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Report from the Independent Workshop on Ozone: NAAQS Science and Policy

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Workshop Organized by:

Texas Commission for Environmental Quality (TCEQ)

Report Prepared by:

Toxicology Excellence for Risk Assessment (TERA)

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Note

This report was drafted by scientists of the Texas Commission on Environmental Quality (TCEQ) and Toxicology Excellence for Risk Assessment (TERA). The draft text was reviewed and revised by the workshop's Policy Panel, Science Panel, and speakers. The members of the Science and Policy Panels served as individuals, presenting their own personal opinions, and not as representatives of their companies, agencies, universities, funding organizations, or other entities with which they are associated.

Contents

Abbreviations and Acronyms

APA	Administrative Procedure Act
APEX	Air Pollutants Exposure
ATS	American Thoracic Society
CASAC	Clean Air Scientific Advisory Committee
CPP	Clean Power Plan
EPA	U.S. Environmental Protection Agency
FCAA	Federal Clean Air Act
GDP	Gross Domestic Product
GSP	Gross State Product
HEI	Health Effects Institute
HREA	Health Risk and Exposure Assessment
ISA	Integrated Science Assessment
MATS	Mercury and Air Toxic Standards
MOA	mode of action
NAAQS	National Ambient Air Quality Standard
NAM	National Association of Manufacturers
NO_x	oxides of nitrogen
O_3	ozone
OMB	Office of Management and Budget
ppb	parts per billion
ppm	parts per million
TCEQ	Texas Commission on Environmental Quality
TERA	Toxicology Excellence for Risk Assessment
VOCs	volatile organic compounds

Executive Summary

The Texas Commission on Environmental Quality (TCEQ) hosted the *Independent Workshop on Ozone NAAQS Science and Policy* on April 7-9, 2015 to engage a multi-disciplinary group of science and policy experts in deliberation on the nexus between scientific findings and implications for public health. The U.S. Environmental Protection Agency (EPA) proposed in late 2014 to lower the primary National Ambient Air Quality Standard (NAAQS) for ozone to within a range from 65 to 70 ppb.[1] The focus of this workshop was on science related to the level (concentration) of the primary NAAQS and an independent evaluation and synthesis of key considerations for approaching the difficult and important ozone NAAQS decision.

Session 1: Background on the Ozone NAAQS

Session 1 speakers provided background and context on the ozone NAAQS. Mr. Seyed Sadredin, Executive Director of the San Joaquin Valley Air Pollution Control District, discussed the air quality challenges currently facing California's San Joaquin Valley and the need to modernize the implementation portion of the Federal Clean Air Act (FCAA). Mr. Henry Nickel, special counsel at Hunton & Williams, LLP, spoke on the statutory scheme and case law surrounding the NAAQS and the importance of putting health effects and benefits into context when setting the standard. Dr. Roger McClellan, an independent advisor on toxicology and human health risk analysis, spoke about the interface between science and policy in a NAAQS review - that the role of science is to inform what are ultimately policy choices and there is no specific scientific algorithm for setting the standard. Dr. Tim Verslycke, a Principal at Gradient, addressed the secondary ozone standard, which is set to protect public welfare, including crops, animals, vegetation, and associated ecosystem benefits.

[1] After the workshop, in October 2015, EPA finalized its ozone NAAQS decision, choosing to set the level of the standard at 70 ppb.

Session 2: Integration of Scientific Evidence to Inform Ozone Effects on Human Health

A panel of scientific experts[2] discussed key issues related to the health effects of ozone including the mode of action (MOA), sensitive subpopulations, adversity of effects, dose response, causality, and personal exposure.[3]

Mode of Action and Adverse Effects

Epidemiological studies have linked ozone exposure to various health effects including mortality, but the Science Panel members were not convinced that the body of evidence demonstrates that ozone exposure at current ambient concentrations can cause mortality. The panelists agreed that the controlled exposure studies showed little effect from ambient ozone concentrations unless the subjects exercised heavily, demonstrating the importance of ventilation rate. Dr. Sabine Lange of TCEQ presented a proposed MOA for ozone-induced respiratory effects based on antioxidants in the respiratory tract lining fluid, but panel members suggested that the mechanism or MOA may be more complicated than just depletion and replenishment of antioxidants. The panel also concluded that there are few data from controlled human exposure studies showing that ozone exposure at ambient concentrations and relevant doses cause adverse effects on cardiovascular health.

The panel discussed that, for the most part, mild asthmatics have not shown greater lung function responses to ozone compared to healthy controls, and that severe asthmatics (who have not been tested) may respond differently. However, severe asthmatics may not be capable of sustaining the heavy exercise protocol used to elicit effects in the controlled exposure studies conducted at ambient ozone concentrations. Panelists favored the American Thoracic Society (ATS) adversity definition, which states that small decrements in lung function should not be considered adverse, unless they are accompanied by relevant symptoms such as

[2] Science Panel: Dr. Robert Phalen, University of California, Irvine; Dr. P. Barry Ryan, Emory University; Dr. George Maldonado, University of Minnesota; and Dr. Mark Utell, University of Rochester; Dr. Michael Dourson from TERA served as facilitator. Dr. Sabine Lange from TCEQ and Drs. Julie Goodman and Sonja Sax from Gradient presented information on key topics and participated in the panel discussions.
[3] Prior to the workshop, Drs. Goodman, Lange, and Sax presented background information on key ozone topics in a two-part webinar (see http://www.tera.org/Peer/ozone/index.html).

wheezing (ATS 2000). The panelists also discussed the need for study results to be reproducible in multiple laboratories and settings before drawing conclusions from them.

Dose-Response

Dr. Lange presented dose-response modeling that showed greater FEV_1 decrements for shorter versus longer exposure durations; and that in the general population people would not receive high enough doses of ozone to reach a level where the mean individual would experience an adverse effect. Changing the ozone concentrations from an 8-hour daily maximum of 75 ppb to 70 ppb or 65 ppb would make little difference in the total ozone dose. The Science Panel thought the finding that the severity of the response (larger FEV_1 decrements) seemed to be minimized with time was potentially important to the understanding of 1-hour exposures and their relative toxicity compared to 8-hour exposures.

The science panelists thought that uncertainties and variability in the ozone health effects studies, the dose-response analyses, and the public health context of the observed and projected adverse effects, should all be used in an integrative fashion to inform a decision about an "adequate margin of safety." Several panelists thought that the controlled human exposure studies performed with concentrations below 75 ppb resulted in very small FEV_1 decrements and that these very small effects were probably not impacting public health and were not clinically significant. These studies alone would not support lowering the standard.

Epidemiological Evidence for Causality

The Science Panel questioned the implications for causality given the large amount of heterogeneity in studies such as Smith et al. (2009) that illustrates significant heterogeneity in mortality estimates between U.S. cities. They thought the studies raise questions of whether ozone is a surrogate for another mortality cause and whether there was some other factor influencing the Smith et al. (2009) results. The Science Panel thought an approach that systematically addressed major study quality characteristics would give one more confidence in the evaluation of the strength and limitations of the studies and quality of the evidence. Panelists emphasized that studies should not be looked at independently, rather all of the

different study approaches should be considered together in a weight of evidence approach to decide if there is a health effect caused by ozone exposure.

Ambient Monitor Concentrations and Personal Exposure

The panel discussed difficulties in relating ambient ozone concentration measurements to personal exposures of people in indoor and outdoor environments, noting that complicated ozone chemistry makes it difficult to extrapolate from the ozone-only controlled human exposure studies to people's ambient air exposures.

Session 3: Socioeconomic Risks and Other Potentially Policy-Relevant Considerations

While the FCAA does not allow for consideration of costs in setting the NAAQS, in the third session speakers discussed the social and economic impacts of proposed changes to the ozone NAAQS to provide context. Dr. Daniel Millimet of Southern Methodist University noted that historically NAAQS regulatory costs have financially impacted the (relatively small) subset of manufacturing businesses that are heavy emitters of regulated pollutants. Business activity and employment in these sectors is relocated away from nonattainment areas, resulting in lower lifetime earnings for workers. Mr. Scott Bloomberg of NERA Economic Consulting noted that by far the largest contributor to the difference between the EPA and others' cost estimates, is the difference in the assumed cost of the unknown controls. Dr. Anne Smith of NERA Economic Consulting presented results of NERA's economic impact analysis of lowering the ozone standard and concluded that no states would escape economic impacts of this rule, primarily due to changes in the energy sector. Dr. John Morrall, formerly with the Office of Management and Budget (OMB), presented results of a health-health analysis for ozone and projected more lives would be lost than saved at a standard set at 60 or 65 ppb, but there would be a small health benefit gain at 70 ppb.

