



Independent Workshop on Ozone NAAQS Science and Policy

**April 7-9, 2015
University of Texas AT&T Conference Center
Austin, Texas**

WORKSHOP ORGANIZED BY



Bryan W. Shaw, Ph.D., *Chairman*
Toby Baker, *Commissioner*
Zak Covar, *Commissioner*
Richard Hyde, *Executive Director*



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

April 7, 2015

Welcome!

Dear Colleagues:

On behalf of the Texas Commission on Environmental Quality (TCEQ), welcome to the ***Independent Workshop on Ozone NAAQS Science and Policy***. We are pleased you have chosen to attend this workshop and join with colleagues from a broad range of affiliations to discuss ambient ozone's health effects and the nexus between the scientific findings and implications for public health. The goal of the workshop is to provide an independent evaluation and synthesis of key considerations for approaching the difficult and complex ozone National Ambient Air Quality Standard (NAAQS) decision.

This workshop will begin with presentations about the context of the ozone NAAQS, including the history of the NAAQS, the legal framework of the Clean Air Act, implementation challenges, as well as the ozone NAAQS welfare standard. Then we will convene a panel of science experts to discuss key scientific findings on ozone health effects. Included in the panel session will be short informative presentations to begin the discussions. The science panel will be followed by socioeconomics experts who will present the potential societal risk of regulation. The workshop will culminate with presentations and discussion amongst a panel of policy experts who will highlight the scientific and societal considerations that they personally conclude, over the course of the workshop discussions, should be given weight in a good policy decision. We invite you to participate in this workshop during the designated Q&A times, when you will have the opportunity to ask questions of the speakers and panel discussants. The reception on Wednesday evening is an opportunity for on-site attendees to mix and mingle and discuss the ozone science and policy decisions with colleagues.

In addition to the 75 attendees at the University of Texas, AT&T Executive Education and Conference Center, we are pleased that more than 200 additional persons are attending remotely through a webcast. By broadcasting the workshop via webcast we are attempting to make the workshop as accessible as possible and reach all those who are interested.

The major overarching themes that emerge from this workshop will be summarized in a workshop report so that all those interested may learn from the experience and insights shared and discussed. A brief

report will be made available at <http://www.tera.org/Peer/ozone/index.html> after the workshop. The proceedings may also be published in a peer-reviewed journal at a later date.

We want to thank our speakers and panel discussants who have contributed their valuable time to make this workshop a success. This workshop was organized by a steering committee comprising Michael Honeycutt, PhD and Sabine Lange, PhD from TCEQ, as well as consultants from Gradient: Julie Goodman, PhD, Sonja Sax, ScD and Tim Verslycke, PhD; from NERA Economics Consulting: Anne Smith, PhD; and from Toxicology Excellence for Risk Assessment (TERA): Michael Dourson, PhD, Jacqueline Patterson and Jeanelle Martinez, PhD. We would like to thank the steering committee for their extensive work planning and organizing the workshop, identifying independent experts and speakers for each session, and for preparing presentations. We hope you find the workshop a productive and educational experience.

Sincerely,



Michael Honeycutt, PhD, Director
Toxicology Division
The Texas Commission on Environmental Quality

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How is our customer service? <http://www.tceq.texas.gov/customersurvey>

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Workshop Goals and Objectives

The Texas Commission on Environmental Quality (TCEQ) is convening this *Independent Workshop on Ozone NAAQS Science and Policy*. The purpose of this workshop is 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 the scientific findings and implications for public health. The goal of this workshop is to provide an independent evaluation and synthesis of key considerations for approaching the difficult and complex ozone National Ambient Air Quality Standard (NAAQS) decision.

TCEQ is sponsoring this workshop because it thinks that the ozone NAAQS review has not been fully effective in communicating to the US Environmental Protection Agency (EPA) Administrator and the public critical facets of the issues that are relevant to making a scientifically-based NAAQS policy decision. At this public workshop, knowledgeable scientists and policy analysts will engage in robust discussions on key issues, so that TCEQ, other states, and interested parties can listen and gain a better understanding. Proceedings of the workshop will be prepared and made public, and TCEQ also intends to provide them to the EPA Administrator.

This workshop is unique because no other public forum addressing ambient ozone has focused on the integration of science and the societal implications into a sound and defensible policy judgment on whether to revise the ozone NAAQS. This workshop will be conducted with a broader policymaking orientation than the EPA's review process assigns to the Clean Air Scientific Advisory Committee (CASAC).

Specifically, this workshop will convene a panel of science experts to discuss key scientific findings on ozone effects, including the uncertainties, unanswered questions, and implications for public health. Socioeconomics experts will present evidence on potential societal risks from regulation. The workshop will then culminate in an integrative discussion by renowned policy experts. The policy experts will highlight the scientific and societal considerations that they personally conclude, over the course of the workshop discussions, should be given weight in a good policy decision. They will also provide their thoughts on how the EPA Administrator could account for those salient considerations, while adhering to the legal requirements of the Clean Air Act.

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Workshop Agenda

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Independent Workshop on Ozone NAAQS Science and Policy

**Sponsored by the Texas Commission on Environmental Quality (TCEQ)
April 7-9, 2015, University of Texas, Austin
AT&T Executive Education and Conference Center, Room 106**

Tuesday, April 7, 2015

Session 1 – Plenary

- | | |
|----------------------|--|
| 7:30 – 8:30 | Workshop Registration |
| 8:30 – 9:00 | Welcome
Michael Honeycutt, Director, Toxicology Division, TCEQ
Bryan Shaw, Chairman, TCEQ |
| 9:00 – 9:30 | <i>Why States Care: Implementation & Impacts of a NAAQS</i>
Seyed Sadredin, Executive Director, San Joaquin Valley Air Pollution
Control District |
| 9:30 – 10:15 | <i>Clean Air Act and Case Law on How a NAAQS Must Be Set</i>
Henry V. Nickel, Special Counsel, Hunton & Williams LLP |
| 10:15 – 10:45 | BREAK |
| 10:45 – 11:15 | <i>Interface Between Science and Policy in a NAAQS Review</i>
Roger O. McClellan, Advisor, Toxicology and Human Health Risk
Analysis |
| 11:15 – 11:45 | <i>Ozone NAAQS Secondary Standard</i>
Tim Verslycke, Principal, Gradient |
| NOON – 1:00 | LUNCH, Room 104 and Courtyard |

