

**EPA'S 2015 OZONE STANDARD:
CONCERNS OVER SCIENCE AND IMPLEMENTATION**

HEARING
BEFORE THE
**COMMITTEE ON SCIENCE, SPACE, AND
TECHNOLOGY**
HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

October 22, 2015

Serial No. 114-44

Printed for the use of the Committee on Science, Space, and Technology



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**EPA'S 2015 OZONE STANDARD:
CONCERNS OVER SCIENCE AND
IMPLEMENTATION**

THURSDAY, OCTOBER 22, 2015

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Committee met, pursuant to call, at 10:10 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Committee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

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Full Committee

***EPA's 2015 Ozone Standard: Concerns Over Science and
Implementation***

Thursday, October 22, 2015
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

The Honorable Jeffrey Holmstead, Partner, Bracewell & Giuliani; Former Assistant
Administrator, Office of Air and Radiation, U.S. Environmental Protection Agency

Mr. Seyed Sadredin, Executive Director and Air Pollution Control Officer, San Joaquin Valley
Air Pollution Control District

Dr. Elena Craft, Senior Health Scientist, Environmental Defense Fund

Dr. Michael Honeycutt, Director, Toxicology Division, Texas Commission on Environmental
Quality

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

HEARING CHARTER

EPA's 2015 Ozone Standard: Concerns Over Science and Implementation

Thursday, October 22, 2015
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

PURPOSE

The House Science, Space and Technology Committee will hold a hearing entitled *EPA's 2015 Ozone Standard: Concerns Over Science and Implementation* on Thursday, October 22, 2015, at 10:00 a.m. in Room 2318 of the Rayburn House Office Building. The purpose of the hearing is to examine the scientific basis of the Environmental Protection Agency's (EPA) final National Ambient Air Quality Standards (NAAQS) for ozone. In addition, witnesses will discuss impacts of these proposed national standards to local communities and address concerns over implementation issues in order to meet these standards.

WITNESSES

- **The Honorable Jeffrey Holmstead**, Partner, Bracewell & Giuliani LLP
- **Mr. Seyed Sadredin**, Executive Director and Air Pollution Control Officer, San Joaquin Valley Air Pollution Control District
- **Dr. Elena Craft**, Senior Health Scientist, Environmental Defense Fund
- **Dr. Michael Honeycutt**, Director, Texas Commission on Environmental Quality, Toxicology Division

BACKGROUND

Ozone (O₃) is a gas that occurs both in the Earth's upper atmosphere as well as at ground level (troposphere). Ozone in the upper atmosphere helps protect the Earth from the sun's harmful rays such as ultraviolet radiation. Ozone at ground level is not directly emitted into the air, but instead is created by chemical reactions between precursor emissions, specifically nitrogen oxide (NOx) and volatile organic compounds (VOC).¹ Ground level ozone is commonly referred to as smog.

¹ <http://www.epa.gov/air/ozonepollution/basic.html>

The Clean Air Act of 1970 (P.L. 91-604, with major legislative updates in 1977 and 1990) directed EPA to set NAAQS for pollutants considered harmful to public health and the environment.² EPA has set standards for six criteria pollutants, including carbon monoxide, lead, nitrogen dioxide, ozone, particle pollution (particulate matter), and sulfur dioxide. The Clean Air Act specifies two categories of standards: primary standards for public health protection and secondary standards for public welfare protection.

The Clean Air Act requires EPA to review the NAAQS every five years to ensure adequate health and environmental protection is being provided. In 1997, EPA replaced the existing ozone NAAQS with an 8-hour standard of 84 parts per billion (using standard rounding conventions). In 2008, EPA issued a final rule revising the ozone standard to a level of 75 parts per billion.³ Last February, EPA finalized⁴ a new set of requirements that state, tribal, and local air quality management agencies must meet for areas where air quality exceeds the 2008 NAAQS.⁵ In July 2011, outside of the normal five year review process, EPA submitted a rule for reconsideration of the 2008 ozone NAAQS that President Obama then subsequently withdrew in September 2011.⁶

Based on the advice of the Clean Air Scientific Advisory Committee (CASAC), the EPA proposed an updated ozone NAAQS which appeared in the Federal Register on December 17, 2014.⁷ The proposal would set more stringent standards, by lowering the primary standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. Publication in the Federal Register begins the public comment period that ended on March 17, 2015. The agency must address significant public comments when it publishes the final standard. On October 1, 2015 the EPA finalized the primary standard for ozone to 70 ppb.

COMPLIANCE WITH THE NAAQS

When the EPA revises the NAAQS for ozone, it must designate areas in the US which meet *attainment* or *nonattainment* of the standard. Attainment refers to a state or region complying with federal regulations, while nonattainment is an area that exceeds the regulated limit. States must individually develop a plan to comply with the NAAQS, including proposals for bringing nonattainment areas into attainment. Reductions in ozone levels can be achieved by a variety of methods including pollution control technologies. Ozone control technologies generally target nitrogen oxides (NOx) and volatile organic compounds (VOCs). Control strategies focus on mission limits along with control equipment that may address specific industrial processes. State environmental agencies must then develop State Implementation Plans (SIPs).⁸ Specifically, after each revised NAAQS is promulgated, both the EPA and states must undertake the following actions:

² <http://www.epa.gov/air/criteria.html>

³ <http://www.gpo.gov/fdsys/pkg/FR-2008-03-27/html/E8-5645.htm>

⁴ <http://www.epa.gov/groundlevelozone/actions.html#feb2015i>

⁵ <http://www.epa.gov/groundlevelozone/pdfs/20150213fr.pdf>

⁶ <http://www.whitehouse.gov/the-press-office/2011/09/02/statement-president-ozone-national-ambient-air-quality-standards>

⁷ <http://www.gpo.gov/fdsys/pkg/FR-2014-12-17/pdf/2014-28674.pdf>

⁸ <http://www.epa.gov/airquality/urbanair/sipstatus/overview.html>

- **“Within two years after NAAQS promulgation:** With input from the states and tribes, EPA must identify or ‘designate’ areas as meeting (attainment areas) or not meeting (nonattainment areas) the standards. Designations are based on the most recent set of air monitoring data.
- **Within three years after NAAQS promulgation:** All states must submit plans, known as state implementation plans (SIPs), to show they have the basic air quality management program components in place to implement a new or revised NAAQS, as specified in Clean Air Act section 110.
- **Within 18-36 months after designations:** Due dates for nonattainment area SIPs are based on the area designation date and vary by pollutant and area classification. SIPs for Ozone, PM_{2.5}, and CO nonattainment areas are generally due within 36 months from the date of designation. Each nonattainment area SIP must outline the strategies and emissions control measures that show how the area will improve air quality and meet the NAAQS. In addition, the CAA mandates that areas adopt certain specified control requirements.”⁹

After a state submits its implementation plan, EPA then reviews and either approves it in full, in part, or disapproves. The public has an opportunity to submit comments on EPA’s proposed actions. If a state fails to submit a plan or if EPA disapproves of the plan, EPA is required to develop a federal implementation plan.¹⁰

SECONDARY STANDARD

In addition to issuing the primary standard, the EPA is required to issue secondary standards that protect the public welfare under Section 109 of the Clean Air Act. The secondary standard is intended to protect ecosystems and sensitive plants. Currently, the secondary ozone standard is equal to the primary ozone standard, based on short-term (8 hour) average concentration measurements. However, plants and foliage are more sensitive to long-term cumulative ozone exposure, causing stunted growth or injury. A cumulative index of exposure is better correlated with plant growth effects than the 8-hour average concentration used to measure human health effects. An appropriate cumulative index must consider not only ambient concentrations of ozone but also other relevant physiological processes.¹¹

ADDITIONAL READING

- U.S. Environmental Protection Agency, National Ambient Air Quality Standards for Ozone, Proposed Rule. Available at: <https://www.federalregister.gov/articles/2014/12/17/2014-28674/national-ambient-air-quality-standards-for-ozone>
- U.S. Environmental Protection Agency, Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone. Available at: <http://www.epa.gov/ttn/ecas/regdata/RIAs/20141125ria.pdf>

⁹ <http://www.epa.gov/airquality/urbanair/sipstatus/process.html>

¹⁰ Ibid

¹¹ pp 75316 of the Federal Register, Proposed Rule, National Ambient Air Quality Standards for Ozone

Appendix A:

Table of Historical Ozone NAAQS¹²

Final Rule/Decision	Primary/Secondary	Indicator	Averaging Time	Level	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

¹² http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_history.html

Appendix B:

Percent Change in Air Quality¹³

	1980 vs. 2013	1990 vs. 2013	2000 vs. 2013
Carbon Monoxide (CO)	-84	-76	-59
Ozone (O₃) (8-hr)	-33	-23	-18
Lead (Pb)	-92	-87	-60
Nitrogen Dioxide (NO₂) (annual)	-58	-50	-40
Nitrogen Dioxide (NO₂) (1-hour)	-60	-46	-29
PM₁₀ (24-hr)	---	-34	-30
PM_{2.5} (annual)	---	---	-34
PM_{2.5} (24-hr)	---	---	-34
Sulfur Dioxide (SO₂) (1-hour)	-81	-76	-62

Notes:

1. --- Trend data not available
2. Negative numbers indicate improvements in air quality
3. In 2010, EPA established new 1-hour average National Ambient Air Quality Standards for NO₂ and SO₂

¹³ <http://www.epa.gov/airtrends/aqtrends.html>

Appendix C:

Percent Change in Emissions:¹⁴

	1980 vs. 2013	1990 vs. 2013	2000 vs. 2013
Carbon Monoxide (CO)	-67	-59	-42
Lead (Pb)	-99	-80	-50
Nitrogen Oxides (NO_x)	-52	-48	-41
Volatile Organic Compounds (VOC)	-53	-39	-18
Direct PM₁₀	-50	-20	-17
Direct PM_{2.5}	---	-24	-32
Sulfur Dioxide (SO₂)	-81	-78	-69

Notes:

1. --- Trend data not available
2. Direct PM10 emissions for 1980 are based on data since 1985
3. Negative numbers indicate reductions in emissions
4. Percent change in emissions based on thousand tons units

National and local air quality trends graphs showing the nation's progress towards clean air are available for: carbon monoxide (CO), ozone (O₃), lead (Pb), nitrogen dioxide (NO₂), particulate matter (PM), and sulfur dioxide (SO₂).

¹⁴ <http://www.epa.gov/airtrends/aqtrrends.html>

Chairman SMITH. The Committee on Science, Space, and Technology will come to order. Without objection, the Chair is authorized to declare recesses of the Committee at any time.

Welcome to today's hearing entitled "EPA's 2015 Ozone Standard: Concerns Over Science and Implementation."

I'll recognize myself for an opening statement and then the Ranking Member.

Today's hearing is on the Environmental Protection Agency's 2015 National Ambient Air Quality Standards for ozone.

The EPA is required to review the ozone standard every five years, but the agency is not required to set new standards. The 2008 standard of 75 parts per billion is just now being implemented, and many states have not had the opportunity to meet the 2008 standard since guidance from the EPA for this standard was not made public until February. However, earlier this month, the EPA further reduced the standard to 70 parts per billion.

At our previous Committee hearings on the EPA's ozone rule, witnesses testified that further reduction of the standard is premature and unnecessary due to the lack of any sound science, and the negative impact it will have on our economy. Unfortunately, the EPA did not address the serious concerns raised by these witnesses. Our hearing today will review the impact of this final rule.

According to EPA's own website—and I think we have a chart to show.

[Slide.]

Chairman SMITH. There it is. Since 1980, ozone levels have decreased by 33 percent. The air we breathe is significantly cleaner and will continue to improve thanks to new technologies. However, many of the technologies that the EPA forces states to use either do not currently exist or will be overly expensive.

At the reduced ozone standard, over 60 percent of the costs of the program are based on technology that does not currently exist. The EPA assumes this technology will somehow be developed to implement their stringent regulations. And these proposed standards are impossible to meet in some places where the ozone level that occurs naturally would be above the standard set by the EPA. Many of these communities would be responsible for ozone that they do not have the ability to control. Wind-blown ozone from countries like China and Mexico further complicate the ability of the U.S. to meet the existing ozone standards.

Ozone scientists Dr. Allen Lefohn and Dr. Owen Cooper raised concerns that "the air transport of urban pollution to rural areas is important for nonattainment considerations."

The EPA has failed to adequately consider these issues. This new ozone rule could cause many areas throughout the United States to be out of compliance with the Clean Air Act through no fault of their own.

A nonattainment designation under the Clean Air Act has serious consequences. It could cause new employers to not move into the state. Businesses would be forced to deal with additional burdensome permitting and compliance obligations, which slow expansion and economic development. Ultimately, good jobs will be lost in these areas.

I am also concerned that the EPA's justification for this rule is not based on good science. In August, I sent both the EPA and the Office of Management and Budget (OMB) letters in which I raised concerns about the proposed rule's overreliance on one study, parts of which contradict previous peer-reviewed studies. My letter also questioned if EPA and OMB properly addressed the issue of background ozone that witnesses raised in previous Science Committee testimony when EPA determined the final standard. I am concerned that neither agency adequately considered background ozone or the overreliance on one study.

Unfortunately, neither agency has provided the information I requested. While EPA claims to base its regulations on the best available science, unless the EPA can prove otherwise, it appears that their claims are nothing more than political rhetoric.

Good science should dictate policy. However, it appears that the EPA conveniently cherry-picks the science that supports its extreme agenda. This is not sound science; it is science fiction. Furthermore, the EPA has regularly chosen to disregard inconvenient scientific conclusions and muzzle dissenting voices.

Today's witnesses will testify on how this proposed rule will impact American small businesses and job creation.

[The prepared statement of Chairman Smith follows:]

PREPARED STATEMENT OF COMMITTEE CHAIRMAN LAMAR S. SMITH

Today's hearing is on the Environmental Protection Agency's (EPA's) 2015 National Ambient Air Quality Standards for ozone.

The EPA is required to review the ozone standard every five years, but the agency is not required to set new standards.

The 2008 standard of 75 parts per billion is just now being implemented. And many states have not had the opportunity to meet the 2008 standard since guidance from the EPA for this standard was not made public until February. However, earlier this month, the EPA further reduced the standard to 70 parts per billion.

At our previous Committee hearings on the EPA's ozone rule, witnesses testified that further reduction of the standard is premature and unnecessary due to the lack of any sound science and the negative impact it will have on our economy. Unfortunately, the EPA did not address the serious concerns raised by these witnesses.

Our hearing today will review the impact of this final rule. According to EPA's own website, since 1980 ozone levels have decreased by 33 percent. The air we breathe is significantly cleaner and will continue to improve thanks to new technologies. However, many of the technologies that the EPA forces states to use either do not currently exist or will be overly expensive.

At the reduced ozone standard, over 60 percent of the costs of the program are based on technology that does not currently exist. The EPA assumes this technology will somehow be developed to implement their stringent regulations.

And these proposed standards are impossible to meet in some places where the ozone level that occurs naturally would be above the standard set by the EPA. Many of these communities would be responsible for ozone that they do not have the ability to control.

Wind-blown ozone from countries like China and Mexico further complicate the ability of the U.S. to meet the existing ozone standards.

Ozone Scientists Dr. Allen Lefohn and Dr. Owen Cooper raised concerns that, "[T]he [air] transport of urban pollution to rural areas is important for nonattainment considerations."

The EPA has failed to adequately consider these issues. This new ozone rule could cause many areas throughout the United States to be out of compliance with the Clean Air Act through no fault of their own.

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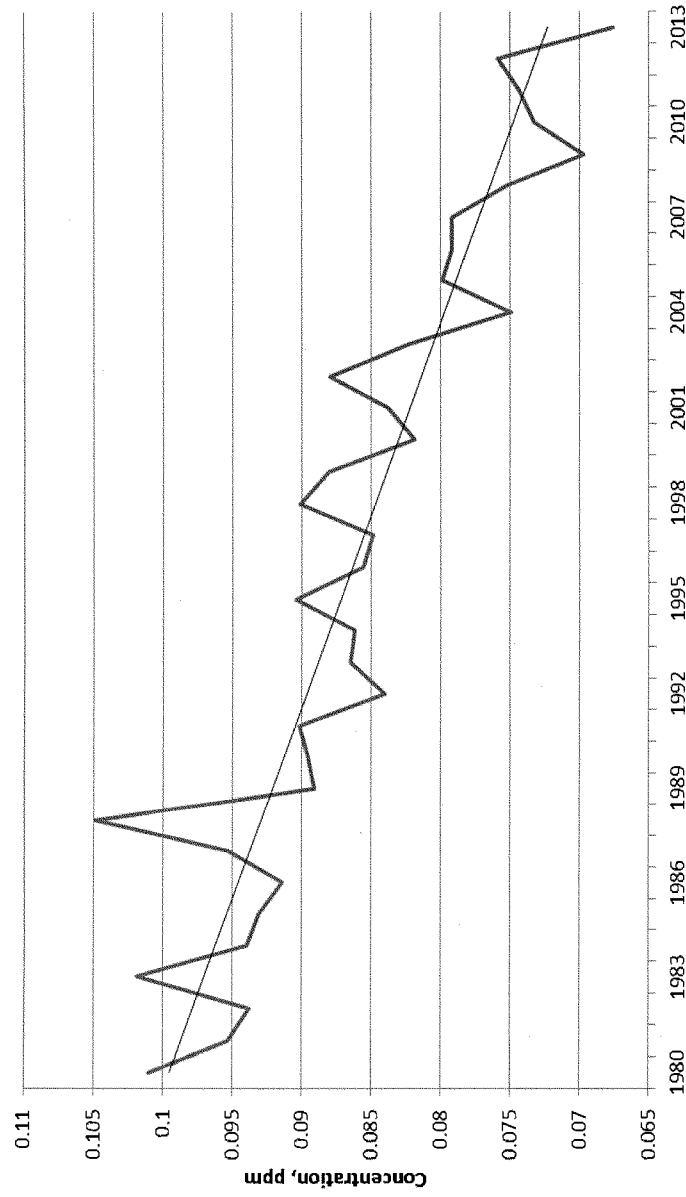
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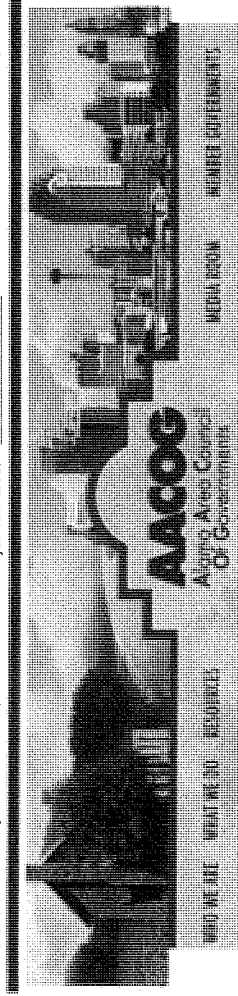
Today's witnesses will testify on how this proposed rule will impact American small businesses and job creation.

Ozone Concentrations, 1980-2013
Annual 4th Maximum of Daily Max 8-Hour Average
National Trend Based on 222 Sites



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proposed growth, and transportation planners may be required to prove that adding capacity to the roadway system would not increase pollution from cars and trucks to qualify for federal highway funds for roadway improvements. At the more stringent "Moderate" level, all the requirements at the Marginal level plus others—such as vehicle emissions inspections—would be made mandatory.

The EPA's announcement that it will lower the amount of acceptable ozone was not a surprise. The EPA had first announced in 2010 that it would be lowering the standard somewhere within the range of 60 to 70 ppb. Many other countries have also adjusted their standards, for example, Canada reset its fourth highest, 8-hour daily maximum threshold to 63 ppb earlier this year.

The Alamo Area Council of Governments (AACOG) Air Improvement Resources (AIR) Executive Committee (which represents a collective voice concerning air quality for the San Antonio-New Braunfels Metropolitan Statistical Area (MSA) through the composition of its membership), have partnered together in a region-wide strategy to attain the new federal standard for ground-level ozone through the recommendation of voluntary air quality control measures. All control measures identified as appropriate for local government adoption by the Air Improvement Resources (AIR) Executive Committee will be taken to all local counties and municipalities for consideration.

AACOG's Natural Resources Director Brenda Williams said, "Up to this point, the region has relied on the voluntary efforts of several leaders, such as the City of San Antonio and CPS Energy, to improve our air. We can no longer rely on the efforts of such leaders alone. While our government partners have resolved to work in a concerted effort to address our air quality challenge, it is AACOG's hope that every business in the area, however large or small, will also take steps to help improve the air, whether it be by allowing more flexible scheduling for employees to avoid peak traffic times or by making their offices, shops, or other facilities more energy efficient."

**AACOG's AIR Executive Committee includes elected officials and representatives from the following counties, cities and planning organizations: Atascosa County; Bandera County; Bexar County; Comal County; Guadalupe County; Kendall County; Medina County; Wilson County; City of Bandera; City of Boerne; City of Floresville; City of Hondo; City of New Braunfels; City of Pleasanton; City of San Antonio; City of Seguin; Alamo Area Council of Governments (AACOG); Alamo Regional Rural Planning Organization; Greater Bexar County Council of Cities (GBCCC); and Alamo Area Metropolitan Planning*

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For more information, contact Brenda Williams, at (210) 362-5246 or

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Chairman SMITH. That concludes my opening statement, and the gentlewoman from Texas, Ms. Eddie Bernice Johnson, is recognized for hers.

Ms. JOHNSON OF TEXAS. Thank you very much, Mr. Chairman. And I must say that at the end of my statement, I have to depart to go to another committee where we are marking up for the first time in some years a Transportation Committee bill—a transportation bill.

But I want to thank you for holding this hearing, and say good morning and welcome to all of our witnesses. I know that the Chairman was very cooperative in postponing this hearing to try to accommodate our witness, who suffered a medical emergency. And while he's still recovering and unable to travel, I'm very pleased to welcome Dr. Elena Craft, who will be providing testimony this morning.

There really is no question that reducing ozone levels from 75 parts per billion to 70 parts per billion will have positive human health and economic benefits throughout the country. While the new rule is not as ambiguous as health professionals had hoped for, it will still have—ambitious, I mean, as the health professionals hoped, it will still have real and meaningful positive impact on the health of all Americans.

Some will likely argue that implementing a lower ozone standard would kill jobs and the economy. We hear it all the time. Some of my colleagues may also suggest that we wait and not, as they say, shift the goalposts with new rules because ozone levels have dropped by 33 percent—you just saw that chart—since 1980. In short, they will use our current success as an excuse to stop trying to do better. They will also attempt to raise doubts about the scientific evidence justifying the new standard and will exaggerate the costs of its implementation.

These kinds of tactics have been used before. Back in the 1960s, the tobacco industry devised a strategy to counter a growing body of scientific and medical evidence that tobacco products unquestionably caused harm. Publicly available tobacco industry documents lay out a detailed strategy that reads in part “doubt is our product since it is the best means of competing with the body of fact that exist in the minds of the general public. It is also the means of establishing a controversy.”

Thus, in any form they could, tobacco industry scientists attempted to raise doubts about the science, doubts about the scientific models used by government scientists that highlighted the negative health effects of tobacco and secondhand smoke. Tobacco executives also emphasized concerns about the economic impact of proposed regulations on the industry and the economy at large.

This strategy served the tobacco industry well, postponing effective action for years, but the American public paid the price in a lower quality of life, increased medical costs, and lost earnings and shortened lives. This same strategy has been mimicked by the oil and gas industry and its attempt to question the scientific evidence pointing to the climate change.

Unfortunately, the Committee has become a favorite forum for rolling out these tactics. We will hear today for the fourth time in five years from you Dr. Michael Honeycutt from my home State

about—from the office of environmental regulations, the Texas Commission on Environmental Quality (TCEQ) which appears to be employing tactics that I've just described.

Instead of following the science supporting a reduction in the levels of ozone pollution, TCEQ, along with the industry, has waged a public media campaign that is not fooling Dallas, a conservative city—but people in Dallas don't believe you—geared toward raising doubts about the science and alleging dire economic consequences of implementing these new health-based standards.

Recent news stories have questioned why the agency spent \$2 million hiring a scientific organization that previously did substantive work for the tobacco industry to help TCEQ raise doubts about the EPA's ozone rule. Americans are not fooled by these tactics anymore.

Time and time again, the evidence shows that, on balance, jobs are created and the economy expands following the passage of major environmental reforms. Stricter pollution limits force us to innovate and create new technologies. With a fair national regulatory system that protects the public, companies do well by doing good.

As it relates to this new ozone rule, EPA estimates the benefits to be more than double the cost, that is, benefits of 2.9 to \$5.9 billion annually compared to the cost of 1.4 billion. Such a return on investment should prove the obvious: that when the environment is healthy, the economy is healthy, too.

For millions of Americans who are suffering from respiratory illnesses such as asthma, ozone pollution has a real and destructive effect on them and their families. Hospital records show it and prove it.

As someone who worked in the public health field before I entered politics, I'm very sensitive to the impacts poor air quality can have on the health of individuals, especially the young, the infirm, and the poor. Unfortunately, those of us from the Dallas-Fort Worth region are very familiar with the negative effects of ozone causing smog and are accustomed to seeing health alerts warning us that the air outside is too polluted for us to breathe safely.

I am attaching to my statement a report compiled by the minority staff that includes excerpts from some 430,000 written comments on the ozone rule by health professionals and others supportive of EPA's actions to reduce ozone pollution.

Mr. Chairman, a strong economy and a healthy environment are not mutually exclusive. We can have both, and we should strive to continue to improve the environment and the air we breathe. I believe EPA's new ozone regulations will help take us to the right direction.

Thank you, Mr. Chairman. I yield back.

[The prepared statement of Ms. Johnson of Texas follows:]

PREPARED STATEMENT OF COMMITTEE RANKING MEMBER
EDDIE BERNICE JOHNSON

Thank you, Mr. Chairman. Good morning and welcome to our witnesses. First, I'd like to thank the Chairman for agreeing to postpone this hearing to try and accommodate our witness who suffered a medical emergency. Unfortunately, Dr. Mark

Mitchell is still not well enough to travel, but I appreciate the consideration showed by the Chairman.

Now, as someone who worked in the public health field before I entered politics, I am very sensitive to the impact poor air quality can have on the health of individuals, especially the young, the infirm, and the poor. Unfortunately, those of us from the Dallas-Fort Worth region are very familiar with the negative effects of smog and are accustomed to seeing health alerts warning us that the air outside is too polluted for us to breathe safely. This year, Dallas has already experienced 32 days where ozone levels exceeded 75 parts-per-billion for more than 8 hours.

For the millions suffering from respiratory diseases, including the 26 million Americans with asthma, which impacts 10-percent of all children, ozone pollution has a real and destructive effect on them and their families. It also negatively impacts the entire economy, resulting in both high healthcare costs and significant lost economic productivity. Reducing ozone levels from 75 parts per billion to 70 parts per billion will have positive human health and economic impacts throughout the country.

And while those of my colleagues and the industries who are opposed to virtually all environmental regulations often forget this point, the Clean Air Act requires that the ozone standard be based on science alone. It explicitly prohibits the EPA from considering economic costs when setting the standard, and rightfully puts the health and well-being of Americans first. The new rule is not as ambitious as health professionals had hoped for, but it will still have a real and meaningful positive impact on the health of all Americans. The scientific evidence supporting the benefits of reduced levels of ozone is clear, consistent, and growing.

Some will likely argue that implementing a lower ozone standard will kill jobs and the economy. Some of my colleagues may also suggest that we wait, and not, as they say, "shift the goal posts" with this new rule because ozone levels have dropped by 33 percent since 1980. In short, they will use our current success as an excuse to stop trying to do better. They will also attempt to raise doubts about the scientific evidence justifying the new standard and will exaggerate the costs of its implementation.

These kinds of tactics have been used before. Back in the 1960's, the tobacco industry devised a strategy to counter a growing body of scientific and medical evidence that tobacco products unquestionably caused harm. Publically available tobacco industry documents lay out a detailed strategy that reads in part:

"Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public. It is also the means of establishing a controversy."

Thus, in any forum they could, tobacco industry scientists attempted to raise doubts about the science, doubts about the medical harm from cigarettes, and doubts about the scientific models used by government scientists that highlighted the negative health effects of tobacco and second-hand smoke. In addition, tobacco industry executives emphasized concerns about the economic impact of proposed tobacco regulations on their industry and the economy at large.

This strategy served the tobacco industry well, postponing effective action for years. The profits enabled by these public relations-based attacks on science went to the companies, but the American public paid the price in a lower quality of life, increased medical costs, lost earnings, and shortened lives. This same strategy has been mimicked by the oil and gas industry in its attempt to question the scientific evidence pointing to climate change. Unfortunately, this Committee has become a favorite forum for rolling out these tactics during consideration of federal regulation of harmful chemicals that harm the environment and endanger the public's health.

We will hear today, for the fourth time in five years, from Dr. Michael Honeycutt, from my home state's office of environmental regulation, the Texas Commission on Environmental Quality or T-C-E-Q; which appears to be employing the tactics that I've just described. Instead of following the science supporting a reduction in the levels of ozone pollution, TCEQ along with industry has waged a public media campaign geared to raising doubts about the science and alleging dire economic consequences of implementing these new health based standards. Recent news stories have questioned why the agency spent nearly \$2 million hiring a scientific organization that previously did substantive work for the tobacco industry to help TCEQ raise doubts about the EPA's ozone rule. As a Texas resident, I have questions about why my tax dollars would be used that way too. I hope that in her testimony Dr. Elena Craft from the Austin office of the Environmental Defense Fund can help describe the body of scientific data on which the new ozone rule is based and also explain the criticisms of both TCEQ and the tactics used by industry to oppose the new ozone rule.

Americans are not fooled by these tactics any more. Time and again, the evidence shows that on balance, jobs are created and the economy expands following the passage of major environmental reforms. Stricter pollution limits force innovation and create new technologies. With a fair national regulatory system that protects the public, companies can do well by doing good. As it relates to this new ozone rule, EPA estimates its benefits to be more than double the costs—that is, benefits of \$2.9 to \$5.9 billion annually compared to costs of \$1.4 billion. Such a return on investment should prove the obvious: that when the environment is healthy, the economy is healthy too.

The American Heart Association, American Lung Association, American Medical Association, and many other public health organizations have all supported lowering the ozone standard to 60 parts-per-billion, which they argue would prevent up to 7,900 premature deaths annually, 1.8 million asthma attacks in children and 1.9 million missed school days nationwide. But they believe any lowering of the ozone standard is a good first step. The community of medical and public health professionals does not believe there is any doubt that reducing ozone levels is a necessary step to help better protect the public's health from the real effects of ozone pollution.

I am attaching to my statement a short compilation that includes a small segment of the 430,000 written comments on the ozone rule by health professionals and others supportive of the EPA's efforts to do their job and protect the environment and the public's health.

Mr. Chairman, a strong economy and a healthy environment are not mutually exclusive. We can have both, and we should strive to continue to improve the environment and the air we breathe. I believe EPA's new ozone regulations will help take us in the right direction.

Thank you, Mr. Chairman, and I yield back.

Chairman SMITH. Thank you, Ms. Johnson.

And the gentleman from Oklahoma, Mr. Bridenstine, the Chairman of the Environment Subcommittee, is recognized for an opening statement.

Mr. BRIDENSTINE. Thank you so much, Mr. Chairman.

To remind folks, today's hearing focuses on the EPA's final rule announced earlier this month to lower the National Ambient Air Quality Standards for ozone to 70 parts per billion down from the current standard of 75 parts per billion. Nothing in today's hearing is regarding tobacco necessarily, as far as I know.

This hearing comes at a critical time as we must carefully review the science, impact, and achievability of this final regulation, a regulation with heavy compliance costs but questionable environmental benefits.

Across the country, ozone levels and emissions for volatile organic compounds have been reduced significantly over the past few decades. My home State of Oklahoma is among those constantly working to improve air quality. Despite this, it is concerning that the EPA is proposing to tighten the standard, and I will remind my colleagues that the existing standard set in 2008 has yet to be fully implemented, and the guidance for State Implementation Plans was only released this past February by the EPA. States must be given a chance to comply with the existing standard before being imposed another onerous set of standards that are not achievable.

This year, this committee has had several hearings to examine this complicated and massive regulation. Here are some of the important facts that we have learned from these hearings: Number one, just one study consisting of 31 participants is being used as the main scientific justification of the costliest regulation in the history of the country according to Dr. Allen Lefohn, a leader in ozone research.

Number two, witnesses testified that natural background ozone contributes a significant amount to the observed total ozone con-

centrations, and with this proposed standard, background or natural ozone may become the main reason areas across the United States exceed the standard. Further, there are even many national parks in the West which regularly will exceed the new standard based on natural ozone.

Contributions from wildfires to the ozone level are considered a part of background. Tightening the existing ozone standards may cause even more unintentional fires of greater intensity as the use of prescribed controlled fires may be limited. This has serious implications, especially to rural and remote areas.

While EPA claims that there are mechanisms to deal with background ozone, EPA has yet to provide details. This is especially true regarding implementation of its Exceptional Event Rule demonstrations. According to testimony of Ms. Cara Keslar from Wyoming's Department of Environmental Quality, "Wyoming has submitted five stratospheric intrusion demonstrations." They submitted five. "One demonstration has been concurred with, and four have yet to be even acted on by the EPA." This is an unacceptable track record, and it is imposing costs on people that can't do anything about the background ozone level.

Number five, rural areas will be hit especially hard by the Clean Air Act's transportation conformity requirements, which could mean withholding of federal highway funds if an area is in nonattainment. Again, this is bureaucratic bullying by the federal government against the states, and it needs to stop.

According to the Oklahoma Department of Transportation, "rural areas do not have the resources to achieve sufficient reductions of pollutants. The proposed action would be detrimental to social and economic development for rural areas across the State of Oklahoma."

Beyond these concerns, it remains troubling to me that those who will bear this regulation's compliance costs may also suffer a decline in their health status. Not surprisingly, the EPA did not include the premature deaths caused by the loss of disposable income when considering the true impact of this standard.

Furthermore, millions of senior citizens living on fixed incomes and low-income Americans may be forced to choose between medications, paying for heat, or paying for their food. Moreover, other existing and proposed EPA regulations such as the proposed Clean Power Plan will further exacerbate the negative economic impact.

This hearing is critical because Congress has the obligation to ensure the EPA adheres to the intent of the Clean Air Act, that the science behind any rule is sound, and that the totality of the impact of any rule is taken into account. We need to understand the totality of the impact.

Before I yield back, I would like to submit a few documents for the record. The first is a group of letters from state and local officials opposing the rule.

The next is a map showing that nearly the entire State of Oklahoma, even some of the more rural areas, will be in nonattainment.

This would be devastating to my state, which is already working very hard on its own, and has been successful, as a matter of fact, to reduce ozone.

I want to thank each of the witnesses for coming this morning, and I look forward to hearing your testimony.
 I yield back the balance of my time, Mr. Chairman.
 [The prepared statement of Mr. Bridenstine follows:]

PREPARED STATEMENT OF ENVIRONMENT SUBCOMMITTEE CHAIRMAN JIM
 BRIDENSTINE

Today's hearing focuses on the Environmental Protection Agency's final rule, announced earlier this month, to lower National Ambient Air Quality Standards for ozone to 70 parts per billion, down from the current standard of 75 ppb.

This hearing comes at a critical time as we must carefully review the science, impact and achievability of this final regulation, a regulation with heavy compliance costs but questionable environmental benefits.

Across the country, ozone levels and emissions for volatile organic compounds have been reduced significantly over the past few decades. My home state of Oklahoma is among those constantly working to improve air quality.

Despite this, it is concerning that the EPA is proposing to tighten the standard, especially since the existing standard, set in 2008, has yet to be fully implemented—and I will remind my colleagues that this is due to the fact that the guidance for state implementation plans was only released this past February by the EPA. States must be given a chance to comply with the existing standard before being imposed another onerous set of standards that are not achievable.

This year, this Committee has held several hearings to examine this complicated and massive regulation. Here are some important facts that we have learned from these hearings:

1. Just one study consisting of 31 participants is being used as the scientific justification of the costliest regulation in the history of this country, according to Dr. Allen Lefohn, a leader in environmental research.
2. Witnesses testified that background ozone contributes a significant amount to the observed total ozone concentrations, and with this proposed standard, background or natural ozone may become the main reason certain areas across the U.S. exceed the standard. Further, there are many national parks in the west which regularly exceed the new standard.
3. Contributions from wildfires to the ozone level are considered a part of background. Tightening the existing ozone standards may cause more unintentional fires of greater intensity as the use of prescribed, controlled fires may be limited. This has serious implications, especially to rural and remote areas.
4. While EPA claims that there are mechanisms to deal with background ozone, EPA has yet to provide details. This is especially true regarding implementation of its Exceptional Event Rule Demonstrations. According to the testimony of Ms. Kara Keslar from Wyoming's Department of Environmental Quality:

"Wyoming has submitted five stratospheric intrusion demonstrations. One demonstration has been concurred with and four have not yet been acted on by EPA." This is an unacceptable track record.

5. Rural areas will be hit especially hard by the Clean Air Act's transportation conformity requirements, which could mean the withholding of federal highway funds if an area is in non-attainment. According to the Oklahoma's Department of Transportation, "Rural areas do not have the resources to achieve sufficient reductions of pollutants. The proposed action would be detrimental to social and economic development for rural areas across the state of Oklahoma."

Beyond these concerns, it remains troubling to me that those who will bear this regulation's compliance costs may also suffer a decline in their health status. Not surprisingly, the EPA did not include the premature deaths caused by the loss of disposable income when considering the true impact of this standard.

Furthermore, millions of senior citizens living on fixed incomes and low-income Americans may be forced to choose between medications, paying for heat, or for their food. Moreover, other existing and proposed EPA regulations such as the proposed Clean Power Plan will further exacerbate the negative economic impact.

This hearing is critical because Congress has the obligation to ensure the EPA adheres to the intent of the Clean Air Act, that the science behind any rule is sound, and that the totality of the impact of any rule is taken into account.

I want to thank each of the witnesses for coming this afternoon and I look forward to hearing their testimony. I yield back the balance of my time.

Chairman SMITH. Thank you, Mr. Bridenstine.

And the gentlewoman from Oregon, Ms. Bonamici, the Ranking Member of the Environment Subcommittee, is recognized for an opening statement.

Ms. BONAMICI. Thank you very much, Mr. Chairman. And thank you to our witnesses for being here today to discuss the Environmental Protection Agency's final National Ambient Air Quality Standards for ozone.

Last week, the EPA took a step in the right direction to maintain clean air and healthy environment for our country. The new standard of 70 parts per billion is not as ambitious as some might have hoped for, but it will have a real and meaningful effect on the health of all Americans.

At a hearing earlier this year on the topic of ozone, one of the witnesses before the Committee, Dr. Mary Rice, stated that there is clear, consistent, and conclusive scientific evidence in support of a standard lower than the current level of 75 parts per billion. She also indicated that the scientific evidence available seven years ago has been supplemented by an even greater understanding of the health effects of ozone exposure.

We must not overlook this point. The Clean Air Act, as passed by Congress, requires that the ozone standard be based on science and health. It prohibits the EPA from considering costs when setting the standard, and it rightfully puts the health and well-being of Americans first.

Despite this fact, we will hear today that implementing a lower ozone standard will have devastating consequences to the economy, but has been shown time and time again, the evidence shows that, on balance, jobs are created and the economy expands following the passage of major environmental reforms.

Regarding this rule, the EPA estimates the benefits to be more than double the costs, that is, benefits of 2.9 to 5.9 billion annually compared to costs of 1.4 billion. Such a return on investment should prove the obvious: that when the environment is healthy, the economy is healthy.

We are already seeing positive results from strong action to protect the air. Since 1980, ozone levels have dropped by 33 percent. Now is not the time to rest on our accomplishments. The only way to ensure we maintain our progress is to keep moving forward.

It's important to point out that the Bush Administration ignored the experts on EPA's Clean Air Scientific Advisory Committee in 2008 and implemented a standard they viewed as not sufficiently protective of public health. Thankfully, the Obama Administration is basing its decision on the science, not industry interests.

Now, let me be clear. In my home State of Oregon, we recognize the challenges associated with implementing a more stringent standard. And I'm glad Mr. Bridenstine raised this point. Wildfires and long-range shifting of ozone from Asia will need to be addressed if we're to achieve a lower standard. That being said, comments the State of Oregon submitted support the EPA's proposal. Specifically, a letter from David Collier, the Air Quality Manager at the Oregon Department of Environmental Quality, on EPA's proposed rule states that "Oregon welcomes the EPA's proposal to lower the ozone NAAQS based on advice provided by the Clean Air

Scientific Advisory Committee in order to provide the adequate protection to human health and welfare.”

In its comments to the EPA, Oregon also recommended the development of guidance and tools to address exceptional events like wildfires and the long-range transport of ozone. Thankfully, the EPA is listening to the needs of states and has expressed in the final rule its commitment to addressing the implementation challenges faced by Western States.

I want to point out that the EPA has concluded that most U.S. counties will be able to reach the new standard without imposing emission controls beyond those already in place or proposed. Specifically, the EPA has estimated that federal regulations like the Fuel Economy Standards, the Interstate Transport Rule, and the Clean Power Plan will reduce emissions to such a degree that only 14 of the 213 counties expected to exceed the 70 parts per billion are likely to find themselves in nonattainment by 2025.

Mr. Chairman, although significant progress has been made in the past 40 years, it is our job and responsibility to build on this legacy and ensure that we continue to improve the quality of our air. A strong economy and a healthy environment are not mutually exclusive. We can have both, and EPA’s rule will continue to take us in the right direction.

Thank you, Mr. Chairman, and thank you again to our witnesses for being here today, and I yield back the balance of my time.

[The prepared statement of Ms. Bonamici follows:]

Opening Statement

Ranking Member Suzanne Bonamici
Subcommittee on Environment,
House Committee on Science, Space, and Technology

“EPA’s 2015 Ozone Standard: Concerns over Science and Implementation”

October 22, 2015

Thank you very much Mr. Chairman and thank you to our witnesses for being here today to discuss the Environmental Protection Agency’s final National Ambient Air Quality Standards for ozone.

Last week, the EPA took a step in the right direction to maintain clean air and a healthy environment for our country. The new standard of 70 parts per billion is not as ambitious as some might have hoped for, but it will have a real and meaningful effect on the health of all Americans. At a hearing earlier this year on the topic of ozone, one of the witnesses before the committee, Dr. Mary Rice, stated that there is clear, consistent, and conclusive scientific evidence in support of a standard lower than the current level of 75 parts per billion. She also indicated that the scientific evidence available 7 years ago has been supplemented by an even greater understanding of the health effects of ozone exposure.

And we must not overlook this point, the Clean Air Act, as passed by Congress, requires that the ozone standard be based on science and health. It prohibits the EPA from considering cost when setting the standard and it rightfully puts the health and well-being of Americans first. Despite this fact, we will hear today that implementing a lower ozone standard will have devastating consequences to the economy, but has been shown time and time again, the evidence shows on balance jobs are created and the economy expands following the passage of major environmental reforms. Regarding this rule, the EPA estimates the benefits to be more than double the costs. That is benefits of \$2.9 to \$5.9 billion annually compared to costs of \$1.4 billion. Such a return on investment should prove the obvious, that when the environment is healthy, the economy is healthy.

We are already seeing positive results from strong action to protect the air. Since 1980, ozone levels have dropped by 33%. Now is not the time to rest on our accomplishments. The only way to ensure we maintain our progress is to keep moving forward. It’s important to point out that the Bush Administration ignored the experts on EPA’s Clean Air Scientific Advisory Committee in 2008 and implemented a standard they viewed as not sufficiently protective of public health. Thankfully, the Obama Administration is basing its decision on the science, not industry interests.

Now let me clear, in my home state of Oregon, we recognize the challenges associated with implementing a more stringent standard, and I'm glad Mr. Bridenstine raised this point. Wildfires and long range shifting of ozone from Asia will need to be addressed if we're to achieve a lower standard. That being said, comments the state of Oregon submitted support the EPA's proposal. Specifically, a letter from David Collier, the air quality manager at the Oregon Department of Environmental Quality, on EPA's proposed rule states that "Oregon welcomes the EPA's proposal to lower the ozone NAAQS based on advice provided by the Clear Air Scientific Advisory Committee in order to provide the adequate protection to human health and welfare."

In its comments to the EPA, Oregon also recommended the development of guidance and tools to address exceptional events like wildfires and the long range transport of ozone. Thankfully, the EPA is listening to the needs of states and has expressed in the final rule its commitment to addressing the implementation challenges faced by western states.

I want to point out that the EPA has concluded that most US counties will be able to reach the new standard without imposing emission controls beyond those already in place or proposed. Specifically, the EPA has estimated that federal regulations like the Fuel Economy Standards, the Interstate Transport Rule, and the Clean Power Plan will reduce emissions to such a degree that only 14 of the 213 counties expected to exceed the 70 parts per billion are likely to find themselves in non-attainment by 2025.

Mr. Chairman, although significant progress has been made in the past 40 years, it is our job and responsibility to build on this legacy and ensure that we continue to improve the quality of our air. A strong economy and a healthy environment are not mutually exclusive. We can have both, and EPA's rule will continue to take us in the right direction.

Thank you Mr. Chairman, and thank you again to our witnesses for being here today, and I yield back the balance of my time.

Chairman SMITH. Thank you, Ms. Bonamici.

And let me introduce our witnesses. Our first witness today is Mr. Jeff Holmstead, a Partner at Bracewell & Giuliani, LLP. Mr. Holmstead is one of the country's leading air quality lawyers and heads the Environmental Strategies Group at Bracewell & Giuliani. He previously served as the Assistant Administrator at the EPA for the Office of Air and Radiation. He also served on the White House staff as Associate Counsel to former President George H.W. Bush. Mr. Holmstead received his bachelor's degrees in economics and English from Brigham Young University and his law degree from Yale.

Our next witness is Mr. Seyed Sadredin, the Executive Director and Air Pollution Control Officer of the San Joaquin Valley Air Pollution Control District. Under his leadership, the district developed a clear mission to improve the valley's health and quality of life through effective and innovative strategies and provide quality customer service to the general public and the regulated community. Mr. Sadredin initiated the implementation of the Technology Advancement Program, which promotes new clean air technology development in the valley. He received his bachelor's degree in mechanical engineering from California State University at Sacramento.

Our third witness today is Dr. Elena Craft, Health Scientist at the Environmental Defense Fund. Dr. Craft has worked on air toxic issues specifically to reduce criteria and greenhouse gas emissions from the energy and transportation sectors. Her efforts have led to the creation of Clean Truck Programs in Houston and other ports around the Southeast. Dr. Craft has been appointed to serve a two-year term on the Environmental Protection Agency's Science Advisory Board Environmental Justice Technical Review Panel. That's the longest name of any panel I've heard of. Dr. Craft received her bachelor's degree in biology from the University of North Carolina, Chapel Hill, her master's degree in toxicology from the North Carolina State University, and her Ph.D. in molecular technology from Duke University.

Our final witness is Dr. Michael Honeycutt, the Director of the Toxicology Division of the Texas Commission on Environmental Quality. Dr. Honeycutt has been employed by the TCEQ since 1996 and has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing health effects reviews of air permit applications, the review of the results of ambient air monitoring projects, and the reviews of human health risk assessments for hazardous waste sites. Dr. Honeycutt is an Adjunct Professor at Texas A&M University, has published numerous articles, and serves as—or served as—or served on numerous external scientific committees. Dr. Honeycutt received his bachelor's degree and Ph.D. in pharmacology and toxicology from the University of Louisiana at Monroe.

We recognize and appreciate all of you being here today and look forward to hearing what you have to say.

And, Dr. Holmstead, we'll begin with you.

**TESTIMONY OF THE HONORABLE JEFFREY HOLMSTEAD,
PARTNER, BRACEWELL & GIULIANI LLP**

The Hon. HOLMSTEAD. Thank you very much for giving me the chance to testify here this morning.

While I know other people will talk a fair bit about the controversies regarding the health science and the effects of ozone, what I'd like to do is just put that to one side and say this: Regardless of what you think about that, the way that we deal with ozone today just no longer makes any sense. Ozone is not a new issue. EPA and state agencies have been focused on reducing ozone levels for more than 40 years. As a country, we have spent much more money on ozone than on any other type of pollution, even though all experts believe that other types of pollution pose a greater risk to public health.

Now, because of EPA's new ozone standard, we will be forced to spend much more money—tens of millions of dollars—for very small incremental reductions in ozone. This is easy to understand. This is because for almost 40 years, most of the cost-effective, reasonable things that can be done to reduce ozone have already been done. Additional reductions will be much more expensive.

Some people think this is okay because the cost is paid by big business, but this is not true. The cost is paid entirely by real people. We all pay the cost in the form of higher prices, smaller retirement accounts, and lower levels of economic growth. This is why we should all care about the cost of regulations, as well as the benefits.

I would like to highlight just two issues. First, the new ozone standard will effectively ban new industrial development in many parts of the country. In many areas, it will be impossible to build or expand an industrial facility even though it would be built with state-of-the-art emission controls and even though the local community might desperately want the jobs it would bring.

Here is why: Anyone who wants to build or expand an industrial facility must first obtain a Clean Air Act permit. In some areas, you can't get such a permit unless you can first show that emissions from the new facility will not "cause or contribute to a violation" of the new ozone standard. But this will not be possible in areas that met the old standard but do not meet the new one. You can't show that a new facility will not contribute to a violation of the new standard because the area, according to EPA, is now in violation. And if you can't make this showing, you can't build a new plant, no matter how clean it is.

EPA says that you might be able to get around this problem by paying another facility in the area to reduce its emissions enough to offset emissions from the new plant. This is called "getting offsets." But in many cases, this will not be possible either. Any areas that exceed the new standard are rural areas where there is little or no industry. They exceed the standard not because of local emissions but because of background ozone and emissions in other areas. In these cases, there are no offsets to be purchased so no plants—no new plants can be built.

A related problem will occur in areas that don't meet the previous standard. To build a plant in these areas, a company has no

choice but to purchase offsets. In fact, it must obtain offset that are between 10 and 50 percent greater than the emissions from the new facility. Now, please note that offsets cannot be created by emission reductions that are required by EPA or state regulations, only by reductions that go beyond what is required.

But remember, for more than 40 years, EPA and States have been looking for every conceivable way to reduce ozone. Where there are any additional reductions to be had, they are very expensive. For example, in the Houston area where there is so much industry, it is possible to purchase offsets, but they are enormously expensive, as much as \$300,000 a ton. Even a relatively small facility with state-of-the-art pollution controls would need to spend tens of millions of dollars just to purchase enough offsets to get a permit.

I will summarize the second issue very briefly. The Clean Air Act program for dealing with ozone was established in 1970 when Congress believed that air pollution was primarily a local problem and that States could solve it by regulating local industry. We now know differently. Ozone is a global issue. When there are high ozone levels, they are largely caused by things outside of a State's control: by cars and trucks, which are regulated by EPA; by natural background; and by emissions from other States and other countries.

The State only has control over emissions from its own industrial facilities, but under the Clean Air Act, it has the sole legal obligation to meet the new standard. In a number of States, however, a State could shut down all the industrial facilities in the whole State and still not meet the standard. Because 70 parts per billion is so close to background ozone levels in some areas, there is simply nothing a State can do to meet the new standard.

As a result, the Clean Air Act now appears to give a rather remarkable authority to EPA, the authority to impose a legal obligation that is impossible to meet. To me, this seems contrary to our long-standing notion about the rule of law and the way the federal government should operate.

Thank you.

[The prepared statement of the Hon. Holmstead follows:]

The 2015 National Ambient Air Quality Standards for Ozone

**Testimony of Jeffrey R. Holmstead
before the
U.S. House Committee on
Science, Space, and Technology**

October 22, 2015

Thank you Chairman Smith, Ranking Member Johnson, and distinguished members of the Committee for inviting me to participate in today's hearing.

My name is Jeff Holmstead. I am a partner in the law firm of Bracewell & Giuliani and have been the head of the firm's Environmental Strategies Group (ESG) since 2006. However, I am not submitting this testimony on behalf of my law firm or any of my clients or the firm's clients. Rather, I am sharing my views as a former government official and an attorney in private practice who has spent more than 25 years working on issues arising under the Clean Air Act.

I have worked on Clean Air Act issues since 1989, when I joined the White House Staff of President George H.W. Bush. In that capacity, I worked closely with the Environmental Protection Agency (EPA) and a number of other stakeholders on the implementation of the 1990 Amendments to the Clean Air Act. I served at the White House until 1993 and then, from 1993 until 2001, I worked as attorney in private practice, where I represented companies and trade associations in a number of different industries on Clean Air Act issues. Beginning in 2001, I had the opportunity to serve for more than four years as the head of the EPA Air Office – the office in charge of implementing the Clean Air Act. My official title was Assistant Administrator of EPA for Air and Radiation. Since 2006, I have been a partner at the law firm of Bracewell & Giuliani, where I work with many different industry groups and companies on a variety of issues related to the Clean Air Act. I am well acquainted with the legal, policy, and practical issues associated with the Clean Air Act.

I am pleased to come before you today to discuss EPA's decision to lower the national ambient air quality standard (NAAQS) for ozone from 75 to 70 parts per billion (ppb). Although this may not seem like a dramatic change, it will have a very substantial impact on many state and local government, on many industries – and especially on anyone seeking to build or expand any type of industrial facility.

The Lessons of History

Ozone is not a new issue. EPA and state environmental agencies have been focused on reducing concentrations of ozone for more than 40 years (although the term ozone was not used in the early years).

In light of this 40-year history, I would like to highlight two key facts related to ozone:

- Ozone levels have been reduced substantially since the 1970s in most parts of the U.S. and especially in urban areas that had previously suffered from the highest levels of ozone.
- Notwithstanding the considerable progress that has been made in reducing ozone concentrations, there are many areas of the country that have not attained the previous standard of 75 parts per billion (ppb), even though it was established in 2008. In fact, there are 8 major urban areas that are still not meeting the standard of 84 ppb that was established in 1997 – almost 20 years ago.

These areas have not been negligent in their efforts to regulate sources of air pollution. In fact, many of them – in California, Texas, and the mid-Atlantic region in particular – have been extremely aggressive (and creative) in regulating virtually every imaginable source of ozone precursors. In fact, as a country, we have already spent more money to address ozone than to address any other air pollutant – even though EPA and most air quality researchers believe that other pollutants pose a much greater health risk.

To be sure, ozone concentrations in these areas will continue to decrease gradually as new, lower-emitting cars, trucks, and non-road engines replace older vehicles and engines. But these decreases will fall far short of what is needed to attain the new ozone standard in many areas of the country. And under the Clean Air Act, states have a legal obligation to make up the difference – to impose additional regulatory requirements that will bring every part of their states into compliance with the new standard. The problem, in many states, is that they have no way to do so.

In my discussions with regulatory officials in these areas, they say that there is little more that they can do to achieve further reductions. When it comes to reducing emissions that affect ozone formation, they have already picked all the low-hanging fruit and most of the high-hanging fruit as well. In some cases, they have picked all the trees bare. Regardless of what EPA says, these states will simply not be able to meet the new legal obligation that EPA has imposed on them. This is a long-term issue that will have an impact businesses and consumers located in these areas, but there is also an immediate impact – a *de facto* ban on new industrial development not only in these areas, but in many other parts of the country as well.

**The Immediate Impact of the New Ozone Standard:
An Effective Ban on Industrial Development in Many Parts of the Country**

The new ozone standard has not yet been published in the Federal Register, but this is expected fairly soon. The new standard will not go into effect, as a legal matter, until 60 days after it is published in the Federal Register, but it has already created a effective prohibition against building or expanding industrial facilities in many parts of the country.

Under the previous ozone standard of 75 ppb, with few exceptions not relevant here, every area of the country is designated as either “attainment” (meaning that it meets the standard) or “nonattainment” (meaning that it does not). Within the next few years, EPA and states will go through the process of re-designating every part of the country as either attainment or nonattainment with the new ozone standard of 70 ppb. The number of nonattainment areas will

increase substantially, and all these new nonattainment areas will face major new regulatory burdens.

But even now – before the final standard is even published in the Federal Register – the new ozone standard has effectively created a ban on industrial development in many parts of the country because of the permitting requirements of the Clean Air Act. Under the Act, any company that wants to build a new industrial facility or expand an existing facility must obtain a “new source review” (NSR) permit before it can begin any type of construction. To obtain an NSR permit for a facility in a current “attainment area” – one that meets the previous ozone standard – a company must first make a showing that the potential emissions from the new or expanded facility will not “cause or contribute” to a violation of any national ambient air quality standard, including the new ozone standard.

But here’s the problem. Now that the standard has been lowered from 75 to 70 ppb, many areas of the country suddenly do not meet the new standard. In such areas, it will be impossible to show that a new facility will not “contribute to” a violation of the new standard because the area is already in violation of the standard. And if a company cannot make this showing, it will not be able to get a permit build or expand any new industrial facility in the area, even if the facility would use state-of-the-art technology to control its emissions as much as possible, and even if the local community desperately wants it to be built.

To be fair, EPA has said that a company may be able to get around this problem by paying the owners of another facility in the area to reduce their emissions enough to offset emissions from the new plant or plant expansion. This is called getting “offsets.” But in many cases, this will simply not be possible. As EPA’s analysis has shown, many areas that exceed the new 70 ppb standard are rural areas, where there is little or no industrial activity. They exceed the standard not because of local emissions, but because of background ozone and emissions in other areas. In these cases, there are no offsets to be purchased. A company won’t have the option of paying someone else to reduce current emissions in the area because, with no existing sources of emissions in the area, there is no one to pay.

A related problem will occur in areas that are currently designated as nonattainment areas under the previous standard of 75 ppb. Because these areas have already been designated as nonattainment, someone who wants to build or expand a facility in such an area does not need to show that the new facility will not cause or contribute to a violation of the standard. However, the new facility may only be built if the permit applicant is able to obtain offsets to cover emissions from the new facility. In other words, it must pay someone else to reduce emissions in an amount that exceeds the emissions that will come from the new facility. In fact, depending on the area, it must obtain offsets that are between 10 and 50 percent greater than the emissions from the new facility.

Not surprisingly, offsets cannot be created by taking actions required by EPA or state regulations. To be counted as an offset, an emission reduction must go beyond what is required by law. But remember, for more than 40 years, EPA and states have been looking for every conceivable way to reduce emissions related to ozone. In many areas, all the cost-effective emission reductions have been mandated by regulation. Where there are any reductions to be had, they are very expensive. For example, in the Houston area, and especially near the Houston

Ship Channel, there are hundreds of industrial facilities, but they already are well controlled. Because there is so much industry, it is possible to purchase offsets, but they are enormously expensive – as much as \$300,000 a ton for ozone precursors. Even a relatively small facility with state-of-the-art controls will emit more than 100 tons per year. The so-called “offset ratio” in the Houston area is 1.4 to 1, meaning that the new facility would need to offset 140 percent of its projected emissions. Thus, even if the new facility will only emit 100 tons per year, the company trying to build it would need to purchase 140 tons of offsets. With offsets selling for \$300,000 a ton, this means an upfront cost of \$42 million just to purchase emission offsets.

As noted above, however, at least there are offsets available in Houston – at least for now. In many parts of the country, there simply are no offsets to be had for any price. In these areas, the new ozone standard will be a de facto ban on most types of industrial development.

Why “Background” Ozone Matters

The basic structure of the Clean Air Act program for dealing with ozone was established back in the 1970s and has remained relatively unchanged since that time. Ozone (then in the form of “total photochemical oxidants”) was thought to be primarily a local issue. If a city had high ozone levels, policymakers believed that it was caused by local sources of emissions. It was understood, of course, that vehicle emissions were the single largest part of the problem in many areas, and EPA was given primary responsibility for regulating those emissions. Otherwise, it was thought that states could meet the ozone standard (which was 120 ppb from 1979 - 1997) simply by adopting more stringent regulations to reduce emissions from industries within their borders.

By the mid-1990s, EPA came to understand that ozone was also a regional issue – not just a local one – and began to develop programs to control emissions from power plants in the eastern U.S. as a way to reduce ozone levels throughout the region.

More recently, government and academic researchers have noted that ozone is truly a global issue. Even without any human activity, there would be natural levels of ozone (not necessarily a constant background level but a level that would vary from time to time and place to place over the year). In addition, it is now clear that a range of industrial and other human activities (like biomass burning) throughout the world contribute to ozone concentrations in the U.S. In a 2011 report, EPA scientists noted that:

A growing body of observational and modeling studies suggests that the international anthropogenic [man-made] contribution to U.S. background ozone levels is substantial and is expected to rise in the future as rapid economic development continues around the world. Of particular concern is rising Asian emissions of nitrogen oxides (NO_x), which can influence U.S. ozone concentrations in the near-term, and methane, which affects background ozone concentrations globally over decadal time scales.

* * * * *

In particular, [a 2010 Report by the Task Force on Hemispheric Transport of Air Pollution] estimated that the contribution of NO_x, non- methane VOC, and

CO emissions in Europe, South Asia, and East Asia to North American ozone concentrations at relatively unpolluted sites is 32% of the contribution of emissions from all four regions (including North America) combined. That contribution is projected to rise to 49% in a conservative emissions growth scenario and to 52% in a scenario of aggressive global economic development.¹

The U.S. can certainly work with other countries to encourage them to reduce emissions that contribute to air quality problems in the U.S. However, for U.S. policymakers, it is important to understand how much we can actually do, within our own borders, to reduce ozone concentrations in the U.S. As far as I know, however, EPA has never made a serious effort to study this issue.

When the ozone standard was still 75 ppb, the former Chair of EPA's Clean Air Science Advisory Committee, Dr. Jonathan Samet, called attention to the significance of EPA standards converging with background levels of ozone:

Although health and welfare effects of ozone will occur regardless of the origin of the ozone (i.e., natural, U.S. anthropogenic emissions or internationally transported emissions), we note that as levels for ozone standards move closer to "background" levels, new issues may arise with implementation. As the Agency moves forward with the next ozone review cycle, it would be well advised to carefully consider any new monitoring and implementation issues that may arise, particularly as background levels vary throughout the country.²

With the ozone standard now set at 70 ppb, we have reached the point where some parts of the country would fail to meet the standard even if they were to eliminate all industrial activity within their borders. EPA officials have finally acknowledged concerns about background ozone and said that they will be adopting new policies to deal with it. But we have not yet seen any of these policies.

In EPA's view, however, the issue of background ozone is not relevant to the question of where the NAAQS should be set. This position is based on the Supreme Court's decision in *Whitman v. American Trucking*, 531 U.S. 457 (2001), which said (among other things) that EPA must set the NAAQS based purely on an assessment of health effects and without considering the cost of meeting any particular standard. Most surprising, the Court also suggested that EPA must set air quality standards without even considering whether they are achievable. As a result, the Clean Air Act appears to give rather remarkable authority to EPA – the authority to impose legal obligations that are impossible to meet. To me, at least, this seems contrary to our long-standing notions about the rule of law.

¹ EPA, Ozone National Ambient Air Quality Standards; Scope and Methods Plan for Health Risk and Exposure Assessment (2011).

² Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee. Letter to Lisa Jackson. February 19, 2010.
[http://yosemite.epa.gov/sab/sabproduct.nsf/610BB57CFAC8A41C852576CF007076BD/\\$File/EPA-CASAC-10-007-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/610BB57CFAC8A41C852576CF007076BD/$File/EPA-CASAC-10-007-unsigned.pdf)

To be fair, this issue has only arisen as background levels of ozone have continued to increase while EPA has simultaneously regulated ozone to lower and lower levels. Certainly, when the Clean Air Act was enacted back in 1970, and even when it was last amended in 1990, Congress did not appear to contemplate this issue – that background emissions would make it impossible for states to meet national ambient air quality standards. Perhaps it is time for Congress to consider this problem. I recognize that it is perhaps beyond the purview of this Committee, but I do believe that this Committee – and EPA’s Clean Air Science Advisory Committee – should take steps to ensure that this issue is fairly presented to policymakers and the public.

The Role of CASAC

As part of the Clean Air Act, Congress created an outside group of science advisors known as the Clean Air Science Advisory Committee (CASAC). Congress created CASAC back in 1977, when it enacted what has now been codified as section 109 of the Clean Air Act.

For many years, CASAC has largely just responded to questions posed by EPA staff. Congress, however, envisioned a broader role for CASAC and also gave CASAC a specific list of responsibilities. Unfortunately, CASAC has largely overlooked two things on this list.

Section 109(d)(2)(C) specifically states that CASAC “shall” (1) “advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity” and (2) “advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.”

Some CASAC observers have downplayed the importance of these responsibilities, arguing that they are not relevant to the question of where the NAAQS should be set. But Congress clearly wanted CASAC to play a broader role than simply advising EPA on the level of the NAAQS.

As noted above, in the effort to reduce ground-level ozone, regulators have already mandated the emission reductions that are the most-cost effective to achieve. In many areas, it will be very costly to businesses and consumers to obtain additional reductions. Under these circumstances, it is especially important for CASAC to advise the Administrator – and through her, other policymakers – about “the relative contribution to [ozone] concentrations of natural as well as anthropogenic activity.” In considering the contribution from anthropogenic sources, CASAC should distinguish between (i) anthropogenic sources that are within the U.S. and therefore subject to control under the Clean Air Act and (ii) anthropogenic sources from outside the U.S., which are not. As a practical matter, the contribution from non-U.S. anthropogenic sources is essentially part of the uncontrollable background. Policymakers and regulators around the country need a valid source of information about background concentrations (attributable to both natural and non-U.S. anthropogenic sources) and the degree to which they effect the ability of certain areas to achieve the ozone NAAQS.

It is perhaps even more important for CASAC to advise the Administrator and other policymakers about the “adverse public health, welfare, social, economic, or energy effects which may result from” further efforts to reduce ozone formation. If, as most experts believe, the low hanging fruit has been picked when it comes to reducing emissions of ozone precursors,

additional actions will be ever more costly in terms of the cost-per-unit of ozone reduced. CASAC clearly has a role in advising policymakers about the tradeoffs that we all face as our society spends more resources to achieve a goal that may not even be achievable in many parts of the country.

Jeff Holmstead is a partner and Head of the Environmental Strategies Group at Bracewell & Giuliani and has repeatedly been recognized by *Chambers USA* as one of the leading environmental lawyers in the country. He has worked on Clean Air Act and climate change issues for more than 25 years – in both the federal government and the private sector. From 1989 to 1993, he worked on the White House staff of President George H.W. Bush, where he was deeply involved in the passage and then the early implementation of the 1990 Amendments to the Clean Air Act. In early 2001, he was nominated by President George W. Bush and confirmed by the Senate to be the Assistant Administrator of EPA for Air and Radiation – a position he held until late 2005.

When not in the government, he has been a lawyer in private practice advising and representing clients on a range of environmental issues. Since he joined Bracewell in 2006, most of his work has been with energy companies and trade associations, including utilities, upstream oil and gas companies, and petroleum refineries. He represents a number of clients dealing with the development, implementation, and enforcement of EPA regulations. Much of work over the last few years has been focused on EPA's efforts to regulate greenhouse gas emissions under the Clean Air Act.

Mr. Holmstead graduated from Yale Law School in 1987 and then served as a law clerk to Judge Douglas H. Ginsburg on the United States Court of Appeals for the DC Circuit. He graduated *summa cum laude* from Brigham Young University in 1984 with degrees in Economics and English. He and his wife are both from Colorado and are the proud parents of four children.

Chairman SMITH. Thank you, Mr. Holmstead.

Mr. Sadredin.

Chairman SMITH. Make sure your microphone is on. Push—

**TESTIMONY OF MR. SEYED SADREDIN,
EXECUTIVE DIRECTOR AND
AIR POLLUTION CONTROL OFFICER,
SAN JOAQUIN VALLEY AIR POLLUTION CONTROL DISTRICT**

Mr. SADREDIN. Good morning, Chairman Smith, Ranking Member Bonamici, Members of the Committee. Good morning. It's a great honor and a pleasure to be here before you today. Thank you for the invitation.

I come from the beautiful and bountiful Central Valley of California, San Joaquin Valley. Over the last three decades, we've done quite a bit of work to improve quality of life and reduce air pollution in San Joaquin Valley.

I'm not here today to urge your committee to curb EPA's authority to set new standards or to—or ask you to—ignore them—

Chairman SMITH. Yes, ignore those bells. Yes.

Mr. SADREDIN. —or ask you to roll back any of the health-protected safeguards in the Clean Air Act that have really brought us to where we are today.

At the outset, I want to say that the Clean Air Act over the last 40 years has resulted in a great deal of reduction in air pollution, improved public health and quality of life in many regions, including our region. What I'm hoping to do, though, is to give you a preview of what might seem to be coming to your neighborhood with the new standard that EPA just published because we have been at the forefront of what we have to do even with old standards that EPA published because of our geography, topography. The problems that we have faced over the last two, three decades are going to be exactly the problems that you might face in your neighborhood soon with the new standard.

And I'm here really today to ask the Congress to provide guidance to EPA. We believe the world is a different world today compared to 25 years ago when the Congress last amended the act, or 40 years ago when the Congress passed the act unanimously—virtually unanimously. There was only a handful of “no” votes.

I think if the Congress understood at the time that you would face a circumstance like we do today, that after having reduced air pollution by over 80 percent in our region and having imposed the toughest regulations on every sector of your economy from the small ma-and-pa operations, drycleaners, paint shops, all the way to your largest power plants and refineries, that you would still face a major gap that would dictate a tremendous penalty on the residents of your region, the businesses that operate in your area. I don't think the bill would have passed unanimously, let alone—even if it would pass at all.

So I just wanted to share with you some of our experiences and really what we're asking the Congress to do in the form of a fine-tuning of the act as we call it. It's our 2015 Clean Air Act modernization that has five specific proposals in it. The first proposal that we have in our legislative initiative that we are taking is to eliminate duplication—duplicative requirements, confusion, and

costly bureaucratic red tape that are—that is—currently happens with our chaotic establishment of the new standards by synchronizing the new standards. When EPA publishes the new standards, let's synchronize the old standards without any rollback. Let's have a unique set of requirements that we have to follow instead of having multiple plans in place.

In our region, for instance, right now, we have six attainment plans in place with four more attainment plans being due in the next four years, all with redundant, duplicative requirements that we have to deal with.

The other requirement—the other change that we're asking—and I agree with what the Ranking Member said—that a good economy and good environment, good public health are not mutually exclusive. In fact, we believe you do need a vibrant economy to have the wherewithal to do all the difficult things that we need to do to improve our air quality.

So in our proposal we are asking that, instead of the formula-based deadlines that the Congress set 25 years ago, to take into account the economic feasibility and technological achievability in setting deadlines. Give us time to get to these tough standards. Don't set impossible deadlines that we're not able to meet. Banning fossil fuel combustion, which is really what it takes for us to meet the new standard, is not doable in—simply in 20 years. We need more time to be able to develop the technology and the infrastructure to do that.

We also ask that the act be amended to really treat different pollutants differently. Not all pollutants are created equally. When the Congress passed the act some 25 years ago with the latest amendments, they thought it was all about VOCs, volatile organic compounds. We are finding today that science dictates that different pollutants have different impacts on air quality, and we need to be able to take—have a system that allows us to have a weighing—appropriate weighing of those pollutants and deal with them.

With respect to extreme nonattainment areas such as we are in—and I'm almost finished—we ask that you remove the requirement for having contingency measures. It is one of those well-intended provisions in the act that are leading to unintended consequences, and I'd be happy to give you more details on that.

And we also ask that, for regions such as California where we have done many things to reduce pollution from mobile sources early on, give us the ability to take credit for those, as opposed to taking those credits away in a way that some of the court rulings are being interpreted by EPA.

And I have details about all of these in my presentation and would be happy to answer any questions you might have.

[The prepared statement of Mr. Sadredin follows:]

**Testimony of Seyed Sadredin
Executive Director/Air Pollution Control Officer
San Joaquin Valley Air Pollution Control District**

**Before the U.S. House of Representatives
Committee on Science, Space and Technology
October 22, 2015**

Chairman Smith, Ranking Member Johnson, and Members of the Committee, my name is Seyed Sadredin and I currently serve as the Executive Director/Air Pollution Control Officer of the San Joaquin Valley Air Pollution Control District. It is an honor and a pleasure to be here before you today to provide testimony and answer your questions. For nearly 35 years, I have served as a regulator charged with implementing air quality management programs in the bountiful and beautiful central valley of California.