Session 4: Integrating Science Considerations into Policy Judgments

The workshop culminated with a panel of distinguished legal, policy, and economics experts[4] who shared and discussed their thoughts and opinions on the current situation and the context for the ozone NAAQS decision.

Mr. Thomas Lorenzen explained the EPA's requirement to set the primary NAAQS at a level requisite to protect public health with an adequate margin of safety. He pointed out that "requisite" means no more or less stringent than necessary, which is a judgment and policy-based decision, rather than being solely based on the science. The Supreme Court, in *Whitman v American Trucking Association*, confirmed that costs were not a permissible basis for setting NAAQS, but Justice Breyer in his concurring opinion implied costs can be accounted for to the extent that they affect the *net* health benefit.

Dr. Donald Arbuckle's remarks put the process of setting the standard into the context of the highly contentious environment within which the EPA Administrator must make her decision. Many interested parties pressure the EPA Administrator, who must draw a bright line across the data and set a standard no matter the uncertainties. Dr. Arbuckle expressed his view that the President and EPA care about data and data analysis and encouraged stakeholders to actively explain and discuss their insights on the important scientific issues and other issues raised in the public comments with various segments of the federal government.

Dr. Paul Portney noted that the FCAA reflects the economic and environmental conditions of half a century ago, when air pollution was a visible problem; reductions in primary pollutants were relatively easy and cheap; and the U.S. economy was strong. Currently cost is accounted for "behind the scenes," and is expressed by tradeoffs that the Administrator makes when weighing the scientific evidence. Dr. Portney believes that the current situation encourages disingenuousness on the part of public officials, fosters cynicism in the public, and undermines public trust in government. He thinks that the FCAA should be revised to allow the

[4] Policy Panel: Mr. Thomas A. Lorenzen, Esq., Dorsey & Whitney LLP; Dr. Donald R. Arbuckle, University of Texas at Dallas; Mr. Charles H. Knauss, Esq., Katten Muchin Rosenman LLP; Dr. Paul R. Portney, Resources for the Future and University of Arizona; and Dr. Chris Whipple, Environ (retired), facilitator.

Administrator to transparently establish air quality standards that protect public health and welfare, while taking into account other factors, including cost of reducing emissions, regional conditions, and impacts on energy supplies.

Mr. Charles Knauss shared his sense that EPA staff consider setting the NAAQS as the "quintessential" exercise in Agency discretion, and that the case law has provided EPA little motivation to set clear criteria for the NAAQS decisions that would allow the public to evaluate in an objective manner whether the science warrants a change in the NAAQS. Justice Breyer (in his concurring opinion in *Whitman v. American Trucking Associations)* noted that the words "requisite to protect public health," must be understood in the context of risks society finds acceptable. Mr. Knauss suggested that in effect, it would be a failure of reasoned decision making, as well as arbitrary and capricious, given the challenge of accurately identifying public health risks at these lower levels, if EPA did not require higher quality studies with a higher degree of scientific certainty in assessing the potential need to tighten a standard.

During the course of the workshop and in the Policy Panel comments and discussions, several common themes emerged. Policy panelists and others commented on the uniqueness of this workshop in bringing together experts in science, economics, policy, and law to discuss this complex and multi-faceted NAAQS decision in an integrative manner. The policy panelists felt that the concerns about implementation, the ozone science, the possibility of net adverse effects on public health, and the cost of compliance raised in the workshop were valid and should be shared with EPA and others.

Both the policy panelists and the other participants frequently mentioned that *context* matters. Justice Breyer's concurring opinion in *Whitman v. American Trucking Associations* provides a roadmap of what the Administrator can consider in making her decision, including comparative risks, whether a rule is more likely to cause more harm to health than it prevents, the severity and distribution of adverse health effects, the number of people affected, and the uncertainties in the estimates. Discussion of the degree of severity of potential health impacts under current ambient conditions and of the degree of uncertainty in those impacts' prevalence or existence

would help place a NAAQS policy decision into a context that allows for reasonable balancing of competing societal objectives.

Introduction

The Texas Commission on Environmental Quality (TCEQ) hosted the *Independent Workshop on Ozone NAAQS Science and Policy* on April 7-9, 2015, in Austin, Texas. The purpose of this workshop was to engage a multi-disciplinary group of science and policy experts to review the scientific evidence regarding ambient ozone's health effects and to deliberate on the nexus between scientific findings and implications for public health. At the time of the workshop, the U.S. Environmental Protection Agency (EPA) was proposing to lower the primary National Ambient Air Quality Standard (NAAQS) for ozone from the current level of 75 parts per billion (ppb) (in the form of the fourth highest maximum daily 8-hour ozone concentration per year, averaged over three years) to within a range from 65 to 70 ppb. EPA had not proposed revision to the averaging time (8 hour) or the statistical form (the fourth highest daily maximum, averaged over three years) (EPA 2014a, EPA 2015). The goal of this workshop was to provide an independent evaluation and synthesis of key considerations for approaching the difficult and important ozone NAAQS decision. This workshop focused on science related to the level (concentration) of the primary NAAQS, and did not directly address changes to the other NAAQS elements. (After the workshop, in October 2015, EPA finalized its ozone NAAQS decision, choosing to set the level of the standard at 70 ppb.)

Ozone (O_3) is a highly reactive chemical that is found both in the stratosphere where it forms the protective ozone layer and in the troposphere (ground level where it causes the harmful air pollution known as smog). Tropospheric ozone is formed from multiple sources, including anthropogenic automobile exhaust and power plant emissions, in addition to natural sources such as wildfires. However, ozone is not emitted directly by these sources, but rather is chemically formed when precursor emissions, in particular oxides of nitrogen (NO_x) and volatile organic compounds (VOCs) are acted upon by ultraviolet radiation. Thus, ozone is a secondary pollutant that is dependent on sunlight for formation, and so it demonstrates diurnal patterns (highest during the afternoon hours) and seasonal patterns (highest during the summer). Although NO_x reacting with sunlight is a primary source of ozone, the chemistry of the reaction is such that NO_x is also capable of scavenging ozone, and therefore ozone concentrations are

diminished in places where NO_x emissions are particularly high (e.g. near busy roadways). In most of the United States NO_x, and not VOCs, are the limiting factor for ozone formation, and so NO_x sources and emissions are typically targeted for ozone reduction.

The workshop was organized by a steering committee[5] into four sessions:

Session 1) Plenary session providing presentations on the background and context of the ozone NAAQS

Session 2) Panel session with discussion by scientific experts: "Integration of scientific evidence to inform the understanding of ozone effects on human health"

Session 3) Plenary session with presentations: "Socioeconomic risks and other potentially policy-relevant considerations"

Session 4) Panel session with discussion by policy experts: "Integrating science considerations into policy judgments"

The workshop speakers and science and policy discussants were asked to participate in the workshop based on consideration of the following criteria, as judged by the Steering Committee: 1) knowledge of the NAAQS process; 2) knowledge of ozone health effects; 3) national/international reputation for excellence in their field of study; 4) perceived lack of bias or conflict of interest; and 5) lack of a stated opinion on the proposed ozone NAAQS.

Dr. Bryan Shaw, Chairman of TCEQ and Mr. Toby Baker, TCEQ Commissioner, welcomed the attendees and thanked them for their participation. Dr. Shaw stressed the critical importance of this workshop and looking at the science behind the ozone NAAQS to ensure that the standard is set in a scientifically defensible way. Mr. Baker discussed some of the impacts and costs associated with tightening the ozone NAAQS and why it is so important to get the decision

[5] Steering Committee included Drs. Michael Honeycutt and Sabine Lange from the TCEQ; Drs. Michael Dourson and Jeanelle Martinez and Ms. Jacqueline Patterson from Toxicology Excellence for Risk Assessment (TERA); Drs. Julie Goodman, Sonja Sax, and Tim Verslycke from Gradient; and Dr. Anne Smith from NERA Economic Consulting.

right. He expressed hope that this workshop can work to bridge the gap between scientific and policy discussions.