Session 2 - Integration of Scientific Evidence to Inform the Understanding of Ozone Effects on Human Health

1:00 – 1:30

Introduction to Session 2

Michael Honeycutt, Director, Toxicology Division, TCEQ
Michael L. Dourson, Toxicology Excellence for Risk Assessment (TERA), Session Facilitator

Outside Experts:

Robert Phalen, University of California, Irvine
Barry Ryan, Emory University
George Maldonado, University of Minnesota
Mark Utell, University of Rochester

Presenters:

Julie Goodman, Gradient
Sabine Lange, TCEQ
Sonja Sax, Gradient

1: 30 – 2: 30

Ozone Mode of Action

Presentation, Sabine Lange, TCEQ
Panel Discussion
Policy Expert Questions

2:30 – 3:30

Controlled Exposure Studies

Presentation, Sabine Lange, TCEQ
Panel Discussion
Policy Expert Questions

3:30 – 4:00

BREAK

4:00 – 5:30

Panel Discussion: Controlled Exposure Studies, continued

5:30 – 6:00

Questions and Comments from Attendees

6:00

ADJOURN FOR DAY

Wednesday, April 8, 2015

Session 2, Continued

- 7:30 – 8:30** **Workshop Registration**
- 8:30 – 8:45** **Welcome, Day 2**
Toby Baker, Commissioner, TCEQ
- 8:45 – 10:00** **Epidemiology Studies**
Presentation, Julie Goodman, Gradient
Panel Discussion
Policy Expert Questions
- 10:00 – 10:15** **BREAK**
- 10:15 – 11:45** **Quantifying and Integrating the Evidence**
Presentation, Julie Goodman, Gradient
Panel Discussion
Policy Expert Questions
- 11:45 – 1:00** **LUNCH, Room 106**
Strengths and Limitations of EPA's Ozone Risk Assessment
Sonja Sax, Gradient

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

- 1:15- 1:30** **Introduction to Session 3**
Michael Honeycutt, Director, Toxicology Division, TCEQ
- 1:30 – 2:15** ***Historical Evidence of Economic Impacts of Environmental Regulation***
Daniel L. Millimet, Professor, Department of Economics, Southern Methodist University
- 2:15 – 3:15** ***Challenges for Estimating Costs of a Tighter Ozone NAAQS***
Scott J. Bloomberg, Vice President, NERA Economic Consulting

- 3:15 – 3:45** **BREAK**
- 3:45 – 4:45** *Assessing the Potential Economic and Distributional Impacts of a Tighter Ozone NAAQS*
Anne E. Smith, Senior Vice President, NERA Economic Consulting
- 4:45 – 5:30** *Health Effects of Regulatory Compliance Costs*
John F. Morrall III, Affiliated Senior Scholar, The Mercatus Center at George Mason University
- 5:30** **ADJOURN FOR DAY**
- 6:00 – 7:30** **Reception in the Interior Courtyard (light appetizers and cash bar)**

Thursday, April 9, 2015

Session 4 - Integrating Science Considerations into Policy Judgments

- 7:30 – 8:30** **Workshop Registration**
- 8:30 – 8:45** **Introduction to Session 4**
Michael Honeycutt, Director, Toxicology Division, TCEQ
Chris G. Whipple, Principal, ENVIRON International Corporation (retired), Session Facilitator
- 8:45 – 10:15** **Integrating Experts' Individual Presentations**
- Donald R. Arbuckle*, Clinical Professor of Public Administration, University of Texas at Dallas
- Charles H. Knauss*, Partner and Co-Head of Environment and Workplace Safety Practice, Katten Muchin Rosenman LLP
- Thomas A. Lorenzen*, Partner, Dorsey & Whitney LLP
- Paul R. Portney*, President Emeritus of Resources for the Future; Dean Emeritus, Eller College of Management, University of Arizona

10:15 – 10:45	BREAK
10:45 – 12:15	Integrating Policy Experts' Discussion Q&A with Other Workshop Attendees
12:15 – 1:00	Policy Experts' Final Remarks
1:00 - 1:15	Closing Michael Honeycutt, Director, Toxicology Division, TCEQ

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Biographies

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Session 1

Seyed Sadredin

Seyed Sadredin is the Executive Director and Air Pollution Control Officer for the San Joaquin Valley Air Pollution Control District. Mr. Sadredin has more than 30 years of experience in directing, developing, applying and administering air quality improvement programs. Since 2006 Mr. Sadredin has led the largest air district in the state of California in an air basin with some of the toughest air quality challenges in the nation.

Serving a region facing tremendous economic and public health challenges beyond air quality, Mr. Sadredin has led the development and implementation of some of the toughest and most innovative air pollution control strategies in the nation while working cooperatively with the regulated community to reduce administrative costs and achieve environmental and economic balance.

Mr. Sadredin has worked with a wide range of stakeholders forming a successful coalition and bringing significant resources to the Valley for voluntary incentive-based emission reduction programs. Under his leadership, the San Joaquin Valley now has access to over \$100 million per year in local, state and federal funds for clean air projects that expedite air quality improvement. To date, Mr. Sadredin has overseen the expenditure of over \$1 billion in public/private investment in the San Joaquin Valley's clean air efforts through voluntary programs.

With a staff of over 300 air quality professionals, Mr. Sadredin has also made employees' welfare and wellbeing a top priority and has instituted a number of programs to motivate and empower employees, while focusing on providing excellent customer service to the general public and the regulated community.

