSTON. I have served on a panel, yes.

Ms. WOOLSEY. You served on the panel. You know, there were public forums. What did the public say when they came before the commission? Is it a commission?

Dr. THURSTON. Well, it's a committee. You know, there is a public comment period but that is usually people like the American Lung Association come forward, and they are obviously very supportive of cleaner air because they are trying to prevent lung disease.

Ms. WOOLSEY. Well, then aren't they trying to destroy business around the country by saying things like that?

Dr. THURSTON. I am unaware of that agenda. No, they want to clean air and bring better health to people, and decrease our health care costs. In other words, if you clean the air, fewer people will go to see their doctors, fewer people will have to end up going to the emergency room, fewer people will have to check into a hospital, and you actually lower your health care costs when those events are fewer. And if we don't control the air, then obviously we are increasing the health care costs relative to what they would be.

Ms. WOOLSEY. And isn't the cost of health care also a burden on business?

Dr. THURSTON. Yes.

Ms. WOOLSEY. So I mean, doesn't that offset the cost of——

Dr. THURSTON. And the American people, yes, and that is something that I think is worthy of spending time trying to reduce.

Ms. WOOLSEY. That is clear.

Okay, now, all of you, many utilities have already installed control devices. If EPA hadn't had those regulations or if they pulled back on the regulations, what kind of incentives will there be for them to make these changes? I mean, why would they do it? Are they going to do it? Mr. Cichanowicz, is the utility industry going to live up to good-faith effort in this regard?

Mr. CICHANOWICZ. The issue I came to discuss was the time it takes to deploy technology. I don't think the topic of whether you do it or not is separate. All I am saying is the time that it takes and the schedule. That is what is key in my testimony and that is what is key in trying to put these systems in.

Ms. WOOLSEY. Okay. How about you, Dr. Smith? Do you have any idea what would happen if we didn't have these regulations?

Dr. SMITH. There are air quality standards that are in place and those air quality standards will cause power plants to put these controls in if there are in areas where there is nonattainment. My point was that the regulations need to be considered on the merits of their own benefits and their own costs, and there are a significant number of regulations that are going into place that don't have benefits anything close to their costs.

Ms. WOOLSEY. Well, costs within the industry, not costs for the heath care costs in the country.

Dr. SMITH. Costs compared to their benefits. The benefits include the health care costs, and those are part of the whole cost-benefit framework.

Ms. WOOLSEY. Dr. Phalen?

Dr. PHALEN. Yes, ma'am. Thank you. That is an excellent question. My experience in California has been that utilities such as Southern California Edison have supported the research, and I have seen some of the strongest advocates for clean air as employees of industry.

Ms. WOOLSEY. Except for Mr. Rohrabacher, aren't we Californians considered the kooks of the world, that we do things because they are the right thing to do and we won't have any business in our state even though it is the eighth economy in the world and all that because we do have these regulations?

Dr. PHALEN. EPA's national air standards are called NAAQS, and for a while California's were called CAAQS.

Ms. WOOLSEY. But ours work.

Dr. PHALEN. But I am firmly against there being a war between industry and the public or industry and regulators. I would like to see a comprehensive evaluation of public health because we know industry is important to public health and we know clean air, as you aptly pointed out, is important to public health. So I see the need to cooperate rather than battle, because whoever wins——

Ms. WOOLSEY. I agree with you totally, and Dr. Honeycutt, if they let me, I will come back to you, but I am going to ask Dr. Thurston a question.

Chairman HARRIS. Yes, we will have one abbreviated second round. Is that okay?

Ms. WOOLSEY. I know, but I am not supposed to be here after this.

Chairman HARRIS. I will give you 30 more seconds.

Ms. WOOLSEY. Thirty-one seconds?

Chairman HARRIS. Thirty more.

Ms. WOOLSEY. Thirty more seconds. So Dr. Thurston, is not—don't you come to the Science Committee thinking that science is what we are supposed to rely on for our information, and——

Dr. THURSTON. Yes.

Ms. WOOLSEY [continuing]. Doesn't it seem kind of counterproductive that we might think we should have a study on what happens to health care overall? Isn't there a worry that then the scientist will come to us and say oh, my gosh, what do we need to do with our air and then this committee will say oh, well, but we don't want to believe that science.

Dr. THURSTON. Well, it is about sound science, and that is the role of CASAC, to make sure that sound science is leading the EPA in their decision making, but you have to remember that after this the OMB, Office of Management and Budget, does a thorough analysis, economic analysis, that has been required since the Clinton Administration to show that the economic benefits outweigh the economic costs, and they would not have any of these regulations—don't worry about the fact of the benefits, because they are going to far outweigh the costs or the regulations are not going to go forward. That is the way it works. So, you know, we have also got to consider that there is another process that follows the Administrator's decision, which is that by OMB that does these economic analyses and does consider the costs, and the benefits have always outweighed of clean air. There is something like—you know, it ranges

depending on the decision but a good rule of thumb is maybe what Benjamin Franklin said: An ounce of prevention is worth a pound of cure. And oftentimes we see about a 16-to-one valuation of the benefits to the costs.

Chairman HARRIS. Thank you very much, Ms. Woolsey.

We have enough time since we are here until noon to have a second round of questioning for five minutes, and I will recognize myself for the first second round here.

Let me just ask Mr. Cichanowicz, because you are an expert in these systems and installing. What percent of these pollution reduction systems have been installed in the past 30 years as opposed to before then?

Mr. CICHANOWICZ. Well, the bulk of them have been installed——

Chairman HARRIS. Close to 100 percent?

Mr. CICHANOWICZ. Yes.

Chairman HARRIS. Okay. When was the last time we had an unemployment rate of nine percent. Was it 30 years ago? So we have never had to install pollution control of this magnitude and cost during a period of recession like we have right now. Would that be correct? I mean, on the order of magnitude of what we are talking about.

Mr. CICHANOWICZ. I believe so.

Chairman HARRIS. Those are just facts, I mean, and we can discuss facts. We have not had an unemployment rate of 9.1 percent since the early 1980s, and almost 100 percent of these pollution controls that we are talking about have had to be installed in periods when we have not had unemployment. So the point to making this decision in a vacuum of jobs. Now, if we have a 16-to-one benefit, I know how to solve our debt problem: spend $1 trillion on air pollution reduction and we solve our national debt because we have a $16 trillion benefit. It is ridiculous on the surface to believe there is a standard of 16 to one, every dollar you spend on this you get $16 worth of benefit. It is patently ridiculous on the surface. That is my editorial comment.

Dr. Smith, let us get to mercury because we just had a hearing about these mercury standards, and my understanding based on today's testimony how this decision was made in your testimony almost none of the benefit claimed from that mercury standard—the heart attacks, the asthma, you know, you hear the whole litany, same litany over and over for every single one we have a hearing on this. None of them really come from mercury, do they? They all come from the co-benefit or the double counting of the particulate matter. Is that right?

Dr. SMITH. Six million dollars of the benefits out of the $150 billion comes from mercury——

Chairman HARRIS. That is close enough to nothing. Okay.

Dr. SMITH [continuing]. Change of 511 IQ points in total aggregate across some 30,000—anyway, a large number of children.

Chairman HARRIS. And Dr. Smith, if I might just interrupt, that would presume that the Faroe study is inaccurate and that in fact by lowering mercury exposure you absolutely get a reduction.

Dr. SMITH. It is presuming that as you reduce the tiny bits of reduction in mercury and get tiny IQ benefit increases.

Chairman HARRIS. Could you just briefly, because I have about two minutes left, just go by this double counting deal again? Because it always amazed me, the testimony was always the same. The EPA would come in and say yes, if we do this rule, we get 34,000 less deaths, 150,000 less asthma attacks, 15,000 less heart attacks, and we kept on hearing the same thing over and over whether it was ozone or mercury or whatever. I am thinking this is pretty amazing because when I went to school, I didn't think mercury caused heart attacks. So could you go through this double counting for the Committee once again?

Dr. SMITH. If I can just take the Utility MACT that has 17,000 deaths. As I was saying, 4,000 of those are due to exposures to PM that are between 11 micrograms per cubic meter and 15 micrograms per cubic meter. All 4,000 of those are due to attainment of the current safe standard for PM, but if EPA tightens the standard down as low as 11, which it is considering doing, those are benefits from the PM standard if those occur. All the rest, if EPA does not tighten the standard below 11, it is saying that all the rest of the benefits, the other 13,000 of them that is in that co-benefits case, aren't really credible enough in order to protect the public health from them. Otherwise EPA should just set the PM standard lower, and EPA is not prepared to do that. It said it is not prepared to go below 11, and that indicates the degree to which those extra 13,000 are just not credible.

Chairman HARRIS. And you also, I think, in your testimony mentioned not only that but that it counts them in one case but not the other. It uses the old standard for the PM when it considers PM deaths but the new standard when it looks at all the other ones. Was that in your testimony also, in your written testimony?

Dr. SMITH. Well, what is happening here is, they are putting the cart before the horse. They count the benefits by putting them into co-benefits for a MACT that has no benefits of its own. And then later it doesn't really have them perhaps to count again for the PM rule but it doesn't need them because they have still got that huge reservoir to keep counting up against in order to justify the PM rule, so basically taking benefits from the rich, which are the PM benefits, and spreading it all around to the other regulations that don't have any benefits of their own to create a complex web of regulation, when in fact the right way to do this and the cost-effective way to do this for our society is to go after the problem directly and decide where to set the PM standard.

Chairman HARRIS. Thank you very much, Dr. Smith.

The gentleman from California, Mr. McNerney, is recognized.

Dr. THURSTON. I would like to respond to that, if I could.

Chairman HARRIS. If Mr. McNerney agrees, you will be more than welcome if he yields time to you.

Mr. MCNERNEY. Thank you, Mr. Chairman.

I just want to say a word or two about the controversy that was brought up with Mr. Miller's questioning. It has become standard for vested interests to bring pseudoscientists forward that are paid for by vested interests to perpetuate the status quo that started as Dr. Thurston brought out on smoking. It is being brought out on global warming. We are seeing it brought out now. So I think it is perfectly appropriate to try to understand what the witnesses' in-

terests are and how it is being paid for. So I think he was perfectly justified in those questions, and I didn't take those as an attack on any particular witness.

The thing I want to ask about is to follow up with Lynn Woolsey's question about the benefits or the pollution equipment that has already been installed in power plants and the benefits of that installation, and I think Dr. Thurston sort of hit it on the head. Developing technology to clean up our air quality is an important economic driver. For example, how many people were employed when that equipment was put in the power plants there that you are discussing? We employed probably thousands of people or more putting in that equipment, and the United States developed that equipment, and now we are able to sell that to other countries. So no, I don't buy the argument that this is entirely detrimental to our economy to have clean air. I think the opposite is absolutely true. So one of the things I would like to point out is the cap and trade that was employed to reduce sulfur dioxide in New England and the northeastern states, the cost was a fraction of what the industry was predicting it would be. The benefits were enormous. We developed technology that put us ahead of the curve. So I would like Dr. Thurston to respond to that.

Dr. THURSTON. I certainly agree. I wanted to bring up the point, though, that, you know, there seems to be—you know, in Dr. Smith's testimony, she started saying well, we can't—shouldn't take credit for the things that happen at the same time. In other words, when you go to clean up, let us say, mercury, you put on control equipment which also captures particulate matter. Well, certainly, they are going to be controlled and they would not otherwise be controlled. There are many power plants in the United States. Because of the way the *Clean Air Act* was written by Congress, the assumption was that older plants would go out of service and they were grandfathered in, and there are many plants, coal-fired power plants, that are spewing pollution virtually uncontrolled relative to the technology we have today, and I think what is happening here is that this rule, by putting on proper particulate matter controls and vapor controls, is closing the loophole on these really gross emitting—they are the low-hanging fruit of air pollution in the United States, these power plants. In other words, this is the biggest bang for our buck that we can get. If we are going to control air pollution, I do think cleaning up these coal-fired power plants that have been operating under this grandfather clause is a really efficient way to clean up our air and get the health benefits that would accrue, and they certainly can because they are not going to happen anyway.

Mr. MCNERNEY. Are we going to create jobs implementing this low-hanging fruit that Dr. Thurston is referring to?

Mr. CICHANOWICZ. It certainly takes people to build and design the power plants, yes.

Mr. MCNERNEY. Thank you.

I think I will yield back.

Chairman HARRIS. Thank you very much.

I now recognize the gentleman from California, Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much.

Just to get on with our little discussion as to what standards we should have here in dealing with one another on a civil and honest basis, I think it is really more important to try to challenge witnesses based on the arguments that they are presenting, rather, the facts that they have and their suppositions they are making rather than trying to discredit them and dismiss them and perhaps smear them as people who lack integrity in terms of what they are saying. I found that to be more important and the best way to go. I have very strong opinions, and I certainly don't challenge someone's integrity, and I would not think of asking Dr. Thurston, well, how many grants have you gotten from the EPA to do your studies, blah, blah, blah. I wouldn't think about that. I think about what is he saying, what is he arguing, and this idea that we are trying to discredit witnesses rather than confront what they say and challenge them is out of line.

Dr. THURSTON. May I respond to that?

Mr. ROHRABACHER. No, you can't. You don't run this hearing, and I have a very limited amount of time, but I will at the end give you a chance to comment on my comments.

Let me just note, I disagree totally with the idea that the American people were smoking because somebody told them a lie and would not testify in Congress that smoking causes cancer. My brother died of cancer. I was after him for years to quit smoking. He knew exactly what he was doing. He was addicted to nicotine, all right? And he couldn't break the habit along with other people. We all know that. It wasn't that they don't know and didn't know, and so I deny that supposition.

Dr. Thurston, would you like to comment on that? No? Okay.

Dr. THURSTON. Well, I mean, I will just say that there was a controversy at the time for decades where the cigarette—maybe you knew and your brother knew, but the cigarette companies certainly did not admit that their product caused those effects.

Mr. ROHRABACHER. Let me just note, I think the idea that the American people didn't know that cigarette smoking was harmful to their health is not something that I believe is the case.

Now, we are talking about the benefits of cleaner air, and let us just note that obviously breathing cleaner air is an important—is something good for your health if that cleaner air is above—is already above the threshold of being unhealthy or being healthy if you are going to—in other words, what is the air at right now? If you breathe more air in and it is above the threshold that will make you unhealthy, then it will not have that impact of being healthy. I think that is the point that we have heard made here.

And one last thing. Mr. Chairman, I ask the kids from my district every time they come in to see me, and I see every child that I can from my district, and I always ask them when I come in the classroom, how many of you think that the air in southern California was better when I went to high school there 45 years ago or is it better today, and 90 percent of these kids, maybe 95 percent, say the air pollution in southern California is so much worse today than it was when you were in school, how lucky you were to live at a time when you are not being poisoned by these terrible people in industry, and in fact, it is just the opposite. It is 180 degrees the opposite. The air in southern California is so much better

now than when I was their age and yet they are being lied to and they are being scared to death and they are being—and the people who are trying to put it in perspective are having their arguments dismissed and having their credibility challenged rather than their arguments being challenged. So I would hope that we have a little more honest discussion, we don't try to frighten people into behavior that will destroy our economy and put people out of work and cause a lot more anxiety.

One last point: I have 10 seconds. I do believe in cleaner air, obviously. We should all believe in cleaner air. I would hope that we develop the small modular nuclear reactors that the nuclear industry, which has been opposed by these very same environmentalists over the years, I would hope that we can get together and support nuclear energy as a solution which we all can agree upon. Thank you very much.

Chairman HARRIS. Thank you very much, Mr. Rohrabacher.

The gentlewoman from California is back, so Ms. Woolsey, you are recognized for five minutes.

Ms. WOOLSEY. Thank you, Mr. Chairman.

Dr. Thurston, as you have heard, many members of the majority party have stated that EPA develops regulations based upon faulty scientific evidence, and could you explain to us how the science that underpins EPA regulations is peer reviewed and the importance of peer-reviewed science?

Dr. THURSTON. Well, certainly. I did want to respond, if I could——

Ms. WOOLSEY. You may. Go ahead. Use my time.

Dr. THURSTON. The Congressman wouldn't ask me about whether I am funded by EPA for research, when in fact, that is what the form asks. It asks, have you had federal support. It does ask that but it does not ask, do you have funding from any vested interest, and I do think that it is a valid thing to get a balanced picture of the full information. In other words, consider the source, and to have not only where people get their funding from the government but where they get their funding from other places as well so, you know, have equal opportunity of information gathering. And right now, the form did ask where have you gotten your funding from the government, but not where I have gotten it from, from industry or vested interests.

Anyway, but in terms of the question of the peer-reviewed science, yes, you know, it is very important, the process that EPA goes through where they have their staff along with experts that they hire, mostly from the academic community, and they go through the literature and they evaluate the reports that are out there, and using peer-reviewed things, things that are published in the literature where the peers of these people have reviewed it, not just a report that has been put out by an interest group or by the government. It has to be a peer-reviewed document, and then that is looked at collectively and the whole picture for various health outcomes and they evaluate each health outcome in terms of whether, you know, it is inconclusive or conclusive or suggestive that there are effects, so they go through and they rank out the effects and see what they think is really well supported and conclusive, and then based on those things——

Ms. WOOLSEY. Do things change because of their review? I mean——

Dr. THURSTON. Well, that is why they do the review every five years. Science is constantly changing, and one of the things that we do find is that as we clean the air, more and more people are living in cleaner air, as the Congressman pointed out, although there are parts of California that have gotten worse—the central valley of California. You know, L.A. has improved, but the central valley of California has gotten worse in the recent years as it has become developed. It used to be an agricultural area. Now it is well developed. And so the pollution levels are actually rising in California in some places, but the question—well, I have lost my train of thought here. But, you know, the science does change over time, and generally, as I was saying, the pollution levels as they go down, we are able to have more people living in cleaner areas, so we are able to study that. If you don't have any people living in clean areas, you can't study it. I mean, part of the reason why we don't see effects at very low levels, or unable to show them definitively, is because we don't have enough people living in clean air. If we have cleaner air, then we will be able to test that hypothesis, and that is one of the limiting things. But over time we are learning more and more, and we are learning about more health outcomes. Neonatal and pregnant mother exposures is an active area of interest that we are finding more and more evidence that suggests that exposures to mothers and young infants are very important to future health, not only their health at the time but future health throughout their life, so and it is the California children's health study that is following children over time and learning more and more about what childhood exposure affect. So it is a learning process, and as time progresses, we learn new things, and so that is why the standards get evaluated.

But I must point out that the standards don't always go down. They have gone up based on this assessment. During the Carter Administration, the ozone standard was actually increased, and so CASAC does not always recommend, as Dr. McClellan might sort of imply, that we always are lowering and lowering. In fact, there is a history of CASAC when the evidence did not support the present standard saying it should be higher. So there is a record going both ways on this.

Ms. WOOLSEY. Okay. I have 16 seconds. Is there anything you want to say that you didn't get to say in your testimony or in your answers?

Dr. THURSTON. Well, I did appreciate the point that was made by the Congressman that as you breathe more air, you get more effects, and we have found that exercising adults, if you go out on a polluted day and exercise, that increases the adverse health effects. And so the advice is always, well, stay indoors on these high air pollution days and don't exercise. But Americans should exercise more, so I think what we really have to work toward is getting cleaner air so that we can exercise every day, not just on the non-polluted days.

Ms. WOOLSEY. Thank you very much.

Chairman HARRIS. Thank you very much, and before we adjourn, I want to thank the witnesses for their valuable testimony and the

Members for their questions. I know there were issues about potential conflicts of interest. You know, it is worthy to note that of the seven CASAC members now, five of them receive funding from the EPA, and we have to decide whether that in fact is a vested interest that may affect the members of the CASAC.

Anyway, the members of the Subcommittee may have additional questions for the witnesses, and we ask you to respond to those in writing. The record will remain open for two weeks for additional comments from the Members.

Again, I want to thank you all for a very informative hearing. The witnesses are excused and the hearing is now adjourned.

[Whereupon, at 11:51 a.m., the Subcommittee was adjourned.]

Appendix

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. Roger O. McClellan,
Advisor, Toxicology and Human Health Risk Analysis

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. During the hearing, Dr. Thurston stated that "there is a history of CASAC when the evidence did not support the present standard, saying it should be higher."

Q1a. In your view and experience with CASAC, is Dr. Thurston correct that there is a history of recommending less stringent standards?

A1a. The quote attributed to Dr. Thurston is correct. Unfortunately, he did not specifically identify the situation to which he was referring. If he had done so his quote would likely have conveyed a different picture. My experience with the setting of National Ambient Air Quality Standards (NAAQS) goes to the early 1970s and predates the *Clean Air Act* Amendment of 1977 which called for the EPA Administrator to seek the advice of a committee of scientists, a committee which is now known as the Clean Air Scientific Advisory Committee (CASAC).

The situation that Dr. Thurston refers to is probably based on the actions of an ad hoc Sub-Committee of EPA's Science Advisory Board chaired by the late Dr. James Whittenberger that advised on the revision of the Ozone NAAQS that occurred in 1979. The Whittenberger Subcommittee pre-dated the organization of CASAC. The original NAAQS for Ozone set in 1971 had a one-hour averaging time and was set at 0.08 ppm measured as photochemical oxidants. The Whittenberger Subcommittee advised that the numerical level for the one-hour averaging time be increased to 0.12 ppm measured as ozone. It was the opinion of the ad hoc Committee that with the change in the measurement method, the numerical level should be changed to provide equivalent health protection. The standard with the new indicator, ozone instead of photochemical oxidants, and set at 0.12 ppm ozone averaged over one hour was issued on February 8, 1979. The point at which the Standard was attained was also revised to "When the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one." A complete exposition on the matter by Dr. Thurston would have conveyed a different impression than his "sound bite" statement. I think his statement is misleading.

Q1b. What motivates members of CASAC to recommend a lower or higher standard?

A1b. In responding to this question it is important to provide some background information on what has been referred to as CASAC. The *Clean Air Act* specifies that a committee to provide advice on the setting of the NAAQS shall consist of seven individuals. Further, it specifies that one individual shall be a member of the National Academy of Science. This has been broadly interpreted to mean an individual who is a member of the National Academy of Sciences, National Academy of Engineering or the Institute of Medicine. The Act also specifies that one member shall be a physician and one member shall represent State air pollution control agencies.

The CASAC members are appointed by the EPA Administrator for a two-year term that may be renewed for a second two-year term. The EPA Science Advisory Board website described an orderly and transparent process for making appointments to advisory committees. In actual practice the selection process is conducted behind closed doors by the EPA Science Advisory Board staff. It is not known to what extent personnel from the EPA's Office of Air Quality Planning and Standards participate in the selection process or other EPA officials from outside of the Science Advisory Board office, including the Administrator's senior science and policy advisors.

In actual practice, the seven members of CASAC rarely meet, deliberate or offer written advice solely as a seven-person committee. Most often, the seven CASAC members are supplemented by an additional six to 15 individuals who are appointed as consultants for a specific review, i.e., the CASAC Ozone Review Panel served through the review that concluded in March 2008 or the Particulate Matter Review Panel that served through the review that concluded in October 2006. The EPA and many others regularly refer to the CASAC Panels as though they were the seven-person CASAC. It is necessary to carefully review minutes or letters related to CASAC activities to discern whether the functions were carried out by CASAC or a specific CASAC Panel consisting of both official Committee members or CASAC augmented by consultants.

Let me now turn to the question of what motivates CASAC members and consultants. First, I can only relate that my service as Chair of CASAC (1988–1992) and as a member of numerous CASAC Panels was motivated by a desire to serve the public by offering advice to the EPA Administrator on scientific matters of air quality of which I was knowledgeable and which I recognized were of enormous scientific and societal importance. I always viewed the scientific advice I and my colleagues offered as being of substantial value to the EPA Administrator in making difficult policy decisions informed by the relevant science.

I suspect many CASAC members and consultants were motivated in the same manner as I was motivated. In other cases, and especially over the last several decades, it is my impression that some CASAC members and consultants have also been strongly motivated by a desire to have scientific publications they authored used in the setting of the NAAQS and, in some cases, a desire to see that more stringent standards were set. In my opinion, during some reviews a strong anti-industry bias has been evident. In some cases, individuals use the "cigarette industry" and how knowledge of the health risks of cigarette smoking developed over the decades as being prototypical of "all industry." In some cases, the view has been expressed that if standards are set lower, industry will find a way to meet them. In my opinion, posturing these complex issues as science versus industry is totally inappropriate. The issue is really how can the science and the settings of NAAQS best serve Society as a whole.

It is also important to recognize that a substantial "clean air research enterprise" has developed, especially over the past two decades. Many individuals are motivated to see the research aspects of the enterprise continued with sustained and, perhaps, even increased funding. Thus, some like to point to the science used in the setting of the various NAAQS as justifying both past as well as additional future research support. The research endeavors in many ways have shifted from the conduct of "issue-resolving" research to "issue-perpetuating" research to be continued through a career of current investigators and their trainees.

I have a personal concern that the focus on air pollution, at current levels in the USA, may in a perverse way be negatively impacting on our efforts as a society to have a positive overall impact on public health. It can be argued that for a number of health endpoints air quality accounts for less than 10% of the attributable risk. Would we as a society achieve greater progress by focusing attention on the 90% or more of attributable risk related to other risk factors? I think so. My concern is that a narrow focus on a single risk factor, air quality may be misguided. Concern over asthma is a great example. There is no question that asthma rates in children, especially in inner cities and minorities, have been increasing in recent years. At the same time air quality has been dramatically improved. In my view it does not make sense to keep trumpeting air pollution as a major concern for influencing asthma and to continue to sponsor research on the link between air pollution and asthma. I think our scarce national resources, both dollars and scientific expertise, would yield a better return by focusing on what causes the disease rather than on a single risk factor—air quality.

Q2. There was some discussion about the independence and impartiality of CASAC during the hearing. You previously served as the Chair of CASAC, as well as on individual panels.

Q2a. What are the major strengths and weaknesses of the current CASAC process?

A2a. The major strength of the NAAQS setting process, including the role of CASAC, is that it should provide an orderly process for the periodic review of the science under-girding the policy judgments that must be made in the setting of the four elements of each NAAQS [(a) the indicator, (b) averaging time, (c) numerical level and (d) statistical form)]. I have several concerns with the NAAQS process as it has evolved, especially during the past two decades. I am very concerned that some individuals have overstated the role of science in the process and understated the role of the EPA Administrator in making the ultimate policy judgments required to set NAAQS. In my opinion, the best contemporary science should inform all the policy judgments that are inherent in the setting of each NAAQS.

However, scientists and others should appreciate that there is *no* scientific methodology for specifying the precise level, averaging time and statistical form of each NAAQS. When scientists state these either as specific numbers or ranges they are offering advice that is a blend of science and their own personal preference for a policy outcome. In stating a range of numerical levels, the highest value in the range has a dominant role in any further deliberations. In essence, the CASAC Panel or CASAC is saying "thou shall not set the NAAQS higher than the upper value in the range." The lower end of the range is most likely a statement of the

policy preference of some individuals on the CASAC Panel. By specifying an upper-bound numerical level for the NAAQS below the existing NAAQS, the CASAC has clearly offered a policy judgment that the standard must be lowered. This is a policy judgment exclusively reserved by the *Clean Air Act* to the EPA Administrator.