In addressing challenges related to implementing the new national ambient air quality standard for ozone recently promulgated by the United States Environmental Protection Agency (U.S. EPA), it is important to hear from regions throughout the nation that have worked over the last four decades to comply with the federal mandates under the Clean Air Act and attain the previous standards. In my opinion, a closer examination of those efforts can provide valuable lessons as we continue our work to chart an effective course for expeditious attainment of the new standard and the resulting benefit in improved public health.

I am not here today to advocate for curbing federal EPA's authority to establish health-protective standards that are scientifically sound and I am not here to advocate for any rollback in relation to the federal Clean Air Act. I appear before you today due to great concern in our region that failure by Congress to provide guidance and correct the structural deficiencies in the Act will lead to economic devastation without commensurate benefit in improving the region's air quality.

Since its adoption, the Clean Air Act has led to significant improvements in air quality and public health benefits throughout the nation. With an investment of over \$40 billion, air pollution from San Joaquin Valley businesses has been reduced by over 80%. The pollution released by industrial facilities, agricultural operations, and cars and trucks is at a historical low, for levels of all pollutants. San Joaquin Valley residents' exposure to high smog levels has been reduced by over 90%.

After more than 25 years since the last amendments to the Clean Air Act in 1990, our experience shows that many well-intentioned provisions are leading to unintended adverse consequences. Without action to address these issues, the Clean Air Act sets many regions up for failure and economic devastation as the new federal standards encroach on background pollution concentrations. The antiquated provisions of the Clean Air Act are now leading to confusion, and lack of updated congressional directive

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has rendered courts and non-elected government bureaucrats as policy makers. We urge the Congress and the President to take bipartisan action to modernize the Act.

The new ozone standard established by EPA approaches the background pollution concentrations in many regions throughout the nation including the San Joaquin Valley. As currently written, the Act does not provide for consideration of technological achievability and economic feasibility in establishing deadlines for attaining the associated federal mandates. When enacting the last amendment to the Act over 25 years ago, Congress did not contemplate the reality that we face today. It is hard to imagine that the Congress, with a nearly unanimous vote to pass the Clean Air Act, envisioned a scenario where after reducing pollution by over 80% and imposing the toughest air regulations on stationary and mobile sources of emissions, a region is left with an enormous gap in meeting the new standard – a gap so large that it cannot be filled by the formula-based deadlines prescribed in the Act. The reality that we face today sets up regions such as the San Joaquin Valley for failure leading to costly sanctions and severe economic hardship. We face these dire consequences despite having already done all of the following:

- ✓ Toughest air regulations on stationary sources (600 rules since 1992)
- ✓ Toughest air regulations on farms and dairies
- ✓ \$40 billion spent by businesses on clean air
- ✓ Over \$1 billion dollars of public/private investment on incentive-based measures reducing over 100,000 tons of emissions
- ✓ Toughest regulations on cars and trucks
- ✓ Toughest regulations on consumer products
- ✓ Reduced emissions by 80% - but need another 90% reduction in emissions to meet the new standard

The background ozone concentration in the San Joaquin Valley is estimated to be greater than 50 ppb with some estimates as high as 60 ppb. The new standard set at 70 ppb leaves little or no room for man-made local emissions. Meeting the new standard requires a virtual ban on fossil-fuel combustion or emissions (see Figures 1 and 2).

Eliminating fossil fuel emissions from all industrial, agricultural, and transportation activities is a daunting task. Nonetheless in our region, we are committed to develop and deploy the needed transformative measures as expeditiously as possible. We support the well-intentioned concepts in the Clean Air Act that call for routine review of health-based air quality standards, clean air objectives that are technology-forcing, and clean-air deadlines that ensure expeditious clean-up and timely action. However, success requires fine-tuning of the federal Clean Air Act to ensure rapid progress towards meeting the standards without unduly penalizing regions with mature air quality programs and disadvantaged communities.

The *2015 Clean Air Act Modernization Proposal* (see Attachment) by the Governing Board of the San Joaquin Valley Air Pollution Control District presents a five prong

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legislative solution that preserves the federal government's ability to routinely reevaluate and set health protective air quality goals based on sound science while avoiding current duplicative requirements and confusion. The proposed changes would also require strategies that lead to the most expeditious air quality improvement while considering technological and economic feasibility. In addition, states would be allowed to focus efforts on meeting new air quality goals in the most expeditious fashion through deployment of scarce resources in a manner that provides the utmost benefit to public health.

The five-pronged *2015 Clean Air Act Modernization Proposal* is summarized as follows:

1. **Eliminate duplicative requirements, confusion, and costly bureaucratic red tape by synchronizing progress milestones when a new standard is published by EPA.**

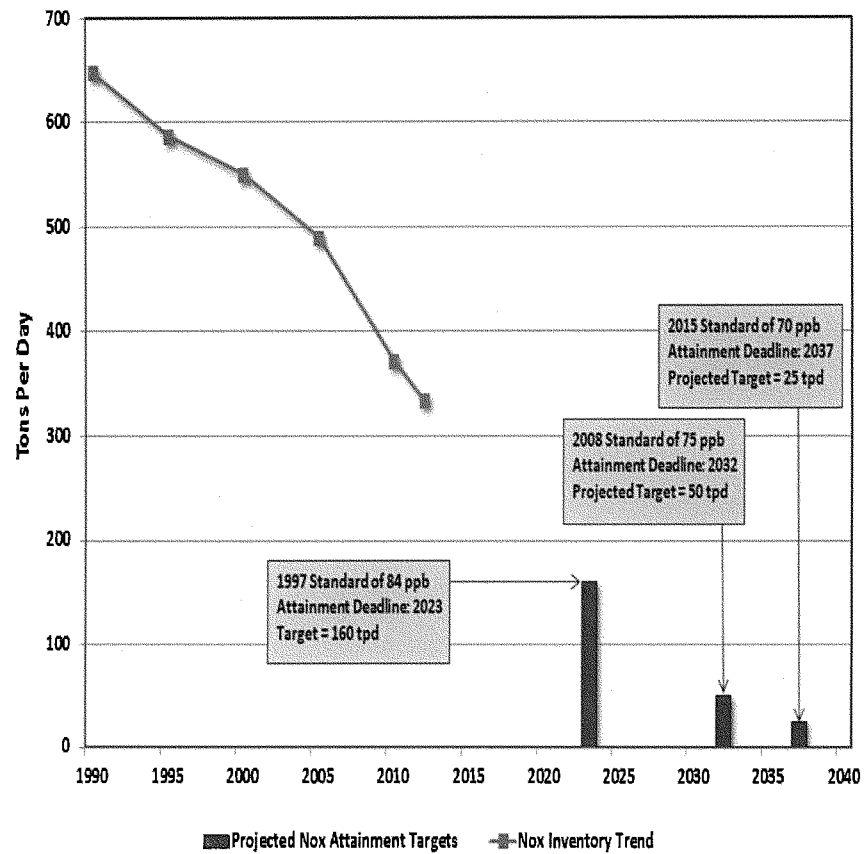
Since the 1970's, EPA has established numerous ambient air quality standards for individual pollutants. We have now reached a point where various regions throughout the nation are subject to multiple iterations of standards for a single pollutant. For instance, there are currently 4 pending standards for ozone and 4 pending standards for PM_{2.5}. Each of these standards requires a separate attainment plan which leads to multiple overlapping requirements and deadlines.

2. **In establishing deadlines and milestones, require control measures that lead to the most expeditious attainment while considering technological achievability and economic feasibility.**

Mobile and stationary sources throughout the nation have now been subject to multiple generations of technology forcing regulations that have achieved significant air quality benefits. Meeting the new standards that approach background concentrations calls for transformative measures that require time to develop and implement. These transformative measures require new technologies that in many cases are not yet commercially available or even conceived. The formula-based deadlines and milestones that were prescribed in the Act 25 years ago now lead to mandates that are impossible to meet. For instance, Figures 1 and 2 below demonstrate the enormous reductions that are still needed to attain the new standard.

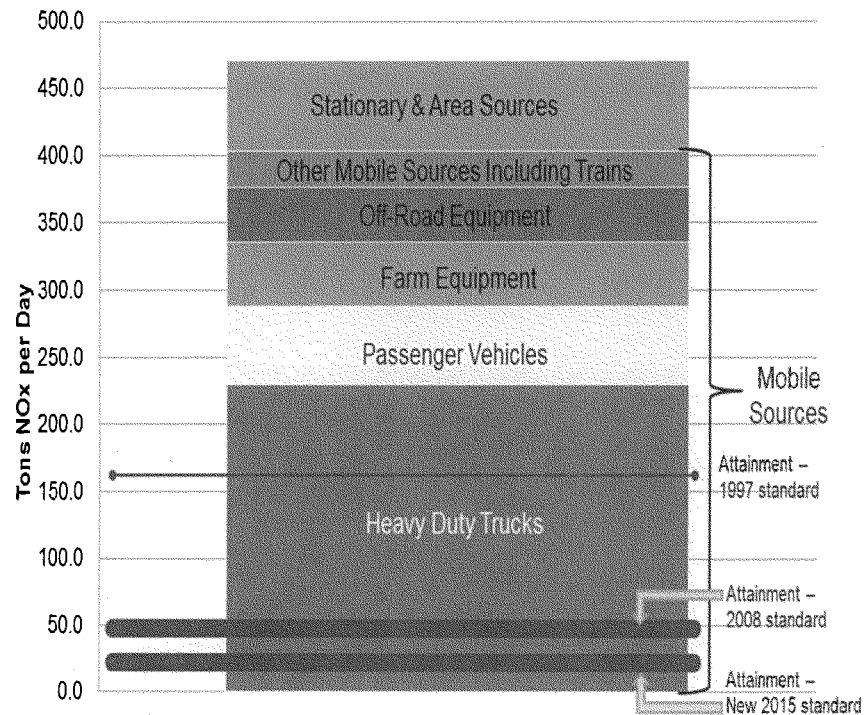
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Figure 1: San Joaquin Valley NO_x Emissions and Targets for Attainment of Federal 8-hour Ozone Standards



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Figure 2: San Joaquin Valley NO_x Emissions by Source Category and Targets for Attainment of Federal Ozone Standards



3. Allow states to focus efforts on meeting new standards in the most expeditious fashion through deployment of scarce resources in a manner that provides the utmost benefit to public health (e.g. greater weight for NO_x reductions).

Currently, the Act as it relates to the demonstration of Reasonable Further Progress or Rate of Progress treats all precursors the same, regardless of their potency in harming public health or achieving attainment. Driven by a rapidly expanding body

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of scientific research, there is now a growing recognition within the scientific community that from an exposure perspective, the National Ambient Air Quality Standards metrics for progress are a necessary but increasingly insufficient measure of total public health risk associated with air pollutants. In particular, control strategies for sources of PM_{2.5} and ozone do not necessarily account for qualitative differences in the nature of their emissions. For PM_{2.5}, toxicity has been shown to vary depending on particle size, chemical species, and surface area. In the case of ozone, differences in the relative potency of ozone precursors, VOCs in particular, are not captured by a strict, mass-based approach to precursor controls.

4. Eliminate the requirement for contingency measures in areas classified as “extreme” non-attainment.

Requiring contingency measures in extreme nonattainment areas is irrational and unnecessary. In fact, it can lead to delayed cleanup if measures are set aside for later implementation as a contingency. Currently, the Act requires all attainment plans to include contingency measures, defined as extra control measures that go into effect without further regulatory action, if planned emissions controls fail to reach the goals or targets specified in the attainment plan. While requiring backup measures was a well-intentioned provision, it does not make sense in areas that have been classified as “extreme” non-attainment for ozone. These areas, by definition, have already implemented all available and foreseeable measures and still need a “black box” of future measures to define and employ. The term “black box” refers to reductions that are needed to attain the standard, but technology to achieve such reductions does not yet exist. No measures are held in reserve in areas that are classified as “extreme” non-attainment for ozone. With no stones left unturned in such plans, requiring contingency measures in such areas makes no sense.

5. Allow states to take credit for all transportation control measures and strategies and not punish areas that have implemented transportation control measures and strategies that have achieved early reductions in emissions.

The Act requirements for severe and extreme ozone nonattainment areas to address vehicle-related emissions growth must be clarified. Section 182(d)(1)(A) requires such areas to develop enforceable transportation control measures (TCMs) and transportation strategies “to offset any growth in emissions from growth in vehicle miles traveled ... and to attain reduction in motor vehicle emissions as necessary.” An area’s vehicle miles traveled (VMT) may increase due to increases in population (i.e., more drivers), people driving further (i.e., sprawl), or increases in pass-through traffic (i.e., goods movement).

Historically, EPA’s section 182(d)(1)(A) approach has allowed the use of vehicle turnover, tailpipe control standards, and the use of alternative fuels to offset the expected increase in VMT. This has allowed for the actual emissions reductions

Testimony of Seyed Sadredin
 U.S. House of Representatives
 Committee on Science, Space and Technology
 October 22, 2015

occurring from motor vehicles to be considered in meeting the applicable requirements. A recent Ninth Circuit Court decision, however, has called EPA's current approach for demonstrating the offsetting of vehicle mile-related emissions growth into question, and has forced EPA to reevaluate its approach. Any change in approach that would require regions to offset vehicle growth regardless of population growth, and without recognition of emission reduction measures such as vehicle turnover and tailpipe control standards, would have a significant impact on many regions' ability to develop an approvable attainment strategy and, under a strict interpretation, would actually render attainment impossible. Many TCMS and transportation strategies have already been implemented in nonattainment areas, and remaining opportunities are scarce and extremely expensive to implement, with relatively small amounts of emissions reductions available. A less inclusive section 182(d)(1)(A) approach would effectively penalize nonattainment areas for having population growth, and would not give credit to the significant emissions reductions being achieved from motor vehicles.

To illustrate this issue, such an interpretation applied to the District's 1997 8-hour ozone standard attainment plan would require the elimination of 5.1 million vehicles, while the vehicle population of the Valley is projected to be only 2.6 million vehicles in 2023.

EPA recently established new guidance to address this issue that provides a potential path for reasonably addressing this Clean Air Act requirement. However, the path provided under this guidance will undoubtedly be challenged in court as it is utilized by regions like the San Joaquin Valley in the coming years. To provide certainty moving forward, the Act should be amended to clearly include the methodology for reasonably satisfying this requirement.

The minor changes embodied in the *2015 Clean Air Act Modernization Proposal*, if enacted, provide for expeditious attainment of the federal health-based standards while minimizing costly sanctions that can be devastating. The sanctions that could otherwise be imposed on the affected communities throughout the nation are as follows:

- De facto ban on new and expanding businesses (2:1 offset requirement)
- Loss of federal highway funds (\$2.5 billion in the San Joaquin Valley)
- Federal takeover and loss of local control
- Expensive federal nonattainment penalties (\$29 million per year in the San Joaquin Valley)

Attachment: 2015 Clean Air Act Modernization Proposal (8 pages)



San Joaquin Valley
AIR POLLUTION CONTROL DISTRICT



HEALTHY AIR LIVING™

2015 Federal Clean Air Act Modernization Proposal

Since its adoption, the Clean Air Act has led to significant improvements in air quality and public health benefits throughout the nation. In many areas of the nation, air pollution levels have been reduced to historical lows. We support the well-intentioned concepts in the Clean Air Act that call for routine review of health-based air quality standards, clean air objectives that are technology-forcing, and clean-air deadlines that ensure expeditious clean-up and timely action.

The Clean Air Act was last amended in 1990. Over the last 25 years, local, state, and federal agencies and affected stakeholders have learned important lessons from implementing the law and it is clear now that a number of well-intentioned provisions in the Act are leading to unintended consequences. This experience can inform efforts to enhance the Clean Air Act with much needed modernization. The following proposal is designed to provide specific language aimed at improving the Act's effectiveness and efficiency.

1. PROBLEM: Since the 1970's, EPA has established numerous ambient air quality standards for individual pollutants. We have now reached a point where various regions throughout the nation are subject to multiple iterations of standards for a single pollutant. For instance, there are currently 4 pending standards for ozone and 4 pending standards for PM2.5. Each of these standards requires a separate attainment plan which leads to multiple overlapping requirements and deadlines. This in turn results in a great deal of confusion, costly bureaucracy, and duplicative regulations, all without corresponding public health benefits.

SOLUTION: When a new standard is published, the old standard for that pollutant should be subsumed. States should be allowed to develop a single attainment plan that harmonizes increments of progress and other milestones without allowing for any rollback or backsliding.

PROPOSED AMENDMENTS: To avoid duplicative requirements and confusion, the RFP milestones must be synchronized when a new standard is published, for any region with a pending implementation plan for an older version of the standard for that pollutant. Towards that end, the first RFP milestone for the new standard should be aligned with the next required milestone for the old standard. The reductions required for aligned milestones shall be either 3 percent of the baseline for the new standard or the RFP emission reduction targets established under the existing plan, whichever is greater.

For ozone, add new subsection 182(k) as follows:

(k) RFP Milestone Alignment for Areas with Pending Attainment Plans

Notwithstanding any other provisions of this section, the RFP milestones and emission reduction targets in areas that have submitted a plan to the Administrator for the older version of a standard for the same pollutant being addressed by a new standard shall be set as follows:

The first RFP milestone for the new standard shall be set at the next RFP milestone date for the existing standard addressed in the current plan. Subsequent milestones will be every three years from the first milestone until attainment. The reductions required at the aligned milestones that address more than one standard shall be either 3 percent of the baseline for the new standard or the RFP emission reduction targets established under the current plan for the older standard, whichever is greater.

For particulates, add new subsection 189(c)(4) as follows:

(4) RFP Milestone Alignment for Areas with Pending Attainment Plans

Notwithstanding any other provisions of this section, the RFP milestones and emission reduction targets in areas that have submitted a plan to the Administrator for the older version of a standard for the same pollutant being addressed by a new standard shall be set as follows:

The first RFP milestone for the new standard shall be set at the next RFP milestone date for the existing standard addressed in the current plan. Subsequent milestones will be every three years from the first milestone until attainment. The reductions required at the aligned milestones that address more than one standard shall be either those required for the new standard or the RFP emission reduction targets established under the current plan for the older standard, whichever is greater.

2. PROBLEM: Mobile and stationary sources throughout the nation have now been subject to multiple generations of technology forcing regulations that have achieved significant air quality benefits. Meeting the new standards that approach background concentrations call for transformative measures that require time to develop and implement. These transformative measures require new technologies that in many cases are not yet commercially available or even conceived. The formula-based deadlines and milestones that were prescribed in the Act 25 years ago now lead to mandates that are impossible to meet.

SOLUTION: In establishing deadlines and milestones, the Act should be amended to require control measures that lead to the most expeditious attainment of health based standards while taking into account technological and economic feasibility. These deadlines and milestones should also consider background pollution concentrations and

the region's geography, topography, and meteorology that affect pollutant formation and dispersion.

PROPOSED AMENDMENTS:

In relation to RFP targets for ozone, amend subsection 182(b)(1)(A)(ii)(III) as follows:

the plan reflecting a lesser percentage than 15 percent includes all measures that can feasibly be implemented in the area, in light of technological achievability and economic feasibility.

In relation to RFP targets for ozone, amend subsection 182(c)(2)(B)(ii) as follows:

an amount less than 3 percent of such baseline emissions each year, if the State demonstrates to the satisfaction of the Administrator that the plan reflecting such lesser amount includes all measures that can feasibly be implemented in the area, in light of technological achievability and economic feasibility.

In relation to RFP targets for ozone, amend subsection 182(e) as follows:

Each State in which all or part of an Extreme Area is located shall, with respect to the Extreme Area, make the submissions described under subsection (d) of this section (relating to Severe Areas), and shall also submit the revisions to the applicable implementation plan (including the plan items) described under this subsection. ~~The provisions of clause (ii) of subsection (e)(2)(B) of this section (relating to reductions of less than 3 percent),~~ ~~The provisions of paragraphs [6] (6), (7) and (8) of subsection (c) of this section (relating to de minimus [7] rule and modification of sources), and the provisions of clause (ii) of subsection (b)(1)(A) of this section (relating to reductions of less than 15 percent)~~ shall not apply in the case of an Extreme Area. For any Extreme Area, the terms "major source" and "major stationary source" includes [8] (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 10 tons per year of volatile organic compounds.

In relation to RFP targets for particulates, amend subsection 189(c)(1) as follows:

Plan revisions demonstrating attainment submitted to the Administrator for approval under this subpart shall contain quantitative milestones which are to be achieved every 3 years until the area is redesignated attainment and which demonstrate reasonable further progress, as defined in section 7501(1) of this title, and which take into account technological achievability and economic feasibility, toward attainment by the applicable date.

In relation to the attainment deadlines for ozone:

Amend section 181(a) by adding the following new subsection 181(a)(6):

Notwithstanding table 1, if an area is already classified as extreme for an existing standard, then the area shall be classified as extreme at the time of designation for the new standard.

Amend section 181(a) by amending table 1 as follows:

TABLE 1		
Area class	Design value*	Primary standard attainment date**
Marginal	0.121 up to 0.138	3 years after November 15, 1990
Moderate	0.138 up to 0.160	6 years after November 15, 1990
Serious	0.160 up to 0.180	9 years after November 15, 1990
Severe	0.180 up to 0.280	15 years after November 15, 1990
Extreme	0.280 and above	~~20 years after November 15, 1990~~ <u>As prescribed in section 181(a)(7)</u>

Amend section 181(a) by adding the following new subsection 181(a)(7):

Areas shall attain the standard as expeditiously as possible with the most effective measures that take into account technological achievability and economic feasibility. The area shall quantify reductions needed to achieve attainment consistent with section 182(e)(5). Every 5 years after the plan is approved by the Administrator, the area shall demonstrate that all measures that are technologically achievable and economically feasible are implemented or will be included in the plan to ensure expeditious implementation. The plan shall also include measures for advancing the development and deployment of new technologies.

Amend section 182(e)(5) as follows:

(5) New technologies

The Administrator may, in accordance with section 7410 of this title, approve provisions of an implementation plan for an Extreme Area which anticipate development of new control techniques or improvement of existing control technologies, and an attainment demonstration based on such provisions, ~~if the State demonstrates to the satisfaction of the Administrator that—~~

~~*(A) such provisions are not necessary to achieve the incremental emission reductions required during the first 10 years after November 15, 1990; and*~~

~~(B)the State has submitted enforceable commitments to develop and adopt contingency measures to be implemented as set forth herein if the anticipated technologies do not achieve planned reductions.~~

~~Such contingency measures shall be submitted to the Administrator no later than 3 years before proposed implementation of the plan provisions and approved or disapproved by the Administrator in accordance with section 7410 of this title. The contingency measures shall be adequate to produce emission reductions sufficient, in conjunction with other approved plan provisions, to achieve the periodic emission reductions required by subsection (b)(1) or (c)(2) of this section and attainment by the applicable dates. If the Administrator determines that an Extreme Area has failed to achieve an emission reduction requirement set forth in subsection (b)(1) or (c)(2) of this section, and that such failure is due in whole or part to an inability to fully implement provisions approved pursuant to this subsection, the Administrator shall require the State to implement the contingency measures to the extent necessary to assure compliance with subsections (b)(1) and (c)(2) of this section.~~

~~Any reference to the term "attainment date" in subsection (b), (c), or (d) of this section which is incorporated by reference into this subsection, shall refer to the attainment date for Extreme Areas.~~

3. PROBLEM: The Act as it relates to the demonstration of Reasonable Further Progress or Rate of Progress treats all precursors the same, regardless of their potency in harming public health or achieving attainment. Driven by a rapidly expanding body of scientific research, there is now a growing recognition within the scientific community that from an exposure perspective, the National Ambient Air Quality Standards metrics for progress are a necessary but increasingly insufficient measure of total public health risk associated with air pollutants. In particular, control strategies for sources of PM_{2.5} and ozone do not necessarily account for qualitative differences in the nature of their emissions. For PM_{2.5}, toxicity has been shown to vary depending on particle size, chemical species, and surface area. In the case of ozone, differences in the relative potency of ozone precursors, VOCs in particular, is not captured by a strict, mass-based approach to precursor controls.

SOLUTION: The Act should be amended to allow states to focus efforts on meeting new standards in the most expeditious fashion through deployment of scarce resources in a manner that provides the utmost benefit to public health. Towards that end, we recommend a more strategic approach in which public health serves as the key factor in prioritizing control measures, regulated pollutants, and sources of emissions. In establishing Reasonable Further Progress or Rate of Progress, the Act should give a greater weight to pollutants that have greater impact on achieving attainment and improving public health. Additionally, in evaluating Reasonably Available Control Technology (RACT), measures that reduce precursors with more impact on ozone formation should be given higher scores than measures that may reduce greater amounts of less potent ozone precursors.

For example, VOC compounds vary significantly in their contribution to the formation of ozone in the San Joaquin Valley. Similarly, NOx emissions reductions have been demonstrated to be approximately 20 times more effective than VOC emissions reductions in reducing the formation of ozone in the San Joaquin Valley. We therefore recommend that in demonstrating Reasonable Further Progress, EPA allow for an alternative approach that can demonstrate equivalent reductions in ozone concentrations as compared to the straight requirement of 3% per year reduction of VOCs and/or NOx.

PROPOSED AMENDMENTS:

Amend Section 182:

(C) NOx control

The revision may contain, in lieu of the demonstration required under subparagraph (B), a demonstration to the satisfaction of the Administrator that the applicable implementation plan, as revised, provides for reductions of emissions of VOC's and oxides of nitrogen (calculated according to the creditability provisions of subsection (b)(1)(C) and (D) of this section), that would result in a reduction in ozone concentrations at least equivalent to that which would result from the amount of VOC emission reductions required under subparagraph (B). Within 1 year after November 15, 1990, the Administrator shall issue guidance concerning the conditions under which NOx control may be substituted for VOC control or may be combined with VOC control in order to maximize the reduction in ozone air pollution. In accord with such guidance, a lesser percentage of VOCs may be accepted as an adequate demonstration for purposes of this subsection. The Administrator shall allow the use of NOx reductions in lieu of VOC reductions. The credit for NOx reductions shall be weighted in proportion to their effectiveness in reducing ozone concentrations in relation to the effectiveness of VOC reductions as demonstrated by the attainment modeling submitted with the plan.

4. PROBLEM: Requiring contingency measures in extreme nonattainment areas is irrational and unnecessary. The Act requires all attainment plans to include contingency measures, defined as extra control measures that go into effect without further regulatory action, if planned emissions controls fail to reach the goals or targets specified in the attainment plan. While requiring backup measures was a well-intentioned provision, it does not make sense in areas that have been classified as "extreme" non-attainment for ozone. These areas, by definition, have already implemented all available and foreseeable measures and still need a "black box" of future measures to define and employ. The term "black box" refers to reductions that are needed to attain the standard, but technology to achieve such reductions does not yet exist. No measures are held in reserve in areas that are classified as "extreme" non-attainment for ozone. With no stones left unturned in such plans, requiring contingency measures in such areas makes no sense.

SOLUTION: We recommend that the Act be amended to eliminate the requirement for contingency measures in areas classified as "extreme" non-attainment by EPA.

PROPOSED AMENDMENTS:

Add to 172(c)(9) as follows:

(9) Contingency measures

Such plan shall provide for the implementation of specific measures to be undertaken if the area fails to make reasonable further progress, or to attain the national primary ambient air quality standard by the attainment date applicable under this part. Such measures shall be included in the plan revision as contingency measures to take effect in any such case without further action by the State or the Administrator.

Notwithstanding this or other sections, contingency measures shall not be required for extreme ozone nonattainment areas.

5. PROBLEM: The Act requirements for severe and extreme ozone nonattainment areas to address vehicle-related emissions growth must be clarified. Section 182(d)(1)(A) requires such areas to develop enforceable transportation control measures (TCMs) and transportation strategies "to offset any growth in emissions from growth in vehicle miles traveled ... and to attain reduction in motor vehicle emissions as necessary." An area's vehicle miles traveled (VMT) may increase due to increases in population (i.e., more drivers), people driving further (i.e., sprawl), or increases in pass-through traffic (i.e., goods movement).

Historically, EPA's section 182(d)(1)(A) approach has allowed the use of vehicle turnover, tailpipe control standards, and the use of alternative fuels to offset the expected increase in VMT. This has allowed for the actual emissions reductions occurring from motor vehicles to be considered in meeting the applicable requirements. A recent Ninth Circuit Court decision, however, has called EPA's current approach for demonstrating the offsetting of vehicle mile-related emissions growth into question, and has forced EPA to reevaluate its approach. Any change in approach that would require regions to offset vehicle growth regardless of population growth, and without recognition of emission reduction measures such as vehicle turnover and tailpipe control standards, would have a significant impact on many regions' ability to develop an approvable attainment strategy and, under a strict interpretation, would actually render attainment impossible. Many TCMs and transportation strategies have already been implemented in nonattainment areas, and remaining opportunities are scarce and extremely expensive to implement, with relatively small amounts of emissions reductions available. A less inclusive section 182(d)(1)(A) approach would effectively penalize nonattainment areas for having population growth, and would not give credit to the significant emissions reductions being achieved from motor vehicles.

To illustrate this issue, such an interpretation applied to the District's 1997 8-hour ozone standard attainment plan would require the elimination of 5.1 million vehicles, while the vehicle population of the Valley is projected to be only 2.6 million vehicles in 2023.

EPA recently established new guidance to address this issue that provides a potential path for reasonably addressing this CAA requirement. However, the path provided under this guidance will undoubtedly be challenged in court as it is utilized by regions like the San Joaquin Valley in the coming years. To provide certainty moving forward, the CAA should be amended to clearly include the methodology for reasonably satisfying this requirement.

SOLUTION: The Act should be amended to allow states to take credit for all transportation control measures and strategies and not punish areas that have implemented transportation control measures and strategies that have achieved early reductions in emissions.

PROPOSED AMENDMENTS:

(1) Vehicle miles traveled

(A) Within 2 years after November 15, 1990, the State shall submit a revision that identifies and adopts specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such area and to attain reduction in motor vehicle emissions as necessary, in combination with other emission reduction requirements of this subpart, to comply with the requirements of subsection [5] (b)(2)(B) and (c)(2)(B) of this section (pertaining to periodic emissions reduction requirements). The State shall consider measures specified in section 7408(f) of this title, and choose from among and implement such measures as necessary to demonstrate attainment with the national ambient air quality standards; in considering such measures, the State should ensure adequate access to downtown, other commercial, and residential areas and should avoid measures that increase or relocate emissions and congestion rather than reduce them. As new ozone standards are established, for areas that have implemented early transportation control strategies and transportation control measures, the baseline for demonstrating compliance under this subsection shall remain fixed at 1990 independent of the baseline date for the new plan.

Seyed Sadredin is the Executive Director and Air Pollution Control Officer for the San Joaquin Valley Air Pollution Control District. Mr. Sadredin reports to a governing board comprised of 13 elected officials and two members appointed by the Governor. Mr. Sadredin has 35 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, public health and air quality challenges, Mr. Sadredin has led the development and implementation of some of the most stringent and 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. Today many of the Valley Air District's pollution control strategies serve as models for other regions throughout the nation.

Mr. Sadredin has worked with a wide range of stakeholders to form a successful coalition that has brought significant financial 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 incentive-based clean air projects expediting air clean-up and improving quality of life throughout the Valley, including the region's many disadvantaged communities. 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. Mr. Sadredin holds a Bachelor of Science degree in Mechanical Engineering.

Chairman SMITH. Okay. Thank you, Mr. Sadredin.
And, Dr. Craft.

**TESTIMONY DR. ELENA CRAFT,
SENIOR HEALTH SCIENTIST,
ENVIRONMENTAL DEFENSE FUND**

Dr. CRAFT. Thank you, Chairman Smith, Ms. Bonamici, Members of the Committee, for the opportunity to testify here today about EPA's revision to the Nation's health-based ambient air quality standard for ground-level ozone.

My name is Elena Craft. I serve as Senior Scientist at Environmental Defense Fund, a national nonpartisan science-based environmental organization where I manage a team working to identify strategies and opportunities to reduce harmful air pollution such as ozone from pollution hotspots.

EDF has over 1 million members. Our organization links science, economics, law, and private sector partnerships to solve our most serious environmental challenges. In addition, I have an adjunct appointment at the University of Texas Health Sciences Center in Houston. And as I was seven months pregnant the last time I testified in front of this committee, I am also the mom of a very busy toddler.

The Clean Air Act is a bedrock public health statute representing the best of a bipartisan America encompassing the values of environmental protection and healthy air that we espouse as a nation. The unanimous vision forged into law by the U.S. Senate has secured healthier air for millions of Americans netting benefits valued at over \$21 trillion between 1970 and 1990.

Indeed, by 2020, EPA estimates the 1990 Clean Air Act amendments will prevent a projected 230,000 deaths, 2.4 million asthma attacks, 200,000 heart attacks, and 5.4 million lost school days. EPA also found that these vital health protections would provide 2 trillion in monetized benefits. Additionally, EPA projects a net overall improvement in economic growth due to the benefits of cleaner air.

The Clean Air Act is sharply focused on ensuring the Nation's health standards that are established solely on the basis of public health. On October 1, EPA established a revised ozone standard of 70 parts per billion, improving America's national air quality standard for ground-level ozone. Why? Because scientific evidence overwhelmingly demonstrates that the previous 75-part-per-billion standard is not requisite to protect human health with an adequate margin of safety as required by the Clean Air Act.

The recommendations of the statutorily established and independent Clean Air Scientific Advisory Committee underscored the need, as determined by the latest scientific evidence, to strengthen the ground-level ozone standard. CASAC found clear scientific support for the need to revise the standard. While recommending a range of 60 to 70 parts per billion, the committee went on to emphasize the inadequacy of a standard at the upper end of the range. At 70 parts per billion, there is substantial scientific evidence of adverse effects, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation.

And CASAC is not alone in concluding that the 2008 ozone standard was inadequate. The American Thoracic Society, the American Academy of Pediatrics, the American Medical Association, the American Heart Association, the American Lung Association, American Public Health Association, Children's Environmental Health Network are just a few of the medical and public health organizations that have supported strengthening the standards.

Some claim that adopting strong ozone standards will cause economic harm. Unfortunately, these sky-is-falling prognostications are not new. The fact is that we can do it and we have done it. Since 1970, our nation has reduced the six pollutants regulated under the National Ambient Air Quality Standards program by almost 70 percent, while GDP has grown by nearly 240 percent. And currently, 90 percent of areas designated for the 1997 ozone health standards now meet those standards.

Regions are not alone in meeting the new health-based standards. America has already taken steps over the past few years that will help reduce ozone smog pollution and help restore healthy air in a cost-effective manner. Some of these protections include the Tier 3 tailpipe standards, recently finalized greenhouse gas and fuel standards for medium and heavy-duty trucks, and EPA's Clean Power Plan.

The Clean Air Act is a vibrant, bipartisan, made-in-America law that has stood the test of time, delivering a stronger, healthier, and more prosperous nation. Let's build on this legacy of bipartisan collaboration and follow the time-tested commonsense path forward in protecting the health of our children and our communities. Thank you very much.

[The prepared statement of Dr. Craft follows:]

Before the United States House Committee on Science, Space, and Technology

EPA's 2015 Ozone Standard: Concerns Over Science and Implementation

Testimony of Elena Craft, Ph.D.

Senior Scientist

Environmental Defense Fund

October 22, 2015

Chairman Smith, Ranking Member Johnson and Members of the Committee, thank you for the opportunity to testify about the U.S. Environmental Protection Agency's revision to the nation's health-based ambient air quality standard for ground-level ozone.

My name is Elena Craft. I serve as senior scientist at Environmental Defense Fund, a national non-partisan science-based environmental organization, where I manage a team working to identify strategies and opportunities to reduce harmful air pollution such as ozone from pollution hotspot areas. EDF is a national environmental organization with over one million members that links science, economics, law, and private-sector partnerships to solve our most serious environmental challenges. In addition, I have an adjunct appointment at the University of Texas Health Sciences Center School of Public Health in Houston.

EDF and its members are deeply concerned about harmful air pollution, including ground-level ozone, and I greatly appreciate the opportunity to testify about the urgent need for strengthened ozone standards to protect human health and the environment.

I. The Clean Air Act: A Bi-partisan Triumph for Public Health, the Environment, and Economy

The Clean Air Act is a bedrock public health statute that has provided for extraordinary, bipartisan progress in protecting Americans' health and the environment for over 40 years. Senator John Sherman Cooper, a Republican from Kentucky, captured the spirit of bipartisan cooperation that led to the United States Senate's historic and unanimous adoption of the modern Clean Air Act in 1970:

We worked together. We disagreed. We worried about many provisions of the bill. At last, however, we joined unanimously in recommending and sponsoring this bill, believing that our approach was one that could make progress toward solution of the problem of air pollution.¹

The unanimous vision forged into law by the United States Senate has secured healthier air for millions of Americans. The net benefits of the Clean Air Act from 1970 to 1990 are valued at

¹ 116 CONG. REC. S32,917 (daily ed. Sept. 21, 1970) (statement of Sen. Cooper).

over \$21 trillion.² By 2020, the Environmental Protection Agency (“EPA”) estimates the 1990 Clean Air Act Amendments will prevent a projected 230,000 deaths; 2.4 million asthma attacks; 200,000 heart attacks; and 5.4 million lost school days,³ as set out in the Table immediately below. EPA also found that these vital health protections would provide \$2 trillion in monetized benefits.⁴ Additionally, EPA projects a net overall improvement in economic growth due to the benefits of cleaner air.⁵

The 1990 Clean Air Act Amendments prevent:

	Year 2010 (Annual)	Year 2020 (Annual)
Adult Mortality - particles	140,000	130,000
Infant Mortality - particles	130	100
Morbidity - ozone	8,000	7,000
Chronic Bronchitis	54,000	70,000
Acute Myocardial Infarction	130,000	100,000
Asthma Exacerbation	1,700,000	2,400,000
Emergency Room Visits	86,000	100,000
Infants Lost Days	1,300,000	1,400,000
Lost Work Days	1,300,000	1,700,000

This chart shows the health benefits of the Clean Air Act programs that reduce levels of fine particles and ozone.

Source: EPA⁶

II. The Clean Air Act’s Two-Step Process: Establishing and Implementing National Health-Based Ambient Air Quality Standards

In 1970, Congress established an effective framework in the fight against air pollution. Congress commanded that the national ambient air quality standards (“NAAQS”) be based on public health considerations alone. Then, economics are thoroughly considered in developing the air pollution control strategies to achieve the health standards. So, the law is sharply focused on

² U.S. Environmental Protection Agency, *The Benefits and Costs of the Clean Air Act, 1970 to 1990*, at 53 (Oct. 1997), available at <http://www.epa.gov/cleanairactbenefits/copy.html>. Estimates of benefits, in 1990 dollars, range from \$5.6 to \$49.4 trillion, with a central estimate of \$22.2 trillion. *Id.*

³ U.S. Environmental Protection Agency, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, at 5-25, tbl. 5-6 (Apr. 2011), available at http://www.epa.gov/cleanairactbenefits/feb11/fullreport_rev_a.pdf.

⁴ *Id.* at 7-3.

⁵ U.S. Environmental Protection Agency, Summary Report, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, at 3, available at <http://www.epa.gov/cleanairactbenefits/feb11/summaryreport.pdf>.

⁶ U.S. Environmental Protection Agency, *Benefits and Costs of the Clean Air Act Amendments of 1990*, Fact Sheet, available at <http://www.epa.gov/cleanairactbenefits/feb11/factsheet.pdf>.

ensuring the nation's health-standards are established solely on the basis of public health, and this same law is broadly encompassing in considering economics when federal, state, and local officials determine how to cost-effectively achieve the health standards.

Protecting Public Health

Some have long protested this carefully calibrated dual system. Some have argued that this two-step inquiry should be conflated rather than distinct, that the nation's health standards should be based on economics and then economics should likewise infuse the policies to achieve the standards. This argument has been thoroughly presented and resoundingly rejected over the past 40-plus years.

This question was answered by a unanimous Senate in 1970. The language crafted by Congress in 1970 is straight forward; its meaning is plain. The Administrator is instructed to establish standards that "are requisite to protect the public health" with "an adequate margin of safety."⁷ The statute thus provides for the health-based standards to be based exclusively on public health and to be precautionary in safeguarding against adverse health effects.

This question has also been consistently answered by the decisions of prior EPA Administrators and numerous judicial decisions of the federal court of appeals in Washington, D.C.⁸

Ultimately, this question was emphatically answered by a unanimous Supreme Court. Justice Antonin Scalia, writing for the high Court, explained that the text of the Clean Air Act is clear, notwithstanding the copious arguments of many lawyers: "

Were it not for the hundreds of pages of briefing respondents have submitted on the issue, one would have thought it fairly clear that this text does not permit the EPA to consider costs in setting the standards.⁹

Justice Scalia then set forth the inquiry the Administrator must make in establishing the nation's health-based air quality standards that is thoroughly anchored in protecting public health:

The EPA, "based on" the information about health effects contained in the technical "criteria" documents compiled under § 108(a)(2), 42 U.S.C. § 7408(a)(2), is to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an "adequate" margin of safety, and set the standard at that level. Nowhere are the costs of achieving such a standard made part of that initial calculation.¹⁰

⁷ Clean Air Act § 109(b)(1), 42 U.S.C. § 7409(b)(1).

⁸ See, e.g., *Am. Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998); *Natural Res. Def. Council v. Adm'r, EPA*, 902 F.2d 962 (D.C. Cir. 1990), vacated in part on other grounds, 921 F.2d 326 (D.C. Cir. 1991); *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176 (D.C. Cir. 1981); *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130 (D.C. Cir. 1980).

⁹ *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 465 (2001).

¹⁰ *Id.*

Considering Costs and Deploying Cost-Effective Solutions

After the health-based standards are established, the Clean Air Act provides a prominent role for consideration of costs in national, state, and local decisions about the pollution control strategies deployed to achieve the health standards. The statute provides for the consideration of costs in setting emission limits for cars, SUVs, trucks, buses, construction equipment, aircraft, fuels, power plants, and industrial facilities.¹¹

States and local governments, in turn, are distinctly responsible for designing the air quality management plans for their communities and entrusted with determining how the clean up burden is allocated to restore healthy air. Justice Scalia succinctly explained that “[i]t is to the States that the Act assigns initial and primary responsibility for deciding what emissions reductions will be required from which sources.”¹²

III. EPA’s Revised Ozone Standard is a Step in the Right Direction but Could Achieve Even Greater Health Protection

On October 1, EPA established a revised ozone standard of 70 parts per billion (“ppb”), improving America’s national air quality standard for ground-level ozone. The standard is expected to prevent up to 660 premature deaths, 230,000 asthma attacks, and 160,000 lost school days across the nation in 2025, excluding California. EPA estimates the benefits at this level of protection provide up to \$5.9 billion in monetized benefits, greatly outweighing the costs of implementation.¹³

Scientific evidence overwhelmingly demonstrates that the previous 75 ppb standard was not requisite to protect human health with an adequate margin of safety, as required by the Clean Air Act.¹⁴

An Extensive Body of Scientific Evidence Demonstrates the Harms Associated with Ozone Pollution

Since 2008, there have been more than 1,000 new studies that demonstrate the health and environmental harms of ozone.¹⁵ In particular, EPA has concluded:

¹¹ 42 U.S.C. §§ 7521(a), 7547(a), 7545, 7541, and 7411(a).

¹² *Whitman*, 531 U.S. at 470.

¹³ U.S. Environmental Protection Agency, By the Numbers fact sheet (October 2015), <http://www3.epa.gov/airquality/ozonepollution/pdfs/20151001numbersfs.pdf>.

¹⁴ Letter from Christopher Frey PhD to Administrator McCarthy, *CASAC Review of the EPA’s Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*, at ii (June 26, 2014), available at [http://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/\\$File/EPA-CASAC-14-004+unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf) (hereinafter “CASAC Letter”).

¹⁵ U.S. Environmental Protection Agency, Fact Sheet, OVERVIEW OF EPA’S UPDATES TO THE AIR QUALITY STANDARDS

Scientific evidence shows that ozone can cause a number of harmful effects on the respiratory system, including difficulty breathing and inflammation of the airways. For people with lung diseases such as asthma and COPD (chronic obstructive pulmonary disease), these effects can aggravate their diseases, leading to increased medication use, emergency room visits and hospital admissions.

Evidence also indicates that long-term exposure to ozone is likely to be one of many causes of asthma development. In addition, studies show that ozone exposure is likely to cause premature death.¹⁶

Scientific and technical analyses—reflected in EPA’s final rule—underscore that the risk of these harmful health effects is even more pronounced for people with asthma and other respiratory diseases, children, older adults, people who work or are active outdoors. An estimated 23 million people have asthma in the U.S., including almost 6.1 million children.¹⁷ Asthma disproportionately impacts communities of color and lower-income communities.¹⁸ Strengthened ozone health standards will help improve air quality in these and all communities across the country.

Children, in particular, are considered the most at risk group because they breathe more air per unit of body weight, are more active outdoors, are more likely to have asthma than adults, and are still developing their lungs and other organs. In fact, EPA’s Children’s Health Protection Advisory Committee—a body of external experts that provide the Administrator with recommendations concerning children’s health—recommends a substantially stronger standard to protect the health of children. CHPAC finds that “[c]hildren suffer a disproportionate burden of ozone-related health impacts due to critical developmental periods of lung growth in childhood and adolescence that can result in permanent disability.”¹⁹

Scientific Evidence Clearly Demonstrates that Strong Ozone Standards are Required to Protect Public Health

FOR GROUND-LEVEL OZONE, <http://www3.epa.gov/ozonepollution/pdfs/20151001overviewfs.pdf> (hereinafter “Ozone Standard Fact Sheet”); see also U.S. Environmental Protection Agency, Integrated Science Assessment for Ozone and Related Photochemical Oxidants, Final Report (Feb. 2013), available at <http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492#Download>.

¹⁶Ozone Standard Fact Sheet, *supra* note 15.

¹⁷ Ozone Standard Fact Sheet, *supra* note 15.

¹⁸ *Id.*

¹⁹ Letter from Sheela Sathyanarayana MD MPH, Chair, Children’s Health Protection Advisory Committee to Christopher Frey PhD, CASAC Review of the Health Risk and Exposure Assessment for Ozone and Policy Assessment for the Review of the Ozone NAAQS: Second External Review Drafts, (May 19, 2014), available at [http://yosemite.epa.gov/sab/sabproduct.nsf/7F79D27B503CB28385257CDE00546CB3/\\$File/CHPAC+May+2014+Letter+&+Attached+2007+Letters.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/7F79D27B503CB28385257CDE00546CB3/$File/CHPAC+May+2014+Letter+&+Attached+2007+Letters.pdf).

The recommendations of the statutorily established and independent scientific advisory committee—the Clean Air Scientific Advisory Committee (“CASAC”)—underscored the need, as determined by the latest scientific evidence, to strengthen the ground-level ozone standard.

In the 1977 Clean Air Act Amendments, Congress established the CASAC to review the scientific and technical basis for the NAAQS and to provide the Administrator with independent advice concerning the establishment, review, and revisions of those standards. Section 109(d) of the Clean Air Act underscores CASAC’s independent scientific charge and broad-based scientific and technical expertise: “[t]he Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.”²⁰ Among other things, the statute requires that CASAC “recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 [42 U.S.C. § 7408] of this title and subsection (b) of this section.”²¹ Consistent with these statutory requirements, the CASAC ozone review panel is currently comprised of scientific experts from numerous universities as well as other independent experts, including a representative from the Electric Power Research Institute.²²

CASAC has reviewed and provided analysis and feedback on EPA’s scientific and policy assessments related to the agency’s revisions of the 2008 ozone standards. In a letter, CASAC emphasized that the latest scientific evidence underscores the inadequacy of the current standard.²³ Specifically, CASAC found “scientific justification that current evidence and the results of the exposure and risk assessment call into question the adequacy of the current standard” and that there is “clear scientific support for the need to revise the standard.”²⁴

Though CASAC recommended a range of 60–70 ppb, the Committee went on to emphasize the inadequacy of a standard at the upper end of that range: “[a]t 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation.”²⁵ Accordingly, CASAC recommended that the Administrator “set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.”²⁶

²⁰ 42 U.S.C. § 7409(d)(2)(A).

²¹ *Id.* § 7409(d)(2)(B).

²² See EPA Clean Air Scientific Advisory Committee (CASAC), *Ozone Review Panel*, <http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean%20Air%20Scientific%20Advisory%20Committee> (last visited Oct. 15, 2015).

²³ CASAC Letter, *supra* note 14, at ii.

²⁴ *Id.* at ii.

²⁵ *Id.*

²⁶ *Id.* at ii-iii.

In reaching this conclusion, CASAC evaluated extensive scientific evidence, including clinical studies, epidemiological studies, and animal toxicology studies—summarized in EPA’s Integrated Scientific Assessment—along with findings from exposure and risk assessments included in EPA’s Health and Risk Exposure Assessment.

IV. Strong Ozone Standards are Achievable and Cost-Effective

Many highly cost-effective, commonsense clean air measures are available to help secure pollution reductions needed to achieve the improved air quality standards. The 40-year history of the Clean Air Act shows that the nation’s public health standards are achievable, through available technologies and innovation by states and businesses. National average ozone concentrations have gone down 33% since 1980 and more than 90% of areas originally designated nonattainment for the 1997 ozone standards now meet those standards.²⁷ Moreover, our nation has often worked to achieve greater reductions than required, sooner, and at lower costs than estimated. Indeed, there are many clean air measures well underway that will help states, communities and families realize vital protections from ozone pollution.

Misplaced “Sky is Falling” Claims Provoke Polarization Over Clean Air Protections for America’s Communities and Families

Some claim that adopting strong ozone standards will cause economic harm. Unfortunately, these “sky is falling” prognostications are not new. In 1997, during another debate over strengthened national public health standards, Senator Spencer Abraham (R-MI) was among those who claimed that the new standards would have serious economic impacts: “Dry cleaning establishments, hair salons, and other small businesses will not be able to absorb the increased costs imposed by these regulations,” the Senator said.²⁸

In fact, our nation made enormous strides in protecting public health from air pollution through commonsense cost-effective solutions. This is consistent with the time tested history of the Clean Air Act. Between 1990 and 2020, a recent EPA report projects that the benefits of the Clean Air Act will outweigh costs by 30 to 1.²⁹

In recent years, similar “sky is falling” claims have been made about clean air standards to control acid rain, cut mercury and other air toxics, reduce soot, and lower tailpipe emissions.

These “sky is falling” claims were recently prominent in the debate over EPA’s landmark mercury and air toxics standards for power plants. EPA Administrator Lisa Jackson signed the final Mercury and Air Toxics Standards in December 2011 at Children’s Hospital in Washington, D.C. Within months, major power companies that had been making “sky is

²⁷ U.S. Environmental Protection Agency, By the Numbers fact sheet (October 2015), <http://www3.epa.gov/airquality/ozonepollution/pdfs/20151001numbersfs.pdf>.

²⁸ 143 CONG. REC. S10813 (daily ed. Oct. 9, 1997) (statement of Sen. Abraham).

²⁹ U.S. Environmental Protection Agency, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, supra note 3.

falling” claims about the compliance costs during EPA’s development of these standards were touting to investors that compliance costs were plummeting:

- On July 20, **American Electric Power CEO Nicholas Akins** confirmed that the company’s projected costs have come down nearly 25% from what AEP originally projected. He added, “[W]e expect it to continue to be refined as we go forward.” In other words, costs will come down even further.³⁰
- On May 15, **Southern Company CFO and Executive Vice President Arthur P. Beatty** stated that the amount the company projects for compliance costs “could be \$0.5 billion to \$1 billion less, because of the new flexibility that [the company has] found in the final rules of the MATS regulation.”³¹
- On August 8, **First Energy CEO Anthony Alexander** stated, “[W]e have significantly reduced our projected capital investment related to MATS compliance.”³²

Based on recent earnings calls, American Electric Power Company’s range of cost estimates has fallen by a third to half, Southern Company’s cost estimates have declined by a third, and FirstEnergy’s costs have fallen approximately 77-85 percent.³³

This is consistent with the history of the Clean Air Act. Initial projections are often higher than actual costs. EDF has evaluated industry cost projections for several past EPA rulemakings where projections were several times higher than actual costs.³⁴ Moreover, since 1970, our nation has reduced the six pollutants regulated under the national ambient air quality standards program by almost 70 percent while GDP has grown by nearly 240 percent as illustrated in the graph below.

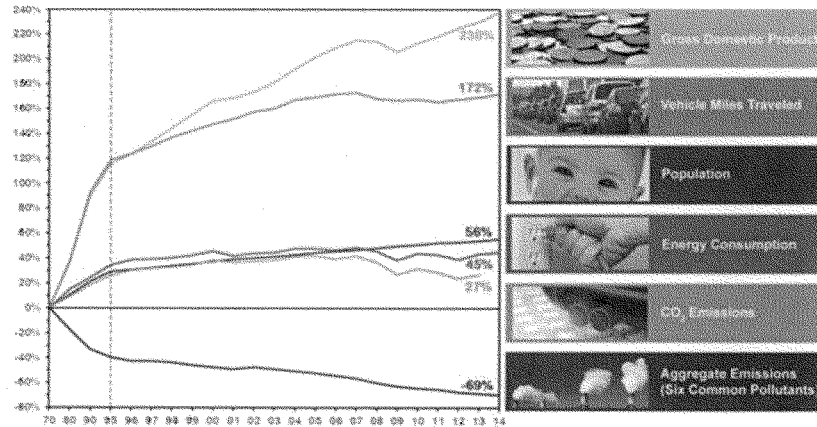
³⁰ Nicholas Akins, American Electric Power Co., Inc. Q2 2012 Earnings Call Transcript (July 20, 2012), *available at* <http://seekingalpha.com/article/736561-american-electric-power-management-discusses-q2-2012-results-earnings-call-transcript?all=true&find=american%2Belectric%2Bpower%2BAEP%2B%2Bjuly%2B12%2C%2B2012>.

³¹ Art Beatty, CFO of Southern Company, Deutsche Bank Clean Tech, Utilities and Power Conference Call Recording (May 15, 2012), *available at* <http://earningscast.com/SO/20120515>.

³² Anthony Alexander, CEO, FirstEnergy, Q2 2012 Results, Earnings Call Transcript (Aug. 8, 2012), *available at* <http://seekingalpha.com/article/790061-firstenergys-ceo-discusses-q2-2012-results-earnings-call-transcript>.

³³ See Env’t. Def. Fund, Blog, *Power Companies’ Declining Estimates of Compliance Costs of the Mercury & Air Toxics Standards (MATS)*, http://blogs.edf.org/climate411/files/2014/05/Declining-costs-of-MATS-compliance.pdf?_ga=1.102810441.834084056.1418406109.

³⁴ Environmental Defense Fund, 3 Times Industry has Missed on Cost Estimates, <https://www.edf.org/climate/3-times-industry-has-missed-cost-estimates>.

Comparison of Growth Areas and Emissions, 1970-2014

Source: U.S. EPA³⁵

Actions Already Underway Will Help Communities Meet Strengthened Ozone Standards

Currently, 90 percent of areas designated nonattainment for the 1997 ozone health standards now meet those standards.³⁶ The U.S. has already taken steps over the past few years that help to reduce ozone smog pollution and help restore healthy air in a cost effective manner. Those protections include: the Tier 3 tailpipe standards, supported by the U.S. auto industry, which will slash smog-forming pollution from new cars beginning in model year 2017 and lower sulfur in gasoline which will reduce pollution from every car on the road (these standards are projected to reduce NOx emissions by about 260,000 tons in 2018 alone, or about 10% of emissions from on-highway vehicles),³⁷ recently finalized greenhouse gas and fuel standards for medium- and heavy-duty trucks; and, EPA's Clean Power Plan, which will substantially reduce smog-forming pollutants from power plant smokestacks nationwide.

These are just a few of the existing and pending national emission standards that will secure substantial reductions and that EPA anticipates will help to achieve broad-based compliance with strengthened ozone air quality standards. Analysis of various clean air measures adopted or soon to be put in place indicates that our nation will reduce the precursors to smog by millions of tons, securing over two million tons of volatile organic compound reductions and over five million

³⁵ U.S. EPA, http://www3.epa.gov/airtrends/images/y70_14.png

³⁶ U.S. Environmental Protection Agency, By the Numbers fact sheet (October 2015), <http://www3.epa.gov/airquality/ozonepollution/pdfs/20151001numbersfs.pdf>.

³⁷ U.S. Environmental Protection Agency, Tier 3 Gasoline Sulfur Standard's Impact on Gasoline Refining, <http://www3.epa.gov/otaq/documents/tier3/420f14007.pdf>.

tons of nitrogen oxides reductions.³⁸ These emissions standards will help to secure the vast majority of reductions needed to meet a strong health-based standard for ozone.

V. There is Broad Support to Strengthen the Health-Based National Ambient Air Quality Standards for Ground-Level Ozone

Leading health and medical associations have strongly recommended that our nation strengthen the health-based standard for ground-level ozone to well below 75 ppb to protect public health. Groups including the American Lung Association, American Public Health Association, American Thoracic Society, Trust for America's Health, Asthma and Allergy Foundation of America, Health Care Without Harm, and National Association of County and City Health Officials recommended an 8-hour ozone standard lower than 75 ppb.³⁹ A strong ozone standard could prevent up to 1.8 million asthma attacks in children, 1.9 million school days missed, and 7,900 premature deaths nationwide every year.

Here are a few examples of the broad support and ample evidence of the need for stronger health-protective ozone standards:

“...Thousands of peer-reviewed medical studies show that breathing ozone pollution is dangerous to human health and the EPA review shows harm is occurring at levels far below what is currently considered ‘safe.’ ”

“This means too many Americans have been informed that the air in their community is safe to breathe based on the outdated standard. The science shows that information was wrong. Every parent in America has a right to know the truth about the air their children breathe.”

...

“For far too long, millions of Americans have been living with a weak and outdated standard.

- **Harold P. Wimmer, National President and CEO of the American Lung Association**⁴⁰

“...“The body of scientific evidence supporting the health benefits of a lower ozone standard has grown substantially in the last few years,” said John R. Balmes, MD, a pulmonary critical care physician and chair of the ATS Environmental Health Policy Committee. “Ozone pollution has been linked to low birth weight, decreased lung function and other respiratory problems in infants and children, worse asthma control in both children and adults, and with cardiovascular disease and increased mortality in adults.”

³⁸ U.S. Environmental Protection Agency, Regulatory Impact Analysis, supra note 29, at tbl. 3-1.

³⁹ Letter from Janice Nolen, et al., to Christopher Frey PhD (May 19, 2014), available at http://blogs.edf.org/climate411/files/2014/11/health_and_medical_org_letter_to_casac_on_o3_naaqs.pdf.

⁴⁰ American Lung Association, Press Release, Lung Association Welcomes Obama Administration's Long Overdue Ozone Pollution Proposal, Calls for Greater Protection, (Nov. 26, 2014), available at <http://www.lung.org/pressroom/press-releases/healthy-air/statement-on-2014-ozone-regs.html>.

- **American Thoracic Society⁴¹**

“...Ozone, the main component of smog, is a dangerous air pollutant formed when emissions from vehicle tailpipes, power plants and factories pollutants including volatile organic compounds such as cancer-causing benzene and nitrogen oxides, combine with strong sunlight. Even at low levels, smog can aggravate asthma, cause and worsen respiratory illnesses, and cause lung damage for those who breathe it repeatedly. Ozone exposure results in excessive hospitalizations and emergency room visits and millions of lost school and work days. For the millions of Latinos who work outdoors in construction, landscaping and other fields, continued exposure can lead to serious health problems.”

- **Adrianna Quintero, Director of Voces Verdes**

“As local elected officials representing big cities and small towns, we want to express our strong support for the Environmental Protection Agency’s (EPA) work to update the ozone (or smog) standard. The current, George W. Bush-era standard of 75 parts per billion (ppb) has been widely acknowledged by the medical community as insufficient to protect public health. As mayors, we are on the front lines of protecting the safety and well-being of our constituents and this long-overdue update will reap tremendous benefits for our communities.”

- **Mayoral letter signed by 70 mayors across the nation⁴²**

VI. Conclusion

A rigorous and extensive body of science demonstrates that EPA’s previous national ambient air quality standard for ground-level ozone needed to be strengthened to protect public health. The Clean Air Act, forged on a bedrock foundation of bipartisan collaboration for our nation, instructs the EPA Administrator to take decisive and protective action against these health harms and to establish standards that are requisite to protect public health with an adequate margin of safety.

At the same time, our nation has commonsense and cost-effective solutions already moving forward that will help to achieve a more protective ozone standard and restore healthy air. These solutions include clean air measures, supported by the U.S. auto industry, that will dramatically reduce the smog-forming emissions from new cars beginning in model year 2017 and the landmark Clean Power Plan that will reduce a suite of health-harming emissions from power plants. Indeed, EPA, states and communities alike carefully consider costs in developing the solutions to restore healthy air, and the time tested history of the Clean Air Act is that our nation has in fact secured cleaner, healthier air at a fraction of the predicted costs.

⁴¹ American Thoracic Society, ATSNNews, EPA Proposes Stricter Ozone Standard (Dec. 5, 2014), available at <http://news.thoracic.org/?p=5515>.

⁴² <https://slcgreen.files.wordpress.com/2015/09/mayors-smog-letter-final-copy-9-21-2015.pdf>

The science and law, along with these innovative solutions, create a strong foundation for carrying out the Clean Air Act's founding bipartisan vision to establish national air quality standards that are protective of the health of our children and communities, and then to work together to find cost-effective, common sense solutions to meet the level of protection that science tells us is necessary to safeguard the health of our nation. This vibrant, bipartisan made-in America law has stood the test of time—delivering a stronger, healthier, and more prosperous nation. If we continue to work together building from this legacy of bipartisan collaboration forged in law we will continue to chart a commonsense path forward in protecting the health of our children and communities, securing a stronger and more prosperous nation, and finding that the sky is clearing, not falling.

Dr. Elena Craft is a Health Scientist at Environmental Defense Fund, a non-profit, non-governmental, and non-partisan environmental organization. Dr. Craft's background is in molecular toxicology; she holds a M.S. degree in toxicology from NC State University, and a PhD from Duke University. She also holds an adjunct assistant professorship at the University of Texas School of Public Health in the Division of Epidemiology, Human Genetics, & Environmental Sciences. Her research experience includes work at both the US EPA and the National Institute of Environmental Health Sciences, where she studied the health effects resulting from exposure to environmental pollutants such as PCBs, dioxins, and metals. Over the last 7 years, she has worked to identify, monitor, and mitigate risk from environmental pollution in highly industrial areas, most specifically around port areas and petrochemical facilities. The citizens who live and work near this massive petrochemical complex are exposed to a disproportionate burden of health risks, as many of the areas surrounding these facilities are pollution "hotspots," where the concentrations of specific pollutants in the areas exceed health-based guidelines.

In the course of her work, Dr. Craft has served in a variety of capacities to advise local, regional, and national planning organizations on a diverse set of environmental and environmental justice issues, including serving as the current chair for the Houston Regional Air Quality Planning Committee, advisor to the Clean Air Task Force of Central Texas, and advisor to the Texas state environmental agency in developing a remediation program for pollution hotspot areas around the state. In addition, Dr. Craft has participated in research endeavors regarding the health effects associated with living in areas where the concentrations of certain pollutants exceed state-adopted health-based screening guidelines, most recently presenting her efforts at the Society of Toxicology Annual meeting on incorporating risk assessment methods as a practical tool for assessing health risks from environmental exposures. Dr. Craft has testified at a number of national hearings, given lectures at a number of universities, and has been interviewed by local, national, and international media on environmental issues, presenting scientific information from a health-based perspective. She is also a member of the Society of Toxicology and Society of Environmental Toxicology and Chemistry and has authored several peer-reviewed papers.

Chairman SMITH. Thank you, Dr. Craft.
And Dr. Honeycutt.

**TESTIMONY OF DR. MICHAEL HONEYCUTT,
DIRECTOR, TEXAS COMMISSION
ON ENVIRONMENTAL QUALITY,
TOXICOLOGY DIVISION**

Mr. HONEYCUTT. Good morning, Mr. Chairman, and Members of the Committee. I'm Dr. Michael Honeycutt, Director of the Toxicology Division at the TCEQ. I lead a division of 14 toxicologists, who are responsible for evaluating a broad spectrum of environmental quality issues, including deriving acceptable levels of air contaminants.

The TCEQ has derived acceptable air contaminant levels for many thousands of air contaminants over the last 30-plus years, and our current team of toxicology risk assessors has over 280 combined years of experience in these fields. We derive these levels using a scientific, peer-reviewed method, and many of these levels and their derivation process have been published in independent scientific journals. Other state governments, federal agencies including the EPA, and other countries use the TCEQ's acceptable air contaminant values.

On October 1 of this year, the EPA decreased the level of the ozone standard from an annual fourth-highest daily maximum 8-hour concentration of 75 parts per billion to 70 parts per billion. Today, I will address considerations of overall health risk, but first, I would like to set the record straight on the ozone science.

Based on our extensive background in deriving acceptable air contaminant levels, we independently reviewed thousands of studies on ozone, including the studies the EPA reviewed as a part of setting the final standard. Ozone is a simple oxidizing chemical that, at high enough concentrations, can cause inflammation in the lungs, and it can reversibly limit the body's ability to inhale and exhale a normal volume of air. However, there remains large uncertainty and variability in the scientific literature.

With regard to changes in lung function and asthma exacerbations, eight out of nine studies investigating lung function changes caused by ozone showed no difference between asthmatics and healthy individuals. As we stated in our comments to EPA, the dose that a person would be expected to receive at 75 parts per billion is almost no different than 70 parts per billion or even 65 parts per billion. And you can see figure 1 in my comments to see that.

Consistent with this finding, the EPA does not predict—let me state it again. The EPA does not predict that a decrease in the ozone standard will cause a statistically significant decrease in asthma attacks. You can see figure 2 for that information.

The basis for setting the standard at 70 parts per billion was to make it lower than the lowest exposure concentration where adverse effects were observed in human controlled exposure studies, which was 72 parts per billion. However, in order to observe any effects at this low ozone concentration, the authors had to expose the human subjects to ozone while they were exercising at moderate to heavy exertion for 50 minutes out of every hour for 6.6

hours. This is an unrealistic exposure scenario for the general public, much less for sensitive groups. Therefore, it would take higher exposure concentrations to have the same effect noted in that study.

Although asthma exacerbations and changes in lung function are the most important and biologically relevant effects, most of the monetary benefits that EPA ascribes to reductions in ozone are from reductions in premature mortality. They do this despite the fact that, from a toxicology standpoint, there is no explanation for how eight hours of ozone exposure at ambient, present-day concentrations on one day can cause premature mortality the next day. In addition, the EPA Administrator has expressed a lack of confidence in the studies associating ozone with premature mortality due to the inherent study uncertainties.

The results from these studies are also contradictory and inconsistent. For example, in the main mortality study that the EPA uses, Smith 2009 showed that only seven out of 98 U.S. cities have a significant association between eight hour ozone concentrations and mortality. Also, astonishingly, the EPA's analysis shows mortality increasing in certain cities, including Detroit and Houston when decreasing the ozone standard from 75 to 70 parts per billion. And no, I did not misread that.

Some inconsistency between study findings is not uncommon. Scientists who are experienced in risk assessment can incorporate these disparate pieces of information into a cohesive characterization of health risk. The EPA would be better advised and critiqued on their risk assessment if a risk assessor was included on the CASAC. A chemical risk assessor is essential to put the potential risk highlighted by the other CASAC experts into context—into context with the inherent background risk present in our daily lives. The Clean Air Act does not require that risks are reduced to zero, and risk assessment with uncertainty analysis can demonstrate the reduction in risk, or lack thereof, from a reduction in a regulatory standard.

The lack of consideration of overall risk is perhaps more apparent—most apparent when reviewing the revisions to the EPA's Air Quality Index in the final rule. According to the new category breakpoints, sensitive members of the public will now be cautioned to consider reducing prolonged or heavy outdoor exertion at 55 parts per billion ozone, a number that has no experimental basis. Beginning at 71 parts per billion, the EPA advises the public to keep their asthma inhalers handy. Anecdotally, we are told that some schools in Texas will cancel recess when they receive this alert.

The problem is that this is based on a single study that showed a mild lung function effect after exposure to 72 parts per billion ozone for 6.6 hours with vigorous exercise. And it is being used to cancel a 20-minute recess. In the Dallas-Fort Worth area of Texas in 2014, there would have been 23 such days that children might not have been able to play outdoors.

These health messages and the new frequency with which they will be released can lead to growing public concern over air quality that is actually getting better and can lead to keeping our children

and ourselves from the well-documented physical and psychological benefits of outdoor exercise.

Let me be clear. Under certain circumstances at high concentrations, ground-level ozone can have negative implications for respiratory health, but our investigations conclude that low concentrations that we see today, the risks to respiratory health are small and are not significantly diminished by the decreased ozone standard.

I have a tremendous amount of respect for the intent of the Clean Air Act, the EPA, and the role that science plays in setting meaningful policy.

I thank you for the opportunity to be here and I'm happy to answer any questions.

[The prepared statement of Mr. Honeycutt follows:]

Good morning, Mr. Chairman and members of the committee. I am Dr. Michael Honeycutt, director of the Toxicology Division at the Texas Commission on Environmental Quality (the TCEQ). I lead a division of 14 toxicologists who are responsible for evaluating a broad spectrum of environmental quality issues, including deriving acceptable levels of air contaminants.

The TCEQ has derived acceptable air contaminant levels for many thousands of air contaminants over the last 30+ years and our current team of toxicology risk assessors has over 280 combined years of experience in these fields. We derive these levels using a scientific, peer-reviewed method and many of these levels and their derivation process have been published in independent scientific journals [1-14]. Other state governments, federal government agencies including the EPA, and other countries, use the TCEQ's acceptable air contaminant values.

On October 1 of this year, the EPA decreased the level of the ozone standard from an annual fourth-highest daily maximum 8-hour concentration of 75 ppb, to 70 ppb. Today I will address considerations of overall health risk, but first, I would like to set the record straight on the ozone science.

Based on our extensive background in deriving acceptable air contaminant levels, we independently reviewed thousands of studies on ozone, including studies the EPA reviewed as a part of setting the final standard.

Ozone is a simple oxidizing chemical that, at high enough concentrations, can cause inflammation in the lungs, and it can reversibly limit the body's ability to inhale and exhale a normal volume of air. However, there remains large uncertainty and variability in the scientific literature. With regard to changes in lung function and asthma exacerbations,

- 8 out of 9 studies investigating lung function changes caused by ozone showed no difference between asthmatics and healthy individuals [15-23].
- As we stated in our comments to the EPA, the dose a person would be expected to receive at 75 ppb is almost no different than at 70 ppb, or even 65 ppb – see Figure 1. Consistent with this finding, the EPA does not predict that a decrease in the ozone standard will cause a statistically significant decrease in asthma exacerbations (attacks) – see Figure 2 [24].
- The basis for setting the standard at 70 ppb was to make it lower than the lowest exposure concentration where adverse effects were observed in human controlled exposure studies, which was 72 ppb [25]. However, in order to observe any effects at this low ozone concentration, the study authors had to expose the human subjects to ozone while they were exercising at moderate to heavy exertion for 50 minutes out of every hour for 6.6 hours [25-28]. This is an unrealistic exposure scenario for the general public, much less for sensitive groups. Therefore, it would take higher concentrations to have the same effect noted in the study.

Although asthma exacerbations and changes in lung function are the most important and biologically relevant effects, most of the monetary benefits that EPA ascribes to reductions in ozone are from reductions in premature mortality [24]. They do this despite the fact that, from a toxicology standpoint, there is no explanation for how 8 hours of ozone exposure at ambient, present-day concentrations on one day causes premature mortality the next day. In addition, the

EPA Administrator has expressed a lack of confidence in the studies associating ozone with premature mortality due to inherent study uncertainties [29]. The results from these studies are also contradictory and inconsistent. For example, in the main mortality study that the EPA uses, Smith et al. (2009) [30] showed that only 7 out of 98 US cities have a significant association between 8 hour ozone concentrations and mortality. Also, astonishingly, the EPA's analysis shows mortality **increasing** in certain cities, including Detroit and Houston when **decreasing** the ozone standard from 75 ppb to 70 ppb [31].

Some inconsistency between study findings is not uncommon. Scientists who are experienced in risk assessment can incorporate these disparate pieces of information into a cohesive characterization of health risk. The EPA would be better advised and critiqued on their risk assessment if a risk assessor was included on the Clean Air Scientific Advisory Committee, or CASAC. A chemical risk assessor is essential to put the potential risks highlighted by the other CASAC experts into context with the inherent background risk present in our daily lives. The Clean Air Act does not require that risks are reduced to zero, and risk assessment with uncertainty analysis can demonstrate the reduction in risk, or lack thereof, from a reduction in a regulatory standard.