Henry Nickel

Henry Nickel is a graduate of the University of Virginia and the George Washington University Law School. He was a partner in the law firm Hunton & Williams for 38 years and is currently Special Counsel to the firm. Mr. Nickel is a member of the bar of every federal Circuit Court of Appeals and the United States Supreme Court. Over the past 45 years, Mr. Nickel has represented clients in virtually every major EPA Clean Air Act stationary source rulemaking. As counsel to the Utility Air Regulatory Group (UARG), he has participated in many complex rulemakings involving risk management, including ambient air quality standards (NAAQS) for ozone and other criteria pollutants, hazardous air pollutants proceedings on radionuclides and mercury emissions from coal-fired plants, and greenhouse gas regulation. He has also represented UARG, States, and individual companies in numerous rulemakings defining requirements governing intra-state and inter-state implementation of NAAQS. Mr. Nickel has argued dozens of Clean Air Act cases in the Courts of Appeals and has represented UARG before the Supreme Court in *ATA v. Whitman* (ozone and PM_{2.5} NAAQS), *EPA v. EME Homer City* (ozone/PM_{2.5} Transport Rule), *UARG v. EPA* (permitting greenhouse gas emissions), and *Michigan v. EPA* (utility air toxics standards).

Roger O. McClellan

Dr. Roger O. McClellan serves as an independent advisor to public and private organizations on issues of air quality in the ambient environment and work place. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. Dr. McClellan is a Diplomate of the American Board of Toxicology and American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences, American Association for Aerosol Research, Society for Risk Analysis, Health Physics Society and American Association for the Advancement of Science. He was elected in 1990 to membership in the Institute of Medicine of the National Academy of Science. He has received numerous awards from professional societies and other organizations for his service. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to comparative medicine and the science under-girding improved air quality. In 2006, he received the New Mexico Distinguished Public Service Award. In 2008, Washington State University presented Dr. McClellan the Regents Distinguished Alumnus Award, the highest recognition the University can bestow on an Alumnus.

Dr. McClellan started his research career with the General Electric Co. Hanford Laboratories (1960-1964), had a special assignment with the Atomic Energy Commission (1965-1966), was the Chief Scientist and Director, Lovelace Inhalation Toxicology Research Institute (1966-1988) and President and CEO of the Chemical Industry Institute of Toxicology (1988-1999). He provided leadership at these institutions for developing internationally recognized programs on the health effects of radioactive materials, chemicals and vehicle emissions.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science, comparative medicine, and human health risk analysis. He has authored over 350 scientific papers and edited 10 books. He serves in an editorial role for a number of journals, including service since 1987 as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of eight universities. He was a founding member of the EPA Science Advisory Board and served on Clean Air Scientific Advisory Committee Panels advising on all the criteria air pollutants.

Dr. McClellan participated in the review of the Ozone National Ambient Air Quality Standard in 1979, 1993, and 1997. He served as CASAC Chair (1987-1992) and advised the EPA Administrator to reaffirm in 1993 the standard set in 1979. He offered advice, as a member of the public, on the setting of the 2008 NAAQS and the 2010 re-consideration attempt and has offered comments at multiple stages in the process leading to the 2014 proposed rule. He is a strong advocate of science-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials and to inform policy makers in developing standards and guidance to protect public health.

Tim Verslycke

Dr. Tim Verslycke is a Principal at Gradient with 15 years of combined consulting and academic research experience in ecological risk assessment. He has a Ph.D. in Bio-Engineering/Applied Biological Sciences and an M.S in Bio-Engineering/Environmental Technology from Ghent University, Belgium. Dr. Verslycke speaks regularly at scientific conferences on this and other topics, and has authored more than 35 peer-reviewed journal articles. His primary area of expertise is environmental toxicology and risk assessment as it relates to contaminated sites, chemical regulation, product safety, and sustainability. Dr. Verslycke also holds an academic position in the Biology Department at the Woods Hole Oceanographic Institution (Woods Hole, MA). Dr. Verslycke formerly served as president of the Society for Environmental Toxicology and Chemistry North Atlantic Chapter (NACSETAC), scientific advisor to the Center for Health and Environment of the Flanders Regional Government (Belgium), and member of the scientific committee of the Flanders Marine Institute (VLIZ, Belgium).

Dr. Verslycke has provided public comment on the secondary National Ambient Air Quality Standard (NAAQS) for ozone and other criteria pollutants. He has also provided public testimony to the Clean Air Scientific Advisory Committee (CASAC) on the secondary ozone NAAQS. Portions of this work have been funded by the Texas Commission of Environmental Quality (TCEQ). Several industry trade organizations have funded other similar work. Dr. Verslycke served on the steering committee for this workshop.

Session 2

Outside Experts

George Maldonado

Dr. George Maldonado has been a professor at the University of Minnesota School of Public Health, Division of Environmental Health Sciences, since 1990. The focus of his research and teaching has been in epidemiologic methodology, with an emphasis on causal reasoning. Supported by an NIEHS NRSA traineeship, he earned a PhD in Epidemiology from the UCLA School of Public Health in 1990, under the supervision of Sander Greenland. His dissertation topic was a methodological study of statistical modeling methods; the result of that work was an understanding of the conditions that are required for statistical modeling methods to yield valid answers to causal questions.

Dr. Maldonado has taught PhD-level courses in epidemiologic methods for over 20 years. Public Health 8140, *Validity Concepts in Epidemiologic Research*, explains the conceptual foundations of causal inference in epidemiology. That course relies heavily on Maldonado and Greenland (2002; *Estimating Causal Effects*) and Maldonado (2013; *Toward a Clearer Understanding of Causal Concepts in Epidemiology*), and it also explains the relationship between an ideal measure of causal effect and error in study results caused by study imperfections (e.g., residual confounding, non-random subject selection, measurement error). That relationship was outlined mathematically in Maldonado (2008; *Adjusting a Relative-Risk Estimate for Study Imperfections*). Maldonado (2008)

is the foundation for another PhD-level course I teach, Public Health 8142, Epidemiologic Uncertainty Analysis. That course continues from Public Health 8140 to examine how to correct study results for all major study imperfections, with the goal of obtaining the best estimate of the causal effect of an exposure on disease.

Robert F. Phalen

Dr. Robert Franklynn Phalen co-directs the Air Pollution Health Effects Laboratory at the University of California, Irvine (UCI). He holds academic appointments in the College of Medicine at UCI: Professor in the Department of Medicine; and Professor in the Center for Occupational and Environmental Health. He teaches medical students, medical residents, graduate students, and undergraduate students at UCI. He is also involved in translating science into plain English for the public.