The CASAC Panel review of the Ozone Reconsideration NAAQS serves to illustrate the point I have made. The CASAC Ozone Panel Chair, Dr. Jonathan Samet, in his March 30, 2011, letter to EPA Administrator Lisa Jackson, stated that establishing a margin of safety was inherently a blend of science and policy. It follows then that identifying a numerical ceiling for the Ozone NAAQS of 70 ppb (eight-hour average) is a blending of science and policy preferences.

Q2b. EPA often cites the public health benefits in its Regulatory Impact Analyses to argue for more stringent standards. Does CASAC or any other scientific body review these analyses?

A2b. The Regulatory Impact Analyses are typically released to the Public after the Administrator's decision on each NAAQS is released. This is done allegedly so that costs of achieving the NAAQS do not influence the Administrator's decisions on each NAAQS in keeping with the Supreme Court decision in the case of *Whitman* v. *American Trucking Associations*. In actual practice, I suspect the Administrator is very knowledgeable of the contents of the Regulatory Impact Analysis when the final proposed NAAQS is sent to the Office of Information and Regulatory Impact Analysis, Office of Management and Budget for review before the final rule is released.

To the best of my knowledge, the Regulatory Impact Analyses are not routinely reviewed by CASAC or any other scientific committee. I suspect that EPA would argue that each Regulatory Impact Analyses is conducted using the basic methodology recommended by various National Research Council/National Academy of Science Committees and various EPA Science Advisory Board Committees. I think the Regulatory Impact Analyses would benefit from critical review by a Committee that included scientists and engineers as well as economists. In my opinion, a conceptual review of the approach used to develop regulatory impact analyses is not adequate. There is a clear need for critical review of multiple Regulatory Impact Analyses to understand the strengths and weaknesses of how the Analyses are conducted and how the results are presented.

In my view, the Agency and society at large would benefit from having several teams, working at arm's length from the Agency, prepare Regulatory Impact Analyses using what they view as best practices. It would be of interest to compare the results of the analyses prepared by the different teams. The current Regulatory Impact Analyses have had, for several decades, primary input from a single EPA contractor. A key consideration in comparing analyses prepared by different teams is how they address issues of uncertainty. In my opinion, EPA's analyses typically understate the uncertainties and systematically overestimate the monetized health benefits of the NAAQS. This issue for the Ozone NAAQS has been clearly illustrated by Dr. Anne Smith in her testimony.

Q2c. What recommendations do you have for improving the CASAC process and ensuring that panels are independent, transparent, balanced, and impartial?

A2c. I offer multiple recommendations for improving the CASAC process:

- (a) There is a need to critically evaluate the process by which CASAC members and consultants are appointed. The appointment process should recognize that biases originate in many ways. The current EPA view appears to be view biases as originating with employment by or serving as a consultant to industry. I argue that academic scientists who are supported by funding from the EPA, NIH and other government agencies also bring their biases to the advisory table; this needs to be recognized. I argue that the biases are reflected in multiple ways (i.e., biases toward seeing specific papers authored by the member or consultant and close colleagues cited and used, biases toward noting the need for more research) and, most importantly, the existence of a strong anti-industry bias.
- (b) The committee process can be improved in multiple ways. As a starting point, the CASAC Panels should maximize the use of face-to-face meetings held in public view and minimize the use of teleconferences.
- (c) CASAC Panel meetings should be of sufficient length (including multiple meetings if necessary) to allow adequate time to discuss the report at hand and elaboration on the strengths and weaknesses of the material prepared by the Agency and its consultants.

- (d) All reports presented to CASAC Panels should have the authors of each section identified, not merely a listing of numerous contributors at the front of the Report.
- (e) Sufficient time should be set aside during CASAC Panel meetings for interested parties to provide oral comments, to complement previously submitted written comments, on each document. The current practice of allowing each commentor three to five minutes for oral comments should be abandoned. The Committee Chair needs to clearly acknowledge the value of public comments. All too often in the past decade, public comments have been dismissed as an obligation for the CASAC Panel to hear in the shortest possible time and for the EPA staff to deal with.
- (f) All deliberations of major issues should be carried out in public open meetings. The practice that has developed in recent decades of having key discussions and the drafting of key conclusions carried out by two or three designated "lead" authors outside of public view should be discontinued. Alternatively, key conclusions and recommendations should be drawn from the "provisional" written comments prepared by individual CASAC members and consultants and made available for public consideration at least two weeks prior to any scheduled meeting.
- (g) Letters from the CASAC Panel Chair to the EPA Administrator should, in general, be much shorter, summarizing key conclusions and recommendations with the comments of individual Panel members attached as an Appendix. This approach would require each Panel member to clearly articulate their views on key issues and recommendations in their written comments. This approach will allow for a range of opinions on the science to emerge and avoid the common practice of hiding behind the "consensus" opinion of the Panel. In my opinion, consensus defined as (a) general agreement, (b) the judgment arrived at by most of those concerned, or (c) group solidarity in sentiment and belief is best used by religious, fraternal or other social groups. In my view, excess emphasis on reaching consensus views on complex scientific issues can obscure underlying uncertainties and ambiguities in data and conclusions. It is my view that CASAC should focus on the science and avoid offering judgments that are inherently statements of a desired policy outcome.

Recommendations from CASAC with regard to specific numerical levels and forms of the Standard should always be identified as a blend of science and policy (See Samet letter of March 30, 2011, to Administrator Jackson). To the extent feasible, Panel members should attempt to differentiate between their views on the science and their personal policy preference as outcomes. It is crucial that the CASAC never preclude the Administrator's policy option of reaffirming the existing NAAQS. Science should always inform the policy judgments made in the setting of each NAAQS, but the science should not be framed as though it dictates a specific numerical outcome or lower.

Q3. The Federal Advisory Committee Act requires that panels be "fairly balanced in terms of points of view," and General Services Administration regulations guiding FACA implementation (41 CFR 102–3.60) require agencies to, in establishing advisory committees, "ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee." In your view, is EPA CASAC membership "fairly balanced in terms of points of view," and is an appropriate "cross-section of those directly affected, interested, and qualified" represented on the Committee?

A3. As I discussed in my answers above, I do not believe the membership of CASAC or recent CASAC Panels have been "fairly balanced in terms of points of view" and have not included a "cross-section of those directly affected, interested, and qualified." To the contrary, the membership has been excessively dominated by scientists that to a large extent have developed the scientific information contained in the documents. In some cases, the individuals have already offered opinions as to how the science should be used to set NAAQS, a more stringent standard based on their science.

In my opinion, a strong argument can be made for excluding, or at least limiting, the portion of individuals from this class (authors of key input) that serve on a specific panel. The subject matter being reviewed should be presented in a manner that would allow broadly knowledgeable scientists to offer a scientific view on the material and its use in Standard setting without the scientist having been directly involved in developing the science under consideration. I have advanced the view elsewhere in these comments that the estimated portion of risk for specific diseases

linked to air pollution is sufficiently small that greater societal benefits might be gained by looking more broadly at other factors influencing the risk of these diseases. This broader view is likely to come from scientists including medical practitioners who can look beyond "air pollution" as the dominant risk factor for the disease of concern. The focus needs to be on improving the health of society, not single risk factors.

Q4. Guidance from both OMB and the National Academies indicates that peer reviewers should not review work products that they were involved in. It appears, however, that 22 of the 25 members of the 2008 ozone reconsideration CASAC panel were reviewing EPA documents that specifically cited their work. Is this appropriate, and if not, what recommendations do you have to better account for and avoid such situations?

A4. I do not take exception to this statement as fact. To be blunt, a "clean air research enterprise" has been created over the past several decades. The "enterprise" wants to be sustained and it wants to be heard and to have influence. One measure of success expressed by some individuals is whether the NAAQS. On the positive side, substantial new scientific information has been developed. However, the approach has become excessively narrow focusing many times on a single risk factor, a specific pollutant, or a broad class of risk factors, air pollution. In my opinion, the utility of this narrow approach may be reaching the point of diminishing returns. I am personally convinced the time has come for CASAC members and consultants to be selected based on a broader health orientation with limited participation of individuals whose focus is on single risk factors (pollutants or air pollution in general).

Q5. Several witnesses mentioned significant health effects and premature mortality associated with socioeconomic status, joblessness, and other economic factors.

Q5a. Please describe the recent literature that suggests a correlation between socioeconomic status and health outcomes.

A5a. In my opinion, recent EPA documents have been seriously deficient in not explicitly acknowledging that the diseases of concern arise from multiple risk factors and that specific air pollutants, and air pollution in general, is not the major causative factor. Supreme Court Justice Stephen Breyer in *Whitman* v. *American Trucking Associations* noted the importance of using a "comparative health" orientation in deciding how low is low enough in setting NAAQS. I have been disappointed that EPA and CASAC have not followed up on this excellent advice.

It is my view, drawing heavily on the opinion of Justice Breyer, that the EPA Administrator should take a broad view of multiple factors when making policy decisions, informed by science, on the level (with or given statistical form) of a specific criteria pollutant that will be protective of public health with an adequate margin of safety. In my opinion, this should definitely include consideration of background levels of the pollutant arising from non-anthropogenic sources including spatial and temporal dimensions.

Two papers come immediately to mind with regard to the role of socioeconomic factors on health. The recent paper, "Losing Life and Livelihood: A Systematic Review and Meta-Analysis of Unemployment and All-Cause Mortality," [D.J. Roelf, E. Shor, K.W. Davidson and J.E. Schwartz, Social Science and Medicine *72*: 840–854 (2011)] provides a comprehensive review of the health impacts of unemployment. The finding that "the risk death was 63% higher among those who experienced unemployment than among those who did not, after adjustment for age and other covariates" is sobering in view of current unemployment in the United States and around the world. The 63% increase in all cause mortality stands in stark contrast to the increased risk of less than 10% estimated for air pollution.

An earlier paper, "All-Cause and Cause-Specific Mortality by Socioeconomic Status Among Employed Persons in 27 U.S. States, 1984–1997," [K. Steenland, S. Hu and J. Walker, Am. J. Public Health 94: 1037–1042 (2004)] compares the impact of socioeconomic status on multiple health outcomes. A key statistic is the Mortality Rate Ratio which is the ratio of the lowest quartile of socioeconomic status over the top quartile of socioeconomic status. In short, a comparison of the poorest one-quarter of the population with the one-quarter most well off. The ratio for all-cause mortality for men was 2.02 and for women it was 1.29. These increases of 102% and 29%, like the 63% increases estimated by Roelf et al. for unemployment, are sobering. Heart disease has been increasingly cited as being of concern for particulate matter. Steenland et al. found that the Mortality Rate Ratio for socioeconomic status was 1.88 for men and 1.84 for women. These increases associated with socio-

economic status of 88% and 84% are substantially greater than those observed for particulate matter.

In my paper, "Role of Science and Judgment in Setting Ambient Air Quality Standards: How Low is Low Enough?" [R.O. McClellan, Air Quality and Atmospheric Health, published online 01 June 2011], I express the view that socioeconomic impacts should be considered by the Administrator as context for setting the NAAQS. It would be appropriate for papers such as those by Roelf et al. (2011) and Steenland et al. (2004) to be discussed within the EPA's various documents undergirding each NAAQS and in the Regulatory Impact Analyses. It would certainly be appropriate for CASAC to review these papers and comment on their scientific quality. In my opinion, the scientific methodology and quality of these papers are certainly equivalent to that found in the various papers that focus on air pollution as a risk factor.

In a few instances, those papers such as the reanalysis conducted by Krewski et al. [Krewski, D., M. Jerrett, R.I. Burnett, R. Ma, F. Hughes, Y. Shi, M.C. Turner, A.C. Pope III, G. Thurston, F.E. Calle, M.I. Thun, "Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality," Health Effects Institute, Cambridge, MA, Report No. 140] with support from the Health Effects Institute, factors such as socioeconomic status are examined as risk factors. Many times the results for the covariate such as socioeconomic status are not reported. Krewski et al. (2009) did include the results in their report to the Health Effects Institute. Not surprisingly, the relative risks of socioeconomic status are greater than for the individual pollutants. Unfortunately, these results are not highlighted and directly compared to the results for individual air pollutants. In short, these important contextual findings are buried in the reports and never surface in the EPA's documents reviewed by CASAC.

I have suggested, only partially tongue in cheek, that the CASAC review process might be strengthened if the CASAC Panels were to include several unemployed and several underemployed scientists. My view is that personal experience with socioeconomic impacts might help CASAC Panels fully appreciate the enormous impact of their advice and the need to draw a clear line between comments on the science and any personal ideological preferences for tightening the NAAQS.

There should be no argument that a healthy population is dependent on a healthy economy—jobs do count! The offering of scientific advice that will inform policy judgments on the setting of NAAQS clearly carries with it substantial responsibility.

Q5b. In your view, does EPA or CASAC adequately take these regulatory consequences into account?

A5b. To the best of my knowledge, the EPA has never in any documentation related to the setting of NAAQS taken account of the impact of socioeconomic status or unemployment on the health of the U.S. population. Moreover, the EPA has not in any documentation related to the setting of NAAQS clearly acknowledged that other risk factors have a substantially greater impact on the health endpoints under consideration than does the specific criteria pollutant or air pollution in general. I am not aware that CASAC has ever advised EPA to take account of the role of socioeconomic factors, unemployment or other risk factors influencing the health endpoints under consideration. In developing the documentation for setting the NAAQS, EPA has "blinders" on with regard to providing any context for the policy judgments that must be made in setting the NAAQS. Likewise, CASAC has had a similar narrow focus as though the setting of the specific NAAQS was the only concern. Indeed, the EPA and CASAC have even given credence to the use of the results from use of a single pollutant models when the results of the use of multipollutants models showed diminished effects from the specific criteria pollutant under consideration. The EPA and CASAC regularly use the language of the *Clean Air Act* and the Supreme Court decision in *Whitman* v. *American Trucking Associations* (2001) to keep a narrow focus on setting the NAAQS under consideration, leaving the impression that providing context for policy judgments would detract from the setting of the NAAQS. Indeed, recent CASAC letters that advise that the NAAQS must be set at some specific level lower than the current NAAQS appear to have the goal of assuring the NAAQS will be lowered.

Q6. You discussed the President's decision to withdraw EPA's proposed reconsideration of the ozone standard. What principles from that decision should be applied to other EPA standards?

A6. I applauded President Obama's decision directing EPA to not proceed with setting of the "reconsideration; Ozone NAAQS. It was the right "common sense" decision. It is unfortunate the President did not have a conversation with EPA Adminis-

trator Jackson in early 2009 indicating the need for using common sense in the setting of NAAQS as well as all other regulatory decisions.

The OIRA/OMB memorandum signed by Cass Sunstein that undergirded the President's decision emphasized several points:

- (a) Decisions on each NAAQS must use the latest science to inform the policy judgments inherent in setting each NAAQS.
- (b) Decisions on each NAAQS should take account of other related regulatory actions. In this specific case in considering the potential for developing a "reconsideration" Ozone NAAQS, Administrator Jackson should have recognized that setting of the Ozone NAAQS in March 2008 had already triggered the next review. In short, the memo emphasizes the need be efficient in use of resources and avoid needless efforts.
- (c) Be respectful of the guidance in the *Clean Air Act* for periodic review of each NAAQS. A corollary is to avoid arbitrary and capricious deviations from that schedule.
- (d) Remember to consider context in taking regulatory actions including the setting of the NAAQS. In this specific instance, the President pointed to the need for considering the current dire state of the economy that among other factors requires predictable regulatory actions. I can only assume the President sought legal counsel in deciding that the language the *Clean Air Act* provided latitude for the decisions of OIAR/OMB and his own actions.

I think these four principles offer a sound foundation for future EPA actions in reviewing and setting NAAQS and making other regulatory decisions.

Q7. Dr. Phalen and Dr. Thurston both mentioned the role of particulate matter constituents in determining health effects, as opposed to particulate matter mass. In your view, what is the validity of developing regulations or estimating regulatory health benefits based upon particulate matter mass?

Q7a. Has your research or research by others been able to identify and rank the relative toxicities of the known components of $PM_{2.5}$?

A7a. In my opinion, the use of a particulate matter mass based metric based on particle size, i.e., Total Suspended Particulate Matter, $PM_{2.5}$ and $PM_{2.5}$ was appropriate at the time each of those indicators was adopted. The science available at the time informed the policy decision to use them. However, even when initially adopted it was recognized that these were relatively crude indicators of the potential toxicity of particulate matter. In short, they provided blunt tools for guiding development and implementation of particulate matter control strategies. However, the science available today clearly indicates that not all particulate matter has equal toxicity potency irrespective of the chemical compositions. It is crucial to recognize this range of potency, especially when EPA with CASAC concurrence has moved toward lower and lower standards as though all Particulate Matter being regulated was as potent as the most potent particulate matter studied. There is clearly both a temporal and spatial pattern to particulate matter potency. For example, the strongest signals of a particulate matter causing morbidity and mortality are in the Northeast USA while it appears that particulate matter levels in California have not resulted in statistically significant increases in health risks.

In my opinion, a strong case can be made for reaffirming the particulate matter NAAQS put in place in 2006 and offering guidance for imposing more stringent particulate matter standards only when there is clear evidence linking an increase in adverse health effects to (a) specific chemical composition on a size selection basis (b) or to particulate matter emitted from specific sources. A $PM_{2.5}$ NAAQS based only on mass and set at lower and lower levels is not consistent with current scientific knowledge.

Q7b. Could you provide your ranking of the toxicity of $PM_{2.5}$ components on either a qualitative or quantitative basis?

A7b. It is not possible in the limited time and space available to provide a complete response to this broad and important question. Suffice it to note that the several EPA documents that undergirded the 1997 and 2006 revisions of the NAAQS for particulate material and the current review described the substantial spatial variability in the composition of particulate matter in the several size ranges. For example, the most recent Integrated Science Assessment for Particulate Matter (December 15, 2009) notes that the contribution of sulfate in the east (16 to 46% of particulate matter, 2.5 m exposures) is substantially greater than in the west (about 4%) while motor vehicle emissions and secondary nitrate are greater sources of exposure in the west (about 9%) as compared to the east (about 4%). Previous documents

have shown as much as a thousandfold difference in the concentration of specific elements (such as vanadium, nickel and lead) in particulate matter samples from across the USA. The same EPA documents report the results of toxicity assays with both ambient particulate matter and specific aerosols such as Carbon Black. Many of these studies have yielded negative results. I would speculate that the differences in toxic potency for aerosols (in the $PM_{2.5}$ size range) are at least as great as the acknowledged difference in the potency of $PM_{2.5}$ versus $PM_{2.5}$ aerosols.

The simple fact is that EPA, in company with CASAC, seems to have a focus on using a "one size fits all" approach in creating a NAAQS for Particulate Matter, 2.5 μ, and driving the standard to lower and lower concentrations. In my opinion, if CASAC were doing its job it would have urged a "time out" and asked—does the current approach make scientific sense? I do not think it does, and from Dr. Robert Phalen's testimony it is clear that he does not think the current exclusive focus on a mass-based NAAQS for $PM_{2.5}$ is appropriate. Likewise, it appears that Dr. George Thurston might agree. I submit that a more scientifically sound approach to promoting public health would be for the EPA to look at complementary (a) PM NAAQS and (b) source specific standards based on the potency of actual emissions from different sources. The National Ambient Air Quality Standards are not the only tool EPA has in the *Clean Air Act* tool box!

A serious problem with EPA and CASAC's approach to evaluating scientific evidence is the current excessive emphasis on "causality." With this approach, causality is evaluated exclusively based on $PM_{2.5}$ mass; all the studies are placed in the same bin. Indeed, one can argue that the approach is directed at having an increasing number of health endpoints identified as causally related to $PM_{2.5}$ exposure, irrespective of the levels of exposure. It is disappointing that CASAC did not offer EPA scientific advice to use the "causality" approach to evaluating key individual constituents in particulate matter.

Q8. Both ozone and particulate matter occur naturally. Could you describe the role of background levels of ozone and particulate matter in setting standards for these pollutants? Have EPA and CASAC properly accounted for these background levels in establishing regulations or estimating health benefits?

A8. The EPA has not acted in a consistent, science-based manner in dealing with background levels of any criteria pollutants including ozone and particulate matter. Some CASAC Panel members and consultants have urged that greater attention be given to background levels. Other individuals have expressed the view that background levels of ozone should not be considered in the setting of the ozone NAAQS, that background should only be considered during implementation of the NAAQS. I strongly disagree with that view.

In my opinion, the EPA needs to do a much better job of creating a scientifically sound understanding of the spatial and temporal dimensions of background levels for all criteria pollutants, especially for ozone and particulate matter, and then using that scientific information to inform policy decisions in the setting of NAAQS. I note the need for acknowledging spatial and temporal dimensions. I make this point because there are clear differences in ozone background across the USA; one size does not fit all. A failure to acknowledge those differences in the setting of NAAQS can penalize certain areas of the USA with naturally occurring higher levels of background ozone.

The temporal pattern of ozone background levels is also very important. This was ignored by EPA and CASAC in the setting of the March 2008 ozone NAAQS. In that case, EPA did a very poor job of characterizing what it called "policy relevant" background ozone. EPA understated the background levels of ozone, especially as they would occur with an eight-hour averaging time and a standard set at about the 98th percentile for exceedances. The result was to substantially overstate the potential benefits of reducing the level of the Standard (see testimony of Dr. Anne Smith). These points were emphasized in a report I provided to EPA in October 2007 as part of the public comment process. This is a very specific example of how EPA and CASAC regularly ignore public comments that do not support their position, a lower NAAQS.

The issue of background levels for $PM_{2.5}$ is also important, especially as regards the 24-hour averaging time standard. The Particulate Matter Integrated Science Assessment (2009) noted that Policy Relevant Background levels, levels in the absence of U.S. anthropogenic sources, had a maximum daily range of 3.1 to 20 $\mu g/m^3$ with a peak of 63 $\mu g/m^3$ at the nine National Parks across the USA. It is hoped that the EPA Administrator will consider these levels when making a policy decision to reaffirm or revise the NAAQS for $PM_{2.5}$.

Q9. As you know, influential studies based on data from the American Cancer Society and the Harvard Six Cities Study provide the basis for major EPA regulations and determines how EPA develops its "deaths avoided" estimates for particulate matter. These data sets were developed with government funds, but are not publicly available so they can be analyzed by other scientists. Do you support making this and similar federally-funded highly influential scientific data and information transparent and publicly available so they can be analyzed by other scientists? Do you support making this and similar federally-funded highly influential scientific data and information transparent and publicly available?

A9. It is my understanding that the Harvard Six Cities Study, initiated by the late Professor Ben Ferris, was funded largely by grants from the National Institutes of Health with perhaps some limited supplemental funding from the EPA. The study also made substantial use of air monitoring data collected with support from the EPA. Individuals in six different studies were enrolled in the study with the explicit understanding that it was being conducted to evaluate the health effects of air pollution. Thus, it is correct that this study was funded largely by U.S. government funds. The Harvard University investigators have indicated in the past that individuals enrolled in the study with the understanding that their identities would not be revealed and, thus, one basis for not releasing the data to other investigators is that the identity of specific subjects might become known.

The American Cancer Society (ACS) studies present quite a different situation. It is my understanding that the ACS cohort of individuals from across the USA were enrolled for the purpose of conducting studies to better understand the occurrence of cancer in the population. It is my understanding that individuals self-enrolled and, thus, it was not a random sample from the U.S. population and is not likely a representative sample of the U.S. population. The study, from its beginnings, has been managed and funded by the ACS. The survival of the enrollees has been followed using National Death Records. It is my understanding that what is known about each enrollee is based on what they provided at the time of self-enrollment, including place of residence and the matched information at death including when and where they died. Obviously, information about each individual's place of residence, life style, occupation, etc., between time of enrollment and death is unknown. The ACS very closely controls access to the ACS data.

Decades ago I urged that these extraordinarily valuable data sets that have a pivotal role in EPA's setting of NAAQS should be made available to other investigators for evaluation. I expressed this view not out of concern for Harvard University investigators to conduct the studies in a competent manner, but rather related to a view that different analytical teams with varied scientific backgrounds might identify alternative approaches to analyzing the data sets. After much negotiation the Health Effects Institute (HEI), jointly funded largely by the EPA and the automotive industry, would sponsor a "re-analysis" of the Harvard Six Cities Study and ACS Study data sets. I was pleased that their re-analysis was conducted. I was very disappointed that a second or third team of analysts were not funded to do parallel analyses.

By and large, the single re-analysis did verify the core findings of the original analyses. Most importantly, the re-analysis revealed additional information over and above that of the original analyses.

It is my personal opinion that any research study conducted with U.S. government funding should, at some reasonable time interval, have provision for the data (stripped of personal identifiers) to be released for evaluation by other competent investigators. This only seems reasonable as an approach to realizing the best return on the expenditure of U.S. government funds. It is obvious that such an approach will pose many logistical challenges. I am confident the hurdles can be overcome if there is a will to serve the public good.

My own personal preference is to require that a procedure be established that will require that for any study results to be used by the EPA in the setting of NAAQS or other standards, the base data from the study be made available (stripped of any personal identifying information) for further analysis by the EPA or other interested parties. It is important to recognize that decisions with multi-billion dollar impacts (both benefits and costs) are being based on the analysis of these very large and complex data sets. Critics of my proposal will likely argue that the standard peer review process used by prestigious scientific journals should be sufficient to assure the quality of the analyses of the original investigators. I am a strong proponent of peer review and fully recognize both its strengths and weaknesses. A comparison of the peer review process used by HEI in conducting the re-analyses of the Harvard Six Cities Study and the ACS Study with the original peer review given the original publications should be sufficient to convince skeptics if the need for something be-

yond the usual peer review when policy decisions informed by science are used to set NAAQS that have enormous impact on society.

Responses by Dr. George Thurston, Professor,
New York University School of Medicine

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. Do recent studies report an association between particulate matter and mortality in all cities and areas of the U.S.?

Q1a. If not, how do you account for this fact that PM is associated with mortality in some cities, but not in others?

Q1b. Similarly, are there cities and areas of the U.S. where no association between ozone and acute mortality are reported? If so, what explains this lack of an association?

A1a–b. While there is a nationwide association found between exposure to air pollution and mortality (e.g., see Pope et al., 2002; Bell et al., 2004; Dominici et al., 2005), there is not always enough statistical power to detect such a size of effect in single cities, due to lower population size (and therefore in numbers of observations) in smaller cities. Thus, the most consistent air pollution–health effects relationships are usually found in large cities, such as New York and Los Angeles, where there are sufficient numbers of people to provide enough statistical power to discern, in a single city, the air pollution effect that is also seen overall nationwide.

As I stated in the hearing on October 4, 2011: "You need enough power, which is one of the quandaries we have is that the places where the people live tend to be the more polluted places, and the less polluted places don't have as many people, so then it becomes more difficult to study at the lower levels." And then, again, later in the hearing, I also stated: "part of the reason why we don't see effects at very low levels, or unable to show them definitively, is because we don't have enough people living in clean air. If we have cleaner air, then we will be able to test that hypothesis."