Session 1: Background on the Ozone NAAQS

Why States Care: Implementation & Impacts of a NAAQS: Seyed Sadredin

Mr. Seyed Sadredin, Executive Director of the San Joaquin Valley Air Pollution Control District, presented first in this session. Mr. Sadredin spoke of the air quality challenges currently facing California's San Joaquin Valley. Although air quality has greatly improved over the last 40 years, the area still struggles to meet the ozone NAAQS standard of 84 ppb, set in 1997. To attain the current ozone NAAQS levels, modernization of the implementation portion of the FCAA is needed, with consideration for the technological achievability and economic feasibility in the mandated deadlines for implementation of the NAAQS.

Clean Air Act and Case Law on How a NAAQS Must be Set: Henry V. Nickel

Mr. Henry Nickel, special counsel at Hunton & Williams, LLP, spoke on the statutory scheme and case law surrounding the NAAQS. Mr. Nickel noted that the NAAQS are the heart of the modern FCAA and are separated into two parts: setting the standard (where implementation costs cannot be considered) and implementing that standard (where costs can be considered). The primary (health-based) standards must be set at a level which is "requisite to protect public health with an adequate margin of safety." He discussed that given the complexities of the law and the air pollution science, it is important to put the health effects and benefits into context when setting the standard.

Interface Between Science and Policy in a NAAQS Review: Roger O. McClellan, Ph.D.

Dr. Roger McClellan, an independent advisor on toxicology and human health risk analysis, spoke about the interface between science and policy in a NAAQS review. Dr. McClellan was a founding member of the Clean Air Scientific Advisory Committee (CASAC). He discussed that the role of science is to inform on what are ultimately policy choices in setting the NAAQS (Bachmann 2007; McClellan 2011). While the Clean Air Act contains general language with

regard to setting the standard, there is no specific scientific algorithm for selecting a specific averaging time, level, and statistical form. The setting of a specific NAAQS therefore, involves a series of policy judgments and choices that are informed by the science. Dr. McClellan noted that the CASAC's focus, when considering the ozone science, has been on just the one element - the level (concentration) of the standard. He emphasized that it is crucial to also address averaging time and statistical form in discussions of the standards (McClellan et al., 2009).

Ozone NAAQS Secondary Standard; Tim Verslycke, Ph.D.

Dr. Tim Verslycke, a Principal at Gradient, spoke on the secondary ozone standard, which is set to protect public welfare, including crops, animals, vegetation, and associated ecosystem services (e.g., benefits such as productivity, carbon storage, water cycling). The EPA's ozone NAAQS proposed rule would keep the indicator, form, level, and averaging time of the secondary (welfare-based) standard the same as the primary (health-based) standard. The effects of ozone on public welfare evaluated by EPA include: visible foliar injury, decreased vegetation growth (i.e., tree biomass and crop yield loss), and effects on ecosystem concerns. He explained how the evidence shows that the existing secondary ozone standard, in its current form and level, protects against all of these public welfare effects, and that tighter standards would have almost no incremental benefit beyond what will be gained by attaining the current ozone NAAQS.

Session 2: Integration of Scientific Evidence to Inform Ozone Effects on Human Health

A panel of scientific experts discussed key scientific issues related to the health effects of ozone including the mode of action (MOA) for potential adverse effects, evidence from controlled human exposure studies, epidemiological studies, exposure analyses, and evidence integration. The Science Panel of experts consisted of Dr. Robert Phalen from the University of California, Irvine; Dr. P. Barry Ryan from Emory University; Dr. George Maldonado from the University of Minnesota; and Dr. Mark Utell from the University of Rochester. The panel was facilitated by Dr. Michael Dourson from TERA. Dr. Sabine Lange from TCEQ and Drs. Julie Goodman and Sonja Sax from Gradient presented information on the key topics and participated in the panel

discussions. Charge questions suggested by the Steering Committee were used to help guide discussion on the topics, but the panel members were free to raise additional issues or questions.

Prior to the workshop, Drs. Goodman, Lange, and Sax presented background information on key ozone topics in a two-part webinar. The webinar, background materials, charge questions and other information for the workshop are available at http://www.tera.org/Peer/ozone/index.html.

Presentation on Mode of Action for Adverse Effects

Dr. Sabine Lange from the TCEQ started the session with a brief overview of ozone dosimetry, physiological uptake, and reactivity, followed by a discussion of the MOA for respiratory effects that might be inferred from this evidence. Ozone is highly reactive in the respiratory tract and approximately 85% of inhaled ozone reacts in the respiratory tract (the rest is exhaled); less than half of inhaled ozone reaches the lungs and very little reacts in the alveoli. However, increased respiration with exercise, and a switch from oronasal to oral breathing, allows ozone to penetrate further, thereby increasing the fraction reacting in the alveoli. Dr. Lange presented the following MOA for respiratory effects of ozone:

- the respiratory tract lining fluid contains antioxidants, which can react with ozone to prevent tissue damage;
- at some threshold dose of ozone the antioxidant capacity is overwhelmed, leading to an interaction between ozone and components of the respiratory tract lining fluid (e.g., proteins and lipids);
- interaction with components of the respiratory tract lining fluid results in formation of damaging secondary reaction products.

In its ozone Integrated Science Assessment (ISA) (EPA 2013), EPA identified a number of possible pathways for respiratory effects resulting from the formation of secondary oxidation products that may lead to direct effects on the respiratory system, as well as a pathway for

systemic inflammation leading to extrapulmonary effects. The mechanisms of antioxidant depletion of ozone suggest a threshold for these ozone-induced respiratory effects. The controlled human exposure studies also suggest a threshold for ozone-induced respiratory effects, but uncertainties remain, including relating the generally higher experimental doses to low ambient doses. In epidemiological studies, ozone exposure has been linked to various health effects including mortality, but a MOA for many of these health effects, particularly mortality, has not been identified.

The Science Panel discussed a number of issues, including MOA, cardiovascular effects, sensitive subpopulations, and adversity of effect.

Science Panel Discussion

Mode of Action

Panel members were not convinced that the body of evidence demonstrates that exposure to ozone at current ambient concentrations can cause mortality. Panelists noted that the epidemiological associations are confounded with exposures to other pollutants (e.g., particulate matter) and non-pollutant factors (e.g., lifestyle choices and ambient temperature) and they thought it hard to conceive of a MOA for mortality at ambient concentrations. For morbidity endpoints, however, some panelists thought that the bronchoconstriction and volume loss measurements (e.g., forced expiratory volume in 1 second, or FEV_1) reflect transient and fairly small changes and that this particular MOA and endpoint may be less relevant for toxicity. The panelists agreed that the controlled exposure studies showed little effect from ambient ozone concentrations unless the subjects exercised heavily, thus demonstrating that ventilation rate is very important.

The panel members did not disagree that the FEV_1 study data indicate that there is a dose threshold for effects from ozone, but they suggested that the mechanism or mode of action may be more complicated than just depletion and replenishment of antioxidants. A panelist noted that ozone is an irritant and some people have an airway response from initial brief

exposures. Another reviewer suggested that some people may already have depleted antioxidants before they are exposed to ozone.

In the context of informing regulatory decisions, panel members discussed what endpoints should be the focus of ozone toxicity studies and noted that the available controlled human exposure studies were not designed to describe a key event or critical effect of ozone exposure. Because ozone enters the body through the lung, a focus on the lung as a target organ is appropriate. In controlled human exposures, lung function is easy to measure, is reproducible, and there is a wealth of knowledge about pulmonary mechanics. A panelist noted that a study in Atlanta (Darrow et al. 2014) showed a correlation between young children developing pneumonia and ozone levels; this may be from an interaction between a virus and ozone, or perhaps mucus clearance and decreased lung function are important parameters that could put these children at greater risk.