He graduated from San Diego State University with a B.S. in physics in 1964, and obtained an M.S. degree in physics with a specialty in nuclear physics in 1966. In 1971, he obtained a Ph.D. in radiation biology and biophysics, with specialization in inhalation toxicology, from the University of Rochester (in NY). His postdoctoral research in aerosol physics and inhaled particle deposition modeling was conducted at the Inhalation Toxicology Research Institute in Albuquerque, NM.

In 1972, Dr. Phalen joined the College of Medicine at UCI to establish the Air Pollution Health Effects Laboratory, which still conducts studies relating to the toxicology of air pollutants. These studies have been supported by a variety of federal agencies (including the U.S. EPA; the National Heart, Lung and Blood Institute; the National Institute of Environmental Health Sciences; and the Centers for Disease Control and Prevention), California state agencies (California Air Resources Board; the Department of Health Services; and others), and numerous private agencies (including the Electric Power Research Institute; the Health Effects Institute; the Charles C. Stocking Trust Fund; Southern California Edison Co.; the Nickel Producers Environmental Research Association; and others). Prior to 1994 his laboratory did animal studies on ozone levels much higher than current levels, which are not relevant to the current Ozone NAAQS. The sponsors of that research were the CA Air Resources Board, the U. S. EPA, and the Electric Power Research Institute.

His research includes: lung modeling for predicting doses from inhaled particles; lung morphometry for mammals; health effects of inhaled air pollutants; and applied aerosol physics. Lung modeling efforts have included inhaled aerosol deposition as a function of age, and comparative modeling in humans and laboratory animals. Another area of research involves the effects of inhaled particle-gas air pollutant mixtures on lung defenses. Most recently he has been involved in modeling the deposition of inhaled aerosols for risk assessments.

He has served on the editorial board of four scientific journals and has published over 150 scientific papers and authored or co-authored books on inhalation toxicology and particulate air pollution.. He has organized and chaired five international scientific conferences on particulate air pollution and human health. Dr. Phalen has received awards from the American Legion, the U.S. Atomic Energy Commission, the International Metallurgical Association, the California Biomedical Research

Association, the Inhalation Specialty Section of the Society of Toxicology, the California Society for Biomedical Research, and the American Association for the Advancement of Science. He is chair of the Board of Directors of the California Society for Biomedical Research. He has two sons, and his wife Katherine is an occupational health nurse.

P. Barry Ryan

Dr. P. Barry Ryan holds joint appointments as Professor in the Department of Environmental Health at Rollins School of Public Health and in the Department of Chemistry at Emory University. He is an associate member of the Cancer Prevention and Control research program at Winship Cancer Institute. He is also a member of the International Society of Exposure Science. He has been active in the exposure assessment field for over 30 years. He has published in excess of 120 peer-reviewed manuscripts and made over 225 presentations of his work to the scientific community. His work focuses on multimedia environmental exposure assessment and the impact of such exposures on health.

Dr. Ryan's work began by focusing on air pollution exposures, but he soon came to the conclusion that even exposures that are dominated by the air inhalation route can have a significant non-inhalation-related pathways. Since the early 1990s, he has investigated multimedia exposure to metals, polynuclear aromatic hydrocarbons, pesticides, perfluorooctanoic acid, and more recently on historical and current-use flame retardants. In his studies, he gathers environmental and biological samples in the field, return samples to his laboratories for analysis, and work up the resulting data using sophisticated statistical methods. Ultimately, the exposures determined are combined with health-related data to suggest correlations of these outcomes with the exposures experienced. His research group maintains a busy and effective analytical chemistry laboratory now taking advantage of Emory's Rollins School of Public Health Analytical Exposure Science and Environmental Health Laboratory (AESEHL). Recent focus of his research group's work has been on neurodevelopmental effects of pesticide exposure in children. He was the PI on Emory's Fogarty 1R21ES015465 Early Pesticide Exposure and Neurodevelopmental Outcomes in a Thai Birth Cohort a collaborative effort between Emory and Chiang Mai University in Thailand to investigate associations between early pesticide exposures and adverse neurodevelopmental outcomes in a prospective birth cohort in Chiang Mai Province. As an offshoot of this work, he was also PI on 1RC1ES018299 Validation & Pilot Testing of Methods for Assessing Infants' Dietary Pesticide Exposure which examined methods of analyzing pyrethroid, carbamate and organophosphorus pesticides in human breast milk, infant formula, and baby food. He was also PI on a related study funded by EPA (EPA RD-82939602 Children's Dietary Exposure to Selected Pyrethroids) which had as its principal goal the assessment of the validity of urinary biomarkers of exposure to organophosphate and pyrethroid pesticides in children as a true measure of environmental exposure they encounter. He also played a major role in the National Children's Study, first as a member of the Advisory Committee in the design phase of the investigation and then as a co-investigator on Emory's two contracts HHSN267200700007C (Stoll, PI) and HHSN27520080024C (Hogue, PI). Under the umbrellas of these two large contracts, he was PI on a large Formative Research project focusing on establishing longitudinal variability for salivary biomarker

measurements in pregnant women and in establishing relationships between such measurements and other common biomarkers of exposure found in blood, urine, hair, and nails.

Mark J. Utell

Dr. Mark J. Utell is professor of medicine and environmental medicine, director of occupational and environmental medicine, and former director of pulmonary and critical care medicine at the University of Rochester Medical Center, Rochester, NY. His research interests have centered on the effects of environmental and occupational toxicants on the human respiratory tract. Dr. Utell is principal investigator on a Henry M. Jackson Foundation Grant for the Advancement of Military Medicine (U.S. Department of Defense) to identify “serum indicators of occupational and environmental PAH exposures in burn pit workers”.

Dr. Utell was co-principal investigator of a U.S. EPA Particulate Matter Research Center at the University of Rochester. He is the former chair of the Health Effects Institute’s (HEI) Research Committee and had oversight for several ozone and PM studies funded by HEI. He has served as chair of EPA’s Environmental Health Committee and was a former member of EPA’s Clean Air Science Advisory Committee (CASAC). He serves as Chair of the external science advisory committees to the Harvard EPA Clean Air Research Center; Columbia University’s NIEHS Environmental Health Sciences Center; and the University of North Carolina’s Center for Environmental Medicine, Allergy & Lung Biology. He previously served on the NRC Board on Environmental Studies and Toxicology and was a member of the NRC Committee on Research Priorities for Airborne Particulate Matter.