The lack of consideration of overall risk is perhaps most apparent when reviewing the revisions to the EPA's Air Quality Index (AQI) in the final ozone rule. According to the new category breakpoints:

- Sensitive members of the public will now be cautioned to consider reducing prolonged or heavy outdoor exertion at 55 ppb ozone, a number that has no experimental basis.
- Beginning at 71 ppb, the EPA advises the public to keep their asthma inhalers handy. Anecdotally, we are told that some schools in Texas will cancel recess when they receive this alert. The problem is that this is based on a single study that showed a mild lung function effect after exposure to 72 ppb ozone for 6.6 hours with vigorous exercise. And it is being used to cancel a 20 minute recess. In the Dallas-Fort Worth area of Texas in 2014, there would have been 23 such days that children might not have been able to play outdoors.

These health messages and the new frequency with which they will be released (see Table 1) can lead to growing public concern over air quality that is actually getting better, and can lead to keeping our children and ourselves from the well-documented physical and psychological benefits of outdoor exercise.

Let me be clear. Under certain circumstances, such as at high concentrations, ground-level ozone can have negative implications for respiratory health. But our investigations conclude that at low concentrations the risks to respiratory health are small, and are not significantly diminished by the decreased ozone standard or activity advice in the revised AQI categories.

I have a tremendous amount of respect for the intent of the Clean Air Act, the EPA, and the role that science plays in setting meaningful policy to protect the health of all Americans. I thank you for the opportunity to be here and I am happy to answer any questions you may have.

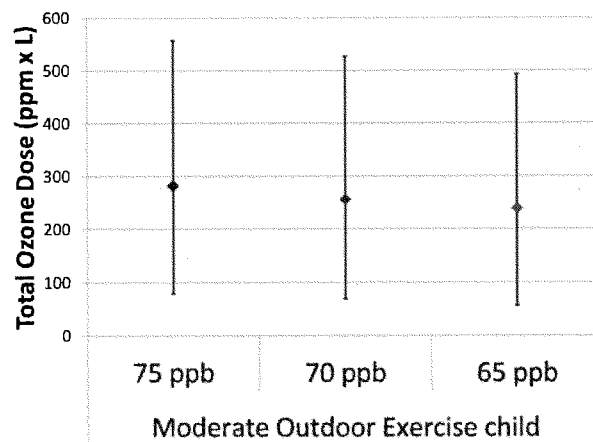


Figure 1. Total dose of ozone changes very little with decreasing the ozone concentration from 75 ppb to 65 ppb

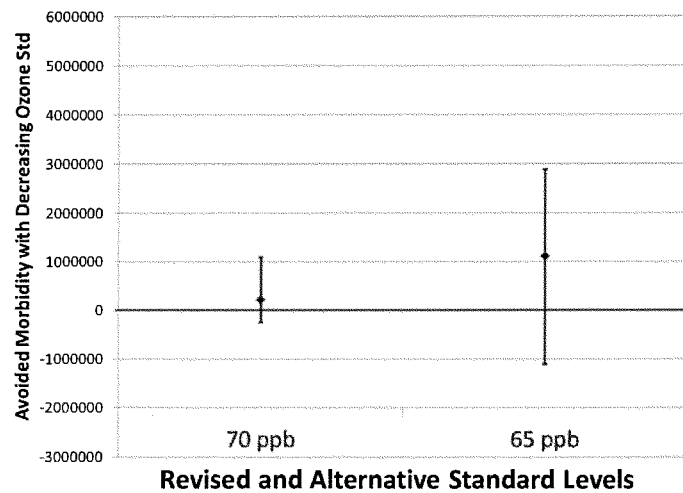


Figure 2. A lower ozone standard will not result in a statistically significant decrease in asthma exacerbations (attacks).

Table 1. The 2015 Air Quality Index categorization scheme will increase the number of days with an air quality alert, even though ambient concentrations remain the same.

Air Quality Index Category	Houston-Galveston-Brazoria						Dallas-Fort Worth-Arlington					
	2012	2013	2014	2015	2015*	2015**	2012	2013	2014	2015	2015*	2015**
Good	283	259	302	274	307	273	259	271	288	252	191	179
Moderate	51	60	44	66	52	79	73	62	65	88	12	21
Unhealthy for Sensitive Groups	28	36	18	20	6	12	31	31	12	23	9	11
Unhealthy	3	9	1	5	0	1	3	9	0	2	0	1
Very Unhealthy	1	2	0	0	0	0	0	3	0	0	0	0

* Air Quality Index categorization scheme based on the 2008 or 2015 ozone national ambient air quality standard.

** 2015 data only includes January through July.

Table 2. Air Quality Index categories and suggested ozone-related health messages.

Air Quality Index	8-Hour Ozone Concentration (ppb)	Activity Advice*
Good (0-50)	0-54	"It's a great day to be active outside."
Moderate (51-100)	55-70	"Unusually sensitive people: <i>Consider reducing</i> prolonged or heavy outdoor exertion. Watch for symptoms such as coughing or shortness of breath. These are signs to take it a little easier. Everyone else: It's a good day to be active outside."
Unhealthy for Sensitive Groups (101-150)	71-85	"Sensitive groups: <i>Reduce</i> prolonged or heavy outdoor exertion. Take more breaks, do less intense activities. Watch for symptoms such as coughing or shortness of breath. Schedule outdoor activities in the morning when ozone is lower. People with asthma should follow their asthma action plans and keep quick relief medicine handy."
Unhealthy (151-200)	86-105	"Sensitive groups: <i>Avoid</i> prolonged or heavy outdoor exertion. Schedule outdoor activities in the morning when ozone is lower. Consider moving activities indoors. People with asthma, keep quick-relief medicine handy. Everyone else: <i>Reduce</i> prolonged or heavy outdoor exertion. Take more breaks, do less intense activities. Schedule outdoor activities in the morning when ozone is lower."
Very Unhealthy (201-300)	106-200	"Sensitive groups: <i>Avoid all</i> physical activity outdoors. Move activities indoors or reschedule to a time when air quality is better. People with asthma, keep quick-relief medicine handy. Everyone else: <i>Avoid</i> prolonged or heavy outdoor exertion. Schedule outdoor activities in the morning when ozone is lower. Consider moving activities indoors."
Hazardous (301-500)	201-Significant Harm Level**	"Everyone: <i>Avoid all</i> physical activity outdoors."

*. Source: US Environmental Protection Agency, *Air Quality Guide for Ozone*, 2015; August. EPA-456/F-15-006
 **. 2-hour average of 600 ppb

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Dr. Honeycutt is the director of the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). He has been employed by the TCEQ since 1996 and has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing health effects reviews of air permit applications, overseeing the review of the results of ambient air monitoring projects, and overseeing the reviews of human health risk assessments for hazardous waste sites. Dr. Honeycutt spearheaded the updating of TCEQ's Effects Screening Levels (ESLs), or toxicity factors for chemicals. The current TCEQ ESL derivation procedure has been through two independent external scientific peer reviews and multiple rounds of public comment (<http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html>). Dr. Honeycutt serves as a technical resource for TCEQ management and staff on issues concerning air and water quality, drinking water contamination, and soil contamination. He also serves as an expert witness in public and state legislative hearings, participates in public meetings, and has conducted hundreds of media interviews.

Dr. Honeycutt is an adjunct professor in two departments at Texas A&M University, has published numerous articles in the peer-reviewed literature, serves or has served on numerous external scientific committees, and has provided invited testimony at Congressional hearings.

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Chairman SMITH. Thank you, Dr. Honeycutt.

I recognize myself for questions.

And, Mr. Holmstead, I would like to direct the first one to you, and that is you've mentioned several examples, but would you just summarize the adverse consequences of this new ozone regulation?

The Hon. HOLMSTEAD. Well, the most immediate one is really that it will ban industrial growth in many parts of the country. That's not universally true, but there will be many parts of the country where, no matter how hard a local community wants to attract new industry, it won't be able to do so because they can't get the permits they need to build or expand a new industrial facility.

The longer-term consequence is that it really does drive up the cost of virtually everything we consume, not only energy, but other products as well.

Chairman SMITH. Okay. Thank you, Mr. Holmstead.

Mr. Sadredin, you mentioned the San Joaquin Valley. Does the technology exist today to actually enable that region to attain the standards that it needs to attain under the proposed rule?

Mr. SADREDIN. The simple answer is no, but that is not limited to the newest standard alone. As we speak, EPA has already classified the San Joaquin Valley as extreme nonattainment even for the 75 parts-per-billion standard and the previous standard of 84 parts per billion. And extreme by definition means that technology today does not exist.

Chairman SMITH. Any idea when the technology might exist or is it just totally unknown?

Mr. SADREDIN. At this point it's unknown. EPA in their own—you know, latest regulatory impact analysis, they talk about technology that does not exist and they don't know when it would be available. And that is why we are urging the Congress to take that into account, make some fine-tuning of the Clean Air Act to allow that to be considered in setting up the deadlines and what it takes, how long it takes to come into attainment.

Chairman SMITH. I know you're considering this but I think you'll find the courts on your side and if you can't comply because the technology is not available, you can't be held accountable. So I hope you succeed in that regard.

Mr. SADREDIN. Thank you.

Chairman SMITH. Dr. Honeycutt, would you spend a little time explaining to us the single study that the entire ozone regulation relies upon and why there are limitations to the science that were relied upon in that study? First of all, I can't believe we're just relying upon one study. That clearly smacks of cherry-picking. But if you'll go into some detail about the flaws in the one study and why only one study was used.

Mr. HONEYCUTT. Sure. It is based on—or the level of the standard is based on one study, the Schelegle 2009 study where 31 people were exposed to ozone at various levels for 6.6 hours, exercising moderately to vigorously for 50 minutes out of every hour during the 6.6 hours. And at the 72 part-per-billion exposure concentration, six of the 31 people had lung decrements—lung function decrements greater than ten percent, which EPA considers adverse.

The problem is the group mean was only 5-1/2 percent, a little over 5 percent. And the group mean wasn't adverse, but what EPA

did was pick out the six that were, so they cherry-picked those six people out of the group, and you're not supposed to do that. That's not scientific. That's why the study authors didn't publish the journal article that way because it wouldn't have been published because nobody would accept that. So that's what it's based on.

Chairman SMITH. If any other organization relied upon a single study involving six out of 31 people, it would be laughable, and the fact that the EPA is going to subject millions of people to an unworkable standard at great cost because of that one flawed study is just amazing. And so I agree with your conclusion.

That also concludes my comments, and we'll go now to the gentleman from Virginia. Do you want to recognize somebody else first?

Okay. Mr. Beyer is recognized for his questions.

Mr. BEYER. Thank you, Mr. Chairman, and thank all of you very much for being here. And I'm actually pleased to be part of this this morning just thinking how far we've come, that we have four witnesses representing both people for and against the ozone rule who are here testifying that clean air is a good thing and that we've come a long way, and all committed to making it better.

And the debate is about the level that was set and the costs and benefits, and that for me the factor of this debate is progress, so thank you.

Mr. Chairman, we have a witness from California here today, and California really has some unique—okay. I don't need to do this for the record so never mind. I'm going to go on. Thank you.

Also for the record, you know, I'm a businessman, family business. We have our 42nd anniversary tomorrow in retail automobile sales and service, and so for 42 years I've been hearing about the devastating consequences of new regulations. I just want to say that that's nuts. I remember 1982 Ronald Reagan's Federal Trade Commission was coming out with the used-car disclaimer on the windows, and everywhere in America, all the things were this is going to be the end of the free market, the end of automobile sales. We adapted to it in about a week.

2009 CAFE standards have been set at 22 miles per gallon from '92 through 2008. President Obama raised it to 35 by 2016, again, devastating consequences. We were told the technology does not exist. Well, it's almost 2016. We'll be at 35 miles per gallon. We're about to sell 17 million new cars in America this year, and manufacturers and dealers are having all-time profit years. If anything has pulled down profits, it's been the internet and the quantization of our product.

Dr. Craft, we just heard Dr. Honeycutt say that all this is based on this one study, six out of 35 people. It's my understanding, though, that before the Schelegle study was done, in the George W. Bush Administration, his EPA Clean Air Scientific Advisory Committee Ozone Review Panel wanted it to be set between 60 and 70 parts and unanimously recommended that and were disappointed when the President, you know, recognizing business pressure, put it at 75. How do you respond to that? And is this really based on one study and six people?

Dr. CRAFT. Thank you. No, it's not. We have sound evidence of the health effects of ozone from three branches of science, con-

trolled human exposures, community health studies, and toxicology studies. EPA reviewed thousands and thousands of papers. They have summarized their scientific findings in the Integrated Scientific Assessment, which was under review by three different Science Advisory Committees. They have published those findings. The public was able to participate in looking at the review that EPA scientists had done.

And just a couple of examples of the—from the summary—from EPA's summary, they looked at respiratory effects, causal relationship between short-term ozone exposure and respiratory health effects. They have looked at cardiovascular effects likely to be causal relationship for short-term exposures to ozone and cardiovascular effects, central nervous system effects suggestive of a causal relationship between ozone exposure and CNS effects, total mortality likely to be a causal relationship between short-term exposures to ozone and total mortality. These are not summaries that were derived from a study that picked out six people.

I guess I wanted to also mention that while the Administrator noted the study in her announcement of the standard, there are other studies that have shown that there is a significant effect below 72. It's the Kim study from 2011. So, you know, the idea that we're relying on just one study is not accurate, and it has been a process where EPA has included the public and has been very transparent in this process.

Mr. BEYER. Great. I'd also like to point out quickly that in the pharmaceuticals, they'll spend hundreds of millions of dollars testing new drugs, and if they get one or two or three adverse effects out of 100,000, they'll take the drug off the market. So six out of 35 actually seems like an awful lot to me.

Dr. Keet at Johns Hopkins had a paper that has been misinterpreted to say that poverty makes asthma worse rather than ozone. Can you respond to this mischaracterization of Dr. Keet's letter?

And I'd like to enter her response for the record, please, without objection.

Chairman SMITH. Without objection.

[The appears in Appendix II]

Dr. CRAFT. Sure. That paper, I think, was misunderstood. The study did not actually look at air pollution at all, so any characterization that air pollution is caused by poverty was not the subject of the study itself. And I think that's what Dr. Keet has sent and submitted as part of her letter.

Chairman SMITH. Thank you, Mr. Beyer.

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

Mr. ROHRABACHER. So we had one person telling us that this is all based on one study, and we have another witness telling us that there are thousands of studies that indicate this. Could you name a few studies, Ms. Craft, that have actually been accepted by the EPA Administrator as being legitimate studies that went into this decision?

Dr. CRAFT. In the Integrated Science Assessment, the EPA derived—they include all of the studies that they looked at in referencing—

Mr. ROHRABACHER. Could you name me a couple of the studies that they—that the—is my understanding that the EPA Adminis-

trator has said that there are thousands of studies that have happened on this but none that can be trusted. Maybe you could name us two or three other studies that have been trusted that would be accepted by the EPA Administrator on this.

Dr. CRAFT. Yes, I guess I'm not sure what you mean by trusted. I mean the EPA looked at all of the available studies. So, for example, Jarrett et al. 2009—

Mr. ROHRABACHER. Okay, so you're saying—say this again now. You're giving us a specific now because I'm going to want Dr. Honeycutt's response to this. So there was a—what study you're talking about now specifically?

Dr. CRAFT. Well, I guess it—is the question what are some of the studies the EPA examined as part of their Integrated Science Assessment?

Mr. ROHRABACHER. No. Which ones were accepted by the EPA Administrator as being specific to this decision? We are being told by Mr. Honeycutt that you—that there's only one study and that we're naming it now that specifically justified these EPA rules. You're telling us that—and that the EPA used as an example of this is why we are putting this new rule out. And you're saying that there are thousands of other studies. Could you name us several that the EPA has cited as reasons for their decision?

Dr. CRAFT. I guess the question is about EPA relying on only one study, and I guess my opinion is that that is a mischaracterization, and I'm not sure where that is characterized in the—

Mr. ROHRABACHER. Well, maybe you could tell us the name of three or four studies that—you're saying there are thousands of them—that the EPA has used to justify this change.

Dr. CRAFT. Well, they've looked at—

Mr. ROHRABACHER. I'm not saying—

Dr. CRAFT. —a lot of studies.

Mr. ROHRABACHER. No, no, what have they said this is what justifies our change, not that there is an amorphous over here. We've looked at thousands of things for and against. As far as we know, the thousands—for all we know, maybe half of them, they believe, were against what they have decided on. What two or three studies—this guy is saying we've—there's only one. You're saying there are thousands. Give us two or three studies that the EPA has used to back up this change in regulation.

Dr. CRAFT. The Jarrett et al. 2009 study, the Kim et al. 2011 study. There is—

Mr. ROHRABACHER. Okay.

Dr. CRAFT. —the Stevens study. I mean I can name—

Mr. ROHRABACHER. Okay. Now, we have—

Dr. CRAFT. —a lot of ozone studies.

Mr. ROHRABACHER. Okay. You've just named three, is that correct?

Dr. CRAFT. Right.

Mr. ROHRABACHER. Okay. Now, go for it, Mr. Honeycutt. What—why—you've said there's only one.

Mr. HONEYCUTT. Actually, the Kim study did not find effects. Well, it found significant decrease in FEV1, a 1.8 percent decrease at 60 parts per billion, but by nobody's definition is that an adverse

effect, not the American Thoracic Association—Society's, not by EPA's, by nobody's.

Mr. ROHRABACHER. Okay. So you're just saying that there has only been one study that shows—

Mr. HONEYCUTT. The Schelegle study.

Mr. ROHRABACHER. —an actual detrimental impact, but—

Mr. HONEYCUTT. Well, it depends on your definition, okay? By EPA's definition it's not unless you pick out the six people. So—

Mr. ROHRABACHER. Okay.

Mr. HONEYCUTT. —the previous—

Mr. ROHRABACHER. So is this—

Mr. HONEYCUTT. The previous a standard was set based on epidemiology data. This one they switched it and based it on the clinical data.

Mr. ROHRABACHER. Okay.

Mr. HONEYCUTT. And CASAC spent a whole day talking about this one study and where they should—how—the phraseology they should use—

Mr. ROHRABACHER. Okay.

Mr. HONEYCUTT. —in—

Mr. ROHRABACHER. I want to get to the one that was just given as an example, and you say that one did not—

Mr. HONEYCUTT. Jarrett 2009.

Mr. ROHRABACHER. And that is not—and that did not justify—

Mr. HONEYCUTT. That is the only long-term study out of 12 that found effects—associations with ozone.

Mr. ROHRABACHER. Yeah, but we just had—what was the—I'm sorry. I'm new to this. I'm a novice on these specific studies now.

Mr. HONEYCUTT. I actually have the studies right here. I can share them with you.

Mr. ROHRABACHER. Oh, so you have—Dr. Craft, you have—the specific study, you just mentioned three studies, is that correct, to us?

Dr. CRAFT. Yes, I mentioned three. Yes.

Mr. ROHRABACHER. Okay. And you're saying those three do not indicate that—and have not been—meet the EPA's justification for the standard change—

Mr. HONEYCUTT. Well, there's different things, okay? There's the—the single study was used to say 72 is the number—

Mr. ROHRABACHER. Yeah.

Mr. HONEYCUTT. —okay? And then they said, well, all these other thousands of studies support that.

Mr. ROHRABACHER. Okay.

Mr. HONEYCUTT. Okay? But there was one study that the EPA says, okay, this is the reason we're going to set it at 72. And CASAC spent a whole day talking about that one study. I watched it.

Mr. ROHRABACHER. But the other studies do indicate that with the—

Mr. HONEYCUTT. The Kim study doesn't.

Mr. ROHRABACHER. Does not. You're saying that this study does or you're saying—

Mr. HONEYCUTT. And actually, the Jarrett study does not either.

Mr. ROHRABACHER. Please go right ahead.

Dr. CRAFT. Well——

Chairman SMITH. The——

Dr. CRAFT. —I guess I just wanted to mention that these studies were done in perfectly healthy individuals. So the fact is is that the Clean Air Act requires that you set a standard that's requisite with an adequate margin of safety. And so that is one of the issues. So maybe a 1.8 percent decremented lung function in a perfectly healthy person is not considered an adverse health effect, but if someone has asthma or COPD, then in fact it is so——

Mr. ROHRABACHER. But that's your opinion and not the EPA's?

Chairman SMITH. The gentleman's time has expired. Thank you, Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you.

Chairman SMITH. And the gentlewoman from Oregon, Ms. Bonamici, is recognized.

Ms. BONAMICI. Thank you very much, Mr. Chairman.

I want to start by aligning myself with Mr. Beyer's comments. I think we can all agree that our constituents, our children, our families expect and deserve to live in an environment where the air they breathe and the water they drink is healthy. So start with that premise.

Also, I want to talk a little bit about how there's been a conversation about the cost and technological challenges associated with implementing the new ozone standard. And we've had this conversation many times in the Committee, that oftentimes the regulation drives innovation and technology. We're a very innovative country and certainly when there's a requirement, our companies step up and develop new technologies. I have confidence in that.

I want to talk, Dr. Craft—we had this conversation in your testimony and my statement about how the Clean Air Act does not permit the EPA to consider the costs or the attainability of technological feasibility. They determine the standard based on public health concerns. So I want you to comment on why that's important, but then I also want you to expand a bit, please, on your comments in your testimony about the prevention of premature death, asthma attacks, and more. Can you talk about the costs saved under the lower standard, costs like healthcare costs and lost productivity?

Dr. CRAFT. Thank you. You know, Congress intentionally set the Clean Air Act to specifically not consider cost, and I think the reason that they did that is because they wanted the integrity of the science to be maintained. The science is a separate and distinct issue from costs or implementation. The primary goal of the standard is that it will protect the health of the population with an adequate margin of safety. I think in past history cost estimates have been overblown and overestimated. If you were to let costs be considered as you evaluate the science, you may come to different conclusions, conclusions that would be unduly influenced by cost estimates. I think that's why Congress is so explicit on this point.

And just as a note on the devastation to the economy, I'd like to read a section from a report from the Texas Commission on Environmental Quality. In 2009, the Houston region reached attainment with a 1997 ozone NAAQS. According to an economic analysis

completed by the TCEQ, the Houston area exhibited the highest economic activity of any three-year period on record during the 2007 through 2009 time period. The analysis further describes that over the last two decades, ozone concentrations and economic growth have rarely been correlated in the Houston area and that many of the years that saw a robust economic growth coincided with declines in the 8-hour and 1-hour ozone design values.

According to TCEQ's analysis, "reducing ozone concentrations in the presence of continuing economic growth through the development of State Implementation Plans and implementing control strategies for emission reduction is possible. Expansion of emitting activities during phases of economic growth certainly makes the task of attaining clean air standards more challenging, but it should not prevent and has not prevented the HGB area, among many others, from making substantial progress in improving air quality."

Ms. BONAMICI. Thank you, Doctor. I want to get one more question in. My time is about to expire.

I would like you to comment, please, on the issue that I mentioned about—like in my home State of Oregon, they have a concern about the background and the long-range transport of ozone or precursors. So I know that the act allows for these exceptional event exceptions when there's something like a wildfire or transport of air pollution from overseas, so can you please talk about what recommendations you might have for the EPA as they begin revising the Exceptional Events Rule?

Dr. CRAFT. Sure. First of all, instances of elevated background ozone in Western States are actually infrequent and have been shown to rarely contribute to exceedances in the NAAQS. Even where background ozone levels can reach a considerable fraction of seasonal mean ozone levels, anthropogenic emission sources are the dominant contributor to the most modeled ozone exceedances of the proposed NAAQS. And the days when ozone levels are elevated do not have higher levels of background ozone.

And then just recently, Janet McCabe, Acting Assistant Administrator, Office of Air and Radiation, issued some guidance. "Under the Clean Air Act, States are not responsible for reducing emissions from background sources. We intend to work directly with responsible air management agencies in these areas to ensure that all Clean Air Act provisions that would provide regulatory relief associated with background ozone are recognized." And they are currently developing those revisions to the Exceptional Events Rule, and I think the process there is that they want to streamline the procedures that the state environmental agencies have to go through to have approval of the exceptional events.

Ms. BONAMICI. Thank you, Dr. Craft.

My time is expired. I yield back. Thank you, Mr. Chairman.

Mr. JOHNSON OF OHIO. [Presiding] I thank the gentlewoman for yielding back.

The Chairman has stepped out and I'm pleased to sit in, and I've got a few questions now if I might. And I'm going to start by submitting two items for the record. The first is a map that shows the nonattainment areas in Ohio, areas that would violate the 70 parts-per-billion standard.

[The information appears in Appendix II]

Mr. JOHNSON OF OHIO. And the second item is a letter by Ohio's Lieutenant Governor Mary Taylor to EPA Administrator McCarthy, and this letter is from March 2015 in which the Lieutenant Governor expresses serious concerns with the proposed rule to change the National Ambient Air Quality Standard for ground-level ozone from 75 parts per billion to a standard in the range of 65 to 70 parts per billion, and asks that the EPA Administrator reconsider these burdensome regulations. And as we all know, the EPA has moved forward with their proposal to lower the standard to 70 parts per billion.

[The information appears in Appendix II]

Mr. JOHNSON OF OHIO. So, Mr. Holmstead and Mr. Sadredin, how do these stringent ozone standards and regulations discourage economic development? Mr. Holmstead, you can go first.

The Hon. HOLMSTEAD. Well, as I've tried to say, I think the biggest issue in the near term is that it just stops people from building new industrial facilities. And I think what's especially pernicious about this standard is that it will bring all these rural areas into nonattainment. And the way the act works—and this is one of the things I just don't think makes any sense—is if you want to build a plant in this rural area where there's no other pollution sources, you can't do it because the only way you can build that plant is if you pay someone else in that area to reduce their emissions. And so you have these communities that would like to have state-of-the-art, best-controlled plants in their communities to provide jobs and economic opportunity, but you can't do it because the Clean Air Act prevents it because of this new standard.

Mr. JOHNSON OF OHIO. Mr. Sadredin?

Mr. SADREDIN. Yes, Mr. Chairman. Every time you establish a standard, it essentially establishes a tolerance limit for your region for pollution above which you simply will be in violation of the standard and the Clean Air Act regulations, which then kicks in very expensive sanctions.

In our region in San Joaquin Valley in California, the background ozone concentration is about 50 to 60 parts per billion, and that is not, you know, on days when—Dr. Elena mentioned that, you know, you should not be worried about attainment because those are not the days you violate the standard. We're talking about ground-level ozone concentrations on the days when our region exceeds the standard. Just simply the background ozone concentration is about 50 to 60. So when you have that and then you look at the standard of 70 parts per billion, you only have that 10 parts-per-billion margin that can be tolerated by manmade local air pollution, which means essentially in your area you have no tolerance for growth. You cannot let new businesses come in. In addition, you have to go after existing businesses to reduce air pollution.

Mr. JOHNSON OF OHIO. If that's the case where you've got that 10 parts-per-billion margin, if that's going to stymie growth, is it accurate to say then, is a safe to say that those areas that are in nonattainment, there is no growth? I mean they are squelched in terms of being able to grow economically?

Mr. SADREDIN. Right. As it's written right now, it requires that even if you're in attainment right now, let's say with the existing standard, before you can permit a new facility, you have to make a finding—scientific finding that the new permit, new facility will not cause a violation or contribute to violating a new standard. In this case, you know, with that 10 parts-per-billion margin of error, that's a very tight standard that is quite difficult to meet, and then you need offsets. As Mr. Holmstead mentioned, you don't have credits to be able to bring in facilities, and so it makes it very costly.

In California we are essentially in the position that businesses do not locate in California unless they have to.

Mr. JOHNSON OF OHIO. Okay. You know, One of the things that has really spurred America's economic energy boom here over the last few years has been the shale play in eastern and southeastern Ohio. Do you think these more stringent ozone standards undermine the benefits that we've seen in the energy revolution, the energy boom with oil and gas?

Mr. SADREDIN. Well, for our region and California in particular, even southern California, to be able to meet the new standard, we have to ban fossil fuel combustion emissions. That has to happen either through totally eliminating fossil fuel combustion—and I'm not only talking about mobile sources—cars and trucks—we're talking about industrial facilities no longer being able to use natural gas, any kind of fuel in their—

Mr. JOHNSON OF OHIO. In an area like eastern and southeastern Ohio where we still get over 60 percent of our energy from coal, that's a heavy lift for us.

My time has expired. I'd like to now go to our colleague, our gentlewoman from Massachusetts, Ms. Clark.

Ms. CLARK. Thank you, Mr. Chairman, and thank you to all the panelists for being here today.

Mr. Chairman, I have a letter supporting the lower ozone standard from locally elected officials from across the country, including Mayor Rob Dolan from my hometown of Melrose. And in that letter they state "the current George W. Bush-era standard of 75 parts per billion has been widely acknowledged by the medical community as insufficient to protect public health. As mayors, we are on the front lines of protecting the safety and well-being of our constituents, and this long-overdue update will reap tremendous benefits for our communities."

I ask that this letter be submitted for the record.

[The information appears in Appendix II]

Ms. CLARK. And I would also like to refer to another letter that I will ask also be submitted for the record, and this is a letter I would like to ask Dr. Craft about. It's dated April 7, 2008, and this is under the Bush Administration. This is from the members of CASAC, the Clean Air Scientific Advisory Committee. And in this letter 18 members of that committee, those scientists, unanimously wrote that they recommend decreasing the primary standard within the range of 60 to 70 parts per million—I'm sorry, per billion. "It is the committee's consensus scientific opinion that the decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an

adequate margin of safety for all individuals, including sensitive populations.”

[The information appears in Appendix II]

Ms. CLARK. Dr. Craft, could you comment on the difference between what we’re hearing today, that this is based on something new and perhaps one study in this letter of April 7th, 2008, where we had 18 members unanimously recommending an even lower standard than the one we’re looking at implementing?

Dr. CRAFT. Yes, thank you. There is strong scientific consensus that the ozone standard must be significantly strengthened. Since the last review, scientific evidence has only grown on the many health risks associated with ozone. It’s documented in EPA’s Integrated Science Assessment. The assessment is a result of a rigorous multiyear expert review process with several public hearings and comment, and it concluded that ozone harms lung health, including causing asthma attacks and increasing the risk of hospital and emergency room visits.

It also concluded that ozone likely caused premature deaths and identified new threats, providing strong evidence linking ozone to cardiovascular harm and low birth weight in newborns.

There have been multiple doctors that have testified in some of these hearings. I’d like to just point out some that were given by Dr. Greg Wellenius. He presented to the Senate Environment and Public Works Committee in December. In his testimony he noted the physiologic mechanisms occurring with ozone exposure: activation of neural reflexes, initiation of inflammation, sensitization of bronchial smooth muscle, changes in immunity, and airway remodeling as some of the underlying physiological mechanisms associated with ozone concentrations below the current standard that contribute to those increased hospital visits, those increased asthma attacks, and those days of missed work and missed school.

Ms. CLARK. Dr. Craft, in the letter from the mayors from across the country, they estimate that taxpayers would save as much as 75.9 billion through lower healthcare costs. Is this in line with the numbers that you’ve seen?

Dr. CRAFT. Yes, it is, and I’d like to point out that six of the top 10 fastest-growing cities in the country are in Texas and California, so the idea that, you know, we’re trampling economic growth because of an onerous ozone standard is not held up in the economic development that’s been reported.

Ms. CLARK. And going back for a second to the April 2008 letter, it’s my understanding that this was based—this unanimous recommendation of 60 to 70 parts per billion was based on almost 1,300 scientific studies at that time in 2008. Is that correct?

Dr. CRAFT. Yes, that’s correct.

Ms. CLARK. Thank you. I yield back.

Mr. JOHNSON OF OHIO. I thank the gentlewoman for yielding back. I now go to—I recognize our colleague Mr. Bridenstine from Oklahoma.

Mr. BRIDENSTINE. Thank you, Mr. Chairman.

So it’s really difficult if not impossible to prove a counterfactual, which means if the economy in Texas is growing, there’s a whole host of reasons that could be, and more regulations does not grow the economy in Texas, same in California.

In fact, I'd like to address the issue specifically that we've been talking about. I grew up in Arlington, Texas. I represent the 1st District of Oklahoma now. I went to college at Rice University down in Houston, Texas. And I'd like to address my question to Dr. Honeycutt.

In your testimony, you wrote "astonishingly"—and every time I read testimony and the word astonishingly shows up, what comes next is critically important. "Astonishingly, EPA's analysis"—that's the EPA's own analysis—"shows mortality increasing in certain cities, including Detroit and Houston, when decreasing the ozone standard from 75 parts per billion to 70 parts per billion." That is astonishing. Did that get taken into account? What they're suggesting is that it's worth maybe increasing mortality for these regulations? Can you address this for us?

Mr. HONEYCUTT. Sure. That's called the NOx disbenefit. And if you look nationwide, there would be a net—according to EPA, a net decrease in mortality, but if you look at a couple—some specific cities, they looked at 12 in particular, those two cities, lowering the standard would actually increase mortality. And it's because NOx both creates and destroys ozone. So what you're going to be doing is increasing ozone concentrations in the inner cities while decreasing it in the suburbs.

Mr. BRIDENSTINE. That is good information that we on the Committee need to hear.

Question for Mr. Sadredin. Maybe you could say that for us. Sorry.

Mr. SADREDIN. Sadredin.

Mr. BRIDENSTINE. Sadredin, thank you. How many different State Implementation Plans does the San Joaquin Valley have in effect today?

Mr. SADREDIN. As we speak today, we have six different State Implementation Plans for ozone and particulate matter, all with multiple milestones, redundant, duplicative timelines that we have to comply with. And as we speak today, we're in the process of writing another plan for the standard that was just replaced, and in the next three years we have to write four additional State Implementation Plans for a total of 10 State Implementation Plans just for ozone and particulate matter.

Mr. BRIDENSTINE. And how difficult is it for your agency to keep up with these SIPs?

Mr. SADREDIN. Yes, you know, that's the least of the problems, you know, the government inefficiency that this brings about, the staff work. The bigger concern that we have with this is the confusion that this brings to the public, to the business community that is subject to these redundant, duplicative regulations, and a tremendous number of lawsuits that each of these same deadlines, same targets that are established in, you know, 10 different vehicles create opportunities for attorneys. Of course, that's good job security for them, but good government it is not. Good public education it is not.

And it is something that could easily be fixed in our opinion. One of the suggestions that we are making in this 2015 Clean Air Act modernization that we're proposing is that, when EPA establishes a new standard, for them to subsume the old standards into the

new one, pick the most stringent requirements from the previous standards, give us a single set of timelines and deadlines to meet, to be able to educate the public, and also make sure we can enforce them effectively in a rapid fashion.

Mr. BRIDENSTINE. And I would just like to conclude by saying that we've heard folks suggest that, you know, certain local officials are in favor of more stringent National Ambient Air Quality Standards for ozone, certain local officials are opposed to it. I can tell you for my State of Oklahoma, local officials are very opposed to it.

I hope everybody understands that if the State of Oregon or the State of California, if other states want to have more stringent plans, that's not going to bother my constituents in the State of Oklahoma. They can go ahead and do those things without having to do it in Oklahoma. And so I just want everybody to understand, when states become implementers of federal policy and then they end up getting bullied by the federal government, if you do this, then X, Y, or Z will happen, that's not the role of the federal government to say that we're going to cut off your highway transportation funding if you don't comply with this new standard. This is federal bullying. It needs to stop. And if Oregon or another state wants to implement more stringent standards, I'm okay with that.

So with that, Mr. Chairman, I'll yield back.

Mr. JOHNSON OF OHIO. I thank the gentleman for yielding back.

I now recognize the gentlewoman from California, Ms. Lofgren.

Ms. LOFGREN. Thank you, Mr. Chairman.

I'm pleased that we have a witness from California on today's panel, as our State has unique challenges when it comes to addressing air pollution.

However, I think the changes to the Clean Air Act suggested by Mr. Sadredin's testimony would have the effect of delaying future efforts by EPA to protect health and the environment, and that's a position that's not supported by most Californians.

In fact, I have a letter from the Coalition for Clean Air based in California that says, "what will not help Californians to breathe easier is the proposal from the San Joaquin Valley Air Pollution Control District to weaken the Clean Air Act."

And I also have a letter from the Central Valley Air Quality Coalition which says, "we learn more every day of the impacts of air pollution on our health, and our valley has become numb to the information because Mr. Sadredin and the Valley Air Board disregarded, blame external factors, and have failed to find a balance between supporting business and protecting public health."

And lastly, I have an op-ed by two current members of the San Joaquin Valley Air District Board, Dr. Alexander Sherriffs and Dr. John Capitman, who write "we cannot support a policy direction which threatens to extend the time valley residents are breathing unhealthful air. The district needs to focus on policy and advocacy to increase the tools and resources to meet more healthful air standards, not on how to delay attainment."

And I'd like a unanimous consent to put these three documents in the record, Mr. Chairman. May I have unanimous consent, Mr. Chairman?

Mr. JOHNSON OF OHIO. Without objection.

[The information appears in Appendix II]

Ms. LOFGREN. Thank you very much.

You know, the Central Valley is—I chair the California Democratic Delegation, and we have a diverse State, and the Central Valley is a key and important element of our State. It's much valued.

It suffers from pollution that comes from the bay area where I live. It blows in on I-5 from—even from Asia but also created in the valley itself, including significant volatile organic compound emissions from dairies and also oil and gas operations. And those things have created a problem in the valley. We have the highest asthma rate among children of any place in the United States right in our Central Valley, and it's a huge problem.

Now, we can change the impact by technology. I come from Silicon Valley, and we know that if you have a problem, you don't have to suffer. You can set standards and meet those standards. And you can—for example, farmers have switched from diesel pumps to electric pumps. They've purchased cleaner-burning tractors thanks to incentive programs. We have—along I-5 we're switching. We now have a very aggressive standard in the State for switching to alternative energy we're going to meet.

You know, we have 1,000 premature deaths every year in the valley because of air pollution, and among all air pollutants contributing to cancer, diesel emissions is number one. So I think we have a great opportunity to promote even cleaner technologies and to create a cleaner environment for the people of the Central Valley and most especially for the children.

So here is my question for you, Dr. Craft. The—with so many children with asthma out in the Central Valley, what is the adverse physiological effects on kids with asthma from ozone pollution, and how can increased exposure to ozone impact the health of children? It costs—the lost time because of health impacts out in the Central Valley is costing the valley \$1 billion a year. I realize you're looking at just the health impacts, not the economy, but we are losing money in the valley because of these adverse health impacts. What can you talk to us about with these children and others with asthma?

Dr. CRAFT. Well, I'd like to say that children are especially vulnerable to the harms of air pollution, particularly those kids with asthma, and so it leads to increases in emergency room visits, missed school days, missed workdays for parents. And it can also lead to permanent long-term damage. Actually, the Gauderman study didn't—looked and saw that air pollution in general showed that if air pollution is reduced, it leads to better lung health later in life. It's—I think there is a lot of evidence supporting the fact that cleaner air is good for lungs of all ages, but especially for our most vulnerable, our kids.

Ms. LOFGREN. Thank you. I'd just like to note that I think some of the objections from these outside groups that are running ads reminds me of the tobacco companies fighting control of tobacco, which caused lung cancer. And, you know, there's a lot of comments made about how regulation and control harm the economy. I'd just like to point out that California, that is embracing the green, looking for health, beat Texas in job growth by 30 percent—

Mr. JOHNSON. [Presiding] Well, very good.

Ms. LOFGREN. —with our approach and—

Mr. JOHNSON. The gentlewoman's time has expired.

Ms. LOFGREN. —I would yield back.

Mr. JOHNSON. Thank you. Mr. Sadredin and Dr. Honeycutt, your names were mentioned there for the last few minutes. Would either one of you care to respond to that?

Mr. SADREDIN. Yes, thank you, Mr. Chairman, just very quickly. I appreciate the good advice from the Congresswoman, and we always look to the bay area, our neighbor, to do their part to help us with the pollution that they sent our way.

But make no mistake, although San Joaquin Valley is a conservative region in California, today, we have put in place the most stringent regulations that you can imagine to the point that Los Angeles now looks up to us in terms of what could be done. And by no means we're asking for delays in getting there, but I urge you to take a look at the chart that I gave the Committee in my testimony on page 5 that talks about how much reductions we have to make.

If you look at that chart, it breaks down emissions by various source categories of air pollution. The top part where it says the stationary and area sources, that's all the valley businesses, oil production, farming operation. As you can see, even if we eliminated all of those sources, just simply said move out of the valley, we'll come nowhere to meeting the standard. The bottom—the two lines that you see on the bottom are where we need to go to meet those standards.

So I know industry cries wolf many times, and as a regulator, I've seen that over the years. But once in a while that boy is right, that the wolf might be coming, and I think this is one of those cases. If you look at the numbers that I have here for you, we have to essentially eliminate all pollution sources in San Joaquin Valley to meet that.

And just one final comment regarding the health impact and the cost, and a lot of times people misrepresent these numbers by saying there's a healthcare cost that you're going to avoid for ozone. It's very minimal and a big part—90 percent plus portion of this cost is the life insurance value that they put on a premature death, which is questionable but it's not a real contribution in a lot of the economy that we are referring to.

Mr. JOHNSON. Sure. Dr. Honeycutt, would you like to respond?

Mr. HONEYCUTT. Sure. The Gauderman study that Dr. Craft just mentioned specifically said that ozone does not affect lung development. And I have it here if you want to read it. And the follow-up that they just released found the same thing, that ozone does not affect lung development. And I have both of those. I'd be happy to read you the conclusions if you'd like.

And also, as far as asthmatics, the data is very clear. Asthmatics are no more sensitive to ozone than non-asthmatics are. And again, I have those studies here. I'd be happy to share them with you.

Mr. WEBER. The Chair now recognizes the gentleman from Georgia. Barry, you're up.

Mr. LOUDERMILK. Thank you, Mr. Chairman.

And I also noticed that every time Mr.—is it Sadredin—speaks, the alarm goes off like it's highlighting we better listen to what he's saying. It's some type of—

Mr. WEBER. Ozone levels must really be high when he speaks.

Mr. LOUDERMILK. I appreciate the testimony here. This is a very important issue because of the impact that it's going to have. And I've always been one that it takes—in business and in everything else, you can only do so much and then you have diminishing returns because you've gone too far.

Mr. Holmstead, does the Clean Air Act allow for special treatment for places where air quality may be affected by emissions from other countries such as Mexico or China or even in other areas of a state or region? My understanding from the testimony I've heard and what I've read is that we're not giving an account for pollution that may be created in another area and move into an area that would cause the receiving area to be in non-attainment. Is there an exemption? Is there allowance for those?

The Hon. HOLMSTEAD. I'm sorry to have to say it's complicated.

Mr. LOUDERMILK. Okay.

The Hon. HOLMSTEAD. In theory, some of those things can be excused. In practice, EPA has never really allowed that. And one of the things you're hearing about is this exceptional events policy. It's been almost impossible for anyone—I mean it takes hundreds of thousands of dollars and years to try to get EPA to excuse one exceptional event.

The other thing I would point out, though, is the Clean Air Act itself—and that's why—you know, we're talking about these levels. What we really should be talking about is the implications of the standard. Everybody agrees that we ought to be improving air pollution, but the way the standard setting works with all the other regulations just doesn't make any sense anymore.

And right now, the Clean Air Act specifically says that certain weather events, the things that cause high episodes of ozone, cannot be excused. It says meteorological inversions and stagnant air. Those are events that are completely outside the control of any State, and yet you're held accountable for those things. And under the Clean Air Act, that's just one other thing that just ought to be changed.

Mr. LOUDERMILK. Well, it's interesting you bring that up because I'm looking at a map here which, Mr. Chairman, I'd like to submit for the record, which is the impact area on the State of Georgia that the new standards would have as far as the areas that would be out of attainment at this point.

And I also have a letter from our governor of our state, Hon. Nathan Deal, who also served in this body at one time, who says that in these areas, it would be impossible for us to reach attainment because of the way the standards are written, and I also point out that the area that is highlighted here that would be in nonattainment is not only the economic center of the State of Georgia but the entire Southeast.

So what is the cost that we could see in an area that is so important—you're talking about one of the largest airports in the nation. Atlanta Hartsfield Airport is in this area; one of the largest power plants in the Southeast is in this area. What type of economic im-

part or hidden cost would we expect to see with the implementation of this standard? Mr. Holmstead?

The Hon. HOLMSTEAD. The only thing we know is—for sure is that the cost of everything will go up, right, because energy is embedded in everything we do. So you're going to be paying more for lots of different things.

The thing that's really hard to judge—and people have said it's certainly true that we've had economic growth even with tighter standards, but that doesn't mean that this next increment isn't going to be enormously expensive. So maybe you can continue to have economic growth there, but it will be much less than it would otherwise be in part because you're making it very difficult for businesses to expand in that area. They just have nowhere to go.

Mr. LOUDERMILK. Dr. Honeycutt, let me read a portion of this letter and maybe you can respond to the same question. Our Governor says, "these rules are in addition to the fuel economy standards and the Tier 3 tailpipe emission standards for cars and trucks implemented by the federal level, which increases costs for businesses and consumers in my State and others." This is after he's gone through a litany of other EPA regulations that have affected our area. "All of these regulations have required substantial investment on the part of Georgia companies and consumers and constitute a moving target for Georgia companies." The moving target is one of those areas that I hear a lot about with federal regulations, that they are unattainable. Could you and Mr. Sadredin comment on that?

Mr. HONEYCUTT. Yes, sir. He's absolutely right. EPA needs to provide the States guidance as soon as they put a rule out, not years later as they have in the past, because their deadlines are flexible, ours are not.

Mr. LOUDERMILK. Mr. Sadredin?

Mr. SADREDIN. You know, it was mentioned earlier that Congress was very clear about not including economic costs in certain standards. The fact of the matter is if you actually read the Supreme Court case, it said Congress failed to give any guidance on that. Therefore, absent guidance from Congress, judges, bureaucrats such as myself, and my colleagues at EPA have become policymakers and they have come up with a scenario where they say don't worry about the cost-effectiveness or economic feasibility when we set this standard. During the implementation, we'll take care of that. And unfortunately, the Clean Air Act, as written right now, does not give them the flexibility and the latitude that they need with those very fixed timelines, deadlines that you have to come into attainment to actually be able to do what they claim the Clean Air Act allows them to do to incorporate the economic feasibility during the implementation phase.

Mr. LOUDERMILK. All right. Thank you.

Mr. Chairman, I move to have both of these documents submitted to the official record.

Mr. WEBER. Without objection.

[The information appears in Appendix II]

Mr. LOUDERMILK. And I yield back.

Mr. WEBER. The gentleman yields back.

Now, the gentleman from Colorado has five minutes to see if he can make Mr. Sadredin make the alarms go off.

Mr. PERLMUTTER. Thank you, Mr. Chairman.

Just a couple things I'd like to introduce into the record if I could. First is an article published in the Durango Herald supporting the decrease from 75 parts to 70 parts dated October 5, 2015. If I could introduce that into the record, sir?

Mr. WEBER. Without objection.

[The information appears in Appendix II]

Mr. PERLMUTTER. The second thing is a little more cumbersome. That's just 1-1/2 pages. This is 1,251 pages, which is the compilation, Dr. Honeycutt, of all the studies, some 2,300 undertaken to—and reviewed by the EPA in preparation for the reduction in the use of ozone numbers. And so I'd like to introduce the 1,251 pages, which compiles the 2,300 studies for the record.

Mr. WEBER. I will allow that if you'll start reading them. Without objection.

[The information appears in Appendix II]

Mr. PERLMUTTER. Well, I will—okay. So Martin, R.V.; Fiore, A.M.; Van Donkelaar, space diagnosed—diagnosis of surface ozone sensitivity to anthropogenic emissions.

Mr. WEBER. They will be admitted, Mr. Perlmutter.

Mr. PERLMUTTER. All right. I guess—and then I'm going to yield to Mr. Beyer.

And I just say to the folks on the panel, you know, in the Denver area we've had ozone issues for years and years and years, and our State prides itself on being very outdoorsy, you know, wanting to get outside, take advantage of, you know, the beautiful climate that we have. But our air is always something that has been difficult and because we do have some of the things that you mentioned in your testimony. You know, we're in a pocket where the weather, you know, creates inversions and things like that.

But each year and each time industry complains that this is going to be unattainable, we can't do it, but then over a course of time, they do. And it's improved the health of Coloradans. And we've got to continue to improve that. Our State has continued to grow, and we have a substantial oil and gas industry. And so as hard as these things are, the economy of Colorado has flourished because people want to come there for a great environment. And part of that is cleaning up our air as best we can from time to time.

And so I appreciate the testimony of everybody. I understand this is hard and it can be expensive, but the rewards are substantial as well, and that's not been so clear today. But in Colorado we've experienced that success and we've experienced that growth, and the health of the population has been improved, I think, over the years, you know, from growing up as a kid and having the brown cloud. It's improved a lot.

And I yield to my friend from Virginia, Mr. Beyer.

Mr. BEYER. Thank you, my good friend, distinguished colleague from Colorado.

I was confused by Dr. Honeycutt's comment on Houston and Detroit. The excellent Democratic staff at the Science Committee dug out a Texas Tribune article that says that "paradoxically, lowering levels of nitrogen oxygen—nitrogen oxide (a pollutant that contrib-

utes to forming ozone) can temporarily increase ozone levels because NOx also helps dissipate fully formed ozone. That's why EPA predicts a slight increase in premature deaths if ozone standards are lowered."

But, Dr. Craft, can you please elaborate on this phenomenon? Is this a reason to not implement these new lower standards?

Dr. CRAFT. No, it's not. It's actually a simulation that's done, and that simulation was done looking specifically at NOx reductions. It did not include reducing some of the other precursors that form ozone, including VOCs. And so when a region has to put together a plan to reduce ozone, what they do is they identify an optimized plan to reduce both NOx and VOCs. And so the idea of NOx scavenging can be addressed through the way that you implement the new standard.

Mr. BEYER. That's great. And one more quick thought. There are 25 seconds. They talk about how, gosh, even the national parks can't get to these ozone standards because of background ozone levels. How high are background ozone levels? Is Dr. McCabe's comment that the EPA will work around that? And does the ozone in the parks come from the parks or as it blown in from somewhere else?

Dr. CRAFT. Well, there aren't a lot of power plants or a ton of mobile sources in the national parks. Most of that is actually coming from sources that are downwind of those national parks. And so addressing those sources will help the areas where we have national parks that are having an occasional exceedance back into attainment.

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

Mr. WEBER. Dr. Honeycutt, you've been mentioned a couple of times now. In the 1,200 page study that Congressman Perlmutter refused to read and here with the article in the Texas Tribune, would you like to take time to respond?

Mr. HONEYCUTT. Sure. Thank you. Yes, I've actually read the human health portions of that document. I didn't read the atmospheric chemistry portions or the welfare portions, but I did read the human health portions.

Yes, as far as the NOx disbenefit, it—if you believe that ozone causes premature mortality, which EPA does, then you have to accept the disbenefit along with the benefit, because if you believe ozone causes premature mortality, then you will see it if you lower NOx in—around highways. So there's no getting around it. There's no doubling down to hurry up and get the emissions because you'll just hasten the deaths then.

So—and as far as asthma again, the question is not does ozone exacerbate asthma? The question is, will lowering the standard from 75 down to 70 or even 60 reduce the number of asthma exacerbations? And according to EPA, the answer is no.

Mr. WEBER. Okay. Thank you.

And the Chair now recognizes the gentleman from Illinois, Mr. LaHood.

Mr. LAHOOD. Thank you, Mr. Chairman, and thank the panelists here today.

I guess in looking at my home State of Illinois and looking at the impact that this proposed rule would have on jobs and economic

growth, I have real concerns about that. And I want to cite a recent analysis and study done by NERA Economic Consulting that is titled "What Could New Ozone Regulations Cost Illinois?" And this is dated August of 2015. In looking at the proposed rule and the effect it would have on Illinois specifically, \$47 billion in gross state product loss between 2017 and 2040, 35,000 lost jobs or job equivalents per year, \$12 billion in total compliance costs, \$650 drop in average household consumption per year, \$1 billion more for residents to own/operate their vehicles statewide in this period. And I will submit this for the record.

[The information appears in Appendix II]

Mr. LAHOOD. And I guess looking at that and a number of other studies that look at what this would do, what causes concern for me as I look at companies, particularly in my district in central and west central Illinois, Caterpillar is based in my district, a Fortune 40 company, very benevolent, generous company, but also has been very proactive in the environmental movement and what they've done at their companies, a company like John Deere, ADM that's in my district. And I look at how they are trying to compete worldwide in the marketplace, and they are trying to obviously create jobs and opportunities, and when I look at this proposed rule, what that would do locally to those companies.

And I guess I couple that with when you look at the statistics, air quality in American cities is the best that it's been in a century. Ozone pollution has declined 33 percent since 1980, nine percent since 2008. And so when I look at those companies and what they're trying to do proactively and then they have to look at this coming down on top of them, I guess, Mr. Holmstead, in looking at that, competing in the world marketplace and whether you're going to create jobs in Illinois or you're going to go to India or China or someplace else, can you talk about that a little bit?

The Hon. HOLMSTEAD. There's one observation I like to make. Certainly, you know, California has done very well economically over the last number of years. There was a time when we used to manufacture things in California. We don't do that anymore; it's just too expensive because heavy manufacturing requires energy. And so that's been to the benefit of other States.

We're getting to the point now where if we turn the rest of the country into California, we will have no choice but to export those jobs. And it's not because companies are bad citizens, but if they compete economically with everybody else on the globe and all of a sudden you drive up their costs too much, the same thing that happened to southern California is going to happen to central Illinois.

And I just think that we—we just need to be smart in how we continue to make environmental progress. That's my—we can continue to make progress but we can do it in a way that's much more reasonable, that is not going to disadvantage U.S. businesses and consumers.

Mr. LAHOOD. And would it be fair to say, Mr. Holmstead, there's a direct correlation between what this rule is going to do and job loss or economic loss with companies like I mentioned and others?

The Hon. HOLMSTEAD. There is no doubt that this will hurt the rate of economic growth. I think it's hard to know—and I have a

great respect for NERA. I think that study looked at even a lower standard, and so that probably overstates the cost. But there's no doubt that it will impose additional costs on businesses. It will make it harder for them to grow and expand, and ultimately, you're going to drive people out of these areas and they're going to have no choice but to go somewhere else.

Mr. LAHOOD. Thank you.

Dr. Honeycutt, I wanted to ask you, so in terms of the effect this will have on state and local resources, you know, when these EPA—if this rule is implemented, in terms of agencies catching up on implementing the current standard when they're already working on a standard now, can you talk a little bit about that?

Mr. HONEYCUTT. Sure. It is substantial. It costs TCEQ—we've put money to the numbers—\$1 million to do a SIP for a moderate area. And so that's just the SIP. That's not even looking at the exceptional events, the long-range transport and things. Those are hundreds of thousands of dollars. So—and that's tax money. So, yes, it's substantial.

Mr. LAHOOD. Thank you. Mr. Chairman, if I could, I'd like to submit this study I just referenced and also a letter from the Tri-County Regional Planning Commission in Peoria, Illinois, asking for a delay in the attainment designation.

Approved without objection, thank you.

[The information appears in Appendix II]

Mr. PALMER. [Presiding] I will assume the Chair for the time being and begin my questions.

And my first question is to Dr. Honeycutt. The EPA admits that much of the control technology to comply with these new standards does not yet exist. I think the latest estimate is only about 40 percent of the emission reductions can be attained with the current control technology. Can you give me some idea how Texas plans to comply with this if we're dealing with—basically with a black box?

Mr. HONEYCUTT. I wish we knew. Most of these sources out there are vehicle emissions or non-road emissions, so we're going to do something with those and we're really not quite sure what yet. This is uncharted territory for not only Texas but for most of the country.

Mr. PALMER. Well, I think the answer is going to be that you will shut down whatever industry is producing these ozone emissions that prevent you from meeting these reduction standards. So if you don't have the control technology to install, and earlier in my career, I worked for Combustion Engineering in the Environmental Systems Division so I have a pretty good idea of what it costs to design, build, and install this equipment. You can't design, build, and install stuff that doesn't yet exist, so the only option is to shut down whatever's producing the emission. So would you concur with that?

Mr. HONEYCUTT. I think at this point in time everything is on the table.

Mr. PALMER. Okay. In regard to these issues of air quality, and I pointed out in this hearing before that since 1980 our GDP has gone up 467 percent, vehicle miles have gone up 94 percent, population has increased 38 percent, energy output has gone up 32 percent, yet emissions have gone down 50 percent. The air is demon-

strably cleaner than it has ever been. Our economy is continuing to grow. I think when we talk about the balance between health and economic growth, one of the interesting things—and asthma has been mentioned several times here—is that there’s peer-review studies out from the medical community, including UCLA, that indicate that even though air quality is dramatically improved, asthma rates have spiked. And particularly in California, the UCLA study, Mr. Sadredin, that the single biggest predictor is low income.

[The information appears in Appendix II]

Mr. SADREDIN. Mr. Chairman, people often mistake the impact of air pollution on asthma claiming that air pollution actually causes asthma. That is a scientifically—there’s little evidence of that in science. We’re talking about exacerbation, and if you look at cases of asthma in some of the more pristine areas on the coast in California, asthma rates are going up much—at a much higher rate compared to Los Angeles and Central Valley where our pollution is higher. So the relationship is not there but it’s something that tugs at your heart when you talk about children with asthma, and that’s a good bumper sticker sort of a justification for the enormity of the Clean Air Act that we’re talking about.

In San Joaquin Valley we have reduced pollution by over 80 percent over the last 20 years. We’ve imposed the toughest regulations you can imagine on farming operations, agriculture, dairies. Unfortunately, some of my colleagues from, you know, urban areas, they think food just shows up on the grocery shelf somehow magically. They don’t really understand all the work that has to go into producing it.

We’re at the point in our region with double-digit unemployment and low level of education with a large portion of our Hispanic population. It is very difficult to envision a scenario where we can meet those new standards without having to actually shut down businesses, as you mentioned. And that’s the point I wanted to get into.

Congressman Lofgren introduced a letter from Central Valley Air Quality Coalition earlier saying that everybody’s okay in California with this. This same group had actually recommended to our agency that we have no-farm days, no-construction days, no-drive days. And we’re not talking about a day or two here and there. We’re talking about 100 days a year during summer having no commercial activity. They thought that’s something that’s reasonable.

Mr. PALMER. Dr. Honeycutt, if you’d like to respond in the time that I have remaining, but I would like to—the NERA study was mentioned earlier. Those numbers have been adjusted to reflect the new standard that the EPA is requiring, and it is a devastating impact on the economy if you’d like to respond.

Mr. HONEYCUTT. Sure, just real quickly. As far as asthma causation, Gina McCarthy testified in July of this year in front of this committee that ozone does not cause asthma, as did a minority witness earlier. However, EPA says that it is likely causal, that ozone likely does cause asthma, which is the same designation they give to premature mortality—total premature mortality and which the benefits are based on. So that’s why there’s some confusion in this

because EPA says one thing and Gina McCarthy said another thing.

Mr. PALMER. Thank you. My time is expired.

I would now like to recognize the gentleman from Arkansas, Mr. Westerman.

Mr. WESTERMAN. Thank you, Mr. Chairman.

Let's see. Dr. Craft, you work for an organization that's very concerned about protecting the environment, making sure we have clean air quality. And is—on the concept of diminishing returns, do you think we'll ever get to a point where we are trying to achieve something that the cost to achieve it is more than it's worth achieving, or should we just make improving air quality the ultimate goal at any cost?

Dr. CRAFT. Well, Environmental Defense Fund uses market-based principles as a foundation for our work. So we've worked successfully with oil and gas industry, for example, to implement control technologies on equipment that saves money and also reduces the amount of pollution in the air.

Getting to the question of diminishing returns, I don't think we're anywhere near where we need to be in terms of reducing the amount of pollution. The question of, you know, how could—how is Texas going to comply, well, you know, we have VOC emissions in Houston that, through studies funded by TCEQ, show that those emissions are underestimated by a factor of five to ten. So looking at reduction of upset events, looking at one million—

Mr. WESTERMAN. I need to—I'm from Arkansas. I'm not from Texas so I need to move on here.

It says here in your testimony that to reduce harmful air pollution such as ozone from pollution hotspot areas—have you ever been to Arkansas?

Dr. CRAFT. Yes, I have. We work closely with Walmart, and so we have an office in Bentonville. I've been there several times.

Mr. WESTERMAN. Okay. So I was there last week in my district, which happens to have about 18,000 square miles of forest. To put that in perspective, just the forests in my district are about 264 times larger than Washington DC. And I like to get out in my district in the forest and breathe the fresh air. Actually, I think the air quality is much better there than it is here, but if you look at the ozone monitors, it's really not that much different than the air quality here in Washington DC. And actually, if you look at some of the information from the EPA, it talks about trees creating a lot of ozone through their VOC emissions. So, you know, if—should we go cut down all the trees in my district so we can improve air quality?

Dr. CRAFT. Well, actually, it's funny that you mention that. We are actually looking into trees as an intervention strategy for places like Houston. So there is evidence that some species of trees release VOCs, but not all species.

Mr. WESTERMAN. So maybe we should just plant plantations of monocrops in Houston to fix the air quality down there. I'm trained in forestry, so that would be kind of interesting if we started doing stuff like that.

Moving along, Mr. Holmstead, are you familiar with EPA's claim that the proposed ozone standard will only impact nine counties?

The Hon. HOLMSTEAD. Yes, that's just silly. They, first of all, assume all kinds of things and run their models and say, look, there's only going to be nine counties that don't attain the standard. The problem—that's not the way the Clean Air Act works. It's not only counties where there might be a monitor; it's everywhere elsewhere EPA predicts using models that you're going to have an area that violates the standard. So that actually really makes me angry. EPA should be at least honest about the implications of this because it's going to affect many, many more parts of the country.

Mr. WESTERMAN. So it's a very dishonest of them not to include non-monitored counties because we know the air mixes and you got these autogenic effects.

What about using the year 2025? Is that dishonest as well?

The Hon. HOLMSTEAD. Well, yes, because all of these regulatory consequences happen now. The permitting problems happen now. All the other regulations happen now. If the Clean Air Act said, great, if EPA says that everyone is going to come into attainment within ten years, if that's the way it worked, that would be great. But we don't wait around. You impose all these obligations now regardless of what EPA projects for 2025.

Mr. WESTERMAN. And so can you explain quickly the actual impact of the ozone rule for those of us not inclined to use EPA's fuzzy math or their fuzzy logic or whatever it is they use? Maybe we need to pump some of the clean air from Arkansas over into the EPA building.

The Hon. HOLMSTEAD. Just very quickly, it will be very hard to expand new businesses in many rural parts of the country. That's the most kind of—the thing people don't understand. This is—what this affects is—rural parts of the country would like to attract new business. That is going to be difficult or impossible.

And then in other areas you just drive up the costs even more, and you do so unnecessarily. There's just a better way to clean the air, but unfortunately, we've become so dug into this statute that was created 45 years ago that just doesn't really work anymore for the way that the world works today.

Mr. WESTERMAN. You can just cut down all the trees in my district and we could meet the air quality.

The Hon. HOLMSTEAD. Well, at some point afterwards I'll tell you a story about VOC emissions and trees. It's actually kind of sad to see what EPA has done in the past about that issue. But we don't have time to talk about it here.

Mr. WESTERMAN. Thank you, Mr. Chairman.

Mr. PALMER. The gentleman's time has expired, but I do want to comment on the gentleman's line of questions and the responses that apparently the EPA has now gotten in the business of determining that there are some good trees and some bad trees and maybe the solution is just clear-cutting. I hope not.

The Chair now recognizes Dr. Abraham, the gentleman from Louisiana.

Mr. ABRAHAM. Thank you, Mr. Chairman.

And I'm going to just hit this from a medical perspective. The tone and the verbiage from EPA has changed over the past several months to this theme of childhood asthma. Gina McCarthy touted, everybody in the EPA touted, and this is what they're trying to

sell, that the ozone is causing this exacerbation. Again, I am limited in my practice as to—I have to do what we call standard of care, and we have to do things based on only evidence-based scientific data. And I usually go to the CDC for my talking points and when I'm trying to determine what's best for my clientele.

I've practiced medicine all my life and I've practiced it in places all over the world, and I look at CDC charts and maps and I see where there are the lowest emissions standards there's the highest asthma. And, Gary, it goes back to your statement of socioeconomic factors being the major cause of exacerbation of asthma, and I can tell you from a practitioner's point, that's very true.

I look at some of these other studies from these nonprofits, and the first thing that we as physicians and any scientist is taught is to look at who's funding the study because of the conflict-of-interest possibility. Where are you getting your money? And, Dr. Craft, when the Congresswoman asked you a question about ozone and the possible developmental lung function, I noticed that you didn't use the word ozone. You admittedly shifted to air pollutants to answer that question.

So, Dr. Honeycutt, I will start with you. I am concerned that we are seeing a lot of bias and conflict of interest in this—in our Scientific Advisory Board, especially the Clean Act Scientific Board. What can we do to combat that? How can we tell our constituents and our patients that what we are being told by EPA, by everyone, are actually based on facts and just not theory and not being pushed by specific interest groups that want to sell a product?

Mr. HONEYCUTT. By the way, I was born and raised in your district and you represent my parents so—

Mr. ABRAHAM. Hey, I didn't know that.

Mr. HONEYCUTT. The CASAC is appointed by EPA. Whenever we do a board like that, we have an external party to vet people and pick them for us. And the panels need to be balanced and—as far as—

Mr. ABRAHAM. Are they now balanced in your opinion?

Mr. HONEYCUTT. No, actually not.

Mr. ABRAHAM. Nor in mine. I will agree with your statement. Go ahead. I'm sorry.

Mr. HONEYCUTT. Oh, they need to be balanced in terms of bias and who they represent, and right now they're not.

Mr. ABRAHAM. Okay. And I think you've answered the question but I'll ask you to answer it again. Will lowering the ozone standards from 70 to 60 do anything for asthma?

Mr. HONEYCUTT. According to the EPA, no.

Mr. ABRAHAM. Yes, and I've seen those studies, too. And is there any evidence—and any panel member can answer this—that ozone—specifically ozone exacerbates asthma? Dr. Craft?

Dr. CRAFT. Yes, I'd like to comment and I guess give the reason for why I didn't mention ozone specifically with the Gauderman study. Ozone actually didn't decline that much over the time period that the Gauderman study focused on, so that's why I discussed air pollution in general.

Mr. ABRAHAM. But—

Dr. CRAFT. To get to your question about—

Mr. ABRAHAM. But you understand, Dr. Craft, that was not the question she asked. I was just referencing the question, the specific question, and I was just looking for a specific answer. And I just didn't see that, and that's the reason I brought that up.

Dr. CRAFT. Right. So to give an example of a study that you requested, I'll refer to, again, the testimony of Dr. Wellenius, who mentioned a 2010 study by scientists at Emory and Georgia Tech looking at a 30 percent increase——

Mr. ABRAHAM. And may I ask who financed that study? Do you know who financed that study?

Dr. CRAFT. I'm not sure who financed that study.

Mr. ABRAHAM. Okay. And see, that's I guess my point. We—like the gentleman from Colorado, he had a 2,200 page study, and there are millions of studies, but I want to know who's got skin in the game as to how the study is going to be presented. So that's all I'll say. I'm out of time and I appreciate the panel being here.

Mr. Chairman, I'll yield back.

Mr. PALMER. Thank you, Dr. Abraham.

I thank the witnesses for their testimony and the Members for their questions. The record will remain open for two weeks for additional written comments and written questions from Members. This hearing is adjourned.

[Whereupon, at 12:25 p.m., the Committee was adjourned.]

Appendix I

ANSWERS TO POST-HEARING QUESTIONS

ANSWERS TO POST-HEARING QUESTIONS

Responses by The Hon. Jeffrey Holmstead

Questions for the Record

Should EPA be looking at the public health dis-benefits from all current and future regulations? What are some of the negative effects on health from a regulation? Has EPA or CASAC looked at the impact of this (or any other) regulation on senior citizens, those living on fixed incomes, and the poor? Furthermore, what decisions will they be forced to make as a result of lost incomes that will affect their health and quality of healthcare

Does EPA's Clean Air Scientific Advisory Committee (CASAC) take these factors into account when reviewing the health effects of a regulation?

Answers from Jeff Holmstead, former Assistant Administrator of EPA for Air and Radiation and head of the Environmental Strategies Group at the Bracewell law firm.

From a policy perspective, EPA should certainly be evaluating all the costs and benefits of its regulations, including the public health dis-benefits (also called adverse health effects). I am not aware of any public policy rationale for ignoring the adverse effects that a regulation may have on public health.

To its credit, EPA does try to estimate the direct costs of its regulations – although many observers believe that, in its recent Clean Power Plan rule, EPA has significantly underestimated the costs. And EPA does evaluate and emphasize all the public health benefits of its regulations. In fact, some of its most extravagant claims about these benefits have recently been called into question.

However, even though EPA normally does a fairly detailed benefit-cost analysis of its major regulations, it has steadfastly refused to look at their public health dis-benefits. And some of EPA's regulations undoubtedly cause adverse effects on public health – particularly on low-income families and people living on fixed incomes, including many senior citizens.

It is especially surprising that EPA ignores these adverse health effects when it comes to the setting of “national ambient air quality standards” (also known as NAAQS) because Congress included a statutory provision designed to ensure that EPA would consider “any adverse public health effects” that would be caused by these standards.

Under the Clean Air Act, Congress created an outside group of science advisors known as the Clean Air Science Advisory Committee (CASAC). Congress created CASAC back in 1977, when it enacted what has now been codified as section 109 of the Clean Air Act. For many years, CASAC has largely just responded to questions posed by EPA staff, but Congress gave CASAC a specific list of responsibilities that goes beyond just answering questions from EPA.

Section 109(d)(2)(C) of the Clean Air Act specifically states that CASAC “shall . . . advise the [EPA] Administrator of *any adverse public health, welfare, social, economic, or energy effects* which may result from various strategies for attainment and maintenance of such national ambient air quality standards.” Notwithstanding this clear congressional directive, CASAC has simply ignored these issues because EPA wants them to be ignored.

These issues are of particular importance when it comes to the new, more stringent ozone standard. EPA and state environmental agencies have been working for more than 40 years on reducing emissions that cause the formation of ozone in ambient air. They have already mandated the emission reductions that are the most-cost effective to achieve. In many areas, it will be very costly to businesses and consumers to obtain additional reductions. Under these circumstances, it is especially important for CASAC to advise the Administrator – and through her, other policymakers – about the “adverse public health, welfare, social, economic, or energy effects which may result from” further efforts to reduce ozone formation. If, as most experts believe, the low hanging fruit has been picked when it comes to reducing emissions of ozone precursors, additional actions will be ever more costly in terms of the cost-per-unit of ozone reduced. CASAC clearly has a role in advising policymakers about the tradeoffs that we all face as our society spends more resources to achieve a goal that may not even be achievable in many parts of the country.

It may be that the most serious adverse health effects caused by EPA regulations are related to job losses. In recent years, EPA regulations have caused a large number of coal-fired power plants and mining operations to shut down and are directly responsible for thousands of people losing their jobs. The stress that comes with job loss as well as the loss of medical insurance undoubtedly cause adverse effects on public health.

Perhaps less obvious is the effect that regulations can have on low- and fixed income Americans more generally. EPA’s regulations have undoubtedly increased the cost of some goods and services – and, in particular, the cost of electricity. Low and fixed-income households spend a disproportionately large percentage of their income on power bills. When those bills increase significantly, they are faced with difficult choices, such as between paying their power bill and paying for medications or healthy food.

There is also academic literature discussing the so-called “health-wealth” effect – the common sense notion that wealthier people tend to be healthier because, among other things, they have better access to health care, medication, exercise opportunities, and healthy food.

There are certainly public health benefits from EPA’s regulation – and sometimes very substantial benefits. But EPA’s regulations also have a number of adverse

effects, including adverse effects on public health. The Agency and CASAC should be required to take these adverse effects into account along with the benefits of both new and existing regulations.