Cardiovascular Effects

Epidemiological studies also suggest cardiovascular effects from ozone, with inflammation being a potential key event leading to cardiovascular endpoints. Panel members thought that in terms of clinical disease processes, inflammation (often measured as influx of white blood cells into the respiratory lining fluid) may be an early signal that has the potential to explain direct effects of ozone on the lung, as well as potential systemic effects, but it is not clear how to interpret inflammation for long-term risk. In addition, while intense exercise may be required to elicit changes in pulmonary mechanics, it is not known if exercise is a requirement for other changes. One panelist noted that there are currently few data from controlled human exposure studies showing that ozone exposure at ambient concentrations and relevant doses causes adverse effects on cardiovascular health; he noted that results of a study by the Health Effects Institute (HEI) on the potential for ozone to cause cardiovascular effects will be released later this year. This multi-center study is measuring clinically significant cardiovascular endpoints and biomarkers in older adults exposed to clean filtered air, 70 ppb and 120 ppb ozone. Participants are ages 55-70 and generally healthy. Exposures are for 3 hours, with exercise every 15 minutes at a level to increase minute ventilation to a predetermined level.

Sensitive Subpopulations

The panel discussed the issue that people have different degrees of susceptibility to respiratory effects from ozone exposure. While the FCAA calls for protection of sensitive subpopulations (e.g., people with asthma, cardiovascular disease or chronic obstructive pulmonary disease), the Act is not intended to protect the most sensitive individual in such groups. Asthmatics are often a subpopulation of concern for air pollutants, but for the most part mild asthmatics have not shown greater lung function responses to ozone compared to healthy control populations in the ozone controlled exposure studies (Linn et al. 1994, Balmes et al. 1997, Koenig et al. 1985, Koenig et al. 1987, Stenfors et al. 2002, Holz et al.1999, Nightingale et al. 1999, Basha et al. 1994). Older adults show smaller lung function responses to ozone than younger age groups in general (Hazucha et al. 2003, McDonnell et al. 2007), but it is not known why this is the case. Panelists noted that controlled human exposure studies have only investigated mild asthmatics, and therefore more severe asthmatics may respond differently. However, severe asthmatics may not be capable of sustaining the heavy exercise protocol needed to elicit effects in the controlled exposure studies conducted at ambient ozone concentrations. It is possible that people with cardiovascular disease are a sensitive subgroup, but panelists noted that there are few data to address this hypothesis.

Adversity of Effects

In the proposed ozone rule, EPA considers transient FEV_1 lung function decrements of ≥ 15% for healthy people and ≥ 10% for sensitive populations (such as those with asthma or other respiratory tract diseases) to be potentially adverse (EPA 2014b). A panelist noted that generally a transient 10% decrease in an individual's lung function is minor and considered very mild; a patient's FEV_1 can vary from one visit to the next by greater than 10%. However, it is difficult to set a single definition of adverse for everyone; one person's physiological variability could be another person's adverse effect. The complexity increases when considering only the more responsive individuals instead of the group response. For example, a 10% reduction in FEV_1 in a person with chronic obstructive pulmonary disease could make the person more symptomatic. Panelists favored the definition of the American Thoracic Society (ATS) that small

decrements in lung function should not be considered adverse, unless they are accompanied by relevant symptoms such as wheezing (ATS 2000). The panelists discussed that the relevant question at hand is: "what is adverse for purposes of standard setting?" Effects such as irritation may briefly impact quality of life, but is irritation an adverse effect for the purpose of setting a national standard?

A Policy Panel member asked the Science Panel what endpoint they think should be the focus for setting the ozone standard, given the uncertainties in mode of action for mortality. One responded that it is easier to identify what should not be the focus – he did not think that a single study showing a borderline effect at the lowest concentration is sufficient by itself; multiple laboratories and settings should be able to reproduce the decrement in order for the results to be considered. Others thought that if ozone diminishes defenses against infectious agents, then maybe that should be further explored.

Presentation on Controlled Human Exposure Studies and New Analysis

Dr. Lange gave a short presentation on the controlled human exposure studies that examined decreased lung function following exposure to ozone, and results of additional dose-response modeling that she and her colleagues have conducted. FEV_1 has been most commonly measured in these studies, and it shows a dose-response with ozone exposure. Dose is calculated from these studies using three parameters: ozone concentration (ppm), duration of exposure (minutes), and ventilation rate (L/min). EPA used work done by McDonnell et al. (2012) for its dose response model in its Health Risk and Exposure Assessment (HREA) (EPA 2014b) and focused on people with greater than average responses. EPA's dose-response analysis for the ozone NAAQS used a ventilation rate of 34-40 L/min (EPA 2014b), while other EPA programs, including air toxics, use a much lower ventilation rate of 14-22 L/min (representing the general population and worker populations) (EPA 1994), and ventilation rates closer to this lower range were used in the Lange dose-response analysis described below.

Dr. Lange noted the following findings:

- Results of this independent analysis show that there was variability in response for shorter (≤ 3 hours) versus longer (6-8 hours) exposure durations: greater FEV_1 decrements are seen at the same dose, if that dose is applied over a shorter period of time. This is consistent with a MOA involving replenishment of protective antioxidants over time.
- In addition, individuals exposed to filtered air showed a high degree of variability in their FEV_1 responses (FEV_1 measurements both increasing and decreasing by approximately 10%), which provides an indication of response variability due to the study protocol alone.
- Children and asthmatics showed lung function responses to ozone exposure similar to those of adults. Using diary-based exercise ventilation rates and durations, coupled with ozone concentrations corresponding to 75 ppb, 70 ppb or 65 ppb, Lange and colleagues calculated ozone doses.[6] They found that this resulted in doses that largely are estimated to cause mean FEV_1 decrements of less than 5% (Figure 1).
- They also found that changing the ozone concentrations from an 8-hour daily maximum of 75 ppb (current standard) to 70 ppb or 65 ppb (alternative standards) made little difference in the total ozone dose to which people in the general population would be expected to be exposed.

Science Panel Discussion

The Science Panel thought Dr. Lange's finding that the severity of the response (larger FEV_1 decrements) seems to be minimized with time is potentially important to aid in understanding a 1-hour exposure and its relative toxicity compared to an 8-hour exposure. Panelists thought it plausible that replenishment of protective antioxidants was causing the diminished response with greater exposure time, although that may not be the entire explanation (e.g., protective mucus thickening and protective shifts in breathing frequency and depth).

[6] This work is in preparation for submission to a peer-reviewed journal. An early report entitled "Ozone FEV1 Dose-Response Analysis" is available at http://www.tera.org/Peer/ozone/ozonebackground.html

Use of Controlled Human Exposure Data

In response to clarifying questions from the Policy Panel about how these results could be considered by the Administrator, Dr. Lange explained that the EPA considered the lowest concentration of ozone (60 ppb) at which a statistically significant decrement in FEV_1 was seen (a mean FEV_1 change of -1.8%, with 3/59 people experiencing FEV_1 decrements >10%; Kim 2011), even though this result required the subjects to be exercising at moderate-high intensity (i.e., with a high ventilation rate) for 50 min/hour for 6 hours. Dr. Lange's new analysis utilized exposure information from an EPA document that used an approximately 9000-person diary study (U.S. EPA 2009) to estimate ozone doses that better reflect the exposure scenario of the general population with regard to exercise. A key finding of the analysis is that based on mean exposure values for the general population, people would not receive high enough doses of ozone to reach a level where the mean individual would experience an adverse effect. Science panelists thought that the Lange analysis provides another perspective on the controlled human exposure study evidence, and the diary data are probably the best available to represent the general population's exposure scenario, although they also have limitations.

Science Panel members explained that the controlled human exposure studies are designed to elicit only reversible effects; these study results do not suggest a permanency to the effects. Chamber studies can help identify clues as to MOA and help evaluate the biological plausibility of the epidemiology findings, and the potential for morbidity or mortality with ongoing exposure.