Dr. Utell has directed and participated in controlled clinical studies and panel studies examining cardiopulmonary responses to air pollutant including ozone and ultrafine particles over the course of many years. In addition to funding from EPA, his air pollution research has been funded by NIH (NHLBI and NIEHS), New York State Energy Development Association (NYSERDA), Electric Power Research Institute (EPRI), HEI, American Petroleum Institute (API), ExxonMobil, and CONCAWE (Conservation of Air and Water in Europe). In 2007, Dr. Utell organized a workshop “Critical considerations in evaluating scientific evidence of health effects of ambient ozone” in Rochester, NY with financial support from API. He is a former recipient of an NIEHS Academic Award in Environmental and Occupational Medicine, an elected fellow of the American Association for the Advancement of Science, and the recipient of the 2013 Mercer Award of the International Society for Aerosols in Medicine and the AAAR (American Association for Aerosol Research). He received his B.A. in psychology from Dartmouth College and his M.D. from Tufts University School of Medicine.

Presenters

Julie E. Goodman

Dr. Julie E. Goodman is an epidemiologist and board-certified toxicologist specializing in human health risk assessment. She is a Principal at Gradient, an environmental consulting firm, and an adjunct faculty member in the Department of Epidemiology at the Harvard T. H. Chan School of Public Health, where she teaches a graduate-level meta-analysis course. Dr. Goodman's primary responsibilities at Gradient include the analysis and interpretation of epidemiology, toxicity, and mode-of-action evidence, apparent disease clusters, and chemical exposures. Over the past decade, much of her work has focused on criteria pollutants (*i.e.*, ozone, PM, NO₂, and SO₂). Some of this work has been funded by TCEQ. Other similar work has been funded by several industry trade organizations, and in the context of litigation support.

Before joining Gradient, Dr. Goodman was a Cancer Prevention Fellow at the National Cancer Institute. She has authored original research articles, review articles, and book chapters on a wide variety of topics; these include weight-of-evidence (WoE) analyses of several substances. She has presented scientific findings and analyses to community groups and regulatory and legislative bodies.

Dr. Goodman has been working with TCEQ on a number of projects. These include an evaluation of how meta-analyses have been or could be applied in the evaluation of health effects of air pollutants, specifically in the context of the NAAQS. She conducted one WoE evaluation of the association between long-term ozone exposure and cardiovascular effects and one on the scientific literature relevant to determining whether ozone exposure has the potential to cause systemic health effects. She also critically reviewed an EPA report exploring potential uses of Next Generation (NexGen) toxicity testing methods and associated interpretation techniques in assessing the risks associated with chemical exposures, *e.g.*, in high-throughput screening programs or detailed quantitative analyses for individual data-rich chemicals, with a focus on ozone. Dr. Goodman worked on a study evaluating whether PM exposure from a forest fire was associated with increased mortality, and has worked on two critiques of the ozone NAAQS review process. Finally, she is working on a systematic review of ozone and asthma exacerbation, as well as a time-series study evaluating the relationship between ozone concentrations and hospitalization rates for asthma in Texas from 2001 to 2011. Dr. Goodman will be a presenter and discussant in the ozone science panel, and she is also on the steering committee of the workshop.

Sabine Lange

Dr. Sabine Lange received a Bachelor's degree in Biomedical Sciences from the University of Western Ontario in Canada in 2003, and a PhD in biochemistry and molecular carcinogenesis from the University of Houston and MD Anderson Cancer Center in 2008. Dr. Lange spent 5 years as a post-doctoral fellow at MD Anderson Cancer Center studying mutagenesis. In mid-2014, she joined the Texas Commission on Environmental Quality (TCEQ) as a Toxicologist where she assesses health effects data of environmental toxicants to determine safe exposure levels to these chemicals.

Since joining TCEQ, Dr. Lange has specialized in the analysis of the data associating ozone exposure with health effects, and she has been involved in the preparation of several manuscripts for publication from this work. She has never received external funding for any work on ozone. Dr. Lange's role in the Independent Workshop on Ozone NAAQS and Science Policy is as a presenter and discussant in the ozone science panel, and she is also on the steering committee of the workshop. Prior to this workshop, she presented background information about ozone mode of action, as well as a new dose-response framework that places ozone human clinical experimental results into a context that makes them easier to use for decision makers. She will summarize this information at the workshop before discussing these and other aspects of the ozone science with the science panelists.

Sonja Sax

Dr. Sonja Sax is an environmental health scientist specializing in exposure assessment and health effects of environmental pollutants, including airborne gases and particles. She earned her Sc.D., in Environmental Science and Engineering from the Harvard T. H. Chan School of Public Health. She is a senior project manager at Gradient, an environmental consulting firm, where she has been actively involved in the investigation of indoor and outdoor air quality problems and regularly performs air dispersion and exposure modeling. She also regularly contributes to the evaluation and interpretation of epidemiological and toxicological studies and in the preparation of technical and expert reports.

Over the past decade, Dr. Sax's work has been primarily focused on ozone and particulate matter. Much of this work has been funded by the Texas Commission of Environmental Quality (TCEQ). Other similar work has been funded by several industry trade organizations, and in the context of litigation support. Prior to working at Gradient, she was a post-doctoral fellow at the Harvard T. H. Chan School of Public Health, where she managed two large exposure assessment projects. She has authored and co-authored original research articles and review articles on a variety of topics, including a weight-of-evidence (WoE) analyses of ozone health effects. She has presented scientific findings and analyses to regulatory and legislative bodies.

Dr. Sax has been working with TCEQ on several projects, including an assessment of how meta-analyses can be applied to the evaluation of health effects of air pollutants. She has worked on several WoE evaluations; one on the evidence of an association between long-term ozone exposure and cardiovascular effects, and another on determining systemic health effects of ozone exposure. Finally, she is working on a systematic review of ozone and asthma exacerbation. Dr. Sax is on the steering committee of this ozone workshop. She presented on using ambient ozone concentrations as surrogates for personal exposure in the pre-workshop webinar and will participate in Session 2.