Q2. You wrote in 2009 that access to vital "records that have informed . . . pivotal research has recently been curtailed sharply, threatening the continuation of the type of research necessary to support future standard setting." You have been a co-author on influential studies based on data from the American Cancer Society and the Harvard Six Cities Study. These data provide the basis for major EPA regulations and determine how EPA gets their "deaths avoided" estimates. These data sets are not publicly available so they can be analyzed by all scientists. Do you support making these data sets transparent and open to outside scrutiny if they are being used to justify regulatory decisions?

A2. While making data available for independent scientists to analyze is an important goal, a major complication is the countervailing priority of protection of patient and/or study subject privacy. To resolve these two important countervailing concerns, these two particular data sets have been released to an independent body (The Health Effects Institute), and their respective results and findings validated independently (see Krewski et al., 2003).

Q3. In both your previous work and your testimony, you have indicated substantial differences in the effects of components of particulate matter, such as PM from Seattle and PM in Detroit. You have stated that "PM composition has an appreciable influence on the health effects attributable to PM" and that "we should be starting to look at more of the constituents."

Q3a. If these constituents are the critical determinant of health effects, does it make sense to develop regulations or to estimate regulatory health benefits based upon particulate matter mass?

Q3b. Have you considered how EPA might develop some type of toxicity-weighted NAAQS?

Q3c. Has your research or research by others been able to identify and rank the relative toxicities of the known components of $PM_{2.5}$?

Q3d. Could you provide your opinion as to the appropriate ranking of $PM_{2.5}$ constituents by toxicity on either a qualitative or quantitative basis?

Q3e. You mentioned the 1989 Pope study about PM and health effects. How did the composition of PM vary between strike and non-strike days?

A3a–e. (3a.) Since the evidence links $PM_{2.5}$ mass with health effects, it is important to continue to regulate that, but other constituent-specific regulations can also be

set, as done in the past with lead (Pb) in particulate matter. This could potentially allow regulations for $PM_{2.5}$ control to be more efficiently focused on controlling the particulate matter with the greatest toxicity, rather than merely those contributing the greatest mass. (3b.) As noted above, it might take the form of regulating $PM_{2.5}$ constituents, as has previously been the case with lead (Pb). (3c.) That goal is the subject of ongoing research by me and others in my field of research. (3d.) I don't think it is possible to quantitatively rank the toxicity of PM constituents at this time, and it likely varies from health endpoint to health endpoint, but generally speaking we have found that the particulate matter air pollution from fossil fuel combustion is among the most strongly associated with adverse health effects, including mortality. (3e.) This has been investigated in depth by intramural researchers at the U.S. EPA. They have discovered that:

- "the 1986/1988 (Utah) extracts contained more sulfate, cationic salts (i.e., calcium, potassium, magnesium), and certain metals (i.e., copper, zinc, iron, lead, strontium, arsenic, manganese, nickel). Although total metal content was (3/4) 1% of the extracts by mass, the greater quantity detected in the 1986 and 1988 extracts suggests metals may be important determinants of the pulmonary toxicity observed." (Dye et al., 2001).

Moreover, these U.S. EPA scientists were also able to replicate key biological effects of this PM using a mixture of such metals, reporting:

- "The parallel epithelial injury induced by the extracts and their surrogate Zn + Cu + V mixtures suggests that these metals are mediating the acute airway epithelial effects observed; however, metal interactions appear to play a critical role in the overall cellular effects induced by the PM-derived extracts. These experimental findings are in good accord with epidemiologic reports of adverse airway and respiratory health effects in Utah Valley residents." (Pagan et al., 2003)

In related research by this group of U.S. EPA investigators, it has been found that the co-presence of sulfates, such as sulfuric acid, can make these transition metals more "bio-available" to cells in the body, and therefore more damaging. Thus, the co-presence of acidic sulfates in such metals containing particles makes them even more potent at damaging the lung (e.g., Gavett et al., 1997). This conclusion is also supported by studies of human respiratory cells (e.g., Veronesi et al., 1999), and by the conclusions of a recent report from the Committee on the Medical Effects of Air Pollutants (COMEAP, 2009).

Q4. Figure 3 in your written testimony appears to indicate that relative risk for $PM_{2.5}$ drops below 1.0 at 14 micrograms per cubic meter ($\mu g/m^3$*) with no data for $PM_{2.5}$ levels lower than 13* $\mu g/m^3$*. In your oral testimony you referred to this graph as an indicator that premature deaths due to $PM_{2.5}$ occurred well below the NAAQS.*

Q4a. Could you explain if this graph or any related study would support EPA's calculating $PM_{2.5}$-related death down to the lowest measured value of approximately 4 $\mu g/m^3$*?*

Q4b. In light of your testimony about the "independent expert advice" provided by CASAC, why have they failed to recommend a NAAQS down to this lowest measured value?

Q4c. This figure shows that much of the data is consistent with a threshold (relative risk of 1.0 or below) at about 15 $\mu g/m^3$*. In your mind, what relative risk would suggest a causal relationship?*

A4a. The graph is not inconsistent with EPA's assumption, and is consistent in that effects are suggested to extend well below the present long-term standard for $PM_{2.5}$.

A4b. There are different health outcomes to consider, and differing strengths of association for the various outcomes at various concentration levels. Also, the setting of a standard is a different process from that used for a risk analysis, so they are not necessarily going to agree on levels of applicability.

A4c. This question is based upon a misinterpretation of Figure 3. The relative risks (RRs) provided in that graph are relative to the mean long-term $PM_{2.5}$ concentration in the study (about 15 $\mu g/m^3$), so the fact that the RRs go below 1.0 only means that, as the concentration goes below the mean, the risk of mortality is proportionally reduced from the mean risk. It does not mean there are no effects below 15 $\mu g/m^3$. Instead, it means that there are mortality risks of $PM_{2.5}$ exposure to con-

centrations below 15 μg/m^3, but they are smaller than if the concentration were 15 μg/m^3. Thus, this would indicate that there are $PM_{2.5}$ mortality risk benefits of reducing $PM_{2.5}$ that extend below 15 μg/m^3.

As I stated on the day of the hearing: "there is the indication that the benefits do keep going down well below the standard to levels about seven micrograms per meter cubed. And the only reason probably we can't show below that (concentration) is that we have no place in the country that is cleaner than that, that has a metropolitan area with enough people to study."

Q5. You discussed the value of peer review in ensuring that scientific information is "not just a report that has been put out by an interest group or by the government." Would you support EPA's Regulatory Impact Analyses being subjected to peer review by CASAC or another body?

A5. Proper peer review is an important aspect of scientific research evaluation, so I strongly support that occurring for all scientific research. U.S. EPA RIAs are public documents that already undergo a significant amount of scrutiny under the present process. It is also important to note that the RIAs are not research, per se, but instead they are documents that rely on published, peer-reviewed literature. Moreover, I am uncertain whether the legislative authority for the U.S. EPA RIA allows for that process to occur under CASAC, in the case of such a regulatory document that is required, not by the *Clean Air Act*, but by a separate Executive Order.

If such a review were deemed to be in the purview of CASAC, I also am also uncertain whether CASAC presently has the proper external environmental economist expertise to review such an economic document. For example, the EPA's recent Air Toxics Rule RIA reportedly examines changes in employment in the directly regulated industry (utilities), and the increased demand for labor directly stemming from the construction and installation of pollution abatement and control (PAC) equipment resulting from this regulation (see Bivens et al., 2011, attached to this letter for inclusion in the record), which is not, to my knowledge, a topic covered by the present expertise of EPA's CASAC. Thus, I see possible legal and logistical barriers to this proposed additional RIA peer review.

References

Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F. 2004. Ozone and short-term mortality in 95 US urban communities, 1987–2000. *JAMA*. 2004 Nov 17;292 (19):2372–8.

Bivens, J. (2011). A lifesaver, not a job killer: EPA's proposed "air toxics rule" is no threat to job growth. Briefing paper #312. Economic Policy Institute, Washington, DC.

COMEAP. (2009). Long-term exposure to air pollution: effect on mortality. London: Committee on the Medical Effects of Air Pollutants (COMEAP), Department of Health.

Dominici F, McDermott A, Daniels M, Zeger SL, Samet JM. 2005. Revised analyses of the National Morbidity, Mortality, and Air Pollution Study: mortality among residents of 90 cities. *J Toxicol Environ Health A*. 2005 Jul 9–23;68(13–14):1071–92.

Dye JA, Lehmann JR, McGee JK, Winsett DW, Ledbetter AD, Everitt JI, Ghio AJ, Costa DL. Acute pulmonary toxicity of particulate matter filter extracts in rats: coherence with epidemiologic studies in Utah Valley residents. *Environ Health Perspect*. 2001 Jun;109 Suppl 3:395–403.

Gavett SH, Madison SL, Dreher KL, Winsett DW, McGee JK, Costa DL. (1997) Metal and sulfate composition of residual oil fly ash determines airway hyperreactivity and lung injury in rats. *Environ Res*. 1997 Feb;72(2):162–72.

Krewski D, Burnett RT, Goldberg MS, Hoover BK, Siemiatycki J, Jerrett M, Abrahamowicz M, White WH. 2003. Overview of the reanalysis of the Harvard Six Cities Study and American Cancer Society Study of Particulate Air Pollution and Mortality. *J Toxicol Environ Health A*. 2003 Aug 22–Oct 10;66(16–19):1507–51.

Pagan I, Costa DL, McGee JK, Richards JH, Dye JA. 2003. Metals mimic airway epithelial injury induced by in vitro exposure to Utah Valley ambient particulate matter extracts. *J Toxicol Environ Health A*. 2003 Jun 27;66(12):1087–112.

Pope, CA III, Burnett, RT, Thun, MJ, Calle, EE, Krewski, D, Ito, K, and Thurston, GD. Lung cancer, cardiopulmonary mortality and long-term exposure to fine particulate air pollution. *J. Am. Med. Assoc. (JAMA)* 287(9):1132–1141 (2002).

Veronesi B, Oortgiesen M, Carter JD, Devlin RB. (1999). Particulate matter initiates inflammatory cytokine release by activation of capsaicin and acid receptors in a human bronchial epithelial cell line. *Toxicol Appl Pharmacol*. 1999 Jan 1;154(1):106–15.

Responses by Dr. Michael Honeycutt, Chief Toxicologist, Texas Commission on Environmental Quality

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. During the hearing, there was some discussion about the independence and impartiality of CASAC. You have frequently been involved in the CASAC process and you were on EPA's "short list" for the most recent particulate matter panel.

Q1a. What are the major strengths and weaknesses of the current CASAC process?

Q1b. EPA often cites the public health benefits in its Regulatory Impact Analyses to argue for more stringent standards. Does CASAC review these analyses?

Q1c. What recommendations do you have for improving the CASAC process and ensuring that panels are independent, transparent, balanced, and impartial?

A1. This question appears to have been meant for Dr. Thurston, but I will also address it.

Strengths

- Formed from non-EPA scientists, engineers, and economists and other social scientists recognized as experts in their fields.
- Should have a wide range of representation from academia, industry, federal, state, and tribal governments, research institutes and non-governmental organizations.
- Chartered to:
- Review the criteria and standards promulgated by EPA, and provide other related scientific and technical advice;
- Recommend to the EPA Administrator any new NAAQS and revisions of existing criteria and standards as may be appropriate;
- Advise the EPA Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS;
- Describe the research efforts necessary to provide the required information;
- Advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic (human-caused) activity;
- Advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of NAAQS.
- Chartered Member Composition:
- At least one member of the NAS;
- At least one physician;
- At least one person representing State air pollution control agencies.

Weaknesses

- Members recommended by EPA staff and appointed by EPA Administrator.
- Financial and administrative support given solely by EPA.
- There are only seven chartered members.
- Current Chartered Member Composition:
- None of the current members appears to be a member of the NAS—a charter requirement;
- While there are two members with an M.D., neither appears to be practicing physicians;
- One member represents the eight northeastern states through a non-profit organization, accounting for approximately 14% (one out of seven members)—most states and tribes are not represented;
- Academia is represented by approximately 57% of the panel (four out of seven members);
- Research organizations represent approximately 29% (two out of seven members);
- Industry, federal and tribal governments, and non-governmental organizations have 0% representation on the current panel.

A1a. It does not appear that the CASAC panel reviews EPS's Regulatory Impact Analyses.

A1b. Appointed membership to the CASAC panel should be an impartial and transparent process that allows for a balanced representation for all interested parties. To achieve this, it would be advisable to have the membership appointed by neutral parties. It is a conflict of interest for a person to pick the members of the review committee that will review their work.

A1c. I believe the CASAC review process should not be run by EPA. It should be run either by another federal organization such as the Council on Environmental Quality or by an independent group such as the NAS. The review panels should be broader than they currently are, with multiple experts in each subject area with varied and balanced views. For example, the ozone CASAC should consist of, at a minimum, two epidemiologists, two toxicologists, two human health risk assessors, two practicing physicians (e.g., pulmonologists), two atmospheric chemists, and two environmental engineers. These experts should represent a variety of interests, including federal government, state government, academia, industry, and non-governmental organizations. Charge questions should not be so pointed as to lead the peer reviewers to a pre-determined conclusion. Of course, peer reviewers should not be reviewing their own work as either bias or the perception of bias could influence the process. EPA should model their peer reviews after those conducted by Toxicology Excellence for Risk Assessment (*www.tera.org*), a non-profit group recognized worldwide for their independent scientific peer reviews.

Q2. The Federal Advisory Committee Act requires that panels be "fairly balanced in terms of points of view," and General Services Administration regulations guiding FACA implementation (41 CFR 102–3.60) require agencies to, in establishing advisory committees, "ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee." In your view, is EPA CASAC membership "fairly balanced in terms of points of view," and is an appropriate "cross-section of those directly affected, interested, and qualified" represented on the Committee?

A2. No, the CASAC membership is not fairly balanced and is not an appropriate cross-section of those directly affected, interested, and qualified, as noted in the response to question 1. The states and tribes are grossly underrepresented, and no CASAC members represent industry.

Q3. Guidance from both OMB and the National Academies indicates that peer reviewers should not review work products that they were involved in. It appears, however, that 22 of the 25 members of the 2008 ozone reconsideration CASAC panel were reviewing EPA documents that specifically cited their work. Is this appropriate, and if not, what recommendations do you have to better account for and avoid such situations?

A3. It is not appropriate for scientists to peer review their own work; it presents a clear conflict of interest. When a panel reviews a document in which a member's work is cited, that member should recuse himself from review of the document. Prior to each review, panel and committee members should sign a legally-binding document stating their conflicts of interest, which should be made available for transparency.

Q4. In recent testimony before our Committee, EPA Assistant Administrator Gina McCarthy stated that the Cross-State Air Pollution Rule would prevent "up to 34,000 premature deaths" and Administrator Lisa Jackson recently stated before another Committee that "if we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer." Do you agree with these statements from the Environmental Protection Agency? In your view, do current levels of particulate matter and ozone cause hundreds of thousands of premature deaths?

A4. I do not agree with the statements that Ms. McCarthy and Ms. Jackson made. The data that EPA used to base these statements cannot be used scientifically to quantitatively "count lives" like EPS did. In my view, current levels of particulate matter and ozone do not cause hundreds of thousands of premature deaths.

EPA relies on studies that take mortality data from ecological epidemiology studies to calculate the number of theoretical deaths that would be avoided with a lower standard. Not only do these studies suffer from severe limitations, but estimates of theoretical lives saved are also meaningless from a scientific and practical standpoint. It is not possible to verify either the current number of deaths due to expo-

sure or the future change in deaths if the standard is lowered. All estimates of lives saved are estimates, not factual. There is no guarantee of increased life expectancy or degree of confidence in such an estimation, since some degree of risk is present in all aspects of daily life. It is impossible to tease out the miniscule risks from low levels of air pollution from the overwhelming risks of diet, genetics, smoking, etc.

Q5. Dr. Phalen and Dr. Thurston both mentioned the role of particulate matter constituents in determining health effects, as opposed to particulate matter mass. In your view, does it make sense to develop regulations or to estimate regulatory health benefits based upon particulate matter mass?

Q5a. Has your research or research by others been able to identify and rank the relative toxicities of the known components of $PM_{2.5}$?

Q5b. Could you provide your ranking of the toxicity of $PM_{2.5}$ components on either a qualitative or quantitative basis?

A5. Particulate matter (PM) in the atmosphere contains both primary (i.e., emitted directly by sources) and secondary (i.e., formed in the air from combustion processes) components, which can be anthropogenic or natural in origin. PM can contain inorganic as well as organic components, including acids (such as nitrates and sulfates), metals, and soil or dust particles.

In general, the potential for adverse health effects depends on the mass concentration, size, shape, and composition of the particles. Differences in the composition of ambient PM introduce uncertainty into estimates of health effects. EPA uses a generic mass concentration of PM for risk (health effects) estimates, in which case they assume all varieties of PM have identical potential for toxicity, which we know is not the case. The estimates, if based solely on the same PM mass level, may result in over- or underestimates, depending on spatial variability in the PM components. Therefore, PM mass concentration most likely is not the primary factor in the reported association. For example, coarse PM ($PM_{2.5}$) in urban or industrial areas is likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural, agricultural, and mining areas.

In its 2009 Integrated Science Assessment (ISA) for PM, EPA recognized that epidemiological studies evaluating health effects associated with long- and short-term fine particle ($PM_{2.5}$) exposures have reported heterogeneity in responses both within and between cities and geographic regions in the U.S. This heterogeneity may be attributed, in part, to differences in the fine particle composition. The ISA concludes "that many constituents of $PM_{2.5}$ can be linked with multiple health effects, and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes." Many different constituents of the fine particle mixture as well as specific source categories of fine particles are linked, at some level, to adverse health effects.

Furthermore, in the Health Effects Institute (HEI) Research Report 161 (Assessment of the Health Impacts of Particulate Matter Characteristic), Dr. Michelle Bell analyzed data on 52 chemical components of $PM_{2.5}$ and found significant associations of $PM_{2.5}$ elemental carbon, nickel, and vanadium content with cardiovascular hospital admissions, although these components contain relatively low percentages of $PM_{2.5}$ total mass.[1] In summary, it is not appropriate to develop regulations or to estimate regulatory health benefits solely based on PM mass without considering chemical composition.

A5a. In a study by Valberg (2004), the chemical components of ambient $PM_{2.5}$ were ranked according to their individual toxicities as a comparison to those using the epidemiological PM-mortality "effect-function" (toxicity per unit mass) methodology. In addition, the HEI launched a National Particle Component Toxicity (NPACT) Initiative to evaluate the comparative toxicity of specific components of PM in 2009.[2] Specifically, HEI NPACT will examine relationships between PM components and health in toxicological studies in 12 locations across the U.S. and companion epidemiological studies in over a hundred cities. The results of these studies could provide information for future PM NAAQS to focus on different PM components.

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[1] 1 Health Effects Institute (HEI). 2011. Fine Particles and Health: Which Components Might Matter? Fall 2011 Update. Available from: *http://pubs.healtheffects.org/getfile.php?u=668*.

[2] Health Effects Institute (HEI). 2007. The HEI National Particle Component Toxicity (NPACT) Initiative: Answering Key Air Pollution Questions. Available from: *http://www.healtheffects.org/Pubs/NPACT.pdf*.

A5b. An example of toxicity rankings of known chemical components in ambient $PM_{2.5}$ can be found in the Valberg (2004) study. [3] The TCEQ has not undertaken such a ranking study.

Q6. In your written testimony you describe the importance of discerning between a statistical significance and actual biological significance of a given adverse health effect. Is there a plausible biological explanation for all of the NAAQS levels endorsed by EPA? Is there a plausible biological explanation for the various health benefits cited by EPA in the accompanying Regulatory Impact Analyses?

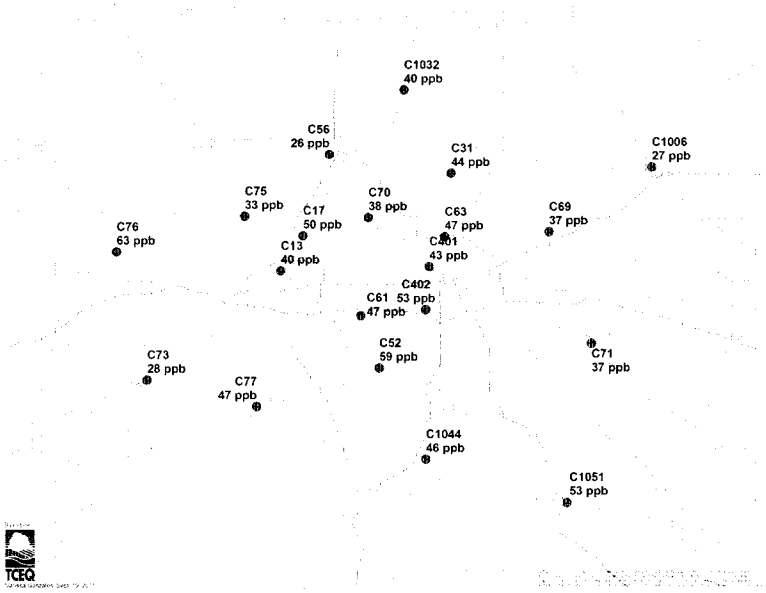
A6. I agree with EPA on the biological bases and regulatory levels for the sulfur oxides, nitrogen dioxide, and carbon monoxide NAAQS. I disagree with EPA on their biological bases and regulatory levels for the ozone and $PM_{2.5}$ NAAQS. I mostly agree with EPA on their biological basis for the lead NAAQS, although I disagree with their regulatory level. I do not think there is a plausible biological explanation for the various health benefits cited by EPA in their ozone and $PM_{2.5}$ NAAQS Regulatory Impact Analyses.

Q7. Can you provide the Committee an explanation of an ecological epidemiological study? How are such studies conducted? What is the value of an ecological epidemiological study compared with a clinical or toxicological study? How are these studies used by EPA and CASAC? Are you aware of how EPA or CASAC weights the evidence derived from these different studies?

A7. In most ecological epidemiology studies, researchers gather death certificates for a certain time period for people in a particular city who died from non-accidental causes, including diseases such as cancer or liver disease. The assumption is that breathing ozone made them die earlier than they would have otherwise. For each time of death, the researchers find out what the outdoor ozone level was at various time periods before the person died. In the case of ozone, for example, suppose a 90-year old person died of congestive heart failure at noon on a particular day. The researchers will find out the eight-hour ozone average for 4 a.m. to noon. Then they will back up an hour and find out the eight-hour ozone average for 3 a.m. to 11 a.m. They will back up another hour, and so on, usually for 36 hours, collecting numerous eight-hour ozone averages that they will then run through various statistical models. They will repeat this process for hundreds to thousands of people, depending on the study. No other patient information is evaluated other than the time of death.

Usually the researchers will use the outdoor ozone readings from the monitor with the highest ozone measured in the city. Some studies average the ozone readings across the city. Using the highest monitor, or even an average value, in a city is unscientific, since ozone levels can vary tremendously across a city, as illustrated in the map on the following page.

[3] Peter A. Valberg. 2004. "Is PM More Toxic Than the Sum of Its Parts? Risk-Assessment Toxicity Factors vs. PM-Mortality 'Effect Functions'." *Inhalation Toxicology*, 16(suppl. 1):19–29.



The map above is of the Dallas-Fort Worth non-attainment area showing (as a typical example) eight-hour ozone concentrations for 1 a.m. to 9 a.m. on September 19 of this year. Monitored ozone concentrations vary by more than 50% across this area, and yet ecological epidemiology studies do not look at the monitor closest to where a person actually lived. Using this map as an example, it is scientifically unsound to assume that a person who had, in reality, been exposed to 33 ppb was exposed to 63 ppb.

These studies did not look at whether those people that died were truly outdoors for eight hours just prior to their death to in fact breathe the ozone. It is most likely that the 90-year old person in our example was in a hospital or hospice in the days preceding their death, where the ozone concentrations were most likely near zero. Even if we assumed that these ill people spent eight hours outdoors just before they died, were they near the monitor that the researchers assumed they were? Were they exposed to other pollutants during that day? Did they take their medications that day? There are a whole host of common sense questions that go unanswered in these studies. Simply put, ecological epidemiology studies cannot tell us if ozone caused these deaths or if these people died prematurely, much less tell us what level of ozone caused their premature death.

These ecological epidemiology studies are the primary studies EPA used to base their previously proposed ozone standard. Ecological epidemiology data has very little, if any, value when compared to toxicological or clinical studies. There are ample, very well-conducted toxicological and clinical studies on which to base the ozone standard. In my opinion, EPA should give ecological epidemiology studies no weight at all in deriving a quantitative standard. Toxicological and clinical studies should be given the most weight, taking into account mode of action, biological plausibility, personal exposure, and what actually constitutes an adverse effect (e.g., a 5% decrement in FEV1 [Forced Expiratory Velocity at one second] is NOT an adverse effect).

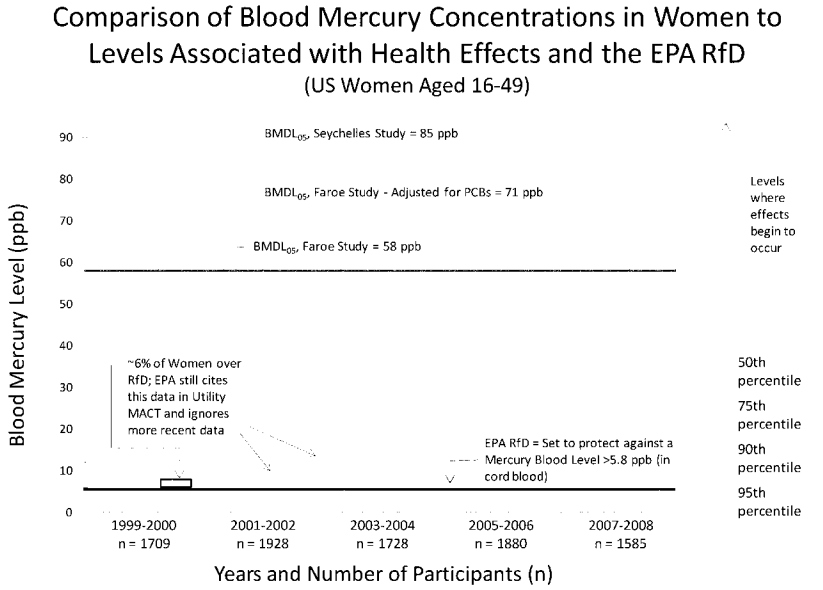
Q8. As you know, influential studies based on data from the American Cancer Society and the Harvard Six Cities Study provide the basis for major EPA regulations and determines how EPA develops its "deaths avoided" estimates for particulate matter. These data sets were developed with government funds, but are not publicly available so they can be analyzed by other scientists. Do you support making this and similar federally funded highly influential scientific data and information transparent and publicly available?