Extrapolation of Results to the Ozone NAAQS

The Science Panel discussed whether the current data provide enough support to lower the standard. Several members noted that setting the standard is a policy decision that should consider scientists' interpretation of the scientific evidence from a public health perspective. One panelist thought that the controlled human exposure studies performed with concentrations below 75 ppb (Adams, 2006; Kim et al., 2011; Schelegle et al., 2009; Adams, 2002) result in very small decrements in FEV_1 and that these very small effects are probably not impacting public health, and are not clinically significant. The panelist did not think these

studies alone would support lowering the standard. Another agreed, and thought that there should be strong evidence that a reduction in the ozone NAAQS will be beneficial to public health. The science panelists thought that uncertainties and variability in these studies, the dose-response analyses of these data (such as that presented by Dr. Lange), and the public health context of the observed and projected effects should be used to inform a decision about an "adequate margin of safety."

Presentation on Epidemiological Evidence

Dr. Julie Goodman from Gradient presented a brief overview of ozone epidemiological evidence, which EPA evaluates together with evidence from toxicity and human exposure studies, to assess whether it supports causal associations between ozone exposure and health endpoints. She briefly explained that in the 2013 Integrated Science Assessment (ISA) (U.S. EPA 2013), EPA upgraded its determinations of health outcome causality for most endpoints, compared to the science assessment in the last cycle of ozone review. She explained that the strengths of the ozone epidemiological studies include a large amount of data available for a variety of populations over many years; well-developed statistical methods to control for temporal trends in ozone levels, temperature, and other factors; and specific study designs to account for time-invariant subject characteristics such as socio-economic status or smoking. However, the ozone epidemiological studies have to deal with a number of issues that contribute to overall uncertainties, such as issues with assessing ozone exposure, confounding by other factors (i.e., other factors besides ozone that contribute to a studied health effect), use of appropriate statistical models (e.g., model assumptions are not met), and publication bias (i.e., the selective publication of studies that find statistically significant effects).

Dr. Goodman presented data from Smith et al. (2009) that illustrate significant heterogeneity in mortality estimates between U.S. cities. Smith et al. (2009) plotted the percent changes in mortality rates per 10 ppb increase in 8-hour ozone concentrations. Some cities had increases in mortality associated with increases in ambient ozone concentrations, while other cities showed decreases, and the majority showed no difference; the reason for these regional

differences has not been determined. If one pools all the cities, the average shows a slight (statistically significant) increase in mortality per 10 ppb increase in ozone concentrations.

Science Panel Discussion

Causality

The Science Panel discussed the issue of heterogeneity of the epidemiological evidence, and particularly the variable results of Smith et al. (2009) and responded to policy panelist questions on how the epidemiological study results should be considered. The Science Panel questioned the implications for causality given the large amount of heterogeneity in the Smith et al. (2009) results. This heterogeneity raised questions of whether ozone is a surrogate for another mortality cause and whether there is some other factor influencing the Smith results. The panel pointed out that when looking at heterogeneity between studies, it is important to compare studies that are all asking the same question, because differences in the outcome can arise from individual parameters, such as target population, regional characteristics, and time differences. Smith et al. (2009), however, was a single analysis of many cities and therefore controlled for many of these parameters. While there are only a few multi-city studies that have investigated ozone effects on morbidity, this same heterogeneity in results has been observed in other studies (Mortimer et al. 2002).

Dr. Goodman pointed out several difficulties when interpreting results of the epidemiological studies. The choice of averaging time (e.g., 1-hour or 8-hour) and lag times can influence the results, and the structure of the parameters in many studies assumes there is no threshold dose below which there is no effect (i.e., that there is risk from exposure to a single molecule). A Science Panel member noted that the ideal epidemiological study would make adjustments for confounding factors in the data, reduce noise and uncertainty, and minimize exposure and disease measurement errors. There are ways that these errors can be corrected, or at least considered, and uncertainty and bias analyses can be performed. Because these analyses have not been done with the ozone-mortality/morbidity studies, scientific judgment has to be used when evaluating the conclusions of these studies. The panel agreed that it is critical to look closely at the data and to pay attention to the error bars. However, the error bars associated

with the effect estimates are statistical error bars only and they do not consider the many sources of uncertainty discussed here; therefore if these other errors or biases were considered, the error bars would be wider.

There was a discussion about the strength of the association, and whether the small effect (1-2% increase in mortality) is real (i.e., causal) while still considering that a 1% increase in mortality translates to thousands of lives if it is applied across the entire U.S. population and whether the sequence in severity of effect, with minor lung effects occurring before mortality for example, is relevant. Other panelists emphasized that studies should not be looked at independently, but rather a weight of evidence approach should be used to decide if there is a health effect and all of the different study approaches (epidemiology, controlled exposure studies, and toxicology) should be considered together. Another panelist noted that even if an epidemiological study is flawed, if there is a strong signal, it will be seen, and one uses experience and judgment to consider study problems and uncertainties to decide whether the results are valid.

Ambient Monitor Concentrations and Personal Exposure

The panel discussed some of the difficulties in relating ambient ozone concentration measurements from monitors to personal exposures of people in indoor and outdoor environments. Ozone is a surrogate or indicator of photochemical oxidants, and while these cannot all be readily measured in the environment, they are probably the pollutants of interest for impact on health. Ozone is produced by secondary reactions of photo-oxidants with sunlight and ozone reacts with both indoor and outdoor surfaces. The reaction of ozone with surfaces depletes ozone, therefore leading to lower levels of ozone indoors (10-30% of outdoor concentrations). However, ozone reaction with surfaces causes formation of other photochemical oxidants; although these are less reactive, little is known about their health effects at concentrations measured in indoor air. Chamber studies are often conducted in an environment with metal surfaces, such that ozone is not depleted and secondary reaction products are not formed (Reiss et al. 1994; 1995; 2012; Weschler, 2001; Weschler et al. 1992). The complicated ozone chemistry makes it more difficult to extrapolate from the ozone-only

controlled human exposure studies to ambient air exposures, where there are many more chemicals present. Combining the uncertainties in estimating personal exposure versus ambient exposure (i.e., exposure measurement error) when interpreting the epidemiological health effect estimates would lead to larger confidence intervals (i.e., less precise health effects estimates) than is indicated by the statistical error estimates from those studies.

Presentation on Evidence Integration

For the final discussion of the Science Panel session, Dr. Goodman presented a method for integrating the evidence used in NAAQS reviews. She and colleagues evaluated over 50 weight-of-evidence frameworks and developed a systematic and transparent set of criteria for scoring studies by quality and integrating the evidence. They tested their qualitative framework with cardiovascular effects linked to long-term and short-term ozone exposure (Goodman et al. 2014, Prueitt et al. 2014), and are currently working on an assessment of asthma and short-term ozone exposure. Dr. Goodman explained that the goal of their integrated approach is to look for consistency and coherence in the evidence, with a consideration of study quality, and how their approach is more systematic and transparent than that used by EPA. She noted that many people contribute to EPA's evaluations, which can lead to inconsistent interpretations of the same studies.

Science Panel Discussion

Evidence Integration

The Science Panel agreed that more transparency is needed and that Dr. Goodman's approach systematically addresses major study quality characteristics and gives one more confidence in the evaluation of the strength and limitations of the studies and quality of the evidence. This would be an important step forward; however, the actual *integrating* of evidence is a series of different questions, for example how to integrate FEV_1 with mortality. It is complicated to integrate these health effects, and while it is not essential to know the actual mechanism, knowing it does provide more confidence in the conclusion. One panelist suggested that in order to improve the process, CASAC should be charged with evidence integration and what in

the process needs improvement; to do this, CASAC should be expanded to have broader representation, including stakeholders to provide more suggestions and critiques. Communicating uncertainty is another complex issue; a panelist suggested this can be captured to a certain extent with Monte Carlo analysis, but it also has its limitations and may result in a wide and flat distribution due to so much uncertainty.