Responses by Dr. Elena Craft

**Questions Following Hearing on October 22, 2015
Before the United States House Committee on Science, Space, and Technology on
“EPA’s 2015 Ozone Standard: Concerns Over Science and Implementation”**

**Elena Craft, PhD
Senior Scientist
Environmental Defense Fund**

Responses to Questions from Representative Johnson

Q: The Texas Commission on Environmental Quality (TCEQ) has come under wide-ranging criticism regarding their use of millions of dollars to hire scientific organizations that have had extensive ties to the tobacco industry in order to help them oppose the new EPA ozone standards. In June of this year the *Houston Chronicle* reported that TCEQ paid one of these firms, Gradient more than \$2.6 million for research on the EPA’s proposed ozone standard. In April TCEQ sponsored a conference that was labelled, “Independent Workshop on Ozone NAAQS Science and Policy.”

Were you in attendance at this workshop? If so, do you believe it was “independent”?

Response: Yes, I was in attendance at TCEQ’s workshop in April of 2015. No, I do not believe it was the workshop was independent. The workshop was advertised as an “independent workshop,” suggesting that multiple perspectives and viewpoints on the science and policy of the standard would be covered. However, the choice of the word independent was misleading – this workshop did not provide a balanced or independent scientific assessment on the available science on ozone exposure and adverse health outcomes. Instead, the workshop was predicated on attacking the stronger ozone standard that had been proposed by EPA and broadly supported by leading scientific and health organizations. This point was emphasized repeatedly throughout the three-day meeting.

In addition, there was no discussion regarding the myriad number of groups¹ who support an even stronger standard than what EPA had proposed at the time. The American Academy of Pediatrics, American Heart Association, American Lung Association, American Medical Association, American Public Health Association, American Thoracic Society, Asthma and Allergy Foundation of America, and Children’s Environmental Health Network, as well as many others, have publicly supported a standard of 60ppb.

In contrast to TCEQ’s workshop, the national process (outlined in the Clean Air Act and established to advise the agency on the science of ozone) has been independent. A recent Inspector General report² that reviewed 47 CASAC and Council member appointments confirmed this, determining “EPA has adequate procedures for identifying potential ethics concerns, including financial conflicts of interest, independence issues and appearances of a lack of impartiality.”

¹ <http://www.lung.org/get-involved/advocate/advocacy-documents/national-health-and-medical.pdf>

² <http://www.epa.gov/oig/reports/2013/20130911-13-P-0387.pdf>

In addition to the partiality exhibited during the workshop, workshop participants presented a one-sided and skewed view of the science and economics around the standard. Some of the notable speakers over the three day workshop included:

- Sayed Sadredin, Executive Director of the San Joaquin Valley Air Pollution Control District, who focused on California's experience in meeting ozone NAAQS. He mentioned several times how industry has cried wolf before on the costs of meeting the ozone NAAQS, but this time it is "for real."
- Sabine Lange, TCEQ toxicologist, presented a "new" analysis by the agency examining ozone dose, or the amount of exposure a person would receive based on ventilation rate and activity level. Not only did the analysis oversimplify the issue of dose, but it left out key factors of dose including dose rate, the need to normalize ventilation rate to body surface area, and the need to correct for filtered air responses. Additionally, the agency has continued to focus on the "mean," or average response in perfectly healthy human individuals – effectively ignoring those vulnerable members of the population, including asthmatics, people with COPD, the elderly, the obese, and children (all together representing about one half of the population). The Clean Air Act is clear in that the primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety."
- Julie Goodman, an industry toxicologist with consulting firm Gradient, focused on the "uncertainty" around the lower estimates of the ozone exposure studies and mortality statistics. Goodman spent a good deal of time during the workshop trying to discredit a few key studies from the ozone literature. One issue with Goodman's criticisms has been that the scientific evidence on ozone exposure and adverse health outcomes has only become more compelling over time, as represented by multiple reports published after the 2008 ozone NAAQS review.
- Anne Smith and Scott Bloomberg of NERA Economic Consulting, an industry consulting firm, spent over two hours at the workshop outlining their analysis of the proposed costs of the clean air rules, which they estimated was an order of magnitude above EPA estimates. No alternative perspectives were provided, the NERA assumptions were never challenged, and the benefits of the ozone NAAQS were not discussed. This was remarkable since: 1) there is a sophisticated, robust analysis³ criticizing NERA's work on this very report, and 2) there has been a postmortem examination⁴ of the accuracy of EPA's cost estimates following several of EPA's rules, concluding that frequently, EPA has actually overestimated the costs associated with the rules studied.

What kinds of tactics have been employed by TCEQ, and others in industry, to oppose EPA's new ozone standard? What parallels can be seen when compared with the tactics that the tobacco industry employed to resist federal regulations to limit the harmful effects of tobacco smoke?

³ <http://earthjustice.org/sites/default/files/files/Clearing%20Up%20the%20Smog%20-%209-10-15%20FINAL%20VERSION.pdf>

⁴ <http://onlinelibrary.wiley.com/doi/10.1002/%28STC%291520-6688%28200021%2919:2%3C%3E1.0.CO;2-8/issuetoc>

Response: TCEQ has engaged in a multilateral attack on the ozone standard. Examples of actions undertaken by the agency include:

- Denying petition⁵ from Dallas medical association to require additional controls from coal-fired power plants outside of Dallas⁶
- Spending upwards of \$3 million taxpayer dollars to hire industry consultants to reevaluate the ozone literature⁷
- Submitting public comments to challenge the standard⁸
- Providing misleading information on the health effects of ozone exposure by asserting that asthmatics are no more susceptible to the harms of ozone exposure than non-asthmatics⁹
- Providing misleading information on how the Administrator selected an ozone standard of 70ppb¹⁰

I have serious concerns that an organization whose mission it is to “protect our state’s public health and natural resources consistent with sustainable economic development,” would instead choose to spend millions of taxpayer dollars on undermining the existing body of scientific evidence supporting a lower ozone standard. It seems to me that by taking a page out of the tobacco industry playbook, TCEQ is failing to live up to their mission, and the people of Texas will suffer as a result. As a fellow Texan, please comment on the actions of TCEQ, and discuss the impact further use of tobacco industry tactics will have on undermining legitimate scientific consensus regarding environmental regulations on both Texans and Americans in general.

Response: TCEQ is charged with protecting our state and its citizens and has instead repeatedly opposed cost-effective, much-needed health protections like the ozone standard. TCEQ is not living up to its duty to protect Texans and ensure open, transparent, scientifically-sound processes for developing state policies to address public health and the environment. We have seen tactics like this deployed time and again on environmental and health issues, including in the battle to regulate tobacco. Given the importance of ozone to public health, it is unfortunate a state environmental agency chose to spend taxpayer money on a workshop designed to mislead the public and present a one-sided perspective on the issue.

Q: The Texas Medical Association, representing 45,000 physicians and the Dallas County Medical Society representing 7,000 medical personnel, have both been severely critical of TCEQ’s environmental policies, particularly regarding ozone.

⁵ <http://www.dallas-cms.org/news/TCEQpetition082613.pdf>

⁶ https://www.tceq.texas.gov/assets/public/comm_exec/agendas/comm/2013/131023.Mrk.pdf

⁷ <http://www.houstonchronicle.com/news/houston-texas/houston/article/TCEQ-funded-ozone-research-under-scrutiny-6351799.php>

⁸ <http://www.tceq.state.tx.us/assets/public/agency/nc/air/TCEQ-Comments-on-EPA-HQ-OAR-2008-0699-NAAQS.pdf>

⁹ <https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-114-SY-WState-MHoneycutt-20151022.pdf>

¹⁰ <https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-114-SY-WState-MHoneycutt-20151022.pdf>

Why have these professional medical associations been so critical of TCEQ and its policies regarding ozone pollution?

According to a petition filed by the Dallas Medical Association¹¹, the TCEQ has allowed facilities outside the Dallas area to operate without requiring adequate control technologies, ultimately leading to increased exposure to ozone in the region.

In response to the agency's lack of action on requiring pollution controls for facilities impacting air quality in the Dallas area, researchers at the University of North Texas conducted a modeling study¹² using data and methodology from the TCEQ to analyze the impact of pollution emitted from coal fired power plants outside of the Dallas area. Results from the study demonstrated that pollution from coal fired power plants outside of the Dallas area were contributing up to 5ppb of the Dallas air shed's ozone.

In part, and as a result of the study findings from the University of North Texas, the Dallas City Council passed a resolution¹³ in October of 2015 requesting that best available control technologies be assessed or retirement of legacy coal-fired power plants be considered as part of the ongoing bankruptcy settlement negotiations that are underway for the facilities modeled.

Responses to Questions from Representative Lofgren

Q: Dr. Craft, in your testimony you describe the Clean Air Act as “a bedrock public health statute that has provided for extraordinary, bipartisan progress in protecting Americans’ health and the environment for over 40 years.” Thanks to the Clean Air Act, Bay Area air is cleaner and healthier to breathe than it was two decades ago, even as Silicon Valley’s population is growing rapidly, bringing more cars, traffic, and emissions. Mr. Sadredin, however, has a different view and states in his testimony that “structural deficiencies in the Act will lead to economic devastation.” Unfortunately, this kind of “sky is falling” rhetoric is far too common when discussing the ozone rule, the Clean Power Plan, or any other kind of environmental regulation, particularly on this Committee.

a. Can you please describe some of the benefits expected to result from implementing the lower ozone standard?

Response: The standard is expected to prevent up to 660 premature deaths, 230,000 asthma attacks, and 160,000 lost school days across the nation in 2025, excluding California. EPA estimates the benefits at this level of protection provide up to \$5.9 billion in monetized benefits, greatly outweighing the costs of implementation.¹⁴

¹¹ <http://www.dallas-cms.org/news/TCEQpetition082613.pdf>

¹² <http://dfwozonestudy.org/>

¹³ <http://www.dallascounty.org/department/comert/district1/documents/AirQualityAttainmentSIGNED.pdf>

¹⁴ U.S. Environmental Protection Agency, By the Numbers fact sheet (October 2015), <http://www3.epa.gov/airquality/ozonepollution/pdfs/20151001numbersfs.pdf>.

b. In your opinion, how do the economic and public health costs of attaining of a lower ozone standard compare to the economic and public health costs of keeping the current standard, or eliminating the standard?

Response: EPA estimates the cost of compliance with a standard of 70 ppb (excluding California) will be \$1.4 billion, which is greatly outweighed by the estimated benefits of \$2.9 to 5.9 billion. History had demonstrated time and again we can reduce pollution cost-effectively. An independent working paper by the Massachusetts Institute of Technology Department of Economics found a 1 ppb ozone reduction in the eastern US yields \$1.74 billion in societal benefits,¹⁵ confirming the significant benefits of reducing ozone pollution.

Retaining the previous standard of 75 ppb would result in hundreds of more premature deaths across the country and hundreds of thousands of asthma attacks in children. Eliminating the standard would jeopardize the health and welfare of millions of Americans. Real health and economic costs are being borne by Americans from ozone pollution through heart attacks, asthma attacks, missed work and school days, hospital visits and early death. The American Lung Association found in a 2015 report that more than 4 in 10 people lived in areas with unhealthy levels of ozone pollution in 2011–2013.¹⁶

c. Also, can you please describe how these “sky is falling” claims have been proven wrong time over time?

Response: In 1997, Senator Max Baucus observed: “Air quality standards have always been met with claims of economic demise. But then technology catches up. Innovative programs are implemented. Further research bolsters the initial decision. In the end, costs are a fraction of initial claims, and everyone breathes cleaner air.”¹⁷

EPA’s March 2011 prospective analysis of the costs and benefits of the 1990 Clean Air Act Amendments found that benefits will exceed costs by more than 30 to 1 between 1990 and 2020.¹⁸ The benefits of MATS are projected to outweigh costs by at least 3-to-1, and up to as much as 9-to-1. If history is any guide, the actual costs will likely be lower than predicted. A Resources for the Future 2010 paper finds that “EPA and other regulatory agencies tend to overestimate the total costs of regulations... These exaggerated adjustment costs are often attributable to underestimates of the potential that technological change could minimize pollution abatement costs.”¹⁹

¹⁵ Deschenes, Olivier et al., “Defensive Investments and the Demand for Air Quality: Evidence from the NOx Budget Program and Ozone Reductions,” Working Paper 12-18, July 15, 2012 Revised: September 27, 2012.

¹⁶ American Lung Association, “State of the Air 2015 – Key Findings for 2011–2013,”

<http://www.stateoftheair.org/2015/key-findings/ozone-pollution.html>

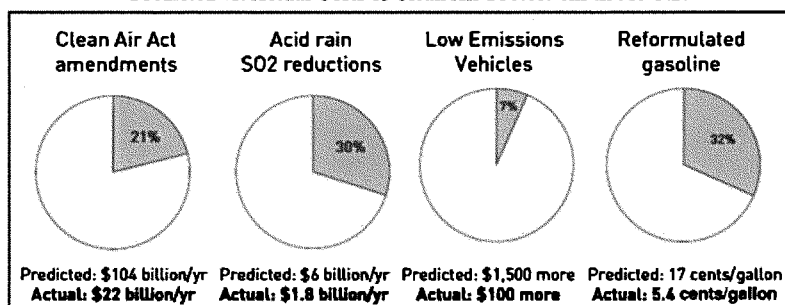
¹⁷ Statement of Senator Max Baucus before the Clean Air, Wetlands, Private Property, and Nuclear Safety Subcommittee, Oct. 22, 1997, available at <http://epw.senate.gov/105th/bau10-22.htm> (last accessed April 24, 2012).

¹⁸ Environmental Protection Agency, “The Benefits and Costs of the Clean Air Act from 1990 to 2020” (2011) available at <http://www.epa.gov/air/sect812/feb11/fullreport.pdf>.

¹⁹ Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, “How Accurate Are Regulatory Cost Estimates?” 1 (2010), available at http://grist.files.wordpress.com/2010/11/harringtonmorgensternnelson_regulatory_estimates.pdf.

Industry cost predictions have also overestimated predicted compliance costs. When Congress was considering the 1990 Clean Air Act Amendments, industry groups estimated the legislation would cost \$104 billion per year.²⁰ In 1995, five years after the amendments became law, EPA estimated the actual annual costs to be \$22 billion.²¹ The graphic and chart below illustrate how actual costs compare with initial predictions in three other cases: acid rain SO₂ reductions; low emissions vehicles; and reformulated gasoline.

Predicted vs. Actual Costs of Clean Air Protections in the U.S.



Predicted versus actual costs of Clean Air Act protections

Program	Predicted Costs	Actual Costs
1990 Clean Air Act Amendments	1990: "The study we are releasing today estimates that the cost of the various proposed amendments...could be as high as \$104 billion per year" ²²	1995: Five years after implementation EPA estimated that implementation of the 1990 CAA protections cost \$22 billion per year—79% less than predicted. ²³
Acid Rain	1990: EPA estimated that Phase II implementation would cost \$6 billion per year. ²⁴ 1990: The Edison Electric	2005: The Office of Management and Budget estimated that the annual cost of reducing SO ₂ is \$1.1-1.8 billion—70% less than predicted. ²⁶

²⁰ Business Roundtable, Clean Air Act Legislation Cost Evaluation (1990).

²¹ E.H. Pechan & Associates, Inc., contracted by EPA. "Clean Air Act Section 812 Prospective Assessment: Cost Analysis Draft Report" (1995).

²² Business Roundtable, Clean Air Act Legislation Cost Evaluation (1990).

²³ E.H. Pechan & Associates, Inc., contracted by EPA. "Clean Air Act Section 812 Prospective Assessment: Cost Analysis Draft Report" (1995).

²⁴ Executive Office of the President, National Science and Technology Council, "National Acid Precipitation Assessment Program, Report to Congress: An Integrated Assessment" 13 (2005) available at <http://www.esrl.noaa.gov/csd/aqrs/reports/napareport05.pdf>.

	Institute estimated that reducing SO ₂ would cost the electric utility industry \$3.6-4.5 billion per year. ²⁵	
Low Emissions Vehicles	1994: Auto manufacturers estimated that low emission vehicles would cost \$1,500 more than comparable car models.²⁷ 1990: The California Air Resources Board estimated the average incremental cost of a low emissions vehicle to be \$170. Industry estimates in California were \$788.²⁸	1995: One year after the manufacturers' estimate, Honda placed a Civic subcompact model on the market that emitted less than half of what was permitted under California law. This vehicle cost only \$100 more than comparable models.²⁹ 1998: The actual incremental cost of low emission vehicle technology was \$83, fully 93% less than predicted.³⁰
Reformulated Gasoline in California	1991: The California Air Resources Board predicted that reformulated gas would lead to a price increase of 12-17 cents per gallon. ³¹	1998: The actual price differential was 5.4 cents per gallon—68% less than predicted. ³²

²⁶ Executive Office of the President, National Science and Technology Council, "National Acid Precipitation Assessment Program, Report to Congress: An Integrated Assessment" 13 (2005) available at <http://www.esrl.noaa.gov/csd/aqrs/reports/napareport05.pdf>.

²⁵ Written Testimony of Fred Krupp, President, Environmental Defense Fund, before the U.S. Senate Committee on Environment and Public Works on "Climate Change and Ensuring America Leads the Clean Energy Transformation", August 6, 2009.

²⁷ Sierra Research, Inc., "The Cost Effectiveness of Further Regulating Mobile Source Emissions" (1994).

²⁸ Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, "On the Accuracy of Regulatory Cost Estimates" (1999) (citing Cackette, "The Cost of Emission Controls on Motor Vehicles and Fuels: Two Case Studies", presented at the 1998 Summer Symposium of the EPA Center on Airborne Organics, MIT Endicott House, Dedham, Mass, Jul. 9-10, 1998).

²⁹ James Bennett, "Honda Meets a Strict Emission Rule Set for 1997 in California", N.Y. Times, August 30, 1995.

³⁰ Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, "On the Accuracy of Regulatory Cost Estimates" (1999) (citing Cackette, "The Cost of Emission Controls on Motor Vehicles and Fuels: Two Case Studies", presented at the 1998 Summer Symposium of the EPA Center on Airborne Organics, MIT Endicott House, Dedham, Mass, Jul. 9-10, 1998).

³¹ Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, "On the Accuracy of Regulatory Cost Estimates" (1999) (citing Cackette, "The Cost of Emission Controls on Motor Vehicles and Fuels: Two Case Studies", presented at the 1998 Summer Symposium of the EPA Center on Airborne Organics, MIT Endicott House, Dedham, Mass, Jul. 9-10, 1998).

³² Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, "On the Accuracy of Regulatory Cost Estimates" (1999) (citing Cackette, "The Cost of Emission Controls on Motor Vehicles and Fuels: Two Case Studies", presented at the 1998 Summer Symposium of the EPA Center on Airborne Organics, MIT Endicott House, Dedham, Mass, Jul. 9-10, 1998).

A Closer Look at Cost-Effectively Reducing SO₂ Pollution

EPA's program to control SO₂ pollution from power plants and reduce acid rain offers a prime example of a clean air policy that has achieved important results at significantly lower costs than predicted. Peabody Coal and the Edison Electric Institute (EEI) initially estimated the costs of reducing 10 million tons of SO₂ (approximately the amount required by Phase I of EPA's Acid Rain Program) would be \$3.9 billion and \$4-5 billion per year, respectively.³³ The U.S. Congressional Office of Technology Assessment projected Phase I compliance costs of \$3-4 billion per year.³⁴

EEI predicted even higher compliance costs for Phase II reductions – at least \$7.5 billion per year (Y2000\$). EPA's first estimate for annual Phase II costs was \$6.1 billion.³⁵

However, with American innovation, actual costs were a small portion of the initial projections. The U.S. Energy Information Administration's 1995 official calculation of costs found that actual annualized costs of compliance with Phase I were \$836 million. In 1998, the Electric Power Research Institute and Resource for the Future estimated total costs of implementation would be \$1.7 and \$1.1 billion, respectively, in 2010.³⁶ Similarly, the U.S. Office of Management and Budget estimated costs of the entire SO₂ program at \$1.1 to \$1.8 billion (Y2000\$) – a fraction of what was projected.^{37,38}

In large part, industry was able to realize lower-than-expected compliance costs due to advances in scrubber pollution control technology. A March 2010 Resources for the Future report explains how technological innovation reduced compliance costs: "Estimates before regulation assumed that scrubbers operate at 85 percent reliability and remove 80 to 85 percent of the sulfur. In fact, scrubbers typically run in excess of 95 percent reliability, removing 95 percent of the sulfur. The original estimate of opportunities to blend low- and high-sulfur coal in older boilers was a 5/95 mixture. In fact, industry was able to achieve a much more efficient 40/60 mixture."³⁹

Breakthrough advances in pollution abatement technology and low cost clean air solutions

³³ M.J. Bradley & Associates for Small Business Association and the Main Street Alliance, "The Clean Air Act's Economic Benefits: Past, Present, and Future" 7 (2010) available at http://www.smallbusinessmajority.org/pdf/Benefits_of_CAA_100410.pdf.

³⁴ Don Munton, "Dispelling the myths of the acid rain story", 40 Environment 4, 27 (1998).

³⁵ Executive Office of the President, National Science and Technology Council, "National Acid Precipitation Assessment Program, Report to Congress: An Integrated Assessment" 13 (2005) available at <http://www.esrl.noaa.gov/csd/aqrs/reports/napareport05.pdf>.

³⁶ Gabriel Chan, Robert Stavins, Robert Stowe, & Richard Sweeney, Harvard Environmental Economics Program, "The SO₂ Allowance Trading System and the Clean Air Act Amendments of 1990: Reflections on Twenty Years of Policy Innovation" 5 (2012).

³⁷ Don Munton, "Dispelling the myths of the acid rain story", 40 Environment 4, 27 (1998).

³⁸ Executive Office of the President, National Science and Technology Council, "National Acid Precipitation Assessment Program, Report to Congress: An Integrated Assessment" 13 (2005) available at <http://www.esrl.noaa.gov/csd/aqrs/reports/napareport05.pdf>.

³⁹ Winston Harrington, Richard Morgenstern, & Peter Nelson, Resources for the Future, "How Accurate Are Regulatory Cost Estimates?" 2 (2010) available at http://grist.files.wordpress.com/2010/11/harringtonmorgensternnelson_regulatory_estimates.pdf.

continue to happen today, driven by American ingenuity and innovation. With smart clean air policies in place, further advancements in American-made pollution controls can simultaneously clean the air and strengthen the economy.

Advances in Mercury Emissions Reductions

The U.S. has also made important progress in the efficacy of mercury pollution controls. In 2005, a large coal-based power company claimed it would be 2018 before Activated Carbon Injection (ACI) could be feasibly installed at most power plants.⁴⁰ EPA's 2005 standards largely reflected a similar perspective.

But, through innovation, U.S. firms have propelled ACI technology more quickly and at lower cost than initially predicted. ACI technology has turned out to be an efficacious pollution control, and the cost of capturing mercury from power plants has dropped substantially. According to the Department of Energy's National Energy Technology Laboratory, the cost of capturing a pound of mercury in 2008 was 1/6 the 1999 price.⁴¹ Advances in the sorbents used to remove mercury have allowed ACI to be used for a wider range of coal types than was expected in 2005, and ACI systems now cost a fraction of other air pollution control devices.⁴²

⁴⁰ An official at American Electric Power stated: "AEP officials have pointed out that reducing mercury emissions is a tremendous challenge because there are no commercial technologies presently available that can capture or remove mercury emissions from a wide range of coal-fired units and a variety of coal types. New technologies are being developed, but they are still in their early stages, although they should be ready in time for the second phase of the cap-and-trade program." John McManus, "AEP favors cap-and-trade system for mercury", *Electric Light and Power* (2005) available at <http://www.elp.com/index/display/article-display/221636/articles/electric-light-power/volume-83/issue-1/departments/generation/aep-favors-cap-and-trade-system-for-mercury.html> (last accessed April 24, 2012).

⁴¹ "NETL: Mercury Control Program Achieves Success", IHS, Jun. 23, 2008, <http://www.ihs.com/News/utilities/2008/netl-mercury-control-program-062308.htm> (last accessed April 24, 2012).

⁴² U.S. Government Accountability Office, "Mercury Control Technologies at Coal-Fired Power Plants Have Achieved Substantial Emissions Reductions" 10 (2009) available at <http://www.gao.gov/new.items/d1047.pdf#page=14> (last accessed April 24, 2012).

Responses by Dr. Michael Honeycutt

Response to Questions

U.S. House Committee on Science, Space, and Technology

EPA's 2015 Ozone Standard: Concerns Over Science and Implementation

Thursday, November 5, 2015

Questions from the Honorable Lamar Smith (R-TX)

Question 1: *Are EPA's assumptions about base case air quality for Texas in 2025 and the amount of controls needed to Texas to achieve a 70 ppb reasonable?*

Response: The EPA's assumptions in the Regulatory Impact Analysis of the Final Revisions to the National Ambient Air Quality Standards (NAAQS) for Ground-Level Ozone¹ are very high level and, as such, may not be representative. For example, according to the EPA's analysis, three Texas counties: Brazoria and Harris Counties in the Houston-Galveston-Brazoria (HGB) area and Tarrant County in the Dallas-Fort Worth (DFW) area are projected to have 2025 design values above the newly promulgated ozone standard (70 ppb). In its analysis, the EPA assumed a national average cost per ton to apply to unidentified controls needed to reach attainment. This one-size-fits-all approach is unlikely to accurately represent the actual cost per ton of reductions in areas such as HGB and DFW, which are already subject to a broad range of stringent regulations that address emissions of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x). Because these areas already have extensive emission control requirements in place, additional emission reductions will likely be more costly than EPA's estimated national average cost per ton.

The controls that will be needed to attain the 70 ppb standard will depend on much more detailed local modeling and control strategy analyses. Further, even once the amount of emissions reduction needed for a specific area have been determined and feasible control measures identified, the cost of the controls must be considered in conjunction with the potential benefit to the nonattainment areas.

Question 2: *During the hearing, Dr. Craft named 3 studies that the EPA has cited to back up the 70 ppb standard. These studies she mentioned included the Jerrett et al. (2009), Kim et al. (2011) and Stevens. Is it true that EPA cited these 3 specific studies at any time of the rule-making process to scientifically justify this regulation, or were they simply cited because EPA had reviewed them and chose not to rely on them due to scientific concerns? What are the limitations and shortcomings associated with these studies that would make EPA or any Federal Agency wary of relying on them?*

¹ USEPA. 2015. Regulatory Impact Analysis of the Final Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone. Vol. EPA-452/R-15-007, September. 480 p.

Response: The Jerrett et al. (2009)² and Kim et al. (2011)³ studies were cited during the rule-making process to scientifically justify this regulation, although the EPA expressed uncertainty in the conclusions that were drawn from these studies and did not rely on them for the level of the revised standard.

The EPA cited Jerrett et al. (2009) as evidence that long-term exposure to ozone is associated with respiratory mortality (Ozone Final Rule, 2015, Section II.A.1.ii)⁴, although they state that “lower confidence should be placed in respiratory mortality risk estimates based on this study” (Ozone Proposed Rule, 2014, Section II.E.4.b.ii)⁵. In addition, the Integrated Science Assessment (ISA) states that there is only *limited evidence* for an association between long-term exposure to ambient ozone concentrations and respiratory mortality in adults (ISA, 2013, Section 7.2.8)⁶. The evidence is limited because this is the *only* study out of twelve that the EPA looked at showing an association between long-term exposure and respiratory mortality.

The EPA used the Kim et al. (2011) study along with several other studies to draw the conclusion that “mean FEV₁ is clearly decreased by 6.6-hour exposures to 60 ppb ozone and higher concentrations in [healthy, young adult] subjects performing moderate exercise” (Ozone ISA, 2013, Section 6.2.1.1; Ozone Final Rule, 2015, Section II.A.1.b.i). However, the Administrator stated that there was more uncertainty in effects occurring at concentrations as low as 60 ppb because a statistically significant increase in respiratory symptoms was not observed at concentrations of 60 ppb or 63 ppb (Ozone Final Rule, 2015, Section II.C.4.a). To meet the American Thoracic Society’s definition of an adverse health effect, a combination of a statistically significant lung function decrement (which was not reported in other studies that exposed humans to 60 or 63 ppb ozone –Adams et al. 2006⁷, Schelegle et al. 2009⁸) together with symptoms is required (ATS, 2000)⁹. Therefore, the effects noted in Kim et al. (2011) are not considered adverse by EPA nor by the American Thoracic Society.

Upon reviewing the recorded Committee Session, it seems that the third paper that Dr. Craft cited was “Stielen”, not “Stevens”. We are not familiar with any papers with either name used in

² Jerrett, M., R.T. Burnett, C.A. Pope, 3rd, K. Ito, G. Thurston, D. Krewski, Y. Shi, E. Calle, and M. Thun. 2009. Long-term ozone exposure and mortality. *The New England journal of medicine*. 360:1085-1095.

³ Kim, C.S., N.E. Alexis, A.G. Rappold, H. Kehrl, M.J. Hazucha, J.C. Lay, M.T. Schmitt, M. Case, R.B. Devlin, D.B. Peden, and D. Diaz-Sanchez. 2011. Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. *American journal of respiratory and critical care medicine*. 183:1215-1221.

⁴ USEPA. 2015. National Ambient Air Quality Standards for Ozone (Final Rule). Vol. FR Volume 80 No. 206.

⁵ USEPA. 2014. National Ambient Air Quality Standards for Ozone (Proposed rule). Vol. FR Vol 79 No. 242.

⁶ USEPA. 2013. Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Final). Vol. EPA/600/R-10/076F, February. 1251 p.

⁷ Adams, W. C. 2006. Comparison of chamber 6.6-h exposures to 0.04-0.08 PPM ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation toxicology*. 18:127-136.

⁸ Schelegle, E.S., C.A. Morales, W.F. Walby, S. Marion, and R.P. Allen. 2009. 6.6-hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans. *American journal of respiratory and critical care medicine*. 180:265-272.

⁹ American Thoracic Society (ATS). 2000. What constitutes an adverse health effect of air pollution? *American journal of respiratory and critical care medicine*. 161:665-673.

the justification for lowering the ozone standard. We searched the documents (EPA's Integrated Science Assessment⁶ and Health Risk and Exposure Assessment¹⁰) used to inform the 2015 ozone rule, and found 1 paper by Stevens (1993, referencing ozone monitors¹¹), and 1 paper by Stephens (1976, discussing effects of long-term ozone exposure in rat lungs¹²), but none by "Stielen" or any spelling variation thereof. Accordingly, we conclude that the third paper referenced by Dr. Craft was not used to scientifically justify this regulation.

TCEQ staff agree with statements by EPA regarding the limited usefulness of the Jerrett et al. (2009) and Kim et al. (2011) studies for support in lowering the ozone NAAQS and that these studies should be given less weight by EPA in considering the potential public health impacts of ozone.

¹⁰ USEPA. 2014. Health Risk and Exposure Assessment for Ozone (Final Report). Vol. EPA-452/R-14-004a, August. 502 p.

¹¹ Stevens, R.K., Drago, R.J., Mamane, Y. 1993. A long path differential optical absorption spectrometer and EPA-approved fixed-point methods intercomparison. *Atmospheric Environment*. 27 (2): 231-236.

¹² Stephens, R.J., Sloan, M.F., Groth, D.G. 1976. Effects of long-term, low-level exposure of NO₂ or O₃ on rat lungs. *Environmental Health Perspectives*. 16: 178-179.

Questions from the Honorable Gary Palmer (R-AL)

Question 1: *Should EPA be looking at the public health dis-benefits from all current and future regulations? What are some of the negative effects on health from a regulation? Has EPA or CASAC looked at the impact of this (or any other) regulation on senior-citizens, those living on fixed-incomes, and the poor? Furthermore, what decisions will they be forced to make as a result of lost income that will affect their health and quality of healthcare?*

Response: TCEQ staff agree that it is appropriate for EPA to look at both the potential public health benefits and dis-benefits in lowering the ozone standard. There are a wide range of possible negative health effects from a regulation that could be evaluated. Particularly with respect to the ozone final rule, many of these effects likely relate to behavioral changes resulting from increased compliance costs and emission reduction strategies in nonattainment areas. For example, senior-citizens and low- or fixed-income individuals may subject themselves to greater risk of temperature-related mortality (mortality related to either very high or low temperatures) to offset increased energy costs as a result of increased emission control strategies at power plants. Because the EPA does not expect the ozone rule to decrease asthma exacerbations (USEPA Regulatory Impact Analysis, Table 6-20)¹ or prevalence, low- or fixed-income asthmatics may bear a disproportionate health burden as they try to maintain existing treatment and medication costs along with increased energy costs. Further, heightened concern over ambient ozone concentrations due to reduced Air Quality Index breakpoints in the Ozone Final Rule may lead to riskier personal behaviors, such as choosing to remain indoors (which increases health effects related to substantially worse air quality), abstaining from exercise (which increases obesity-related health effects), and cancelling recess for school children. To our knowledge, neither the EPA nor CASAC has looked at the impact of ozone regulation on senior-citizens, those living on fixed-incomes, and the poor. In general, the regulatory impact analyses are inequitable in their evaluation of regulatory health costs and benefits. In other words, the health benefits of reduced premature mortality may be considered, but the additional health costs of job loss or increased utility bills are excluded. While it is difficult to say what decisions (e.g. paying for food or medicine vs. electricity) these groups will need to make as a result of increasing costs from a lower ozone standard, we can say that scientific studies have found adverse health consequences, such as increased mortality, associated with decreased socioeconomic status (Steenland et al. 2004)¹³.

Question 2: *Does EPA's Clean Air Scientific Advisory Committee (CASAC) take these factors into account when reviewing the health effects of a regulation?*

Response: While the Clean Air Act states in section 109(d) that CASAC shall “advise the Administrator of any adverse public health, welfare, social, economic or energy effects which

¹³ Steenland, K., S. Hu, and J. Walker. 2004. All-cause and cause-specific mortality by socioeconomic status among employed persons in 27 US states, 1984-1997. *American journal of public health*. 94:1037-1042.

may result from various strategies for attainment and maintenance of such national ambient air quality standards”, the CASAC has not undertaken such a review.

In a letter dated June 26, 2014, the Chair of CASAC, Dr. H. Christopher Frey stated that “Separate from the standard-setting process, the CASAC would be receptive to a request from EPA to review EPA analyses of “adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards” (42 U.S. Code § 7409)¹⁴.” To our knowledge the EPA has not completed, nor have they asked CASAC to review, any such analyses.

¹⁴ Frey, H.C. 2014. CASAC Review of the EPA’s Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. *In* EPA-CASAC-14-004.

Response to Questions**U.S. House Committee on Science, Space, and Technology***EPA's 2015 Ozone Standard: Concerns Over Science and Implementation*

Thursday, November 5, 2015

Question from the Honorable Eddie Bernice Johnson (D-TX)

Question 1: Dr. Honeycutt, the Texas Commission on Environmental Quality (TCEQ) has come under wide-ranging criticism regarding their use of millions of dollars to hire scientific organizations that have had ties to the tobacco industry in order to help them oppose the new EPA ozone standards. The organization Toxicology Excellence for Risk Assessment (TERA), for instance, was paid by TCEQ to help organize your "Independent Workshop on Ozone NAAQS Science and Policy," that was held from April 7-9, 2015. In addition, in June of this year the Houston Chronicle reported that TCEQ paid another firm that had conducted extensive research for the tobacco industry, the Gradient Corporation, more than \$2.6 million for research on the EPA's proposed ozone standard. The Texas Tribune reported in October that TCEQ had hired Gradient again under an estimated \$1.5 million contract to conduct an analysis of arsenic.

In the minds of many, particularly the vast majority of the scientific community, these are not 'independent' scientific organizations. They are normally hired by industry to help raise doubts about regulatory or other issues that may impact their clients. Since the independence of scientific analysis is important and something this Committee should value, I would like to understand how your public organization has funded its various efforts to oppose federal regulations, including the Environmental Protection Agency's (EPA's) new standards on ground-level ozone pollution known as National Ambient Air Quality Standards (NAAQS).

- *Please provide a list of all expenditures by TCEQ in its analysis, presentation or marketing efforts related to ozone issues from 2010 to present. This should include the expenditures to all outside, non-TCEQ parties, including Gradient and TERA, regarding their various work related to ozone or the EPA's NAAQS standards. Please identify the organization or individual paid, the amount paid, the date of the payment and a brief description of the expense.*
- *Please also provide the total payments TCEQ has made to Gradient since 2010. For each individual payment please include the amount paid, the date of the payment and a brief description of the expense.*
- *Please also provide the total payments TCEQ has made to the Toxicology Excellence for Risk Assessment (TERA) since 2010. For each individual payment please include the amount paid, the date of the payment and a brief description of the expense.*

Remarks:

The Texas Commission on Environmental Quality (TCEQ) takes its statutory obligation to provide for the consideration of natural resources and protection of the environment, including air quality, seriously. In fact, the State of Texas has achieved some of the largest ambient ozone reductions in the country (see Figure 1). Therefore, we respectfully disagree with any suggestion that TCEQ's efforts lack objectivity.

In your testimony, you asserted that the Texas Commission on Environmental Quality (TCEQ) has used "tobacco industry tactics" in its ozone analysis. Unlike the unethical and illegal tactics

you referenced, the TCEQ has used peer-reviewed published data, our own analyses based on our extensive experience in conducting chemical risk assessment, and the United States Environmental Protection Agency's (EPA) own analyses to support our comments regarding ozone health effects. Our analyses, communications, and comments are available to members of the public. It is notable that most reviewers have not refuted the specific points we make in our data analyses.

The scientists at the TCEQ are experts in the field of air pollution toxicology and risk assessment, as are many scientists at the EPA. As scientists in a common area, it is our obligation to peer review the EPA's work, as it is their obligation to peer review our work. There is a voluminous amount of material on ozone that has been generated to inform the current understanding of how ozone can cause health effects, and how the regulation of this chemical would directly affect Texas and many other States. In our analysis, we observed many inconsistent results, biases and errors in the ozone health data or how it was analyzed, and uncertainties in modeling and extrapolation to real-world exposure scenarios¹. Because of our preliminary findings, the size of literature on this chemical, and its importance, the TCEQ contracted for external review various aspects of ozone health effects, in addition to its independent research and evaluation of the data. The contract with Gradient states:

The purpose of this umbrella Contract is to advance the knowledge in this field and to encourage and challenge the [EPA] to conduct an objective and rigorous scientific review and evaluation of the available scientific evidence in order to obtain the required support for a proposed lowering of a NAAQS.

Utilizing the contractors' knowledge and expertise on ozone with our chemical risk assessment expertise better qualified us to provide the EPA with meaningful, data-driven feedback on the ozone standard. This work also filled in some gaps in the EPA's analysis that were important to understanding the health effects of ozone, for example the consideration of ozone dose instead of concentration in human exposure studies². Our intention was not to oppose federal regulations, but rather to provide a scientific peer review.

With our investigations, and that of our contractors, it became clear to us that there is considerable uncertainty in the field about what health effects ozone exposure actually causes and whether or not these occur at present-day ambient concentrations. Some of our findings were significant, and prompted sharing what we had learned. We aired our concerns to the EPA in written comments, as well as to CASAC, with little feedback. This, in part, led us to organize the Independent Workshop on Ozone NAAQS Science and Policy in April of 2015, in order 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." This unique workshop, which was open to all registrants and was broadcast for free online³, brought together scientific, socioeconomic and policy experts to discuss the multi-faceted aspects of a further reduced ozone standard. The

¹ Shaw, B.W., S.S. Lange, and M.E. Honeycutt. 2015. "Lowering the Ozone Standard Will Not Measurably Improve Public Health." *Env. Manager*, May pp. 26-31.

² Texas Commission on Environmental Quality (TCEQ). 2013. "Comments by Texas Commission on Environmental Quality regarding agency information collection activities; proposed collection; comment request; 8-hour ozone national ambient air quality standard implementation rule, EPA ICR No. 2236.04". EPA Docket ID No. EPA-HQ-OAR-2003-0079.

³ <http://www.tera.org/Peer/ozone/index.html>

independent expert panelists were selected because they did not have a vested interest in the ozone science or the standard nor had they published new papers for the current ozone NAAQS review or made public statements on it. Therefore, they could provide a fresh perspective on the data. Various participants presented their research or knowledge of the ozone NAAQS regulatory law, ozone science, and the implementation and socioeconomic repercussions of the ozone NAAQS. Dr. Sabine Lange of TCEQ also outlined the TCEQ's analysis on vulnerable populations, showing that asthmatics and children were no more vulnerable to lung function changes caused by ozone than healthy adults⁴. This is supported by the scientific, peer-reviewed literature⁵. The dialogue that was generated by the discussions of the expert panelists, the presenters and the audience further validated the uncertainties and lingering questions in the ozone field, and clarified the many facets that should be considered in a difficult policy decision such as this one.

The press has on more than one occasion questioned the TCEQ for disagreeing with some of the EPA's conclusions based on our review of what the science demonstrates. They often quote scientists (usually in the field of air pollution, although not always) who have points of view that differ from ours. We have often stated that we are very interested in having an open dialogue with other scientists about the ozone science, and therefore we have reached out to the scientists quoted in articles. Some have spoken to us and we have had amiable scholarly conversations with them (e.g. Dr. Jennifer Vanos, Texas Tech University; Dr. Daniel Cohen, Rice University) where it became clear that we often share concerns about the ozone standard. Sadly, some of the researchers did not return our requests to discuss the science (e.g. Dr. Arch Carson, University of

⁴ <http://www.tera.org/Peer/ozone/index.html>

⁵ Balmes, J. R., R. M. Aris, L. L. Chen, C. Scannell, I. B. Tager, W. Finkbeiner, D. Christian, T. Kelly, P. Q. Hearne, R. Ferrando, and B. Welch. 1997. "Effects of ozone on normal and potentially sensitive human subjects. Part I: Airway inflammation and responsiveness to ozone in normal and asthmatic subjects." *Res Rep Health Eff Inst* (78):1-37; discussion 81-99.

Basha, M. A., K. B. Gross, C. J. Gwizdala, A. H. Haidar, and J. Popovich, Jr. 1994. "Bronchoalveolar lavage neutrophilia in asthmatic and healthy volunteers after controlled exposure to ozone and filtered purified air." *Chest* no. 106 (6):1757-65.

Holz, O., R. A. Jorres, P. Timm, M. Mucke, K. Richter, S. Koschyk, and H. Magnussen. 1999. "Ozone-induced airway inflammatory changes differ between individuals and are reproducible." *Am J Respir Crit Care Med* no. 159 (3):776-84. doi: 10.1164/ajrccm.159.3.9806098.

Horstman, D. H., B. A. Ball, J. Brown, T. Gerrity, and L. J. Folinsbee. 1995. "Comparison of pulmonary responses of asthmatic and nonasthmatic subjects performing light exercise while exposed to a low level of ozone." *Toxicol Ind Health* no. 11 (4):369-85.

Koenig, J. Q., D. S. Covert, S. G. Marshall, G. Van Belle, and W. E. Pierson. 1987. "The effects of ozone and nitrogen dioxide on pulmonary function in healthy and in asthmatic adolescents." *Am Rev Respir Dis* no. 136 (5):1152-7. doi: 10.1164/ajrccm.136.5.1152.

Koenig, J. Q., D. S. Covert, M. S. Morgan, M. Horike, N. Horike, S. G. Marshall, and W. E. Pierson. 1985. "Acute effects of 0.12 ppm ozone or 0.12 ppm nitrogen dioxide on pulmonary function in healthy and asthmatic adolescents." *Am Rev Respir Dis* no. 132 (3):648-51.

Linn, W. S., D. A. Shamoo, K. R. Anderson, R. C. Peng, E. L. Avol, and J. D. Hackney. 1994. "Effects of prolonged, repeated exposure to ozone, sulfuric acid, and their combination in healthy and asthmatic volunteers." *Am J Respir Crit Care Med* no. 150 (2):431-40. doi: 10.1164/ajrccm.150.2.8049826.

Nightingale, J. A., D. F. Rogers, and P. J. Barnes. 1999. "Effect of inhaled ozone on exhaled nitric oxide, pulmonary function, and induced sputum in normal and asthmatic subjects." *Thorax* no. 54 (12):1061-9.

Stenfors, N., J. Pourazar, A. Blomberg, M. T. Krishna, I. Mudway, R. Helleday, F. J. Kelly, A. J. Frew, and T. Sandstrom. 2002. "Effect of ozone on bronchial mucosal inflammation in asthmatic and healthy subjects." *Respir Med* no. 96 (5):352-8.

Texas School of Public Health; Dr. Robert Haley, University of Texas Southwestern and the Dallas County Medical Association; Ms. Janice Nolen, American Lung Association).

Contract Expenditures:

The TCEQ has contracts with several organizations to enhance the agency's expertise on important toxicological issues. All of the contracts the TCEQ has entered into were competitively bid using the state statutory procurement requirements, which ensure that the bidding process is fair, transparent, and open to all qualified applicants. All records of the contract bidding and award are available for public inspection through Public Information Requests. The TCEQ's ozone research-related contracts have been funded with state-appropriated revenue from the Texas Clean Air Act and Texas Emissions Reduction Program accounts. No federal funding has been used for these projects.

The more detailed expenditure information you requested is respectfully provided in the attached documents. To give you some context, the TCEQ alone has already spent almost **\$1.4 billion** in state funds since 2001 for grant projects to reduce NO_x emissions in an effort to reduce ozone levels in Texas. This money has been used largely for replacing or upgrading heavy-duty vehicles, equipment, and locomotives, which states are preempted from regulating. Coincidentally, the EPA projects that meeting the 2015 70 ppb ozone standard will cost the entire country (excluding California) \$1.4 billion⁶, but this estimate does not include costs typically borne by state and local governments. Over \$118 million per year for fiscal years 2016 and 2017 (\$236 million total, again, in state funds) has been appropriated to TCEQ for additional NO_x reduction projects to continue our goal of achieving the 2008 75 ppb standard.

TERA:

A contract with Toxicology Excellence for Risk Assessment (TERA), now a part of the University of Cincinnati, helps us conduct toxicity factor peer reviews. TERA's knowledge in risk assessment and organizing and conducting workshops on specific toxicological constituents led us to seek their expertise with the Ozone Workshop. According to their website, TERA has received exactly \$635 for work done directly for tobacco companies over a period of more than 20 years as a non-profit organization. They have indirectly received approximately \$6,000 for work done as a subcontractor to a consulting firm whose client was funded by tobacco companies. TERA conducts training courses in risk assessment, particularly dose-response assessment, for many government agencies and companies, as well as in public workshops open to all. TERA was paid less than \$6,000 plus travel expenses for one training course for a tobacco company. TERA has trained hundreds of scientists in the public training courses and some of these people (less than a dozen) worked for tobacco companies and their fees were likely paid for by their companies. TERA has also worked with many governmental entities including Health Canada, the Consumer Product Safety Commission, the Food and Drug Administration, the National Institute of Occupational Safety and Health, the National Library of Medicine, the EPA, the United States Air Force, and the Ontario Ministry of Environment⁷.

⁶ USEPA. 2015. Regulatory Impact Analysis of the Final Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone. Vol. EPA-452/R-15-007, September. 480 p.

⁷ <http://www.tera.org/about/FundingSources.html>

Gradient:

The TCEQ has paid Gradient a total of \$1.65 million for ten major projects, many of which have culminated in articles published in the peer-reviewed literature⁸. Not all of these projects have addressed ozone, as detailed in the attached document. Some of the money (approximately 15%) on a new \$1.5 million contract with Gradient is ear-marked for a toxicity factor study of arsenic.

Gradient has had a wide variety of clients, including local, State and Federal Agencies. A partial list of their governmental and other clients include: the City of New York, the City of Los Angeles, the City of Northampton, the City of Pittsfield, the United States Department of Justice, the EPA, the Agency for Toxic Substances and Disease Registry, the State of California, the State of Minnesota, the Environmental Health Research Foundation, Harvard University, and more. Dr. Julie Goodman, Gradient Principal, has also done *pro bono* work for the Massachusetts Environmental Justice Assistance Network. Further, Dr. Lorenz Rhomberg, the Gradient scientist heading the TCEQ's arsenic study, is an expert held in the highest regard. For example, he currently serves on two separate EPA Science Advisory Boards, he is or has been a member of seven committees of the National Academy of Sciences, and was awarded the Outstanding Practitioner of the Year award by the Society for Risk Analysis in 2009.

In reference to the inference that because Gradient takes industry money they must be biased towards the answer that industry wants, we point out that every scientist who does work on ozone (or anything else) receives funding from someone, which could create a potential conflict of interest. For example, members of CASAC receive millions of dollars in funding from the EPA⁹, which could be interpreted as preventing these people from carrying out a truly independent review of the EPA's science. In addition, CASAC members are often reviewing their own work in the EPA documents, which creates a potential conflict in their interpretation of the importance and quality of their own work. Although referenced by another witness in oral testimony as evidence that EPA is independent, the EPA's Office of the Attorney General's

⁸ Prueitt, R.L., H.N. Lynch, K. Zu, S.N. Sax, F.J. Venditti, and J.E. Goodman. 2014. "Weight-of-Evidence Evaluation of Long-Term Ozone Exposure and Cardiovascular Effects." *Crit. Rev. in Tox.* 44(9):791-822. Goodman, J.E., R.L. Prueitt, S.N. Sax, D.M. Pizzurro, H.N. Lynch, K. Zu, and F.J. Venditti. 2015. "Ozone Exposure and Systemic Biomarkers: Evaluation of Evidence for Adverse Cardiovascular Health Impacts." *Crit. Rev. in Tox.* 45(5):412-452.

Goodman, J.E., C. Petito Boyce, S.N. Sax, L.A. Beyer, and R.L. Prueitt. 2015. "Rethinking Meta-Analysis: Applications for Air Pollution Data and Beyond." *Risk Anal.* 35(6):1017-1039.

Long-Range Fine Particulate Matter from the 2002 Quebec Forest Fires and Daily Mortality in Greater Boston and New York City." *Air Qual. Atmos. Health* DOI 10.1007/s11869-015-0332-9.

Goodman, J.E., S.N. Sax, S. Lange, and L. Rhomberg. 2015. "Are the Elements of the Proposed Ozone National Ambient Air Quality Standards Informed by the Best Available Science?" *Reg. Tox. Pharmacol.* 72:134-140.

Goodman, J.E., C. Petito Boyce, D.M. Pizzurro, and L.R. Rhomberg. 2014. "Strengthening the Foundation of the Next Generation Risk Assessment." *Reg. Tox. Pharmacol.* 68:160-170.

⁹ [http://science.house.gov/sites/republicans.science.house.gov/files/documents/03-19-](http://science.house.gov/sites/republicans.science.house.gov/files/documents/03-19-2014%20Smith%20to%20Administrator%20McCarthy.pdf)

[2014%20Smith%20to%20Administrator%20McCarthy.pdf](http://www.epw.senate.gov/public/_cache/files/d55fa42f-7c41-456e-893f-2963eb26e07e/lettertoelkins080411.pdf)

http://www.epw.senate.gov/public/_cache/files/d55fa42f-7c41-456e-893f-2963eb26e07e/lettertoelkins080411.pdf

report “EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees,”¹⁰ states:

“We found that the EPA has adequate procedures for identifying potential ethical concerns, including financial conflicts of interest, independence issues and appearances of a lack of impartiality. However, the EPA can better document its decisions on selecting members with independence and partiality concerns.”

Further, some of the work that the EPA heavily relied on for this ozone NAAQS review (the McDonnell 2012¹¹ study that generated the MSS model; the Schelegle 2009¹² study that showed adverse effects in heavily exercising adults at 72 ppb) was partially or fully funded by the American Petroleum Institute. These types of conflicts are not new concerns in science, but are balanced by disclosure of all conflicts of interest and funding sources, as well as by an objective assessment of the science behind the methods, analysis and conclusions of the work. A central principle of science is judging the scientific work by its own merits, because everyone has potential conflicts, and everyone is susceptible to over-conflating their own work.

Finally, I want to reiterate the goal of the work conducted by the TCEQ and my staff. The TCEQ continuously works toward a better understanding of health and environmental data in order to make the most efficient use of taxpayer funds in keeping the air and water clean and safely disposing of waste. The work we have done with ozone and the comments we have made regarding the science behind the standard are just two examples of how we meet this goal. The TCEQ has notably reduced ambient levels of all criteria pollutants as well as numerous other air toxics. According to the Centers for Disease Control and Prevention¹³, Texas has one of the lowest incidence rates of asthma and cancer in the country (see the figures below). These figures demonstrate the state’s continued commitment to protection of human health and the environment, as well as the TCEQ’s great working relationship with the EPA’s Region 6 office in developing, implementing, and evaluating pollutant reduction strategies. We would welcome the opportunity to sit down with you and discuss the ozone health effects data, our analyses, and EPA’s analyses in more detail as we have with many other people and organizations.

¹⁰ USEPA, 2013. “EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees.” Office of Inspector General. 13-P-0387 September. <http://www2.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf>

¹¹ McDonnell, W.F., P.W. Stewart, M.V. Smith, C.S. Kim, and E.S. Schelegle 2012. “Prediction of Lung Function Response for Populations Exposed to a Wide Range of Ozone Conditions.” *Inhal. Tox.* 24(10):619-633.

¹² Schelegle, E.S., C.A. Morales, W.F. Walby, S. Marion, and R.P. Allen 2009. “6.6-Hour Inhalation of Ozone Concentrations from 60 to 87 Parts Per Billion in Healthy Humans.” *Am. J. Respir. Crit. Care Med.* 180:265-272.

¹³ Centers for Disease Control and Prevention, U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 1999–2012 Incidence and Mortality Web-based Report*. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2015. Available at: www.cdc.gov/uscs. Centers for Disease Control and Prevention, National Center for Environmental Health. 2015. *Adult Self-Reported Lifetime Asthma Prevalence Rate (Percent) by State or Territory: BFRSS 2012*. Behavioral Risk Factor Surveillance System. Available at: <http://www.cdc.gov/asthma/brfss/2012/brfssdata.htm>

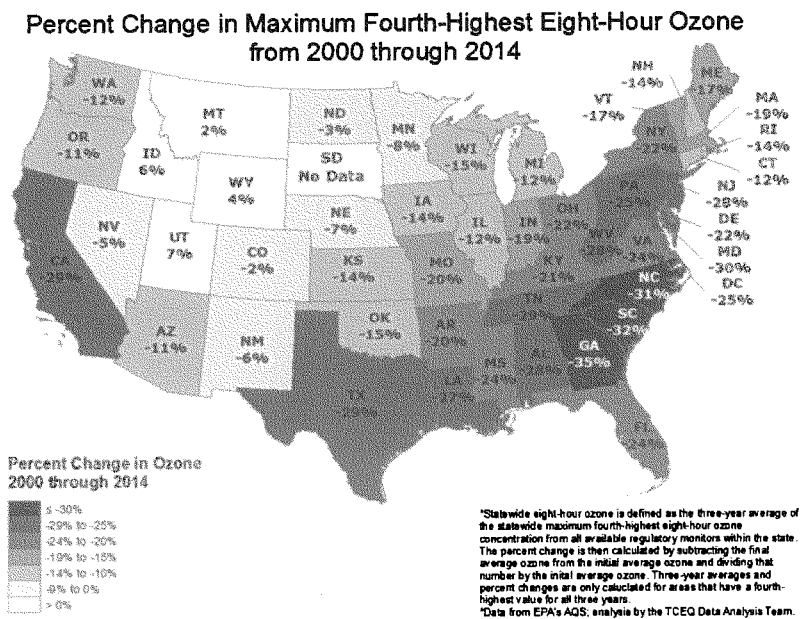


Figure 1. The state of Texas has some of the largest reductions in ambient ozone concentrations in the country.

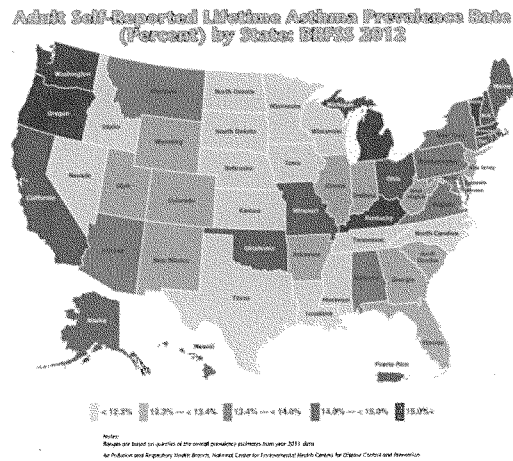


Figure 2. Texas has one of the lowest incidence rates of asthma in the country.

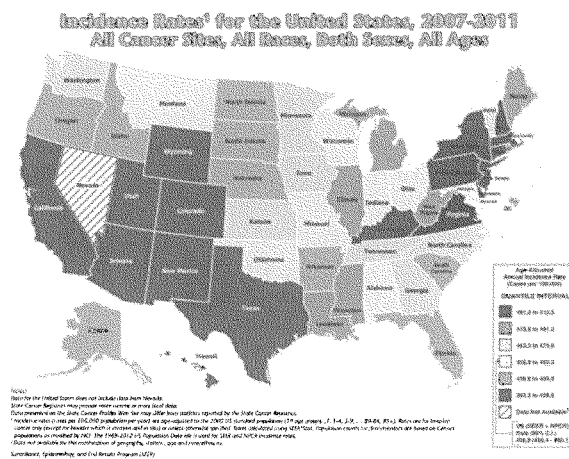


Figure 3. Texas has one of the lowest incidence rates of cancer in the country.

Attachment

Contract Expenditures

Gradient 582-13-32032

	Invoice #	Billing Dates	Invoice Amount	Date Paid
Work Order #1	21306100	6/4/13-6/28/13	\$ 47,556.70	9/5/2013
PCR #33833	21307128	6/29/13-7/26/13	\$ 969.00	8/28/2013
WO Amount	21307022	6/29/13-7/26/13	\$ 35,118.60	9/10/2013
\$300,000.00	21308011	7/27/13-8/31/13	\$ 97,324.70	10/3/2013
	21308012	7/27/13-8/31/13	\$ 119,031.00	10/3/2013
		TOTAL	\$ 300,000.00	
Work Order # 2	21311013	10/28/13-11/22/13	\$ 7,381.00	2/6/2014
PCR # 41242	21312041	11/23/13-12/27/13	\$ 14,551.80	3/13/2014
WO Amount	2140038	12/28/13-1/24/14	\$ 16,681.50	3/13/2014
\$200,000.00	2140156	2/12/14-2/21/14	\$ 16,359.60	4/10/2014
	2140287	2/22/14-3/28/14	\$ 8,396.90	7/2/2014
	2140429	3/29/14-4/25/14	\$ 4,072.20	6/13/2014
	2140542	4/26/14-5/23/14	\$ 3,732.50	7/10/2014
	2140683	5/24/14-6/27/14	\$ 9,587.00	8/14/2014
	2140931	8/28/14-8/31/14	\$ 119,237.30	9/29/2014
		TOTAL	\$ 199,999.80	
Work Order # 3	21311014	9/28/13-11/22/13	\$ 30,000.00	2/6/2014
PCR # 41243				
WO Amount		TOTAL	\$ 30,000.00	
\$30,000.00				
Work Order # 4	21311015	11/5/2013-11/22/13	\$ 2,299.30	2/3/2014
PCR # 41445	21312043	11/23/13-12/27/13	\$ 1,755.00	3/11/2014
WO Amount	2140039	12/28/13-1/24/14	\$ 13,306.00	3/13/2014
\$54,000.00	2140158	2/1/14-2/21/14	\$ 14,383.00	4/10/2014
	2140684	5/24/14-6/27/14	\$ 8,853.00	8/14/2014
	2140932	6/28/14-8/15/14	\$ 13,403.00	9/25/2014
		TOTAL	\$ 53,999.30	
Work Order # 5	21311014	12/5/13-12/13/13	\$ 5,500.00	2/6/2014
PCR # 41894	2140227	2/15/14-2/21/14	\$ 780.40	3/25/2014
WO Amount	2140543	4/26/14-5/23/14	\$ 4,474.00	7/9/2014
\$20,500.00	213134	5/24/14-8/31/14	\$ 9,745.50	9/29/2014
		TOTAL	\$ 20,499.90	
Work Order # 6	2140432	4/6/14-4/25/14	\$ 11,228.60	7/2/2014
PCR # 42658	2140545	4/25/14-5/23/14	\$ 495.00	7/10/2014
WO Amount	2140546	4/26/14-5/23/14	\$ 3,440.00	7/10/2014

\$722,000.00	2140685	5/24/14-6/27/14	\$ 9,991.50	8/14/2014
	2140686	5/24/14-6/27/14	\$ 17,903.00	8/14/2014
	2140933	6/28/14-8/31/14	\$ 115,720.95	9/29/2014
	2140934	6/28/14-8/31/14	\$ 115,719.80	9/29/2014
	2141362	10/27/14-11/28/14	\$ 8,405.40	1/14/2015
	2141505	11/29/14-1/2/15	\$ 16,396.80	2/5/2015
	2141659	1/3/15-1/30/15	\$ 65,776.40	3/5/2015
	2141799	1/31/15-2/27/15	\$ 39,879.00	4/2/2015
	2141927	2/28/15-4/3/15	\$ 23,548.90	5/7/2015
	2142082	4/4/15-5/1/15	\$ 34,016.60	6/4/2015
	2150028	5/2/15-5/29/15	\$ 16,300.90	7/13/2015
			\$ 27,602.30	7/13/2015
	2150163	5/30/15-7/3/15	\$ 31,008.50	8/13/2015
	2150314	7/4/15-7/31/15	\$ 44,842.60	9/3/2015
	2150546	8/1/15-8/31/15	\$ 139,772.60	10/8/2015
	TOTAL		\$721,998.85	

Work Order # 7	2140288	3/5/14-3/28/14	\$ 20,000.00	7/2/2014
PCR # 42875		TOTAL	\$ 20,000.00	
WO Amount				
\$20,000.00				

Work Order # 8	2140936	7/9/14-8/31/14	\$ 13,878.00	10/2/2014
PCR # 44770			\$ 16,129.50	10/2/2014
WO Amount		TOTAL	\$ 30,007.50	
\$30,010.00				

Work Order # 9	2140935	7/16/14-8/31/14	\$ 19,999.00	10/2/2014
PCR # 44826		TOTAL	\$ 19,999.00	
WO Amount				
\$20,000.00				

Work Order # 10	2141224	9/10/14-9/26/14	\$ 34,014.50	11/25/2014
PCR # 50893	2141363	10/27/14-11/28/14	\$ 38,222.00	1/14/2015
WO Amount	2141660	1/3/15-2/27/15	\$ 41,350.00	3/5/2015
\$250,000.00	2141800	1/31/15-2/27/15	\$ 16,914.60	4/2/2015
	2141507	11/29/14-1/2/15	\$ 22,638.90	4/9/2015
	2141930	2/28/15-4/3/15	\$ 55,139.80	5/7/2015
	2142084	4/4/15-5/1/15	\$ 41,720.00	6/4/2015
	TOTAL		\$ 249,999.80	

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Ozone Weight-of-Evidence and Meta-Analyses

Work Order No. 582-13-32032-01

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Work Order Amount (Maximum Not-to-Exceed): \$300,000

Amount in Contract After this Work Order: \$ 250,000

Effective Date of the Work Order: Date of the Notice to Proceed

End Date of Work Order: August 31, 2013

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice to Proceed and must be completed no later than August 31, 2013. Gradient Corporation (contractor) must submit a final payment invoice/request as well as a release of claims within 60 days of TCEQ's approval of the final technical deliverable for this Work Order. The Contractor must submit a budget for work that can be completed by August 31, 2013 (Tasks 1 and 2). The Contractor must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to evaluate certain aspects of the science behind the NAAQS.

Background

The EPA is on a five year review cycle for the review and promulgation of each NAAQS. For example, EPA is currently undergoing review of the ozone National Ambient Air Quality Standards (NAAQS) and has recently released the third draft *Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants* (US EPA, 2012a), as well as first drafts of the *Health Risk and Exposure Assessment (REA) for Ozone First External Review Draft* (US EPA, 2012b) and the *Policy Assessment [PA] for the Review of the Ozone National Ambient Air Quality Standards* (US EPA, 2012c). In the ISA, EPA reviewed new studies published since the last NAAQS review and, based on its review, conducted a risk assessment of selected health outcomes. In the draft PA, EPA integrated the finding from the ISA and REA and made recommendations on changes to

the NAAQS. Although both the REA and PA are preliminary drafts, the initial drafts suggest that EPA is likely to recommend a lower ozone NAAQS. A lower ozone NAAQS will lead to a significant expenditure of state and local resources, therefore it is imperative that the ozone NAAQS be supported by scientific studies used in and published since the last scientific review.

TASKS AND DELIVERABLES

1. Weight-of-Evidence (WoE) Evaluation of Ozone and Cardiovascular Effects

Background

The National Research Council Formaldehyde Review Panel called on the Environmental Protection Agency (EPA) to undertake a program to develop a transparent and defensible methodology for weight-of-evidence (WoE) assessments (NRC, 2011). The Panel's report contains a "roadmap" for reform and improvement of the risk assessment process. While the Panel did not specify methods to be adopted, it used the approach that was described in the Particulate Matter Integrated Science Assessment (ISA), which is the same as the ozone approach, as an example of a useful framework for providing insights from which EPA could formulate a more rigorous approach. There are some factors specified in this framework, such as the consideration of Bradford Hill's causality "aspects" and weighing of alternative views on controversial issues, which are crucial for any WoE analysis. As discussed below, there are other features, however, that are lacking. In addition, although EPA claims to use a WoE framework in the ozone ISA, the framework is not applied consistently.

Regarding the issues with the framework itself, there are no clear statements in the ISA indicating how EPA applies the Bradford Hill aspects or how its causality judgments consider all aspects jointly. For example, the ISA says the strength of an association should be considered, but it provides no indication of what constitutes a strong association. Most associations in epidemiology studies are weak, and because of the methodological limitations inherent in such studies, findings could be due to chance. EPA also does not explicitly describe how it evaluates alternative hypotheses or what criteria it uses to determine which hypothesis is most supported by the data. It is not evident that EPA considers any hypothesis beyond ozone as a causal factor for specific health effects.

Regarding the application of the framework, perhaps the most serious issue is that studies are not always evaluated in a consistent manner; this is particularly the case for epidemiology studies. Sometimes, a particular feature that is considered a limitation in one study is not mentioned in the discussion of another. For example, EPA states that one limitation of the Girardot et al. (2006) study is the outcome measurement, in that lung function measurements were taken by "less well-trained technicians," but EPA does not have a qualification for studies that rely on self-administered peak expiratory flow, which has been demonstrated to be a highly unreliable outcome measurement. Studies with the most rigorous methods should be given the greatest weight in an analysis, but, based on these criteria, it is not clear whether or how individual studies

are weighted in the ISA. In general, rather than explicitly stating all results, the ISA highlights positive associations and often omits discussions of negative associations, making results seem more consistent than they actually are.

Scope

The Contractor will evaluate the EPA framework, focusing on areas where more guidance is needed to ensure a transparent, balanced evaluation and proposing improvements to the framework based on other available WoE frameworks [e.g., the Adami et al. (2011) or Hypothesis-Based Weight-of-Evidence (Rhombert et al., 2010) Frameworks]. Specifically, the Contractor will critically review the ozone WoE framework, discussing aspects that are critical, as well as those that are missing or that need to be expanded to be useful. Based on the Contractor's extensive review of other available frameworks, the Contractor will make recommendations for improvements to the EPA framework that best fit the purpose of a NAAQS evaluation. The evaluation will be summarized in a manuscript to be submitted for publication in a suitable peer-reviewed journal indexed on PubMed in 2014.

Deliverable

The Contractor will apply this modified WoE framework to address the association between ozone cardiovascular effects. The Contractor will contrast their analysis to that conducted by EPA and determine whether and how differences between EPA's framework and the modified framework lead to different conclusions. The Contractor will summarize the results of the analysis in a manuscript to be submitted for publication in a suitable peer-reviewed journal indexed on PubMed. The Contractor will discuss the appropriate journal with TCEQ. The Contractor will address one set of comments from TCEQ and one set from peer reviewers.

2. Evaluation of the Utility of Meta-analyses of Epidemiology, Controlled Human Exposure, and Toxicology Studies of Ozone Health Effects

Background

There are several instances in EPA's evaluation of the scientific data in which positive data are given more weight than null or negative data. A meta-analysis is a statistical analysis of the results of all applicable independent studies with the aim of producing a single effect estimate. If conducted correctly, a meta-analysis can help ensure an analysis is objective and considers all relevant data, and has more statistical power to assess associations than individual studies. Meta-analyses can be challenging, however, when data across studies are heterogeneous.

Scope

EPA has conducted or relied on meta-analyses of epidemiology and controlled human exposure studies in its evaluations of ozone and other criteria pollutants. The Contractor

will evaluate the utility of meta-analyses of these data in assessing causal associations and exposure-response relationships. The Contractor will focus on ozone, although the task may be expanded to include the evaluations of meta-analyses conducted for other criteria pollutants (for example, EPA relied heavily on a meta-analysis to evaluate nitrogen dioxide controlled human exposure data). The Contractor will assess the strengths and limitations of conducting meta-analyses, determine whether EPA has used and interpreted this methodology in an appropriate manner, and consider whether there may be other opportunities, such as for toxicology data, to use meta-analyses to determine causal associations. This will contribute to an understanding of whether EPA's conclusions are supported by the scientific evidence – that is, whether EPA is using the methodology correctly, and, if it is not, whether the correct approach would result in a different conclusion).

Deliverable

The Contractor's evaluation will first be summarized in a white paper and discussed at an expert workshop that is being organized by the Harvard Center for Risk Analysis and supported by the National Science Foundation. The workshop paper will then be modified and submitted for publication to an appropriate peer-reviewed journal indexed on PubMed. The Contractor will address one set of comments from TCEQ and one set of comments from peer reviewers.

References

- Adami, HO; Berry, SC; Breckenridge, C; Smith, L; Swenberg, J; Trichopoulos, D; Weiss, NS; Pastoor, T. 2011. "Toxicology and epidemiology: Improving the science with a framework for combining toxicological and epidemiological evidence to establish causal inference." *Toxicol. Sci.* 122(2):223-234.
- Girardot, SP; Ryan, PB; Smith, SM; David, WT; Hamilton, CB; Obenour, RA; Renfro, JR; Tromatore, KA; Reed, GD. 2006. "Ozone and PM_{2.5} exposure and acute pulmonary health effects: A study of hikers in the Great Smoky Mountains National Park." *Environ. Health Perspect.* 114(7):1044-1052.
- Hill, AB. 1965. "The environment and disease: Association or causation?" *Proc. R. Soc. Med.* 58:295-300.
- National Research Council (NRC). 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde." National Academies Press. Accessed on April 8, 2011 at <http://www.nap.edu/catalog/13142.html>, 194p., April.
- Rhomberg, LR; Bailey, LA; Goodman, JE. 2010. "Hypothesis-based weight of evidence: A tool for evaluating and communicating uncertainties and inconsistencies in the large body of evidence in proposing a carcinogenic mode of action - Naphthalene as an example." *Crit. Rev. Toxicol.* 40:671-696.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

INSTRUCTIONS TO CONTRACTOR

The Contractor's principal investigator shall provide TCEQ with a Work Plan document within 14 days of the date of this Work order. The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES:** A discussion of the quality assurance/quality control procedures to be followed by the Contractor shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work Order and Contract.
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the completion of the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;

9. MISCELLANEOUS INFORMATION OR ELEMENTS; and

10. SIGNATURE BY CONTRACTOR: The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff shall review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor shall be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit, of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. **582-13-32032-01** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

TCEQ:

Texas Commission on Environmental Quality

By: Richard A. Hyde
(Authorized Signature)

Richard A. Hyde, P.E.
(Printed Name)

Deputy Executive Director
(Title)

Date: 6/12/13

Texas Commission on Environmental Quality (TCEQ)

**WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT**

Review of Ozone Exposure and Inflammatory Biomarkers

Work Order No. 582-13-32032-02 (PCR No. 41242)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Work Order Amount (Maximum Not-to-Exceed): \$120,000

Amount in Contract After this Work Order: \$ 130,000

Effective Date of the Work Order: Date of the Notice to Proceed

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice to Proceed and must be completed no later than April 15, 2014. Gradient Corporation (contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order. The Contractor must submit a budget for work that can be completed by April 15, 2014.

Purpose

The purpose of the Contract is to assess whether there is sufficient evidence of a mode of action by which ozone exposure could cause extrapulmonary effects.

TASKS AND DELIVERABLES

Ozone Exposure and Inflammatory Biomarkers: Evidence of Adverse Systemic Health Impacts?

Background

US EPA recently evaluated studies of biomarkers of systemic inflammation and oxidative stress and concluded that they provide evidence of a potential mode of action for extrapulmonary effects (*e.g.*, cardiovascular, neurological, and reproductive) of ozone exposure (US EPA, 2013). For example, US EPA indicated changes in lipid ozonides, chemokines, and cytokines after ozone exposure provide mechanistic support for associations observed in epidemiology studies (*e.g.*, cardiovascular mortality) (US EPA, 2013).