A8. Yes, I strongly support making these types of data and similar information publicly available. The reproducibility of results by independent scientists is of paramount importance in science, and this is a criterion of good science which cannot be tested using data not publicly available. This is particularly important and relevant to highly influential data with significant implications for regulation, public health, and the economy. Independent scientific analyses may reveal significantly disparate results depending upon the methods and assumptions utilized in the analyses and/or that initial conclusions were not adequately scientifically defensible to withstand any reasonable level of scientific scrutiny. Any medical privacy concerns may be alleviated through appropriate coding of potentially identifying information (e.g., names, addresses). The antithesis of governmental transparency is a highly influential government analysis based on hidden data, a predicament for EPA only exacerbated by the fact that the non-publically available datasets were developed using taxpayer dollars. Clearly, important underlying data such as these should be publically available so that the resulting scientific findings, by EPA or any other entity, may be vetted through additional scientific analyses and peer review.

Questions submitted by Representative Randy Neugebauer

Q1. You discussed in your testimony that "EPA may have the most conservative safe level for mercury in the world." Could you provide a comparison of EPA's reference dose for mercury and the blood mercury concentrations associated with health effects?

A1. The figure below shows levels of mercury in blood associated with health effects from studies done on people in the Faroe Islands and the Seychelles Islands, and data from recent surveys of blood mercury concentrations in U.S. women aged 16–49, as compared to the blood mercury level that EPA's RfD is set to protect against (5.8 ppb). EPA is causing unnecessary alarm in the public by using decade-old data in their assertions that 6% of women of child-bearing age have mercury in their blood at a level capable of causing adverse effects in the developing fetus. Newer data documenting decreases in blood mercury concentrations over time show this statement to be false and misleading. Additionally, adverse effects are associated with much higher blood mercury levels.



Source: CDC (Centers for Disease Control and Prevention). 2009. National Center for Health Statistics, National Health and Nutrition Examination Survey (NHANES). Decreases over time occurred for each of the four percentiles, but were most pronounced at the 90th and especially 95th percentiles. For example, during the 1999-2000 survey, 10 percent of surveyed women age 16 to 49 had blood mercury levels of ≥ 4.9 ppb. In the 2007-2008 survey, however, the 90th percentile value had decreased to 2.7 ppb.

There are no widespread mercury health effects issues in the United States. In fact, unwarranted concerns about mercury may be causing women to avoid eating fish, which itself could lead to adverse health effects. Researchers from the University of Rochester recently published a 17-year follow-up to the Seychelles study. heir conclusions are as follows: "At age 17 years there was no consistent pattern of adverse associations present between prenatal MeHg (methylmercury) exposure and detailed domain specific neurocognitive and behavioral testing. There continues to be evidence of improved performance on some endpoints as prenatal MeHg exposure increases in the range studied, a finding that appears to reflect the role of beneficial nutrients present in fish as demonstrated previously in younger subjects. These findings suggest that ocean fish consumption during pregnancy is important for the health and development of children and that the benefits are long lasting."[4]

[4] Philip W. Davidson, et al., 2011. ″Fish Consumption and prenatal methylmercury exposure: Cognitive and Behavioral Outcomes in the Main Cohort at 17 years from the Seychelles Child Development Study.″ *Neurotoxicology*, In Press.

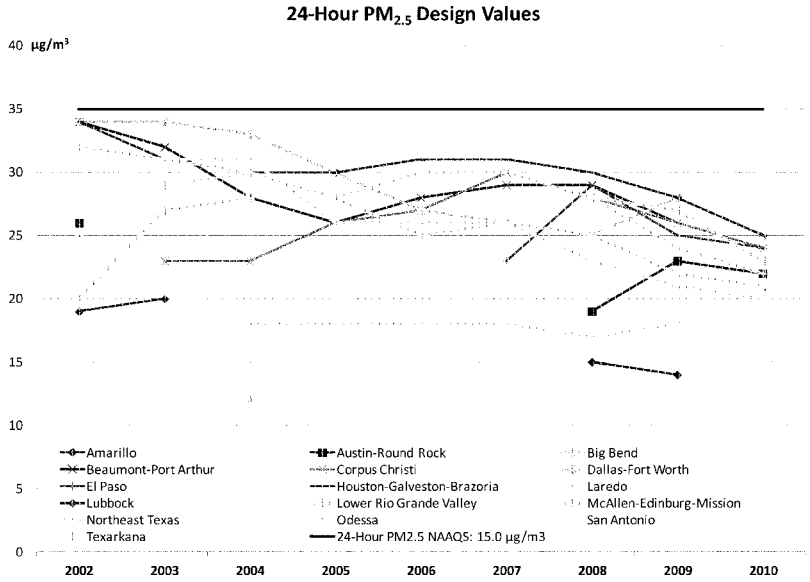
Q2. How has air quality in Texas changed over the last 10 and 20 years? Have particulate matter, ozone, and mercury levels increased or decreased? If air quality has improved, is this progress due to steps taken by Texas or is this just the result of federal enforcement of Clean Air Act requirements?

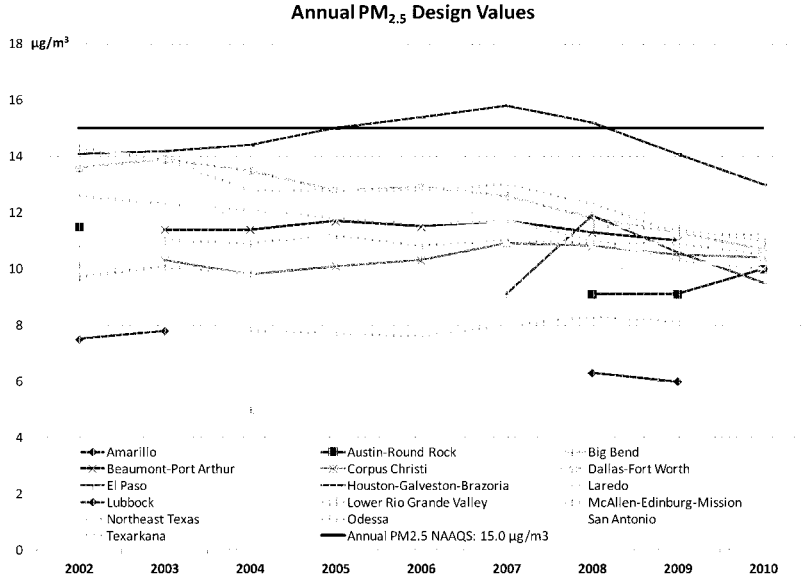
A2. With a vigorous economy, a rich supply of natural resources and a diverse population, Texas continues to see improvement in air quality throughout the state. Ambient air monitoring data demonstrate trends of decreasing concentrations over time for particulate matter and ozone, and reported mercury emissions have continued to decrease. The strides that Texas has made in reducing emissions, and more importantly ambient concentrations of ozone, is more impressive considering the population increase (meaning more cars and electricity needs) and Texas' position as an economic engine of the entire country. Texas now has the second largest population in the country, behind California. Between the 2000 and 2010 census, Texas' population increased by 20.6%, which equates to 4,293,741 people.

Although Texas has some of the most highly industrialized and populated areas in the nation, air quality in these and other areas of the state continues to improve and is comparable to or better than that of similar areas in other states. The state has been especially successful in reducing ozone air pollution. For example, in the last 10 years (2000 through 2010), ozone levels in Texas have decreased by 27% statewide. By comparison, the rest of the nation averaged only a 14% decrease in ozone levels over this same time period. Nitrogen oxides (NO_2), a main precursor to ozone formation, decreased substantially in Texas from 2000 to 2009. Point source NO_2 emissions were reduced from 796,247 tons per year (TPY) in 2000 to 336,417 TPY in 2009, a decrease of 57.75%. In the Houston-Galveston area alone, one of the most comprehensively controlled industrialized complexes in the world, over 180,000 tons of ozone-producing NO_2 emissions had been reduced by 2009. This reduction equates to more than the total NO_3 emitted from all Texas power plants in 2009 (~145,000 tons).

Until 2006, all the $PM_{2.5}$ monitors in the Houston area had recorded design value readings lower than the NAAQS of 15.0 micrograms per cubic meter ($\mu g/m^3$)—except for the Clinton Drive monitor, which is on a heavily traveled road across the street from the entrance to the Port of Houston Authority (PHA). To determine the cause of the elevated readings at this monitor, the TCEQ funded a series of in-depth studies. The studies concluded that the high readings were confined to a small area near the monitor, which is in close proximity to heavy truck traffic at the port entrance, unpaved shipyards along the Houston Ship Channel, and railroad tracks that run parallel to the road. To remedy the situation, the TCEQ worked in cooperation with the PHA, the City of Houston, Harris County, and local industry. Subsequent readings, in 2009, at the Clinton Drive monitor showed an annual average of 12.6 $\mu g/m^3$ of $PM_{2.5}$ that translates to a design value of 14.1 $\mu g/m^3$ for 2007 through 2009. On October 8, 2009, the EPA sent a letter to the governor concerning violations of the annual $PM_{2.5}$ standard at the Clinton Drive monitor in Harris County for the design value years of 2006 through 2008. On February 4, 2010, the governor submitted to the EPA a recommendation that Harris County remain designated as attainment for the 1997 annual $PM_{2.5}$ standard of 15 $\mu g/m^3$. On April 29, 2010, the EPA regional administrator signed a letter stating that he concurred with the governor's recommendation that Harris County remain attainment for $PM_{2.5}$.

$PM_{2.5}$ design values are presented in the figures below to show 10-year trends. There are two $PM_{2.5}$ standards, the 24-hour and an annual. All areas in Texas meet both NAAQS and most areas have shown decreases in both design values since 2002.



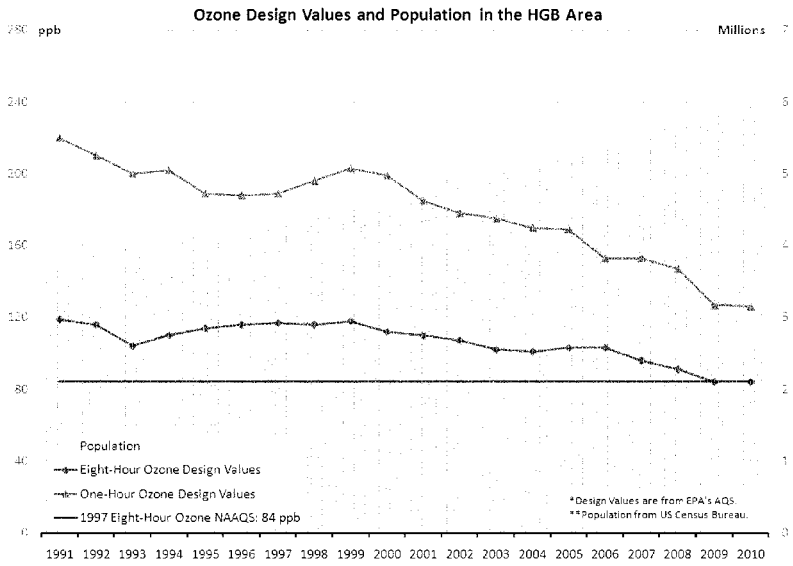


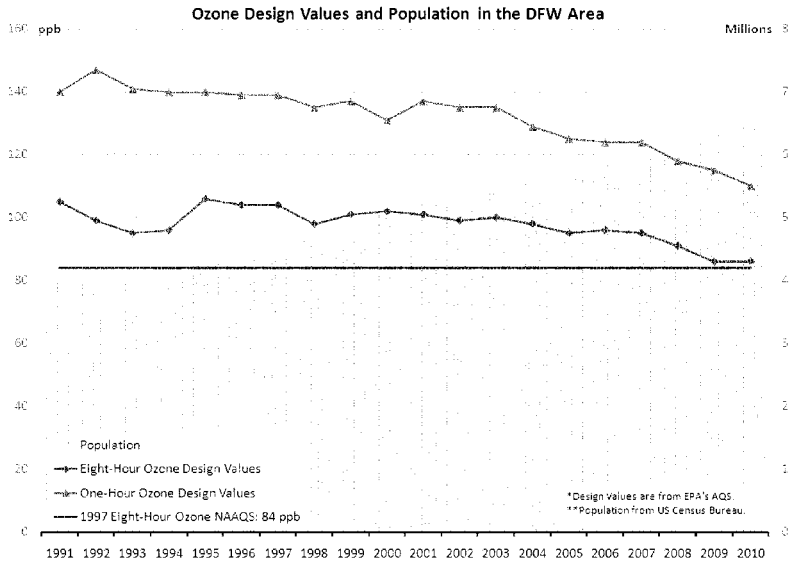
Currently, Texas has one nonattainment area for the $PM_{2.5}$ NAAQS—El Paso. In 2010, the El Paso area did not meet the $PM_{2.5}$ NAAQS.

The El Paso area typically observes exceedances of the $PM_{2.5}$ standard, but mostly from dust storms created by high winds, and, high winds in El Paso typically qualify as an exceptional event. Most likely, the Texas Commission on Environmental Quality (TCEQ) will be petitioning the EPA for an exceptional event, thereby excusing the exceedances of the $PM_{2.5}$ standard. EPA may take up to three years to consider

TCEQ's request, which may delay any potential redesignation of the El Paso area to attainment.

In the last 10 to 20 years, air quality in Texas has seen significant improvement, especially with ozone. Specifically the one-hour and eight-hour ozone design values for two of Texas' most populated and heavily monitored areas—the Houston-Galveston-Brazoria (HGB) and Dallas-Fort Worth (DFW) areas have decreased significantly. In the early 1990s, the ozone design values in HGB were some of the highest in the nation, 220 parts per billion (ppb) for one-hour and 120 for eight-hour. As of 2010, they were down to 126 ppb and 84 ppb, respectively. In DFW, the one-hour design value was near 150 ppb in the 1990s and by 2010 the area had attained the standard; for the eight-hour standard, the area's design value was as high as 105 ppb and in 2010 it was at 86 ppb. From 1990 through 2010, the population of each area has grown by several million.





Improvements in air quality are not limited to the HGB and DFW areas. Other areas of Texas have also reaped the benefits of improved air quality, including Beaumont/Port Arthur, which today is attaining the 1997 eight-hour ozone standard and was redesignated attainment by the EPA in 2010. Other areas in Texas with regulatory ozone monitors have also shown improvements. Austin, San Antonio, and Tyler/Longview have implemented air quality strategies on a voluntary basis that are part of the statewide improvements, and have allowed them to remain attainment. The only areas that are designated in nonattainment of the 1997 eight-hour ozone standard are the HGB and DFW areas.

U.S. anthropogenic mercury emissions have decreased, while mercury emissions from other parts of the world have increased.[5] According to EPA, the U.S. contribution to global anthropogenic mercury emissions has declined from 10 percent in 1990 to five percent in 2005, due to reductions in U.S. emissions and increases in emissions from other countries. Specifically in the U.S., emissions of mercury for coal-fired units above 25 megawatts (MW) decreased from 46 tons in 1990 to an estimated 29 tons in 2010. Mercury is naturally present in coal in trace amounts, which is then emitted when the coal is burned. From 2000 to 2010, mercury and mercury compound releases to the air in Texas ranged from a minimum of 12,776 pounds in 2009 to a maximum of 16,639 pounds in 2000, according to the EPA's Toxic Release Inventory (TRI). Just using the two endpoints of reporting year 2000 and reporting year 2010, the percent decrease for mercury and mercury compound emissions is 11.3%. Over the last 11 years, the reported emissions have fluctuated from year to year, but all are less than reported emissions in 2000. TRI changed the reporting status of mercury and mercury compounds beginning with reporting year 2000, lowering the threshold reporting criteria for manufacturing and processing from 25,000 lbs to 10 lbs. Previous to reporting year 2000, only one facility reported air emissions for mercury and mercury compounds. After the change in reporting criteria for reporting year 2000, the number of facilities reporting mercury or mercury compounds air emissions has been about 80 each year.

In Texas, protection of air quality predates the Federal *Clean Air Act*, and state requirements are often more stringent than what is required by the federal statute. States are given primary responsibility for ensuring air quality protection under the Federal *Clean Air Act*, with EPA's role primarily supervisory and secondary to the role of the states. States, including Texas, are responsible for developing state im-

[5] EPA. 2011. Draft National Emission Standards for Hazardous Air Pollutants From Coal and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units. May 3.

plementation plans (SIP) which contain the necessary control strategies for ensuring that states attain and maintain the NAAQS. SIPs must also contain major and minor permitting programs, and provisions for public participation. These programs are developed and managed by the states, with the exception of some states that rely on EPA to manage their Prevention of Significant Deterioration (PSD) permitting programs, the programs that permit major sources of air pollutants. Texas has been delegated authority to manage its own PSD permitting program from EPA (with the exception of greenhouse gas permits), and permits both major and minor sources of air pollutants in the state. In Texas, with the exception of certain activities that produce de minimis amounts of air pollution, all stationary sources that produce air contaminants must be permitted. Texas has also developed a variety of robust rules to set limits on types of air pollution, particularly in the state's nonattainment areas, to ensure that those areas meet and attain the NAAQS by the applicable Federal *Clean Air Act* deadlines. The following strategies have resulted in significant reductions in nitrogen oxides (NO_χ) and volatile organic compounds (VOC) over the last 10 years in Texas:

- The NO_χ Mass Emission Cap and Trade (MECT) program required an overall 80% reduction in NO_χ emissions from sources in the program and applies to most point sources on the Houston-Galveston-Brazoria (HGB) emissions inventory and even some minor sources that are not included in the point source inventory (phased implementation from 2002 to 2008).
- A comprehensive suite of rules adopted for the Dallas-Fort Worth (DFW) 1997 eight-hour ozone nonattainment area requiring NO_χ reductions from cement kilns, power plants, industrial boilers, stationary engines used in the oil and gas industry, and many other sources (March 2009 to March 2010).
- Rules for enhanced monitoring and testing of flares, cooling towers, and other sources in the HGB area with highly reactive VOC (HRVOC) emissions known to cause rapid formation of ozone (January 2006).
- Annual and short-term limits on HRVOC emissions for sources in Harris County (January 2007).
- More stringent requirements for VOC storage tanks in the HGB area to address VOC emissions from roof landings on floating roof storage tanks and from flash emissions on crude oil and condensate tanks that were found using new technology, like gas-imaging cameras, that allow the operators to observe plumes of VOC emissions that would normally not be visible (January 2009).

While not required by federal regulations, Texas has also adopted regional control strategies that required reductions from certain sources in counties outside the nonattainment areas. These controls help improve air quality in areas like DFW by reducing transport of pollution from outside the area. Examples of such regional control strategies include:

- East and Central Texas Utility Rule (Senate Bill 7): Required NO_χ and SO_2 reductions from grandfathered power plants in East Texas (2003 to 2005).
- Regional Cement Kiln Rule: Required NO_χ reductions from cement kilns in Bexar, Comal, Ellis, Hays, and McLennan counties (2003 to 2005).
- East Texas Combustion Rule: Requires NO_χ reductions from certain stationary gas-fired engines in 33 attainment counties east and southeast of DFW, primarily in the oil and gas industry (March 2010).

In addition to rules that are required for implementation of the NAAQS, Texas has also worked to develop innovative permitting mechanisms to allow flexibility while requiring sources to control their emissions. Texas has required all major sources of air pollution that were uncontrolled under the Federal *Clean Air Act*, because of grandfathered status, to obtain air quality permits that contain federally enforceable emissions limitations. In this way, Texas has gone beyond what is required by the federal statute to ensure that emission sources in the state will have control requirements that can be enforced to ensure protection of the state's air quality resources.

Because of innovative programs for point sources, Texas has seen 58% reduction to point source NO_χ emissions from 2000 through 2009. The strides that Texas has made in reducing emissions and more importantly ambient concentrations of ozone is more impressive considering the population increase (meaning more cars and electricity needs) and Texas' position as an economic engine of the entire country. Texas now has the second largest population in the country behind California. Between April 1, 2000, and July 1, 2009, Texas population increased by more than 840,000 people, more than any other state, and its mobile source emissions still decreased.

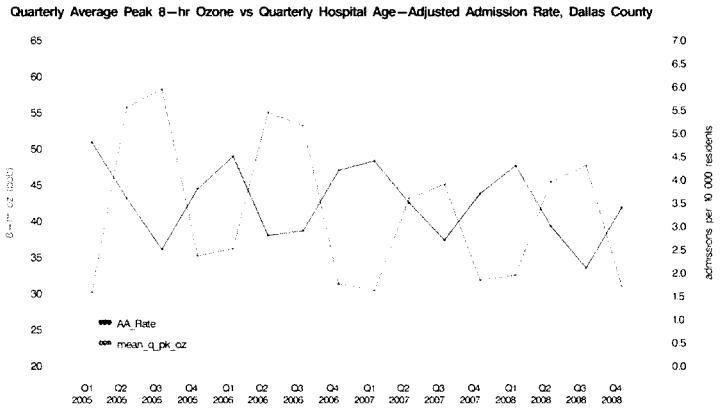
The Federal Government has the primary responsibility to regulate mobile sources. States have very little ability to effect change in this area. The Texas Legislature, however, chose to fund one of the most aggressive, if not the most aggressive, programs to reduce NO_χ from mobile sources. The TCEQ has provided over $900,000,000 in grants through its Texas Emissions Reduction Plan program to provide financial incentives to upgrade or replace older heavy-duty vehicles, non-road equipment, locomotives, marine vessels, and stationary equipment to reduce NO_χ emissions in eligible areas. Over $150,000,000 has been provided through the Drive A Clean Machine program to repair gasoline vehicles that fail emission tests and replace old vehicles with newer cleaner cars and trucks. Texas also has requirements for cleaner-burning fuel that are more stringent than federal fuel requirements in order to reduce NO_χ and VOC emissions (Texas Low Emission Diesel and Low Reid Vapor Pressure Gasoline programs).

Q3. Could you explain the significance of the four-year air quality study conducted by Texas A&M University and Driscoll Children's Hospital on the connection between hospital admissions and ambient ozone levels?

A3. This study was conducted in the Corpus Christi area and provides Texas-specific data on pediatric asthma patients compared with air quality indicators (e.g., ozone). The results of this study are consistent with results of numerous other studies in showing that hospital emissions for respiratory symptoms such as asthma are not directly related to ozone levels. As with numerous other studies, more hospital admissions occurred on days with an ozone air quality in EPA's good range than on days when air quality for ozone was in EPA's bad range. Therefore, this suggests that air quality indicators like ozone do not predict hospital admissions related to respiratory symptoms.

It is widely known that hospital admissions for asthma are much higher in the winter than in the summer. As an example, see the graph below the TCEQ developed for ozone concentrations versus asthma hospital admissions for Dallas County, Texas, for 2005 to 2008.

Dallas County



As can be seen, when ozone levels increase, hospital admissions for asthma decrease and when ozone levels decrease, hospital admissions for asthma increase. This phenomenon occurs worldwide.

As can be seen, when ozone levels increase, hospital admissions for asthma decrease and when ozone levels decrease, hospital admissions for asthma increase. This phenomenon occurs worldwide.

Q4. EPA recently released several "technical adjustments" to their Cross-State Air Pollution Rule. In the view of the Texas Commission on Environmental Quality, are these adjustments sufficient to alleviate the economic and reliability impacts of this regulation in Texas?

A4. The TCEQ believes that Texas should not be included in the CSAPR for $PM_{2.5}$. Texas was not included in the rule for $PM_{2.5}$ at proposal. The TCEQ has technical concerns with the EPA claim that Texas is contributing to the monitor in Granite City, Illinois, that we were not allowed an opportunity to comment on.

The EPA did recently propose on October 6, 2011, revisions to the CSAPR that would provide an additional 70,067 tons of SO_2 allowances to the Texas CSAPR budget and a delay until 2014 for the implementation of the assurance provisions limiting interstate trading. Based on TCEQ's initial review of the EPA's proposed revisions, while the proposal may lessen some of the impact of the CSAPR on some Texas utilities it does not address TCEQ's overall concerns regarding the feasibility of such substantial reductions in sulfur dioxide (SO_2) emissions in an unprecedented short period of time. Even accounting for the additional allowances proposed for Texas' budget, recent SO_2 scrubber startups, and announced SO_2 scrubber startups for 2012, the TCEQ expects that substantial SO_2 reductions will still be needed in Texas for the 2012 control period. While the 2012 control period is an annual compliance, companies must reduce their SO_2 emissions early enough in the year to avoid running out of allowance mid-year and being forced to shut down. Companies must certify compliance with the CSAPR and there are significant penalties associated with a company's actual SO_2 emissions exceeding the allowances held. Therefore, companies are unlikely to gamble compliance on SO_2 allowances becoming available at the end of the 2012 control period. The EPA's intent for delaying the assurance provisions until 2014 is to encourage trading in the initial two years of the CSAPR program. However, Texas is still limited to trading with Group Two states which still does not appear to be a viable trading market for SO_2 allowances sufficient to address Texas' concerns. In effect, companies will only have a matter of months to achieve the large reductions in SO_2 emissions that the EPA is mandating with the CSAPR which leaves some companies with limited options for compliance. The TCEQ will continue reviewing the EPA proposed revisions to the CSAPR and plans on submitting comments to the EPA on the proposal. However, the TCEQ does not consider the CSAPR as finalized or the proposed revisions to the rule to be cost-effective and certainly not the $500 per ton claimed by the EPA.

Responses by Dr. Robert F. Phalen, Professor of Medicine, and Co-Director, Air Pollution Health Effects Laboratory, University of California, Irvine

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. During the hearing, Dr. Thurston said that asthma was being exacerbated by current levels of air pollution and that "we are really underestimating the benefits of clean air." In your view, what is the cause of increased asthma rates over the last several decades?

A1. Although I am not an expert on asthma, the fact that asthma is on the increase while air quality has significantly improved implies that other factors are dominant. Such factors include: (1) obesity; (2) overmedication of children's infections; (3) lack of immune challenge to allergens during early childhood; (4) increased exposure (after developing asthma) to indoor allergens, e.g., from insect infestations; and (5) poverty.

Q2. Both you and Dr. Thurston mentioned the importance of particulate matter constituents as opposed to mass.

Q2a. Please discuss the research that shows variability in particulate matter and health effects associations.

Q2b. In light of the importance of particulate matter speciation, does it make sense to develop regulations or to estimate regulatory health benefits based upon particulate matter mass?

Q2c. Did the CASAC particulate matter panel on which you served discuss whether it was appropriate to regulate PM on the basis of mass?

A2a. Numerous studies indicated that PM components, rather than PM mass, are resonsible for the health effects. A good example is the study by M.D. Bell et al.; Hospital admissions and chemical composition of fine particulate air pollution (*Am. J. Respir. Crit. Care Med.*, 179(12):1115–1120, 2009) in which vanadium, elemental carbon, and nickel were driving hsopital admissions in persons aged 65 years or older. Also relevant is the study of 35,789 elderly Californians for J.E. Enstrom (*Inhal. Toxicol.*, 12(14): 803–816, 2005) that found the small risk of fine particles found prior to 1982 vanished during the period of 1983–2002. These study examples imply that PM mass is a poor indicator of health effects.

A2b. I believe that it does not make sense to regulate fine particulate mass for health purposes.

A2c. My CASAC-PM panel did discuss the use of PM mass for regulatory purposes. The apparent reason for sticking with mass was the lack of enough research to set individual component standards. I believe that it was a mistake to continue and propose mass-based standards.