Michael L. Dourson, Science Panel Facilitator

Dr. Michael L. Dourson is the Director of Toxicology Excellence for Risk Assessment (TERA). He received his PhD in toxicology from the University of Cincinnati in 1980 and is a Diplomate of the American Board of Toxicology (ABT). He has led TERA's development of partnerships among diverse groups to address chemicals of high visibility, such as formaldehyde, perchlorate, chloroform, and soluble nickel, and cooperative ventures such as the Voluntary Children's Chemical Exposure Program, the International Toxicity Estimates for Risk database (available at Toxnet), and the Alliance for Risk Assessment. He also worked 15 years for EPA, holding several leadership roles and winning awards for joint efforts, such as the creation of EPA's Integrated Risk Information System. In 2003, he won the Society of Toxicology (SOT) Lehman award for major contributions that improve the scientific basis of risk assessment. In 2007, he was elected a Fellow of the Academy of Toxicological Sciences. In 2009, he won the International Society of Regulatory Toxicology and Pharmacology's International Achievement Award in recognition of his outstanding contributions nationally and internationally to the advancement of regulatory science. In 2009, he was also selected a Fellow for the Society for Risk Analysis (SRA) for substantial achievement in science relating to risk analysis and service to SRA.

Dr. Dourson has co-published over 150 papers on specific chemical assessments and risk methods, including methods for assessing risk in sensitive subgroups and on use of animal and human data in the assessment of risk. He has also co-authored well over 100 government risk assessment documents, made well over 100 invited presentations, and chaired well over 100 sessions at scientific meetings and independent peer reviews. He has been elected to multiple officer positions in the American Board of Toxicology, the Society of Toxicology (SOT), and the Society for Risk Analysis. In addition to numerous appointments on government panels, such as EPA's Science Advisory Board, he is also a media resource specialist in risk assessment for the SOT, member on the editorial board of several journals, and vice chair of the NSF International Health Advisory Board.

Dr. Dourson's expertise lies in the use of experimental animal and human, including sensitive human, data in deriving safe levels of exposure to various chemicals. He has chaired over 100 chemical or issue specific risk assessment panels, including those devoted to the World Trade Center disaster, the recent chemical spill in the Elk River of West Virginia, and EPA's Science Advisory Board review of the Ammonia Integrated Risk Information System document.

Research funding for TERA is approximately two-thirds government and other nonprofit work, and approximately one-third for industry and industry-related. TERA's projects have included several that were sponsored by the Texas Commission on Environmental Quality, including the present assignment to help organize and conduct this workshop. TERA has organized peer reviews for Health Canada on several of their assessments of air pollutants, including smog, as well as coarse particulate matter, diesel exhaust, and sulphur oxides. Dr. Dourson has not otherwise previously worked on ozone issues directly.

Session 3

Daniel L. Millimet

Dr. Daniel L. Millimet received a BA in economics from the University of Michigan in 1994 and a PhD in economics from Brown University in 1999. He has been a professor in the Department of Economics at Southern Methodist University in Dallas, Texas since 1999. Dr. Millimet is a senior coeditor of *Advances in Econometrics*, an associate editor of *Empirical Economics*, and a co-editor of the *Journal of the Association of Environmental and Resource Economists*. In addition, he has held the position of research associate with the Institute for the Study of Labor (IZA) in Bonn, Germany, since 2008. Dr. Millimet's research has been funded by the U.S. Department of Agriculture, the International Council for Canadian Studies Program, the Commission for Environmental Cooperation, and the Hunger Center of the North Texas Food Bank. Much of this research entails the application of rigorous statistical analysis to observational data in order to test hypotheses concerning interrelationships between environmental policies, environmental quality, and economic outcomes. In particular, Dr. Millimet has studied the causal effect of ozone nonattainment under the Clean Air Act on firm location decisions, the causal effect of environmental policy more broadly on local economic activity, and a variety of economic and political determinants of environmental policy and quality.

Scott Bloomberg

Scott Bloomberg is a Vice President at NERA Economic Consulting in the Energy & Environment group. He has more than 15 years of experience working on energy-related issues. His primary areas of focus are on economic and strategic issues facing the energy and large energy-consuming sectors. Areas of specialization include assessing national and regional effects of proposed environmental regulations and resource planning in the electricity sector. Mr. Bloomberg has helped clients understand the inter-relationships among fuel markets (particularly natural gas and coal), environmental regulation/policy, and technological progress.

With respect to the current ozone NAAQS, Mr. Bloomberg has co-authored reports commenting on the Regulatory Impact Analysis (RIA) and on the potential economic impacts associated with complying with a 65 ppb standard. The National Association of Manufacturers has funded a study on this topic. The Texas Commission on Environmental Quality has also funded a separate, Texas-only study.

Mr. Bloomberg is a member of the Society of Benefit Cost Analysis (SBCA). He holds a BA (with honors) in Economics and Mathematical Methods in the Social Sciences from Northwestern University, and an MBA (with honors) from the University of Chicago, Booth School of Business.

Anne Smith

Dr. Anne Smith is a senior vice president of NERA Economic Consulting and co-head of its Environmental Group. She is an economist and decision analyst who specializes in methods of risk assessment, benefit and cost analysis, and economic impact analysis. A key goal driving her work has been to help make better decisions possible through quality analysis of what is known and not known about the decision options, and through clear communication of analysis insights to decision makers.

Dr. Smith has conducted analyses of a wide range of policy issues, including air quality, food safety, nuclear waste cleanup, and global climate change, working for corporations, research institutions, non-profit organizations, and governments. Dr. Smith has testified before committees of the U.S. Congress on numerous occasions, including on ambient air quality standards. With respect to the current ozone NAAQS review, Dr. Smith has prepared technical comments on EPA's health risk assessments, including both the epidemiology-based and clinical-study based risks. She has also prepared comments on the regulatory impact analysis, and conducted economic impact analyses. Funding for these different studies has come from the Utility Air Regulatory Group, the American Petroleum Institute, the National Association of Manufacturers, and the Electric Power Research Institute. The Texas Commission on Environmental Quality has also funded separate, similar work. She also served on the steering committee for this Independent Ozone Workshop.