Scope

The Contractor will review controlled human exposure, epidemiology, animal, and mechanistic studies related to ozone and biomarkers of inflammation and oxidative stress. The Contractor will discuss the strengths and limitations associated with these studies, and determine if results are consistent and coherent within and across studies and across different lines of evidence. Overall, the Contractor will conduct an assessment of whether there is sufficient evidence of a mode of action by which ozone exposure could cause extrapulmonary effects.

Deliverable

The Contractor will provide a detailed outline of the biomarkers manuscript by November 30, 2013 and a complete draft of the manuscript by April 15, 2014.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

INSTRUCTIONS TO CONTRACTOR

The Contractor's principal investigator shall provide TCEQ with a Work Plan document within 14 days of the date of this Work order. The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES:** A discussion of the quality assurance/quality control procedures to be followed by the Contractor shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work Order and Contract.
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be

sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the completion of the Work Order.

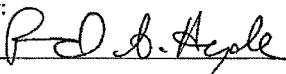
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff shall review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor shall be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit, of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. **582-13-32032-02** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

TCEQ:

Texas Commission on Environmental Quality

By: 

Richard A. Hyde, P.E.

Deputy Executive Director

Date: 10/21/13

Texas Commission on Environmental Quality
UMBRELLA CONTRACT
BETWEEN TCEQ and GRADCO, LLC dba GRADIENT

Contract No. 582-13-32032
Work Order No. 582-13-32032- 2 (PCR 41242) - Amendment 1

Original Amount of Umbrella Contract: \$550,000
Amendment 1 Amount: \$550,000
Amendment 2 Amount: \$550,000
Current Amount of Umbrella Contract: \$1,650,000

Work Order

Original Total WO Amount: (Maximum Not-to-Exceed): \$120,000

Total Work Order Amount with this amended increase: \$200,000

Effective Date of the Amended Work Order: Date Signed by TCEQ

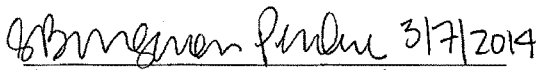
As authorized in Contract No. 582-13-32032, (Contract) the Parties agree as follows:

The Work Order Number 582-13-32032-2 Maximum Not-to-Exceed amount is increased from \$120,000 to \$200,000 due to an increase over what was originally expected in the number of studies related to ozone and biomarkers of inflammation and oxidative stress. The contractor will use these studies to conduct an assessment of whether there is sufficient evidence of a mode of action by which ozone exposure could cause extrapulmonary effects.

All other conditions and requirements, including the Scope of Work Order 582-13-32032-2 remain unchanged.

Texas Commission on
Environmental Quality (TCEQ)

Stephanie Bergeron Perdue
Printed Name
Title: Deputy Executive Director


Signature Date of Signature 3/7/2014

Texas Commission on Environmental Quality

**UMBRELLA CONTRACT
BETWEEN TCEQ and GRADCO, LLC dba GRADIENT**

Contract No. 582-13-32032

Work Order No. 582-13-32032- 2 (PCR 41242) - Amendment 2

Original Amount of Umbrella Contract: \$550,000

Contract Amendment 1 Amount: \$550,000

Contract Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order

Original Total WO Amount: (Maximum Not-to-Exceed): \$120,000

Total Work Order Amount with Amendment 1: \$200,000

Total Work Order Amount with this Amendment 2: No change

Effective Date of the Amended Work Order: Date Signed by TCEQ

As authorized in Contract No. 582-13-32032, (Contract) the Parties agree as follows:

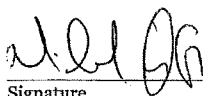
The Work Order Number 582-13-32032-2 end date of April 15, 2014 is extended to August 31, 2014.
All other conditions and requirements, including the Scope of Work Order 582-13-32032-2 remain unchanged.

Texas Commission on
Environmental Quality (TCEQ)

Michael Honeycutt, Ph.D.

Printed Name

Title: Toxicology Division Director



Signature

7-3-14

Date of Signature

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

*Review of Next Generation Risk Assessment: Incorporation of Recent Advances in
Molecular, Computational, and Systems Biology*

Work Order No. 582-13-32032-03 (PCR No. 41243)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Work Order Amount (Maximum Not-to-Exceed): \$30,000

Amount in Contract After this Work Order: \$ 100,000

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon this issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Work Order and must be completed no later than November 13, 2013. Gradient Corporation (contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to prepare comments on the EPA document titled "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology", which is out for a 45 day public comment period.

TASKS AND DELIVERABLES

Background

US EPA recently released a report, "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology," which describes the Next Generation Risk Assessment (NexGen) program (US EPA, 2013). This program is a multi-organization effort to develop new risk assessment approaches that incorporate molecular, computational, and systems biology methodology. The ultimate goal of the program is to advance risk assessment science using tools that will enable assessments that are more efficient, less expensive, and more robust.

Scope

The Contractor will evaluate the overall NexGen risk assessment methodology and framework and provide general comments on the approach, identifying strengths and limitations. In addition, we will comment on the approach as it is applied in the example of ozone and inflammation and lung injury.

Deliverable

The Contractor will provide a draft of written comments on the draft US EPA document by November 7, 2013. The Contractor will provide the approvable Final Written Comments by November 13, 2013. Timely delivery of the Comments is essential and material to the Contract.

TCEQ - Project Representative
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 E-mail: michael.honeycutt@tceq.texas.gov

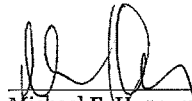
No Work Plan is required.

Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order.

Work Order No. **582-13-32032-03** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

TCEQ:

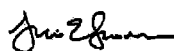
Texas Commission on Environmental Quality



Michael E. Honeycutt, Ph.D.
 Toxicology Division Director

Date: 10-11-13

GRADCO, LLC dba GRADIENT



Julie E. Goodman, Ph.D., DABT
 Principal

Date: 10/10/13

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Association Between PM_{2.5} from Forest Fires and Daily Mortality

Work Order No. 582-13-32032-04 (PCR No. 41445)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Work Order Amount (Maximum Not-to-Exceed): \$54,000

Amount in Contract After this Work Order: \$ 46,000

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon this issuance of a Texas Commission on Environmental Quality (TCEQ) Notice to Proceed and must be completed no later than August 15, 2014. Gradient Corporation (contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order. The contractor must submit a budget for work that can be completed by August 15, 2014.

Purpose

The purpose of the Contract is to examine associations between PM_{2.5} from forest fires and daily mortality.

TASKS AND DELIVERABLES

Background

Many scientists studying the impact of ambient PM_{2.5} levels stress the importance of capitalizing on "natural experiments" that can provide key evidence when evaluating the case for causality in epidemiologic associations. For example, in the mid-1980's, the closure of a Utah Valley steel mill, and the reunification of East and West Germany are widely cited as "natural experiments" providing evidence that helps interpret the linkage between ambient PM air quality and health outcomes. Forest fires occur frequently in Texas and the rest of the United States, providing another "natural experiment" opportunity that can help TCEQ provide information to the public to address their concerns over PM_{2.5} from forest fires.

Scope

The Contractor will collect the necessary air-quality and daily-mortality data, design/conduct appropriate epidemiological analyses, evaluate quantitatively the degree to which daily mortality may be impacted by PM_{2.5} during forest fires, and prepare a manuscript for publication in a peer-reviewed journal.

Deliverable

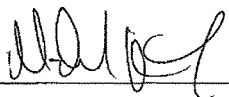
The Contractor will provide a draft journal article by August 15, 2014.

TCEQ - Project Representative
Name: Michael Honeycutt, Ph.D.
Phone: 512.239.1793
Fax: 512.239.1794
E-mail: michael.honeycutt@tceq.texas.gov

Work Order No. **582-13-32032-04** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

TCEQ:

Texas Commission on Environmental Quality



Michael E. Honeycutt, Ph.D.
Toxicology Division Director

Date: 10-28-13

Texas Commission on Environmental Quality (TCEQ)

**WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT**

*Preparation of Journal Article on Next Generation Risk Assessment: Incorporation of
Recent Advances in Molecular, Computational, and Systems Biology*

Work Order No. 582-13-32032-05 (PCR No. 41894)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Work Order Amount (Maximum Not-to-Exceed): \$5,500

Amount in Contract After this Work Order: \$40,500

Effective Date of the Work Order: Date Signed by TCEQ

Time Line

The work shall begin on the date signed by the Texas Commission on Environmental Quality (TCEQ)-executed Work Order and must be completed no later than August 31, 2014. Gradient Corporation (contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to publish a journal article based on previously-prepared comments on the EPA document titled "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology."

TASKS AND DELIVERABLES

Background

US EPA recently released a report, "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology," which describes the Next Generation Risk Assessment (NexGen) program (US EPA, 2013). This program is a multi-organization effort to develop new risk assessment approaches that incorporate molecular, computational, and systems biology methodology. The ultimate goal of the program is to advance risk assessment science using tools that will enable assessments that are more efficient, less expensive, and more robust. Gradient prepared comments on the report on behalf of TCEQ for submittal to EPA.

Scope

The Contractor will edit the previously-prepared report into the appropriate format for a peer-reviewed journal, submit the article, and respond to any peer-reviewer comments.

Deliverable

The Contractor will provide an approvable draft of the journal article by August 31, 2014.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

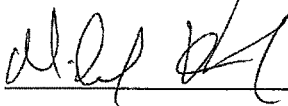
No Work Plan is required.

Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order.

Work Order No. **582-13-32032-05** is issued as of the date signed by TCEQ. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

TCEQ:

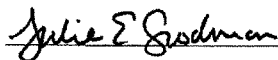
Texas Commission on Environmental Quality



Michael E. Honeycutt, Ph.D.
 Toxicology Division Director

Date: 12-5-13

GRADCO, LLC dba GRADIENT



Julie E. Goodman, Ph.D., DABT
 Principal

Date: 12/5/13

Texas Commission on Environmental Quality

UMBRELLA CONTRACT BETWEEN TCEQ and GRADCO, LLC dba GRADIENT

Contract No. **582-13-32032**

Work Order No. 582-13-32032-5 (PCR 41894) - Amendment 1

Original Amount of Umbrella Contract: \$550,000
Amendment 1 Amount: \$550,000
Current Amount of Umbrella Contract: \$1,100,000

Work Order

Original Total WO Amount: (Maximum Not-to-Exceed): \$ 5,500

Total Work Order Amount with this amended increase: \$20,500

Effective Date of the Amended Work Order: Date Signed by TCEQ

1. Purpose of Work Order Amendment 1

As authorized in Contract No. 582-13-32032, (Contract) Scope of Work Section, Paragraphs titled, Introduction and 2. Background, the Parties agree as follows:

The Work Order Number 582-13-32032-5 is amended to add a Work Order Task and to increase the Maximum Not-to-Exceed Amount of the Work Order as detailed below.

2. Added Work Order Task

Deliverable: Present the published journal article entitled "Regulatory Toxicology and Pharmacology" at the Health Effects Institute 2014 Annual Conference held on May 4-6, 2014 in Alexandria, VA.

3. Increase in Work Order Maximum not-to-exceed Amount

The Maximum not-to-exceed Amount of the Work Order is increased from \$5,500 to \$20,500.

4. Conditions and Requirements of Work Order 582-13-32032-5

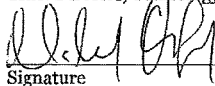
All other conditions and requirements of Work Order 582-13-32032-5 remain unchanged.

Texas Commission on
Environmental Quality (TCEQ)

Michael Honeycutt, Ph.D.

Printed Name

Title: Director, Toxicology Division



Signature

1-31-14

Date of Signature

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Association Between Ozone and Asthma

Work Order No. 582-13-32032-06 (PCR No. 42658)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$722,000

Amount in Contract After this Work Order: \$323,500

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31, 2015 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. Gradient Corporation (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to examine associations between ozone and asthma.

TASKS AND DELIVERABLES

Background

The USEPA established the 8-hour ozone National Ambient Air Quality Standard based on the prevention of premature mortality. The Dallas County Medical Society (DCMS) recently filed a petition for rulemaking to the TCEQ to require more stringent controls for power plants. The DCMS asserted that power plant emissions increase ambient ozone, which in turn exacerbates asthma.

Scope

1. The Contractor will provide a comprehensive review and report of the scientific literature addressing potential impact of ozone on asthma including, but not limited to, the following elements:
 - Epidemiology studies that report correlations between ambient ozone levels and asthma-related endpoints such as: incidence, exacerbation, medication use, hospitalization, ER visits, etc.
 - Strength of effect – often very small relative risks
 - Acute exposure vs chronic exposure scenarios – weight of evidence for each
 - Are asthmatics (children and/or adults) more sensitive or susceptible to asthma-related effects attributable to ozone exposure?
 - What is the evidence that ozone exposure causes or contributes to new cases of asthma versus exacerbation of asthma?
 - Lag times reported should be summarized as well as consistency of observed effects across various lag times
 - Asthma prevalence vs asthma incidence and how asthma data are collected (do you currently have asthma vs ever diagnosed with asthma?)
 - Adequacy of certain measures of asthma such as school absences.
 - We are interested in U.S. studies as well as Texas-specific studies, if available
 - Pediatric asthma rates are increasing, but ozone concentrations generally decreasing – please address hypothesized explanations including, but not limited to:
 - Other asthma triggers (smoking, pollen, etc.)
 - Evidence linking increasing use of acetaminophen and asthma
 - Obesity and asthma
 - Genetics
 - Confounding variables and any evidence of the size of the effect they may have on the ozone-asthma relationship
 - Evidence of publication bias (for instance, differences between single-city studies versus multi-city reports, evidence that negative results are underreported, etc.).

- Differences between meta analysis results and individual reports
- Clinical studies exposing human volunteers to ozone and any reported asthma-related endpoints (wheezing, FEV decrements, etc.)
 - Both of the above should indicate levels of ambient ozone/doses that are associated with health effects and the general severity of effects across the dose-response.
 - Discussion on what level of FEV decrement or combination of effects should be considered (clinically) adverse
 - Limitations of using filtered air in clinical studies instead of some level of background ozone concentrations
 - Evidence that individuals may adapt to ozone exposure (for instance, <http://www.ncbi.nlm.nih.gov/pubmed/7235372> and <http://www.ehjournal.net/content/7/1/22>)
- Animal studies: potential MOAs, consistency with human studies, important differences in doses leading to health effects, and key differences between animal models and humans.
- Background ambient ozone levels
- Evidence for thresholds for key health effects
 - Uncertainty analysis/uncertainty characterization (including, but not limited to known issues regarding model selection and statistical methods (lag structure, degrees of freedom, splines, etc.). Confounding variables may also be summarized here.
- 2. The contractor will perform studies looking at available asthma (or similar) data and available air quality data.

Deliverable

The Contractor will provide a final draft report conforming to the Work Order requirements by August 31, 2015.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

Work Order No. **582-13-32032-06** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

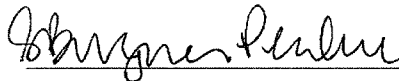
The work shall begin on the signature date below and the deliverable is due by August 31, 2015. The Contractor must clearly state on each invoice that all the work described was performed either or on or before August 31, 2014; or on or after September 1, 2014.

Instructions to Contractor:

The contractor project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work Order. This Work Plan document should include the work that can be finished by August 31, 2014 and the remaining work that will be finished on or before August 31, 2015.

TCEQ:

Texas Commission on Environmental Quality



Stephanie Bergeron Perdue
Deputy Executive Director

Date: 3/7/2014

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Review of Welfare Effects of Ozone

Work Order No. 582-13-32032-07

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$20,000

Amount in Contract After this Work Order: \$ 303,500

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than March 17, 2014 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. Gradient Corporation (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to review and provide comments on the USEPA's draft Welfare Risk and Exposure Assessment for Ozone and the welfare portions of EPA's draft Policy Assessment for Ozone.

TASKS AND DELIVERABLES

Background

In February 2014, the USEPA released two documents for public comment: 1) Welfare Risk and Exposure Assessment for Ozone and 2) Policy Assessment for Ozone. The documents are available for a 60 day public comment period, which are due to EPA on March 28, 2014.

Scope

The contractor will review the two draft documents and provide comments in the form of bullet points on the technical merits of EPA's analysis of ozone welfare effects, specifically agricultural effects.

Deliverable

The Contractor will provide a draft report conforming to the Work Order requirements by March 17, 2014.

TCEQ - Project Representative
Name: Michael Honeycutt, Ph.D.
Phone: 512.239.1793
Fax: 512.239.1794
E-mail: michael.honeycutt@tceq.texas.gov

No Work Plan is required.

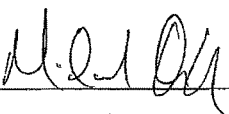
Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order by the signature below.

Work Order No. **582-13-32032-07** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin on the signature date below and the deliverable is due March 17, 2014.

TCEQ:

Texas Commission on Environmental Quality



Michael Honeycutt, Ph.D.
Director, Toxicology Division

Date: 3-3-14

Texas Commission on Environmental Quality (TCEQ)

**WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT**

Commentary on the Elements of the National Ambient Air Quality Standards

Work Order No. 582-13-32032-08 (PCR 44770)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$30,010

Amount in Contract After this Work Order: \$ 273,490

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31 2014 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. Gradient Corporation (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to review and provide commentary on the USEPA's evaluation of Elements of the National Ambient Air Quality Standards, specifically the relationship between exposures in epidemiology, controlled exposure, and toxicology studies with respect to the NAAQS' averaging times using ozone as an example.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, each of which one or more averaging times that are used to ascertain compliance. Since the NAAQS are based on epidemiology, controlled exposure, and toxicology studies, it stands to reason that the

averaging times for the NAAQS should be based on these studies and have a biological basis.

Scope

The Contractor will provide a comprehensive review and report of the scientific literature addressing exposure times from epidemiology, controlled exposure, and toxicology studies as they relate to the NAAQS averaging times, using ozone as an example.

Deliverable

The Contractor shall provide TCEQ with a Work Plan document within 14 days of the date of this Work Order.

The Contractor will complete the commentary draft by August 31, 2014 and submit the commentary for publication by September 30, 2014.

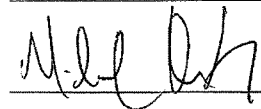
TCEQ - Project Representative
Name: Michael Honeycutt, Ph.D.
Phone: 512.239.1793
Fax: 512.239.1794
E-mail: michael.honeycutt@tceq.texas.gov

Work Order No. **582-13-32032-08** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin upon the issuance of a Notice to Proceed and the deliverable is due by August 31, 2014.

TCEQ:

Texas Commission on Environmental Quality



Michael Honeycutt, Ph.D.
Director, Toxicology Division

Date: 7/9/14

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Ozone Science Workshop

Work Order No. 582-13-32032-09 (PCR 44826)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$20,000

Amount in Contract After this Work Order: \$ 253,490

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31 2014 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. Gradient Corporation (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standard (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, draft Health Risk and Exposure Assessment, draft Welfare Risk and Exposure Assessment, and a draft Policy Assessment. The Clean Air Scientific Advisory Committee (CASAC) has met and

reviewed each of these documents, and has endorsed a lower range for the ozone standard. EPA is scheduled to propose a new NAAQS for ozone by December 2014, and to finalize a standard by October of 2015.

Scope

The Contractor will assist TCEQ, NERA Economic Research Associates, Inc. (NERA), and Toxicology Excellence for Risk Assessment (TERA) in planning a workshop to discuss the science that bears on the ozone NAAQS. The Contractor will provide support for the planning and implementation of the workshop, as well as follow-up. This work order covers the development of draft charge questions, a draft meeting agenda, and an initial list of potential participants. This will involve reviewing EPA ozone documents, as well as other documents, particularly the peer-reviewed literature, to determine the most relevant topics and experts.

Deliverable

The Contractor will provide their recommendations to TCEQ in a brief report by August 31, 2014.

TCEQ - Project Representative
Name: Michael Honeycutt, Ph.D.
Phone: 512.239.1793
Fax: 512.239.1794
E-mail: michael.honeycutt@tceq.texas.gov

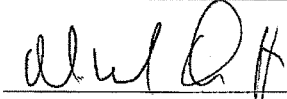
Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order by the signature below.

Work Order No. 582-13-32032-09 is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin on the signature date below and the deliverable is due August 31, 2014.

TCEQ:

Texas Commission on Environmental Quality



Michael Honeycutt, Ph.D.
Director, Toxicology Division

Date: 7-16-14

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE UMBRELLA CONTRACT
FOR NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Ozone Science Workshop

Work Order No. 582-13-32032-10 (PCR 50893)

Contract No.: 582-13-32032

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$250,000

Amount in Contract After this Work Order: \$3,490

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31, 2015 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. Gradient Corporation (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standard (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, draft Health Risk and Exposure Assessment, draft Welfare Risk and Exposure Assessment, and a draft Policy

Assessment. The Clean Air Scientific Advisory Committee (CASAC) has met and reviewed each of these documents, and has endorsed a lower range for the ozone standard. EPA is scheduled to propose a new NAAQS for ozone by December 2014, and to finalize a standard by October 2015.

Scope

The Contractor will assist TCEQ, NERA Economic Research Associates, Inc. (NERA), and Toxicology Excellence for Risk Assessment (TERA) in planning a workshop to discuss the science that bears on the ozone NAAQS. The Contractor will provide support for the planning and implementation of the workshop, as well as follow-up. This work order covers the development of charge questions and a meeting agenda, identification of participants, preparation of technical materials for the participants, advertisement of the workshop, attendance and participation in the workshop (including moderating and rapporteurs), and preparation of proceedings and a workshop summary. This will involve reviewing EPA ozone documents, as well as other documents, particularly the peer-reviewed literature, to determine the most relevant topics and experts.

In addition, the Contractor will assist TCEQ and TERA in researching, analyzing data, and writing and editing a manuscript about ozone dose-response relationships.

Deliverable

The Contractor will provide their recommendations for the workshop as well as the draft workshop proceedings and report by August 31, 2015.

The Contractor will provide comments on a draft ozone dose-response manuscript by August 31, 2015.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

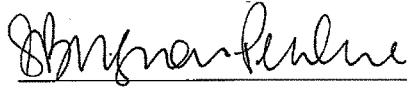
Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order by the signature below.

Work Order No. 582-13-32032-10 is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin on the signature date below and the deliverable is due August 31, 2015.

TCEQ:

Texas Commission on Environmental Quality

A handwritten signature in black ink, appearing to read 'Stephanie Bergeron Perdue', written over a horizontal line.

Stephanie Bergeron Perdue
Deputy Executive Director

Date: 9/10/2014

Texas Commission on Environmental Quality

UMBRELLA CONTRACT
BETWEEN TCEQ AND GRADCO, LLC dba GRADIENT

Contract No. 582-13-32032

Work Order No. 582-13-32032-10 Amendment 1

Original Amount of Umbrella Contract: \$550,000

Amendment 1 Amount: \$550,000

Amendment 2 Amount: \$550,000

Current Amount of Umbrella Contract: \$1,650,000

Work Order Amount (Maximum Not-to-Exceed): \$250,000

Amount in Contract after this Work Order: \$3,490

Effective Date of the Work Order Amendment: Date of last signature

PURPOSE OF AMENDMENT 1

The Parties to Contract 582-13-32032 agree to amend WO Number 582-13-32032-10 to add the following to the Scope and Deliverables:

Scope

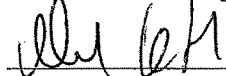
The Contractor will also participate in writing and editing a manuscript about changing the way that the NAAQS are set.

Deliverable

The Contractor will provide comments on a draft NAAQS modifications manuscript by August 31, 2015.

All other conditions and requirements of Work Order Number 582-13-32032-10, remain unchanged.

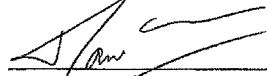
**TEXAS COMMISSION ON
ENVIRONMENTAL QUALITY:**



**Michael Honeycutt, Ph.D.
Director, Toxicology Division**

Date: 9-26-14

GRADIENT



**Manu Sharma
Principal/Operations Manager**

Date: 9/26/14

TERA 582-13-30037

	Invoice #	Billing Dates	Invoice Amount	Date Paid
Work Order # 1	4289	3/21/13-3/31/13	\$ 3,085.25	4/29/2013
PCR # 32046	4310	4/1/13-4/26/13	\$ 3,092.75	5/23/2013
WO Amount	4344	4/27/13-5/31/13	\$ 11,035.50	7/9/2013
\$30,000.00	4372	6/1/13-6/28/13	\$ 3,487.25	7/29/2013
		TOTAL	\$ 20,700.75	
Work Order # 2	4288	3/21/13-3/31/13	\$ 3,880.75	4/29/2013
PCR # 32048	4309	4/1/13-4/26/13	\$ 1,642.72	5/23/2013
WO Amount	4343	4/27/13-5/31/13	\$ 18,325.75	7/9/2013
\$28,000.00	4365	6/1/13-6/28/13	\$ 4,145.96	8/2/2013
		TOTAL	\$ 27,995.18	
Work Order # 3	4501	11/5/13-11/29/13	\$ 7,264.00	1/2/2014
PCR # 41410	4537	11/30/13-12/31/13	\$ 4,899.00	1/16/2014
WO Amount	4570	12/31/13-1/31/14	\$ 2,806.75	3/3/2014
\$19,000.00		TOTAL	\$ 14,969.75	
Work Order # 4	4594	2/18/14-3/5/14	\$ 16,068.00	4/8/2014
PCR # 42624	4735	6/1/14-7/3/14	\$ 1,401.25	7/11/2014
WO Amount	4777	7/4/14-8/29/14	\$ 267.00	9/17/2014
\$18,000.00		TOTAL	\$ 17,736.25	
Work Order # 5	4730	6/25/14-6/27/14	\$ 790.00	7/7/2014
PCR # 44431	4763	6/28/14-7/25/14	\$ 798.00	8/18/2014
WO Amount	4785	7/26/14-8/29/14	\$ 1,834.75	9/17/2015
\$4,122.00		TOTAL	\$ 3,422.75	
Work Order # 6	4762	7/16/14-7/25/14	\$ 4,349.25	8/19/2014
PCR # 44832	4778	7/26/14-8/31/14	\$ 9,300.20	12/31/2014
WO Amount		TOTAL	\$ 13,649.45	
\$13,655.00				
Work Order # 7	4810	9/3/14-9/26/14	\$ 10,656.00	11/20/2014
PCR # 50678	4827	9/26/14-10/31/14	\$ 9,753.25	1/14/2015
WO Amount	4868	11/1/14-11/28/14	\$ 5,175.25	1/14/2015
\$40,000.00	4896	11/28/14-12/31/14	\$ 5,758.75	2/10/2015
	4920	1/1/15-1/30/15	\$ 5,157.25	3/10/2015
	4950	1/31/15-2/27/15	\$ 2,488.75	3/18/2015
		TOTAL	\$ 38,989.25	

Work Order # 8	4951	2/25/15-2/27/15	\$	2,866.00	3/12/2015
PCR # 53786	4988	2/28/15-3/27/15	\$	1,732.00	4/20/2015
WO Amount	5005	3/28/15-4/24/15	\$	35,401.22	5/28/2015
\$40,000.00		TOTAL	\$	39,999.22	

Work Order # 9	4993	3/19/15-3/27/15	\$	72,396.25	5/14/2015
PCR # 54027	5000	3/28/15-4/24/15	\$	55,049.92	5/28/2015
WO Amount	5043	4/11/15-5/31/15	\$	7,626.12	7/14/2015
\$140,000.00		TOTAL	\$	135,072.29	

Work Order # 10	5080	7/5/15-8/14/15	\$	8,229.50	9/24/2015
PCR # 56363	5102	8/1/15-8/31/15	\$	5,015.50	11/12/2015
WO Amount		TOTAL	\$	13,245.00	
\$20,000.00					

Work Order # 11	5137	10/2/15-10/31/15	\$	7,203.00	12/22/2015
PCR # 60956	5149	11/1/15-11/30/15	\$	1,600.00	1/7/2016
WO Amount		NOT FINAL INVOICE			
\$10,000.00		TOTAL	\$	8,803.00	

Texas Commission on Environmental Quality

**WORK ORDER UNDER THE UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSEMENT**

*Letter Peer Review
Isoprene Section 4.2 Carcinogenic Potential
Development Support Document*

Work Order No. 582-13-30037-01

Contract No.: **582-13-30037**

Original Amount of Umbrella Contract: **\$300,000**

Work Order Amount (Maximum Not-to-Exceed): **\$30,000**

Amount in Contract After this Work Order: **\$270,000**

Effective Date of the Work Order: Date of the Notice to Proceed

End Date of Work Order: July 1, 2013

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice To Proceed. Toxicology Excellence for Risk Assessment, the Contractor, must submit a budget for all work that can be completed before July 1, 2013. All work must be completed before July 1, 2013. The Contractor must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

This Work Order is for a scientific letter peer-review of Section 4.2 *Carcinogenic Potential* of the Development Support Document (DSD) for isoprene. Section 4.2 of the isoprene DSD is a summary report of the carcinogenic potential and toxicity assessment of isoprene and is approximately 10 pages long with a carcinogenic modeling report of approximately 300 pages.

TASKS AND DELIVERABLES

Task 1 - Select key personnel and create preliminary schedule:

- 1.1 The Contractor shall submit a Personnel Eligibility List (PEL) providing the names of key personnel, and their Curriculum Vitae.
- 1.2 The Contractor's Program Manager shall provide a Project Manager. The Project Manager shall read and understand Section 4.2 of isoprene's DSD and Revised RG-442 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2012).

- 1.3 The Contractor shall create a schedule of deadlines and data deliverables and obtain TCEQ approval. Section 4.2 of isoprene's DSD shall be distributed to peer-reviewers. The peer-review group shall review Section 4.2 of isoprene's DSD and prepare written comments within a 30-day time period. The Contractor must submit a budget for all work that can be completed before July 1, 2013. All work must be completed before July 1, 2013.

Deliverable: Schedule of deadlines and data deliverables

Task 2 - Organize and conduct the letter peer review and prepare draft peer-review report

- 2.1 The Contractor Project Manager shall ensure the peer review is conducted. The contractor shall maintain a website that provides information on the peer-review and provides the peer-review report to interested parties.
- 2.2 The Contractor Project Manager shall interact with TCEQ staff concerning content of the isoprene DSD, its objectives and will prepare the Charge to Reviewers.
- 2.3 The Contractor shall select technical peer reviewers and convene a balanced group of peer reviewers based on the criteria set forth in the Contract Scope of Work.
- 2.4 The Contractor shall ensure that the Scope of Work is followed in organizing, and conducting the letter peer review and prepare a draft peer-review report.
- 2.5 To improve efficiency of the review, the Contractor will screen the written review comments, determine which charge questions remain unresolved after the written review, and prepare a focused charge of unresolved issues.
- 2.6 The draft peer-review report will be distributed to TCEQ staff and the peer reviewers, in order for TCEQ to clarify reviewer comments and to allow the scientific experts to discuss and resolve any issues that were not clear in the written review comments.

Deliverable: Draft peer-review report and follow-up written review to resolve any outstanding issues

Task 3 – Prepare Letter Peer-Review Report:

- 3.1 After the peer reviewers and TCEQ staff review the draft report, the Project Manager will direct key staff to prepare the peer-review report in Microsoft Word

and pdf format. The peer-review report will include the reviewers' written comments, as well as the contractor's summary report of the discussion and conclusions reached by the scientific experts.

- 3.2 The peer-review report will be distributed to the peer-review group members and TCEQ staff. Comments from group members and TCEQ staff will be incorporated in the final peer review report. The notes shall be placed in the final peer review report to the TCEQ Project Manager. This report shall detail the nature of the review and the findings and conclusions of the review group. Positive as well as negative aspects of the review should be noted. The final peer-review report shall also disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the TCEQ or issue under peer review consideration. If there is a group report, any partial or complete dissenting statements should be included with the group's final report.

Deliverable: Final letter peer-review report

Quality Assurance/Quality Control (QA/QC) Procedures

A discussion of the quality assurance/quality control procedures to be followed by the Contractor staff shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work order, Contract, and the specific requirements, if any, listed below:

None.

TCEQ - Project Representative

Roberta Grant, Ph.D.
Toxicology Division
phone: 512.239.4115
fax: 512.239.1794
e-mail: rgrant@tceq.state.tx.us

INSTRUCTIONS TO CONTRACTOR

The contractor project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work Order. The cost of preparing the Work Plan shall not exceed \$1500.00 without requesting and receiving TCEQ's written approval for expending a greater amount of effort in preparing the Work Plan. The cost of Work Plan preparation shall be included as a separate cost line item or category that details the number of hours spent in preparing the Work Plan and the cost of the Work Plan preparation.

The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the

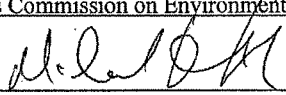
following headings:

1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES;**
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff will review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor will be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit, of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. **582-13-30037-01** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment is issued by TCEQ raising that amount.

TCEQ:
Texas Commission on Environmental Quality

By: 

(Authorized Signature)

Michael Honeycutt, Ph.D.

(Printed Name)

Toxicology Division Director

(Title)

Date:

2-21-13

Texas Commission on Environmental Quality

**WORK ORDER UNDER THE UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSEMENT**

*Letter Peer Review with Follow-up Teleconference
Hexavalent Chromium Section 4.2 Carcinogenic Potential
Development Support Document*

Work Order No. Contract No.: 582-13-30037-02

Contract No.: 582-13-30037
Original Amount of Umbrella Contract: \$300,000
Total Amount of Umbrella Contract (Remaining): \$270,000
Work Order Amount (Maximum Not-to-Exceed): \$62,000
Amount in Contract After this Work Order: \$208,000
Effective Date of the Work Order: Date of the Notice to Proceed
End Date of Work Order: July 15, 2013

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice to Proceed. Toxicology Excellence for Risk Assessment, the Contractor, must submit a budget for all work that can be completed before July 15, 2013. All work must be completed before July 15, 2013. The Contractor must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

This Work Order is for a scientific, technical letter peer-review with follow-up teleconference of Section 4.2 *Carcinogenic Potential* of the Development Support Document (DSD) for hexavalent chromium compounds. Section 4.2 of the hexavalent chromium DSD is a summary report of the carcinogenic potential and toxicity assessment of hexavalent chromium and is approximately 40-45 pages long.

TASKS AND DELIVERABLES

Task 1 - Select key personnel and create preliminary schedule:

- 1.1 The Contractor shall submit a Personnel Eligibility List (PEL) providing the names of key personnel, and their Curriculum Vitae.
- 1.2 The Contractor's Program Manager shall provide a Project Manager and Facilitator. The Project Manager and Facilitator shall read and understand Section 4.2 of hexavalent chromium's DSD and Revised RG-442 TCEQ Guidelines to

Develop Toxicity Factors (TCEQ 2012).

- 1.3 The Contractor shall create a schedule of deadlines and data deliverables and obtain TCEQ approval. Section 4.2 of hexavalent chromium's DSD shall be distributed to peer-reviewers. The peer-review group shall review Section 4.2 of hexavalent chromium's DSD, prepare written comments, and participate in the teleconference. The Contractor must submit a budget for all work that can be completed before July 15, 2013. All work must be completed before July 15, 2013.

Deliverable: Schedule of deadlines and data deliverables

Task 2 - Organize and conduct the letter peer review, prepare draft peer-review report, and conduct teleconference

- 2.1 The Contractor Project Manager shall ensure the peer review is conducted. The contractor shall maintain a website that provides information on the peer-review and provides the peer-review report to interested parties.
- 2.2 The Contractor Project Manager shall interact with TCEQ staff concerning content of the hexavalent chromium DSD, its objectives and will prepare the Charge to Reviewers.
- 2.3 The Contractor shall select technical peer reviewers and convene a balanced group of peer reviewers based on the criteria set forth in the Contract Scope of Work.
- 2.4 The Contractor shall ensure that the Scope of Work is followed in organizing, and conducting the letter peer review and prepare the draft peer-review report.
- 2.5 A follow-up call will be scheduled by the Contractor after the draft peer-review report has been distributed in order for TCEQ to clarify reviewer comments and to allow the scientific experts to discuss and resolve any issues that were not clear in the written review comments.
 - 2.5.1 To improve efficiency of the call, the Contractor will screen the written review comments, determine which charge questions remain unresolved after the written review, and prepare a focused charge of unresolved issues for the conference call.
 - 2.5.2 "Listen only" phone lines will be made available for members of the public who want to listen to the conference call. Alternatively, an audio recording may be prepared and made available to interested parties.

Deliverable: Draft peer-review report and follow-up teleconference to resolve any outstanding issues

Task 3 – Prepare Letter Peer-Review Report:

- 3.1 After the teleconference, the Project Manager will direct key staff to prepare the peer-review report in Microsoft Word and pdf format. The peer-review report will include the reviewers' written comments, as well as the contractor's summary report of the discussion and conclusions reached by the scientific experts during the conference call.
- 3.2 The peer-review report will be distributed to the peer-review group members and TCEQ staff. Comments from group members and TCEQ staff will be incorporated in the final peer review report. The notes shall be placed in the final peer review report to the TCEQ Project Manager. This report shall detail the nature of the review and the findings and conclusions of the review group. Positive as well as negative aspects of the review should be noted. The final peer-review report shall also disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the TCEQ or issue under peer review consideration. If there is a group report, any partial or complete dissenting statements should be included with the group's final report.

Deliverable: Final letter peer-review report following the teleconference

Quality Assurance/Quality Control (QA/QC) Procedures

A discussion of the quality assurance/quality control procedures to be followed by the Contractor staff shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work order, Contract, and the specific requirements, if any, listed below:

None.

TCEQ - Project Representative

Roberta Grant, Ph.D.
Toxicology Division
phone: 512.239.4115
fax: 512.239.1794
e-mail: rgrant@tceq.state.tx.us

INSTRUCTIONS TO CONTRACTOR

The contractor project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work order. The cost of preparing the Work Plan shall not exceed \$1500.00 without requesting and receiving TCEQ's written approval for expending a greater amount of effort in preparing the Work Plan. The cost of Work Plan preparation shall be included as a separate cost line item or category that details the

number of hours spent in preparing the Work Plan and the cost of the Work Plan preparation.

The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

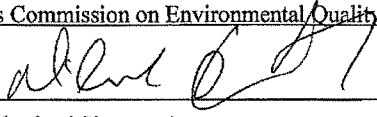
1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES;**
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff will review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor will be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. 582-13-30037-02 is issued as of the date shown below. The amount

shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment is issued by TCEQ raising that amount.

TCEQ:
Texas Commission on Environmental Quality

By: 

(Authorized Signature)

Michael Honeycutt, Ph.D.

(Printed Name)

Toxicology Division Director

(Title)

Date: 2-21-13

Texas Commission on Environmental Quality

**WORK ORDER UNDER THE UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSEMENT**

Carbon Disulfide External Technical Review

**Work Order No. 582-13-30037-03
PCR No. 41410**

Contract No.: **582-13-30037**
Original Amount of Umbrella Contract: **\$300,000**
Total Amount of Umbrella Contract (Remaining): **\$208,000**
Work Order Amount (Maximum Not-to-Exceed): **\$19,000**
Amount in Contract After this Work Order: **\$189,000**
Effective Date of the Work Order: Date of the Notice to Proceed
Projected Date for Completion of Work: March 15, 2014

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-signed Notice to Proceed. Toxicology Excellence for Risk Assessment, the Contractor, must submit a budget for all work that can be completed before March 15, 2014. All work must be completed before March 15, 2014. The Contractor must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

~~This Work Order is for a scientific, external technical letter review of the Development~~ Support Document (DSD) for carbon disulfide. The carbon disulfide external technical review shall be conducted by one to four reviewers, to be determined by the project manager. The carbon disulfide DSD is a summary report of the acute and chronic toxicity assessment of carbon disulfide.

TASKS AND DELIVERABLES

Task 1 - Select key personnel and create preliminary schedule:

- 1.1 The Contractor shall submit a Personnel Eligibility List (PEL) providing the names of key personnel, and their Curriculum Vitae.
- 1.2 The Contractor's Program Manager shall provide a Project Manager. The Project Manager shall read and understand issues related to the carbon disulfide DSD and Revised RG-442 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2012).
- 1.3 The Contractor shall create a schedule of deadlines and data deliverables and obtain TCEQ approval.

Deliverable: Schedule of deadlines and data deliverables

Task 2 - Organize and conduct the technical peer review

- 2.1 The Contractor shall ensure that the Scope of Work is followed in organizing and conducting the external technical review.
- 2.2 The Contractor's Project Manager shall interact with TCEQ staff concerning content of the carbon disulfide DSD, its objectives, and will prepare the Charge to Reviewers.
- 2.3 The Contractor shall conduct an administrative review of the DSD to ensure it is complete and ready for review.
- 2.3 The Contractor shall convene a balanced group of peer reviewers based on the criteria set forth in the Contract Scope of Work. One to four technical peer reviewers may be selected, to be determined by the project manager.

Deliverable: Preparation of charge questions, administrative review of DSD, and selection of external peer reviewers

Task 3 Conduct of Technical Peer Review

- 3.1 The Contractor shall distribute the carbon disulfide DSD and relevant scientific papers to the peer reviewers and provide a deadline for receipt of technical comments.
- 3.2 The peer-review group shall review the carbon disulfide DSD, prepare written comments, and submit them to the Contractor.
- 3.3 The Contractor shall review the comments. If needed, the Contractor shall ask clarifying questions concerning the peer reviewers' comments.
- 3.4 Technical comments are sent to the TCEQ.
- 3.5 After TCEQ receives and reviews the technical comments, TCEQ staff have the option of asking TERA to call or email the technical reviewers to ask clarifying questions.

Deliverable: Conduct of the technical review, and receipt of technical comments

TCEQ - Project Representative

Shannon Ethridge, MS, DABT
 Toxicology Division
 phone: 512.239.1822
 fax: 512.239.1794
 c-mail: Shannon.Ethridge@tceq.texas.gov

INSTRUCTIONS TO CONTRACTOR

The Contractor's project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work order. The cost of preparing the Work Plan shall not exceed \$1500.00 without requesting and receiving TCEQ's written approval for expending a greater amount of effort in preparing the Work Plan. The cost of Work Plan preparation shall be included as a separate cost line item or category that details the number of hours spent in preparing the Work Plan and the cost of the Work Plan

preparation.

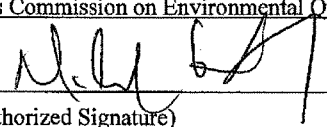
The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES:** A discussion of the quality assurance/quality control procedures to be followed by the Contractor staff shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work order, Contract, and the specific requirements, if any, listed below:
None.
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff will review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor will be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is

accepted, shall become an attachment, an Exhibit of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. **582-13-30037-03** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment is issued by TCEQ raising that amount.

TCEQ:Texas Commission on Environmental QualityBy: 

(Authorized Signature)

Michael Honeycutt, Ph.D.

(Printed Name)

Toxicology Division Director

(Title)

Date: 10-28-13

Texas Commission on Environmental Quality
WORK ORDER UNDER THE UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK
ASSESSMENT

Science and Decisions Workshop VIII
Scientific Panel Review of Case Study for
Weight of Evidence Approach for Chemicals with Limited Toxicity Data
Work Order No. 582-13-30037-04

Contract No.: **582-13-30037**
 Original Amount of Umbrella Contract: **\$300,000**
 Total Amount of Umbrella Contract (Remaining): **\$223,000**
 Work Order Amount (Maximum Not-to-Exceed): **\$18,000**
 Amount in Contract after this Work Order: **\$205,000**
Effective Date of the Work Order: Date of the Notice to Proceed
Date for Completion of Work: August 31, 2014

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice to Proceed. Toxicology Excellence for Risk Assessment (TERA), the Contractor, must submit a budget for all work. The date for completion of Science and Decisions workshop activities must be completed before August 31, 2014. The Contractor must submit a final payment invoice/request as well as a release of claims within 60 days of TCEQ's approval of the final technical deliverable for this Work Order.

Background

The Alliance for Risk Assessment (ARA) is a collaboration of organizations teaming to take on projects that are too big or too complex for an individual company or organization to address. The work of the ARA focuses resources to help meet the needs of State, Local, and Tribal risk assessors (www.allianceforrisk.org). ARA has sponsored seven Science and Decisions Workshops in collaboration with a coalition of sponsors and collaborators. Sponsors and collaborators to date include government agencies, industry groups, scientific societies, non-profit organizations/consortia, and consulting groups. The Texas Commission on Environmental Quality (TCEQ) is a sponsor in the coalition.

A dose response advisory science panel (Science Panel) consisting of 8-10 scientific experts participated in the last five workshops. Case studies were developed by outside parties and reviewed by the Science Panel. The aim of the workshops is to seek ways to move the science of dose-response assessment forward, based in part on recent NAS (2007, 2008) publications. The goal is for coalition members to contribute scientific expertise, time, and funding towards the effort of advancing dose-response assessment. The products of the workshops were meeting reports and an interactive website that

linked problem formulation with dose response method and risk management outcome (posted on the ARA website at http://www.allianceforrisk.org/ARA_Dose-Response.htm).

The Toxicology Division has prepared a case study on Weight of Evidence Approach for Chemicals with Limited Toxicity Data which includes developing safe inhalation levels of silanes/siloxanes in air using a read across approach, as well as other procedures used to develop safe inhalation levels for chemicals with limited toxicity data. This Work Order is for the Contractor to arrange for this case study to be presented at the next Science and Decisions Workshop and to have the case study reviewed by the Science Panel. The next Science and Decisions Workshop is scheduled for May 19-22 at the Texas Commission on Environmental Quality.

TASKS AND DELIVERABLES

Task 1 - Select key personnel and create preliminary schedule:

- 1.1 The Contractor shall submit a Personnel Eligibility List (PEL) providing the names of key personnel, and their Curriculum Vitae.
- 1.2 The Contractor's Program Manager shall provide a Project Manager.
- 1.3 The Contractor shall create a schedule of deadlines and data deliverables and obtain TCEQ approval. The Contractor must submit a budget for all work. The Science and Decisions Workshop must be completed before August 31, 2014.

Deliverable: Schedule of deadlines and data deliverables

Task 2 - TERA Administrative Review of Weight of Evidence Case Study:

- 2.1 TCEQ will provide the Contractor with the draft case study. Contractor staff will review the case study to ensure it is in the format required by the Science Panel.
- 2.2 The Contractor shall interact with TCEQ staff concerning content of the case study and its objectives. TCEQ staff will finalize the case study file based on the Contractor's review.

Deliverable: TCEQ case study ready for review by the Science Panel

Task 3 - Arrangements for Review by the Science Panel

- 3.1 The Contractor will arrange for the case study to be reviewed by the Science Panel at the May 2014 Science and Decisions Workshop.
- 3.2. The Contractor will arrange for the ARA fee to be paid in advance of the Workshop. The ARA fee will cover the preparation of the workshop report.

Deliverable: Review by the Science Panel

Task 4 – Science Panel Comments

4.1 After the Science and Decisions Workshop, a draft summary of comments from the Science Panel on the TCEQ case study will be made available to TCEQ staff. TCEQ staff will review the comments and submit suggested changes.

Deliverable: Workshop Report containing the Science Panels' comments on the TCEQ case study. The ARA fee, which will be paid in advance prior to the Science and Decisions Workshop, will cover the preparation of the workshop report.

TCEQ - Project Representative

Tiffany Bredfeldt, Senior Toxicologist
Toxicology Division
phone: 512.239.1799
fax: 512.239.1794
e-mail: tiffany.bredfeldt@tceq.texas.gov

INSTRUCTIONS TO CONTRACTOR

The contractor project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work Order. The cost of preparing the Work Plan shall not exceed \$1,000.00 without requesting and receiving TCEQ's written approval for expending a greater amount of effort in preparing the Work Plan. The cost of Work Plan preparation shall be included as a separate cost line item or category that details the number of hours spent in preparing the Work Plan and the cost of the Work Plan preparation. The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

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2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES:** A discussion of the quality assurance/quality control procedures to be followed by the Contractor staff shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work Order, Contract, and the specific requirements, if any, listed below;
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff will review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the

Work Plan by TCEQ, the Contractor will be issued a Notice to Proceed and work shall commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit, of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. ~~582-13-30037-04~~ is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment is issued by TCEQ raising that amount.

TCEQ:

Texas Commission on Environmental Quality

By:



(Authorized Signature)

Roberta L. Grant, Ph.D.

(Printed Name)

Toxicology Section Manager

(Title)

Date:

2/18/14

Texas Commission on Environmental Quality

WORK ORDER UNDER THE UMBRELLA CONTRACT BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT

Entering Hexavalent Chromium Toxicity Factors from the Chromium Development Support Document on the International Toxicity Estimates for Risk (ITER) Database

Work Order No. 582-13-30037-05 (PCR 44431)

Contract No.: **582-13-30037**

Original Amount of Umbrella Contract: **\$300,000**

Total Amount of Umbrella Contract (Remaining): **\$205,000**

Work Order Amount (Maximum Not-to-Exceed): **\$10,000**

Amount in Contract after this Work Order: **\$195,000**

Effective Date of the Work Order: Date of the Notice to Proceed

Date for Completion of Work: August 31, 2014

Time Line

The work shall begin upon issuance of a Texas Commission on Environmental Quality (TCEQ)-executed Notice To Proceed. Toxicology Excellence for Risk Assessment (TERA), the Contractor, must submit a budget for all work. All work must be completed before August 31, 2014. The Contractor must submit a final payment invoice/request as well as a release of claims within 60 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The carcinogenic section of the Hexavalent Chromium (Cr(VI)) Development Support Document and the Unit Risk Factor (URF) have been finalized based on a peer review organized by TERA and public comments. In addition, there was a peer review pursuant to acceptance to the journal *Regulatory Toxicology and Pharmacology*: Haney, J.T., Erraguntla, N., Sielken, R.L., et al., 2014. Development of an inhalation unit risk factor for hexavalent chromium. *Regul. Tox. Pharmacol.* 68:201-211. The Development Support Document, which underwent a 90-day public comment period, will be finalized in July-August 2014.

Since the Cr(VI) carcinogenic section and URF development underwent an external scientific peer review, the URF value is eligible to be entered into the International Toxicity Estimates for Risk (*ITER*) database. The chronic Reference Value for Cr(VI) underwent a 90-day public comment period. This may be mentioned on the *ITER* database, but the numerical value of the ReV does not need to be included.

This Work Order is for the Contractor to enter the Cr(VI) URF value on the *ITER* database. *ITER* is a free Internet database of human health risk values and cancer classifications for over 600 chemicals of environmental concern from authoritative scientific organizations worldwide. *ITER* presents human health risk data in tabular format enabling a side-by-side comparison of human health risk data for easy comparison, along with a synopsis explaining differences in data and a

link to each organization for more information. *ITER* is part of the National Library of Medicine's TOXNET compilation of databases, and any data added to *ITER* becomes available to the risk assessment community on the TOXNET system.

ITER is a database (i.e., resource) that the Contractor owns and National Library of Medicine leases to use on TOXNET. The Contractor uploads all data to *ITER*. This work includes drafting the *ITER* file, conducting QA, finalizing the file, loading it to *ITER*, and making it public. The data loaded into *ITER* will be uploaded to TOXNET within one week of being added to *ITER*.

TASKS AND DELIVERABLES

Task 1 - Select key personnel and create preliminary schedule:

- 1.1 The Contractor shall submit a Personnel Eligibility List (PEL) providing the names of key personnel, and their Curriculum Vitae.
- 1.2 The Contractor's Program Manager shall provide a Project Manager.
- 1.3 The Contractor shall create a Work Plan with a Budget and a schedule (Time line) of deadlines and data deliverables and obtain TCEQ approval. The Contractor must include in the Work Plan a budget for all work. All work, including posting the Cr(VI) URF file to the *ITER* database, must be completed before August 31, 2014.

Deliverable: Work Plan with a Budget and a Schedule of deadlines and data deliverables

Task 2 - Draft ITER File of Cr(VI)'s Unit Risk Factor:

TCEQ will provide TERA staff with the final carcinogenic section of the Chromium DSD. TERA staff will prepare a draft *ITER* file in consultation with TCEQ staff by August 1st, 2014. TCEQ staff will review the draft *ITER* file. The Contractor shall interact with TCEQ staff concerning content of the Cr(VI) toxicity factors file and its objectives and finalize the *ITER* file

Deliverable: Preparation of final Cr(VI) URF *ITER* file.

Task 3 - Loading the Finalized Cr(VI) URF file to ITER.

The contractor will load the finalized Cr(VI) toxicity factor file to *ITER* and make it public. The data loaded into *ITER* will be uploaded to TOXNET within one week of being added to *ITER*.

Deliverable: Finalized Cr(VI) URF file loaded to *ITER*

TCEQ - Project Representative

Joseph (Kip) Haney, Senior Toxicologist
 Toxicology Division
 phone: 512.239.5691
 fax: 512.239.1794
 e-mail: joseph.haney@tceq.texas.gov

INSTRUCTIONS TO CONTRACTOR

The contractor project manager shall provide TCEQ with a Work Plan document within 14 days of the date of this Work Order. The cost of preparing the Work Plan shall not exceed \$700.00 without requesting and receiving TCEQ's written approval for expending a greater amount of effort in preparing the Work Plan. The cost of Work Plan preparation shall be included as a separate cost line item or category that details the number of hours spent in preparing the Work Plan and the cost of the Work Plan preparation. The Work Plan shall contain the following pieces of information and any others deemed necessary by TCEQ to address the intent of the Work Order (e.g., figures, tables, work products, processes, deliverables). Each of the sections shall be named or titled using the following headings:

1. **PRINCIPAL INVESTIGATOR(S):** The name(s) of the principal investigator(s) assigned to the Work Order and the names of alternate personnel in the event the principal investigator is unavailable to perform assigned tasks;
2. **KEY PERSONNEL:** The Contractor staff to be assigned to the Work Order must be personnel who have been approved as key personnel under the Contract; if a person who has not been approved is submitted, the contract procedures for approval of substitute personnel must be followed;
3. **QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES:** A discussion of the quality assurance/quality control procedures to be followed by the Contractor staff shall be included in the Work Plan. All work must be completed in accordance with the QA/QC procedures specified in the Work Order, Contract, and the specific requirements, if any, listed below;
4. **TIME LINE:** The schedule for the project described by the Work Plan (if there is a conflict with the time line included in the Work Order, the Contractor shall bring this to the attention of TCEQ staff);
5. **BUDGET:** The budget for the Work Order. The budget submitted shall be sufficiently detailed to allow TCEQ to easily determine the hours, prices, and personnel, by classification, related to each task and deliverable, and shall also include a total for the Work Order.
6. **TECHNICAL APPROACH/METHOD:** The technical approach/method for the Work Order shall contain detailed descriptions of the tasks and deliverables and the dates that deliverables shall be provided to the TCEQ by the Contractor;
7. **PROJECT MILESTONES & WORK BREAKDOWN STRUCTURE;**
8. **MODELS AND SOFTWARE TO BE USED BY CONTRACTOR:** Models, software, and any other tools in addition to those already specified in the Work Order;
9. **MISCELLANEOUS INFORMATION OR ELEMENTS;** and
10. **SIGNATURE BY CONTRACTOR:** The Contractor shall have the Work Plan document signed and dated by a person with the authority to bind the Contractor to the performance of the Work Plan (please include the title and printed name of the person signing the Work Plan). The Work Plan shall include the Contractor's company/organization name in a prominent place on the Work Plan and the Contractor's name shall also appear above the Contractor's signature block.

The TCEQ staff will review the Work Plan and either comment and suggest changes, or shall approve the Work Plan as prepared by the Contractor. Following approval of the Work Plan by TCEQ, the Contractor will be issued a Notice to Proceed and work shall

commence on the date indicated in the Notice to Proceed. The Work Plan, after it is accepted, shall become an attachment, an Exhibit, of the Work Order and all terms and conditions in the Contract regarding the Work Order shall also apply to the Work Plan.

Work Order No. **582-13-30037-05** is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment is issued by TCEQ raising that amount.

TCEQ:

Texas Commission on Environmental Quality

By:



(Authorized Signature)

Roberta L. Grant, Ph.D.

(Printed Name)

Manager, Toxicology Section

(Title)

Date:

6-18-14

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE TOXICITY FACTORS PEER REVIEW UMBRELLA
CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT
(TERA)

Ozone Science Workshop

Work Order No. 582-13-30037-06 (PCR 44832)

Contract No.: 582-13-30037

Original Amount of Umbrella Contract: \$300,000

Work Order Amount (Maximum Not-to-Exceed): \$13,655

Amount in Contract After this Work Order: \$ 187,223

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31 2014 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. TERA (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standards (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, draft Health Risk and Exposure Assessment, draft Welfare Risk and Exposure Assessment, and a draft Policy Assessment. The Clean Air Scientific Advisory Committee (CASAC) has met and reviewed each of these documents, and

has endorsed a lower range for the ozone standard. EPA is scheduled to propose a new NAAQS for ozone by December 2014, and to finalize a standard by October of 2015.

Scope

The Contractor will assist TCEQ, NERA Economic Research Associates, Inc. (NERA), and GRADCO, LLC (Gradient) in planning a workshop to discuss the science that bears on the ozone NAAQS. The Contractor will provide support for the planning and implementation of the workshop, as well as follow-up. This work order covers the development of draft charge questions, a draft meeting agenda, identification of potential participants, and assistance locating a venue. This will involve reviewing EPA ozone documents, as well as other documents, particularly the peer-reviewed literature, to determine the most relevant topics and experts.

Deliverable

The Contractor will provide their recommendations to TCEQ in a brief report by August 31, 2014.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

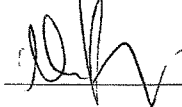
Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order by the signature below.

Work Order No. 582-13-30037-06 is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin on the signature date below and the deliverable is due August 31, 2014.

TCEQ:

Texas Commission on Environmental Quality



Michael Honeycutt, Ph.D.
 Director, Toxicology Division

Date: 7-16-14

Texas Commission on Environmental Quality (TCEQ)
WORK ORDER UNDER THE TOXICITY FACTORS PEER REVIEW UMBRELLA
CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT
(TERA)

Ozone Science Workshop

Work Order No. 582-13-30037-07 (PCR 50678)

Contract No.: 582-13-30037

Original Amount of Umbrella Contract: \$300,000

Work Order Amount (Maximum Not-to-Exceed): \$39,000

Amount in Contract After this Work Order: \$ 148,223

Effective Date of the Work Order: Date Signed

Time Line

The work shall begin upon the date signed by the Texas Commission on Environmental Quality (TCEQ) and must be completed no later than August 31, 2015 unless extended by TCEQ. The Work Order does not expire on the required delivery date and continues until closed or terminated by the TCEQ. TERA (Contractor) must submit a final payment invoice/request as well as a release of claims within 45 days of TCEQ's approval of the final technical deliverable for this Work Order.

Purpose

The purpose of the Contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standards (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, draft Health Risk and Exposure Assessment, draft Welfare Risk and Exposure Assessment, and a draft Policy Assessment. The Clean Air Scientific Advisory Committee (CASAC) has met and reviewed each of these documents, and has endorsed a lower range for the ozone standard. EPA is scheduled to propose a new NAAQS for ozone by December 2014, and to finalize a standard by October of 2015.

Scope

The Contractor will assist TCEQ, NERA Economic Research Associates, Inc. (NERA), and GRADCO, LLC (Gradient) in planning a workshop to discuss the science that bears on the ozone NAAQS. The Contractor will provide support for the planning and implementation of the workshop, as well as follow-up. This work order covers the organization and facilitation of regularly scheduled and ad hoc teleconferences with the workshop steering committee; the identification of potential participants, and contacting speakers for availability and interest; assistance in drafting the charge questions and agenda; and assistance in choosing an appropriate venue. This will also involve reviewing EPA ozone documents, as well as other documents, particularly the peer-reviewed literature, to determine the most relevant topics and experts.

In addition, the Contractor will assist TCEQ and Gradient to explore data and issues related to mode of action and dose response for pulmonary effects seen in the clinical studies of ozone exposure. Results from this work will aid in the preparation of a manuscript.

Deliverable

The Contractor will provide the workshop agenda, participant list and other organizational information to TCEQ in a brief report by April 30, 2015.

The Contractor will provide comments on a draft ozone dose-response manuscript by August 31, 2015.

TCEQ - Project Representative
 Name: Michael Honeycutt, Ph.D.
 Phone: 512.239.1793
 Fax: 512.239.1794
 E-mail: michael.honeycutt@tceq.texas.gov

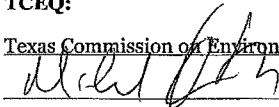
Notice to Proceed. The Contractor is authorized to proceed with performance of the Work Order by the signature below.

Work Order No. 582-13-30037-07 is issued as of the date shown below. The amount shown as "Work Order Amount" in the heading of this Work Order is the maximum amount to be paid to the Contractor for this work unless a Work Order Amendment raising that amount is issued by TCEQ.

The work shall begin on the signature date below and the deliverable is due August 31, 2015.

TCEQ:

Texas Commission on Environmental Quality



Michael Honeycutt, Ph.D.
 Director, Toxicology Division

Date: 9-3-14

Texas Commission on Environmental Quality (TCEQ)

UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT (TERA)

Contract No. 582-13-30037

Work Order No. 582-13-30037-08 (PCR 53786)

Original Amount of Umbrella Contract: \$300,000

Amendment 1 Amount: \$300,000

Current Amount of Umbrella Contract: \$600,000

Work Order Amount (Maximum Not-to-Exceed): \$40,000

Amount in Contract after this Work Order: \$408,223

Effective Date of the Work Order: Date of signature

PURPOSE OF WORK ORDER

Scope

The Contractor will engage the University of Texas at Austin AT&T Executive Education and Conference Center to hold an Ozone Science Workshop on April 7-9, 2015. TCEQ will pay for Contractor's hours worked in accordance with Contract prices. TCEQ will reimburse Contractor's approved related costs.

Deliverable

The Contractor will enter a valid contract by February 25, 2015.

A Work Plan is not required for this Work Order. This Work Order serves as the Notice to Proceed.

**TEXAS COMMISSION ON
ENVIRONMENTAL QUALITY:**



**Michael Honeycutt, Ph.D.
Director, Toxicology Division**

Date: 2-25-15

Texas Commission on Environmental Quality (TCEQ)

UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT (TERA)

Contract No. **582-13-30037**

Work Order No. 582-13-30037-09 (PCR 54027)

Original Amount of Umbrella Contract: \$300,000

Amendment 1 Amount: \$300,000

Current Maximum Amount of Umbrella Contract: \$600,000

Work Order Amount (Maximum Not-to-Exceed): \$140,000

Amount in Umbrella Contract after this Work Order: \$268,223

Effective Date of the Work Order: Date of signature

PURPOSE OF WORK ORDER

The purpose of the Contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standards (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, Health Risk and Exposure Assessment, Welfare Risk and Exposure Assessment, and Policy Assessment. The Clean Air Scientific Advisory Committee (CASAC) has met and reviewed each of these documents, and has endorsed a lower range for the ozone standard. EPA has proposed a new NAAQS for ozone and have to finalize a standard by October of 2015.

Scope

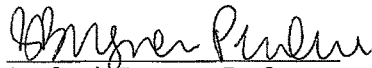
The Contractor will communicate with workshop participants (including making travel arrangements) as well as attendees; will maintain and update a website to provide information about the workshop; will organize and administer workshop and webcast registration; will organize the pre-workshop webinar; will be involved in the implementation of the workshop; will facilitate a session of the workshop; will act as the rapporteurs for the workshop; and will participate in writing of the workshop proceedings as well as other follow-up documents.

Deliverable

The Contractor will provide a work plan and a budget for the workshop-related tasks by March 30, 2015.

The Contractor will provide rapporteur notes of the workshop, and will provide comments on draft Proceedings and other workshop summary documents by August 31, 2015.

**TEXAS COMMISSION ON
ENVIRONMENTAL QUALITY:**



**Stephanie Bergeron Perdue
Deputy Executive Director**

Date: 3/13/2015

Texas Commission on Environmental Quality (TCEQ)

**UMBRELLA CONTRACT
BETWEEN TCEQ AND TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT (TERA)**

Contract No. **582-13-30037**

Work Order No. 582-13-30037-10 (PCR 56363)

Original Amount of Umbrella Contract: \$300,000

Amendment 1 Amount: \$300,000

Current Maximum Amount of Umbrella Contract: \$600,000

Work Order Amount (Maximum Not-to-Exceed): \$20,000

Amount in Umbrella Contract after this Work Order: \$248,223

Effective Date of the Work Order: Date of signature

PURPOSE OF WORK ORDER

The purpose of the Contract is to facilitate the development or consideration of an appropriate ozone National Ambient Air Quality Standards (NAAQS) based on unbiased analysis of experts and the science so that this information can potentially be considered by the United States Environmental Protection Agency (USEPA) administrator and others during the current ozone NAAQS review and rulemaking process.

TASKS AND DELIVERABLES

Background

The USEPA develops NAAQS for six chemicals, including ozone. The USEPA has prepared a final Integrated Science Assessment, Health Risk and Exposure Assessment, Welfare Risk and Exposure Assessment, and Policy Assessment for ozone. The Clean Air Scientific Advisory Committee (CASAC) has met and reviewed each of these documents, and has endorsed a lower range for the ozone standard. In March of 2015 TCEQ submitted comments on the EPA's proposed rule, which included novel analyses completed by scientists at TCEQ, in collaboration with scientists at TERA and Gradient. EPA has proposed a new NAAQS for ozone and has to finalize a standard by October of 2015.

Scope

The Contractor will participate in writing, revising and publishing manuscripts that address TCEQ's novel ozone data analyses and other ozone work.

Deliverable

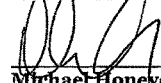
The Contractor will provide comments on drafts of manuscripts and revisions of manuscripts by August 31, 2015.

The Contractor will provide a work plan and a budget for the ozone manuscripts by June 15, 2015.

Notice to Proceed

The Contractor is authorized to proceed with performance of the Work Order by the signature below.

**TEXAS COMMISSION ON
ENVIRONMENTAL QUALITY:**



**Michael Honeycutt, Ph.D. Director
Toxicology Division**

5-22-15

(Date)

Appendix II

ADDITIONAL MATERIAL FOR THE RECORD

DOCUMENTS SUBMITTED BY COMMITTEE CHAIRMAN LAMAR S. SMITH

Congress of the United States
Washington, DC 20515

June 9, 2015

The Honorable Thomas L. Tidwell
Chief, U.S. Forest Service
Yates Building, 5th Floor, NW Wing
201 Fourteenth Street, SW
Washington, DC 20250

Dear Chief Tidwell,

The Committee on Science, Space, and Technology, and the Committee on Agriculture (“the Committees”) are conducting oversight of the effects of the U.S. Environmental Protection Agency’s (EPA) proposed ozone National Ambient Air Quality Standards (NAAQS) released on December 17, 2014, (“the proposed rule”) and its implications for your agency. EPA’s proposed rule may affect numerous U.S. Forest Service (USFS) programs including the service’s ability to conduct prescribed burning. As part of this oversight initiative, the Committees are writing to request documents and information relating to the effects these changes may have on the USFS.

As you may know, the EPA issued its proposed rule lowering the primary ozone standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. In addition to tightening the ozone standard, EPA also proposes to extend the ozone monitoring season in 33 states¹, significantly increasing the likelihood of new nonattainment designations. The regulatory burden flowing from this rule is likely to render it the costliest rule EPA has ever proposed. As it relates to USFS, we are concerned that your agency’s ability to conduct prescribed burns and appropriately manage wildfires will be negatively affected by the proposed rule. Prescribed burning is crucial to maintaining healthy ecosystems and is used as a preventative measure against future, more destructive, wildfires. According to EPA, prescribed burning can also benefit plant and animal species that depend on natural fires for propagation, habitat restoration, and reproduction. We agree with this assessment.

Wildland fires (a term that includes wildfires and prescribed fires) can increase ozone levels and cause non-attainment designation. EPA confirmed in its proposed rule that emissions from prescribed burning or wildfires are a component of background ozone and can “significantly contribute to periodic high O₃ levels.”² As EPA lowers the ozone standard, many more of these wildland fires will cause exceedances. According to EPA’s proposal, researchers have concluded that a policy focusing on suppressing wildfires “only delays the inevitable,

¹ <http://www.epa.gov/ttn/naaqs/standards/ozone/data/Rice-2014-O3MonitoringSeasonAnal-EPA-HQ-OAR-2008-0699-0383.pdf>

² National Ambient Air Quality Standards for Ozone, 79 Fed. Reg. 75234 (proposed Dec. 17, 2014) available at <http://www.gpo.gov/fdsys/pkg/FR-2014-12-17/pdf/2014-28674.pdf> (last visited May 27, 2015) [hereinafter NAAQS proposed rule].

promising more dangers and destructive fires.”³ The critical question, in this case, is whether EPA’s proposed lower ozone standards will allow USFS and the states sufficient flexibility to appropriately manage prescribed burning and wildfires given their effect on ozone levels. EPA states that the Clean Air Act requires the Agency “to set the NAAQS at levels requisite to protect public health and welfare without regard to the source of the pollutant,”⁴ but then also notes that EPA may consider “proximity to background levels as a factor in the decision to set a new standard.”⁵

The manner in which EPA balances these competing objectives will have significant repercussions for the USFS in managing fires and for state efforts to attain a lower standard. According to your agency’s statistics, there are “tens of thousands of wildland fires each year, impacting millions of acres. In 2012 alone, 67,774 wildland fires burned, covering 9,326,238 acres.”⁶ These statistics alone suggest that the ozone formed from most, if not all, wildland fires should be considered a part of background ozone whose proximity EPA may consider in setting a new standard.

By setting a lowering the ozone standard, many more expected wildland fires will cause ozone exceedances. To avoid nonattainment, states may be forced to submit hundreds if not thousands of exceptional event petitions. This will place an intolerable burden on states. Additionally, there are potentially adverse consequences for the USFS. As EPA states in the proposal, determining the impact of wildland fire emissions on specific ozone observations “is challenging” and can involve “a variety of analytical tools (e.g., regression modeling, back trajectories, satellite imagery, etc.) to support the exclusion of O₃ data affected by large fires”⁷ that are both expensive and time consuming to perform. If EPA determines wildland fires are to be considered part of background ozone, it could save USFS and the states time and money and have significant benefits in saving lives and improving environmental quality. On April 29, 2015, Oklahoma’s Secretary and Commissioner of Agriculture Jim Reese testified:

Prescribed burning is a technique that prevents wildfires, manages smoke contributions to the atmosphere, saves lives and property, and improves grassland and forest health. All these things are beneficial for the health of the environment, economy, and human health. Being in non-attainment because of this EPA proposed rule can prohibit these beneficial aspects of prescribed fire.⁸

EPA’s proposal to expand the ozone-monitoring season and to include ozone readings from the Agency’s monitors in remote areas will further compound the problem⁹ by increasing

³ Stephens, S.L., J.K. Agee, P.Z. Fulé, M.P. North, W.H. Romme, T.W. Swetnam, and M.G. Turner. 2013. Managing forests and fire in changing climates. *Science* 342:41-42. (doi: 10.1126/science.1240294)

⁴ NAAQS proposed rule.

⁵ *Id.*

⁶ Wild Land Fire & Fuel, About Wildland Fires, U.S. Dep’t of Agric., U.S. Forest Serv. *available at* <http://www.fs.fed.us/research/wildland-fire/> (last visited May 27, 2015).

⁷ *Id.*

⁸ *Reality Check Part II: The Impact of EPA’S Proposed Ozone Standards on Rural America*, 114th Cong. (Apr. 29, 2015) (statement of Jim Reese, Sec’y & Comm’r of Agric., Okla. State Bd. of Agric.).

⁹ *Id.*

the number of wildland fires that may contribute to possible ozone exceedances. It is unclear whether EPA fully understands the magnitude of the challenge and the significant costs it will impose on states and the USFS, if EPA lowers the existing ozone standard while expanding the ozone monitoring network and season as proposed.