Presentation on EPA Ozone Risk Assessment

Dr. Sonja Sax (Gradient) presented the strengths and limitations of EPA's ozone risk assessment. The EPA risk assessment is considered by the Administrator when determining whether to change or retain the current NAAQS. EPA's ozone risk assessment included an exposure assessment for at-risk individuals, a risk assessment for lung function decrements using controlled exposure studies, and a risk assessment of mortality and morbidity endpoints based on epidemiological data. EPA used the Air Pollutants Exposure (APEX) model to estimate personal exposure to ozone, which simulates individuals' time-activity patterns for a year (e.g., geographic location, time spent at home, at work, and outdoors). The model then estimates the risk of a lung function decrement at defined cut-offs (e.g., >10%) for those individuals. Limitations of this model include potentially outdated modeling data (e.g., time-activity data); limited data on children and at-risk populations; and no consideration of averting behavior, such as staying indoors during peak ozone times. The model also estimates risk following a single hour of exposure, whereas the NAAQS is based on an 8-hour average. In addition, the risk assessment does not quantify the uncertainties, and therefore does not include confidence bounds on the point estimates.

For the epidemiologically-based morbidity and mortality risk estimates, EPA used the BenMAP model. Results suggest small mortality risks; and confidence intervals for many of the model results include zero, even in the primary ("core") analysis. Due to the uncertainties in the epidemiological studies, the EPA Administrator has stated that she places less weight on this portion of the risk assessment. Even with the limitations in the risk assessment, the results show that the largest health benefit would result just from lowering the current ozone levels in nonattainment locations, to meet the current ozone NAAQS set at 75 ppb.

Session 3: Socioeconomic Risks and Other Potentially Policy-Relevant Considerations

The FCAA does not allow for consideration of costs in setting the NAAQS. However, in the third session speakers discussed evaluation of social and economic impacts in order to provide context and insights on potential impacts from lowering the ozone standard.

Historical Evidence of Economic Impacts of Environmental Regulation: Daniel L. Millimet, Ph.D.

Dr. Daniel Millimet, an economics professor in the Department of Economics at Southern Methodist University, presented historical insights regarding costs from environmental regulations and policies. Dr. Millimet focused on the historical evidence of economic impacts of environmental regulation through a detailed literature review. He discussed empirical studies assessing the impact of environmental regulations and nonattainment status on the probability of new businesses starting up in an area, the number of new or existing jobs, firm productivity, patterns of international trade, and the earnings of workers. Historically, NAAQS regulatory costs have financially impacted the (relatively small) subset of manufacturing businesses that are heavy emitters of regulated pollutants (e.g., Condliffe and Morgan, 2009). Business activities and hence employment, in these manufacturing sectors are relocated away from nonattainment areas, resulting in lower lifetime earnings for workers (Walker, 2013). However, heavy-emitting firms that do build plants in nonattainment areas tend to build plants that are initially larger (Becker and Henderson, 2000). Regulatory costs also increase imports of pollution-intensive manufacturing goods, but this effect is concentrated within industries that emit a significant amount of regulated pollutants and have low transportation and other costs related to moving overseas (Ederington, Levinson, and Minier, 2005).

Challenges for Estimating Costs of a Tighter Ozone NAAQS: Scott J. Bloomberg, MBA

Mr. Scott Bloomberg, Vice President at NERA Economic Consulting, discussed the methods used to calculate compliance costs and the challenges of these calculations. EPA estimated the direct compliance costs associated with reducing the ozone standard to 65 ppb. The EPA analysis

assumed that all of the monitors in the country (with a few exemptions) would attain the standard by the year 2025 (except California, which would attain by 2037), although not all states would be required to make reductions. EPA defined two types of controls to lower emissions of NOx, thereby reducing ozone: known controls using currently-available technologies (average of direct compliance costs estimated at $3,400/ton NOx reduced), and unknown controls using technologies that have yet to be identified and developed (cost of $15,000/ton NOx reduced). EPA estimated that more than 80% of the costs will be attributable to the unknown controls and that nationwide cost will be $16 billion (2011 dollars, Texas' share is between $4 and $6 billion). EPA assumed baseline emissions included reductions from the proposed Clean Power Plan (CPP) proposal but if that is not implemented in the form proposed by EPA, the total reductions needed could be greater and the ozone rule's compliance costs could be higher. EPA estimated that states will need to rely on controls well outside of nonattainment areas, including in other states; therefore, even areas and states that are in attainment were projected to bear direct costs from a lowering of the standard.

NERA conducted alternative analyses of the costs of complying with a 65 ppb ozone standard (funding for these projects was from the National Association of Manufacturers (NAM) and from TCEQ). NERA did not include the proposed CPP in their baseline estimate, and they assumed a compliance date of 2023 for all states except California or Utah (consistent with those states' nonattainment status being classified as marginal or moderate nonattainment, as projected by EPA). The alternative analyses also assumed that the costs of unknown controls would increase with additional required reductions. NERA also provided a more detailed analysis of Texas, with a focus on Eastern Texas (the counties that EPA defined as the "Within TX Buffer"). NERA's analysis estimated the annualized compliance costs of reducing ozone concentrations to 65 ppb at approximately $155 billion nationwide (2011 dollars), with a preliminary cost estimate of $54 billion per year in Texas alone.[7] Policy Panel and audience members questioned some of the NERA assumptions (e.g., proposed CPP not being included in the baseline estimates, and the possibility of states accepting more burdensome higher

[7] NERA's final cost estimate, which was developed after the workshop, was $51 billion per year (2011 dollars). The NAM released an updated analysis in August 2015 to leverage the insights from TCEQ's final state-level analysis; its national annualized cost estimate rose to about $162 billion per year.

nonattainment classifications in return for more time for attainment). NERA noted that these are alternative assumptions that would lead to different cost estimates, but the most significant uncertainty, and by far the largest contributor to the difference between the EPA and NERA cost estimates, was the difference in the assumed cost of the unknown controls.

Assessing the Potential Economic and Distributional Impacts of a Tighter Ozone NAAQS: Anne E. Smith, Ph.D.

Dr. Anne Smith, Senior Vice President at NERA Economic Consulting, presented on economic impacts of lowering the ozone standard to 65 ppb for both the entire U.S. and for Texas. She highlighted the findings of the economic analysis that NERA has done in separate projects funded by NAM and by TCEQ. The EPA did not do an economic impact analysis for the 2014 proposed ozone rule, although it has done them for past ozone rules (e.g., see Appendix 5b in U.S. EPA Final Ozone NAAQS Regulatory Impact Analysis, March 2008). NERA's economic impact model simulates economic interactions, accounts for market outcomes and contains the best available current data on markets and technologies. The economic impact model accounted for a variety of factors that could be affected by spending on compliance costs, including changes in household spending power, economic activity, market shares, employment, and geographical locations of production and demands.

Based on the estimated compliance costs described by Mr. Bloomberg, NERA's model projected that the annualized national Gross Domestic Product (GDP) loss would be $140 billion/year (annualized over 2017 through 2040), with a household consumption loss averaging $830/year. For Texas, NERA's preliminary estimate of these impacts would be a $30 billion/year relative reduction in Gross State Product (GSP), with a household consumption loss of $1,850/year.[8] Different economic sectors would suffer different impacts, and in Texas, the coal industry (in the energy sector) and agriculture (in the non-energy sector) would have the largest percentage losses. Although there are states that are not projected to need NOx reductions in order to

[8] NERA's final impact estimates, which were developed after the workshop, were $30 billion/year GSP and $1,690/year per household, respectively. The NAM released an updated analysis in August 2015 to leverage the insights from TCEQ's final state-level analysis; its national GDP impact estimate remained $140 billion/year, while the national average cost per household rose to $840 per household per year.

control ozone to meet a 65 ppb standard, there are no states that would escape economic impacts of this rule, primarily due to changes in energy markets, which affect all states.

Dr. Smith closed the presentation by noting several limitations of the macroeconomic impact analysis beyond the basic one of uncertainty in what the compliance cost inputs should be. These included that the model projects conditions under equilibrium, with full-employment; it thus provides no insight on the magnitude of transitional impacts such as numbers of worker layoffs as a result of business transitions to other areas or other sectors, and duration of any period of unemployment that may result from such transition. She also noted that the economic impacts were only those associated with direct spending to reduce emissions; effects of constraints on development projects in areas with nonattainment and local government costs to implement the standard were not included, because the model does not contain the sub-state detail necessary to capture these effects on local economies.