Q3. During the hearing, there was some discussion about the independence and impartiality of CASAC. You served on the most recent CASAC panel for particulate matter.

Q3a. What are the major strengths and weaknesses of the current CASAC process?

Q3b. EPA often cites the public health benefits in its Regulatory Impact Analyses to argue for more stringent standards. Does CASAC review these analyses?

Q3c. What recommendations do you have for improving the CASAC process and ensuring that panels are independent, transparent, balanced, and impartial?

A3a. Please see my submitted testimony on seven weaknesses of the CASAC-PM process.

A3b. The claimed benefits do not take into account offsetting adverse consequences that also affect health, such as economic impacts of the proposed new standards.

A3c. More CASAC representation by experts on the economy, industry, agriculture, and overall public health would be helpful.

Q4. The Federal Advisory Committee Act requires that panels be "fairly balanced in terms of points of view," and General Services Administration regulations guiding FACA implementation (41 CFR 102–3.60) require agencies to, in establishing advisory committees, "ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, in-

terested, and qualified, as appropriate to the nature and functions of the advisory committee." In your view, is EPA CASAC membership "fairly balanced in terms of points of view," and is it an appropriate "cross-section of those directly affected, interested, and qualified" represented on the Committee?

A4. My answer to 3c. above applies here.

Q5. Guidance from both OMB and the National Academies indicates that peer reviewers should not review work products that they were involved in. It appears, however, that 22 of the 25 members of the 2008 ozone reconsideration CASAC panel were reviewing EPA documents that specifically cited their work. Is this appropriate, and if not, what recommendations do you have to better account for and avoid such situations?

A5. The funding-related and other potential conflicts of interest of CASAC-PM members appeared to influence their input, to the detriment of the public good. I believe that there is adequate scientific expertise in the U.S. to form a panel of scientists that did not perform the work that is reviewed, or receive substantial support from regulatory agencies that was not balanced by other sources.

Q6. How much do we know about the relationship between air pollutants like particulate matter and human health effects? Are there areas that need to be studied more?

A6. There are perhaps thousands of studies that relate to the effects of inhaled air pollutants. The problem is not so much about a lack of information, but the selection of information on the direct effects of individual pollutants without due consideration of the totality of risk factors faced by the public. Driving the levels of individual pollutants down to very small concentrations can have a net harmful effect on public health. The logical basis of current PM regulations is weak; the pulic deserves better.

Q7. As you know, influential studies based on data from the American Cancer Society and the Harvard Six Cities Study provide the basis for major EPA regulations and determine how EPA develops its "deaths avoided" estimates for particulate matter. These data sets were developed with government funds, but are not publicly available so they can be analyzed by other scientists. Do you support making this and similar federally funded highly influential scientific data and information transparent and publicly available?

A7. I do believe that publically funded research must be transparent and available to the public. However, I'm not strongly supportive of requiring such disclosure retroactively, except in cases where the data are directly responsible for setting a standard. My concern is that retroactive requirements can place an unnecessary burden on the research community without additional funding (e.g., for personnel) for this potentially large task.

Responses by Dr. Anne E. Smith,
Senior Vice President, Nera Economic Consulting

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. During the hearing, Dr. Thurston stated that the benefits associated with particulate matter reductions "keep going down well below the standard to levels about seven micrograms per meter cubed."

Q1a. What does the literature suggest about these effects?

A1a. The study Dr. Thurston refers to is based on a database first established by the American Cancer Society ("ACS") in 1982. At the time that the individuals were recruited for the ACS study, they had to be at least 30 years old. The average age of all the individuals at the time of recruitment was 59 years. The study Dr. Thurston refers to has tracked the survival outcomes of those individuals since 1982, thus building up estimates of the average mortality risk at each age level in dozens of cities across the U.S. Researchers have then assessed whether a statistical correlation exists between the estimated average mortality risk in each city and the cities' average ambient $PM_{2.5}$ concentrations, after attempting to control for all the other major factors that contribute to mortality risk. With this as background, I will explain why Dr. Thurston's statement that the $PM_{2.5}$-mortality risk association has been observed to levels as low as seven micrograms per cubic meter is not an appropriate indication of what the literature suggests.

The estimates of differences in mortality risk across cities are built up by following the survival outcomes of the people in each city over many years. This means that the observations of their mortality risks at each age, if attributable to air pollution at all, could be a result of exposures they experienced many years in the past, or that they accumulated over a long period of time. For example, all of the individuals in the ACS database were exposed to U.S. pollution levels since at least 1952 (i.e., 30 years before 1982), and the average individual in the database experienced U.S. pollution levels dating back to 1923. As researchers using the ACS database have stated, "In the 1950s, levels of air pollution in most North American and European cities were 10 to 50 times higher than those found today."[1] Since the mortality risk estimated for each city is based on many years of tracking these people, recent average $PM_{2.5}$ concentrations such as those in 2000, cannot be viewed as indicative of the $PM_{2.5}$ exposure level that most affected their observed survival outcomes. Those individuals who had not already died by 2000 would have already lived at least 48 years of their lives while being exposed to earlier, higher $PM_{2.5}$ levels. Yet, Dr. Thurston's statement that the $PM_{2.5}$-mortality relationship is observed down to concentrations as low as seven micrograms per cubic meter is just a statement that the lowest annual average $PM_{2.5}$ concentration reported among the dozens of cities in the ACS database was about seven micrograms per cubic meter in the most recent update of the study, i.e., concentrations measured during 1999–2000.[2] It is misleading to imply that the estimated mortality-risk relationship has been observed down to that level because $PM_{2.5}$ levels in that city were higher in the many earlier years of the study period during which most of the deaths used to estimate each city's average mortality risk occurred. That is comparable to assuming that recent lower levels of $PM_{2.5}$. accounted for the health outcomes of people who died as much as several decades ago.

While the lowest level in the cities in the most recent update of the ACS cohort study was about 7.5 micrograms per cubic meter, the lowest annual average $PM_{2.5}$ level at the time that those individuals' survival outcomes were first being tracked (i.e., about 1820) was 10 micrograms per cubic meter, and the levels across all the cities ranged from 10 to 38 micrograms per cubic meter, with an average of 20 micrograms per cubic meter.

Another problem with Dr. Thurston's assertion that effects have been observed down to about seven micrograms per cubic meter is that an observed statistical trend based on a scatter of data across multiple cities cannot be attributed to any single city within that dataset—it is an average across all the cities. It is

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[1] Krewski et al., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, Special Report, Health Effects Institute, July 2000, p. 33

[2] The lowest measured level of 7.5 micrograms per cubic meter among the ACS cities was for the $PM_{2.5}$ concentrations that were used in Pope et al. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to fine Particulate Air Pollution," *JAMA*, Vol. 287(9), March 2002, pp. 11332–1141.

unsupportable to assert that the association exists at the lowest measured level because the data establishing that association are sparsest at the ends of the range. This makes it impossible to assign statistical confidence to any quantitative estimates of a concentration-response relationship at the extreme ends of the range of data. The quantitative estimate of the concentration-response relationship is an average slope based on many data points (as many data points as there are cities in the analysis), and the statistical reliability of that average slope estimate weakens rapidly for concentrations at the far ends of the range of observations of concentrations in the dataset.

Q1b. What levels have CASAC and EPA considered in setting ambient standards for particulate matter?

A1b. EPA staff, with CASAC's concurrence, is only considering tightening the annual $PM_{2.5}$ standard to a level somewhere between 11 and 13 micrograms per cubic meter. This range does not extent lower than 11 micrograms per cubic meter in large part because of the lack of statistical confidence that the same magnitude of effect exists for cities with $PM_{2.5}$ concentrations at or near the lower bound of the studies.

Q2. You outlined in your testimony the problems with EPA's Regulatory Impact Analyses, which are used to generate health benefits like premature deaths avoided by a regulation.

Q2a. Are these health estimates peer reviewed by EPA's Clean Air Scientific Advisory Committee or any other body?

A2a. EPA's Regulatory Impact Analyses are not reviewed by EPA's Clean Air Scientific Advisory Committee. They are not subject to public comment and response either, because they are not required under the *Clean Air Act*, but only by an Executive Order.

Q2b. Last month, President Obama made the decision to withdraw EPA's reconsidered ozone standard last month, citing feasibility concerns and the need for the "best available science." Prior to that decision, EPA's analysis claimed that the new standard would prevent 12,000 premature deaths a year. Was this analysis significantly different from the analysis conducted for CSAPR or the Utility MACT? Did EPA rely on particulate matter co-benefits in this analysis as well?

A2b. EPA's supplemental RIA for the ozone standard reconsideration reported a range of estimates of avoided premature deaths for each of five different alternative standard levels. These estimates included premature mortality due to ozone and to $PM_{2.5}$. The majority of the avoided premature deaths were due to particulate matter co-benefits rather than due to ozone. For example, for the 0.070 ppm alternative ozone standard, EPA estimated that ozone-related mortality would be reduced by 250 to 1,100 deaths per year, while the benefits of coincidental reductions in $PM_{2.5}$ were estimated to be 430 to 4,200 deaths per year. Both sets of mortality reduction estimates were calculated in the same manner as for other RIAs such as CSAPR and Utility MACT.

These coincidental $PM_{2.5}$-related mortality risk reductions under a regulation that is not designed nor intended to reduce $PM_{2.5}$ are called "$PM_{2.5}$ co-benefits." In the case of the ozone RIA, the $PM_{2.5}$ co-benefits were based solely on estimates of reduced NO_χ emissions, which EPA projected would cause ambient $PM_{2.5}$ concentrations to decline too, as a result of efforts to reduce NO_χ to attain the tighter ozone standard. EPA is reporting $PM_{2.5}$ co-benefits in nearly all of its air regulation RIAs, including the Utility MACT, in which $PM_{2.5}$ co-benefits accounted for at least 99.99% of all the benefits of that rule. (In that case, to co-benefits were due solely to reductions of SO_2 emissions that would come from efforts to reduce acid gases required by the Utility MACT.) Thus the entire cost-benefit case for the Utility MACT rests on $PM_{2.5}$ reductions, despite the fact that neither $PM_{2.5}$ nor its precursor, SO_2, are air toxics that are the target and sole purpose of the Utility MACT.

PM_3-related benefits are also calculated in a comparable manner in the CSAPR RIA. In the latter case, however, CSAPR is intended specifically to reduce ambient $PM_{2.5}$ (to assist in attainment of the $PM_{2.5}$ NAAQS) and thus in that RIA, those estimates are categorized as direct benefits, not co-benefits.

Q3. President Obama recently said that "I reject the argument that says for the economy to grow, we have to roll back . . . rules that keep our kids from being exposed to mercury." What percentage of the benefits claimed in the Utility or Mercury MACT comes from mercury?

A3. Only 0.0004% to 0.011% of the benefits claimed in the Utility MACT comes from any air toxic reduction, and all of that is due to just one of the many air toxics in that rule, mercury. Stated in dollars, the benefits estimated from mercury in the Utility MACT RIA are between $0.5 million and $6 million per year, relative to the rule's estimated annual cost of $10,900 million per year. These small benefits are estimated even though the Utility MACT rule is projected to reduce utility mercury emissions from 28.7 tons per year to 6.8 tons per year.

Q4. In calculating costs for Regulatory Impact Analyses, EPA frequently cites single-year annual costs instead of net present value of cost streams. In your view, is this the appropriate approach to estimating regulatory compliance costs?

A4. Regulatory compliance costs and benefits should be considered on a present value basis. EPA's practice of reporting the costs and benefits for a single year can be misleading, especially if the baseline of emissions is declining after the single year selected. For example, $PM_{2.5}$ and SO_2, and NO_χ can all be expected to keep declining after 2015 even if the Utility MACT rule is not imposed because there are specific standards already in effect that will take effect between now and 2020. However, EPA reports its $PM_{2.5}$ co-benefits only for 2016, at a point in time where $PM_{2.5}$ emissions should be on a steady decline through 2019 (which is the latest attainment date for the 2006 $PM_{2.5}$ NAAQS). Thus, there must be a declining trend in baseline risks, and hence $PM_{2.5}$ co-benefits should be much smaller soon after 2016, yet the annual costs will not decline. Thus, choosing 2016 as the single year for reporting the benefits and costs from the Utility MACT gives an overstated impression of the size of the benefits relative to their costs. If a single year is assessed, it should be selected as the year in which all other existing regulations are fully implemented. At a minimum, EPA should report the trend in annual benefits and costs in future years. Nevertheless, a present value of costs and benefits would be a more sensible way of addressing this problem, rather than to report costs and benefits only for a single point in time.

Q5. Your testimony outlined EPA's reliance on coincidental particulate matter co-benefits to justify a variety of Clean Air Act regulations. Executive Order 12866 states that each "agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations."

Q5a. Does this reliance on PM co-benefits meet this requirement to avoid duplicative regulations?

A5a. The practice of relying on $PM_{2.5}$ co-benefits in RIAs for rules that are not addressing $PM_{2.5}$ directly is inconsistent with the purpose of RIAs. The purpose of RIAs is to provide policy makers and the public with an understanding of which types of rules are best serving the public interest. RIAs are useful only if they can help identify laws and regulations that are not providing benefits in a degree that warrants the extra regulatory complexity that they impose on our society. The current reliance on $PM_{2.5}$ co-benefits is inconsistent and incompatible with this purpose because it masks the regulatory burden of new regulations that have few or no direct benefits of their own. At the same time, any PM co-benefits that are deemed credible would be gained much more cost effectively by direct regulation of $PM_{2.5}$ itself, as already provided for by the *Clean Air Act*. Thus, reliance on co-benefits from pollutants that already have regulatory frameworks in place, such as $PM_{2.5}$, allows RIAs to encourage growth in regulations that are unnecessarily duplicative of the existing provisions under the *Clean Air Act* to protect the public health in the most cost-effective manner, which is a serious concern if those regulations cannot be justified based on their own direct benefits.

Q5b. In your view, has EPA provided adequate evidence that it is not counting coincidental and incremental $PM_{2.5}$ reductions more than once for these various regulations?

A5b. EPA states that it includes all existing regulations in its baseline, but never provides sufficient evidence in its reports or associated technical documentation for anyone to confirm that point. In addition, double-counting is almost surely occurring when multiple regulations are being analyzed simultaneously, rather than in a sequence that actually would allow each RIA's baseline to account for all other regulations that will be in effect by the time the additional new rule is actually being implemented. Another problem in which double-counting occurs relates to EPA's practice of reporting benefits for a single year. As I explained in my response to Question 4 above, if the year selected for reporting benefits of a new rule is earlier than the year in which another existing rule would be fully implemented, then the benefits reported for the new rule will effectively be overstated because they will be tem-

porary in nature, and a few years later would be the benefits that were originally attributed to the existing rule.

Q5c. What are the problems with taking PM benefits and spreading them around to other regulations that have insignificant benefits of their own?

A5c. The practice of taking PM benefits that should be attributed to PM regulations themselves and spreading them around to other regulations that have insignificant benefits of their own subverts the entire purpose of RIAs, which is to help policy makers and the public recognize excessive and non-productive regulatory requirements, and to be informed enough to decide whether certain laws and regulations might be better to reform than to continue. The practice of attributing PM benefits to changes in PM exposures that are in attainment with the $PM_{2.5}$ NAAQS also undercuts the motivation of policy analysts and EPA to grapple with whether those estimates are credible enough to tighten the $PM_{2.5}$ NAAQS directly. If they are that credible, then the only cost-effective way to address those risks is via their direct regulation. Thus the practice of spreading PM benefits around to other regulations also leads to cost-ineffective methods of dealing with the main air quality risks that our public health may be facing.

Questions submitted by Representative Judy Biggert

Q1. On September 21st, NERA Economic Consulting released a new economic analysis on four major EPA rules affecting electric generating units: the Utility MACT; the Cross-State Air Pollution Rule; rules on cooling water intake structures, and the classification of coal combustion residuals as hazardous. What did this analysis find about the employment and electricity price impacts of these rules?

A1. NERA's analysis finds that these regulations will decrease employment and increase electricity rates. On average over the period 2012–2020, when these four regulations are being implemented, NERA estimates 183,000 fewer jobs in each year. On average over the period 2012–2020, NERA estimates that electricity rates would be 6.5% higher on a national average basis. This electricity rate impact varies significantly by region of the U.S., with a range from 0% to 14%. The largest rate impacts are in regions that rely more extensively on coal-fired generation. A copy of the full NERA report on this analysis can be downloaded at *http://www.americaspower.org/sites/default/files/NERA_Four_Rule_Report_Sept_21.pdf*.

Q2. A recent analysis conducted by EPA found that the Clean Air Act results in $2 trillion of economic benefits. Do you agree with this analysis? How did EPA arrive at this figure, and what was the role of "willingness to pay" surveys that estimate the value of a "statistical life?"

A2. The EPA analysis mentioned is summarized in an EPA report sometimes referred to as the Second Prospective Benefit-Cost Analysis of the *Clean Air Act*. This analysis attempted to estimate the benefits that will be derived by 2020 as a result of the 1990 *Clean Air Act* Amendments ("CAAA"). About 90% of the $2 trillion estimate is due to projected reductions in mortality risk from reductions in ambient $PM_{2.5}$ in 2020, relative to what EPA projected ambient $PM_{2.5}$ concentrations would be in 2020 but for the 1990 CAAA. The $2 trillion is not an estimate of financial benefits, such as would appear in measures of GDP or average household income. Rather, this estimate is intended to reflect the improved "sense of well-being" of the U.S. population as a result of EPA's projected large improvement in mortality risk, also known as willingness to pay ("WTP").

The WTP measure that EPA used to value the mortality risk reductions is called the value of statistical life ("VSL"). It is not the value assigned to an individual life. Rather, it is a summary statement of the WTP for a very small change in risk of dying, such as a change in risk of dying in a given year of one in 10,000. If that WTP is found to be an average of $800 across the entire affected population, then the VSL would be $8 million, which simply means that for every 10,000 people benefitting from this amount of risk reduction, there would be one less life lost per year, and yet the aggregate WTP among those 10,000 affected people would be 10,000 times $800, or $8 million. Hence, the WTP for this risk reduction would be $8 million per expected life saved, or per "statistical" life saved. One difficulty with the estimate of VSL is obtaining a sound estimate of what people are actually willing to pay for those small risk reductions. EPA's VSL estimate is based on a mixture of two types of evidence: (1) estimates based on wage data of what workers are willing to give up in annual pay to work in jobs have lower on-the-job death risks and (2) direct questionnaires that present a certain hypothetical risk reduction opportunity to survey respondents and ask them to state what they would be willing to pay to have that risk reduction. Both of these methods present significant methodological difficulties. The VSL that EPA has used in this study is based on a review of 21 wage-risk studies and five WTP survey studies. All but one of the survey studies asked about WTP for changes in job and other accidental risks, rather than about disease risk.

I do not agree with the $2 trillion estimate for several reasons, which are explained in more detail in a paper I co-authored with W. David Montgomery in June 2011, which can be downloaded from the website of the National Taxpayers Union at: *http://www.ntu.org/news-and-issues/energy-environment/macro_vs_wtp_v19-pdf3.pdf*. Three of the primary reasons I consider the $2 trillion estimate to be far overstated are:

- (1) The size of the risk reduction being valued in the EPA analysis is far larger than the 1-in-10,000 to 1-in-100,000 risk reductions in the WTP studies from which EPA's VSL assumption is derived. These values for very small risk changes cannot be simply linearly increased to represent values for much larger risk changes such as 1-in-1,000 to 1-in-100, but the latter are the levels of annual risk change that EPA is attributing to the $PM_{2.5}$ reductions from the

CAAA. Due to budget constraints, a valid WTP for these much larger risk changes, if it were to be measured, would likely be much smaller.

- (2) I believe that the mortality risk change that EPA has assumed for each unit of change in average annual $PM_{2.5}$ concentrations is overstated to the point of non-credibility. EPA is assuming a range on $PM_{2.5}$ concentration-response relationships that implies that there is a 25% probability that $PM_{2.5}$ caused more than 25% of all deaths nationwide in the U.S. when ambient concentrations were like those that existed in the period around 1980.
- (3) EPA's baseline of $PM_{2.5}$ but for the 1990 CAAA is far too high. EPA assumes that no $PM_{2.5}$ NAAQS standard would have been imposed if the 1990 CAAA had not been enacted, which is not a credible assumption. All of the authority necessary to issue the $PM_{2.5}$ NAAQS and its associated emissions regulations was provided in the *Clean Air Act* of 1977. In fact, the 1990 CAAA did not make any changes to Section 109 of the 1977 *Clean Air Act*, which is what established the NAAQS process that exists today. Thus, the $PM_{2.5}$ baseline in EPA's analysis is grossly overstated, and thus the $2 trillion of benefits due to reductions in $PM_{2.5}$ "due to the 1999 CAAA" is also grossly overstated.

Q3. If EPA had not incorporated coincidental particulate matter co-benefits (including health benefits associated with reductions below the National Ambient Air Quality Standard), how many EPA Clean Air Act regulations would have passed a simple cost-benefit test in the last two years?

A3. I interpret "pass a simple cost-benefit test" to mean that the estimate of annual benefits exceeds the estimate of annual costs in the year that EPA analyzed in its RIA. The concept of "particulate matter co-benefits" only applies to rules that do not directly aim to reduce ambient $PM_{2.5}$. I have identified 13 RIAs released in the last two years for emission-reducing rules under the *Clean Air Act* that do not directly aim to reduce ambient $PM_{2.5}$.

- Of these 13, two were to reduce greenhouse gases. Both of the greenhouse gas rules pass the cost-benefit test without accounting for $PM_{2.5}$ co-benefits, but only because EPA has estimated that these rules will have negative costs, and so they would pass the cost-benefit test even with zero direct benefits.
- The 11 remaining RIAs are for regulations of air toxics ("NESHAP"), ambient air quality standards ("NAAQS") and new source performance standards ("NSPS"). Of these 11, not one passes the simple cost-benefit test without incorporating coincidental $PM_{2.5}$ co-benefits, yet all but two do pass the cost-benefit test based on their $PM_{2.5}$ co-benefits. (One exception is an RIA for a recently proposed rule for NSPS and NESHAP for the oil and natural gas industry. That RIA discusses $PM_{2.5}$ co-benefits qualitatively, but does not provide any quantitative estimates; if EPA quantifies its co-benefits in a future draft of the RIA, that rule may also pass a cost-benefit test based on $PM_{2.5}$ co-benefits. The other exception is a NESHAP for area sources from industrial boilers. In that case the cost lies just a bit higher than the high end of the estimated range of $PM_{2.5}$ co-benefits.)

The 13 RIAs are listed in the table below:

Year of RIA	Rule	Rule Status
2010	Light-Duty Vehicle CAFE and GHG Standard	Final
2010	SO_2 1-hour NAAQS	Final
2010	Portland Cement Manufacturing NESHAP and NSPS	Final
2010	Existing Stationary Compression Ignition Engine NESHAP	Final
2010	NESHAP for major sources: Industrial, Commercial and Institutional Boilers and Process Heaters	Final
2011	Commercial and Industrial Solid Waste Incineration Unit NSPS	Final
2011	NESHAP for Area Sources: Industrial, Commercial and Institutional Boilers	Final
2011	Medium and Heavy-Duty Truck GHG Standard	Final
2011	Reconsideration of Ozone NAAQS	Closed
2011	Utility Boiler NESHAPS	Proposed
2011	Mercury Cell Chlor Alkali Plant Mercury Emissions NESHAP	Proposed
2011	Sewage Sludge Incineration Units NSPS and Emission Guidelines	Proposed
2011	Oil and Natural Gas Industry NSPS and NESHAP	Proposed

Responses by Mr. J. Edward Cichanowicz, Consultant

Questions submitted by Representative Andy Harris, Chairman, Subcommittee on Energy and Environment

Q1. Could you provide the Committee with your estimate of the number of electric generating units (EGUs) that will be regulated by the Cross-State Air Pollution Rule and the Utility MACT? Could you also provide the number or percentage of these units that will require additional air pollution control systems to comply, and the number or percentage of those EGUs that may not be able to acquire and install these systems in time to comply with the rules?

A1. The Cross-State Air Pollution Rule (CSAPR) will require approximately 60 generating units to retrofit control technology. Approximately half of these units will not be able to install the required equipment by the CSAPR mandate. The Utility MACT, based on EPA estimates, will require 533 generating units to retrofit fabric filter control equipment, with 90 units also requiring "semi-dry" scrubbers. Significantly less than half of these units will be able to comply with the Utility MACT mandate.

In summary, about 600 units—approximately half of the 1,200 generating units in the U.S—will be required to retrofit control technology for both the CSAPR and the Utility MACT. Less than half of these 600 units will be able to meet the respective CSAPR or Utility MACT compliance mandate.

Q2. Short of ceasing operations, are there any options available to these non-compliant EGUs under the Clean Air Act that can guarantee these units can come into compliance without facing an enforcement by EPA or citizen suits?

A2. The only option—other than ceasing operation—for non-compliant units is to switch the source fuel to natural gas, if adequate supplies and delivery pipeline are available. The cost for natural gas (in terms of cost per million Btu of energy content) significantly exceeds the cost of solid fuel (coal), which will proportionally increase generating costs. Further, significant capital investment could be required to provide for natural gas access.

The switch to natural gas is not perceived to be a realistic option on a national basis.

Q3. In your opinion, what about EPA's assumptions for installation timelines of pollution control equipment is incorrect? If EPA were to fix the timeline problem, would you agree with the other technology assumptions they make?

A3. As noted in my written testimony, EPA's assumptions about the time required to retrofit the key control technologies—24 and 27 months depending on the control device—are too optimistic (e.g., presume a shorter schedule than realistic). Recent experience shows in most cases these control technologies will require 40–50 months. As a result, it will not be possible for the complete national inventory of generating units to comply with the CSAPR.

Some of EPA's key technology assumptions are correct while others are not. Assumptions about the control capability of the selective catalytic reduction (SCR) "catalytic reactors" for NO_χ, and the flue gas desulfurization (FGD) "scrubbers" for SO_2 are generally accurate. In contrast, EPA assumptions about the control capability of dry sorbent injection (DSI) to remove hydrogen chloride (HCI) are optimistic. These overly optimistic assumptions address the (a) degree of HCI removal achievable, (b) availability of the highly specialized sorbent, (c) impact on power generation equipment, and (d) other environmental impacts such as solid byproduct management.

Q4. How many power plants are currently utilizing dry sorbent injection (DSI) to meet the proposed Utility MACT requirements? How does their real world capture rate compare with EPA's proposed standard?

A4. Only two of the total of 28 generating units reported by EPA to apply dry sorbent injection utilize this approach at conditions that reflect the Utility MACT. Even these two units—which utilize western coal with low chlorine and high inherent alkalinity—do not reflect the conditions that will be experienced by the national inventory of units that must comply with the Utility MACT.

Q5. According to your testimony, fast-tracking pollution control in the manner advocated by EPA could compromise design quality and equipment construction equipment. Should we also be concerned that EPA's compliance deadlines could compromise worker safety?

A5. I have spent considerable time at plants during construction activities and heavy equipment maintenance. Worker safety should be considered in developing plans to fast-track installation, particularly conducting field work that requires relocating or installing material with cranes.