In order to assist the Committees in understanding any analysis the USFS has engaged in with regard to the proposed rule, we request that the Service provide the following documents and information, in electronic format, unless otherwise noted below:

1. A narrative describing any and all steps taken by USFS to work with the EPA on the proposed rule, including but not limited to information related to the effect of wildland fires on ozone levels.
2. All documents and communications between and among employees of USFS and employees of EPA related to the proposed rule.
3. All documents and communications between and among employees of USFS and employees of the Office of Management and Budget referring or relating to EPA's proposed rule.
4. The USFS's best estimates of the millions of acres of USFS managed land that may be included in nonattainment areas if EPA expands the ozone-monitoring season as proposed and lowers the existing ozone standard to 70 ppb, 65 ppb or 60 ppb.
5. Estimates for 2013 and 2014 of the number of wildland fires in the US by state, and any USFS's projections for the next ten years with regards to the number of wildland fires.
6. Does the USFS operate any ozone monitors and if yes, where are the monitors located? Is data gathered from monitors shared with EPA?
7. A description of how previous ozone nonattainment designations have effected USFS management practices, including the management of wildland fires.
8. Has the USFS worked with states in the past to submit exceptional events petitions?

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X. The Committee on Agriculture is the principal authorizing committee for all matters related to agriculture in the House of Representatives and "shall have general oversight responsibilities" as set forth in House Rule X.

Please provide the requested documents and information, in electronic format, as soon as possible, but no later than 5:00 p.m. on June 23, 2015. When producing documents to the Committees, please deliver them to the following locations:

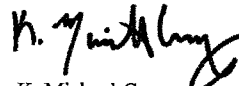
- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building; and,
- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building; and,
- Majority Staff of the House Agriculture Committee in Room 1300 of the Longworth House Office Building; and,
- Minority Staff of the House Agriculture Committee in Room 1010 of the Longworth House Office Building

If you have any questions about this request, please contact Richard Yamada of the Science Committee at 202-225-6371, or Ashley Callen of the Agriculture Committee staff at 202-225-2171. Thank you for your attention to this matter.

Sincerely,



Lamar Smith
Chairman
Committee on Science,
Space, and Technology



K. Michael Conaway
Chairman
Committee on Agriculture



Jim Bridenstine
Chairman
Subcommittee on Environment
Committee on Science,
Space, and Technology

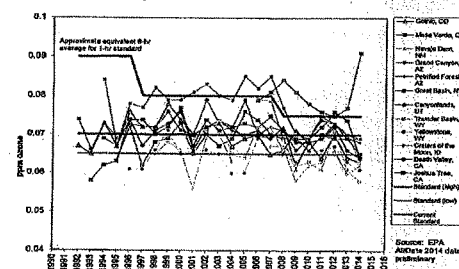
cc: The Honorable Eddie Bernice Bernice Johnson, Ranking Minority Member, House
Committee on Science, Space, and Technology

The Honorable Collin Peterson, Ranking Minority Member, House Committee on
Agriculture

The Honorable Jonathan Jarvis
Director
The National Park Service
1849 C Street, NW
Washington, D.C. 20240

On October 1, 2015, the Environmental Protection Agency is expected to finalize a regulatory proposal to lower the existing 75 parts per billion (ppb) ozone National Ambient Air Quality Standard (ozone NAAQS) to 65-70 ppb. In addition to imposing billions in new costs on cities across the country, an unheralded element of the proposed ozone standard is its potential impact on rural areas and our national parks.

FIGURE 3. Fourth High, Daily Maximum Ozone Values at Rural Monitors



Source: Colleen Dolanay, Utah DEQ, February 18, 2015 email

¹ Western States Air Resources Council, comments to House Science, Space, and Technology Committee, pg 13, 16 March, 2015. TS.

lack of air quality monitoring may have prevented these areas in the past from being formally classified as nonattainment, this will change due in part due to EPA's decision in 2011 to make the Agency's Clean Air Status and Trends Network (CASTNET) monitors regulatory compliant. As EPA notes, most CASTNET sites are located in rural or remote locations away from pollutant emission sources and heavily populated areas.² According to EPA, The National Park Service (NPS) operates more than 20 CASTNET sites within national parks and Class 1 areas.

The classification of parks as nonattainment areas under EPA's final ozone standard will trigger a number of control requirements under the Clean Air Act (CAA), including the development of a baseline emission inventory, new source review controls and permitting requirements, new obligations to achieve emission offsets, and the development of a state implementation plan. The nonattainment classification will also importantly trigger Transportation and General Conformity requirements under Section 176 of the CAA to assure that federal agencies do not "engage in, support in any way or provide financial assistance for, license or permit, or approve, any activity which does not conform to an implementation plan."³ A conformity determination must demonstrate that implementation of any project will not cause any new violations of the air quality standard, increase the frequency or severity of violations of the standard, or delay timely attainment of the standard or any interim milestone.

We note that in the past, the NPS response to a park nonattainment designation has been to request even larger nonattainment designations to help shift the emission control burden on to sources outside the park. While we agree that manmade sources outside the park should be appropriately evaluated, emission sources inside the parks cannot and should not escape scrutiny or compliance with the requirements of the CAA. In the operation of national parks, these strictures could affect a broad number of federal actions and management decisions that must now be evaluated against a motor vehicle emission budget and the overall goals of the state plan to identify sufficient emission reductions to bring the area into attainment.

In order to assist the Committees with their oversight, please produce the following documents, in electronic format:

- All documents and information on which national parks are currently classified as nonattainment areas based on current monitoring data as well as how many additional parks could be classified as a nonattainment area if EPA finalizes a 70 ppb, 65 ppb or 60 ppb standard. Also, please comment if you agree with the USFS initial estimates of the millions of acres in park service land that would be impacted.
- All documents and communication regarding NPS's position whether EPA's proposed standards are close to background ozone levels and the basis of how NPS makes this judgment.
- All documents and information on which national parks are currently subject to ozone maintenance plans.

² EPA, *Clean Air Status and Trends Network (CASTNET) 2012 Annual Report*, pg 5

³ <http://www.epa.gov/otaq/stateresources/transconf/regs/caasec176c.pdf>, pg 1

- All documents and information of all existing emission inventories, maintenance plans and nonattainment plans for US parks to comply with the current ozone NAAQS.
- All documents and information on the primary sources of ozone related emissions inside the parks and the steps the NPS has taken to reduce emissions inside the parks. Please list all nitrogen oxide (NOx) and volatile organic compound (VOC) emission producing equipment currently used in the parks.
- All documents and communications referring or related to NPS's ability to achieve the lower ozone standards at existing parks without having to close or limit the public's access to the parks. Please list what analyses the NPS conducts to make this determination.
- All documents and communications related to NPS's responsibility for the development of a baseline emission inventory of emission sources with the park, if EPA classifies a national park as a non-attainment area in addition to all documents and communications on NPS's interpretation of its obligations under the general conformity requirements of the CAA, specifically the daily activities and decisions that the NPS interprets as being covered under the CAA's Section 176 prohibition against any federal agency engaging in, supporting in any way or providing financial assistance for, the licensing or permitting, or approval, of any activity which does not conform to an implementation plan. Please state how the NPS will assure compliance.
- All documents and communications related to how the NPS will work with states in developing appropriate implementation plans that address national parks.
- All documents and information on approximately how many fires occur on national park lands annually. Please also provide all documents and communications related to how the NPS has conducted an analysis to determine their contribution to ozone values in the parks. Please provide all documentation related to the extent man-made emission sources outside the parks are being asked to reduce emissions in order to compensate for ozone created by fires.

When producing documents to the Committees, please deliver them to the following locations:

- Majority Staff of the House Committee on Natural Resources in 1324 Longworth House Office Building; and
- Minority Staff of the House Committee on Natural Resources in 1329 Longworth House Office Building; and
- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building; and,

- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building

The Committees appreciate your input on these important questions. Please respond no later than June 24, 2015. If you have any questions, please contact staff at the Committee on Science, Space, and Technology at (202) 225-6371 or staff at the Committee on Natural Resources at (202) 225-2761.

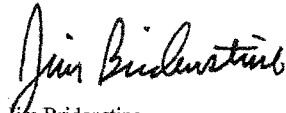
Sincerely,



Lamar Smith
Chairman
Science, Space, and Technology



Rob Bishop
Chairman
Natural Resources



Jim Bridenstine
Chairman
Environment Subcommittee
Science, Space, and Technology

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space, and Technology

The Honorable Raul Grijalva, Ranking Minority Member, House Committee on Natural Resources

Congress of the United States
Washington, DC 20515

July 28, 2015

The Honorable Jonathan Jarvis
Director
National Park Service
1849 C Street, NW
Washington, DC 20240

Dear Director Jarvis,

We are writing to acknowledge receipt of a July 27, 2015, letter from the National Park Service (NPS) in response to a letter that we wrote to you on June 10, 2015.

Unfortunately, the responses contained in NPS's letter are deficient and do not substantively address the specific requests contained in our original letter. Furthermore, NPS did not provide the Committee with any documents responsive to this request. It appears that NPS has completely disregarded the Committee's additional requests and has no plans to provide these additional documents. NPS's lack of effort in responding to our request leads the Committees to conclude that the NPS has not taken our request seriously and is attempting to obfuscate Congressional oversight of the NPS's role in the promulgation of the U.S. Environmental Protection Agency's proposed rule for ozone. Therefore, we ask that you provide all documents and communications responsive to the Committee's June 10, 2015, letter by August 5, 2015.

If NPS fails to provide the responsive documents by the deadline noted above, the Committees will consider use of compulsory process.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X. The Committee on Natural Resources is the principal authorizing committee for all matters related to public lands in the House of Representatives and "shall have general oversight responsibilities" as set forth in House Rule X.

Please provide the requested documents and information, in electronic format, as soon as possible, but no later than noon on August 5, 2015. When producing documents to the Committees, please deliver them to the following locations:

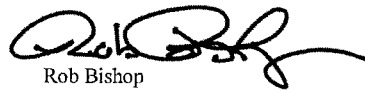
- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building; and,
- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building; and,
- Majority Staff of the House Committee on Natural Resources in Room 1324 of the Longworth House Office Building; and,
- Minority Staff of the House Committee on Natural Resources in Room 1329 of the Longworth House Office Building

If you have any questions about this request, please contact Richard Yamada of the Committee on Science, Space and Technology at 202-225-6371, or Casey Hammond of the Committee on Natural Resources at 202-225-2761. Thank you for your attention to this matter.

Sincerely,



Lamar Smith
Chairman
Committee on Science,
Space, and Technology



Rob Bishop
Chairman
Committee on Natural Resources



Jim Bridenstine
Chairman
Subcommittee on Environment
Committee on Science,
Space, and Technology

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space, and Technology

The Honorable Raul Grijalva, Ranking Minority Member, House Committee on Natural Resources

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

July 29, 2015

The Honorable Thomas L. Tidwell
Chief, U.S. Forest Service
Yates Building, 5th Floor, NW Wing
201 Fourteenth Street, SW
Washington, DC 20250

Dear Chief Tidwell:

We are writing to acknowledge receipt of the July 21, 2015, letter from the Office of Congressional Relations at the United States Department of Agriculture (USDA) in response to a letter that we wrote to you on June 9, 2015.

Unfortunately, the response was deficient and did not contain the majority of requested documents. Specifically, USDA only provided the Committees one document responsive to our request. As previously stated in our letter dated June 9, 2015, we are conducting oversight of the United States Forest Service's role in the promulgation of the U.S. Environmental Protection Agency's (EPA) proposed rule for ozone. This matter is time sensitive because EPA has set an October 1, 2015, deadline for finalizing the rule. With regard to this specific oversight initiative, the Committees are particularly interested in USDA fulfilling request numbers two and three. These are the priority. To reiterate, those requests included:

1. All documents and communications between and among employees of USFS and employees of EPA related to the proposed rule.
2. All documents and communications between and among employees of USFS and employees of the Office of Management and Budget referring or relating to EPA's proposed rule.

Please provide the priority requests noted above on or before August 5, 2015, and thereafter all other documents and communications requested in the Committees' June 9, 2015 letter.

If USDA fails to provide the response documents by the deadline noted above, the Committee will consider use of compulsory process.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

The Committee requests that USDA produce documents and communications, in electronic format. When producing documents to the Committees, please deliver them to the following locations:

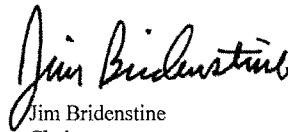
- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building; and,
- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building; and,

If you have any questions about this request, please contact Richard Yamada of the Science Committee at 202-225-6371. Thank you for your attention to this matter.

Sincerely,



Lamar Smith
Chairman
Committee on Science,
Space, and Technology



Jim Bridenstine
Chairman
Subcommittee on Environment
Committee on Science,
Space, and Technology

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space, and Technology

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

August 31, 2015

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

On December 17, 2014, the U.S. Environmental Protection Agency (EPA) issued its proposed rule for ozone National Ambient Air Quality Standards (NAAQS). The proposed rule would set more stringent standards, lowering the primary standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. If enacted, this rule is likely to be the costliest rule EPA has ever proposed.¹

We are concerned that EPA may not have properly analyzed the underlying scientific issues that have been raised since the official comment period for the rule has closed. These issues include serious concerns raised about background ozone and the reliance on a single study as the basis for setting the proposed standard. The American people deserve a thorough and complete analysis of this proposed rule.

The Committee is concerned about the impact of background ozone on the attainability of EPA's proposed ozone standard across the entire United States. Background ozone comes from both natural sources and foreign emission sources.² As EPA admits its proposed rule:

[T]here is no question that, as the levels of alternative prospective standards are lowered, background will represent increasingly larger fractions of total O₃ levels and may subsequently complicate efforts to attain these standards.³

¹ <http://www.nam.org/Newsroom/Press-Releases/2015/02/NAM--Proposed-Ozone-Rule-Still-The-Most-Costly/>

² <http://www.asl-associates.com/natural.htm>

³ Federal Register, Vol. 79, No. 242 75383

The Honorable Gina McCarthy
August 31, 2015
Page 2

In testimony before the Committee and in response to follow-up questions from Committee Members, Dr. Allen Lefohn, an expert on ozone and a past Executive Editor of the journal *Atmospheric Environment*, indicated that the large amount of emission reductions required to meet EPA's proposed lower ozone standard highlights the importance of background ozone levels throughout the U.S.⁴ Dr. Lefohn also noted that ozone formed from background sources across the U.S. predominates during the spring months when anthropogenic sources have a much smaller impact.⁵ We are concerned about modeling results that indicate that exceedances of the proposed ozone standard will occur during the springtime, even when emissions are dramatically reduced across the U.S.⁶ EPA's recent proposal⁷ to extend the ozone-monitoring period to include the month of March will identify violations of the proposed standard that are associated with uncontrollable factors, which is especially concerning.⁸ Furthermore, the locations affected by the aforementioned monitoring season change can appear anywhere across the U.S., creating compliance issues for the entire country, not exclusively limited to the western U.S.⁹

In addition to concerns related to background ozone, the Committee notes that EPA's proposed rule places the greatest weight on controlled human exposure studies, citing significant uncertainties with epidemiologic studies:

[T]he effects reported in controlled human exposure studies are due solely to O₃ exposures, and interpretation of study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies). Therefore, she places the most weight on information from these controlled human exposure studies.¹⁰

Of these human exposure studies, however, it appears that only *one* controlled human exposure study, published in 2009 by Schelegle et al., shows effects that may be considered adverse at ozone concentrations below the current standard.¹¹ The Schelegle study found small, reversible impacts at ozone concentrations roughly equivalent to 72 ppb.¹² EPA's proposed rule notes that controlled human exposure studies at lower ozone concentrations (60 and 63 ppb) "did not show statistically significant increases in respiratory symptoms compared to filtered air controls."¹³

⁴ <http://docs.house.gov/meetings/SY/SY00/20150317/103159/HHRG-114-SY00-Wstate-LefohnA-20150317.pdf>

⁵ H. Comm. on Science, Space and Technology, *Reality Check: The Impact and Achievability of EPA's Proposed Ozone Standards*, 114th Congress (Mar. 17, 2015), Questions for the Record, Dr. Allen Lefohn

⁶ *Ibid*

⁷ <http://www.epa.gov/ttn/naaqs/standards/ozone/data/Rice-2014-O3MonitoringSeasonAnal-EPA-HQ-OAR-2008-0699-0383.pdf>

⁸ H. Comm. on Science, Space and Technology, *Reality Check: The Impact and Achievability of EPA's Proposed Ozone Standards*, 114th Congress (Mar. 17, 2015), Questions for the Record, Dr. Allen Lefohn

⁹ *Ibid*

¹⁰ 75288, Federal Register, Vol. 79, No. 242

¹¹ Schelegle et al., 6.6-Hour Inhalation of Ozone Concentrations from 60 to 87 Parts per Billion in Healthy Humans, *Am J Respir Crit Care Med*. 2009 Aug 1;180(3):265-72.

¹² *Ibid*

¹³ 75304, Federal Register, Vol. 79, No. 242

The Honorable Gina McCarthy
 August 31, 2015
 Page 3

Based on this evidence, the proposal states that the Administrator concludes that the controlled human exposure studies “strongly support setting the level of a revised [ozone] standard no higher than 70 ppb.”¹⁴

However, the 2009 Schelegle et al. study contains serious deficiencies that were not discussed in the proposed rule. For example, this study does not replicate key results from previous peer-reviewed studies, and another peer-reviewed study¹⁵ has raised questions about the lack of consistency between Schelegle’s results and the two studies by Adams et al (2003, 2006).¹⁶

We noted that there was a relative lack of coherence of the 70 and 80 ppb experiments reported by Schelegle et al. (2009) compared with the other 4 studies, as well as an inconsistency of response by subjects.¹⁷

The Committee is concerned with such a heavy reliance on one potentially flawed study as basis for EPA’s proposed rule, and believes that these concerns warrant further deliberation before EPA finalizes the rule.

The aforementioned concerns raise many questions about the necessity and validity of enacting a new, more stringent ozone NAAQS rule. In order to assist the Committee with its oversight, please provide the following documents, in electronic format:

1. All documents and communications referring or relating to EPA’s analysis of the influence of background ozone in the springtime on the attainment of a lower ozone standard throughout the entire United States.
2. All documents and communications referring or relating to EPA’s analysis of the relationship between background ozone and the anthropogenic emissions reductions that will be required during both the summer and the spring to attain the proposed lower standards.
3. All documents and communications referring or relating to any plan or strategy to address the influence of background ozone on the attainment of a lower ozone standard.
4. All documents and communications referring or relating to EPA’s analysis of estimates for mortality and morbidity health risk that were influenced by background ozone and also by anthropogenic sources, as ozone emissions are reduced.

¹⁴ 75304, Federal Register, Vol. 79, No. 242

¹⁵ Lefohn AS, Hazucha MJ, Shadwick D, Adams WC., “An alternative form and level of the human health ozone standard”, *Inhal Toxicol.* 2010 Oct;22(12):999-1011

¹⁶ Adams W.C. Comparison of chamber 6.6-h exposures to 0.04-0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhal Toxicol* 2006;18:127-136

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

¹⁷ Lefohn AS, Hazucha MJ, Shadwick D, Adams WC., “An alternative form and level of the human health ozone standard”, *Inhal Toxicol.* 2010 Oct;22(12):999-1011

The Honorable Gina McCarthy
August 31, 2015
Page 4

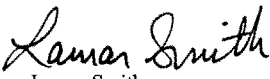
5. All documents and communications referring or relating to EPA's analysis of the influence of background ozone and anthropogenic sources on lung function risk estimates.
6. All documents and communications referring or related to the 2009 Schelegle et al. study.
7. All documents and communications between EPA and the Office of Management and Budget (OMB) regarding background ozone issues and the 2009 Schelegle et al study.
8. All documents and communications between EPA and outside groups referring or related to the 2009 Schelegle et al study.

Because the rule must be finalized by October 1, 2015, please provide responses as soon as possible, but no later than 5:00 p.m. on Monday, September 14, 2015. When producing documents to the Committee, please deliver production sets to the following locations:

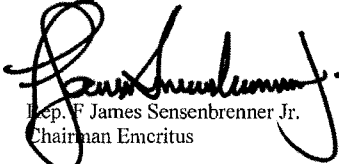
- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building
- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building

If you have any questions about this request, please contact Richard Yamada or Joe Brazauskas of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

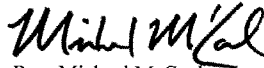

Rep. Lamar Smith
Chairman


Rep. Frank Lucas
Vice Chairman


Rep. F. James Sensenbrenner Jr.
Chairman Emeritus


Rep. Dana Rohrabacher
Member of Congress

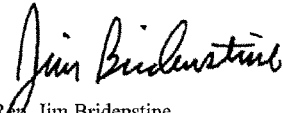

Rep. Randy Neugebauer
Member of Congress


Rep. Michael McCaul
Member of Congress

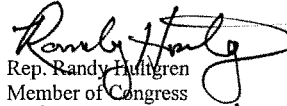
The Honorable Gina McCarthy
August 31, 2015
Page 5



Rep. Mo Brooks
Member of Congress



Rep. Jim Bridenstine
Chairman
Subcommittee on Environment



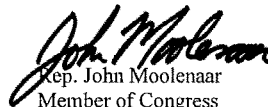
Rep. Randy Hultgren
Member of Congress



Rep. Randy Weber
Chairman
Subcommittee on Energy



Rep. Bill Johnson
Member of Congress



Rep. John Moolenaar
Member of Congress



Rep. Steve Knight
Member of Congress



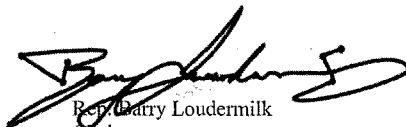
Rep. Brian Babin
Chairman
Subcommittee on Space



Rep. Bruce Westerman
Member of Congress



Rep. Gary Palmer
Member of Congress



Rep. Garry Loudermilk
Chairman
Subcommittee on Oversight



Rep. Ralph Lee Abraham
Member of Congress

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on
Science, Space and Technology

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

August 31, 2015

The Honorable Shaun Donovan
The Office of Management and Budget
Eisenhower Executive Office Building, Room 251
1650 Pennsylvania Avenue, NW
Washington, DC

Dear Director Donovan:

On December 17, 2014, the U.S. Environmental Protection Agency (EPA) issued its proposed rule for ozone National Ambient Air Quality Standards (NAAQS). The proposed rule would set more stringent standards, lowering the primary standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. If enacted, this rule is likely to be the costliest rule EPA has ever proposed.¹

We are concerned that EPA may not have properly analyzed the underlying scientific issues that have been raised since the official comment period for the rule has closed. These issues include serious concerns raised about background ozone and the reliance on a single study as the basis for setting the proposed standard. The American people deserve a thorough and complete analysis of this proposed rule.

The Committee is concerned about the impact of background ozone on the attainability of EPA's proposed ozone standard across the entire United States. Background ozone comes from both natural sources and foreign emission sources.² As EPA admits in its proposed rule:

[T]here is no question that, as the levels of alternative prospective standards are lowered, background will represent increasingly

¹ Press Release, Nat'l Assoc. of Manufacturers, *NAM: Proposed Ozone Rule Still Most Costly in U.S. History*, Feb. 26, 2015, available at <http://www.nam.org/Newsroom/Press-Releases/2015/02/NAM--Proposed-Ozone-Rule-Still-The-Most-Costly/>.

² A.S.L. & Associates, *Natural Background: An Important Issue*, available at <http://www.asl-associates.com/natural.htm>.

The Honorable Shaun Donovan
August 31, 2015
Page 2

larger fractions of total O₃ levels and may subsequently complicate efforts to attain these standards.³

In testimony before the Committee and in response to follow-up questions from Committee Members, Dr. Allen Lefohn, an expert on ozone and a past Executive Editor of the journal *Atmospheric Environment*, indicated that the large amount of emission reductions required to meet EPA's proposed lower ozone standard highlights the importance of background ozone levels throughout the U.S.⁴ Dr. Lefohn also noted that ozone formed from background sources across the U.S. predominates during the spring months when anthropogenic sources have a much smaller impact.⁵ We are concerned about modeling results that indicate that exceedances of the proposed ozone standard will occur during the springtime, even when emissions are dramatically reduced across the U.S.⁶ EPA's recent proposal to extend the ozone-monitoring period to include the month of March will identify violations of the proposed standard that are associated with uncontrollable factors, which is especially concerning.⁷ Furthermore, the locations affected by the aforementioned monitoring season change can appear anywhere across the U.S., creating compliance issues for the entire country, not exclusively limited to the western U.S.⁸

In addition to concerns related to background ozone, the Committee notes that EPA's proposed rule places the greatest weight on controlled human exposure studies, citing significant uncertainties with epidemiologic studies:

[T]he effects reported in controlled human exposure studies are due solely to O₃ exposures, and interpretation of study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies). Therefore, she places the most weight on information from these controlled human exposure studies.⁹

Of these human exposure studies, however, it appears that only *one* controlled human exposure study, published in 2009 by Schelegle et al., shows effects that may be considered adverse at

³ Nat'l Ambient Air Quality Standards for Ozone; Proposed Rule, 79 Fed. Reg. 75,383 (Dec. 17, 2014) (to be codified at 40 CFR Parts 50, 51, 52, et al.).

⁴ H. Comm. on Science, Space and Technology, *Reality Check: The Impact and Achievability of EPA's Proposed Ozone Standards*, 114th Congress (Mar. 17, 2015), Testimony of Dr. Allen Lefohn.

⁵ H. Comm. on Science, Space and Technology, *Reality Check: The Impact and Achievability of EPA's Proposed Ozone Standards*, 114th Congress (Mar. 17, 2015), Questions for the Record, Dr. Allen Lefohn.

⁶ *Id.*

⁷ U.S. EPA, Memorandum From Joan Rice to Ozone NAAQS Docket, Nov. 19, 2014, *available at* <http://www.epa.gov/ttn/naaqs/standards/ozone/data/Rice-2014-O3MonitoringSeasonAnal-EPA-HQ-OAR-2008-0699-0383.pdf>; H. Comm. on Science, Space and Technology, *Reality Check: The Impact and Achievability of EPA's Proposed Ozone Standards*, 114th Congress (Mar. 17, 2015), Questions for the Record, Dr. Allen Lefohn.

⁸ *Id.*

⁹ Nat'l Ambient Air Quality Standards for Ozone; Proposed Rule, 79 Fed. Reg. 75,383 (Dec. 17, 2014) (to be codified at 40 CFR Parts 50, 51, 52, et al.).

The Honorable Shaun Donovan
August 31, 2015
Page 3

ozone concentrations below the current standard.¹⁰ The Schelegle study found small, reversible impacts at ozone concentrations roughly equivalent to 72 ppb.¹¹ EPA's proposed rule notes that controlled human exposure studies at lower ozone concentrations (60 and 63 ppb), "did not show statistically significant increases in respiratory symptoms compared to filtered air controls."¹² Based on this evidence, the proposal states that the Administrator concludes that the controlled human exposure studies "strongly support setting the level of a revised [ozone] standard no higher than 70 ppb."¹³

However, the 2009 Schelegle et al. study contains serious deficiencies that were not discussed in the proposed rule. For example, this study does not replicate key results from previous peer-reviewed studies, and another peer-reviewed study has raised questions about the lack of consistency between Schelegle's results and the two studies by Adams et al (2003, 2006).¹⁴

We noted that there was a relative lack of coherence of the 70 and 80 ppb experiments reported by Schelegle et al. (2009) compared with the other 4 studies, as well as an inconsistency of response by subjects.¹⁵

The Committee is concerned with such a heavy reliance on one potentially flawed study as basis for EPA's proposed rule, and believes that these concerns warrant further deliberation before EPA finalizes the rule.

As of today, one of the most expensive rules ever issued by EPA, affecting almost every sector of the economy, will now have only 34 days of interagency review. OMB's role in the regulatory review process is to ensure adequate review of the final draft rule.¹⁶ We have serious concerns that given the purported impacts of this rule, this amount of time is inadequate for serious interagency review.

The aforementioned concerns raise many questions about the necessity and validity of enacting a new, more stringent ozone NAAQS rule. In order to ensure that OMB has undertaken adequate and proper analysis of the ozone NAAQS rule, please provide the following documents:

¹⁰ Schelegle et al., 6.6-Hour Inhalation of Ozone Concentrations from 60 to 87 Parts per Billion in Healthy Humans, *Am. J. Respir. Crit. Care Med.* Aug. 1, 2009.

¹¹ *Id.*

¹² Nat'l Ambient Air Quality Standards for Ozone; Proposed Rule, 79 Fed. Reg. 75,304 (Dec. 17, 2014) (to be codified at 40 CFR Parts 50, 51, 52, et al.).

¹³ *Id.*

¹⁴ Lefohn AS, Hazucha MJ, Shadwick D, Adams WC., An Alternative Form and Level of the Human Health Ozone Standard, *Inhal Toxicol.* Oct. 22, 2010; Adams W.C., Comparison of Chamber 6.6-h exposures to 0.04-0.08 ppm Ozone Via Square-wave and Triangular Profiles on Pulmonary Responses. *Inhal Toxicol* 2006; Adams W.C., Comparison of Chamber and Face-mask 6.6-hour Exposure to 0.08 ppm Ozone Via Square-wave and Triangular Profiles on Pulmonary Responses, *Inhal Toxicol* 2003.

¹⁵ Lefohn AS, Hazucha MJ, Shadwick D, Adams WC., An Alternative Form and Level of the Human Health Ozone Standard, *Inhal Toxicol.* Oct. 22, 2010.

¹⁶ https://www.whitehouse.gov/omb/OIRA_QsandAs

The Honorable Shaun Donovan
August 31, 2015
Page 4

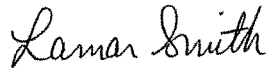
1. All documents and communications between or among OMB, EPA, and the Executive Office of the President referring or relating to background ozone.
2. All documents and communications between or among OMB, EPA, and the Executive Office of the President referring or relating to the 2009 Schelegle et al. study.
3. All documents and communications between or among OMB and all other Federal Agencies referring or relating to whether these Agencies had an adequate opportunity and time to properly review, evaluate, and comment on the draft final rule.
4. All documents and communications between or among OMB, EPA, and the Executive Office of the President referring or relating to whether EPA will have an adequate opportunity and time to properly evaluate and incorporate comments from other Federal Agencies on the draft final ozone NAAQS rule

Because the rule must be finalized by October 1, 2015, please provide responses as soon as possible, but no later than 5:00 p.m. on Monday, September 14, 2015. When producing documents to the Committee, please deliver production sets to the following locations:

- Majority Staff of the House Science Committee in Room 2321 of the Rayburn House Office Building
- Minority Staff of the House Science Committee in Room 394 of the Ford House Office Building

If you have any questions about this request, please contact Richard Yamada or Joe Brazauskas of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,



Rep. Lamar Smith
Chairman



Rep. Frank Lucas
Vice Chairman



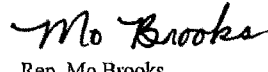
Rep. Dana Rohrabacher
Member of Congress

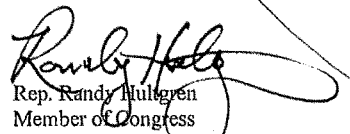


Rep. Randy Neugebauer
Member of Congress

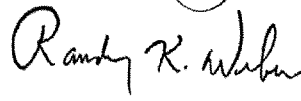
The Honorable Shaun Donovan
August 31, 2015
Page 5


Rep. Mike McCaul
Member of Congress

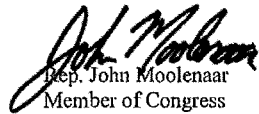

Rep. Mo Brooks
Member of Congress


Rep. Randy Hultgren
Member of Congress


Rep. Jim Bridenstine
Chairman
Subcommittee on Environment

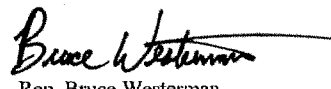

Rep. Randy Weber
Chairman
Subcommittee on Energy

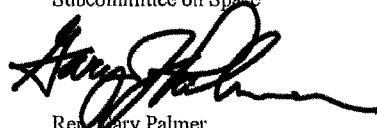

Rep. Bill Johnson
Member of Congress

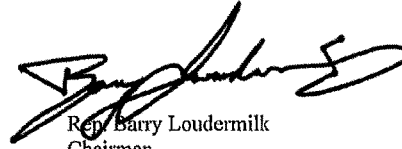

Rep. John Moolenaar
Member of Congress


Rep. Steve Knight
Member of Congress


Rep. Brian Babin
Chairman
Subcommittee on Space


Rep. Bruce Westerman
Member of Congress


Rep. Gary Palmer
Member of Congress


Rep. Barry Loudermilk
Chairman
Subcommittee on Oversight

The Honorable Shaun Donovan
August 31, 2015
Page 6

A handwritten signature in black ink, appearing to read 'R. Lee Abraham', with a long horizontal flourish extending to the right.

Rep. Ralph Lee Abraham
Member of Congress

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on
Science, Space and Technology

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

September 24, 2015

Mr. Denis McDonough
Chief of Staff
The White House
Washington, DC 20500

Dear Mr. McDonough:

On December 17, 2014, the U.S. Environmental Protection Agency (EPA) issued its proposed rule for ozone National Ambient Air Quality Standards (NAAQS). The proposed rule would set more stringent standards, lowering the primary standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. If enacted, this rule is likely to be the costliest rule EPA has ever issued.¹

The Committee is concerned with recent news reports related to EPA's proposed final standard, which was submitted to OMB on August 28, 2015, for final review before publication by October 1, 2015. These reports suggest that officials within various White House offices are urging the President to disregard EPA's suggested final standard in favor of a stricter limit preferred by environmental lobbying organizations. For example, one report states that "EPA appears intent on finalizing a 'primary' health-based NAAQS of 70 ppb, but faces calls from the White House Council on Environmental Quality (CEQ) to choose a stricter 68 ppb limit," and that outside groups are meeting with the Administration "to argue for their preferred level for the air standard."² Other news reports relay a similar narrative.³

Any new lower ozone standard is unnecessary at this time and could cause devastating harm to the economy. However, it is even more troubling that whatever scientific analyses used by EPA to determine its final recommended limit are being disregarded by White House officials for purely political reasons. The American people deserve a thorough, science-based analysis of the proposed ozone rule, not one based on partisan political considerations.

¹Nat'l Assoc. of Manufacturers, Press Release, *NAM: Proposed Ozone Rule Still Most Costly in U.S. History*, Feb. 26, 2015, available at <http://www.nam.org/Newsroom/Press-Releases/2015/02/NAM--Proposed-Ozone-Rule-Still-The-Most-Costly/>.

²Stuart Parker, *EPA Said To Support 70 ppb Standard In Final Ozone NAAQS Rulemaking*, Inside EPA, Sept. 3, 2015 available at <http://insideepa.com/daily-news/epa-said-support-70-ppb-standard-final-ozone-naaqs-rulemaking>.

³Amanda Reilly, Greenwire, *White House sets stakeholder meetings on EPA ozone plan*, Sept. 4, 2015, available at <http://www.eenews.net/greenwire/2015/09/04/stories/1060024285>.

Denis McDonough
September 24, 2015
Page 2

To assist the Committee's efforts to ensure adherence to sound science and objective analysis in agency rulemaking, please produce the following documents in electronic format:

1. All documents and communications between or among the Office of Management and Budget, the Executive Office of the President, and the EPA referring or relating to the final ozone NAAQS rule.
2. All documents and communications between or among the Office of Management and Budget, the Executive Office of the President, and outside groups, including but not limited to the Natural Resources Defense Council, Sierra Club, and the League of Conservation Voters referring or relating to the final ozone NAAQS rule.

Additionally, I request that the following individuals be made available for transcribed interviews:

1. Howard Shelanski, Administrator, Office of Information and Regulatory Affairs
2. Christy Goldfuss, Managing Director, Council on Environmental Quality

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

Please provide the requested documents and information, as soon as possible, but no later than noon on October 8, 2015. When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 394 of the Ford House Office Building. The Committee prefers, if possible, to receive all documents in electronic format.

If you have any questions about this request, please contact Richard Yamada or Joe Brazauskas of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,



Rep. Lamar Smith
Chairman
Committee on Science, Space,
and Technology

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

September 24, 2015

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

On December 17, 2014, the U.S. Environmental Protection Agency (EPA) issued its proposed rule for ozone National Ambient Air Quality Standards (NAAQS). The proposed rule would set more stringent standards, lowering the primary standard from the current 75 parts per billion (ppb) to a range of 65 to 70 ppb. If enacted, this rule is likely to be the costliest rule EPA has ever issued.¹

The Committee is concerned with recent news reports related to EPA's proposed final standard, which was submitted to OMB on August 28, 2015, for final review before publication by October 1, 2015. These reports suggest that officials within various White House offices are urging the President to disregard EPA's suggested final standard in favor of a stricter limit preferred by environmental lobbying organizations. For example, one report states that "EPA appears intent on finalizing a 'primary' health-based NAAQS of 70 ppb, but faces calls from the White House Council on Environmental Quality (CEQ) to choose a stricter 68 ppb limit," and that outside groups are meeting with the Administration "to argue for their preferred level for the air standard."² Other news reports relay a similar narrative.³

Any new lower ozone standard is unnecessary at this time and could cause devastating harm to the economy. However, it is even more troubling that whatever scientific analyses used

¹ Press Release, Nat'l Assoc. of Manufacturers, *NAM: Proposed Ozone Rule Still Most Costly in U.S. History*, Feb. 26, 2015, available at <http://www.nam.org/Newsroom/Press-Releases/2015/02/NAM--Proposed-Ozone-Rule-Still-The-Most-Costly/>.

² Stuart Parker *EPA Said To Support 70 ppb Standard In Final Ozone NAAQS Rulemaking*, Inside EPA, Sept. 3, 2015 available at <http://insideepa.com/daily-news/epa-said-support-70-ppb-standard-final-ozone-naaqs-rulemaking>

³ Amanda Reilly, *White House sets stakeholder meetings on EPA ozone plan*, Greenwire, Sept. 4, 2015, available at <http://www.eenews.net/greenwire/2015/09/04/stories/1060024285>.

The Honorable Gina McCarthy
September 24, 2015
Page 2

by EPA to determine its final recommended limit are being disregarded by White House officials for purely political reasons. The American people deserve a thorough, science-based analysis of the proposed ozone rule, not one based on partisan political considerations.

To assist the Committee's efforts to ensure adherence to sound science and objective analysis in agency rulemaking, please produce the following documents in electronic format:

1. All documents and communications between or among EPA, Office of Management and Budget, and the Executive Office of the President referring or relating to the final ozone NAAQS rule.

Additionally, I request that the following individuals be made available for transcribed interviews:

1. Janet McCabe, Acting Assistant Administrator, Office of Air and Radiation
2. Joel Beauvais, Associate Administrator, Office of Policy

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

Please provide the requested documents and information, as soon as possible, but no later than noon on October 8, 2015. When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 394 of the Ford House Office Building. The Committee prefers, if possible, to receive all documents in electronic format.

If you have any questions about this request, please contact Richard Yamada or Joe Brazauskas of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

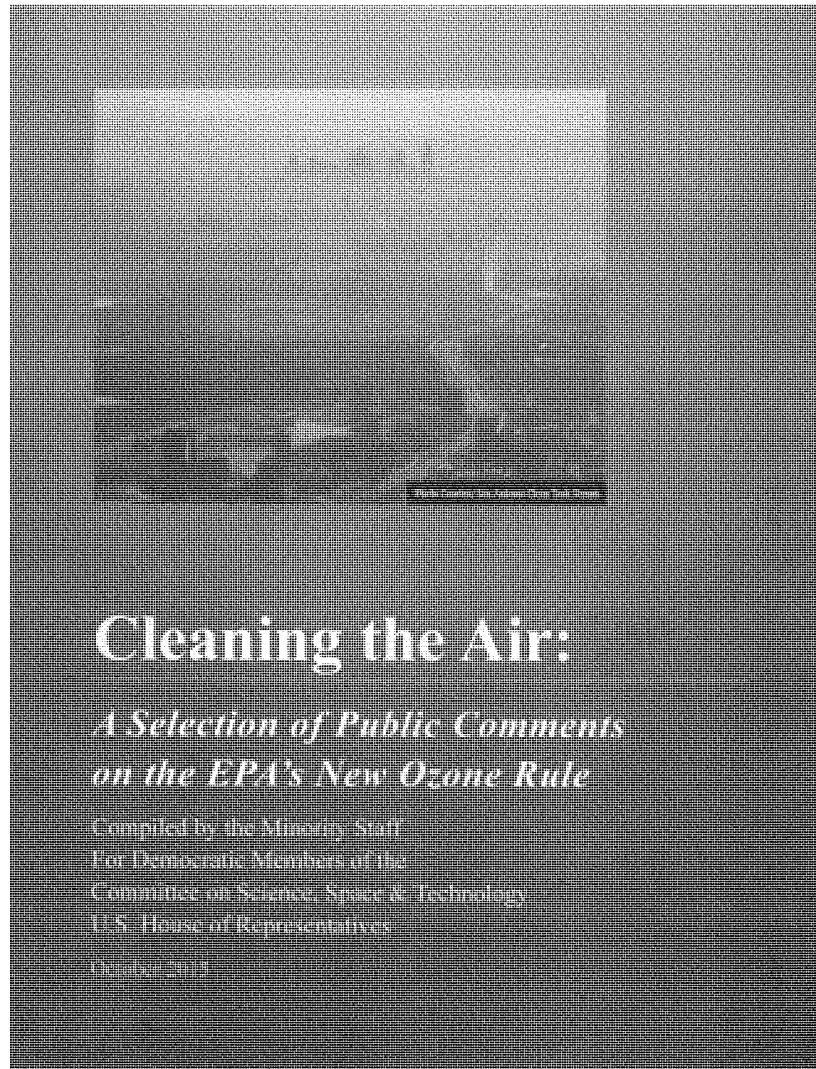
Sincerely,



Rep. Lamar Smith
Chairman
Committee on Science, Space,
and Technology

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

REPORT SUBMITTED BY COMMITTEE RANKING MEMBER EDDIE BERNICE JOHNSON



Cleaning the Air:

A Selection of Public Comments on the EPA’s New Ozone Rule

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Public Health Consequences of Ozone	4
Why Smoke is Harmful - Graphic	
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Ozone Economics	20
Ozone Graphic	

2

Background

On October 1, 2015, the Environmental Protection Agency (EPA) lowered the National Ambient Air Quality Standards (NAAQS) for ground-level ozone from 75 parts per billion (ppb) to 70 ppb to better protect the public's health. Ground level ozone is created by the chemical reactions between oxides of nitrogen (NO_x) and volatile organic compounds (VOC) when they are exposed to sunlight. Major sources of these two chemicals include industrial facilities, electric utilities, vehicles exhaust and gasoline fumes. Ozone is a key component in smog and scientific evidence that exposure to ozone harms the environment and human health, particularly those with respiratory illnesses, such as asthma, has been known for decades and has been accumulating steadily for years.

In 2008, under the George W. Bush administration, the ozone standard was lowered from 80-parts-per-billion (80 ppb) to 75 ppb. However, at the time, the 18 members of the Clean Air Scientific Advisory Committee's (CASAC's) Ozone Review Panel (composed of medical professionals and scientists) unanimously opposed this move, endorsing instead a National Ambient Air Quality Standard (NAAQS) for ozone of between 60 and 70 ppb. In a letter to the then EPA Administrator Stephen Johnson, they argued: "[T]he members of the CASAC Ozone Review Panel do not endorse the new primary ozone standard as being sufficiently protective of public health." Furthermore, they wrote: "It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard [at 75-ppb] fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

The EPA's recent decision to further lower the ozone standard to 70 ppb was based on a review of nearly 2,300 studies, including more than 1,000 new studies published since the 2008 review. As would be expected, the EPA's decision was strongly criticized by the industries who release precursor ozone chemicals into the environment, including the National Association of Manufacturers, the American Petroleum Institute, and the American Chemistry Council. These industries have used tactics first employed by the tobacco industry in the 1960s to raise doubts about the scientific and medical evidence that supports a lowering of the ozone standard, and they claim that implementing the new standard will result in job losses and dire economic consequences.

In stark contrast, the vast majority of public health organizations support a lower ozone standard and believe the new rule will help reduce healthcare costs substantially, such as the \$56 billion spent on medical costs and lost productivity due to complications from asthma each year. The new rule should help diminish those costs. Many medical organizations have pushed for an ozone rule of 60 ppb, but believe any reduction in the amount of ground-level ozone will be beneficial. Unlike the for-profit industries opposed to the new EPA regulation, the public health community believes there is *no doubt* that reducing ozone is a necessary step to help better protect the public's health.

In its decision to reduce the ozone standard from 75-to-70 ppb the EPA received more than 430,000 written comments on the proposed standard. The report below includes excerpts of those comments, divided into three key sections: 1) Public Health; 2) Environmental Justice; and 3) Economics. These public comments were accessed from www.regulations.gov.

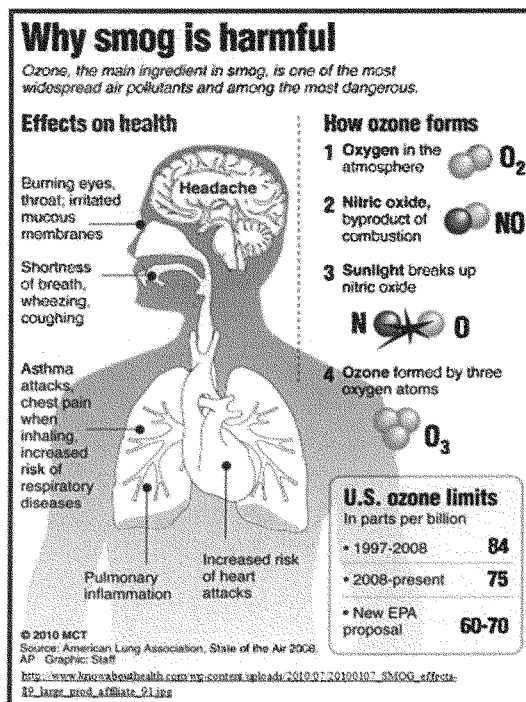
The excerpts included here are from well-established national medical organizations, such as the American Lung Association, and other organizations that were supportive of the EPA's efforts to reduce the levels of ozone pollution in the environment. To see the levels of ground-level ozone in your location visit www.airnow.gov or the American Lung Association's www.stateoftheair.org.



Public Health Consequences of Ozone Pollution

The public health consequences from ozone pollution are significant. This is particularly true for large segments of our society who suffer from respiratory illnesses, including nearly 26 million Americans with asthma, including 10 percent of all children, who are most at risk from high levels of ozone. Asthma is a complicated multifaceted disease that has genetic roots and is exacerbated by environmental factors, such as exposure to ozone. In the U.S. alone, each year asthma accounts for almost 2 million emergency room visits, 439,000 hospitalizations, more than 14 million doctor visits, 14 million lost work days, more than 10.5 million lost school days and 3,600 deaths.

The American Heart Association, American Lung Association, American Medical Association, American Public Health Association, American Thoracic Society, Asthma and Allergy Foundation of America and American Academy of Pediatrics, among many other public health organizations, have supported an EPA ozone rule as low as 60 part-per-billion (ppb), which they believe is truly protective of the health and safety of *all* individuals. These organizations argue that an ozone level of 60 ppb would prevent up to 7,900 premature deaths annually, 1.8 million asthma attacks in children and 1.9 million missed school days nationwide. They believe the EPA move to push the ozone standard down from 75 ppb to 70 ppb is a good step, but does not go far enough.



The text which follows includes public comments submitted to the EPA prior to October 1, 2015, on the "Proposed Rule: National Ambient Air Quality Standards for Ozone." The comments were submitted by public health organizations, medical associations and environmental justice groups.



Physicians Caring for Texans

<http://www.texmed.org/>

Mission

Texas Medical Association was organized by 35 physicians in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and the improvement of public health. Today, with more than 48,000 physician and medical student members, TMA is the nation's largest state medical society.



<http://www.dallas-cms.org/>

Mission

Established in 1876, the mission of the Dallas County Medical Society is to advocate for physicians and their patients, to promote a healthy community and to enhance professionalism in the practice of medicine.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-2792>

5

Robert W. Haley, MD, FACE, F ACP
 Dallas County Medical Society & Texas Medical Association
 Before the
 U.S. Environmental Protection Agency
 "Proposed Rule: National Ambient Air Quality Standards for Ozone"
 Arlington, Texas

January 29, 2015

"... I'm a specialist in internal medicine at Parkland Hospital in Dallas and a medical epidemiologist with 40 years' experience doing epidemiologic research and teaching epidemiology and statistics. ... In my testimony today I represent the 7,000 physicians of the Dallas County Medical Society and the 45,000 physicians of the Texas Medical Association."

"The physicians of our state ... are very concerned about the effects of air pollution on the health of our patients, especially the effects of high ground-level ozone

(The 7,000 physicians of the Dallas County Medical Society, supported by the 45,000 physicians of the Texas Medical Association, strongly endorse lowering the ozone standard 10 ppb to 65 ppb, or lower.

concentrations on asthma attacks in children, chronic lung disease exacerbations, and heart attacks in our older patients, and premature deaths in all age groups. Our reading of the scientific literature finds compelling evidence for the adverse effects of ozone on human health down to ozone levels of around 40 ppb."

"We've heard recent arguments by state environmental officials claiming that ozone levels below 75 ppb do not harm human health and may even be beneficial, based on the fact that asthma rates are highest in the winter when ozone levels are the lowest. However, every physician knows that colds and influenza infections and cold temperatures, which occur mostly in the winter, are the main cause of the high rates of asthma and chronic lung disease exacerbations in the winter, just as high ozone levels are an important contributor in the summer."

"As physicians who care for these patients and see the asthma attacks, respiratory failure, hospitalizations and premature deaths ... the 7,000 physicians of the Dallas County Medical Society, supported by the 45,000 physicians of the Texas Medical Association, strongly endorse lowering the ozone standard 10 ppb to 65 ppb, or lower."



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

<https://www.aap.org/>

Mission

The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults. The AAP is a professional membership organization of 64,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents and young adults.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-0671>

Samantha Ahdoot, MD, FAAP
On behalf of the
American Academy of Pediatrics
Before the

U.S. Environmental Protection Agency
“Proposed Rule: National Ambient Air Quality Standards for Ozone”

January 29, 2015

“My name is Dr. Samantha Ahdoot; I am here representing the American Academy of Pediatrics (AAP), a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists.... The AAP supports the EPA’s proposed ozone pollution limits of between 65 and 70 parts per billion (ppb) as a critical and overdue first step. There is clear and compelling scientific evidence that supports the need for an even stricter standard of 60 ppb, or even lower, but bringing down the allowable ozone pollution below the current limit of 75 ppb will help children’s health.

For children who already have asthma, the health consequences of ozone pollution are even more pronounced than in children without asthma, often

As a pediatrician, I can prescribe inhalers and treat asthma attacks, but unfortunately I cannot reduce the risk that ozone pollution poses to my young patients. ... The solution to air pollution is not to keep children inside. The solution is to clean the air.

requiring trips to the emergency room or intensive care unit for treatment. On high ozone days, many of these children are forced to stay home or to see their pediatrician, missing school or

other recreational activities. Their parents are forced to miss work, which puts a significant economic drain on middle-income families and on the economy as a whole.

In my region of Northern Virginia, which ranks 9th for the worst ozone pollution in the United States, more than 200,000 children are diagnosed with asthma. As a pediatrician, I can prescribe inhalers and treat asthma attacks, but unfortunately I cannot reduce the risk that ozone pollution poses to my young patients. The EPA’s proposed new lower standard is a step in the right direction to help limit the amount of ozone our children are exposed to on a daily basis, whether during their walk to the bus stop or their outdoor sports activity. The solution to air pollution is not to keep children inside. The solution is to clean the air.



<http://medicaladvocatesforhealthyair.org/>

Mission

Medical Advocates for Healthy Air is a group of health professionals who educate their patients and other practitioners about the connection between poor air quality and disease. MAHA members also advocate for stronger policies that will restore clean and healthy air to North Carolina. Using in-person and written testimony to government agencies, articles, and sign-on letters, MAHA is committed to reducing the impact of ozone pollution, fine particulates and air toxins.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-1985>

Lawrence W. Raymond, MD, ScM
 On behalf of undersigned members of the
Medical Advocates for Healthy Air
 Before the

U.S. Environmental Protection Agency

"Proposed Rule: National Ambient Air Quality Standards for Ozone"

March 17, 2015

"As medical and health professionals who work and live in North Carolina, we are writing to express our strong support of the EPA's proposed revisions to the ... national ambient air quality standards for ground level ozone. [Our] members urge the EPA to adopt a standard of 60 parts per billion which according to the Clean Air Scientific Advisory Committee, corresponds to the lowest exposure concentration at which pulmonary inflammation has been reported. ...

[North Carolina] data currently indicates more than 138,000 cases of pediatric asthma, a disease known to be exacerbated by poor air quality. Such exacerbations have been directly and indirectly

Scientific studies indicate a positive association between chronic exposure to ground level ozone formation and childhood asthma, other respiratory hospital admissions, missed school and work days and increased decrements in health adult lung function.

associated with high levels of ground level ozone. Effects of ozone pollution have already taken a significant toll on children, older adults, people who are active outdoors, and people suffering

from lung and heart disease, chronic obstructive pulmonary disease and diabetes....

Scientific studies referenced in the EPA's Proposed Rule published in the December 17, 2014 Federal Register ... indicate a positive association between chronic exposure to ground level ozone formation and childhood asthma, other respiratory hospital admissions, missed school and work days and increased decrements in health adult lung function.

We believe it is critical for the federal government to take action to further limit ground level ozone pollution to 60 parts per billion ... We urge the EPA to adopt standards that result in the maximum positive impact on public health."



<http://www.thoracic.org/>

Mission

In 1905, a small group of physicians decided that the best way to improve care for tuberculosis patients was the share their experiences and discoveries. Now, ATS is an international society with more than 15,000 members, and it is the world's leading medical association dedicated to advancing clinical and scientific understanding of pulmonary diseases, critical illnesses and sleep-related breathing disorders.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-3235>

Thomas Ferkol, MD
 On behalf of the
American Thoracic Society
 Before the

Senate Environment and Public Works Committee
 "EPA's Proposed Ozone National Ambient Air Quality Standard"

February 2, 2015

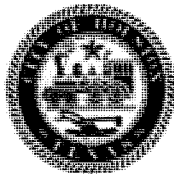
"My name is Dr. Tom Ferkol. I am a pediatric pulmonologist at the Washington University in St. Louis School of Medicine, and also the current president of the American Thoracic Society.

Ozone is a potent oxidant that damages the airways and lungs. The American Thoracic Society strongly supports EPA's proposal to strengthen the National Ambient Air Quality Standard for ozone. If anything, we are disappointed EPA did not go further in recommending a stronger standard of 60 ppb.

For several years, the ATS has encouraged the EPA to issue a more protective ozone standard. The scientific evidence available seven years ago justifying this recommendation has been supplemented by an even greater understanding of the health effects of ozone exposure, including greater respiratory disease in infants and children, reduced lung function, and increased mortality in adults. Indeed, there is clear, consistent, and conclusive evidence that we believe should compel EPA to establish an ozone standard no higher than 60 ppb.

While the evidence on ozone and respiratory effects is comprehensive and compelling, recent studies have shown adverse health effects beyond the lung. ... The ATS strongly urges EPA and the Administration to finalize a more protective ozone standard of 60 ppb.

While the evidence on ozone and respiratory effects is comprehensive and compelling, recent studies have shown adverse health effects beyond the lung. ... The ATS strongly urges EPA and the Administration to finalize a more protective ozone standard of 60 ppb."


CITY OF HOUSTON

Department of Health and Human Services

www.houstontx.gov/health
Mission

The Houston Health Department provides traditional public health services and seeks to use innovative methods to meet the community's present and future needs. Their mission is to work in partnership with the community to promote and protect the health and social well-being of all Houstonians. It is the first health department in Texas and the second in a large U.S. city to earn national accreditation

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-3058>

Stephen L. Williams, M.Ed, MPA
 On behalf of the
Houston Department of Health and Human Services
 Before the

U.S. Environmental Protection Agency
 "Proposed Rule: National Ambient Air Quality Standards for Ozone"

March 16, 2015

"The City of Houston Department of Health and Human Services has found adverse health effects associated with ozone at levels lower than the current National Ambient Air Quality Standard for ground-level ozone. The health department, in conjunction with academic partners, has conducted local health impact assessments to evaluate the association between air pollution and two acute health events in Houston: cardiac arrest and asthma attacks. These studies ... indicate that ozone is an

important trigger for both types of events."

The City of Houston ... health department, in conjunction with academic partners, has conducted local health impact assessments to evaluate the association between air pollution and two acute health events in Houston: cardiac arrest and asthma attacks. These studies ... indicate that ozone is an important trigger for both types of events.

... Ozone and nitrogen dioxide are important triggers of ambulance treated asthma attacks in Houston with 20 and 8 ppb increase in ozone and nitrogen dioxide, respectively, in a multi-pollutant model. Both pollutants are simultaneously high

but below the EPA standard at certain times of the year. ...

An hourly average increase of 20 ppb ozone increase for the eight-hour average daily maximum was associated with an increased risk of [out-of-hospital cardiac arrest] on the day of the event of 3.9%. ... Effects were stronger for men, African Americans or those aged over 65."



Serving Districts of Columbia, Delaware, Maryland,
New Jersey, Pennsylvania, Virginia & West Virginia

www.lung.org/

Mission

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. Their goals are to defeat lung cancer, improve the air we breathe, reduce the burden of lung disease on afflicted patients and families, and eliminate tobacco use. The Mid-Atlantic chapter serves about five million people in the District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, Virginia, and West Virginia.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-1461>

Kevin Stewart
American Lung Association of the Mid-Atlantic
Before the
U.S. Environmental Protection Agency

"Proposed Rule: National Ambient Air Quality Standards for Ozone"

January 29, 2015

"I am Kevin Stewart and I serve as the Director of Environmental Health for the American Lung Association of the Mid-Atlantic. I am representing not only some five million people in our service area who suffer from chronic lung disease, but also the millions more who desire to breathe clean air and so protect their good health. ...

A truly immense body of evidence demonstrates that ambient ozone pollution significantly harms people's health, and that it does so at levels commonly found in the United States. Adverse

Each year in the [U.S.], ozone causes on the order of a million lost school and work days, hundreds of thousands of asthma attacks, and thousands of premature deaths. Simply put, ozone 'smog' worsens and causes disease and even death for real people.

outcomes of this exposure range from acute symptoms to chronic inflammation, from greater

susceptibility to respiratory infections to lung disease episodes requiring medical treatment or hospitalization, from increased risk of asthma attacks to premature death. Each year in the United States, ozone causes on the order of a million lost school and work days, hundreds of thousands of asthma attacks, and thousands of premature deaths. Simply put, ozone 'smog' worsens and causes disease and even death for real people.

... [P]opulations at risk in our service area and known to be living with elevated ozone levels include at least the following: 7.4 million infants, children and teens under 18; 4.5 million persons aged 65 and above; 700,000 children with asthma; 2.4 million adults with asthma; 1.5 million adults with chronic bronchitis or emphysema; and some 2.1 million persons with heart disease....

Therefore, the American Lung Association of the Mid-Atlantic urges EPA to adopt as the primary standard the strongest value recommended for consideration by its own expert staff and by its own independent advisory panel ..."

Ozone and Environmental Justice

Minority communities are often most at risk from the deleterious health effects of environmental pollution. They often live in neighborhoods adjacent to industrial sites or key transportation routes, such as highways or railway lines and are frequently exposed to high levels of toxic contaminants. Because of their economic status they are often unable to afford key medicines to help them cope with illnesses that are either linked to environmental pollution or exacerbated by exposure to environmental pollutants, such as ozone, that are known to worsen respiratory illnesses.

The EPA's decision to reduce the levels of ozone to 70-parts-per-billion will benefit many of the individuals in these communities significantly. It will improve their health, reduce hospitalizations, prevent premature deaths and reduce the costs they expend on medications and their time away from work due to the human health effects of exposure to ozone pollution.

The EPA has developed a web-based tool called the "Environmental Justice Screening and Mapping Tool" or EJSCREEN that allows individuals to combine demographic and environmental data to highlight specific geographic areas combined with environmental data, such as ozone levels. To search for data in your location go here: <http://www2.epa.gov/ejscreen>. The maps below highlight minority populations and ozone levels in Washington, D.C., indicating that some of the highest concentrations of ozone are located in minority neighborhoods.

Washington D.C.'s minority population



Ozone levels in Washington D.C.





www.thoracic.org/

Mission

In 1905, a small group of physicians decided that the best way to improve care for tuberculosis patients was the share their experiences and discoveries. Now, ATS is an international society with more than 15,000 members, and it is the world's leading medical association dedicated to advancing clinical and scientific understanding of pulmonary diseases, critical illnesses and sleep-related breathing disorders.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OAR-2008-0699-3235>

Gibbe H. Parsons, MD
 On behalf of the
American Thoracic Society
 Before the

Senate Environment and Public Works Committee
 "EPA's Proposed Ozone National Ambient Air Quality Standard"

February 2, 2015

"I am Gibbe Parsons, MD, a Pulmonary/Critical Care Professor Emeritus at University of California Davis Health System. I have been at U.C. Davis for 44 years, volunteered with the American Lung Association, and been a member of the American Thoracic Society for most of those years. ...

Ozone is a potent oxidant that damages airways and lungs, especially in asthmatics, young children and other susceptible populations. The most recent standard for ozone is ... 75 ppb. ... [In] the 7-8 years since that level was established by EPA, many scientific studies have shown the deleterious effects of ambient air levels of ozone in the health of children, asthmatic adults, the elderly and normal adults. ...

A long term study of air pollution and health has been ongoing in Atlanta, Georgia since 1993, monitoring daily ozone and other

Ozone is a potent oxidant that damages airways and lungs, especially in asthmatics, young children and other susceptible populations. ... Children born pre-term and among children born to African American mothers had especially high rates of ED [Emergency Department] visits for asthma and wheeze.

pollutants levels and taking daily counts of emergency department visits for asthma or wheeze among children age 5-17. ... Children born pre-

term and among children born to African American mothers had especially high rates of ED visits for asthma and wheeze. ...

In sum there is evidence that ozone pollution, at levels permitted by the current standard, is damaging to the human lung and contributes to disease. We strongly encourage the EPA and the Administration to move forward with a strong standard of 60 ppb to protect our nation's health from the known health effects of ozone."

CUNY CENTER for URBAN



ENVIRONMENTAL REFORM

<http://cuer.law.cuny.edu/>
Mission

The Center for Urban Environmental Reform is a social justice initiative of the City University of New York School of Law. The goal is to expand participation in public decision-making and to increase transparency and overall access to information in order to enhance both the legitimacy of environmental decision-making processes and the fairness of the decisions reached.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-3303>

Rebecca Bratspies

On behalf of the

CUNY Center for Urban Environmental Reform

Before the

U.S. Environmental Protection Agency

"Proposed Rule: National Ambient Air Quality Standards for Ozone"

March 17, 2015

"I am writing on behalf of the CUNY School of Law Center for Urban Environmental Reform to express strong support for the agency proposal to revise the primary National Ambient Air Quality Standard for Ozone downward from its current 75ppb level to a more protective 60 ppb level.

... [S]etting the standard at 60ppb will achieve the public health protections at the heart of the Clean Air Act – preventing up to 7,900 premature deaths in 2025 alone, as well as avoiding 1.8 million childhood asthma attacks and 1.9 million missed days of school each year.

Moreover, the impacts of ozone pollution are not distributed equally across all communities. Poor and minority communities are much more exposed to ozone pollution, and thus bear a disproportionate share of the ill health effects from the current, inadequate ozone NAAQS. ... EPA must set the ozone NAAQS at a level that protects all Americans, including those most vulnerable to the effects of ozone pollution, and those currently most exposed to the pollution.

[T]he impacts of ozone pollution are not distributed equally across all communities. Poor and minority communities are much more exposed to ozone pollution, and thus bear a disproportionate share of the ill health effects from the current, inadequate ozone NAAQS. ... EPA must set the ozone NAAQS at a level that protects all Americans, including those most vulnerable to the effects of ozone pollution, and those currently most exposed to the pollution.

... For these reasons, the CUNY Center for Urban Environmental Reform urges EPA to adopt a stronger, more protective standard of 60 parts per billion."



<http://www.psr.org/>

Mission

Physicians for Social Responsibility has been working for more than 50 years to create a healthy, just and peaceful world for both the present and future generations. PSR uses medical and public health expertise to address issues such as prevention of nuclear war and proliferation, reversing the trajectory towards climate change, and protecting the public and the environment from toxic chemicals. In 1985, its international affiliate, International Physicians for Prevention of Nuclear War, was the recipient of the Nobel Peace Prize.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OAR-2008-0699-1173>

Physicians for Social Responsibility

Before the

U.S. Environmental Protection Agency

“Proposed Rule: National Ambient Air Quality Standards for Ozone”

February 17, 2015

“[Physicians for Social Responsibility’s] mission is to protect human life from the gravest threats to health and survival. It is in this context that we submit our comments on the proposed changes in the [NAAQS Rule] for ozone.

On the basis of the scientific evidence as put forth in the peer-reviewed medical and scientific literature it is clear to use that the current primary standard of 0.075 ppm or daily maximum 8 hour concentration averaged over 3 years ... fails to protect the health of Americans, particularly sensitive populations.

The history of NAAQS for ozone is troubled by excessive political influences that have blocked or delayed establishing a primary standard that protects health with what the Agency itself refers to as an ‘adequate margin of safety.’ ...

We recognize that the Agency is and will continue to be under enormous pressure by some vested interests to maintain the present standard. The Agency must remain steadfast in its mission to protect human health and the environment. Americans of all persuasions breathe the same air and that air must not be a threat to our health, particularly the health of vulnerable populations who are least able to speak for themselves.

... [W]e call on the Agency to establish a primary 8-hour standard that is no higher than 60 ppb.”

We recognize that the Agency is and will continue to be under enormous pressure by some vested interests to maintain the present standard. The Agency must remain steadfast in its mission to protect human health and the environment. Americans of all persuasions breathe the same air and that air must not be a threat to our health, particularly the health of vulnerable populations who are least able to speak for themselves.



<http://www.ejleadershipforum.org/>

Mission

The Environmental Justice Leadership Forum on Climate Change comprises over 45 organizations working to develop just policies and mechanisms that equitably reduce carbon emissions in all counties. These environmental justice advocates interact with scientists and representatives of environmental groups to inform state and federal political and legislative action.

For full statement, see here: <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OAR-2008-0699-2267>

Environmental Justice Leadership Forum on Climate Change Before the U.S. Environmental Protection Agency “Proposed Rule: National Ambient Air Quality Standards for Ozone”

“The Environmental Justice Leadership Forum on Climate Change is led by racially diverse people who are community organizers, public health experts, healers, youth leaders, environmental and social scientists, lawyers, and policy advocates dedicated to a healthy and just environment and economy. Across the United States and tribal lands, Forum members live in and work in Environmental Justice communities, where residents are overburdened with dirty air due to both stationary and mobile pollution sources ... [that] negatively impact our health and fuel climate change. ...

The evidence is clear that in the United States, economically disadvantaged and minority populations share a disproportionate burden of air pollution exposure and risk, specifically higher residential exposure to traffic and traffic-related air pollution.

According to the American Lung Association's 2014 State of the Air Report, [44.8% of] people in the United States live in areas with unhealthy levels of O₃ ... Inequality in average NO₂ concentration is disproportionate to the inequality in average income,

nonwhites experience 4.6ppb (38%) higher residential outdoor NO₂ concentrations than whites, and within individual urban areas, after controlling for income, nonwhites are, on average, exposed to higher outdoor residential NO₂ concentrations than whites; and, after controlling for race, lower-income populations are exposed to higher outdoor residential average NO₂ concentrations than higher-income populations.

The evidence is clear that in the United States, economically disadvantaged and minority populations share a disproportionate burden of air pollution exposure and risk, specifically higher residential exposure to traffic and traffic-related air pollution.

In conclusion, on behalf of the millions of people across this country that are living everyday with ‘bad air’, we hope you ... adhere to the Agency’s theme and your pledge to ‘keep environmental justice a priority’. Give us the strongest standard at 60 ppb for Ozone – we deserve it.”



<http://livingwellblack.org/>

Mission

Living Well Black is a non-profit organization dedicated to improving health, wealth, and success in the Black community through outreach, empowerment, and advocacy. They advocate for policies that support their efforts to improve Black lives.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-2735>

Janell Mayo Duncan

On behalf of

Living Well Black

Before the

U.S. Environmental Protection Agency

“Proposed Rule: National Ambient Air Quality Standards for Ozone”

March 17, 2015

“LWB is an organization formed in 2012 to bring consumer health and safety information to the African American community. In addition, in many areas of life, African Americans face a disproportionate burden of diseases.... There are critical actions that can be taken to narrow this gap. ...

African Americans suffer disproportionately from asthma and other diseases and conditions worsened by air pollution. Rates of hospitalizations and deaths due to asthma are both three times higher among African Americans than among whites. Black children visited the emergency department for asthma at a rate 260% higher [than] white children, had a 250% higher hospitalization rate, and had a 500% higher death rate from asthma than white children. Because African Americans suffer higher rates of asthma, stronger ozone standards are expected to reduce the symptoms of those suffering from asthma. In addition, strong standards are likely to provide an added benefit to African American communities often overburdened by air pollution.

African Americans suffer disproportionately from asthma and other diseases and conditions worsened by air pollution. ... Because African Americans suffer higher rates of asthma, stronger ozone standards are expected to reduce the symptoms of those suffering from asthma. In addition, strong standards are likely to provide an added benefit to African American communities often overburdened by air pollution.

In its Final Rule, we urge the EPA to adopt O₃ limits of 60 ppb. We believe that this stronger standard is more appropriately protective of vulnerable populations, and will better reduce the disproportionate health burden suffered by African Americans from asthma and other lung diseases and conditions.”



<http://www.movingforwardnetwork.com/>

The Moving Forward Network is a nationwide coalition of community-based organizations, advocates, scientists and researchers committed to improving the freight transportation system in the areas of environmental justice, public health, quality of life, the environment and labor. They facilitate information sharing, funding research, peer-to-peer training, facilitating workshops, and creating national campaigns.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-1807>

Angelo Logan
 On behalf of the
Moving Forward Network
 Before the

U.S. Environmental Protection Agency
 “Proposed Rule: National Ambient Air Quality Standards for Ozone”

March 16, 2015

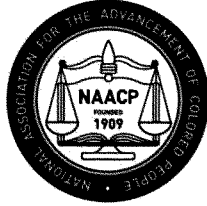
“In the United States, more than 13 million Americans (3.5 million of whom are children) live near major marine ports or railyards. Freight transportation activity ... exacts a heavy toll on human health. Communities near freight transportation facilities and busy truck routes are often low-income communities of color, and suffer higher rates of asthma, premature death, and risks of lung cancer than the general population. Our Network represents these communities.

Communities near freight transportation facilities and busy truck routes are often low-income communities of color, and suffer higher rates of asthma, premature death, and risks of lung cancer than the general population. ... [T]he Network highly encourages EPA to set the standard consistent with the recommendations to the Clean Air Scientific Advisory Committee and the many scientific studies indicating that adverse health [effects] are associated with very low levels of ozone.

The Clean Air Act is abundantly clear — NAAQS must be set at a level “requisite to protect the public health” with “an adequate margin of safety.” 42 U.S.C. § 7409(b)(1). Given this mandate, the Network highly encourages EPA to set the

standard consistent with the recommendations to the Clean Air Scientific Advisory Committee and the many scientific studies indicating that adverse health [effects] are associated with very low levels of ozone. To ensure compliance with the law, EPA must set the NAAQS at a level of 60 ppb.

... Attached to this letter are statements from Network members who live, work and play in communities harmed by air pollution from the freight industry. These statements underscore the need for EPA’s swift action in this area.”



<http://www.naacp.org/>

Mission

The mission of the National Association for the Advancement of Colored People is to ensure the political, educational, social, and economic equality of rights of all persons and to eliminate race-based discrimination.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-4143>

Hilary O. Shelton
 On behalf of the
National Association for the Advancement of Colored People
 Before the
 U.S. Environmental Protection Agency
 “Proposed Rule: National Ambient Air Quality Standards for Ozone”

July 23, 2015

“On behalf of the NAACP, our nation’s oldest, largest, and most widely recognized grassroots-based civil rights organization, I am writing to express our organization’s support for an updated, strong final ozone rule which mandates a standard of no more than 60 parts per billion. This rule is important to the NAACP and to the communities we serve and represent because air pollution is a serious problem which disproportionately affects too many racial and ethnic minorities.

Approximately 71% of African Americans live in areas in violation of air pollution standards.

Studies have determined that race, over income, is the #1 predictor of whether a person lives near a polluting facility.