Before joining NERA, Dr. Smith headed the Climate & Sustainability Group at Charles River Associates. Prior to that, she headed the Environmental Policy Practice and served on the Board of Directors at Decision Focus Incorporated; earlier she served as a decision analyst at SRI International and as an economist in the Office of Policy Planning and Evaluation at the U.S. Environmental Protection Agency. Dr. Smith received her BA degree in Economics from Duke University and her MA and PhD degrees in Economics from Stanford University, where her studies concentrated in industrial organization, decision sciences, and labor economics. Her PhD degree included a minor in Stanford's Engineering-Economic Systems Department (presently known as the Department of Management Sciences and Engineering).

John F. Morrall III

Dr. John F. Morrall III is an independent contractor and Affiliated Senior Scholar with the Mercatus Center of George Mason University. He is an expert in the areas of regulatory reform and oversight, benefit-cost analysis, Regulatory Impact Analysis (RIA), and risk management. He worked for six Presidents on regulatory policy in the Executive Office of the President from 1975 until September 2008. He was Acting Deputy Administrator for the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget from 2006 to 2007, the highest career position in OIRA. He was the first lead author for OMB's annual *Report to Congress on the Costs and Benefits of Federal Regulations*. He is the recipient of various awards, including a SES Presidential Rank Award from President George W. Bush.

Dr. Morrall has been both a Visiting Economist at the American Enterprise Institute for Public Policy Research and a Brookings Institution Economic Policy Fellow. Prior to his government service he was an Assistant Professor of International Economics at the University of Florida. He has also taught at American University, George Washington University, Indiana University and the University of North Carolina at Chapel Hill.

He received an A.B. from Tufts University, *Magna Cum Laude* in the economics honors program, and a Ph.D. from the University of North Carolina at Chapel Hill also in economics. He is the author of three books and over two dozen articles in the areas of international economics, benefit-cost analysis, labor economics, risk regulation and regulatory policy and reform. Three of his articles have been reproduced in *Classics in Risk Management*. His work has been cited by *the Washington Post*, *the New York Times*, *the Wall Street Journal*, *Business Week*, and *the Economist*. He has also consulted with officials of various foreign governments in over 20 foreign capitals on the United States experience with regulatory reform, RIA and benefit-cost analysis. Dr. Morrall has not received any compensation or done any direct work on the Ozone NAAQS standards from the time he retired from OMB until this conference.

Session 4

Donald R. Arbuckle

Dr. Donald R. Arbuckle came to the Public Affairs program at the University of Texas at Dallas in the fall of 2006. He teaches undergraduate and graduate level courses in public affairs and public policy making. His expertise lies in Federal regulatory affairs, administrative practice, and the practice and politics of the Presidency. He is a Ph.D. adviser, and, in addition, teaches at the Archer Center Summer Graduate Internship Program in Washington, D.C. The class comprises about 20 students chosen by a competitive process from graduate programs throughout the University of Texas System.

In the summer of 2006, Dr. Arbuckle retired after surviving 25 years at the White House Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA). Between 1996 and 2006, he was the career executive in charge of OIRA, the responsibilities of which included Presidential review of regulations and collections of information under the Paperwork Reduction Act; Executive Branch information and information technology policy; and Federal Government statistical policy. In this capacity, he was responsible for review of virtually all EPA regulations, including Presidential review of the agency's Ozone and other NAAQS regulations.

In 1995, Dr. Arbuckle received the Distinguished Service Award, the highest award given by OMB; and in 2001 he was awarded a Meritorious Presidential Rank Achievement Award, one of the highest awards given in the Executive Branch to career executives. He also served for many years as a recruiter for OMB, and was one of the founders in 1987 of the White House Athletic Center.

Before joining OMB in 1981, Dr. Arbuckle served as an analyst at the National Transportation Safety Board. Prior to that, in a singularly ill-timed career move, he accepted a Professorship of American Civilization at Pahlavi University in Shiraz, Iran, where he watched the Iranian Revolution unfold before escaping to Bahrain.

Dr. Arbuckle was educated at Harvard College and has Masters and Ph.D. degrees from the University of Pennsylvania. He served in the U.S. Navy from 1968 to 1972. Dr. Arbuckle's wife Carlisle served as an administrative law judge at the Commerce Department's Patent and Trademark Office until her retirement in 2011. He and his wife have three children spread between Austin, Texas, Chapel Hill, North Carolina, and Jacksonville, Florida.

Charles H. Knauss

Charles H. Knauss is Partner and co-heads Katten's Environmental and Workplace Safety practice, serves on the firm's Board of Directors, and is a nationally recognized leader on most legal and policy issues related to clean air and climate change, having served Congress and in the private sector as counsel to US manufacturing and energy interests for over 30 years. Mr. Knauss received his A.B. in Biology from Brown University and his J.D. from the University of Michigan School of Law.

From 1987-1990, Mr. Knauss served as Minority Counsel to the US House of Representatives Committee on Energy and Commerce acting as lead negotiator for the landmark 1990 Clean Air Act Amendments. He was one of only three House staff required to sign off on every provision of this comprehensive law. After leaving Capitol Hill, Mr. Knauss invested the next 25 years in shepherding the statutory provisions through implementation. EPA Administrator Michael Leavitt appointed Mr. Knauss to serve on the Clean Air Act Advisory Committee, a senior-level policy committee established to advise EPA on issues related to implementing the Clean Air Act. He also founded and is counsel to the Air Permitting Forum, a group of Fortune 100 companies that advocates on Clean Air issues across the country and also develops practical and effective advice for all aspects of the permit process. In addition, Mr. Knauss has successfully represented numerous companies in obtaining Clean Air Act permits for significant energy and manufacturing developments and expansions—particularly important in the face of stringent national ambient air quality standards threatening the survival of a project—and on enforcement actions alleging failure to obtain permits or failure to meet regulatory requirements.

Mr. Knauss is known for his special ability to craft and negotiate effective regulatory and legislative solutions to previously intractable problems, ranging from financial/tax to food-safety to transportation to energy/environmental. In 2015, Knauss was named by the National Law Journal to its inaugural list of 50 Environmental and Energy Trailblazers. *Chambers USA* reports that clients say Chuck: is "an absolutely superb lawyer, top of the list, extraordinarily smart and very strategic in his thinking," "one of the very few top air law practitioners in the country" and "the best air lawyer in DC." His clients include large corporations in the manufacturing and energy sectors, including automotive, aerospace, pharmaceutical, chemical, paper, refinery, conventional and renewable power generation and utility companies.