Q6. EPA has cited instances where pollution controls have been installed in less than the 40–50 month timeline cited in your testimony. Is EPA correct to use those examples as representative of the entire electricity industry? Is there anything about those examples that make them significantly different than normal experience?

A6. EPA is not correct in citing the examples noted for two reasons. First, the time required to complete a project cited by EPA does not include the total start-to-finish scope, but reflects only a portion of the work. Specifically, almost without exception, EPA estimates "start" time as when contracts for final engineering are awarded. EPA ignores the permitting and preliminary engineering steps that require significant time. Also, some of the installations cited by EPA reflect less challenging applications than typically encountered.

Q7. According to a report by the Clean Energy Group (CEG), a consortium of energy companies that stands to profit from EPA's regulations, the amount of pollution controls required to satisfy CSAPR is less than the number of controls that industry installed between 2008 and 2010, proving industry can meet EPA requirements. Is the CEG correct, or are there problems with its analysis?

A7. Although it is true the number of controls required for the CSAPR is less than those retrofit between 2008 and 2010, the CEG ignores the difference in start time. In general, much of the work to install the control technologies that were completed in 2008 and 2010, as referenced by the CEG, was started in 2005. Many projects started prior to 2005. The key difference between the start times and deployment dates for these projects is due to the specifics of the Clean Air Interstate Rule (CAIR), the relevant mandate for projects installed during the 2008 to 2010 time period. Specifically, compared to the CSAPR, the CAIR offered a greater time period between when the rule was finalized and when units had to be in compliance. Further, the CAIR contained provisions that offered a financial incentive for owners of generating units to deploy control technology early. In contrast, the CSAPR does not contain such provisions; in fact, the usual disincentives exist that penalize owners for early work for the CSAPR if the rule is not issued in final form as proposed.

Questions submitted by Representative Judy Biggert

Q1. The Environmental Protection Agency has claimed that they can provide a one-year extension for the 2015 Utility MACT compliance date. In your testimony, you outline the 10 steps needed to add pollution control equipment to an existing power plant. In your view, would a one-year extension provided on a case-by-case basis be sufficient to allow utilities to go through all 10 steps?

A1. No. The one-year extension would help alleviate, but not eliminate, the significant delay. Analysis that I have conducted for the Utility MACT (described in a reference submitted with my testimony) shows the extension of one year would enable only about 50% of the projects to be completed. [1] This same analysis shows that a two-year extension is required for about 95% of projects to be completed.

[1] See Figure 1-2 of "Feasibility of Retrofitting Fabric Filter Particulate Matter Control Technology to the Electric Generating Unit Inventory as Projected by EPA," July 2011.

Appendix 2

Additional Material for the Record

ADDITIONAL MATERIAL FOR THE RECORD

REPRINT OF ARTICLE BY DR. ROGER O. MCCLELLAN, ADVISOR, TOXICOLOGY AND HUMAN HEALTH RISK ANALYSIS: "ROLE OF SCIENCE AND JUDGMENT IN SETTING NATIONAL AMBIENT AIR QUALITY STANDARDS: HOW LOW IS LOW ENOUGH?", *Air Quality and Atmospheric Health* (published online 01 June 2011).

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Role of science and judgment in setting national ambient air quality standards: how low is low enough?

Roger O. McClellan

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Abstract The Clean Air Act (CAA) requires listing as criteria air pollutants those pollutants that arise from multiple sources and are found across the United States. The original list included carbon monoxide, nitrogen oxides, sulfur oxides, particulate matter, photochemical oxidants (later regulated as ozone), and hydrocarbons. Later, the listing of hydrocarbons was revoked and lead was listed. The CAA requires the EPA Administrator to set National Ambient Air Quality Standards (NAAQS) for these pollutants using the "latest scientific knowledge" at levels that, in the judgment of the Administrator, are "requisite to protect public health" while "allowing an adequate margin of safety" without considering the cost of implementing the NAAQS. The NAAQS are set using scientific knowledge to inform the Administrator's policy judgments on each NAAQS. Recently, there has been increasing tension and debate over the role of scientific knowledge versus policy judgment in the setting of NAAQS. This paper reviews key elements of this debate drawing on the opinion of Supreme Court Justice Stephen Breyer, in *Whitman v. American Trucking Associations*, to resolve the conundrum posed by the CAA language. I conclude that scientists should carefully distinguish between their interpretations of scientific knowledge on specific pollutants and their personal preferences as to a given policy outcome (i.e., specific level and form of the NAAQS), recognizing that these are policy judgments as to acceptable levels of risk if the science does not identify a threshold level below which there are no identifiable health risks. These policy judgments are exclusively delegated by the CAA to the EPA Administrator who needs to articulate the basis for their policy judgments on the level and form of the NAAQS and associated level of acceptable risk.

Keywords Clean Air Act · Criteria pollutants · Ozone · Particulate matter · Policy · Risk · Regulations

Introduction

In this paper, I briefly review key aspects of the Clean Air Act (1970) with regard to the setting of National Ambient Air Quality Standards (NAAQS) for criteria pollutants noting various landmark decisions. I address the primary or health-based Standards and do not consider the secondary or welfare-based Standards, although the core concepts are also relevant to the setting of the secondary Standards. I highlight actions of the last two EPA Administrators (Stephen Johnson and Lisa Jackson) and the Clean Air Scientific Advisory Committee (CASAC) related to the setting of NAAQS for particulate matter and ozone that serve to illustrate the growing tension and debate over the role of scientific knowledge and policy judgments in the setting of NAAQS. I conclude with recommendations for the role of CASAC in synthesizing and interpreting the science on criteria pollutants and offering scientific advice that informs the EPA Administrator's policy judgments on acceptable health risks that, in turn, are linked to the level and statistical form of the NAAQS primary Standard.

This paper was presented in the concluding plenary session on "Regulatory and Policy Implications" at the "American Association for Aerosol Research International Specialty Conference: Air Pollution and Health: Bridging the Gap from Sources to Health Outcomes," March 22–26, 2010, San Diego, CA.

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The Clean Air Act

The Clean Air Act (CAA), initially passed in 1963, is the principal national statute in the United States concerned with air quality. The original CAA (1963) directed the then Department of Health, Education and Welfare (HEW) to prepare, "compile and publish criteria on the effects of air pollutants," hence the identification of "criteria pollutants" and "criteria documents" summarizing the scientific knowledge on certain air pollutants arising from multiple sources and found across the United States as a basis for Standard setting. The National Air Pollution Control Administration (NAPCA) within HEW was assigned responsibility for administering the CAA. When the U.S. Environmental Protection Agency (EPA) was created in 1970, responsibility for administering the CAA was transferred from NAPCA to the new agency. Bachmann (2007) provides an in-depth review of the evolution of Air Quality Management in the United States from 1900 through 2006, with emphasis on the NAAQS, for those readers interested in an in-depth coverage of the topic. John Bachmann prepared his historical review soon after he retired from EPA's Office of Air Quality Planning and Standards where he had a central role for more than three decades in the setting of NAAQS for all the criteria pollutants. Readers interested in legal details of the CAA will find the summary of Martineau and Novello (2004) useful.

In 1970, amendments to the CAA (1970) were passed that required the listing of air pollutants that "may reasonably be anticipated to endanger public health and welfare" and to issue air quality criteria for them. These air quality criteria are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air, in varying quantities."

The pollutants originally designated as "criteria pollutants" because of their ubiquitous distribution and potential to endanger health were photochemical oxidants (later regulated as ozone), particulate matter (later regulated as total suspended particulates, then as PM_{10}, and $PM_{2.5}$), carbon monoxide, sulfur oxides (regulated as sulfur dioxide), nitrogen oxides (regulated as NO_2), and non-methane hydrocarbons (later dropped as a criteria pollutant). The EPA (1971) established NAAQS for these pollutants, soon after the Agency was created, using existing scientific documentation, i.e., criteria. As I will discuss below, the EPA later added lead as a criteria pollutant with legal prodding from the National Resources Defense Council.

In 1977, several key amendments were made to the CAA (1977). Concern about slow action of the EPA in preparing criteria documents and reassessing NAAQSs prompted a legislated requirement that the NAAQSs be reevaluated not later than January 1, 1980, and at 5-year intervals thereafter. Reevaluation was not intended to automatically result in changes in the NAAQSs for a pollutant; rather, reevaluation was intended to ensure that the scientific database was reviewed and that the NAAQSs were consistent with current knowledge. To my knowledge, this requirement for mandatory review every 5 years is unique to the setting of the NAAQS in the United States. Indeed, I know of no other statute calling for an updating of the science and reconsideration of the Standard every 5 years.

Peer review of the earliest criteria documents prepared by the EPA was carried out by various committees of the agency's Science Advisory Board as I will discuss later. A 1977 amendment to the CAA institutionalized the peer-review process for the NAAQS (CAA 1977). The amendment requires the EPA Administrator to appoint an independent scientific committee, composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing state air pollution control agencies to advise the Administrator on the science informing the policy judgments made in setting the NAAQS. The EPA has implemented this provision of the CAA by appointing a Committee, which designated itself as the CASAC. The CASAC is directly responsible to the EPA Administrator, although it functions administratively as one of the standing committees of the EPA Science Advisory Board. Traditionally, the requirement for one CASAC member to be a member of the National Academy of Sciences has been broadly interpreted to also include membership in either the National Academy of Engineering or the Institute of Medicine. To complement the expertise of regular members of the CASAC, consultants with specialized expertise usually have been added to the review panels for specific pollutants.

The CAA was amended again in 1990 (CAA 1990). Although major changes were made in the CAA with these amendments, especially with regard to the regulation of hazardous air pollutants, there were no changes in the fundamental approach to dealing with the setting of NAAQS for criteria pollutants. However, there were changes in the CAA that have had major impact on the regulation of emissions of PM and precursors especially from large power plants.

National Ambient Air Quality Standards

Section 109 of the CAA (1970) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQSs for criteria pollutants identified under Section 108. The primary Standards are to be set to protect public health; secondary Standards are to be set to protect the

public welfare such as effects on soils, water, crops, visibility, and deterioration of property. In this paper, I focus on the use of scientific knowledge and judgment in the setting of the primary Standards. However, the issues discussed are also broadly applicable to the setting of secondary Standards.

Section 109(b)(1) defines a primary NAAQS as one that "the attainment and maintenance of which in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, is requisite to protect the public health." The margin of safety, as interpreted by the EPA, is intended to address uncertainties associated with inconclusive scientific and technical information at the time the Standard is set and to account for hazards that research has not yet identified.

The primary Standards are intended to protect against "adverse effects, not necessarily against all identifiable effects of changes produced by a pollutants." Although Congress did not rigorously define an adverse effect, it did provide general guidance in the legislative history of the debate on the CAA (Library of Congress 1974). Congress was concerned with effects ranging from cancer, metabolic and respiratory disease, and impairment of mental processes to headaches, dizziness, and nausea.

Congress also noted concern for sensitive population groups in setting the NAAQSs. In particular, Congress noted that the Standards should protect "particularly sensitive citizens such as bronchial asthmatics and those with emphysema who in the normal course of daily activity are exposed to the ambient environment." This has been interpreted to exclude individuals who are not performing normal activities, such as individuals who are hospitalized. Further guidance was given noting that the Standard is statutorially sufficient whenever there is "an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to the ambient air."

The challenge of interpreting the language of the CAA was noted in an editorial by Donald Kennedy on "Risk versus Risk" published when he served as Editor-in-Chief of Science (Kennedy 2005). He wrote "In the United States and some other industrial democracies, where people and their governments tend to be risk averse, legislatures, courts, and administrative entities usually create a presumption favoring more safety rather than less. The definitions of risk in law are often vague ("reasonable certainty of no harm" or "adequate margin of safety") and are likely to encourage an unrealistic belief that risks can be minimized or even eliminated altogether." I think Kennedy has captured the conundrum posed by the language of the CAA, a conundrum that has been addressed by Supreme Court Justice Stephen Breyer as I will relate later.

Standard-setting process

The process for developing and issuing NAAQS is quite complex. Key elements of the process, as used until quite recently, include preparation and review of (a) criteria document, (b) staff paper, (c) more recently a risk assessment, and (d) a regulatory decision package leading to the Administrator's policy judgment decisions as to the proposed and final NAAQS which are published in the Federal Register. Traditionally, CASAC focused its attention on reviewing the Criteria Documents and Staff Papers and, more recently, a formal Risk Assessment. As an aside, the process was changed at the end of 2006 (Peacock 2006) with an Integrated Science Assessment and Policy Assessment Document replacing the Criteria Document and Staff Paper. Time will tell if these changes really improve the overall process.

In addition to the documents noted above, the Agency now prepares a Regulatory Impact Analysis which is required under Executive Order 12866 issued by President Clinton (1993) that applies to economically significant rules that have "an annual effect on the economy of $100 million or more or adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety or site, local, or tribal governments or communities." The Regulatory Impact Analysis is not considered during the NAAQS rulemaking process given the prohibition of consideration of cost in the setting of the NAAQS, as will be discussed later.

The first Criteria Document prepared and released by the EPA addressed lead as a criteria air pollutant. This document was prepared and the review initiated before a Clean Air Scientific Advisory Committee was mandated by the CAA Amendments of 1977. Lead was not one of the original criteria pollutants. In 1975, the Natural Resources Defense Council (NRDC), with legal leadership from Attorney David Schoenbrod, sued EPA to have lead listed as a criteria pollutant. The EPA argued that it was already dealing effectively with reducing lead in air through its program to remove lead from gasoline. The Second Circuit Court disagreed (NRDC v. Train 1976) and on March 1, 1976, ordered EPA to identify lead as a criteria pollutant and begin the process of developing a NAAQS. At the time, EPA's Science Advisory Board (SAB) was in the process of assuming review responsibility for scientific activities across the Agency consolidating review functions brought to EPA from its predecessor organizations such as the National Air Pollution Control Administration (NAPCA). The EPA had just disbanded the National Air Quality Criteria Advisory Committee which had operated under NAPCA as well as other media specific advisory committees in favor of a series of discipline-oriented Committees; e.g., health, engineering and ecology.

In 1976, I was asked, as a member of the SAB Executive Committee, to chair an ad hoc Committee to review the criteria document on lead. Preparation of this document had already been initiated by EPA in anticipation of the Second Circuit Court decision. It was prepared by a Criteria and Special Studies Office within the Office of Research and Development located at EPA's Health Effects Laboratory in Research Triangle Park, NC. The first draft, released November 18, 1976, was viewed as unacceptable by the Ad Hoc Committee. The Committee was concerned with the poor scientific quality of the document. In addition, as noted by Bachmann (2007), the Committee was concerned that the document recommended a specific numerical Standard, a value of 5 $\mu g/m^3$, which was inconsistent with the intent of the CAA to separate the scientific assessment of the relevant criteria and the setting of the specific NAAQS.

The views of the Ad Hoc Committee members varied. Indeed, some members wanted the Committee to assume responsibility for re-writing the Criteria Document and recommending a specific Standard. As Chair, I emphasized our role was advisory to the Administrator, not to serve as substitutes for EPA staff to prepare the Criteria Document. The EPA proceeded to prepare a second draft which was released on May 27, 1977. The Committee viewed it as improved, but felt it was still not adequate for setting a lead Standard. The Agency proceeded to develop a third draft released on August 22, 1977. The Committee offered modest comments on the third draft which were considered by the Agency as it prepared the final criteria document released on December 14, 1977 (EPA 1977a) which served as a basis for the proposed lead NAAQS (EPA 1977b). As Chair, I conveyed to the Agency the view that the final version—"accurately reflected the available scientific literature and provided an adequate scientific basis for promulgation and issuance of a Standard for airborne lead." The first lead NAAQS was issued in 1978 (EPA 1978).

The experience with the lead criteria document served as a stimulus for EPA to create a separate Environmental Criteria Assessment Office within the Agency's Office of Research and Development. For three decades, this office was headed by Lester Grant. Grant originally came to the EPA from the University of North Carolina-Chapel Hill as an Inter-Government Personnel Act assignee to assist with revision of the criteria document on lead.

As noted by Bachmann (2007), the Office of Air Quality Planning and Standards (OAQPS) prepared an analysis to support the Lead Standard which was reviewed by EPA scientists, policymakers and the public. However, it was not reviewed by the SAB Ad Hoc Committee. That analysis served as a basis for the proposed NAAQS for lead (EPA 1977b) and the final lead NAAQS (EPA 1978). Bachmann (2007) has noted—"As for all NAAQS decisions, the final choice on the Standard was constrained and informed by the scientific information, but ultimately based on the policy judgment of a politically responsible decision-maker, the EPA Administrator. After consideration of and reaction to public comments, and review and discussion on the final package by OMB, the Administrator promulgated a Pb Standard of 1.5 $\mu g/m^3$ quarterly average in TSP." I strongly agree with Bachmann's first sentence assessment of the role of scientific information informing the policy judgments of the EPA Administrator. This will be a recurring theme in the remainder of this paper.

In many ways, the experience EPA gained in setting the lead NAAQS influenced the NAAQS process for subsequent NAAQS decisions. The OAQPS analysis evolved into preparation of formal Staff Papers that would be subjected to review by the CASAC. The first activity of the newly created CASAC, initially chaired by Sheldon Friedlander, was the review of a combined criteria document for particulate matter and Sulfur Oxides. Subsequently, separate addenda were prepared for Sulfur Oxides and particulate matter and separate Standards issued for the two pollutants. Sulfur Dioxide was identified as the indicator for Sulfur Oxides and Total Suspended Particulate (TSP) as the indicator for particulate matter.

Without going into the administrative or legal details, it is important to note that EPA, in carrying out mandated NAAQS actions in the early days, used an "informal rulemaking process" to propose and promulgate Standards (Bachmann 2007). The informal process focused on the end product, the NAAQS. The process was not always well documented as to how decisions were reached on the four elements of each NAAQS; the indicator, averaging time, specific numerical concentration and the statistical form. The DC Circuit Court of Appeals subsequently found that the record of this informal process did not give the Court a sufficient basis to complete its judicial review of the rules that were promulgated. This led to the final rule for the secondary Sulfur Dioxide Standard being revoked in 1973 as recounted by Berry (1984) in his review of NAAQS decision-making. This judicial decision led EPA to develop more rigorous procedures, including documentation, for the setting of each NAAQS (Pedersen 1975). As noted by Bachmann (2007), these procedures addressed the following points: "(1) EPA was to make available to the public the information and technical methodologies it relied upon by the time of proposal; (2) the preambles to proposal and final rules were to provide a detailed explanation of EPA's decision; (3) EPA was required to respond to all "significant" comments on the proposal by the time it issues its final rule; and (4) all of the above documents, analyses, preambles, and responses constituted the record that the court would examine in reviewing the final Standard decision. Objections not raised

in the record could not be raised in court. The halcyon days of a speedy NAAQS process were over." I agree that the speed of the process was reduced, however, I would add that the transparency of the process was also substantially improved. Congress apparently agreed and these provisions were substantially codified by the CAA Amendments of 1977.

EPA's implementation of the CAA, especially its setting of NAAQS even with improved documentation, has been a matter of continuing controversy and litigation (some persons might argue that controversy and litigation were enhanced by improved documentation in the record). Bachmann (2007) summarizes many of the key legal cases in his review. In this paper, I will only highlight certain of the key legal cases.

The 1997 revisions of the Ozone NAAQS (EPA 1997a) and Particulate Matter NAAQS (EPA 1997b) proved to be very contentious, including the discussions within CASAC. The CASAC PM Panel members had a range of views on the $PM_{2.5}$ Standard that was being set for the first time supplementing the PM_{10} Standard. This range of views was clearly articulated in the CASAC Chair's letter (Wolff 1996) to the Administrator by including a Table showing the views of each individual.

The contentious nature of the debate over these revised NAAQS prompted Administrator Browner to involve President Clinton. Bachmann (2007) recounts that Administrator Browner had a 1-h meeting on these Standards with the President—"she reported that the President quickly accepted her decision and spent much of the time discussing how to reduce unnecessary burdens in the implementation process. This resulted in some of us writing the first draft of a letter that was later sent by President Clinton (Clinton 1997) to EPA directing implementation be carried out so as to "maximize common sense, flexibility, and cost effectiveness."" Not surprisingly, President Clinton (New York 1997) had a role in announcing the tighter Standards which included for the first time a separate $PM_{2.5}$ Standard to supplement the PM_{10} Standard and a shift from a 1-h averaging time to an 8-h averaging time Standard for Ozone.

The issuance of a revised PM NAAQS triggered the case of *American Trucking Associations v. EPA* (ATA 1999). The Court found "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particulate Standards." The Court went on to find "ample support" for EPA's decision to regulate coarse particulate pollution, but vacated the 1997 PM_{10} Standards, concluding in part that PM_{10} is a "poorly matched indicator for coarse particulate pollution" because it includes fine particulates which were separately regulated as $PM_{2.5}$. Subsequently, EPA removed the vacated 1997 PM_{10} Standard allowing the 1987 PM_{10} Standard to remain in place along with the new $PM_{2.5}$.

In addition, the three judge panel held, two to one, that EPA's approach to setting the level of the PM and Ozone Standards in 1997 effected "an unconstitutional delegation of legislative authority." The Judicial Panel found that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and particulate matter are reasonable." However, it remanded the rule to EPA. The Judicial Panel stated that when the Agency considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for drawing lines" to determine the level at which the Standards should be set. The Judicial Panel also found that the Administrator, under the CAA, is not permitted to consider the cost of implementing these Standards in setting them.

Not surprisingly, the nature of the Circuit Court opinion resulted in cross appeals being filed on the several issues. The Supreme Court in February 2001 issued a unanimous opinion upholding EPA's position on both the Constitutional and cost issues (*Whitman v. American Trucking Associations* 2001). On the Constitutional issue, the Supreme Court held that the statutory requirement that the NAAQS be "requisite" to protect public health with an adequate margin of safety sufficiently guided EPA's discretion, affirming EPA's approach of setting Standards that are neither more nor less stringent than necessary.

Supreme Court Justice Breyer, who participated in the *Whitman v. American Trucking Associations* Case, is well known and highly regarded for his opinions and writings on risk assessment and regulation (Breyer 1982, 1993). Thus, it is not surprising that he took the opportunity in *Whitman v. American Trucking Associations* (2001) to offer comments on the Standard-setting process and, specifically, the identification of the level of the NAAQS and the associated level of health risk. While concurring that EPA cannot consider the costs of implementing the NAAQS, he went on to note—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 specifies 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.

The discretion would seem sufficient to 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 healthy society; hence a Standard demanding the return of the Stone Age would not prove "requisite to protect the public health."

Although I rely more heavily than does the Court upon legislative history and alternative sources of statutory flexibility, I reach the same ultimate conclusion, Section 109 does not delegate to the EPA authority to base the national ambient air quality Standards, in whole or in part, upon the economic costs of compliance."

The case of *Whitman v. American Trucking Associations* (2001) is widely cited for the conclusion that EPA cannot consider the economic costs of compliance in the setting of NAAQS. Unfortunately, in my opinion, insufficient attention is given to the thoughtful guidance of Justice Breyer on exercising policy judgment in deciding on an acceptable level of health risk, a judgment that in turn determines the level and statistical form of each NAAQS. It is interesting that Justice Breyer's opinion appeared in Administrator Johnson's notice of the Ozone NAAQS (EPA 2008), but did not appear in Administrator Jackson's "reconsideration" proposal for ozone (EPA 2010a) which will be discussed later.

Paradigm shift

At this juncture, it is appropriate to note that it is my view that a paradigm shift has taken place in the use of scientific knowledge and policy judgments in the selection of the level and form of each NAAQS over the past four decades. In my opinion, the paradigm shift has been driven in part by the nature of the growing body of scientific evidence of pollution effects. In the 1970s, most scientists and regulators viewed the criteria pollutants as having a threshold in the concentration–response relationship for non-cancer endpoints, the major concern for the criteria pollutants. This was different than the prevailing view for cancer causing agents which were assumed to have linear, non-threshold, concentration response relationships.

In the early 1970s, the available data on each criteria pollutant were quite modest, with attention in the review process focusing on only a few epidemiological studies. For those few studies, attention often focused on whether a relative risk on the order of 2.0 was observed and whether it was statistically significant or not. For a given criteria pollutant there were few, if any, controlled human exposure studies. The data from laboratory animal studies had frequently been acquired in short-term studies with exposure concentrations much higher than ambient concentrations. This raised questions about extrapolation from laboratory animals to humans and high to low exposure concentrations. The general approach taken to evaluating the published studies was to identify the lowest levels where effects were statistically significant and assume this was the inflection point in the concentration–response relationship. It could then be readily argued that setting the Standard at a lower concentration than that at which

effects were observed satisfied the requirement for "an adequate margin of safety."

In contrast, the most recent reviews of the criteria pollutants have involved thousands of papers with observations ranging from the human population level to studies of intact laboratory animals to studies of effects of air pollutants on cells and molecules. Despite the huge number of published studies, the focus has ultimately centered in the Staff Paper on the results of a few studies where attention turns to the relevance of the results for informing policy judgments on the level and statistical form of the Standard. For the epidemiological studies, the debate often focuses on whether relative risks of less than 1.1 for excess morbidity and mortality are significant. Of course, the specific relative risk number is dependent on the denominator being used. For controlled exposure clinical studies, attention has focused on the lowest levels with statistically significant changes and whether the changes are adverse.

A news report (Taube 1995) in Science, that I view as a classic report, highlighted the issues involved in the search for subtle links between diet, lifestyle, or environmental factors and disease, especially using retrospective observational studies. I especially liked the quote at the end attributed to UCLA Professor Greenland in offering advice to his "most sensible, level-headed, estimatable colleagues." Remember, he says—"there is nothing sinful about going out and getting evidence, like asking people how much do you drink and checking breast cancer records. There's nothing sinful about seeing if that evidence correlates. There's nothing sinful about checking for confounding variables. The sin comes in believing a casual hypothesis is true because your study came up with a positive result, or believing the opposite because your study was negative."

It is interesting to note that CASAC discussions of criteria pollutant effects have frequently focused initially on the level of the Standard, devoid of any consideration of the statistical form of the level. This approach was in keeping with traditional practice in the setting of Standards such as Threshold Limit Values for occupational exposures to chemicals (McClellan 1999, 2010c). That approach has traditionally involved a review of the available human data on a toxic chemical to determine a no-observed effect level, or the lowest observed effect level, and then use of a safety factor to arrive at an acceptable exposure level set at a lower level. In the absence of adequate human data, laboratory animal data are used and an additional safety factor applied to account for the potential that the animal observations might not adequately predict human effects. This approach was routinely used for a wide range of health responses that were assumed to have an exposure-response relationship that exhibited either a true or practical threshold, an excess of effects above some level and an absence of effects below that level. A review of the earliest Criteria Documents and, indeed, also the Staff Papers, documents that a similar line of reasoning was used in the setting of the NAAQS—identify levels where an increase in effects is observed and then set the Standard at a lower level.