...African American children have double the risk for asthma than white

children.... In 2009, African Americans overall were 3 times more likely to die from asthma related causes than the White population, and currently African Americans are hospitalized for asthma at 3 times the rate of White Americans.

The issue is sufficiently important to the NAACP, that in 2011 the delegates to our national convention passed a resolution ... calling for an updated strong final Ozone rule mandating a standard of approximately 60 ppb. ...”

This [ozone] rule is important to the NAACP and to the communities we serve and represent because air pollution is a serious problem which disproportionately affects too many racial and ethnic minorities. ... [I]n 2011 the delegates to our national convention passed a resolution ... calling for an updated strong final Ozone rule mandating a standard of approximately 60 ppb.



<http://www.weact.org>

Mission

West Harlem Environmental Action, Inc. (WE ACT for Environmental Justice) is a Northern Manhattan community-based organization whose mission is to build healthy communities by assuring that people of color and/or low-income participate meaningfully in the creation of sound and fair environmental health and protection policies and practices.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OAR-2008-0699-2252>

Peggy Shepard, Cecil Corbin-Mark, and Jalonnie White-Newsome
 On behalf of

**West Harlem Environmental Action, Inc.
 (WE ACT for Environmental Justice)**

Before the

U.S. Environmental Protection Agency

“Proposed Rule: National Ambient Air Quality Standards for Ozone”

March 17, 2015

“According to the New York Department of Health and Mental Hygiene, in 2012, children aged 0 to 4 in Harlem visited the emergency room 280 times because of asthma. There is no doubt that children in Northern Manhattan are suffering disproportionately from asthma, which is exacerbated by the formation of Ozone and other social stressors. On behalf of the children, the adults and other susceptible populations that are subjected to breathing dirty air, WE ACT strongly urges the Agency to move forward with a more stringent 8-hour ozone standard of 60 ppb.

WE ACT is respectfully asking the Agency to ... finalize a standard of 60 ppb for Ozone, to protect low income, and/or, communities of color, and Indigenous Peoples across the nation. Members of the public health community, as well as Clean Air Scientific Advisory Council ... agree that the current primary NAAQS for ozone is not

... Since Harlem is not ‘lacking’ in the ingredients that form Ozone, it is extremely important that we use all of the regulatory and non-regulatory mechanisms to protect the health of some

of our most overburdened, sensitive populations.

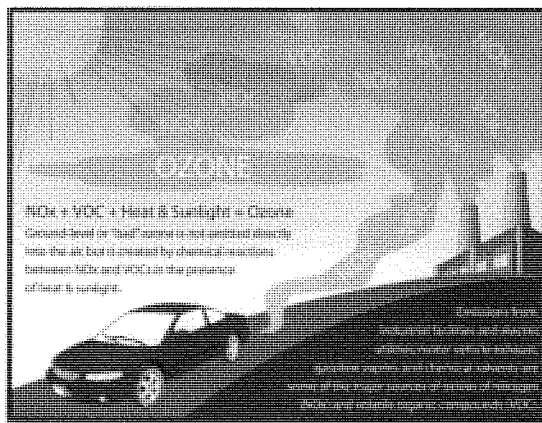
... WE ACT is respectfully asking the Agency to ... finalize a standard of 60 ppb for Ozone, to protect low income, and/or, communities of color, and Indigenous Peoples across the nation. Members of the public health community, as well as Clean Air Scientific Advisory Council ... agree that the current primary NAAQS for ozone is not protective of human health.

... On behalf of WE ACT and the 1000s of residents in Northern Manhattan, we hope that you ... adhere to the Agency’s ... pledge to “keep environmental justice a priority.”

Ozone Economics

The industries and industry groups impacted by the new ozone regulations, particularly the National Association of Manufacturers (NAM) launched a blizzard of television ads during the run up to the release of the EPA's final ozone rule publicly announced on October 1, 2015 that questioned the science supporting the proposed new rule and its economic impact. Industry has claimed the new rule will result in dire economic consequences. However, industry has a long track record of exaggerating the costs of environmental regulations.

In a report to Congress on the costs and benefits of federal regulations, the Office of Management and Budget (OMB) estimated that major rules promulgated by EPA from 2003 to 2013 created between \$165 billion and \$850 billion in benefits, compared to costs of \$38 billion to \$46 billion. Industry also claims the imposition of new regulations will kill jobs and stymie economic growth. But, since the adoption of the Clean Air Act in 1970, the economy has more than tripled in size at the same time that key pollutants have been reduced by over 70 percent.



Industry also neglects to mention the public health costs of ozone pollution, or, the fact that under the Clean Air Act the ground-level ozone rule is a health based standard that is supposed to be based solely on scientific evidence and not economic considerations. Reducing ozone levels in the environment is likely to decrease healthcare costs. Improved pollution control requirements often force innovation and create new technologies, new jobs and even entirely new industries. Current ozone levels hinder economic productivity. For adults, asthma leads to more than 14 million lost work days per year and for children more than 10.5 million lost school days per year. Reduced levels of ozone pollution are likely to lead to lower levels of lost productivity at school and work. The EPA estimates the benefits from this new ozone rule to be more than double the costs – that is benefits of \$2.9 to \$5.9 billion annually compared to costs of \$1.4 billion.

It is also important to acknowledge that the vast majority of the public has favored a new, stronger, ozone standard even in the face of arguments by industry groups that claim EPA's new ozone rule will have a negative impact on the economy. A poll conducted for the American Lung Association in August 2015 found that 73 percent of registered voters favored stricter limits on ozone, including 52 percent of registered Republicans.



uphc.org

Mission

Utah Physicians for a Healthy Environment is dedicated to protecting the health and well-being of the citizens of Utah by promoting science-based health education and interventions that result in progressive, measurable improvements to the environment. The organization encourages the development of renewable sources of energy, such as wind, as an essential step toward avoiding the unhealthy consequences of our excessive reliance on coal and petroleum.

For full statement, see here:
[http://www.regulations.gov/#?documentDetail:D=EPA-HQ-OAR-2008-0699-3865](http://www.regulations.gov/#?documentDetail=D=EPA-HQ-OAR-2008-0699-3865)

Brian Moench, MD
 Utah Physicians for a Healthy Environment
 Before the
 U.S. Environmental Protection Agency
 "Proposed Rule: National Ambient Air Quality Standards for Ozone"

March 17, 2015

"Many of the illnesses that our health professionals treat are caused by, or exacerbated by, environmental pollution. We therefore offer our expertise to inform the debate about how society should deal with these threats to human health.

Without evidence, business interests reflexively claim that the health benefits of virtually any tightening of air quality standards are uncertain, while the costs, in terms of lost jobs and reduced economic

output, are guaranteed. We prefer to base our conclusions on evidence. The evidence shows that, with respect to the tightening of the current ozone ambient air standards that are

Without evidence, business interests reflexively claim that the health benefits of virtually any tightening of air quality standards are uncertain, while the costs, in terms of lost jobs and reduced economic output, are guaranteed. We prefer to base our conclusions on evidence. The evidence shows that, with respect to the tightening of the current ozone ambient air standards that are proposed in this rule, the opposite is true.

proposed in this rule, the opposite is true. The health benefits of the lower range of the ozone standards proposed in this rulemaking are known with reasonable certainty. We demonstrate that just a partial estimate of the economic benefits that would flow from their adoption are so large as to overwhelm any realistic estimate of compliance costs. ...

Our children need the tighter ozone standards on which EPA seeks public comment in this rulemaking. We urge the EPA to adopt a primary NAAQS ozone standard of 60 ppb."



<http://content.sierraclub.org/coal/illinois/healthy-community-alliance>

Mission

The Central Illinois Healthy Community Alliance is a coalition of individuals and organizations committed to creating a sustainable and healthy community for Central Illinois. CIHCA is concerned about the decades of air and water pollution created by local coal plants and is working to transition the region to a cleaner energy economy by reducing energy use and moving to renewables.

For full statement, see here: <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-1512>

Central Illinois Healthy Community Alliance

Before the

U.S. Environmental Protection Agency

"Proposed Rule: National Ambient Air Quality Standards for Ozone"

March 17, 2015

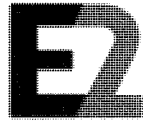
"As the [EPA] considers updated protections from dangerous smog (ground-level ozone) pollution, protection of public health and peer-reviewed science must be the standards used in making this decision. Health experts, epidemiologists, and numerous medical organizations have clearly stated that the existing Bush-era standard of 75 parts per billion is not adequate to protect public health, particularly vulnerable populations such as children, the elderly and those with breathing ailments like asthma. These same experts report that smog pollution at levels as low as 55 or 60 ppb can trigger asthma attacks and send children to the hospital. A 12-city EPA analysis showed that reducing the level of smog pollution to 60 parts per billion would save 4-5 times as many lives compared to a weaker standard of 70 parts per billion.

Since the Clean Air Act was enacted into law more than 40 years ago, big polluters have tried at every turn to mislead the public and elected officials with doom and gloom economic scenarios. While they continue to cry wolf, the reality is that the Clean Air Act has been one of the most successful statutes every signed into law. Their claims of economic catastrophe have never materialized.

In order to best protect our public health, particularly children's health, I strongly urge you to set the standard at 60 ppb....

Since the Clean Air Act was enacted into law more than 40 years ago, big polluters have tried at every turn to mislead the public and elected officials with doom and gloom economic scenarios. While they continue to cry wolf, the reality is that the Clean Air Act has been one of the most successful statutes every signed into law. Their claims of economic catastrophe have never materialized.

Thank you for your consideration, the opportunity to comment and for all EPA's work to protect communities from dangerous pollution."



<http://e2.org>

Mission

Environmental Entrepreneurs (E2) is a nonpartisan, national community of business leaders who promote sound environmental policies that grow the economy. Its members are entrepreneurs, investors, and professionals from every sector of the economy who collectively have been involved in the financing, founding or development of more than 1,700 companies that have created more than 570,000 jobs.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OAR-2008-0699-3647>

Environmental Entrepreneurs Before the U.S. Environmental Protection Agency “Proposed Rule: National Ambient Air Quality Standards for Ozone”

March 17, 2015

“As members of Environmental Entrepreneurs, we recognize that ... [proposed new ozone] standards will provide an opportunity for communities to innovate the energy, manufacturing, and transportation systems they rely upon to lower emissions, improve economic productivity, and provide a healthier, higher quality of life for Americans across the country.

... Avoiding [asthma attacks, missed school and work days and premature

Critics of strong ground level ozone standards have claimed that these standards are a death sentence for local economies...

History has shown us that this is false. Populations have grown, economies expanded, and miles traveled by car have all continued to grow nationwide – all while new standards have cleaned up our air... Indeed, the Office of Management and Budget reviewed 32 major EPA rules and determined that their benefits were up to \$550.7 billion dollars, compared to a combined total of \$28.5 billion in costs. ...

deaths due to high ozone levels] would produce economic benefits of between \$6.4 billion to \$38 billion by 2025, significantly outweighing costs, ... estimated at \$3.9 billion to \$15 billion over the same time frame....

Critics of strong ground level ozone standards

have claimed that these standards are a death sentence for local economies... History has shown us that this is false. Populations have grown, economies expanded, and miles traveled by car have all continued to grow nationwide – all while new standards have cleaned up our air... Indeed, the Office of Management and Budget reviewed 32 major EPA rules and determined that their benefits were up to \$550.7 billion dollars, compared to a combined total of \$28.5 billion in costs. ...

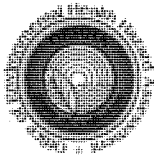
These facts demonstrate that strong pollution standards are a net positive for the American economy as well as providing a cleaner environment and improved public health. ...”



<http://www.arb.ca.gov/>

Mission

The California Air Resources Board is a part of the California EPA. Its mission is to promote and protect public health, welfare and ecological resources through the effective and efficient reduction of air pollutants while recognizing and considering the effects on the economy of the state.



www.ochha.ca.gov

Mission

The Office of Environmental Health Hazard Assessment is California's lead state agency for the assessment of health risks posed by environmental contaminants. It is one of five state departments within the California EPA.

For full statement, see here:
<http://www.regulations.gov/>
 #!documentDetail:D=EPA-HQ-OAR-2008-0699-3438

Richard W. Corey
 On behalf of the
California Air Resources Board,
 George Alexeef
 On behalf of the
Office of Environmental Health Hazard Assessment
 Before the

U.S. Environmental Protection Agency
 "Proposed Rule: National Ambient Air Quality Standards for Ozone"

"ARB and OEHA ... agree with the U.S. EPA staff conclusion that the current 8-hour ozone standard of 0.075 ppm does not adequately protect public health. ...

Strengthening the ozone standard would provide health benefits for California, particularly in the South Coast Air Basin and the San Joaquin Valley, such as reductions in premature mortality, hospitalizations, emergency department visits for asthma, and lost work and school days. ...

Strengthening the ozone NAAQS will also provide significant economic benefits to California. These benefits are tied to reduced health care costs and fewer lost work days and school absences. ... [A] more stringent ozone NAAQS will result in reduced damage to the State's crops, as well as its forests, and ecosystems. The latter will, in turn, reduce tinder accumulation and will help to reduce risk of wildfires, which also affect air quality.

Strengthening the ozone standard would provide health benefits for California, particularly in the South Coast Air Basin and the San Joaquin Valley, such as reductions in premature mortality, hospitalizations, emergency department visits for asthma, and lost work and school days. ...

... [It] will also provide significant economic benefits to California. ... [A] more stringent ozone NAAQS will result in reduced damage to the State's crops, as well as its forests, and ecosystems. The latter will, in turn, reduce tinder accumulation and will help to reduce risk of wildfires, which also affect air quality."



<http://earthjustice.org/>

Mission

Earthjustice is the largest nonprofit environmental law organization. It seeks to leverage its expertise to hold accountable those who break environmental laws.

For full statement, see here:
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-4231>

Seth Johnson, On behalf of

Earthjustice

Before the

U.S. Environmental Protection Agency

"Proposed Rule: National Ambient Air Quality Standards for Ozone"

September 29, 2015

"Polluters' opposition to any strengthening of the ozone NAAQS has focused on the costs of complying ... that is a legally irrelevant argument.

Polluters' opposition to any strengthening of the ozone NAAQS has focused on the costs of complying ... that is a legally irrelevant argument.

...

In February 2015, NERA Economic Consulting issued a report for the National Association of Manufacturers making extreme claims about the cost and job impacts of meeting a 65 ppb standard. ... [That] report grossly overstates compliance costs, due to major flaws, math errors, and unfounded assumptions

... The [EPA] has proposed to strengthen the national clean air standard for ozone to protect public health.

In February 2015, NERA Economic Consulting issued a report for the National Association of Manufacturers making extreme claims about the cost and job impacts of meeting a 65 ppb standard. NERA's cost estimates are more than ten times higher than those made by EPA....

The NERA report grossly overstates compliance costs, due to major flaws, math errors, and unfounded assumptions.... Among other things:

- NERA significantly inflated the emission reductions needed to meet the 65 ppb standard... [These] flaws led NERA to overstate compliance costs by more than 700 percent.
- Applying a more reasonable estimate of needed emission reductions to EPA's cost estimation approach yields an annual cost figure \$1.4 billion/year lower than EPA's projected cost...
- NERA's analysis ... suffers from a math error of about \$70 billion – nearly half of NERA's annualized cost estimate.
- NERA's claims that a revised standard will lead to significant job losses and harm to the economy are unfounded and unsupportable.

DOCUMENTS SUBMITTED BY REPRESENTATIVE JIM BRIDENSTINE



March 16, 2015

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator McCarthy,

In the four decades since the Clean Air Act was signed into law, our states have driven unprecedented improvements in air quality. We have done so while adhering to the core principle that meaningful environmental measures can and must coexist with free market policies that promote job growth and economic freedom. Your agency's new proposed change to the National Ambient Air Quality Standard (NAAQS) for ground-level ozone jettisons these free market policies in favor of an onerous, job-crushing standard. As chief protectors of our states' economies, we oppose this proposed change to the NAAQS for ground-level ozone.

The proposed NAAQS is so extreme that even some of our pristine national parks may not be able to satisfy it. It goes without saying that most cities and counties have no chance of attaining this standard. Indeed, many areas of our states have background levels of ozone at or near the levels you are proposing. According to an estimate by the Congressional Research Service, EPA's power-grab could plunge anywhere from 76% to 96% of the counties currently monitored for ozone into nonattainment.

Nonattainment is an economic penalty box so severe that needed economic growth is stunted. In nonattainment areas, any growth is predicated on successfully navigating a bureaucratic maze of federal and state regulators. New development resulting in any new ozone emissions in the area must be offset with emission reductions elsewhere—turning economic development into a zero-sum game. Some businesses will be forced to employ costly control measures. Some will likely scrap existing facilities and equipment altogether. The end result, of course, is that the costs will be passed on to hard-working Americans. Millions of Americans could be affected in a much more direct and devastating way: it is estimated that the proposed standard could cost the equivalent of 1.4 million jobs annually.

Nonattainment also jeopardizes needed transportation infrastructure projects. Roads that would add desperately needed capacity in nonattainment areas would be subject to review by multiple federal agencies—despite the fact that many of these projects may actually reduce ozone emissions by relieving congestion. This additional level of oversight is sure to both delay needed transportation projects and make them more expensive—if not thwart them altogether. It's no wonder many are calling this "the most expensive regulation ever."

All of this says nothing of the dozens of massive new regulations put in place or proposed by your agency over the past several years: regulations like the Mercury and Air Toxics Standards, the Boiler MACT, fuel economy standards for cars and trucks, regional haze rules, the Cross-State Air Pollution Rule, Tier 3 tailpipe emissions standards, and of course the Clean Power Plan. Taken together, these regulations impose billions of dollars in new costs on our states and our citizens. Moreover, these regulations collectively work to lower ozone emissions already. Piling on the additional burden and expense of a lower ozone standard simply isn't necessary. In fact, many of our states have seen a dramatic decrease in ozone levels over the past decade under the current, more flexible standard.

Our states' resources are not infinite. At a time when we should be focusing on growing the economy and creating jobs, the EPA is imposing a steady stream of complex, expensive new regulations that require an army of policy and technical experts and lawyers to decipher, respond to, and ultimately implement. The proposed NAAQS for ozone is the most onerous and expensive yet. We ask you to instead keep the current standard of 75 parts per billion (ppb) in place.

Sincerely,



Governor Asa Hutchinson
Arkansas



Governor Nathan Deal
Georgia



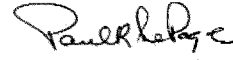
Governor C.L. "Butch" Otter
Idaho



Governor Michael R. Pence
Indiana



Governor Bobby Jindal
Louisiana



Governor Paul R. LePage
Maine



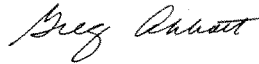
Governor Phil Bryant
Mississippi



Governor Mary Fallin
Oklahoma



Governor Nikki Haley
South Carolina

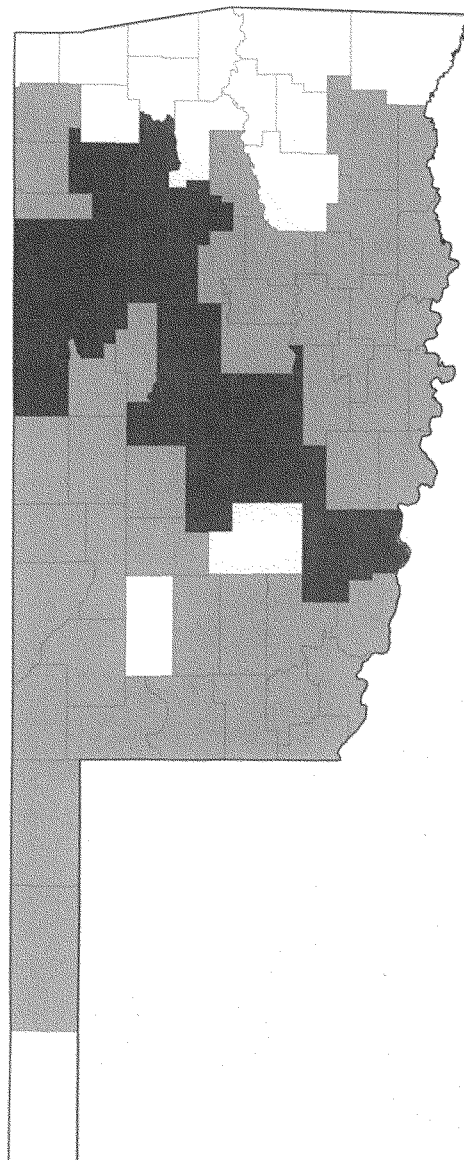


Governor Greg Abbott
Texas



Governor Scott Walker
Wisconsin

Oklahoma **Projected 8-Hour Ozone Nonattainment Areas**



■ Monitored CBSAs and rural counties that would be violating a 70 ppb standard
 ■ Unmonitored areas that are anticipated to violate a 70 ppb standard based on spatial interpolation

Based on a 3-year period, 2012-2014.
 Source: URS, August 3, 2015

DOCUMENT SUBMITTED BY REPRESENTATIVE DON BEYER

JOHNS HOPKINS
UNIVERSITY

Department of Pediatrics
 School of Medicine / CMSC 1102
 The Johns Hopkins Hospital / Baltimore, MD 21287-3923
 (410) 955-5883 / FAX (410) 955-0229
 Division of Immunology and Allergy

October 2, 2015

The Honorable Eddie Bernice Johnson
 2468 Rayburn Office Building
 United States House of Representatives
 Washington, D.C. 20515

Dear Representative Johnson,

We are writing to give more information and perspective about our recent publication "Neighborhood poverty, urban residence, race/ethnicity, and asthma: Rethinking the inner-city asthma epidemic"ⁱ and its implications for the relationship between asthma and air pollution, as we understand that this paper is still being misunderstood as a finding that undermines the relationship between air pollution and asthma. We are writing today to again clarify the findings of the study and to direct your attention to even more research recently published showing the respiratory health benefits of lowering air pollutionⁱⁱ.

In the above referenced study we used data from the National Health Interview Survey (NHIS) to examine the relationship between metropolitan status (i.e., living in an Urban, Suburban, Medium Metro or Small Metro/Rural area), poverty, race/ethnicity and prevalence of asthma among children in the U.S. This survey, conducted by the Centers for Disease Control is a nationally representative sample covering all 50 states. In our study we found that poverty and race/ethnicity were major risk factors for asthma prevalence, but that living in an urban metropolitan area was not a risk factor for asthma prevalence. This study's finding has been misinterpreted by some who believe that it suggests that air pollution in general, and ozone in particular, is not important for asthmaⁱⁱⁱ.

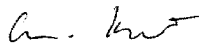
This is an erroneous conclusion to draw from the study's results because first, our study did not examine air pollution, and second, residence in an urban area cannot be taken as a surrogate for high air pollution exposure, as air pollution is not confined to urban areas. In fact, ozone levels are actually highest in suburban areas downwind from urban areas rather than in urban areas themselves^{iv}, and there is substantial variability across the U.S. between regions and areas. For example, air pollution levels are very high in non-urban areas in the California Central Valley.

Most importantly, a link between air pollution in general, and ozone levels in particular, and respiratory health outcomes is supported by many studies that have used a variety of methods that are more appropriate for this question^v.

Our findings and those of others instead highlight that children with asthma live in all types of metropolitan areas throughout the U.S., and suggest the need for comprehensive policies, including reducing pollution, to reduce the prevalence of asthma and to reduce risk to those with asthma, wherever they live.

Thank you for your interest in this matter. Please contact me with any questions

Sincerely,



Corinne A. Keet, MD, PhD
Assistant Professor of Pediatrics
Johns Hopkins School of Medicine
Baltimore, MD 21287
Email: ckeet1@jhmi.edu
Phone: 410-955-5883

Elizabeth C. Matsui, MD, MHS
Johns Hopkins School of Medicine

ⁱ Keet CK, et al. Journal of Allergy and Clinical Immunology 2015;135(3): 655-62

ⁱⁱ Gauderman WJ, et al., New England Journal of Medicine. 2015; 372(10):905-13

ⁱⁱⁱ For example: <http://instituteeforenergyresearch.org/analysis/study-undermines-scientific-basis-epas-ozone-rule/>

^{iv} Simon, H et al. Environmental Science and Technology. 2015, 49, 186-195

^v For example:

Meng, YY et al. J Epidemiol Community Health 2010; 64: 142-147.

Kim CS et al. Am J Respir Crit Care Med. 2011, 183:1215-1221.

Gleason JA et al. Environmental Research 132 (2014) 421-429.

Rice MB et al. Am J Respir Crit Care Med. 2013. 188(11): 1351-1357

DOCUMENTS SUBMITTED BY REPRESENTATIVE BILL JOHNSON



MARY TAYLOR
LT. GOVERNOR
STATE OF OHIO

March 17, 2015

The Honorable Gina McCarthy, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator McCarthy:

Last November, your agency issued proposed rules to change the National Ambient Air Quality Standard (NAAQS) for ground-level ozone from the current standard of 75 parts per billion (ppb) to a standard in the range of 65 to 70 ppb. I am writing to express serious concerns with the proposal and to encourage you to maintain the current NAAQS for ground-level ozone.

In Ohio, we have worked hard to establish a balanced regulatory system, led by the state's Common Sense Initiative that was created in 2011. We believe that the state and businesses should work in partnership to ensure a strong regulatory system promoting compliance, not punishment. This does not mean that we do not value the protections to health, safety, and the environment that are achieved through a strong regulatory system. In fact, the State of Ohio has seen significant improvement in the quality of the air we breathe since enactment of the federal Clean Air Act. However, we believe and have instructed our agencies to adhere to the core principle that protection of the environment and economic progress are not mutually exclusive. When evaluating proposed regulations, we require our agencies to articulate the need for the regulation, including any scientific analysis, as well as the economic impact in order to determine whether the purpose of the regulation justifies the impact. We believe that the current proposal to change the NAAQS would fail under this analysis due to both the economic impact and the lack of a scientific basis for reducing the standard below the current 75 ppb.

As mentioned above, in Ohio we demand that our agencies justify their regulatory actions with science, and we do understand that the EPA's interpretation of the Clean Air Act is that decisions are to be based on health considerations only. Even under this standard, we believe the proposal fails to meet your criteria. According to the Ohio EPA, your agency is relying on the same basic research that was used years ago, and upon which the EPA made the determination in 2010 to not tighten the standard. We do not believe there is anything in the toxicological or epidemiological analysis that justifies a standard below 75 ppb.

Moreover, the proposed changes have the potential for large economic impacts, both in Ohio and throughout the country. It is estimated that an NAAQS of 65 ppb could cause up to \$22

billion in lost gross state product between 2017 and 2040, and perhaps more than \$840 million in compliance costs. Based on current data, at least 34 out of 88 Ohio counties would be out of compliance with the proposed standard. In 2011, the federal Office of Information and Regulatory Affairs (OIRA) cited the unpredictability and uncertainty a new NAAQS would cause to the economy in urging your predecessor not to move forward with a similar proposal.

Ohio is in the process of implementing dozens of massive new regulations put in place by your agency over the past several years: regulations like the Mercury and Air Toxics Standards, the Boiler MACT, fuel economy standards for cars and trucks, regional haze rules, the Cross-State Air Pollution Rule, Tier 3 tailpipe emissions standards, and of course the Clean Power Plan. Taken together, these regulations impose billions of dollars in new costs. They will also drive major reductions in the emissions that cause ozone, making a new NAAQS even less necessary.

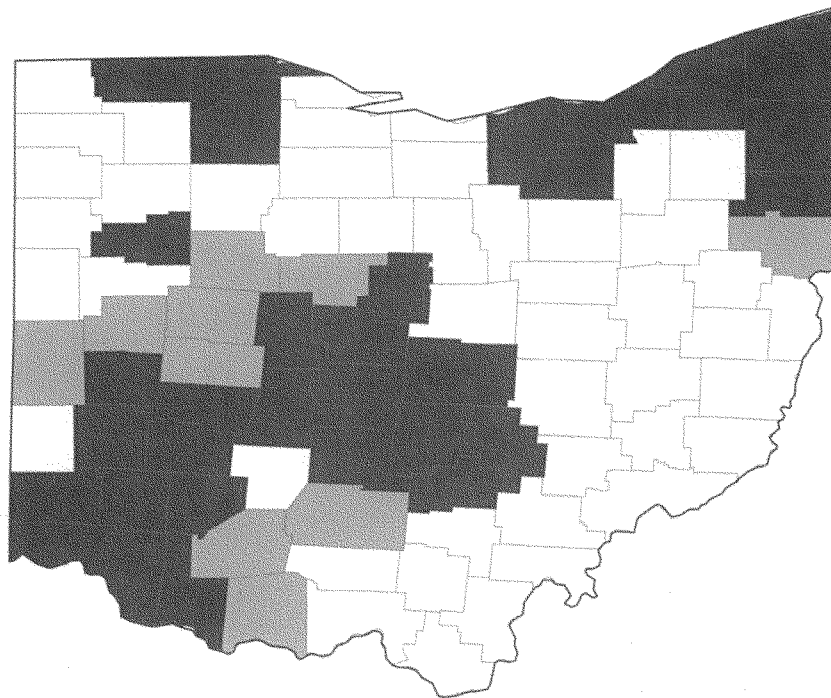
We are focused on creating jobs and developing a compliance friendly environment. However, the EPA continues to strain our resources by imposing a steady stream of complex and expensive new regulations that require an army of policy and technical experts and lawyers to decipher, respond to, and ultimately implement. Again, we do not believe that environmental protection and economic development are mutually exclusive. The current standard is helping improve the quality of our air, and any further reduction is unjustified. We ask you to reconsider these burdensome regulations and maintain the current standard of 75 ppb.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary Taylor".

Mary Taylor
Lt. Governor

Ohio **Projected 8-Hour Ozone Nonattainment Areas**



 Unmonitored areas that are anticipated to violate a 70 ppb standard based on spatial interpolation
 Monitored CBSAs and rural counties that would be violating a 70 ppb standard

Based on a 3-year period, 2012-2014.
 Source: URS, August 3, 2015

DOCUMENTS SUBMITTED BY REPRESENTATIVE KATHERINE CLARK

September 21, 2015

President Barack Obama
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear President Obama,

As local elected officials representing big cities and small towns, we want to express our strong support for the Environmental Protection Agency's (EPA) work to update the ozone (or smog) standard. The current, George W. Bush-era standard of 75 parts per billion (ppb) has been widely acknowledged by the medical community as insufficient to protect public health. As mayors, we are on the front lines of protecting the safety and well-being of our constituents and this long-overdue update will reap tremendous benefits for our communities. To best guard our families and constituents from this dangerous pollutant, we urge EPA to stay true to the science and in setting the standard follow the guidance of expert medical organizations like the American Lung Association, the American Heart Association, the American Thoracic Society, and the American Academy of Pediatrics.

Smog pollution, much of it coming from power plant emissions and vehicle exhaust, represents a particularly widespread threat to families nationwide. According to the American Lung Association's 2014 State of the Air report, approximately 45% of the population – or 140.5 million people – live in counties that received a grade of "F" for their air pollution. This is especially problematic for sensitive populations such as children, the elderly, those with breathing ailments, outdoor workers, low-income families and communities of color. The Clean Air Act is clear in requiring EPA to set a standard not just protective of healthy individuals, but also protective of these vulnerable populations.

Nearly 26 million Americans, including 7 million children, suffer from asthma. According to the Centers for Disease Control and Prevention, minority children living in poor socio-economic conditions are at a greater risk. For instance, 16% of African American children had asthma in 2010, compared to 8.2% of White children. Low-income families are more likely to live close to sources of pollution and roadways, have lower access to medical information and health insurance, and die from asthma-related complications.

EPA's own analysis shows that the strongest option under consideration would save taxpayers as much as \$75.9 billion annually when fully implemented through lower health care costs. Each year, this would translate into as many as 7,900 lives saved and 1.8 million asthma attacks and 1.9 million missed school days avoided.

Clean, healthy air and water are fundamental American rights and we are eager to work with your Administration to secure and implement the strongest possible protections from smog pollution.

Respectfully,

Alta, UT - Tom Pollard	Minneapolis, MN - Betsy Hodges
Alton, IL - Brant Walker	Moab, UT - Dave Sakrison
Ames, IA - Ann Campbell	Mosier, OR - Arlene Burns
Ann Arbor, MI - Christopher Taylor	Mukilteo, WA - Jennifer Gregerson
Baltimore, MD - Stephanie C. Rawlings-Blake	Muncie, IN - Dennis Tyler
Bloomington, IN - Mark Kruzan	New York City, NY - Bill de Blasio
Borough of West Chester, PA - Carolyn Comitta	Newburyport, MA - Donna D. Holaday
Bridgeport, CT - Bill Finch	Newton, MA - Setti Warren
Burlington, VT - Miro Weinberger	Norman, OK - Cindy S. Rosenthal
Carmel, IN - James C. Brainard	North Chicago, IL - Leon Rockingham
Charlotte, NC - Dan Clodfelter	Northampton, MA - David Narkewicz
Chicago, IL - Rahm Emanuel	Oakland, CA - Libby Schaaf
Clarkston, GA - Ted Terry	Ogden, UT - Mike Caldwell
College Park, MD - Andrew Fellows	Park Forest, IL - John A. Ostenburg
Decatur, GA - Jim Baskett	Philadelphia, PA - Michael Nutter
Elkhart, IN - Dick L. Moore	Pittsburgh, PA - William Peduto
Evanston, IL - Elizabeth Tisdahl	Salt Lake City, UT - Ralph Becker
Fayetteville, AR - Lioneld Jordan	San Francisco, CA - Ed Lee
Ferndale, MI - David Coulter	Santa Fe, NM - Javier M. Gonzales
Fridley, MN - Scott Lund	Santa Monica, CA - Kevin McKeown
Garden Grove, CA - Bao Nguyen	Seattle, WA - Ed Murray
Glen Carbon, IL - Robert Jackstadt	Somerset, MD - Jeffrey Z. Slavin
Grand Rapids, MI - George Heartwell	Somerville, MA - Joseph Curtatone
Greenfield, MA - William F. Martin	South Bend, IN - Pete Buttigieg
Highland Park, IL - Nancy Rotering	South Miami, FL - Philip K. Stoddard, PhD
Ketchum, ID - Nina Jonas	St. Louis, MO - Francis G. Slay
Kingston Springs, TN - Francis A. Gross	St. Petersburg, FL - Rick Kriseman
Las Cruces, NM - Ken Miyagishima	Sugar Creek, MO - Matt Mallinson
Little Rock, AR - Mark Stodola	Syracuse, NY - Stephanie A. Miner
Long Beach, CA - Robert Garcia	Torrance, CA - Patrick J. Furey
Los Angeles, CA - Eric Garcetti	University City, MO - Shelley Welsch
Malden, MA - Gary Christenson	Village of Lombard, IL - Keith Giagnorio
Malibu, CA - John Sibert	Warren, MI - Jim Fouts
Medford, MA - Michael McGlynn	West Hollywood, CA - Lindsey P. Horvath
Melrose, MA - Robert J. Dolan	Winthrop, MA - James McKenna



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

April 7, 2008

EPA-CASAC-08-009

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the
Final Rule for the National Ambient Air Quality Standards for Ozone

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC or Committee), augmented by subject-matter-expert Panelists — collectively referred to as the CASAC Ozone Review Panel — met via a public advisory teleconference on March 28, 2008. The purpose of this conference call was to hold follow-on discussions concerning the Final Rule for the National Ambient Air Quality Standards (NAAQS) for ozone, which the Agency published on March 12, 2008. The Ozone Panel roster is attached as Appendix A.

In our most-recent letters to you on this subject — EPA-CASAC-07-001, dated October 24, 2006, and EPA-CASAC-07-002, dated March 26, 2007 — the CASAC unanimously recommended selection of an 8-hour average Ozone NAAQS within the range of 0.060 to 0.070 parts per million for the primary (human health-based) Ozone NAAQS. Moreover, with regard to the secondary (welfare-related) ozone standard, the Committee recommended an alternative secondary standard of cumulative form that is substantially different from the primary Ozone NAAQS in averaging time, level and form — specifically, the W126 index within the range of 7 to 15 ppm-hours, accumulated over at least the 12 “daylight” hours and the three maximum ozone months of the summer growing season.

The CASAC now wishes to convey, by means of this letter, its additional, unsolicited advice with regard to the primary and secondary Ozone NAAQS. *In doing so, the participating members of the CASAC Ozone Review Panel are unanimous in strongly urging you or your successor as EPA Administrator to ensure that these recommendations be considered during the next review cycle for the Ozone NAAQS that will begin next year.*

March 12, 2008 was the first time since 1997 that the primary standard for ozone was updated, and the CASAC commends you for taking a step in the right direction by lowering the primary eight-hour ozone standard from 0.08 parts per million to 0.075 ppm. The Committee is also pleased that the Agency has abandoned the artificial use of only two decimal places for the standard, as reported in ppm. As noted in the CASAC's previous letters to you on this subject, this practice has allowed the rounding-down of ozone concentrations as high as 0.084 ppm to meet the previous standard of 0.08 ppm.

Nevertheless, the members of the CASAC Ozone Review Panel do not endorse the new primary ozone standard as being sufficiently protective of public health. The CASAC — as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards — *unanimously recommended* decreasing the primary standard to within the range of 0.060–0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations.

As you are well aware, numerous medical organizations and public health groups have also expressed their support of these CASAC recommendations. We sincerely hope that, in light of these scientific judgments and the supporting scientific evidence, you or your successor will select a more health-protective primary ozone standard during the upcoming review cycle.

The CASAC was also greatly disappointed that you failed to change the form of the secondary standard to make it different from the primary standard. As stated in the preamble to the Final Rule, even in the previous 1996 ozone review, "there was general agreement between the EPA staff, CASAC, and the Administrator, ... that a cumulative, seasonal form was more biologically relevant than the previous 1-hour and new 8-hour average forms (61 FR 65716)" for the secondary standard. *Therefore, in both the previous review and in this review, the Agency staff and its advisors agreed that a change in the form of the secondary standard was scientifically well-justified.*

The CASAC was pleased to see that the EPA Deputy Administrator clearly articulated a robust scientific defense of this position when he responded to Ms. Susan Dudley of the Office of Management and Budget (OMB) in a memorandum dated March 7, 2008 that, "In light of the available information, EPA believes that ozone-related effects on vegetation are clearly linked to cumulative, seasonal exposures and are not appropriately characterized by the use of a short-term (8-hour) daily measure of ozone exposure." However, the Committee was disappointed and surprised that written correspondence from OMB to the Agency apparently thwarted the opportunity to take a major step forward in setting a separate secondary ozone standard that is different in form from the primary standard. The CASAC is particularly dismayed at the suggestion that setting a secondary NAAQS that is different from the primary NAAQS is somehow against the law — which is not only at odds with a plain-language reading of the Clean Air Act but is also contrary to the Agency's previous actions in setting a separate secondary standard for the initial NAAQS for both particulate matter and sulfur oxides, the latter of which (*i.e.*, for SO₂) remains in effect.

Unfortunately, this scientifically-sound approach of using a cumulative exposure index for welfare effects was not adopted, and the default position of using the primary standard for the secondary standard was once again instituted. Keeping the same form for the secondary Ozone NAAQS as for the primary standard is not supported by current scientific knowledge indicating that different indicator variables are needed to protect vegetation compared to public health. The CASAC was further disappointed that a secondary standard of the W126 form was not considered from within the Committee's previously-recommended range of 7 to 15 ppm-hours. *The CASAC sincerely hopes that, in the next round of Ozone NAAQS review, the Agency will be able to support and establish a reasonable and scientifically-defensible cumulative form for the secondary standard.*

We recognize that it will be difficult to bring the country into compliance with lower primary and secondary ozone standards. However, the fact that it is difficult does not mean that it is not achievable. The substantial progress made to date in lowering ambient ozone levels testifies to this. The CASAC believes that, in the future, we as a nation can devise effective and efficient ways to decrease ambient ozone concentrations to a sufficiently health- and welfare-protective level. However, in order to support this vital objective, EPA's recent record of not adequately funding ozone research must end. The CASAC strongly supports the provision of additional funds to address the research needs that Agency staff have identified as being necessary for informing the process of setting both the primary and secondary ozone standards.

As always, the members of the CASAC wish the Agency well in our crucial — and mutual — efforts to protect both human health and the environment.

Sincerely,

/Signed/

Dr. Rogene F. Henderson, Chair
Clean Air Scientific Advisory Committee

Attachment: Appendix A

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively-located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: <http://www.epa.gov/casac>.

Appendix A – Roster of the CASAC Ozone Review Panel

U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office Clean Air Scientific Advisory Committee (CASAC) CASAC Ozone Review Panel

CASAC MEMBERS

Dr. Rogene Henderson (Chair), Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Ellis Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo [M.D.], Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown,[§] Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. Donna Kenski,[†] Director of Data Analysis, Lake Michigan Air Directors Consortium (LADCO), Rosemont, IL

Dr. Armistead (Ted) Russell,[§] Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Jonathan Samet [M.D.],[†] Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

PANEL MEMBERS

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Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

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Dr. Sverre Vedal, Professor of Medicine, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. James (Jim) Zidek, Professor, Statistics, Science, University of British Columbia, Vancouver, BC, Canada

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov)

[§]Dr. Crawford-Brown was appointed to the Clean Air Scientific Advisory Committee in October 2006; Dr. Russell was a member of the CASAC Ozone Review Panel and was appointed to the Clean Air Scientific Advisory Committee in October 2006.

[†]Dr. Kenski and Dr. Samet were appointed to the Clean Air Scientific Advisory Committee in October 2007.

*Dr. Harkema did not participate in this current CASAC Ozone Review Panel activity.

DOCUMENTS SUBMITTED BY REPRESENTATIVE ZOE LOFGREN



October 20, 2015

The Honorable Lamar Smith, Chairman
 The Honorable Eddie Bernice Johnson, Ranking Member
 Committee on Science, Space and Technology
 U.S. House of Representatives
 U.S. Capitol
 Washington, DC

Re: EPA's 2015 Ozone Standard

Dear Chairman Smith and Ranking Member Johnson:

The Coalition for Clean Air is dedicated to restoring clean, healthy air to California by advocating for effective public policy and practical business solutions. Although California's air is much cleaner than it was when our organization was founded in 1971 – largely because of strong Clean Air Act standards that have driven technological improvements, our state still has the worst air quality in the country and the only two “extreme” ozone non-attainment areas in the country. Our residents are depending on the federal Clean Air Act for health protection.

The new national ozone standard set by EPA is an important step forward that will save lives and avoid health emergencies, but does not go far enough. A standard of 65 ppb or lower is warranted by the scientific evidence and would better protect public health. Health impacts from ozone exposure have been identified in research below the level of the current standard. A large body of scientific evidence shows that asthma attacks as well as hospitalizations and emergency room visits for respiratory illnesses and premature deaths occur at levels below the current standard.

Ozone pollution threatens public health and can be deadly. Ozone is a corrosive gas that can burn our lungs and airways, causing them to become inflamed, reddened, and swollen. Children, teenagers, seniors, and people with lung diseases like asthma, chronic bronchitis, emphysema, and others are particularly vulnerable to the health effects of ozone. Health effects of ozone exposure can range from shortness of breath, chest pain and coughing to increased asthma attacks and even premature death.

What will **not** help Californians to breathe easier is the proposal from the San Joaquin Valley Air Pollution Control District to weaken the Clean Air Act. As Air District Board Members Dr. Alexander Sherriffs and Dr. John A. Capitman have said: “The district needs to focus on policy and advocacy to increase the tools and resources to meet more healthful air standards – not on how to delay attainment.” By proposing to delay attainment, the District does a disservice to all the people breathing unhealthy air in the San Joaquin Valley, especially vulnerable populations like children, seniors, and those suffering from asthma and other respiratory diseases.

Sincerely,

Bill Magavern
 Policy Director

800 Wilshire Boulevard, Suite 1010
 Los Angeles, California 90017
 (213) 223-6860

1107 Ninth Street, Suite 440
 Sacramento, California 95814
 (916) 527-8048

www.ccair.org



October 21, 2015

House Committee on Science, Space & Technology
2321 Rayburn House Office Building
Washington, DC 20515
Fax (202) 226-0113

Re: Hearing on EPA's 2015 Ozone Standard: Concerns Over Science and Implementation

The Central Valley Air Quality (CVAQ) Coalition requests the following comments be included as the House Committee on Science, Space & Technology considers the science and implementation of the Environmental Protection Agency (EPA)'s newly released ozone standard of 70 ppb.

The Central Valley Air Quality (CVAQ) Coalition is a partnership of more than 70 member organizations committed to creating clean air in the San Joaquin Valley of California since 2003. Our coalition originally advocated for the most health protective possible standard of 60ppb. We urge the committee to support the implementation of the 70 ppb standard, which represents a level of health protection that is long overdue and at the very least it is in the right direction.

On October 22, 2015 the committee will hear from the San Joaquin Valley Air Pollution Control District, Air Pollution Control Officer (APCO), Seyed Sadredin. It is important that the committee understand Mr. Sadredin's perspective and his efforts on behalf of the San Joaquin Valley. Our coalition believes he does not represent the public; instead he represents interests of industry and Agriculture in our Valley. While he represents a public health agency, the Valley Air Board members, whose political campaigns and personal income are directly tied to our polluting industries, determine the fate of his position. Thus, his perspective is biased.

Mr. Sadredin advocates for the interests of business, even while our Valley, with over 4 million residents, has the highest asthma rates in California. He claims businesses have done all they could and cleaning our air is the responsibility of the individual. This stance was demonstrated when he convinced the Valley, that the EPA levied a \$29 million fee via a DMV surcharge on all motorists, for not meeting an ozone standard. He failed to clarify that the decision was made by himself and the Valley Air Board, to place the financial burden on all Valley motorists, rather than business. For the past ten years, our coalition has debated with Mr. Sadredin on strategies

for clean air. The District has ignored significant sources of ozone pollution, such as volatile organic compound (VOC) emissions from dairies and Oil and Gas operations, and they have also failed to implement aggressive measures on agricultural equipment and mobile sources within their purview.

Rather than look for additional control measures, Mr. Sadredin has employed tactics of scapegoating. The Air District has funneled hundreds of thousands of dollars into examining ozone pollution traveling to our Valley from Asia, while ignoring the majority of our homegrown pollution. In recent years, the Air District has blamed the drought for our bad air, taking no responsibility for the consequences of failed air quality plans from previous years. Currently, the blame falls on the EPA and the Clean Air Act, claiming the Act is antiquated and EPA sets unrealistic standards. Without strong guidance from the EPA and the Clean Air Act, the Valley Air District representing the air basin with the worst air pollution in the nation, would define its own path to clean air with little regard for public health.

The Air District's decisions and inaction have real and lasting impacts on our health. Our children are regularly kept indoors from recess and sports activities and we lose billions of dollars every year in missed school and work days, visits to the emergency room and health care costs. We learn more everyday of the impacts of air pollution on our health and our Valley has become numb to the information, because Mr. Sadredin and the Valley Air Board disregard it, blame external factors and have failed to find a balance between supporting business and protecting public health.

Our coalition urges you to support the EPA's decision of implementing a standard of 70 ppb and to hear Mr. Sadredin with skepticism. Mr. Sadredin does not represent the interests of Valley residents and Valley businesses have not done enough. On the other hand, residents have endured enough – decades of poor health and misinformation with no accountability. We need your help in guiding our local leaders to protect our health.

Sincerely,

A handwritten signature in cursive script that reads "D. Weller".

Dolores Weller
CVAQ Director

Opinion Columns & Blogs^[1]

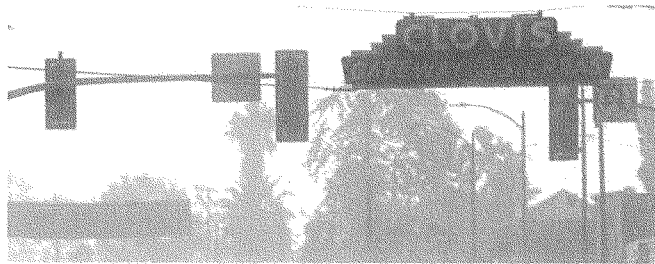
September 30, 2015

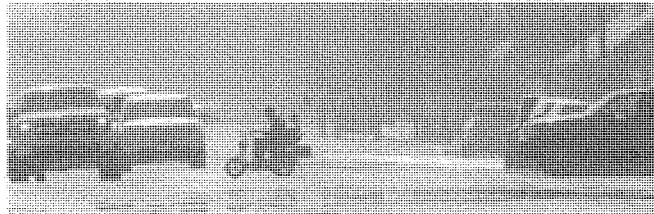
Alex Sherriffs and John Capitman: Don't back off demands for cleaner air

Two dissenting members of Valley air board want to increase
resources for cleaner air, not delay attainment

Valley can be proud of efforts that result in better air quality, but we
still have far to go

Any changes to the Clean Air Act must unequivocally help us move
forward





A typical smoggy day in Old Town Clovis last fall. JOHN WALKER
Fresno Bee file

By Alex Sherriffs and John Capitman

We are responding to a commentary in the Sept. 23 Bee written by five of our fellow board members at the San Joaquin Valley Air Pollution Control District.

They support federal legislation that we believe will weaken, not strengthen, efforts to improve the Valley's air quality. As a practicing physician and as a professor of public health policy serving on the board, we cannot support a policy direction which threatens to extend the time Valley residents are breathing unhealthful air.

Generalities in the op-ed sounded good, but we cannot endorse many details of the legislative language, particularly as public discourse of its implications has been limited. The district needs to focus on policy and advocacy to increase the tools and resources to meet more healthful air standards – not on how to delay attainment.

Thanks to the Clean Air Act, the Valley's air is cleaner and more healthful than it was five, 10 and 25 years ago. The Clean Air Act represents 40 years of federal legislation driving efforts to combat air pollution. It got lead out of gasoline. It fights lung- and eye-burning ozone, and it has saved hundreds of thousands of lives by cleaning soot and tiny particulates from our air.

The Clean Air Act sets standards based on what the latest and best science tells us about the impacts of air quality on health. First and foremost, the Clean Air Act is about achieving better health for us all.

The Valley has made important investments to reach Clean Air Act goals. Thanks to federal, state and air district regulations, our businesses use cleaner technologies and have adopted more sustainable and efficient practices. Trucks have to upgrade to lower-emission, more fuel-efficient engines. The public has been essential in its demand for and acceptance of cleaner-burning, higher-mileage and alternative-fuel cars. The public also has been on board in its support of incentives, financed by state bonds and DMV fees specific to the Valley.

Agriculture, too, has played an important role. Farmers have switched from diesel pumps to electric pumps and have purchased cleaner-burning tractors, thanks to incentive programs.

Schools have been able to purchase less polluting buses, decreasing our children's direct exposure to toxic diesel emissions. Those incentives have helped businesses adopt cleaner technologies sooner. We all benefit: Businesses get assistance buying cleaner

equipment ahead of deadlines, and the public sees cleaner air sooner.

We can all be proud of the combination of efforts that has resulted in better air quality. But we still have far to go. We still share the worst childhood asthma rates in the nation with the heavily polluted Los Angeles basin. We still have more than 1,000 premature deaths every year in the Valley because of air pollution. Among all the air pollutants contributing to cancer, diesel emissions remain the No. 1 cause.

Whenever we think about the costs of cleaning up, we must remember, too, the costs of not making things better for our children and grandchildren. The annual monetary cost of Valley air pollution in lost days of work, lost school days and health costs is over \$1 billion. That human suffering and monetary expense may not make daily headlines, but it is real and immediate.

We need to focus on achieving the health goals ahead, not on finding ways to delay success. Many thought that achieving current ozone standards would be impossible due to the costs and the lack of technology, but thanks to regulations put in place, and especially cleaner trucks and buses, we are on a path of success into the 2030s.

Creating a cleaner and more healthful future requires change. How we will balance competing needs is never certain. We have great opportunities to promote even cleaner technologies, garner more support and financing to implement those strategies, and to be certain we include disadvantaged communities in that economic success.

<http://www.fresnobee.com/opinion/opn-columns-blogs/article371132...>

Every day of delay is more deaths, millions of dollars in unnecessary health costs, and new cases of asthma. Any changes to the Clean Air Act must unequivocally help us move forward and strengthen our hand for cleaner, more healthful air.

Alexander Sherriffs, M.D., is a physician with Adventist Health Community Care in Fowler. John A. Capitman, Ph.D., is executive director of the Central Valley Health Policy Institute. They are San Joaquin Valley Air Pollution Control District board members.

1. <http://www.fresnobee.com/opinion/opn-columns-blogs/>

DOCUMENTS SUBMITTED BY REPRESENTATIVE BARRY LOUDERMILK



guidance was only just issued by EPA this month. These rules are in addition to fuel economy standards and Tier 3 tailpipe emission standards for cars and trucks implemented at the federal level which increase costs for businesses and consumers in my state and others. All of these regulations have required substantial investments on the part of Georgia companies and consumers and constitute a moving target for Georgia companies. I urge you to defer setting a more stringent ozone standard to allow these existing regulations to have an impact and to avoid the costly planning and economic burden of additional regulation.

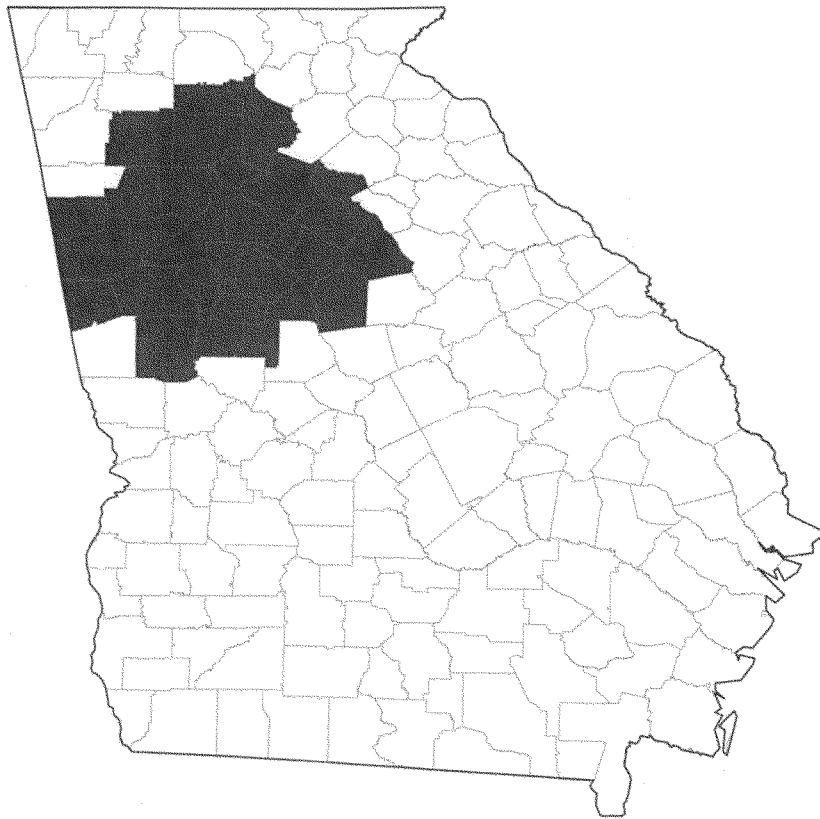
The currently proposed revision to the ozone NAAQS may be the most expensive regulation in our nation's history. It is my duty to my constituents to urge you to set an ozone standard that does not place this undue burden on states. We ask you to keep the current standard of 75 parts per billion (ppb) in place.

Sincerely,

Nathan Deal

Nathan Deal

Georgia Projected 8-Hour Ozone Nonattainment Areas



■ Monitored CBSAs and rural counties that would be violating a 70 ppb standard

Based on a 3-year period, 2012-2014.
Source: URS, August 3, 2015



STATE OF GEORGIA

OFFICE OF THE GOVERNOR

ATLANTA 30334-0090

Nathan Deal
GOVERNORFebruary 20th, 2015The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave N.W.
Washington, D.C. 20460

Dear Administrator McCarthy,

In the four decades since the Clean Air Act was signed into law, the State of Georgia has achieved unprecedented improvements to the quality of the air we breathe. We have done so while adhering to the core principle that protection of the environment must be balanced with economic progress. It is for this reason that I, in my role as guardian of our state's quality of life, oppose changing the National Ambient Air Quality Standard (NAAQS) for ground-level ozone at this time.

Your agency is contemplating a NAAQS so stringent that even some of our country's pristine national parks may not be able to satisfy it. Many areas in Georgia have background levels of ozone at or near the levels under consideration, making it almost impossible for these cities and counties to come into compliance. If they cannot, new business development will be constrained as these counties are placed in nonattainment status, an economic penalty box that makes it so hard to build something new that many companies simply build elsewhere. Existing businesses in Georgia would also be impacted, as additional unknown control measures will likely be required to achieve a more stringent standard. In the end, Georgia citizens will have less money to spend on food, clothing and other basic needs because they will be spending this money instead on the new costs that have been passed through to them from ozone regulations. This all adds up to what many are calling the "most expensive regulation ever."

My state is already in the process of planning for and implementing dozens of massive new regulations put in place by your agency over the past several years, regulations like the Mercury and Air Toxics Standards, the Boiler MACT, regional haze rules, the Cross-State Air Pollution Rule, and most recently the Clean Power Plan. Very notably, states have only begun to implement the ozone NAAQS put in place in 2008, a standard for which implementation

DOCUMENTS SUBMITTED BY REPRESENTATIVE ED PERLMUTTER

2/18/2016

The Durango Herald 10/05/2015 | Ozone rules

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[Back](#)

Article published Oct 5, 2015

Ozone rules

Challenge in meeting standards
 no reason to set lower bar

The Environmental Protection Agency last week released new standards for ground-level ozone, lowering the maximum allowable saturation of the gas from 75 parts per billion to 70 ppb. In doing so, the EPA has raised concerns across states and various sectors about whether the new standard is attainable, and, if not, what the federal ramifications will be. Those are legitimate questions, but they are not sufficient to derail a needed rule that protects public health. Without stringent standards, however difficult they are to reach, improving air quality is merely aspirational. That is not enough.

The new standard was derived from extensive research into the health effects of ground-level ozone. The EPA is compelled by the Clean Air Act to ensure that public health is not unduly affected by ambient contaminants, and ozone is a known culprit in harming respiratory health. Asthmatic children, in particular, see increased illnesses as a result of high ozone levels. In lowering the ceiling of allowable ozone – which results when nitrogen and volatile organic compounds react in sunlight – the EPA estimates significant cost and health savings. Primary sources of nitrogen oxides and VOCs include vehicle exhaust, industrial facilities and power plants.

At or below 70 ppb, the EPA says there will be 230,000 fewer asthma attacks each year nationally – excluding California, which is considered separately – as well as 28,000 fewer missed worker days and up to 360 prevented premature deaths. The agency expects these and other health benefits to save up to \$5.9 billion each year, while achieving the standards should only cost \$1.4 billion, according to the EPA. With numbers like those, there should be no question as to the efficacy and value of decreasing the ozone threshold.

But the issue is more complex than such stark math would suggest. The EPA's current 75 ppb standard – issued in 2008 – has not yet been met nationwide, and Colorado is among the states struggling to meet it. Front Range communities consistently report numbers above the threshold, despite a statewide plan to reduce ozone and other emissions – an effort led by the Colorado Department of Public Health & Environment, compelled by the EPA. Southwest Colorado has not recently exceeded the 75 ppb ceiling, but is expected to struggle to meet the 70 ppb standard.

The CDPHE, through the Colorado Air Quality Control Commission, has had its ozone-reducing plan in place since 2008, and there have been improvements resulting from a multi-strategy approach including increased monitoring, vehicle emissions standards, new controls on gas and oil industry emissions and phasing out old power plants. Nevertheless, the problem is not wholly resolved, and there is concern that the new rule is simply out of

reach given the challenges associated with curbing ozone levels, which is a regional problem as much as a local one.

However daunting the challenge, though, it is one we must rise to meet. Air quality standards are in place to protect human and environmental health, and ozone is known to negatively affect both. Setting a lower, easier-to-reach standard may be appealing for those who must modify their practices in order to limit their emissions, but it would compromise health for hundreds of thousands of Americans. That must be the top priority in setting pollution standards, regardless of how difficult meeting them might be. The EPA set a high bar and was right to do so.

**U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
Full Committee Hearing**
EPA's 2015 Ozone Standard: Concerns over Science and Implementation

October 22, 2015

DOCUMENT FOR THE RECORD

Submitted by Congressman Ed Perlmutter (D-CO)

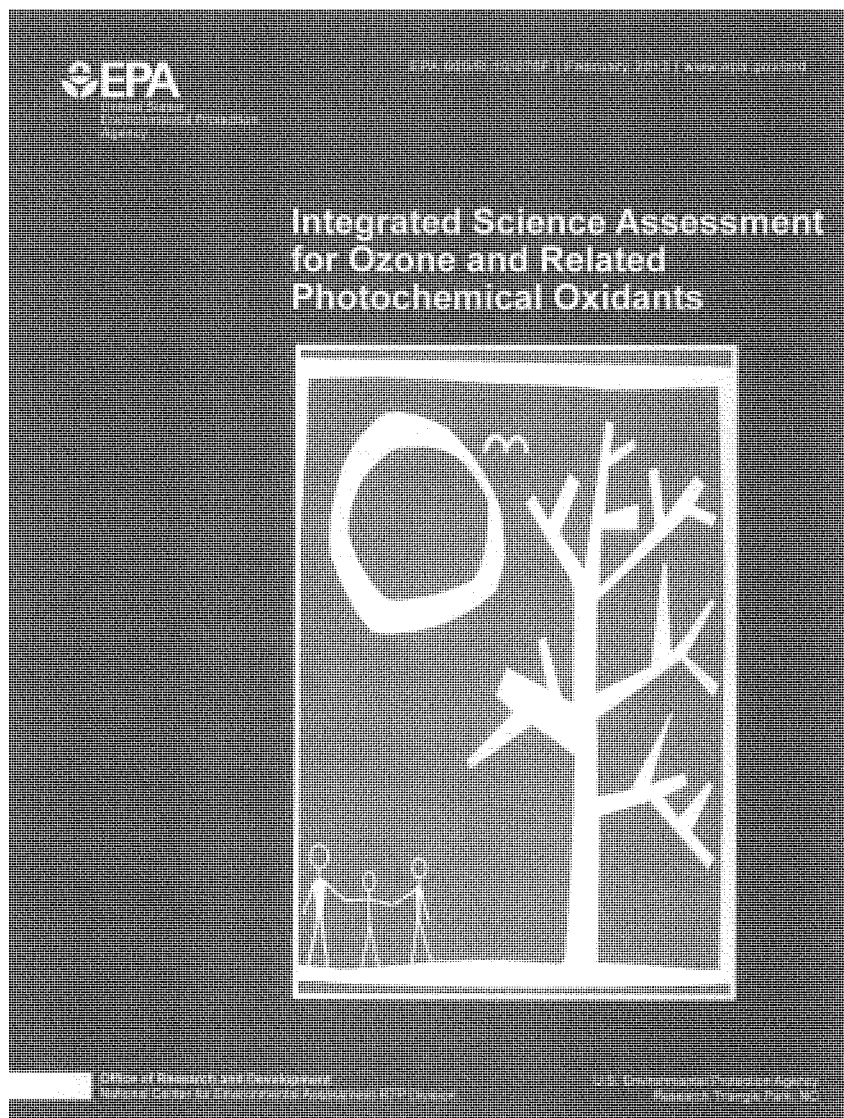
1) Integrated Science Assessment (ISA) for Ozone – 1251 pages

Full document can be accessed here: <https://www.epa.gov/isa/integrated-science-assessment-isa-ozone>

Full pdf of ISA can be accessed here:

http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=511347

2) Preamble to the Integrated Science Assessment (ISA) for Ozone



Integrated Science Assessment for Ozone and Related Photochemical Oxidants

National Center for Environmental Assessment-RTP Division
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, NC

DISCLAIMER

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

PREAMBLE

Process of ISA Development

This preamble outlines the general process for developing an Integrated Science Assessment (ISA) including the framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments. The ISA provides a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the National Ambient Air Quality Standards (NAAQS). The general process for NAAQS reviews is described at <http://www.epa.gov/ttn/naaqs/review.html>. Figure I depicts the general NAAQS review process and information for individual NAAQS reviews is available at www.epa.gov/ttn/naaqs. This preamble is a general discussion of the basic steps and criteria used in developing an ISA; for each ISA, specific details and considerations are included in the introductory section for that assessment.

The fundamental process for developing an ISA includes:

- literature searches;
- study selection;
- evaluation and integration of the evidence;
- development of scientific conclusions and causal judgments.

An initial step in this process is publication of a call for information in the Federal Register that invites the public to provide information relevant to the assessment, such as new or recent publications on health or welfare¹ effects of the pollutant, or from atmospheric and exposure sciences fields. EPA maintains an ongoing literature search process for identification of relevant scientific studies published since the last review of the NAAQS. Search strategies are designed for pollutants and scientific disciplines and iteratively modified to optimize identification of pertinent publications. Papers are identified for inclusion in several additional ways: specialized searches on specific topics; independent review of tables of contents for journals in which relevant papers may be published; independent identification of relevant literature by expert scientists; review of citations in previous assessments and identification by the public and the Clean Air Scientific Advisory Committee (CASAC) during the external review process. This literature search and study selection process is depicted in Figure II. Publications considered for inclusion in the ISA are added to the Health and Environmental Research Online (HERO) database developed by EPA (<http://hero.epa.gov/>); the references in the ISA include a hyperlink to the database.

¹ Welfare effects as defined in Clean Air Act (CAA) section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

Studies that have undergone scientific peer review and have been published or accepted for publication and reports that have undergone review are considered for inclusion in the ISA. Analyses conducted by EPA using publicly available data are also considered for inclusion in the ISA. All relevant epidemiologic, controlled human exposure, toxicological, and ecological and welfare effects studies published since the last review are considered, including those related to exposure-response relationships, mode(s) of action (MOA), and potentially at-risk populations and lifestyles. Studies on atmospheric chemistry, environmental fate and transport, dosimetry, toxicokinetics and exposure are also considered for inclusion in the document, as well as analyses of air quality and emissions data. References that were considered for inclusion in a specific ISA can be found using the HERO website (<http://hero.epa.gov>).

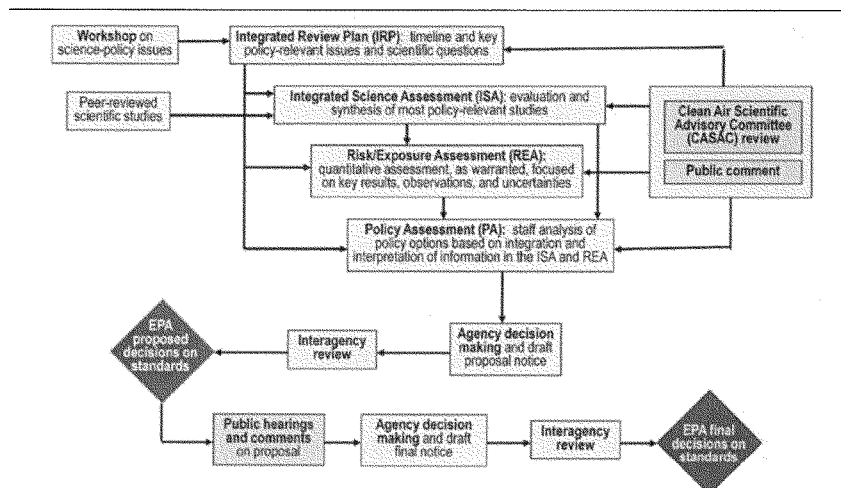


Figure I Illustration of the key steps in the process of the review of National Ambient Air Quality Standards.

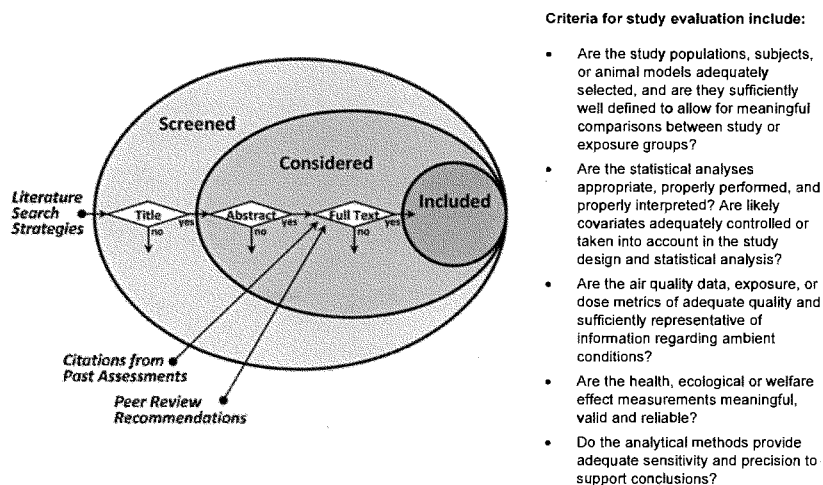


Figure II Illustration of processes for literature search and study selection used for development of ISAs.

Each ISA builds upon the conclusions of previous assessments for the pollutant under review. EPA focuses on peer reviewed literature published following the completion of the previous review (2006 O₃ AQCD) and on any new interpretations of previous literature, integrating the results of recent scientific studies with previous findings. Important earlier studies may be discussed in detail to reinforce key concepts and conclusions or for reinterpretation in light of newer data. Earlier studies also are the primary focus in some areas of the document where research efforts have subsided, or if these earlier studies remain the definitive works available in the literature.

Selection of studies for inclusion in the ISA is based on the general scientific quality of the study, and consideration of the extent to which the study is informative and policy-relevant. Policy relevant and informative studies include those that provide a basis for or describe the relationship between the criteria pollutant and effects, including studies that offer innovation in method or design and studies that reduce uncertainty on critical issues, such as analyses of confounding or effect modification by copollutants or other variables, analyses of concentration-response or dose-

response relationships, or analyses related to time between exposure and response. Emphasis is placed on studies that examine effects associated with pollutant concentrations relevant to current population and ecosystem exposures, and particularly those pertaining to concentrations currently found in ambient air. Other studies are included if they contain unique data, such as a previously unreported effect or MOA for an observed effect, or examine multiple concentrations to elucidate exposure-response relationships. In general, in assessing the scientific quality and relevance of health and welfare effects studies, the following considerations have been taken into account when selecting studies for inclusion in the ISA.

- Are the study populations, subjects, or animal models adequately selected, and are they sufficiently well defined to allow for meaningful comparisons between study or exposure groups?
- Are the statistical analyses appropriate, properly performed, and properly interpreted? Are likely covariates adequately controlled or taken into account in the study design and statistical analysis?
- Are the air quality data, exposure, or dose metrics of adequate quality and sufficiently representative of information regarding ambient conditions?
- Are the health, ecological or welfare effect measurements meaningful, valid and reliable?
- Do the analytical methods provide adequate sensitivity and precision to support conclusions?

Considerations specific to particular disciplines include the following: In selecting epidemiologic studies, EPA considers whether a given study: (1) presents information on associations with short- or long-term pollutant exposures at or near conditions relevant to ambient exposures; (2) addresses potential confounding by other pollutants; (3) assesses potential effect modifiers; (4) evaluates health endpoints and populations not previously extensively researched; and (5) evaluates important methodological issues related to interpretation of the health evidence (e.g., lag or time period between exposure and effects, model specifications, thresholds, mortality displacement).

Considerations for the selection of research evaluating controlled human exposure or animal toxicological studies include a focus on studies conducted using relevant pollutant exposures. For both types of studies, relevant pollutant exposures are considered to be those generally within one or two orders of magnitude of ambient concentrations. Studies in which higher doses were used may also be considered if they provide information relevant to understanding MOA or mechanisms, as noted below.

Evaluation of controlled human exposure studies focuses on those that approximated expected human exposure conditions in terms of concentration and duration. Studies should include control exposures to filtered air, as appropriate. In the selection of controlled human exposure studies, emphasis is placed on studies that: (1) investigate potentially at-risk populations and lifestages such as people with asthma or

cardiovascular diseases, children or older adults; (2) address issues such as concentration-response or time-course of responses; and (3) have sufficient statistical power to assess findings.