Thomas A. Lorenzen

Thomas A. Lorenzen is a partner in the Washington, D.C. office of Dorsey & Whitney LLP, focusing on environmental law and the federal rulemaking process. He presently represents numerous companies and trade organizations in connection with EPA's proposed ozone standards, climate change regulations, "Waters of the United States" rule, and regulations governing production of ethanol and other advanced biofuels. He also represents companies requiring counsel in environmental compliance matters, appellate litigation, and administrative actions. From 2004 until joining Dorsey in June 2013, Mr. Lorenzen was an Assistant Chief in the U.S. Department of Justice's Environment and Natural Resources Division. In that role, he supervised the federal government's legal defense of all EPA rules, regulations and other final actions judicially reviewable under the various federal pollution control statutes.

Over his 16-year career at Justice, Mr. Lorenzen managed or personally litigated dozens of seminal environmental cases under the Clean Air Act, Clean Water Act, Safe Drinking Water Act, and other federal pollution control statutes, including *Massachusetts v. EPA* and *Coalition for Responsible Regulation v. EPA* (in which the U.S. Supreme Court upheld the EPA's authority to regulate greenhouse gas emissions under the Clean Air Act and the D.C. Circuit and Supreme Court subsequently upheld most of EPA's first suite of greenhouse gas regulations); *EPA v. EME Homer City Generation* (in which the Supreme Court ultimately upheld EPA's Cross-state Air Pollution Rule); *Entergy Corp. v. Riverkeeper* (in which the Supreme Court affirmed the EPA's authority to weigh costs against benefits in determining how to regulate cooling water intake structures under the Clean Water Act); and many NAAQS establishment and implementation cases. He also worked closely with the White House, EPA and other federal agencies to develop many of the rules that he and his Justice Department team later defended. He is a recipient of numerous Department of Justice awards, including the prestigious John Marshall Award for Providing Legal Advice, awarded by the Attorney General in 2010 for his work with the White House, EPA and the Department of Transportation in developing the Light-duty Motor Vehicle Greenhouse Gas Rule.

Mr. Lorenzen is a highly-regarded lecturer and commentator on matters of environmental and administrative law. He regularly teaches seminars on environmental law, administrative law, and effective appellate advocacy for the American Bar Association, American Law Institute, Environmental Law Institute, D.C. Bar, Minnesota Bar, and local and national law schools. He appears frequently in the pages of *Forbes*, the *Los Angeles Times*, *InsideEPA*, *Greenwire*, *ClimateWire*, the *BNA Daily Environmental Report*, and *Law360*, and has been a guest on PBS's *Nightly Business Report*, NPR's *Marketplace*, C-SPAN, CBS News, and E&ETV.

For 12 years before joining the Department of Justice in 1997, Mr. Lorenzen was in private practice, where he developed expertise in environmental compliance counseling and due diligence, trial court and appellate litigation, and corporate transactional practice. He received his B.A. from UCLA in 1982, and his J.D. from Harvard Law School in 1985.

Paul R. Portney

Dr. Paul R. Portney retired in May of 2014 from the University of Arizona where for nine years he was a Professor of Economics. From 2005-2011 he was dean of the university's Eller College of Management. From 1972-2005 he was with Resources for the Future (RFF), an independent and non-partisan think tank in Washington, DC specializing in energy and environmental research. From 1989-1995 he was RFF's Vice President and was its President and CEO from 1995-2005. He has held visiting teaching positions at UC-Berkeley (1977-79) and Princeton University (1992-94); from 1979-1980 he was the Chief Economist at the Council on Environmental Quality.

Dr. Portney serves on the board of directors for Empire District Electric, a publicly-traded electric and gas utility headquartered in Missouri. In addition, he is a member of the Global Advisory Board of the Institute for Energy Efficiency at UC-Santa Barbara, serves on the board of trustees of the Johnson Foundation in Racine, WI, and is a member of the External Advisory Board for the Graham Institute for Sustainability at the University of Michigan.

Chris G. Whipple, Policy Panel Facilitator

Dr. Chris G. Whipple was a Principal in Environ International's Emeryville, California office until his March 2015 retirement. He still consults for Environ on a part-time basis. His expertise is with the management of risks to health and the environment. Major emphases of his work have been with risks associated with radioactive materials, including radioactive wastes, with hazardous air pollutants and with environmental mercury. In the past, Dr. Whipple has worked on issues regarding air toxics from power plants, especially mercury and radionuclides.

Dr. Whipple has served on numerous national committees to study and advise on radioactive waste management, including committees of the National Academy of Sciences, Environmental Protection Agency, and National Council on Radiation Protection and Measurements (NCRP), of which he is an elected member. He currently serves on NCRP's Program Area Committee on Environmental Radiation and Radioactive Waste and chaired its Nominations Committee in 2015. He was elected to membership in the National Academy of Engineering in 2001 and is a designated National Associate of the National Academies. Dr. Whipple has chaired the National Academy of Sciences Board on Radioactive Waste Management, and NAS Committees on the Review of the Hanford Site's Environmental Remediation Science and Technology Plan, Models in the Regulatory Decision Process, Medical Isotope Production without Highly Enriched Uranium, and the Committee on Risk-Based Approaches for Securing the DOE Nuclear Weapons Complex. He also served two terms on the Academies' Board on Environmental Studies and Toxicology. Dr. Whipple currently co-chairs the Academies' Report Review Committee. He was a charter member of the Society for Risk Analysis and served as its second president. In 1990, he received the society's outstanding service award. He is a Fellow of the American Academy for the Advancement of Science and of the Society for Risk Analysis. His experience prior to joining Environ includes positions as Vice President of ICF Consulting and ICF Kaiser International, and Technical Manager for Environmental Risk Assessment of EPRI's Environment Division. He holds a B.S degree in engineering science from

Purdue University, and an M.S. and Ph.D., also in engineering science, from the California Institute of Technology. In 2004, he received Purdue's Distinguished Engineering Alumni Award.

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Registered Attendees

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Independent Workshop on Ozone NAAQS Science and Policy

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Summer Barber
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BP America Production Company

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