The implementation of Standards set with this approach soon revealed that if the Standard was to be rigorously enforced, i.e., no exceedances of the specific level of the Standard, the practical effect would be to cause average levels of the pollutant to be reduced to levels far below the Standard so as to avoid the occasional high concentration exceeding the Standard. Fortunately, common sense prevailed and the EPA, over time, moved to the practice of routinely linking attainment of the specific level of the Standard to a statistical form such as the 98th percentile 24-h concentration averaged over 3 years, or the fourth highest 8-h average concentration during a 3-year period. In my experience, most of the attention of the CASAC in the NAAQS-setting process has focused on the level of the Standard with limited discussion of the statistical form of the Standard. In doing so, there has been a failure to recognize that the stringency of the Standard and the degree of health protection provided depends on both the level and statistical form of the Standard for a particular indicator and averaging time. In fact, there have been occasions when CASAC has deliberated at length on the level of a prospective Standard and, then in a casual manner, turned its attention to what would be the appropriate statistical form for that level. That this is the case is not surprising since few scientific papers discuss the implications of the reported results in terms of the frequency with which a given health effect may be observed.

The challenges of selecting appropriate averaging times and statistical forms for the NAAQS are substantial. The original epidemiological and toxicological studies that provide the scientific information that should inform the setting of the NAAQS do not always report results with an averaging time that is the same as used for the Standard. Hence, the need to make extrapolations from results reported based on one metric, such as average daily exposure, to second metric, such as an 8-h or shorter averaging time. The setting of Standards at extreme values, the 98th percentile for NO_2 (EPA 2010b) and the 99th percentile form as done with the 1-h averaging time Standard for SO_2 (EPA 2010c), results in extremely stringent Standards that at best are only very loosely related to the underlying data.

In my view, decisions on the selection of specific levels and averaging times for the NAAQS are policy judgments properly reserved to the Administrator informed by the available scientific knowledge. In the 1990s, concurrent with the increasingly widespread use of formal risk analysis

in the record could not be raised in court. The halcyon days of a speedy NAAQS process were over." I agree that the speed of the process was reduced, however, I would add that the transparency of the process was also substantially improved. Congress apparently agreed and these provisions were substantially codified by the CAA Amendments of 1977.

EPA's implementation of the CAA, especially its setting of NAAQS even with improved documentation, has been a matter of continuing controversy and litigation (some persons might argue that controversy and litigation were enhanced by improved documentation in the record). Bachmann (2007) summarizes many of the key legal cases in his review. In this paper, I will only highlight certain of the key legal cases.

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> "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

I participated as a member of the CASAC Panel that provided advice on the setting of the $PM_{2.5}$ Standard in 1997. There was much discussion about the uncertainty associated with the shift from a PM_{10} to a $PM_{2.5}$ Standard, especially the uncertainty in a shift from dependence on only the PM_{10} indicator to $PM_{2.5}$ indicator. There was strong scientific support for introducing the $PM_{2.5}$ indicator, although at the time, there was limited epidemiological data from studies in which $PM_{2.5}$ had actually been measured. There was no clear scientific evidence on the presence or absence of a threshold in the concentration–response relationship for either acute or chronic responses. The big issues related to the levels and associated form—"how low was low enough?" The prevailing tone in hallway conversations focused on two points. First, it was argued that it was important to introduce a $PM_{2.5}$ indicator which, in turn, would mandate the monitoring of $PM_{2.5}$. The availability of the $PM_{2.5}$ monitoring data would then allow the conduct of epidemiological studies to directly evaluate a potential concentration–response association for this indicator. Second, it was argued that in the absence of convincing data on $PM_{2.5}$ the final action contemplated by the Agency should not represent a drastic increase in the stringency of the PM Standard. In my opinion the new $PM_{2.5}$ annual Standard set at 15 $\mu g/m^3$ *did* increase the stringency of the PM Standard and represented a policy judgment call on the part of the Administrator that was very precautionary. In contrast, in my opinion, the setting of $PM_{2.5}$ 24-h averaging time Standard at 65 $\mu g/m^3$ was much less precautionary. The level and form of the new Standards was as follows:

(1) The annual $PM_{2.5}$ Standard is met when the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations, from single or multiple community-oriented monitors, is less than or equal to 15 $\mu g/m^3$, with fractional parts of 0.05 or greater rounded up.
(2) The 24-h $PM_{2.5}$ Standard is met when the 3-year average of the 98th percentile of 24-h $PM_{2.5}$ concentrations at each population-oriented monitor within an area is less than or equal to 65 $\mu g/m^3$, with fractional parts of 0.5 or greater rounded up.
(3) The form of the previous 24-h PM_{10} Standard is revised to be based on the 3-year average of the 99th percentile of 24-h PM_{10} concentrations at each monitor within an area.

Review of the PM Standard that would lead to revision of the 1997 PM Standard moved forward in the early 2000s. In 2004, as the new Criteria Document for PM was reviewed, it was decided that the CASAC would abandon CASAC's practice of issuing "closure letters." "Closure Letters" had traditionally been sent by the CASAC Chair to the EPA Administrator at key junctures, such as completion of revision of a Criteria Document or Staff Paper, signifying the work product was scientifically acceptable for regulatory decision-making. Some individuals had viewed the "closure letters" as a way by which CASAC impeded progress in the setting of NAAQS in a timely manner. I viewed the "closure letters" as an effective approach to ensuring that EPA was preparing documents that included the latest scientific information and analyses, even if it required the Agency to develop Revisions or Addendums.

After reviewing and commenting on the Criteria Document (EPA 2004) and Staff Paper (EPA 2005), CASAC recommended that the 24-h $PM_{2.5}$ Standard be set in the range of 25 35 $\mu g/m^3$ and the annual $PM_{2.5}$ Standard be set in the range of 13–14 $\mu g/m^3$ (Henderson 2005, 2006a; Table 1).

There was strong pressure within the CASAC PM Panel to provide consensus advice to the Administrator. In the end, two consultant members of the PM Panel who had both served as Chair of CASAC (myself and another) did not deem it appropriate to join with other members of the Panel in endorsing the specific levels others wished to recommend to the Administrator. I held strongly to the view that the difference between leaving the Standard at 15 $\mu g/m^3$ and reducing it to 14 $\mu g/m^3$ was not a scientific decision, but rather a matter of policy judgment that should be left to the discretion of the Administrator. In my opinion, Administrator Johnson, as the politically responsible decision-maker (using the words of John Bachmann 2007 in describing the 1974 Lead NAAQS decision) was not bound by the recommendations of CASAC as they were an advisory committee. In my opinion, the Administrator alone had the authority to make policy judgment calls in retaining or revising the annual $PM_{2.5}$ Standard, then at 15 $\mu g/m^3$ and the 24-h $PM_{2.5}$ Standard, then at 65 $\mu g/m^3$ (EPA 1997a). The Administrator issued a final rule with the annual $PM_{2.5}$ Standard retained at 15 $\mu g/m^3$ and the 24-h Standard reduced to 35 $\mu g/m^3$ (EPA 2006b).

Table 1 National ambient air quality standards for $PM_{2.5}$ and ozone, the old standard, CASAC recommendations and administrator's final rule

Indicator (unit)	Old standard	CASAC	New standard
$PM_{2.5}$—24 h ($\mu g/m^3$)	65[a]	30–35[b]	35[c]
Annual ($\mu g/m^3$)	15[a]	13–14[b]	15[c]
Ozone—8 h (ppb)	84[d]	60–70[e]	75[f]

[a] EPA 1997a, b

[b] Henderson 2006a, b; Henderson et al. 2006c

[c] EPA 2006b

[d] EPA 1997a, b, set at 0.08 ppm which by rounding convention equals 84 ppb

[e] Henderson 2007, 2008

[f] EPA 2008

After the final PM rule was issued in 2006 (EPA 2006b), the seven formal members of CASAC (Henderson et al. 2006c) sent a letter to the Administrator expressing concern that the EPA Administrator had not decreased the $PM_{2.5}$ Annual Standard from 15 $\mu g/m^3$ to 13–14 $\mu g/m^3$ in combination with the setting of the 24-h Standard at 35 $\mu g/m^3$, the upper end of the ranges they had recommended. In my view, the CASAC recommendation that the Administrator had to reduce the annual Standard by at least 1 $\mu g/m^3$ indicated that the CASAC failed to appreciate that the setting of any NAAQS involves policy judgments, reserved by the CAA to the EPA Administrator, informed by the science. Presumably, the CASAC would have found it acceptable if the Administrator had reduced the Annual $PM_{2.5}$ Standard from 15 to 14 $\mu g/m^3$, or even to 13 $\mu g/m^3$.

Perhaps it would be useful for me to elaborate on why I think it is not appropriate for CASAC to recommend a bright line upper bound on the NAAQS, even assuming no change in the statistical form of the Standard. The Committee, when commenting on the science undergirding the Standard, had noted that it had not identified a threshold in the ambient exposure concentration–response relationship for $PM_{2.5}$. Consistent with this assessment of the science, the EPA in its Risk Assessment had used a linear exposure concentration–response model to estimate risk that would be avoided and risks that would remain if the Standards were set at various specific levels and with an assumed statistical form. There were estimated risks associated with retaining the Standard at 15 $\mu g/m^3$ and reducing it to 14 or 13 $\mu g/m^3$. By endorsing a level of 14 $\mu g/m^3$ for the annual Standard, the CASAC was indicating its support for setting the Standard at a particular level of estimated risk. In my opinion, a decision on acceptable risk (i.e., the residual risk level when the Standard is attained) is a policy decision left to the discretion of the EPA Administrator under the authority of the CAA. The Committee's blended scientific and policy judgment advice would have been clearer if they had stated their specific advice by indicating both the specific numerical level and the associated morbidity and mortality. Of course, the estimates of morbidity and mortality should have had an indication of the associated uncertainties.

Let us now turn to revision of the Ozone NAAQS. Final action on revision of the Ozone Standard set in 1997 (EPA 1997b) followed almost 2 years after the decision on the $PM_{2.5}$ Standard. The ozone review included a Criteria Document (EPA 2006c) which summarized publications through 2005. This document served as the basis for a subsequent staff paper (EPA 2007a) and risk assessment (EPA 2007b). Again, CASAC (Henderson 2006b, 2007) offered very prescriptive advice on the level of the Standard indicating that the level of the revised 8-h averaging time Standard should be lowered to no greater than 0.070 ppm down from the 1997 Standard of 0.08 ppm which by rounding convention was effectively 0.084 ppm. The 1997 Standard is met when the 4th highest 8-h average value over a 3-year period does not exceed 0.084 ppm (Table 1).

The CASAC letter on the Ozone Staff Paper (Henderson 2007) commented on policy relevant background (PRB) noting "the Final Ozone Staff Paper does not provide a sufficient base of evidence from the peer-reviewed literature to suggest that the current approach to determining a PRB is the best method to make this estimation." The letter concludes with the statement—"Thus, PRB is irrelevant to the discussion of where along the concentration–response function a NAAQS with an averaging time that provides enhanced public health protection should be." The CASAC apparently failed to appreciate that identification of scientifically valid levels for PRB for different sections of the country can have a profound influence on realizable public health benefits (see discussion in McClellan et al. 2009) and the calculated benefit and residual risks for various levels and forms of the Standards.

As the Agency's activities on revision of the Ozone NAAQS were proceeding, I participated in June 2007 with a small group of scientists at a meeting held in Rochester, NY to discuss critical considerations in evaluating scientific evidence of health effects of ambient ozone. The discussions at the Rochester Conference focused on the scientific interpretation of the data available on the health effects of exposure to ambient concentrations of ozone, controlled ozone exposure studies with human volunteers, long-term epidemiological studies, time-series epidemiological studies, human panel studies, and toxicological investigations. The deliberations also dealt with the issue of background levels of ozone of non-anthropogenic origin and issues involved with conducting formal risk assessment of the health impacts of current and prospective levels of ambient ozone. The participants, while offering comments on the science informing the revision of the Ozone NAAQS, did not feel it appropriate to offer policy judgments on the level and form of the Ozone NAAQS then under consideration. A report based on the Rochester Conference has been published (McClellan et al. 2009). The deliberations at the Rochester Conference were summarized and included with my comments (McClellan 2007) submitted to the EPA Ozone Docket on the proposed Ozone Standard (EPA 2007c).

Administrator Johnson, in March 2008 (EPA 2008), issued a final revised Standard for Ozone with the primary 8-h average Standard set at 75 ppb retaining the statistical form the same as the 1997 primary Standard—the Standard is attained when the fourth highest 8-h average value over a 3-year period does not exceed 75 ppb. The CASAC was displeased with the policy judgment of Administrator Johnson to set the Standard at 75 ppb rather than heeding

their recommendation to set the Standard in the range of 0.060–0.070 ppm (Henderson 2008). As an aside, Administrator Johnson also decided to set the secondary Standard for Ozone equal to the primary Standard. In doing so, he did not heed CASAC's advice to set a secondary Standard with a different cumulative form. The CASAC had recommended a sigmoidally weighted W126 index, accumulated over 12 "daylight" hours and over at least the three maximum ozone months of the summer growing season (Henderson 2008).

Some CASAC members have argued that by giving the EPA Administrator a range (0.060–0.070 ppm), the CASAC had not taken away the Administrator's discretion in making policy judgments on the level and form of the NAAQS. To the contrary, I argue that the upper value in the range is in effect a bright line that CASAC has indicated the Administrator should not go above based on the science. In short, under the new paradigm, CASAC has defined for the Administrator the upper level of excess risk that CASAC deems acceptable, even though they have not clearly identified the specific health risk level associated with the 0.070 ppm level.

I firmly believe that Administrator Johnson's decisions on both the primary and secondary ozone Standards were consistent with the legislative authority accorded the Administrator under the CAA. Much was made of the fact that in the setting of the Ozone Standards, discussions took place between White House staff and, perhaps then President Bush, as the Standard was finalized. This is hardly surprising. Recall Bachmann (2007) recounted the discussions between President Clinton and Administrator Browner in 1997 and the draft memo to EPA Administrator Browner prepared by EPA staff for ultimate issuance over the signature of President Clinton (Clinton 1997).

As soon as President Obama was sworn in on January 20, 2009, the then-White House Chief of Staff, Rahm Emanuel, issued a memorandum (Emanuel 2009) stating —"It is important that President Obama's appointees and designees have the opportunity to review and approve any new or pending regulations." The Emanuel memorandum then proceeded to outline explicit conditions for what qualified as new or pending regulations—for example, "all proposed or final regulations that have not been published in the Federal Register" and "consider extending for 60 days the effective date of regulations that have been published in the Federal Register but not yet taken effect." The revised NAAQS for ambient ozone, published in the Federal Register, March 12, 2008 (EPA 2008), could hardly be viewed as new or pending in January 2009. Indeed, in the fall of 2008, the EPA had already initiated action on the next review of the Ozone NAAQS (Martin 2008). In initiating the new review, it was noted that CASAC advice on the previous review of the Standard represented "a mixture of scientific and policy considerations." Nonetheless, EPA Administrator Lisa Jackson in late 2009, decided to proceed with "reconsideration" of the final Ozone NAAQS rule issued in March 2008 (EPA 2008). The decision to proceed with a "reconsideration" proposal was formally announced in the Federal Register in January 2010 (EPA 2010a). The "reconsideration" proposal noted—"With respect to CASAC's recommended range of standard levels, EPA observed that the basis for CASAC's recommendation appears to be a mixture of scientific and policy consideration."

Administrator Jackson has stated that the "reconsideration" rule will be based on the same record used to propose the 2008 Standard, essentially the scientific information available through late 2005 and included in the 2006 Criteria Document (EPA 2006a). Recall the earlier discussion of EPA moving to a formal rulemaking process at the insistence of the Court. The approach of using the "old scientific record" was apparently taken with a view that it offered a "fast track" to a revision of the Ozone Standard without creating a new record. The "reconsideration" proposal (EPA 2010a) states that consideration will be given to setting the primary Standard set in the range of 60 to 70 ppb. The announced date for release of the final "reconsideration" Standard has continually shifted from August 2010 to October 2010 to December 2010 to July 2011. In accord with the review plan laid out in October 2008, the EPA staff proceeded with preparation of the Integrated Science Assessment reviewing the new scientific information to be considered in the next 5-year review triggered by promulgation of the March 2008 Ozone NAAQS. Ironically, the Integrated Science Assessment, the document replacing the old criteria document, for ozone, was released on March 2, 2011 (EPA 2011a), all while EPA's reconsideration of the old record remains pending.

I offered comments (McClellan 2010a) on the appropriateness of the Administrator proceeding with a "reconsideration" Standard for ozone and offered comments (McClellan 2010b) to the EPA Ozone Docket on the specifics of the proposal. In my view, the proposal for the Administrator to reconsider a rulemaking, the setting of a NAAQS, formally completed 9 months earlier by the previous Administrator in another Administration is without precedent. It has the potential to serve as a bad precedent with every change in Presidential Administration triggering a review of actions completed by the previous Administration with a view to potentially reconsidering the rules. In short, the new Administrator is saying "if I had been in office before I was appointed, I would have made a different policy judgment call." Administrator Jackson's use of the CASAC position in 2008 to justify the "reconsideration" action, in my opinion, moves CASAC out of its scientific advisory role into a strategic, policy-driving

Standard-setting role. This is troubling since Administrator Johnson, in issuing the 2008 Standard, had noted (perhaps with trepidation) that the CASAC recommendation "appears to be a mixture of scientific and policy considerations," a view informed by EPA staff analysis (Martin 2008). I agree with the assessment that CASAC, in recommending specific levels, is on a path of mixing scientific interpretations with policy judgments.

Administrator Jackson, in early 2011 (EPA 2011b), called on the CASAC to offer further clarification of the views it expressed earlier. The specific advice being solicited by the Administrator from CASAC is detailed in a memorandum from Lydia Wegman, Office of Air Quality Planning and Standards to CASAC (Wegman 2011). Many of the questions appear to be directed at attempting to distinguish between CASAC's interpretation of the old science and the policy judgments that resulted in CASAC's 60–70 ppb recommended range for the Standard. It proved challenging for CASAC to address these questions based only on the "old record" of pre-2006 science while ignoring the new scientific information on ozone (Samet 2011).

The substantial new scientific information on ozone that has been published in the 5 years since the Criteria Document (EPA 2006c) was prepared is documented in the recently released Integrated Science Assessment (EPA 2011b). The current drama over the "reconsideration" ozone rule has the potential to damage the credibility of CASAC by drawing it more tightly into the "regulatory web of policy judgments" that are the exclusive dominion of the Administrator under the authority of the CAA. My advice (McClellan 2011) to the Administrator and CASAC was to withdraw the "reconsideration" proposal and ask CASAC to expeditiously proceed with review of the new science now available in the Integrated Science Assessment (EPA 2011a).

Call for sound science

Over the last several decades, there have been increasingly loud calls from multiple quarters for using "sound science" to make regulatory decisions such as the setting of NAAQS. The call has come from both Non-Government Organizations (NGOs) representing multiple sectors, from Industry and from the scientific community. In my opinion, all of these groups and the individuals within them have difficulty separating the science from their policy-driven preferred outcomes. As a scientist and as a citizen, I strongly support the use of all the available scientific information to inform public policy decisions. In general, I think the efforts of individuals and organizations to critically review and synthesize relevant scientific information for the various Agency rulemaking activities has had a positive impact. This includes the situations in which original scientific data files were made available (actions that I applaud) and re-analyses conducted. Indeed, I think more such analyses should be conducted, especially when the original data were acquired with public funding. By the same token, I would urge industry groups to make available to other investigators data acquired under industry sponsorship.

What I decry, however, is the desire by some to label certain reviews or analyses as either "acceptable" or "dead on arrival" based on the source of funding without regard to scientific quality of the review or analyses. Over my career, I have encountered exceptionally high-quality reviews and analyses performed by scientists in academic, industrial, and environmental organizations with sponsorship from government, NGOs, and industry. I have also noted some reviews and analyses from these same quarters that I thought were of inferior scientific quality. In my opinion, scientific quality and rigor is not defined by the source of funding for the work.

I have great concern that the advocates of "sound science," be it NGO, academics or industry, may have unrealistic expectations as to what "sound science" can deliver. Sound science does not in and of itself make for sound decisions. As I have noted in this paper, science alone cannot identify an acceptable level of health risk, since such levels inherently represent a policy judgment call. Sound science can only inform what are ultimately policy judgments or political decisions. This is especially the case for the setting of NAAQS, in the absence of a clearly defined threshold, which involve decisions as to acceptable health risks which are linked to the level (and form) of the Standard.

Setting NAAQS at acceptable levels of risk

Let us now return to the critical issue of "how low is low enough?" for setting a specific NAAQS. It is apparent that the body of science on any given criteria pollutant today is such that it is difficult to argue that the current Standards, if attained, would result in a world that is free of any risk of adverse effects from air pollution on the populations of the United States. As Justice Breyer wrote, we live in a world that is not free of all risk. I draw guidance from Justice Breyer's statement on his interpretation of the words of the CAA—"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." The "her" in Justice Breyer's opinion is a reference to past EPA Administrator Christine Whitman.

However, in my opinion, the discretion that Justice Breyer assigns to the EPA Administrator does not extend to

the CASAC, either as individuals or acting collectively. Each of the individuals serving on CASAC may be an extraordinarily competent scientist or engineer or have other specialized knowledge of air quality and its health and environmental effects. Because of this special expertise, these individuals have a special role in interpreting the scientific knowledge that the Administrator will use in making policy judgments on the level and form of the Standard recognizing that the level and form, in turn, determine the level of acceptable risk that it is estimated Society will bear for that specific pollutant.

As broadly knowledgeable health and environmental scientists, CASAC members are in a unique position to offer advice to the Administrator that will provide the "comparative health consequences" context that Justice Breyer has called for in his opinion. For example, it would be refreshing if CASAC members were to more broadly draw on their experience as health specialists. In doing so, when debate begins on the public health significance of an excess risk of 0.1 for some health endpoint per 10 ppb increase in ozone at 60, 70, or 80 ppb averaged over 8 h, they could offer comments on the multiple factors that influence the health risks for that endpoint. This discussion, in my opinion, should even be extended to recognize that complex factors such as the socio-economic status of individuals have a profound influence on health (Table 2; Steenland et al. 2004). I will readily admit that differences in air quality associated with socio-economic status may have a role in the differences reported by Steenland et al. (2004) and other investigators. However, that admission does not serve as a basis for not providing scientific context to decisions on "how low is low enough" in setting NAAQS.

I suspect that this was the kind of input Administrator Bill Ruckelshaus was seeking when he noted in 1983 that a decision on the PM Standard "could not be made solely on science, and asked if under the statute "is there room to consider other non-scientific factors in making the major social policy judgment of picking a precise number from a range of scientifically justified values" (Bachmann 2007). Justice Breyer has answered former Administrator Ruckelshaus' question in the affirmative. Indeed, Justice Breyer has recommended the use of comparative health consequences as a context for Standard setting. In doing so, he has indicated that the boundaries of the relevant science for setting a NAAQS are not restricted exclusively to the health effects of the specific pollutant under consideration. This common sense approach has not been evident in many of the recent CASAC deliberations or the policy judgments of the Administration.

Table 2 The impact of socio-economic status on mortality (Steenland et al. 2004)

Mortality	Men	Women
All causes	2.02 (1.95 209)[a]	1.29 (1.25 1.32)
Heart disease	1.88 (1.83–1.93)	1.84 (1.76–1.93)
Stroke	2.25 (2.14 2.37)	1.53 (1.44 1.62)
Diabetes	2.19 (2.07–2.32)	1.85 (1.72–2.00)
COPD	3.59 (3.35–3.83)	2.09 (1.91–2.30)
Lung cancer	2.15 (2.07–2.23)	1.31 (1.25–1.39)
Breast cancer	–	0.76 (0.73–0.79)
Colorectal cancer	1.21 (1.16–1.27)	0.91 (0.86–0.96)
External causes	2.67 (2.58 2.78)	1.41 (1.35 1.48)

Mortality rate ratio = $\frac{\text{Lowest quartile}}{\text{Highest quartile}}$ of socioeconomical status

[a] 95% confidence interval

Conclusions

The United States now has nearly a half century of experience of improving air quality under the federal statute, the Clean Air Act, first enacted in 1963. The amendments of 1970, 1977 and 1990 substantially strengthened the CAA. Remarkable progress has been made in improving air quality as assessed using multiple criterion. The establishment of National Ambient Air Quality Standards for criteria pollutants by the EPA and the implementation programs of the individual States have contributed significantly to that success. Every decade from 1970 to the present has seen major actions with regard to the NAAQS and, in general, more stringent Standards. In many instances, Standards have been attained or nearly attained, and then a new more stringent Standard has been introduced. As some have said, we were almost there and then they moved the goal posts, i.e. lowered the Standards.

Now, more than at any time in the past, the policy judgment question must be asked "How low is low enough?" for each of the NAAQS. In my opinion, the guidance of Justice Breyer provides the Administrator broad latitude to make policy judgments consistent with our common goal of enhancing the health of all Americans.

Whatever path is chosen to go forward, there will remain a need for policy judgments informed by the best available scientific information. In creating new scientific information, I urge scientists to think broadly and adopt a strong comparative health benefit orientation. For example, when conducting epidemiological investigations, include multiple air pollutants and other factors, including socio-economic status that may influence the health endpoints being evaluated. Then report on all of the tested associations, not just the results for a single air pollutant. The resulting broader base of knowledge will allow Society to make decisions as to what actions will yield the most improvement in health at the lowest net cost to Society.

When future Integrated Science Assessment Documents are prepared, I urge that they include information that will help put the reported health effects of the specific pollutant in context. One approach to this might be the development of a generic document that reviews current knowledge on the multiple factors that influence morbidity and mortality from respiratory and cardiovascular disease, the major health outcomes for key criteria pollutants. This information could then be used in multiple Policy Assessment Documents. Both the Integrated Science Assessment and Policy Assessment Documents should more clearly identify and characterize the health effects role of the specific pollutant under consideration as well as the role of co-pollutants and other factors influencing the health outcomes evaluated. Policy Assessment Documents need to include "determinate criterion for drawing lines" as called for by the DC Circuit Court in its *American Trucking Associations v. EPA* (1999) opinion. These are needed to provide a clearer basis for the Administrator's policy judgments on the level and form of the Standard. These criteria, along with a strong comparative health context, should provide an improved basis for the Administrator's policy decisions.

I also strongly urge the CASAC to focus on the scientific rigor of the scientific content and analyses in the Integrated Science Assessment and Policy Assessment Document, and avoid the temptation of offering policy judgments as to a specific upper-bound level and form of the Standard or what they view as acceptable ranges. If CASAC cannot avoid this temptation to stay out of the "policy judgment thicket," then it needs to be clear as to the specific scientific knowledge that informs their personal policy preferences. CASAC is required to comment to the Administrator under CAA § 109(d)(2)(B) "on any new national ambient air quality Standards and revisions of existing criteria or Standards as may be appropriate." However, in offering comments, CASAC needs to very carefully articulate where CASAC scientific interpretations leave off and CASAC policy judgments begin. Moreover, it is important for EPA Administrators to recognize they need not be bound by CASAC's specific policy preferences or range of policy preference outcomes. While the CASAC members are citizens and are certainly entitled, just like any citizen, to have personal preferences as to policy outcomes, CASAC members, acting in that role, should not view themselves as broadly representative of Society at large.