Health Effects of Regulatory Compliance Costs: John F. Morrall, Ph.D.

Dr. John Morrall, formerly with the Office of Management and Budget (OMB) and currently an Affiliated Senior Scholar with the Mercatus Center at George Mason University, presented on the health effects of regulatory costs and how changing economic conditions can negatively impact health, known as health-health analysis. The discovery that wealthier is healthier goes back to studies during the early 1800s in the UK and France and today in epidemiology is known as the income-health gradient. Lutter and Morrall (1994) review this literature and describe how and why it was first used by OMB in 1993 to review regulations. Health-health analysis considers both the intended health consequences of a regulation (the health benefits) and the unintended indirect health consequences of a regulation that result from the diversion of resources from other health enhancing activities (health dis-benefits). Dr. Morrall noted that this type of analysis allows for the assessment of comparative health risks, which is statutorily allowed in setting NAAQS standards. Dr. Morrall presented an example calculation, based on published literature (Lutter, Morrall and Viscusi, 1999), using one life lost for every $25 million increase in costs. Using the Smith et al. (2009) study that is the basis for EPA's short-term ozone mortality benefits and EPA's estimates of compliance costs, 900 lives are projected to be saved

from decreasing ozone from 75 ppb to 60 ppb (this does not consider the projected lives saved from reducing $PM_{2.5}$). However, using one life lost/$25 million in costs (with EPA's costs and unknown controls at $20,000 per ton of NOx), 2000 lives could be lost as a result of the economic cost to attain 60 ppb, resulting in a health dis-benefit of 1100 lives lost. A 65 ppb ozone standard is projected to result in a health dis-benefit of 130 lives lost, while a 70 ppb ozone standard is projected to result in a health benefit of 24 lives gained. In response to Policy Panel and audience questions, Dr. Morrall noted that the numbers of lives will change drastically with higher estimates of compliance costs (such as those presented by Mr. Bloomberg), that his calculations did not factor in the additional links between a worsening income distribution and mortality, and that his analysis focused on mortality, but similar analyses could include morbidity endpoints as well.

Session 4: Integrating Science Considerations into Policy Judgments

The Policy Panel discussion in the final workshop session addressed considerations of the FCAA legal frame work, the context of setting the NAAQS, and the process that the EPA Administrator uses to make her decision. The Policy Panel was composed of Mr. Thomas A. Lorenzen, Esq., former attorney with the Department of Justice who defended many challenges to EPA rules, and at that time of the workshop was partner at Dorsey & Whitney LLP; Dr. Donald R. Arbuckle, with the Office of Management and Budget (OMB) for 25 years, currently a professor of public affairs at the University of Texas at Dallas; Mr. Charles H. Knauss, Esq., formerly minority counsel for the U.S. House of Representatives Committee on Energy and Commerce who helped author the 1990 FCAA Amendments, currently partner and co-head of the Environment and Workplace Safety Practice at Katten Muchin Rosenman LLP; and, Dr. Paul R. Portney, President Emeritus of Resources for the Future and Dean Emeritus, Eller College of Management, University of Arizona. Dr. Chris Whipple, recently retired from Environ, was the facilitator for the panel.

Policy Panel Individual Comments

To begin this session, the four policy experts provided their thoughts on the current situation and the framework and rules within which the ozone NAAQS decision must be made. Mr. Lorenzen described ground rules for what EPA may and may not take into account given legal considerations and court decisions that frame the NAAQS process. Dr. Arbuckle addressed pressures from the numerous parties who will scrutinize and criticize the Administrator as she makes her decision. Dr. Portney discussed why the FCAA should be changed to align better with today's economy and current levels of pollution. Mr. Knauss commented on the need for clear decision principles that reflect both the NAAQS legal framework and the uncertainties in the science as EPA considers increasingly stringent standards. These presentations were followed by a discussion among the Policy Panel and other workshop participants.

Thomas A. Lorenzen

Mr. Lorenzen spoke on the legal considerations that the EPA and the Administrator must take into account when setting a standard. EPA is tasked with setting the primary NAAQS at a level requisite to protect public health with an adequate margin of safety, and Mr. Lorenzen pointed out that "requisite" is the key word; it means no more nor less stringent than necessary and that this is a judgment- and policy-based decision, rather than being solely based on the science. The FCAA gives the Administrator much latitude in making her policy judgment. The Supreme Court, in *Whitman v American Trucking Association*, confirmed that costs were not a permissible basis for setting NAAQS, but Justice Breyer in his concurring opinion implied costs can be accounted for to the extent that they affect the *net* health benefit. Reflecting on the health-health analysis presented by Dr. Morrall at the workshop, Mr. Lorenzen noted that EPA looks at the health benefits of lowering the NAAQS, and a credible argument could be made that dis-benefits (e.g., loss of income and resulting health impacts, reduced social services) are a proper part of the health analysis and should be considered in the decision. According to Justice Breyer, a rule likely to cause more harm to health than it prevents is not a rule that is "requisite to protect public health." If the Administrator fails to consider a key piece of information, then the decision could be considered arbitrary and capricious.

Case law addressing the NAAQS has also demonstrated that EPA is allowed to depart from CASAC's recommendations, although a justifiable explanation is required. EPA is permitted to take a weight of evidence approach to setting the standard, using studies from one area to fill data gaps or ambiguities in other areas, and may more heavily weight those studies that show positive associations between the pollutant and the health effect. TCEQ and others should share their analyses and findings so that EPA is aware of this information and can consider it and the scientific uncertainties fully when evaluating the evidence they use to support their decision. When the courts litigate the decisions of the Administrator, the EPA is given the highest level of deference on matters of technical or scientific expertise, and absolute deference for their scientific conclusions; the courts defer to EPA on its interpretations of the scientific evidence unless they are very obviously flawed.

Donald R. Arbuckle

Dr. Arbuckle's remarks put the process of setting the standard into the context of the highly contentious environment within which the EPA Administrator must make her decision. Parties whose interests are affected include the following: Congressional members and their staff; the President, (to whose subordinate, the EPA Administrator, the law provides the final regulatory authority to decide), White House staff, and the OMB; the court system that ultimately assesses whether the Administrator has met the Administrative Procedure Act (APA) "arbitrary and capricious" standard; a press that needs stories; the myriad affected parties, most of whom are predisposed to disagree with any EPA decision; and EPA staff, who have their own various points of view. All of these groups bring pressures to bear on the EPA Administrator, and this cacophony of voices in turn affects her ability, and her freedom, to interpret the scientific evidence and its uncertainties. The EPA docket provides for public view a remarkable volume of scientific literature on the ozone NAAQS, and while reviewers have the luxury of critiquing what the EPA has done and pointing out the uncertainties, the Administrator still has to make a decision. The Administrator cannot set the standard as a range, or refuse to make a decision because there are uncertainties in the data. The Administrator must draw a bright line across the data and set a standard (which may include choosing to retain the existing standard) no matter what the uncertainties are. Dr. Arbuckle expressed his view that EPA and the President

do care about data and analysis and want to do the right thing by the public, so it is important that interested and affected parties actively explain and discuss their insights on these important scientific issues and other issues raised in the public comments. Dr. Arbuckle encouraged stakeholders to discuss their concerns with various segments of the federal government, including EPA and OMB, the Council on Environmental Quality and Council of Economic Advisors, and members of Congress.

Paul R. Portney

Dr. Portney discussed the historical setting that surrounded the writing of section 109 of the FCAA (the section that addresses setting the NAAQS). In 1970, air pollution was a visible problem; reductions in primary pollutants were relatively easy and cheap; and the U.S. was in the middle of the best 50 years of the country's economic history. Today, air quality has been steadily improving for the last 40 years, additional improvements in air quality are much more expensive to attain, and we are coming off the worst economic experience since the Great Depression. The FCAA reflects the economic and environmental conditions of half a century ago. If the FCAA were written today, Dr. Portney believes it would take into account such things as cost, background concentrations, security of the energy infrastructure, and other factors, in addition to protecting public health and welfare. In the current situation (working with a 45-year old law), cost is accounted for "behind the scenes," and is expressed by tradeoffs that the Administrator makes when deciding on how to weigh the scientific evidence. If the costs associated with lowering the standard are too great, the Administrator may determine that there are too many uncertainties in the scientific data to warrant lowering the standard. Dr. Portney believes that the current situation encourages disingenuousness on the part of public officials; fosters cynicism in the general public about government and the law; and undermines public trust in government. He believes that the FCAA should be revised to allow the Administrator to transparently establish air quality standards that protect public health and welfare, while taking into account other factors, including cost of reducing emissions, regional conditions, and impacts on energy supplies.