It is critically important that EPA Administrators recognize, as Administrator William Ruckelshaus so clearly did in 1983, that Standards cannot be set solely on science and that the ultimate decision on a level and form of a Standard necessarily reflects policy judgments. Administrators should not seek to find "scientific cover" for these policy judgments in the deliberations offered by CASAC. If this is done, it has the potential to transform the Clean Air Scientific Advisory Committee into a de facto Clean Air Standards Setting Committee, thereby usurping the policy role of the Administrator. I do not think that is consistent with the language of the CAA. The Administrator, as a public official appointed by the President and confirmed by the Senate, is expected to have a broad perspective reflective of all of Society, not just a specific scientific constituency, when making policy judgments in setting National Ambient Air Quality Standards.

Declaration of Interest I have participated, beginning in the mid-1970s, as a member of numerous CASAC Panels providing advice to the EPA Administrator on the setting of the NAAQS for all the criteria pollutants. I served as Chair of CASAC in 1988–1992 when the debate began on shifting the averaging time for the ozone Standard from 1 to 8 h. I served on the CASAC PM Panels that provided advice on the $PM_{2.5}$ Standards promulgated in 1997 and 2006. I served on the CASAC Ozone Panel that provided advice on the Standard promulgated in 1997. I did not serve on the CASAC Ozone Panel that provided advice to the EPA Administrator on the Standard promulgated in 2008. However, I did follow that activity closely and offered comments to CASAC and EPA on the science informing the Administrator's judgments on the Ozone NAAQS. The views I share in this paper are my own professional views based on three decades of experience participating in the NAAQS setting process. I regularly serve as an advisor to both public and private organizations on air quality issues. This includes the American Petroleum Institute (API) and various companies in the energy and transportation sectors. The views I have expressed are not necessarily those of the API or any organization I advise.

References

American Trucking Associations, Inc. vs U.S. Environmental Protection Agency (1999) DC Circuit, May 19, 1999

Bachmann J (2007) Will the circle be unbroken: a history of the U.S. National Ambient Air Quality Standards. J Air Waste Manage Assoc 57:652–697

Berry MA (1984) A method for examining policy implementation: a study of decision-making for the national ambient air quality standards, 1964–1984; U.S. Environmental Protection Agency, Research Triangle Park, NC

Breyer S (1982) Regulation and reform. Harvard University, Cambridge, MA

Breyer S (1993) Breaking the vicious circle: toward effective risk regulation. (Based on 1992 Oliver Wendell Holmes lectures at Harvard Law School). Harvard University, Cambridge, MA

CAA (1963) The Clean Air Act of 1963

CAA (1970) The Clean Air Act amendments of 1970-P.L. 91–04 (December 31, 1970), Plus technical amendments made by P.L. 92–157 (November 18, 1971)

CAA (1977) The Clean Air Act amendments of 1977

CAA (1990) The Clean Air Act amendments to 1990, Public Law No. 101–549; 104 STAT 2399, 1990

Clinton WJ, President (1993) Executive Order 12866—regulatory planning and review. Fed Regis 58:51735–51744

Clinton WJ, President (1997) Memorandum for the administrator of the environmental protection agency implementation of revised air quality standards for ozone and particulate matter

Emanuel R (2009) Assistant to the President and Chief of Staff, Memorandum to the Heads of Executive Departments and Agencies, Fed Reg 74(13):4435–4436

Henderson RF (2005) Letter to administrator on particulate matter standard from CASAC Chair, Rogene Henderson to EPA Administrator Stephen Johnson, June 6, 2005

Henderson RF (2006a) Clean air scientific advisory committee recommendations concerning the proposed national ambient air quality standards for particulate matter: Letter from CASAC Chair, Rogene Henderson to EPA Administrator Stephen Johnson, March 21, 2006

Henderson RF (2006b) Clean air scientific advisory committee's review of the agency's draft ozone staff paper: letter from CASAC chair, Rogene Henderson to administrator Stephen Johnson dated October 24, 2006, EPA-CASAC-07-001

Henderson RF, Cowling EB, Crapo JD, Miller FJ, Poirot RL, Speizer FE, Zielinska B (2006c) Clean air scientific advisory committee recommendations concerning the proposed national ambient air quality standards for particulate matter: letter to EPA administrator Stephen L. Johnson, EPA-CASAC-LTR-06-002, March 21, 2006; EPA clean air scientific advisory committee, Washington, DC

Henderson RF (2007) Clean air scientific advisory committee's review of the agency's final ozone staff paper: letter from CASAC Chair, Rogene Henderson to administrator Stephen Johnson dated March 26, 2007, EPA-CASAC-07-002

Henderson RF (2008) Clean air scientific advisory committee recommendations concerning the final rule for the national ambient air quality standards for ozone: letter from CASAC Chair, Rogene Henderson, to EPA Administrator Stephen Johnson, April 7, 2008, EPA-CASAC-08-009

Kennedy D (2005) Risk versus risk. Science 309:2137, 30 September 2005

Library of Congress (1974) A legislative history of the clean air amendments of 1970, Vol. 1; Serial number 93–18; Environmental Policy Decision, Congressional Research Service, Library of Congress, Washington, DC

Martin K (2008) Building on the last ozone NAAQS Review: key policy relevant issues. Presentation to EPA Workshop on Science/Policy Issues for Next Periodic Review of Ozone NAAQS, October 29, 2008

Martineau R, Novello D (2004) The Clean Air Act handbook, 2nd edition

McClellan RO (1999) Human health risk assessment: a historical overview and alternative paths forward. Inhal Tox 11:477–518

McClellan RO (2007) Comments on national ambient air quality standards for ozone: proposed rule. Submitted on October 9, 2007 to Docket ID No. EPA-HQ-OAR-2005-0172

McClellan RO, Frampton MW, Koutrakis P, McDonnell WF, Moolgavkar S, North DW, Smith AE, Smith RL, Utell MJ (2009) Critical considerations in evaluating scientific evidence of health effects of ambient ozone: a conference report. Inhal Toxicol 21(2):1–36

McClellan RO (2010a) Comments on proposed "Reconsideration" national ambient air quality standard for ozone for presentation at the public meeting. U.S. Environmental Protection Agency, Arlington, VA, February 2, 2010

McClellan RO (2010b) Comments on the proposed "Reconsideration" national ambient air quality standard submitted on March 9, 2007 to the Ozone Docket

McClellan RO (2010c) Hazard and risk assessment and management. In: Jon Ayres G, Roy Harrison M, Maynard R, Gordon Nichols L (Eds.), Textbook of Environmental Medicine Chapter 4 1st Ed., Hodder Education: London, UK pp 59–88

McClellan RO (2011) Written statement for consideration by the clean air scientific advisory committee (CASAC) Ozone review panel at the panel's teleconference meeting on February 18, 2011

New York Times (1997) Clinton sharply tightens air pollution regulations despite concern over costs. NY Times, June 26, 1997

NRDC vs Train (1976) 411F. Supp. 864 (S.D.N.Y.) aff'd 545F.2d 320 (2nd Cir. 1976)

Peacock M (2006) Memorandum from Marcus Peacock, deputy administrator to Dr. George Gray and Bill Wehrun. Process for reviewing the national ambient air quality standards, December 7, 2006; available at http://www.epa.gov/ttn/naaqs/memo process for reviewing naaqs.pdf (accepted 2007)

Pedersen WF (1975) Formal records and informal rulemaking. Yale Law J 38:38–88

Rhomberg LR, Goodman JE, Haber LT, Dougson M, Andersen MT, Klaunig JE, Meek B, Price PS, McClellan CSM (2011) Linear low-dose extrapolation for non-cancer health effects is the exception, not the rule. Crit Rev Toxicol 41(1):1–19; available at http://informahealthcare.com/toc/itx/41/1

Samet JM (2011) Clean air scientific advisory committee (CASAC) Response to charge questions on the reconsideration of the 2008 Ozone national ambient air quality standard. EPA-CASAC-11-004. Letter from CASAC Chair, Jonathan M. Samet to Administrator Lisa P. Jackson, March 30, 2011

Steenland K, Hu S, Walker J (2004) All-cause and cause-specific mortality by socioeconomic status among employed persons in 27 U.S. States, 1984–1997. Am J Public Health 94:1037–1042

Taube G (1995) Epidemiology faces its limits. Science 269:164–169

U.S. Environmental Protection Agency (1971) National primary and secondary ambient air quality standards. Fed Reg 36:8186

U.S. Environmental Protection Agency (1977a) Air quality criteria for lead (released December 14, 1977). EPA/600/8-77/017

U.S. Environmental Protection Agency (1977) Lead ambient air quality standard proposal. Fed Regis 42:63076

U.S. Environmental Protection Agency (1978) National ambient air quality standard for lead. Fed Regis 43:46246

U.S. Environmental Protection Agency (1997a) National ambient air quality standard for particulate matter. Final Rule Fed Reg 62:38652–38760, July 18, 1997

U.S. Environmental Protection Agency (1997b) National ambient air quality standard for ozone. Final Rule Fed Reg 62(138):38855–38896, July 18, 1997

U.S. Environmental Protection Agency (2004) Air quality for particulate matter (October 2004). 600/P-99/002aF-bF, Washington, DC

U.S. Environmental Protection Agency (2005) Review of the national ambient air quality standards for particulate matter: policy assessment of scientific and technical information (December 2005). EPA-452/R-05-005a, Washington, DC

U.S. Environmental Protection Agency (2006a) National ambient air quality standards for particulate matter: proposed rule. Fed Regis 71:2620–2708

U.S. Environmental Protection Agency (2006b) National ambient air quality standards for particulate matter: final rule. Fed Regis 71:61144–61233

U.S. Environmental Protection Agency (2006c) Air quality criteria for ozone and related photochemical oxidants (Final). Washington, DC: EPA/600/R-05-004aF-cF

U.S. Environmental Protection Agency (2007a) Review of the national ambient air quality standards for ozone: policy assessment of scientific and technical information

U.S. Environmental Protection Agency (2007b) Ozone health risk assessment for selected urban areas, EPA-452/R-07-009

U.S. Environmental Protection Agency (2007) National ambient air quality standards for ozone: proposed rule 40 CFR part 50. Fed Regis 72:37818–37919

U.S. Environmental Protection Agency (2007d) Regulatory impact analyses: 2007 Proposed revisions to the national ambient air quality standards for ground-level ozone. Released August 2, 2007. www.epa.gov/ttn/ecas/ria.html#ria2007

U.S. Environmental Protection Agency (2008) National ambient air quality standards for ozone: final rule 40 CFR parts 50 and 58. Fed Regis 73:16436–16514

U.S. Environmental Protection Agency (2010a) National ambient air quality standards for ozone. Proposed Rule Fed Reg 75:2938, January 19, 2010

U.S. Environmental Protection Agency (2010b) Primary national ambient air quality standards for nitrogen dioxides: final rule. Fed Reg 75:6474, February 9, 2010

U.S. Environmental Protection Agency (2010c) Primary national ambient air quality standard for sulfur dioxide: final rule. Fed Regis 75:35520–35603, June 22, 2010

U.S. Environmental Protection Agency (2011a) Integrated science assessment for ozone and related photochemical oxidants (First External Review Draft). U.S. Environmental Protection Agency, Washington, DC. EPA/600/R-10/076A

U.S. Environmental Protection Agency (2011b) Notification of Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC): Ozone Review Panel for Reconsideration of the 2008 National Ambient Air Quality Standard. Fed Reg 76:10895, February 28, 2011

Wegman LN (2011) Solicitation of CASAC Advice on EPA's Reconsideration of the 2008 Primary Ozone National Ambient Air Quality Standard. Letter to Holly Stallworth, Designated Federal Official, CASAC, January 25, 2011

White RH, Cote I, Zeise L, Fox M, Dominici F, Burke TA, White PD, Hattis DB, Samet JM (2009) State-of-the-Science Workshop Report: Issues and Approaches in Low Dose-Response Extrapolation for Environmental Health Risk Assessment. Available at: http://www.ehponline.org/members/2008/11502/11502.pdf. Environmental Health Perspectives 117(2): doi:10.1289/ehp.11502

Whitman vs American Trucking Associations (2001) 531 U.S. 457, 121 S. Ct. 903149L. Ed. 2d1

Wolff GT (1996) Letter to Carol M. Browner, U.S. Environmental Protection Agency Administrator, closure on draft Office of Air Quality Planning and Standards (OAPQS Staff Paper) (Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Science and Technical Information)

LETTER FROM DR. ROGER O. MCCLELLAN, DVM, MMS, DSC (HONORARY) TO HONORABLE LISA P. JACKSON, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, MAY 6, 2011.

ATTACHMENT 4

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May 6, 2011

Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

SUBJECT: Comments on EPA-CASAC-11-004 Clean Air Scientific Advisory Committee (CASAC) Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standards

Dear Administrator Jackson:

The purpose of this letter is to communicate to you my views on several critical scientific issues that inform the policy judgments you must make in a potential revision of the primary, health-based, National Ambient Air Quality Standard (NAAQS) for ozone. My comments are based on my professional experience as an Inhalation Toxicologist and Risk Analyst and my past service on numerous Clean Air Scientific Advisory Committee (CASAC) Panels, including service for four years as Chair of CASAC.

My comments focus on the CASAC Response (EPA-CASAC-11-004) to Charge Questions submitted to CASAC in a January 26, 2011 Memorandum from the Office of Air Quality Planning and Standards. These Charge Questions were considered in three CASAC Teleconferences (February 18, 2011, March 3, 2011, and March 23, 2011). I offered written and oral comments to the CASAC Panel at the February 18, 2011 meeting. In my opinion, the CASAC deliberations during the three teleconferences represented a re-opening of the rulemaking and associated docket (EPA-HQ-OAR-2005-0172) for the Ozone National Ambient Air Quality Standard promulgated in March 2008. Hence, I request that this letter be made an official part of the Docket and considered as you proceed with reconsideration of the March 2008 Standard with your final decision expected by the end of July 2011.

I offer the following comments related to the CASAC letter of March 30, 2011 from the Committee Chair, Jonathan M. Samet to you (EPA-CASAC-11-004).

(1) By offering these comments on reconsideration of the Standard promulgated in March 2008, I am not endorsing reconsideration of the March 2008 Standard which was promulgated following the Agency's normal formal rulemaking process for revising NAAQS. The Court may determine that the only appropriate course of action for revision of the March 2008 Standard is a new review such as the one already initiated by the Agency.

(2) At the outset, I wish to emphasize it is my view that the NAAQS for any criteria pollutant must be based on the best available contemporary science. However, the Clean Air Act exclusively delegates to the EPA Administrator the authority to make the policy judgments essential for setting the specific level and form of each NAAQS for a particular indicator and averaging time. The EPA has previously noted that CASAC advice offered in 2007-2008 on setting the Primary Ozone Standard (8-hour average) in the range of 60 to 70 ppb represented a blend of science and policy judgment. In my opinion, the CASAC advice in the March 30, 2011 letter remains a blend of science and judgment. Indeed, the blended advice in the letter does not preclude your reaffirming the March 2008 Primary Standard set at 75 ppb.

(3) As noted by CASAC, "deliberations were constrained to the evidence assembled in the prior review that ended in 2008, i.e. a science record that closed in 2006. This constraint imposed an artificial boundary on our discussions." Indeed, the "old record" references few publications dated after 2005. As you are aware, many new publications on various aspects of ozone have appeared in the past five years, for example, numerous publications on background levels, epidemiological studies, controlled exposure studies, and experimental studies reporting mechanisms of action. I was pleased to note that this new literature has been included in the Integrated Science Assessment for Ozone and Related Photochemical Oxidants, First External Review Draft (EPA/600/R-10/076A) released by the Agency in March 2011 as part of the next Ozone NAAQS review triggered by the setting of the ozone NAAQS in March 2008. Individual CASAC panelists, as well as many members of the public who testified before CASAC in responding to the Charge Questions, noted some of the key new publications. It is difficult, if not impossible, for scientists such as the CASAC Panelists to "blind" themselves to the new science. Despite their best efforts, the Panelists undoubtedly allowed the new science to influence the opinions reflected in the March 30, 2011 CASAC letter.

(4) In my professional opinion, CASAC inappropriately concluded that "the scientific evidence that was assembled by EPA and reviewed by CASAC shows no "threshold" or level below which there is no risk of decrement in lung function following short-term exposure to ozone." In reaching this judgment the CASAC inappropriately concluded that brief exposure to 0.06 ppm Ozone produced "clinically relevant" lung function responses in some individuals and resulted in a group decrease in lung function, a conclusion at odds with that of the scientist who reported the original observations.

(5) If the CASAC conclusion that the ozone concentration-response relationship lacks a threshold is accepted, it serves to emphasize that the CASAC recommendation for the setting of the ozone standard in the range of 60 to 70 ppb is a policy judgment. This is the case based on the CASAC opinion that the Standard is being set at a level with effects. The level of the Standard is then best viewed as an acceptable level of risk. That this is the case is further emphasized by the CASAC statement – "Thus, considering the available evidence and the

finding of the exposure and risk assessment, a substantial number of susceptible individuals are at risk and the degree of protection afforded to them would increase as the NAAQS is lowered. The evidence available suggests that an adequate margin of safety cannot be achieved for all and that a level should be set that reduces the at-risk population to a minimally acceptable number, with a reasonable degree of certainty." It is clear that the decision on the level, and the associated acceptable risk, requires policy judgments. The Clean Air Act specifically and exclusively authorizes the EPA Administrator to make those policy judgments. The Act does not extend that policy judgment authority to CASAC.

(6) The EPA documentation on Policy Relevant Background (PRB) in the 2006 Criteria Document that was used as a basis for the policy judgments made in setting the March 2008 Standard was seriously flawed. It is unfortunate that none of the specific Charge Questions in the January 26, 2011 memo addressed PRB issues.

However, Dr. Barbara Zielinska, an atmospheric chemist who was one of the CASAC Panelists, addressed the PRB issue in her written comments which are appended to the March 30, 2011 CASAC letter. Dr. Zielinska noted – "In the 2006 Criteria Document and 2007 Staff Paper, which served as a basis for the setting of the Ozone 2008 NAAQS, EPA relied on a global model (GEOS-Chem) with emphasis on a particular GEOS-Chem PRB simulation for the year 2001 (Fiore et al., 2003). The resulting modeled PRB range was reported to be 15-35 ppb, depending on location and month. The newer versions of GEOS-Chem model that are currently being used are greatly improved over the version used by Fiore et al. (2003) for the 2001 simulation. They predict higher PRB levels and are more consistent with observational analysis." Later she noted, "During the 2005-2007 CASAC Ozone Panel deliberations, the uncertainties and inconsistencies of this model (Fiore et al., 2003) were discussed. The model did not agree with observations that indicated higher background ozone levels (often exceeding 50 ppb), and evidence of stratospheric intrusion events during the winter and spring seasons. Since EPA's ozone risk estimates are sensitive to the assumed PRB levels, it is important to reflect these model uncertainties in the risk analysis."

Since the PRB assumptions previously used were wrong and substantially under-estimated PRB, it is crucial that the issue be considered in any revision of the March 2008 primary Standard. I might add that the issue of PRB is also of great importance in any revision of the secondary Standard. It would be scientifically inappropriate to take action on revision of the March 2008 Standards, either as a "reconsideration" rule or as a rule developed during the regular Ozone NAAQS review process recently initiated, without recognizing the serious deficiencies in the earlier EPA assumptions on PRB.

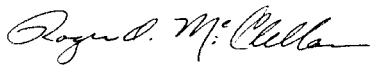
(7) The potential risks of exposure to ozone used as a basis for the policy judgments made in setting the March 2008 primary Standard at 75 ppb were grossly exaggerated due to the under-estimation of PRB as discussed above. It is surprising that CASAC elected to include two tables from the January 19, 2010 Proposed Rule that relate information on reduced health risks with Standards set a various levels without commenting on the substantial uncertainties in the calculated benefits related to under-estimating PRB, i.e. background of 15 to 35 ppb. If a more plausible background level of 40 ppb were assumed, a level consistent with recent GEOS-Chem modeling, more than 90% of the benefits estimated by EPA and CASAC would disappear.

(8) It is noteworthy that the January 26, 2011 Charge Questions did not specifically request that CASAC offer advice on Ozone mortality estimates. This is surprising since EPA in announcing the "reconsideration" proposal in January 2010 called attention to reduced mortality if the Standard were set in the range of 60-70 ppb. During the recent CASAC deliberations one of the Panelists noted "they (CASAC) recommended the EPA not perform the Ozone Mortality estimates, but EPA went ahead and did them anyway." As another Panelist noted, the mortality estimates are not ready for "prime time." EPA ignored this scientifically sound advice.

In summary, the CASAC Panel's Responses to the January 26, 2011 Charge Questions continue to blend scientific advice with the policy judgments of Panel members. The responses do not provide a compelling scientific basis for your exercising policy judgment in selecting any specific level for the primary health-based, Ozone Standard (8-hour) within the range of 60 to 75 ppb. The decision on a specific level, and the associated form, is a policy judgment that the Clean Air Act exclusively assigns to the EPA Administrator. Indeed, the CASAC Panel's responses to the Charge Questions emphasizes that the earlier CASAC recommendation that the Standard be set in the range of 60 to 70 ppb was based on their policy judgments and not exclusively on the available scientific information. Thus, the conundrum remains for the Agency to separate the Panel's scientific advice from the Panel preference for a specific policy outcome, a primary standard set at 70 ppb or lower.

I applaud the Agency for initiating the next comprehensive review of the Ozone NAAQS in a timely manner, including review of an additional five years of scientific knowledge. The fact that the next review is already under way provides a compelling basis for your reaffirming now the March 2008 standard set at 75 ppb and proceeding in an expeditious and orderly manner to complete the next review by 2013. The new information, especially on policy relevant background, will likely have substantial impact on the estimated risks associated with standards set at alternative levels and forms. The scientific information, acquired from 2006 to date, when appropriate reviewed by CASAC will undoubtedly have impact on the policy judgments the Administrator must make in any revision of the Ozone NAAQS.

Respectfully,



Roger O. McClellan
Past Chair, Clean Air Scientific Advisory Committee

xc: Assistant Administrator for Air and Radiation, Gina McCarthy

References:

Fiore, A., Jacob, H., Lin, H., Yartosca, R., Fairlie, T. and Li, Q. (2003), Variability in Surface Ozone Background over the United States: Implication for Air Quality. J. Geophys. Res. 108, D24, 4784.

McClellan, R.O., "Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919 (Docket ID No. EPA-HQ-OAR-2005-0172) (Prepared on October 9, 2007).

McClellan, R.O., "Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 75, No. 11/Tuesday, January 19, 2010, pp 2938-3052 (Prepared March 22, 2010).

McClellan, R.O., "Written Statement for Consideration by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel at the Panel's Teleconference Meeting on February 18, 2011 (Prepared on February 7, 2011).

Samet, J.M. (2011) Clean Air Scientific Advisory Committee (CASAC) Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standard. EPA-CASAC-11-004. Letter from CASAC Chair, Jonathan M. Samet to Administrator Lisa P. Jackson, March 30, 2011.

U.S. Environmental Protection Agency (2011). Integrated Science Assessment from Ozone and Related Photochemical Oxidants, First External Review Draft. EPA/600/R-10/076A.

MEMO FROM HONORABLE CASS R. SUNSTEIN, ADMINISTRATOR, OFFICE OF MANAGEMENT AND BUDGET, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, SEPTEMBER 2, 2011.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

September 2, 2011

Dear Administrator Jackson:

On July 11, 2011, the Environmental Protection Agency (EPA) submitted a draft final rule, "Reconsideration of the 2008 Ozone Primary and Secondary National Ambient Air Quality Standards," for review by the Office of Information and Regulatory Affairs (OIRA) under Executive Orders 13563 and 12866. The President has instructed me to return this rule to you for reconsideration. He has made it clear that he does not support finalizing the rule at this time.

OIRA shares EPA's strong and continued commitment to using its regulatory authorities, including the Clean Air Act (the Act), to protect public health and welfare. Over the last two and a half years, EPA has issued a significant number of rules to provide such protection. We also recognize that the relevant provisions of the Clean Air Act forbid EPA to consider costs in deciding on the stringency of national ambient air quality standards, both primary and secondary.

Nonetheless, we believe that the draft final rule warrants your reconsideration. We emphasize three related points:

1. Under the Act, finalizing a new standard now is not mandatory and could produce needless uncertainty. The Act explicitly sets out a five-year cycle for review of national ambient air quality standards. The current cycle began in 2008, and EPA will be compelled to revisit the most recent standards again in 2013. The new scientific work related to those forthcoming standards has already started (see point 2 below). A key sentence of Executive Order 13563 states that our regulatory system "must promote predictability and reduce uncertainty." In this light, issuing a final rule in late 2011 would be problematic in view of the fact that a new assessment, and potentially new standards, will be developed in the relatively near future.

2. The draft reconsideration necessarily depends on the most recent recommendations of the Clean Air Scientific Advisory Committee (CASAC), which in turn rely on a review of the scientific literature as of 2006. Executive Order 13563 explicitly states that our regulatory system "must be based on the best available science." As you are aware, work has already begun on a new and forthcoming scientific review, "based on the best available science." We urge you to reconsider whether to issue a final rule in late 2011, based on evidence that is no longer the most current, when a new scientific assessment is already underway.

3. Under your leadership, EPA has taken a series of strong and unprecedented steps to protect public health by reducing harmful air pollution in general and ozone in particular. For example, EPA and the Department of Transportation recently finalized the first joint rule reducing air pollution (including ozone) from heavy-duty

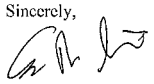
trucks, with overall net benefits of $33 billion. EPA also recently finalized its Cross-State Air Pollution Rule, which will reduce air pollution (including ozone) and which is projected to prevent 13,000 to 34,000 deaths annually, producing annual estimated net benefits in excess of $100 billion. In addition, EPA has proposed national standards for mercury and other toxic pollutants; EPA's preliminary estimates, now out for public comment, suggest that these standards will prevent 6,800 to 18,000 premature deaths annually. These standards, whose annual net benefits are currently estimated to exceed $40 billion, are projected to reduce ozone as well. Cumulatively, these and other recently proposed and finalized rules count as truly historic achievements in protecting public health by decreasing air pollution levels, including ozone levels, across the nation.

As noted, Executive Order 13563 emphasizes that our regulatory system "must promote predictability and reduce uncertainty." Executive Order 12866, incorporated in Executive Order 13563, states that each "agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations . . . ." Executive Order 12866 also states that the "Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with . . . the President's priorities . . . ." In light of these requirements, and for the foregoing reasons, I am requesting, at the President's direction, that you reconsider the draft final rule.

More generally, the President has directed me to continue to work closely with all executive agencies and departments to implement Executive Order 13563 and to minimize regulatory costs and burdens, particularly in this economically challenging time. The President has instructed me to give careful scrutiny to all regulations that impose significant costs on the private sector or on state, local, or tribal governments.

We look forward to continuing to work with you to create, in the words of Executive Order 13563, a regulatory system that will "protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation."

Sincerely,



Cass R. Sunstein

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