Charles H. Knauss

Mr. Knauss discussed how science is being evaluated under the FCAA and case law, and the potential legal options to address the extraordinary challenge posed by the NAAQS program. He noted that this workshop is remarkable in the level of interaction among scientists and policy experts and for the quality and sincerity of the resulting discourse. The workshop provided a rare opportunity for policy experts to directly question science experts and he appreciated the Science Panel responding to the alternative perspectives the policy experts posed in their questions as they sought to gain insight and understanding. It is his sense that EPA staff consider setting the NAAQS as the "quintessential" exercise in Agency discretion, and that the case law has provided EPA little motivation to set clear criteria for the NAAQS decisions that would allow the public to evaluate in an objective manner whether the science warrants a change in the NAAQS. He noted also that the Administrator is not bound to follow the recommendations of CASAC. Mr. Knauss thus echoed the theme of others in this panel that the NAAQS decision is informed by the scientific evidence but policy considerations also play a major role in any decision, and added the point that the lack of clear criteria may actually be harmful to the process and the faith that the public has in the selection of any given level for the NAAQS.

Mr. Knauss also noted that while the five-year review process is mandatory, the statutory language indicates that EPA has discretion to make a decision not to revise the standard, since revisions are "as [the Administrator] deems appropriate" – and EPA has to determine whether a revision is appropriate taking into account the relevant factors. In setting a standard in the first instance, EPA must determine if a standard is requisite, and then in subsequent evaluations whether a revision is appropriate. Thus, on revision, EPA is to evaluate whether a new standard is both "necessary" (i.e., requisite) to protect health and "appropriate" in light of the full range of relevant factors. Mr. Knauss noted that these issues are being addressed by the Supreme Court in *Michigan v. EPA*, which will address the legality of EPA's Mercury and Air Toxic Standards (MATS).

According to Mr. Knauss, the Supreme Court decision in *Whitman v. American Trucking Associations* is also relevant here, including Justice Breyer's concurring opinion, which establishes several important principles that guide standard-setting under the "Goldilocks" test. The FCAA requires EPA to set standards which in the judgment of the Administrator are "requisite" to protect the public health. Building on the majority's opinion that requisite means sufficient but not more than necessary to protect public health with an adequate margin of safety, Justice Breyer noted that the words "requisite" and "public health," must be understood in the context of risks society finds acceptable. The Administrator may consider whether a proposed rule promotes safety overall. Hewing to these speed bumps in Justice Breyer's decision, Mr. Knauss suggested that the keys to a reasoned decision-making principle may be evident. As the standard becomes more and more stringent and as the ability of the science to accurately identify public health benefits of tighter standards at such low levels diminishes, the Administrator needs to consider whether the degree of certainty she should demand from the studies must also be tightened for her to fulfill her statutory obligation to engage in reasoned decision making. According to Mr. Knauss, it is reasonable to conclude that the degree of certainty required of studies should increase as you consider lower and lower levels of the standard because the uncertainty regarding potential public health risk reduction that might be realized is also increasing. In effect, it would be a failure of reasoned decision making, as well as arbitrary and capricious, if EPA did not require higher quality studies with a higher degree of scientific certainty at these low levels in assessing the need for a tighter standard. As the potential net and overall public health improvement diminish, a reasoned decision maker must demand more certainty that those public health improvements will actually occur since the margin of error in the studies themselves could eliminate any benefits or even result in a net negative impact. Given the uncertainties presented during the course of this workshop for each of the major health end points evaluated by EPA, Mr. Knauss questioned whether EPA can sufficiently make this case in the context of the currently proposed NAAQS revision.

Mr. Knauss also recommended that stakeholders discuss the issues raised in the public comments and this workshop with EPA and OMB staff; people can go in after the comment period ends and explain their comments to staff. It is important for people implementing the

law (e.g., states) to believe that the regulations make sense and to avoid creating cynicism about the law. He thought that the current decisions on ozone, if made unreasonably, might be the trigger for a revision to the FCAA, particularly if there is a credible threat that major areas of the country could face sanctions for failure to attain.

Policy Panel Discussion

During the course of the workshop and in the Policy Panel comments and discussions, several common themes emerged. Policy panelists and others commented on the uniqueness of this workshop in bringing together experts in science, economics, policy, and law to discuss this complex and multi-faceted NAAQS decision in an integrative manner. To the participants' knowledge, this was the first time the different types of experts met together at the same time to talk directly with one another and gain valuable insight and understanding regarding the data, uncertainties, and issues. The policy panelists felt that the concerns regarding implementation, the ozone science, the possibility of net adverse effects on public health, and the cost of compliance raised in the workshop were valid and should be shared with EPA and others.

Both the policy panelists and the other participants frequently mentioned that *context* matters. The Administrator is to set standards that are "requisite to protect the public health" with "an adequate margin of safety." (Section 109, FCAA). In wrapping up the policy panelists' discussion, Mr. Knauss explained that Justice Breyer's concurring opinion in *Whitman v. American Trucking Associations* provides a roadmap of what the Administrator can consider in making her decision, including comparative risks, whether a rule is more likely to cause more harm to health than it prevents, the severity and distribution of adverse health effects, the number of people affected, and the uncertainties in the estimates. The scientific evidence for revising the current ozone standard does not plainly establish that a more stringent standard would be "requisite" given the considerable uncertainty with regard to causality, health impacts, and subsequent estimation of benefits at the very low levels EPA proposes to set the standard. Reasoned decision making regarding the public health effects in the context of very low concentrations for a proposed NAAQS requires the Administrator to demand more

certainty from the studies in evaluating whether the public health gains projected from their findings are real. Discussion of the degree of severity of potential health impacts under current ambient conditions and of the degree of uncertainty in those impacts' prevalence or existence helps place a NAAQS policy decision into a context that allows for reasonable balancing of competing societal objectives.

Even though the public comment period was closed, the policy panelists said there were still opportunities and a need for further discussion with different parts of the federal government. The policy panelists encouraged stakeholders and interested parties to meet with EPA, OMB, Congressional representatives, and others to further explain the concerns raised in public comments. The EPA Administrator must act in the face of uncertainty and provide an adequate margin of safety, but she must give a rationale for what she decides. EPA is required to respond to all of the public comments, and those submitting comments should make sure that the issues they raised are understood by EPA so that EPA can give them full consideration. This is particularly important because the courts give deference to EPA on interpretation of the science. The scientific uncertainties, including the increasing uncertainties in assessing public health improvements at more stringent NAAQS levels, must be assessed along with potential disbenefits in making the policy decision on where to set the ozone standard.

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Appendix A

History of the National Ambient Air Quality Standards for Ozone During the Period 1971-2008

Final Rule/Decision	Primary/ Secondary	Indicator [1]	Averaging Time	Level [2]	Form
1971 36 FR 8186 Apr 30, 1971	Primary and Secondary	Total photochemical oxidants	1-hour	0.08 ppm	Not to be exceeded more than one hour per year
1979 44 FR 8202 Feb 8, 1979	Primary and Secondary	O_3	1-hour	0.12 ppm	Attainment is defined when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, is equal to or less than 1
1993 58 FR 13008 Mar 9, 1993	EPA decided that revisions to the standards were not warranted at the time				
1997 62 FR 38856 Jul 18, 1997	Primary and Secondary	O_3	8-hour	0.08 ppm	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
2008 73 FR 16483 Mar 27, 2008	Primary and Secondary	O_3	8-hour	0.075 ppm	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years

[1] O_3 = ozone
[2] Units of measure are in parts per million (ppm).
Table from http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_history.html (EPA, 2015)