Review of the animal toxicological evidence focuses on studies that approximate expected human dose conditions, which vary depending on the dosimetry, toxicokinetics, and biological sensitivity of the particular laboratory animal species or strains studied. Emphasis is placed on studies that: (1) investigate animal models of disease that can provide information on populations potentially at increased risk of effects; (2) address issues such as concentration-response or time-course of responses; and (3) have sufficient statistical power to assess findings. Due to resource constraints on exposure duration and numbers of animals tested, animal studies typically utilize high-concentration exposures to acquire data relating to mechanisms and assure a measurable response. Emphasis is placed on studies using doses or concentrations generally within 1-2 orders of magnitude of current levels. Studies with higher concentration exposures or doses are considered to the extent that they provide useful information to inform understanding of interspecies differences between healthy and at-risk human populations. Results from *in vitro* studies may also be included if they provide mechanistic insight or further support for results demonstrated *in vivo*.

These criteria provide benchmarks for evaluating various studies and for focusing on the policy-relevant studies in assessing the body of health, ecological and welfare effects evidence. As stated initially, the intent of the ISA is to provide a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the NAAQS, not extensive summaries of all health, ecological and welfare effects studies for a pollutant. Of most relevance for inclusion of studies is whether they provide useful qualitative or quantitative information on exposure-effect or exposure-response relationships for effects associated with pollutant exposures at doses or concentrations relevant to ambient conditions that can inform decisions on whether to retain or revise the standards.

The general process for ISA development is illustrated in Figure III. In developing an ISA, EPA reviews and summarizes the evidence from studies of atmospheric sciences; human exposure, toxicological, controlled human exposure and epidemiologic studies; and studies of ecological and welfare effects. In the process of developing the first draft ISA, EPA may convene a peer input meeting in which EPA the scientific content of preliminary draft materials is reviewed to ensure that the ISA is up to date and focused on the most policy-relevant findings, and to assist EPA with integration of evidence within and across disciplines. EPA integrates the evidence from across scientific disciplines or study types and characterizes the weight of evidence for relationships between the pollutant and various outcomes. The integration of evidence on health, and ecological or welfare effects, involves collaboration between scientists from various disciplines. As an example, an evaluation of health effects evidence would include the integration of the results from epidemiologic, controlled human exposure, and toxicological studies, and application of the causal framework (described below) to draw conclusions. Integration of results

on health or ecological effects that are logically or mechanistically connected (e.g., a spectrum of effects on the respiratory system) informs judgments of causality. Using the causal framework described in the following section, EPA scientists consider aspects such as strength, consistency, coherence, and biological plausibility of the evidence, and develop causality determinations on the nature of the relationships. Causality determinations often entail an iterative process of review and evaluation of the evidence. Two drafts of the ISA are typically released for review by the CASAC and the public, and comments received on the characterization of the science as well as the implementation of the causal framework are carefully considered in revising and completing the final ISA.

Integrated Science Assessment Development Process

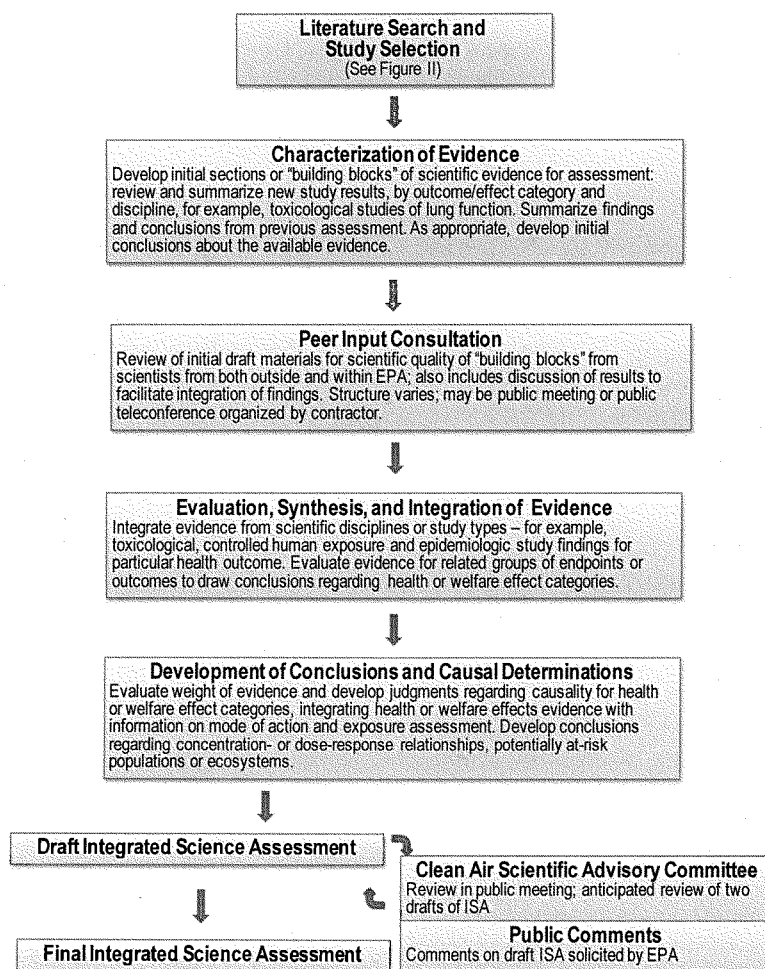


Figure III Characterization of the general process of ISA development.

EPA Framework for Causal Determination

EPA has developed a consistent and transparent basis for integration of scientific evidence and evaluation of the causal nature of air pollution-related health or welfare effects for use in developing ISAs. The framework described below establishes uniform language concerning causality and brings more specificity to the findings. This standardized language was drawn from sources across the federal government and wider scientific community, especially the National Academy of Sciences (NAS) Institute of Medicine (IOM) document, *Improving the Presumptive Disability Decision-Making Process for Veterans* (Samet and Bodurow, 2008), a comprehensive report on evaluating causality. This framework:

- describes the kinds of scientific evidence used in establishing a general causal relationship between exposure and health effects;
- characterizes the process for integration and evaluation of evidence necessary to reach a conclusion about the existence of a causal relationship;
- identifies issues and approaches related to uncertainty;
- provides a framework for classifying and characterizing the weight of evidence in support of a general causal relationship.

Approaches to assessing the separate and combined lines of evidence (e.g., epidemiologic, controlled human exposure, and animal toxicological studies) have been formulated by a number of regulatory and science agencies, including the IOM of the NAS (Samet and Bodurow, 2008), International Agency for Research on Cancer (IARC, 2006), U.S. EPA (2005), and Centers for Disease Control and Prevention (CDC, 2004). Causal inference criteria have also been described for ecological effects evidence (U.S. EPA, 1998; Fox, 1991). These formalized approaches offer guidance for assessing causality. The frameworks are similar in nature, although adapted to different purposes, and have proven effective in providing a uniform structure and language for causal determinations.

Evaluating Evidence for Inferring Causation

The 1964 Surgeon General's (U.S. Department of Health, Education and Welfare [HEW]) report on tobacco smoking defined "cause" as a "significant, effectual relationship between an agent and an associated disorder or disease in the host" (HEW, 1964). More generally, a cause is defined as an agent that brings about an effect or a result. An association is the statistical relationship among variables; alone, however, it is insufficient proof of a causal relationship between an exposure and a health outcome. Unlike an association, a causal claim supports the creation of counterfactual claims, that is, a claim about what the world would have been like under different or changed circumstances (Samet and Bodurow, 2008).

Many of the health and environmental outcomes reported in these studies have complex etiologies. Diseases such as asthma, coronary heart disease (CHD) or cancer

are typically initiated by multiple agents. Outcomes depend on a variety of factors, such as age, genetic susceptibility, nutritional status, immune competence, and social factors (Samet and Bodurow, 2008; Gee and Payne-Sturges, 2004). Effects on ecosystems are often also multifactorial with a complex web of causation. Further, exposure to a combination of agents could cause synergistic or antagonistic effects. Thus, the observed risk may represent the net effect of many actions and counteractions.

Scientific findings incorporate uncertainty. “Uncertainty” can be defined as having limited knowledge to exactly describe an existing state or future outcome, e.g., the lack of knowledge about the correct value for a specific measure or estimate. Uncertainty analysis may be qualitative or quantitative in nature. In many cases, the analysis is qualitative, and can include professional judgment or inferences based on analogy with similar situations. Quantitative uncertainty analysis may include use of simple measures (e.g., ranges) and analytical techniques. Quantitative uncertainty analysis might progress to more complex measures and techniques, if needed for decision support. Various approaches to evaluating uncertainty include classical statistical methods, sensitivity analysis, or probabilistic uncertainty analysis, in order of increasing complexity and data requirements. However, data may not be available for all aspects of an assessment and those data that are available may be of questionable or unknown quality. Ultimately, the assessment is based on a number of assumptions with varying degrees of uncertainty.

Publication bias is a source of uncertainty regarding the magnitude of health risk estimates. It is well understood that studies reporting non-null findings are more likely to be published than reports of null findings. Publication bias can result in overestimation of effect estimate sizes (Ioannidis, 2008). For example, effect estimates from single-city epidemiologic studies have been found to be generally larger than those from multicity studies which is an indication of publication bias in that null or negative single-city results may be reported in a multicity analyses but might not be published independently (Bell et al., 2005).

Consideration of Evidence from Scientific Disciplines

Moving from association to causation involves the elimination of alternative explanations for the association. The ISA focuses on evaluation of the findings from the body of evidence, drawing upon the results of all studies determined to meet the criteria described previously. Causality determinations are based on the evaluation, integration, and synthesis of evidence from across scientific disciplines. The relative importance of different types of evidence varies by pollutant or assessment, as does the availability of different types of evidence for causality determination. Three general types of studies inform consideration of human health effects: controlled human exposure, epidemiologic, and toxicological studies. Evidence on ecological or welfare effects may be drawn from a variety of experimental approaches (e.g.,

greenhouse, laboratory, field) and numerous disciplines (e.g., community ecology, biogeochemistry, and paleontological/historical reconstructions).

Direct evidence of a relationship between pollutant exposures and human health effects comes from controlled human exposure studies. Such studies experimentally evaluate the health effects of administered exposures in human volunteers under highly controlled laboratory conditions. Also referred to as human clinical studies, these experiments allow investigators to expose subjects to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels. These studies provide important information on the biological plausibility of associations observed in epidemiologic studies. Essential dose-response profiles and ranges of response severity can be established with these studies. In some instances, controlled human exposure studies can also be used to characterize concentration-response relationships at pollutant concentrations relevant to ambient conditions. Controlled human exposures are typically conducted using a randomized crossover design, with subjects exposed both to the pollutant and a clean air control. In this way, subjects serve as their own controls, effectively controlling for many potential confounders. Considerations for evaluating controlled human study findings include the generally small sample size and short exposure time used in experimental studies, and that severe health outcomes are not assessed. By experimental design, controlled human exposure studies are structured to evaluate physiological or biomolecular outcomes in response to exposure to a specific air pollutant and/or combination of pollutants. In addition, the study design generally precludes inclusion of subjects with serious health conditions, and therefore the results often cannot be generalized to an entire population. Although some controlled human exposure studies have included health-compromised individuals such as those with respiratory or cardiovascular disease, these individuals may also be relatively healthy and may not represent the most sensitive individuals in the population. Thus, observed effects in these studies may underestimate the response in certain populations.

Epidemiologic studies provide important information on the associations between health effects and exposure of human populations to ambient air pollution. In epidemiologic or observational studies of humans, the investigator generally does not control exposures or intervene with the study population. Broadly, observational studies can describe associations between exposures and effects. These studies fall into several categories: e.g., cross-sectional, prospective cohort, panel, and time-series studies. Cross-sectional studies use health outcome, exposure and covariate data available at the community level (e.g., annual mortality rates and pollutant concentrations), but do not have individual-level data. Prospective cohort studies have some data collected at the individual level, generally health outcome data, and in some cases individual-level data on exposure and covariates are collected. Time-series studies evaluate the relationship for changes in a health outcome with changes in exposure indicators, such as an association between daily changes in mortality with air pollution. Panel studies include repeated measurements of health outcomes, such as respiratory symptoms or heart rhythm variable, at the individual level. "Natural experiments" offer the opportunity to investigate changes in health related to a change in exposure, such as closure of a pollution source.

In evaluating epidemiologic studies, consideration of many study design factors and issues must be taken into account to properly inform their interpretation. One key consideration is evaluation of the potential contribution of the pollutant to a health outcome when it is a component of a complex air pollutant mixture. Reported effect estimates in epidemiologic studies may reflect: independent effects on health outcomes; effects of the pollutant acting as an indicator of a copollutant or a complex ambient air pollution mixture; effects resulting from interactions between that pollutant and copollutants.

In the evaluation of epidemiologic evidence, one important consideration is potential confounding. Confounding is "... a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null)" (Rothman and Greenland, 1998). One approach to remove spurious associations (due to possible confounders); is to control for characteristics that may differ between exposed and unexposed persons; this is frequently termed "adjustment." Scientific judgment is needed to evaluate likely sources and extent of confounding, together with consideration of how well the existing constellation of study designs, results, and analyses address the potential for erroneous inferences. A confounder is associated with both the exposure and the effect; for example, confounding can occur between correlated pollutants that are associated with the same effect.

Several statistical methods are available to detect and control for potential confounders, with none of them being completely satisfactory. Multivariable regression models constitute one tool for estimating the association between exposure and outcome after adjusting for characteristics of participants that might confound the results. The use of multipollutant regression models has been the prevailing approach for controlling potential confounding by copollutants in air pollution health effects studies. Finding the likely causal pollutant from multipollutant regression models is made difficult by the possibility that one or more air pollutants may be acting as a surrogate for an unmeasured or poorly measured pollutant or for a particular mixture of pollutants. In addition, pollutants may independently exert effects on the same system; for example, several pollutants may be associated with respiratory effects through either the same or different modes of action. The number and degree of diversity of covariates, as well as their relevance to the potential confounders, remain matters of scientific judgment. Despite these limitations, the use of multipollutant models is still the prevailing approach employed in most air pollution epidemiologic studies and provides some insight into the potential for confounding or interaction among pollutants.

Confidence that unmeasured confounders are not producing the findings is increased when multiple studies are conducted in various settings using different subjects or exposures, each of which might eliminate another source of confounding from consideration. For example, multicity studies can provide insight on potential confounding through the use of a consistent method to analyze data from across locations with different levels of copollutants and other covariates. Intervention

studies, because of their quasi-experimental nature, can be particularly useful in characterizing causation.

Another important consideration in the evaluation of epidemiologic evidence is effect modification, which occurs when the effect differs between subgroups or strata; for example, effect estimates that vary by age group or potential risk factor. As stated by Rothman and Greenland (1998):

“Effect-measure modification differs from confounding in several ways. The main difference is that, whereas confounding is a bias that the investigator hopes to prevent or remove from the effect estimate, effect-measure modification is a property of the effect under study ... In epidemiologic analysis one tries to eliminate confounding but one tries to detect and estimate effect-measure modification.”

When a risk factor is a confounder, it is the true cause of the association observed between the exposure and the outcome; when a risk factor is an effect modifier, it changes the magnitude of the association between the exposure and the outcome in stratified analyses. For example, the presence of a pre-existing disease or indicator of low socioeconomic status may act as effect modifiers if they are associated with increased risk of effects related to air pollution exposure. It is often possible to stratify the relationship between health outcome and exposure by one or more of these potential effect modifiers. For variables that modify the association, effect estimates in each stratum will be different from one another and different from the overall estimate, indicating a different exposure-response relationship may exist in populations represented by these variables.

Exposure measurement error, which refers to the uncertainty associated with the exposure metrics used to represent exposure of an individual or population, can be an important contributor to uncertainty in air pollution epidemiologic study results. Exposure error can influence observed epidemiologic associations between ambient pollutant concentrations and health outcomes by biasing effect estimates toward or away from the null and widening confidence intervals around those estimates (Zeger et al., 2000). There are several components that contribute to exposure measurement error in air pollution epidemiologic studies, including the difference between true and measured ambient concentrations, the difference between average personal exposure to ambient pollutants and ambient concentrations at central monitoring sites, and the use of average population exposure rather than individual exposure estimates. Factors that could influence exposure estimates include nonambient sources of exposure, topography of the natural and built environment, meteorology, measurement errors, time-location-activity patterns, and the extent to which ambient pollutants penetrate indoor environments. The importance of exposure error varies with study design and is dependent on the spatial and temporal aspects of the design.

The third main type of health effects evidence, animal toxicological studies, provides information on the pollutant's biological action under controlled and monitored exposure circumstances. Taking into account physiological differences of the experimental species from humans, these studies inform characterization of health

effects of concern, exposure-response relationships and MOAs. Further, animal models can inform determinations of at-risk populations. These studies evaluate the effects of exposures to a variety of pollutants in a highly controlled laboratory setting and allow exploration of toxicological pathways or mechanisms by which a pollutant may cause effects. Understanding the biological mechanisms underlying various health outcomes can prove crucial in establishing or negating causality. In the absence of human studies data, extensive, well-conducted animal toxicological studies can support determinations of causality, if the evidence base indicates that similar responses are expected in humans under ambient exposure conditions.

Interpretations of animal toxicological studies are affected by limitations associated with extrapolation between animal and human responses. The differences between humans and other species have to be taken into consideration, including metabolism, hormonal regulation, breathing pattern, and differences in lung structure and anatomy. Also, in spite of a high degree of homology and the existence of a high percentage of orthologous genes across humans and rodents (particularly mice), extrapolation of molecular alterations at the gene level is complicated by species-specific differences in transcriptional regulation. Given these differences, there are uncertainties associated with quantitative extrapolations of observed pollutant-induced pathophysiological alterations between laboratory animals and humans, as those alterations are under the control of widely varying biochemical, endocrine, and neuronal factors.

For ecological effects assessment, both laboratory and field studies (including field experiments and observational studies) can provide useful data for causality determination. Because conditions can be controlled in laboratory studies, responses may be less variable and smaller differences may be easier to detect. However, the control conditions may limit the range of responses (e.g., animals may not be able to seek alternative food sources) or incompletely reflect pollutant bioavailability, so they may not reflect responses that would occur in the natural environment. In addition, larger-scale processes are difficult to reproduce in the laboratory.

Field observational studies measure biological changes in uncontrolled situations, and describe an association between a disturbance and an ecological effect. Field data can provide important information for assessments of multiple stressors or where site-specific factors significantly influence exposure. They are also often useful for analyses of larger geographic scales and higher levels of biological organization. However, because conditions are not controlled, variability is expected to be higher and differences harder to detect. Field surveys are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. The presence of confounding factors can make it difficult to attribute observed effects to specific stressors.

Intermediate between laboratory and field are studies that use environmental media collected from the field to examine response in the laboratory, and experiments that are performed in the natural environment while controlling for some environmental conditions (i.e., mesocosm studies). This type of study in manipulated natural environments can be considered a hybrid between a field experiment and laboratory

study since some aspects are performed under controlled conditions but others are not. They make it possible to observe community and/or ecosystem dynamics, and provide strong evidence for causality when combined with findings of studies that have been made under more controlled conditions.

Application of Framework for Causal Determination

In its evaluation and integration of the scientific evidence on health or welfare effects of criteria pollutants, EPA determines the weight of evidence in support of causation and characterizes the strength of any resulting causal classification. EPA also evaluates the quantitative evidence and draws scientific conclusions, to the extent possible, regarding the concentration-response relationships and the loads to ecosystems, exposures, doses or concentrations, exposure duration, and pattern of exposures at which effects are observed.

To aid judgment, various “aspects”¹ of causality have been discussed by many philosophers and scientists. The 1964 Surgeon General’s report on tobacco smoking discussed criteria for the evaluation of epidemiologic studies, focusing on consistency, strength, specificity, temporal relationship, and coherence (HEW, 1964). Sir Austin Bradford Hill (Hill, 1965) articulated aspects of causality in epidemiology and public health that have been widely used (Samet and Bodurow, 2008; IARC, 2006; U.S. EPA, 2005; CDC, 2004). These aspects (Hill, 1965) have been modified (Table I) for use in causal determinations specific to health and welfare effects for pollutant exposures (U.S. EPA, 2009d).² Although these aspects provide a framework for assessing the evidence, they do not lend themselves to being considered in terms of simple formulas or fixed rules of evidence leading to conclusions about causality (Hill, 1965). For example, one cannot simply count the number of studies reporting statistically significant results or statistically nonsignificant results and reach credible conclusions about the relative weight of the evidence and the likelihood of causality. Rather, these aspects provide a framework for systematic appraisal of the body of evidence, informed by peer and public comment and advice, which includes weighing alternative views on controversial issues. In addition, it is important to note that the aspects in Table I cannot be used as a strict checklist, but rather to determine the weight of the evidence for inferring causality. In particular, not meeting one or more of the principles does not automatically preclude a determination of causality [see discussion in CDC (2004)].

¹ The “aspects” described by Sir Austin Bradford Hill (Hill, 1965) have become, in the subsequent literature, more commonly described as “criteria.” The original term “aspects” is used here to avoid confusion with “criteria” as it is used, with different meaning, in the Clean Air Act.

² The Hill aspects were developed for interpretation of epidemiologic results. They have been modified here for use with a broader array of data, i.e., epidemiologic, controlled human exposure, ecological, and animal toxicological studies, as well as *in vitro* data, and to be more consistent with the U.S. EPA (2005) Guidelines for Carcinogen Risk Assessment.

Table I Aspects to aid in judging causality.

Aspect	Description
Consistency of the observed association	An inference of causality is strengthened when a pattern of elevated risks is observed across several independent studies. The reproducibility of findings constitutes one of the strongest arguments for causality. If there are discordant results among investigations, possible reasons such as differences in exposure, confounding factors, and the power of the study are considered.
Coherence	An inference of causality from one line of evidence (e.g., epidemiologic, controlled human exposure [clinical], or animal studies) may be strengthened by other lines of evidence that support a cause-and-effect interpretation of the association. Evidence on ecological or welfare effects may be drawn from a variety of experimental approaches (e.g., greenhouse, laboratory, and field) and subdisciplines of ecology (e.g., community ecology, biogeochemistry, and paleontological/historical reconstructions). The coherence of evidence from various fields greatly adds to the strength of an inference of causality. In addition, there may be coherence in demonstrating effects across multiple study designs or related health endpoints within one scientific line of evidence.
Biological plausibility	An inference of causality tends to be strengthened by consistency with data from experimental studies or other sources demonstrating plausible biological mechanisms. A proposed mechanistic linking between an effect and exposure to the agent is an important source of support for causality, especially when data establishing the existence and functioning of those mechanistic links are available.
Biological gradient (exposure-response relationship)	A well-characterized exposure-response relationship (e.g., increasing effects associated with greater exposure) strongly suggests cause and effect, especially when such relationships are also observed for duration of exposure (e.g., increasing effects observed following longer exposure times).
Strength of the observed association	The finding of large, precise risks increases confidence that the association is not likely due to chance, bias, or other factors. However, it is noted that a small magnitude in an effect estimate may represent a substantial effect in a population.
Experimental evidence	Strong evidence for causality can be provided through "natural experiments" when a change in exposure is found to result in a change in occurrence or frequency of health or welfare effects.
Temporal relationship of the observed association	Evidence of a temporal sequence between the introduction of an agent, and appearance of the effect, constitutes another argument in favor of causality.
Specificity of the observed association	Evidence linking a specific outcome to an exposure can provide a strong argument for causation. However, it must be recognized that rarely, if ever, does exposure to a pollutant invariably predict the occurrence of an outcome, and that a given outcome may have multiple causes.
Analogy	Structure activity relationships and information on the agent's structural analogs can provide insight into whether an association is causal. Similarly, information on mode of action for a chemical, as one of many structural analogs, can inform decisions regarding likely causality.

Determination of Causality

In the ISA, EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation¹. In developing this hierarchy, EPA has drawn on the work of previous evaluations, most prominently the IOM's *Improving the Presumptive Disability Decision-Making Process for Veterans* (Samet and Bodurov, 2008), EPA's Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), and the U.S. Surgeon General's smoking report (CDC, 2004). This weight of evidence evaluation is based on integration of findings from various lines of evidence from across the health and environmental effects disciplines. These separate judgments are integrated into a qualitative statement about the overall weight of the evidence and causality. The five descriptors for causal determination are described in Table II.

Determination of causality involves the evaluation and integration of evidence for different types of health, ecological or welfare effects associated with short- and long-term exposure periods. In making determinations of causality, evidence is evaluated for major outcome categories or groups of related endpoints (e.g., respiratory effects, vegetation growth), integrating evidence from across disciplines, and assessing the coherence of evidence across a spectrum of related endpoints to draw conclusions regarding causality. In discussing the causal determination, EPA characterizes the evidence on which the judgment is based, including strength of evidence for individual endpoints within the outcome category or group of related endpoints.

In drawing judgments regarding causality for the criteria air pollutants, the ISA focuses on evidence of effects in the range of relevant pollutant exposures or doses, and not on determination of causality at any dose. Emphasis is placed on evidence of effects at doses (e.g., blood Pb concentration) or exposures (e.g., air concentrations) that are relevant to, or somewhat above, those currently experienced by the population. The extent to which studies of higher concentrations are considered varies by pollutant and major outcome category, but generally includes those with doses or exposures in the range of one to two orders of magnitude above current or ambient conditions. Studies that use higher doses or exposures may also be considered to the extent that they provide useful information to inform understanding of mode of action, interspecies differences, or factors that may increase risk of effects for a population. Thus, a causality determination is based on weight of evidence evaluation for health, ecological or welfare effects, focusing on the evidence from exposures or doses generally ranging from current levels to one or two orders of magnitude above current levels.

¹ Both the CDC and IOM frameworks use a four-category hierarchy for the strength of the evidence. A five-level hierarchy is used here to be consistent with the EPA Guidelines for Carcinogen Risk Assessment and to provide a more nuanced set of categories.

In addition, EPA evaluates evidence relevant to understand the quantitative relationships between pollutant exposures and health, ecological or welfare effects. This includes evaluation of the form of concentration-response or dose-response relationships and, to the extent possible, drawing conclusions on the levels at which effects are observed. The ISA also draws scientific conclusions regarding important exposure conditions for effects and populations that may be at greater risk for effects, as described in the following section.

Table II Weight of evidence for causal determination.

	Health Effects	Ecological and Welfare Effects
Causal relationship	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (i.e., doses or exposures generally within one to two orders of magnitude of current levels). That is, the pollutant has been shown to result in health effects in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. For example: a) controlled human exposure studies that demonstrate consistent effects; or b) observational studies that cannot be explained by plausible alternatives or are supported by other lines of evidence (e.g., animal studies or mode of action information). Evidence includes multiple high-quality studies	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures i.e., doses or exposures generally within one to two orders of magnitude of current levels). That is, the pollutant has been shown to result in effects in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. Controlled exposure studies (laboratory or small- to medium-scale field studies) provide the strongest evidence for causality, but the scope of inference may be limited. Generally, determination is based on multiple studies conducted by multiple research groups, and evidence that is considered sufficient to infer a causal relationship is usually obtained from the joint consideration of many lines of evidence that reinforce each other.
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures, but important uncertainties remain. That is, the pollutant has been shown to result in health effects in studies in which chance and bias can be ruled out with reasonable confidence but potential issues remain. For example: a) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent; or b) animal toxicological evidence from multiple studies from different laboratories that demonstrate effects, but limited or no human data are available. Evidence generally includes multiple high-quality studies.	Evidence is sufficient to conclude that there is a likely causal association with relevant pollutant exposures. That is, an association has been observed between the pollutant and the outcome in studies in which chance, bias, and confounding are minimized, but uncertainties remain. For example, field studies show a relationship, but suspected interacting factors cannot be controlled, and other lines of evidence are limited or inconsistent. Generally, determination is based on multiple studies in multiple research groups.
Suggestive of a causal relationship	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited. For example, (a) at least one high-quality epidemiologic study shows an association with a given health outcome but the results of other studies are inconsistent; or (b) a well-conducted toxicological study, such as those conducted in the National Toxicology Program (NTP), shows effects in animal species.	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but chance, bias and confounding cannot be ruled out. For example, at least one high-quality study shows an effect, but the results of other studies are inconsistent.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.	The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.
Not likely to be a causal relationship	Evidence is suggestive of no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations, are mutually consistent in not showing an effect at any level of exposure.	Several adequate studies, examining relationships with relevant exposures, are consistent in failing to show an effect at any level of exposure.

Quantitative Relationships: Effects on Human Populations

Once a determination is made regarding the causal relationship between the pollutant and outcome category, important questions regarding quantitative relationships include:

- What is the concentration-response, exposure-response, or dose-response relationship in the human population?
- What is the interrelationship between incidence and severity of effect?
- What exposure conditions (dose or exposure, duration and pattern) are important?
- What populations and lifestages appear to be differentially affected (i.e., more at risk of experiencing effects)?

To address these questions, the entirety of quantitative evidence is evaluated to characterize pollutant concentrations and exposure durations at which effects were observed for exposed populations, including populations and lifestages potentially at increased risk. To accomplish this, evidence is considered from multiple and diverse types of studies, and a study or set of studies that best approximates the concentration-response relationships between health outcomes and the pollutant may be identified. Controlled human exposure studies provide the most direct and quantifiable exposure-response data on the human health effects of pollutant exposures. To the extent available, the ISA evaluates results from across epidemiologic studies that characterize the form of relationships between the pollutant and health outcomes and draws conclusions on the shape of these relationships. Animal data may also inform evaluation of concentration-response relationships, particularly relative to MOAs and characteristics of at-risk populations.

An important consideration in characterizing the public health impacts associated with exposure to a pollutant is whether the concentration-response relationship is linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Of particular interest is the shape of the concentration-response curve at and below the level of the current standards. Various sources of variability and uncertainty, such as low data density in the lower concentration range, possible influence of exposure measurement error, and variability between individuals in susceptibility to air pollution health effects, tend to smooth and “linearize” the concentration-response function, and thus can obscure the existence of a threshold or nonlinear relationship [2006 O₃ AQCD (U.S. EPA, 2006b)]. Since individual thresholds vary from person to person due to individual differences such as genetic level susceptibility or pre-existing disease conditions (and even can vary from one time to another for a given person), it can be difficult to demonstrate that a threshold exists in a population study. These sources of variability and uncertainty may explain why the available human data at ambient concentrations for some environmental pollutants (e.g., particulate matter [PM], O₃, lead [Pb], environmental tobacco smoke [ETS], radiation) do not exhibit thresholds for cancer or noncancer health effects, even though likely mechanisms include nonlinear processes for some key events.

Finally, identification of the population groups or lifestages that may be at greater risk of health effects from air pollutant exposures contributes to an understanding of the public health impact of pollutant exposures. In the ISA, the term “at-risk population” is used to encompass populations or lifestages that have a greater likelihood of experiencing health effects related to exposure to an air pollutant due to a variety of factors; other terms used in the literature include susceptible, vulnerable, and sensitive. These factors may be intrinsic, such as genetic or developmental factors, race, sex, lifestage, or the presence of pre-existing diseases, or they may be extrinsic, such as socioeconomic status (SES), activity pattern and exercise level, reduced access to health care, low educational attainment, or increased pollutant exposures (e.g., near roadways). Epidemiologic studies can help identify populations potentially at increased risk of effects by evaluating health responses in the study population. Examples include testing for interactions or effect modification by factors such as sex, age group, or health status. Experimental studies using animal models of susceptibility or disease can also inform the extent to which health risks are likely greater in specific population groups.

Quantitative Relationships: Effects on Ecosystems or Public Welfare

Key questions for understanding the quantitative relationships between exposure (or concentration or deposition) to a pollutant and risk to ecosystems or the public welfare include:

- What elements of the ecosystem (e.g., types, regions, taxonomic groups, populations, functions, etc.) appear to be affected, or are more sensitive to effects? Are there differences between locations or materials in welfare effects responses, such as impaired visibility or materials damage?
- Under what exposure conditions (amount deposited or concentration, duration and pattern) are effects seen?
- What is the shape of the concentration-response or exposure-response relationship?

Evaluations of causality generally consider the probability of quantitative changes in ecological and welfare effects in response to exposure. A challenge to the quantification of exposure-response relationships for ecological effects is the great regional and local spatial variability, as well as temporal variability, in ecosystems. Thus, exposure-response relationships are often determined for a specific ecological system and scale, rather than at the national or even regional scale. Quantitative relationships therefore are estimated site by site and may differ greatly between ecosystems.

Concepts in Evaluating Adversity of Health Effects

In evaluating health evidence, a number of factors can be considered in delineating between adverse and nonadverse health effects resulting from exposure to air

pollution. Some health outcomes, such as hospitalization for respiratory or cardiovascular diseases, are clearly considered adverse. It is more difficult to determine the extent of change that constitutes adversity in more subtle health measures. These include a wide variety of responses, such as alterations in markers of inflammation or oxidative stress, changes in pulmonary function or heart rate variability, or alterations in neurocognitive function measures. The challenge is determining the magnitude of change in these measures when there is no clear point at which a change becomes adverse. The extent to which a change in health measure constitutes an adverse health effect may vary between populations. Some changes that may not be considered adverse in healthy individuals would be potentially adverse in more at-risk individuals.

The extent to which changes in lung function are adverse has been discussed by the American Thoracic Society (ATS) in an official statement titled *What Constitutes an Adverse Health Effect of Air Pollution?* (ATS, 2000b). An air pollution-induced shift in the population distribution of a given risk factor for a health outcome was viewed as adverse, even though it may not increase the risk of any one individual to an unacceptable level. For example, a population of asthmatics could have a distribution of lung function such that no identifiable individual has a level associated with significant impairment. Exposure to air pollution could shift the distribution such that no identifiable individual experiences any clinically relevant effects. This shift toward decreased lung function, however, would be considered adverse because individuals within the population would have diminished reserve function and therefore would be at increased risk to further environmental insult. The committee also observed that elevations of biomarkers, such as cell number and types, cytokines and reactive oxygen species, may signal risk for ongoing injury and clinical effects or may simply indicate transient responses that can provide insights into mechanisms of injury, thus illustrating the lack of clear boundaries that separate adverse from nonadverse effects.

The more subtle health outcomes may be connected mechanistically to health events that are clearly adverse. For example, air pollution may affect markers of transient myocardial ischemia such as ST-segment abnormalities and onset of exertional angina. These effects may not be apparent to the individual, yet may still increase the risk of a number of cardiac events, including myocardial infarction and sudden death. Thus, small changes in physiological measures may not appear to be clearly adverse when considered alone, but may be a part of a coherent and biologically plausible chain of related health outcomes that range up to responses that are very clearly adverse, such as hospitalization or mortality.

Concepts in Evaluating Adversity of Ecological Effects

Adversity of ecological effects can be understood in terms ranging in biological level of organization; from the cellular level to the individual organism and to the population, community, and ecosystem levels. In the context of ecology, a population is a group of individuals of the same species, and a community is an assemblage of populations of different species interacting with one another that inhabit an area.

An ecosystem is the interactive system formed from all living organisms and their abiotic (physical and chemical) environment within a given area (IPCC, 2007a). The boundaries of what could be called an ecosystem are somewhat arbitrary, depending on the focus of interest or study. Thus, the extent of an ecosystem may range from very small spatial scales to, ultimately, the entire Earth (IPCC, 2007a).

Effects on an individual organism are generally not considered to be adverse to public welfare. However if effects occur to enough individuals within a population, then communities and ecosystems may be disrupted. Changes to populations, communities, and ecosystems can in turn result in an alteration of ecosystem processes. Ecosystem processes are defined as the metabolic functions of ecosystems including energy flow, elemental cycling, and the production, consumption and decomposition of organic matter (U.S. EPA, 2002). Growth, reproduction, and mortality are species-level endpoints that can be clearly linked to community and ecosystem effects and are considered to be adverse when negatively affected. Other endpoints such as changes in behavior and physiological stress can decrease ecological fitness of an organism, but are harder to link unequivocally to effects at the population, community, and ecosystem level. The degree to which pollutant exposure is considered adverse may also depend on the location and its intended use (i.e., city park, commercial, cropland). Support for consideration of adversity beyond the species level by making explicit the linkages between stress-related effects at the species and effects at the ecosystem level is found in *A Framework for Assessing and Reporting on Ecological Condition: an SAB report* (U.S. EPA, 2002). Additionally, the National Acid Precipitation Assessment Program (NAPAP, 1991) uses the following working definition of “adverse ecological effects” in the preparation of reports to Congress mandated by the Clean Air Act: “any injury (i.e., loss of chemical or physical quality or viability) to any ecological or ecosystem component, up to and including at the regional level, over both long and short terms.”

On a broader scale, ecosystem services may provide indicators for ecological impacts. Ecosystem services are the benefits that people obtain from ecosystems (UNEP, 2003). According to the Millennium Ecosystem Assessment, ecosystem services include: “provisioning services such as food and water; regulating services such as regulation of floods, drought, land degradation, and disease; supporting services such as soil formation and nutrient cycling; and cultural services such as recreational, spiritual, religious, and other nonmaterial benefits.” For example, a more subtle ecological effect of pollution exposure may result in a clearly adverse impact on ecosystem services if it results in a population decline in a species that is recreationally or culturally important.

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LEGISLATIVE AND HISTORICAL BACKGROUND

Legislative Requirements for the NAAQS Review

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the National Ambient Air Quality Standards (NAAQS). Section 108 (42 USC §7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her “judgement; cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;” ... “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources” and “for which ... [the Administrator] plans to issue air quality criteria...” (CAA, 1990a). Air quality criteria are intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare, which may be expected from the presence of [a] pollutant in ambient air ...” [42 USC §7408(b)].

Section 109 (CAA, 1990b) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria have been issued. Section 109(b)(1) defines a primary standard as one “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”¹ A secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”²

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. (1981), cert. denied, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may

¹ The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group” [S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970)].

² Welfare effects as defined in section 302(h) include, but are not limited to, “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being” (CAA, 2005).

pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for a margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-1162; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting standards that are "requisite" to protect public health and welfare, as provided in Section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. [See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76. (2001)]. Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F.2d at 1185.

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards ... and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate..." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria ... and the national primary and secondary ambient air quality standards ... and shall recommend to the Administrator any new ... standards and revisions of existing criteria and standards as may be appropriate ..." Since the early 1980s, this independent review function has been performed by CASAC.

History of the NAAQS for Ozone

Tropospheric (ground-level) O₃ is the indicator for the mix of photochemical oxidants (e.g., peroxyacetyl nitrate, hydrogen peroxide) formed from biogenic and anthropogenic precursor emissions. Naturally occurring O₃ in the troposphere can result from biogenic organic precursors reacting with naturally occurring nitrogen oxides (NO_x) and by stratospheric O₃ intrusion into the troposphere. Anthropogenic precursors of O₃, especially NO_x, and volatile organic compounds (VOCs), originate from a wide variety of stationary and mobile sources. Ambient O₃ concentrations produced by these emissions are directly affected by temperature, solar radiation, wind speed, and other meteorological factors.

NAAQS are comprised of four basic elements: indicator, averaging time, level, and form. The indicator defines the pollutant to be measured in the ambient air for the purpose of determining compliance with the standard. The averaging time defines the time period over which air quality measurements are to be obtained and averaged or cumulated, considering evidence of effects associated with various time periods of exposure. The level of a standard defines the air quality concentration used (i.e., an ambient concentration of the indicator pollutant) in determining whether the standard is achieved. The form of the standard specifies the air quality measurements that are to be used for compliance purposes (e.g., the annual fourth-highest daily maximum 8-h concentration, averaged over 3 years), and whether the statistic is to be averaged across multiple years. These four elements taken together determine the degree of public health and welfare protection afforded by the NAAQS.

Table III Summary of primary and secondary NAAQS promulgated for O₃ during the period 1971-2008.

Final Rule	Indicator	Avg Time	Level (ppm)	Form
1971 (36 FR 8186)	Total photochemical oxidants	1-h	0.08	Not to be exceeded more than 1 hour per year
1979 (44 FR 8202)	O ₃	1-h	0.12	Attainment is defined when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, is ≤ 1
1993 (58 FR 13008)	EPA decided that revisions to the standards were not warranted at the time.			
1997 (62 FR 38856)	O ₃	8-h	0.08	Annual fourth-highest daily maximum 8-h concentration averaged over 3 years
2008 (73 FR 16483)	O ₃	8-h	0.075	Form of the standards remained unchanged relative to the 1997 standard

Table III summarizes the O₃ NAAQS that have been promulgated to date. In each review, the secondary standard has been set to be identical to the primary standard. These reviews are briefly described below.

EPA first established primary and secondary NAAQS for photochemical oxidants in 1971. Both primary and secondary standards were set at a level of 0.08 parts per million (ppm), 1-h avg, total photochemical oxidants, not to be exceeded more than 1 hour per year. The standards were based on scientific information contained in the 1970 O₃ AQCD.

In 1977, EPA announced the first periodic review of the 1970 AQCD in accordance with Section 109(d)(1) of the Clean Air Act. In 1978, EPA published an AQCD. Based on the 1978 AQCD, EPA published proposed revisions to the original NAAQS in 1978 (U.S. EPA, 1978b) and final revisions in 1979 (U.S. EPA, 1979a). The level of the primary and secondary standards was revised from 0.08 to 0.12 ppm;

the indicator was revised from photochemical oxidants to O₃; and the form of the standards was revised from a deterministic to a statistical form, which defined attainment of the standards as occurring 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 one.

In 1982, EPA announced plans to revise the 1978 AQCD ([U.S. EPA, 1978a](#)). In 1983, EPA announced that the second periodic review of the primary and secondary standards for O₃ had been initiated ([U.S. EPA, 1983](#)). EPA subsequently published the 1986 O₃ AQCD ([U.S. EPA, 1986](#)) and 1989 Staff Paper ([U.S. EPA, 1989](#)). Following publication of the 1986 O₃ AQCD, a number of scientific abstracts and articles were published that appeared to be of sufficient importance concerning potential health and welfare effects of O₃ to warrant preparation of a Supplement to the 1986 O₃ AQCD ([Costa et al., 1992](#)). Under the terms of a court order, on August 10, 1992, EPA published a proposed decision ([U.S. EPA, 1992](#)) stating that revisions to the existing primary and secondary standards were not appropriate at the time ([U.S. EPA, 1992](#)). This notice explained that the proposed decision would complete EPA's review of information on health and welfare effects of O₃ assembled over a 7-year period and contained in the 1986 O₃ AQCD ([U.S. EPA, 1986](#)) and its Supplement to the 1986 O₃ AQCD ([Costa et al., 1992](#)). The proposal also announced EPA's intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O₃ in light of emerging evidence of health effects related to 6- to 8-hour O₃ exposures. On March 9, 1993, EPA concluded the review by deciding that revisions to the standards were not warranted at that time ([U.S. EPA, 1993](#)).

In August 1992, EPA announced plans to initiate the third periodic review of the air quality criteria and O₃ NAAQS ([U.S. EPA, 1992](#)). On the basis of the scientific evidence contained in the 1996 O₃ AQCD ([U.S. EPA, 1996a](#)) and the 1996 Staff Paper ([U.S. EPA, 1996e](#)), and related technical support documents, linking exposures to ambient O₃ to adverse health and welfare effects at levels allowed by the then existing standards, EPA proposed to revise the primary and secondary O₃ standards on December 13, 1996 ([U.S. EPA, 1996d](#)). The EPA proposed to replace the then existing 1-hour primary and secondary standards with 8-h avg O₃ standards set at a level of 0.08 ppm (equivalent to 0.084 ppm using standard rounding conventions). The EPA also proposed, in the alternative, to establish a new distinct secondary standard using a biologically based cumulative seasonal form. The EPA completed the review on July 18, 1997 by setting the primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-h avg concentration, averaged over 3 years, and setting the secondary standard identical to the revised primary standard ([U.S. EPA, 1997](#)).

On May 14, 1999, in response to challenges to EPA's 1997 decision by industry and others, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Cir.) remanded the O₃ NAAQS to EPA, finding that Section 109 of the CAA, as interpreted by EPA, effected an unconstitutional delegation of legislative authority. In addition, the D.C. Cir. directed that, in responding to the remand, EPA should

consider the potential beneficial health effects of O₃ pollution in shielding the public from the effects of solar ultraviolet (UV) radiation, as well as adverse health effects. On January 27, 2000, EPA petitioned the U.S. Supreme Court for certiorari on the constitutional issue (and two other issues) but did not request review of the D.C. Cir., ruling regarding the potential beneficial health effects of O₃. On February 27, 2001, the U.S. Supreme Court unanimously reversed the judgment of the D.C. Cir. on the constitutional issue, holding that Section 109 of the CAA does not delegate legislative power to the EPA in contravention of the Constitution, and remanded the case to the D.C. Cir. to consider challenges to the O₃ NAAQS that had not been addressed by that Court's earlier decisions. On March 26, 2002, the D.C. Cir. issued its final decision, finding the 1997 O₃ NAAQS to be "neither arbitrary nor capricious," and denied the remaining petitions for review. On November 14, 2001, in response to the D.C. Cir. remand to consider the potential beneficial health effects of O₃ pollution in shielding the public from effects of solar (UV) radiation, EPA proposed to leave the 1997 8-h O₃ NAAQS unchanged (U.S. EPA, 2001). After considering public comment on the proposed decision, EPA published its final response to this remand on January 6, 2003, reaffirming the 8-h O₃ NAAQS set in 1997 (U.S. EPA, 2003). On April 30, 2004, EPA announced the decision to make the 1-h O₃ NAAQS no longer applicable to areas 1 year after the effective date of the designation of those areas for the 8-h NAAQS (U.S. EPA, 2004). For most areas, the date that the 1-h NAAQS no longer applied was June 15, 2005.

EPA initiated the next periodic review of the air quality criteria and O₃ standards in September 2000 with a call for information (U.S. EPA, 2000). The schedule for completion of that rulemaking later became governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental and public health organizations. Based on the 2006 O₃ AQCD (U.S. EPA, 2006b) published in March 2006, the Staff Paper (U.S. EPA, 2007b) and related technical support documents, the proposed decision was published in the Federal Register on July 11, 2007 (U.S. EPA, 2007a). The EPA proposed to revise the level of the primary standard to a level within the range of 0.075 to 0.070 ppm. Two options were proposed for the secondary standard: (1) replacing the current standard with a cumulative, seasonal standard, expressed as an index of the annual sum of weighted hourly concentrations cumulated over 12 daylight hours during the consecutive 3-month period within the O₃ season with the maximum index value, set at a level within the range of 7 to 21 ppm-h; and (2) setting the secondary standard identical to the revised primary standard. The EPA completed the rulemaking with publication of a final decision on March 27, 2008 (U.S. EPA, 2008f), revising the level of the 8-hour primary O₃ standard from 0.08 ppm to 0.075 ppm and revising the secondary standard to be identical to the primary standard.

In May 2008, state, public health, environmental, and industry petitioners filed suit against EPA regarding that final decision. At EPA's request the consolidated cases were held in abeyance pending EPA's reconsideration of the 2008 decision. A notice of proposed rulemaking to reconsider the 2008 final decision was issued by the Administrator on January 6, 2010. Three public hearings were held. The Agency solicited CASAC review of the proposed rule on January 25, 2010 and additional

CASAC advice on January 26, 2011. On September 2, 2011, the Office of Management and Budget returned the draft final rule on reconsideration to EPA for further consideration. EPA decided to coordinate further proceedings on its voluntary rulemaking on reconsideration with the ongoing periodic review, by deferring the completion of its voluntary rulemaking on reconsideration until it completes its statutorily-required periodic review. In light of that, the litigation on the 2008 final decision is no longer being held in abeyance and is proceeding. The 2008 O₃ standards remain in effect.

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DOCUMENTS SUBMITTED BY REPRESENTATIVE DARIN LAHOOD



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EPA Docket Center (EPA/DC),
 Mailcode 28221T,
 Attention Docket ID No. OAR-2008-0699,
 1200 Pennsylvania Ave. NW.,
 Washington, DC 20460

March 4, 2015

Subject: National Ambient Air Quality Standards for Ozone: 40 CFR Parts 50, 51, 52, et al., Docket ID No. EPA-HQ-OAR-2008-0699

Dear Administrator McCarthy:

In response to the EPA's request for public comment on the proposed ozone NAAQS, the members of the Peoria/Pekin Urbanized Area Transportation Study (PPUATS) Policy Committee, which serves as the Metropolitan Planning Organization (MPO) for the Peoria Metropolitan Statistical Area, recognizes that high levels of ozone diminish air quality and harm public health. PPUATS strongly supports the science-based goal of protecting the health of our citizens as our efforts and successes of recent years demonstrate, and we look forward to cooperatively working with the EPA to improve the nation's air quality and our collective public health. However, our organization requests that EPA delay nonattainment designations that are currently scheduled to occur in October 2017. This would allow our region more time to gauge the success of recent and forthcoming air quality improvement efforts. PPUATS does not wish for the region or any individual jurisdiction within the region to be designated as nonattainment for ozone, let alone any other pollutant. Please consider the following list of recommendations regarding the process of potentially lowering the primary standard for ozone to a level within the range of 0.065 to 0.070 parts per million (ppm).

1. The PPUATS region has two ozone monitors, both of which are trending downwards, but delaying the designation past October 2017 would allow the region more time to observe the benefits of air quality improvement efforts.

Over the past few years, transit usage in the region has increased substantially, and the local transit agency utilizes buses that not only run on a 20 percent biodiesel mix, but also the bus exhaust is cleaner than the air taken in by the engine. Also, delaying the designation would allow our region to observe the air quality benefits of federal fuel and vehicle standards ("Tier 3"), which are set to begin in 2017.

2. EPA should recognize the role of interstate and intrastate transportation in the calculations and implementation of ozone standards. While we welcome discussions with the EPA on methods to mitigate local contributions to ozone formation, we cannot enact reduction strategies which act beyond our jurisdiction. Moreover, those agencies responsible for air quality management beyond the Peoria MSA must provide appropriate reductions within their jurisdictions and authorities, as required, to assist the local nonattainment region's efforts to regain attainment



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status. Delaying the non/attainment designations past 2017 would allow our region more time to coordinate with other regions whose emissions might impact our region and vice versa.

3. Nonattainment areas receive money from the federal government (CMAQ) to improve their air quality and achieve compliance with NAAQS. If the ozone standards are tightened and the PPUATS region falls into nonattainment (along with several other MPOs across the nation), there is concern our region would not receive an appreciable amount of CMAQ funding to aid in regaining compliance with NAAQS and returning to attainment status. The Peoria MSA has a strong history in industrial and manufacturing businesses, which continues to this day. Our region has managed to keep its attainment status (under the current regulations) while still promoting these businesses that provide thousands of jobs and manufacture products that are shipped all over the world. Again, delaying the designations would allow our region more time to work with regional private sector industries to develop strategies that might reduce emissions without negatively impacting their operations.

Although currently on hiatus, our organization launched Clean Air Action, an ongoing initiative that first kicked off in 2009 to maintain clean local air and encourage individuals, in addition to business and industry, to take common sense measures to keep ozone levels down and reduce pollution. This effort began after the standards for acceptable levels of ozone were reduced from 0.80 parts per million (ppm) to 0.75 ppm. It appears that we will need to re-activate this initiative and reengage with the community to bring awareness to the ozone issue, along with developing some new strategies that will further reduce our ozone emissions. As noted previously, the ozone levels recorded at our two monitoring stations are trending downwards, so we believe our region is taking air quality concerns seriously and making some significant progress. Delaying the attainment designation would surely allow our region the time necessary to both reduce ozone levels and avoid nonattainment should the standard be lowered to 0.65 – 0.70 ppm.

In making these comments, our organization and region accepts the need to set standards at a level protective of human health and of the environment. But we also want to avoid nonattainment and the consequences of such designation. We believe that significant progress in reducing the region's ozone emissions has been made and we hope EPA allows more time for our region to build upon recent successes because there is more work we need to do on this issue. We look forward to working cooperatively with EPA and Illinois EPA to ensure excellent air quality for our citizens.

Sincerely,

James Dillon
PPUATS Policy Chair &
Mayor of West Peoria

NEW OZONE RULES COULD BE MOST EXPENSIVE REGULATIONS EVER

What Could New Ozone Regulations Cost Illinois?¹



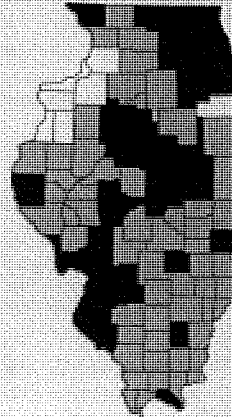
\$46.5 Billion Gross State Product Loss from 2017 to 2040
35,613 Lost Jobs or Job Equivalents per year

ILLINOIS | Illinois would be in mostly out of attainment*

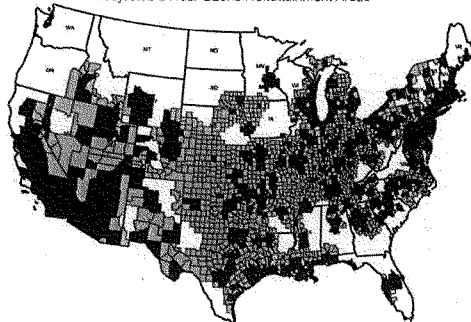
* If California for Counties in the Red and Orange

1. Manufacturers won't be able to expand unless other businesses in the area shut down.
2. Federal highway funds could freeze.
3. Economic growth will halt.

Source: EPA, July 7, 2014. Because all counties in a metropolitan, micropolitan or combined statistical area will be included in any potential nonattainment area, some counties could be included and other excluded at the time of designation. Based on a 3-year period: 2011-2013.



Projected 8-Hour Ozone Nonattainment Areas



The recent study by NERA Economic Consulting found that a stricter ozone regulation at 65 ppb could cost the U.S.:¹

- » **\$140 billion** in lost GDP per year and **\$1.8 trillion** from 2017 to 2040; and
- » **1.4 million** fewer jobs or job equivalents per year on average through 2040.

Based on 2011-2013 data accessed from <http://www.epa.gov/airtrends/> and <http://www.epa.gov/airdata/>.

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EPA SHOULD NOT CHANGE THE CURRENT OZONE STANDARDS ✓

DON'T IMPOSE UNNECESSARY REGULATION

The U.S. government has a responsibility to keep federal regulations sensible and not change standards on businesses and consumers needlessly.

GIVE STATE AND LOCAL GOVERNMENTS A CHANCE TO MEET THE MOST RECENT STANDARDS BEFORE CHANGING THEM AGAIN

Despite having spent billions of dollars on reducing air pollution, several metropolitan areas are having a very tough time meeting the current standards. The EPA should focus on helping these communities meet the old standards before placing new standards.

DON'T SET STANDARDS THAT CAN'T BE ACHIEVED BECAUSE OF BACKGROUND LEVELS

There are many areas of the country where the naturally occurring level of ozone is above what the EPA is considering, so it is not right to hold a county or state to a standard that is impossible to reach.

DON'T SET STANDARDS THAT THREATEN AMERICA'S COMPETITIVENESS AND AMERICAN JOBS

Tightening ozone standards could increase costs to the American public, reduce America's ability to compete internationally, and threaten American jobs.

Costs could be even higher if EPA finalizes a 50ppb standard, which is included in the proposal. These standards could reduce U.S. GDP by \$276 billion per year and \$3.4 trillion from 2017 to 2040 and result in 2.8 million fewer jobs or job equivalents, according to a previous study by NERA Economic Consulting.

AIR QUALITY PROGRESS WILL CONTINUE

The nation's air quality has improved over the past several years, and ozone emissions will continue to decline without new regulations.

HEALTH DATA SHOW THE CURRENT STANDARDS ARE PROTECTIVE

These new standards are not justified from a health perspective because the science is simply not showing a need to reduce ozone levels.

GET INVOLVED: See what actions you can take at: <http://www.energytomorrow.com/>

LEARN MORE: Find the new study by NERA Economic Consulting at: <http://www.nam.org/ozone>



TRI-COUNTY REGIONAL PLANNING COMMISSION

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EPA Docket Center (EPA/DC),
 Mailcode 28221T,
 Attention Docket ID No. OAR-2008-0699,
 1200 Pennsylvania Ave. NW.,
 Washington, DC 20460

March 4, 2015

Subject: National Ambient Air Quality Standards for Ozone: 40 CFR Parts 50, 51, 52, et al., Docket ID No. EPA-HQ-OAR-2008-0699

Dear Administrator McCarthy:

In response to the EPA's request for public comment on the proposed ozone NAAQS, the members of the Peoria/Pekin Urbanized Area Transportation Study (PPUATS) Policy Committee, which serves as the Metropolitan Planning Organization (MPO) for the Peoria Metropolitan Statistical Area, recognizes that high levels of ozone diminish air quality and harm public health. PPUATS strongly supports the science-based goal of protecting the health of our citizens as our efforts and successes of recent years demonstrate, and we look forward to cooperatively working with the EPA to improve the nation's air quality and our collective public health. However, our organization requests that EPA delay nonattainment designations that are currently scheduled to occur in October 2017. This would allow our region more time to gauge the success of recent and forthcoming air quality improvement efforts. PPUATS does not wish for the region or any individual jurisdiction within the region to be designated as nonattainment for ozone, let alone any other pollutant. Please consider the following list of recommendations regarding the process of potentially lowering the primary standard for ozone to a level within the range of 0.065 to 0.070 parts per million (ppm).

1. The PPUATS region has two ozone monitors, both of which are trending downwards, but delaying the designation past October 2017 would allow the region more time to observe the benefits of air quality improvement efforts.

Over the past few years, transit usage in the region has increased substantially, and the local transit agency utilizes buses that not only run on a 20 percent biodiesel mix, but also the bus exhaust is cleaner than the air taken in by the engine. Also, delaying the designation would allow our region to observe the air quality benefits of federal fuel and vehicle standards ("Tier 3"), which are set to begin in 2017.

2. EPA should recognize the role of interstate and intrastate transportation in the calculations and implementation of ozone standards. While we welcome discussions with the EPA on methods to mitigate local contributions to ozone formation, we cannot enact reduction strategies which act beyond our jurisdiction. Moreover, those agencies responsible for air quality management beyond the Peoria MSA must provide appropriate reductions within their jurisdictions and authorities, as required, to assist the local nonattainment region's efforts to regain attainment.



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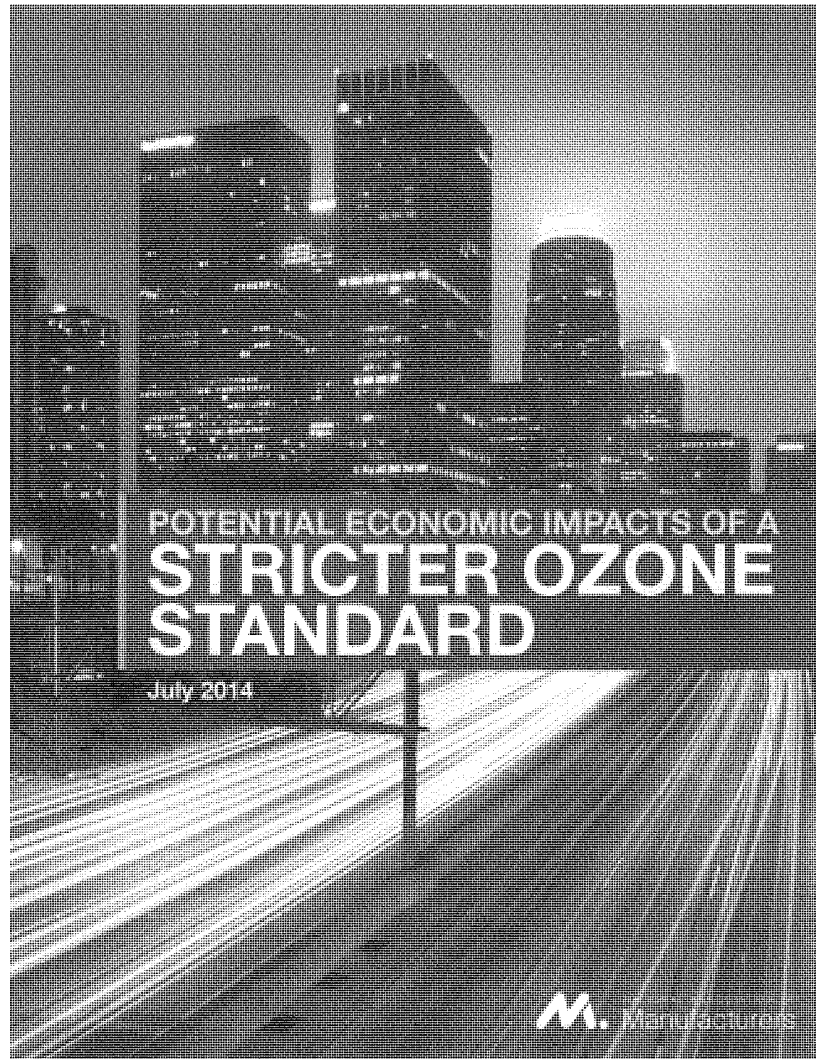
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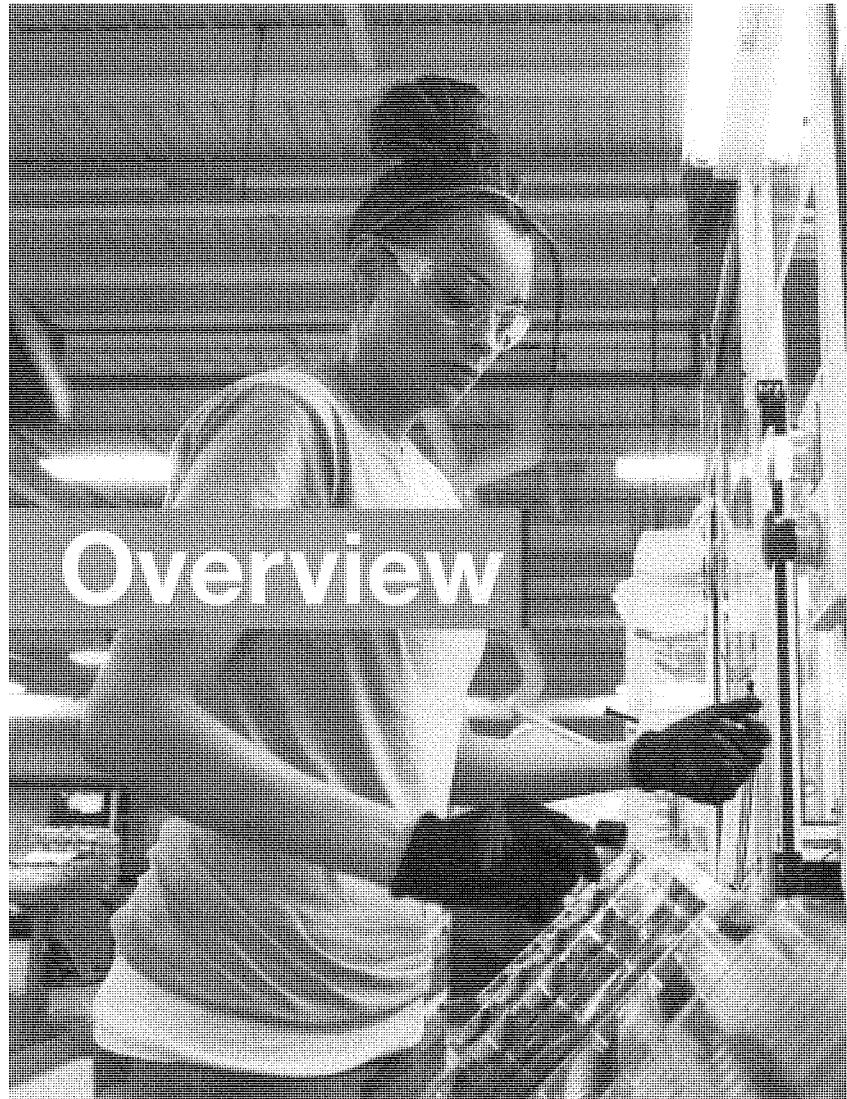
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Sincerely,

James Dillon
 PPUATS Policy Chair &
 Mayor of West Peoria





[illegible][illegible]

- Reduce U.S. GDP by \$2.6 billion per year and \$3.4 billion from 2017 to 2040.
- Result in 2.9 million fewer job equivalents per year on average through 2040.
- Cost the average U.S. household \$1,375 per year in the form of lost consumption, and increase natural gas and electricity costs for manufacturers and households across the country.

1. The first step in the process is to identify the problem. This involves gathering information about the situation and understanding the needs of the stakeholders involved.

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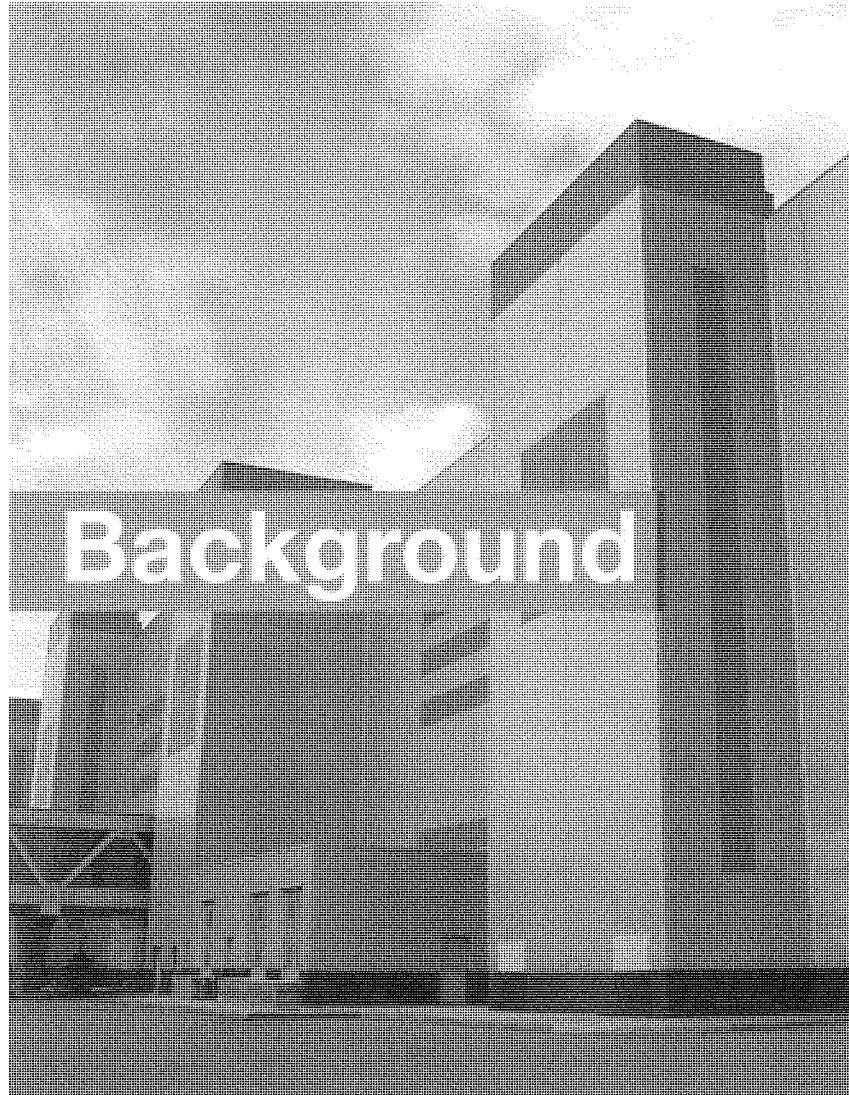
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¹ The data presented in this article represent a single, nonrandomly selected, cross-sectional snapshot of the information age. Although the data are not representative of the entire population, they do provide a useful illustration of the current state of the information age. For more information on the data, see <http://www.eric.ed.gov/fulltext/ED454611.pdf>.

- **Projected 2015 revenue** of \$2.2 billion (vs. \$1.8 billion in 2014) will be a result of 4.1 million additional prescriptions, a 1.5 percentage-point increase in net sales, and a 1.5 percentage-point increase in net sales per prescription.

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What Is Ground-Level Ozone?

Ground-level ozone is a major air pollutant that is harmful to human health and the environment. It is formed by a chemical reaction between nitrogen oxides (NOx) and volatile organic compounds (VOCs) in the presence of sunlight. Ground-level ozone is a key component of smog and is responsible for many of the health and environmental problems associated with air pollution. It is a major concern for public health and the environment, and it is one of the most common air pollutants in the United States.

What Are Ozone Regulations?

Under the Clean Air Act, the EPA is instructed to select a primary NAAQS for ground-level ozone that protects the nation's public health within an "adequate margin of safety."² In March 2008, the EPA lowered the primary NAAQS for ground-level ozone from 84 ppb³ to 75 ppb. The EPA is again considering tightening the NAAQS for ground-level ozone with its proposed regulation expected in December 2014 and final regulation in October 2015. The EPA has stated its intent to revise the existing standard and is contemplating tightening the standard to as low as 60 ppb in its most recent draft policy assessment for NAAQS for ground-level ozone.⁴

After the EPA establishes an NAAQS, it is the responsibility of each individual state to ensure that all counties and metropolitan areas in that state are in compliance with the standard. Areas that are above the standard (not in compliance with the NAAQS) are referred to as "nonattainment" areas. Areas below the standard (in compliance with the NAAQS) are referred to as "attainment" areas. While states have some flexibility in implementing regulations and other programs to meet the NAAQS for ground-level ozone, there are other federally mandated programs that states must adhere to if an area in the state is in nonattainment.

The greatest costs to comply with ozone regulations generally occur in nonattainment areas. The consequences for nonattainment are severe and can include a loss of industry and economic development resulting from increased costs, delays and uncertainties from restrictive permitting requirements; loss of federal highway and transit funding; requirements that any new emissions in the area be offset or the facility cannot be built; and technical and formula changes for commercial and consumer products.

As is demonstrated in the orange and red portions of the map in Figure 1, if a 60 ppb ozone standard were in place today, the vast majority of the country would likely be in nonattainment.

Unlike regulations that target specific sectors, a new ozone standard would directly affect virtually every sector of the economy because a wide range of stationary, mobile and area sources emit ozone precursors (NOx and VOCs).

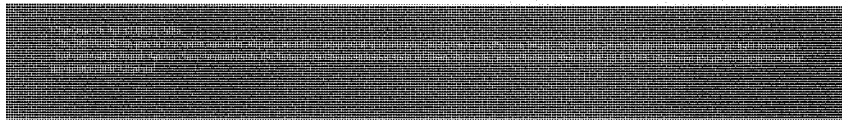
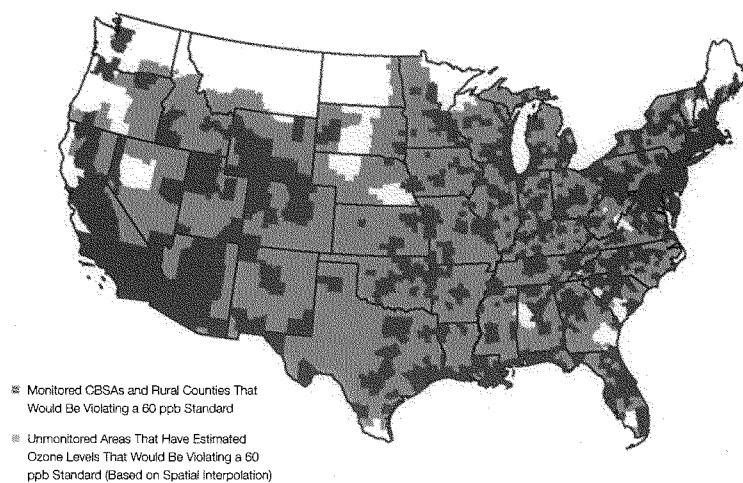
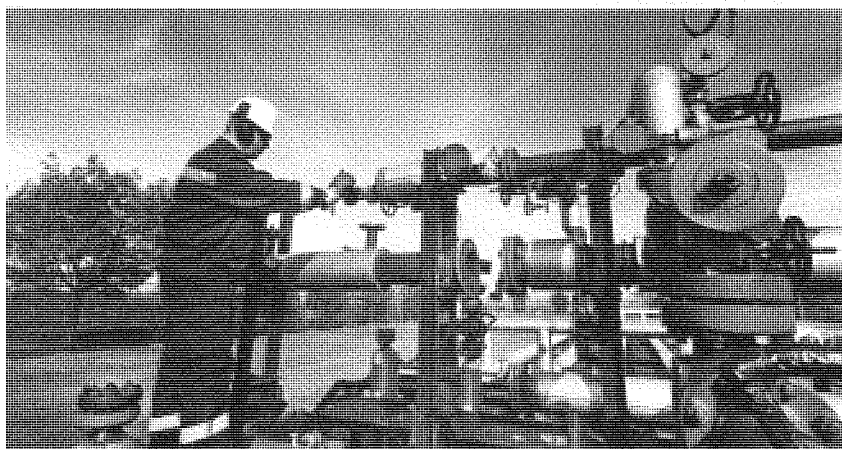
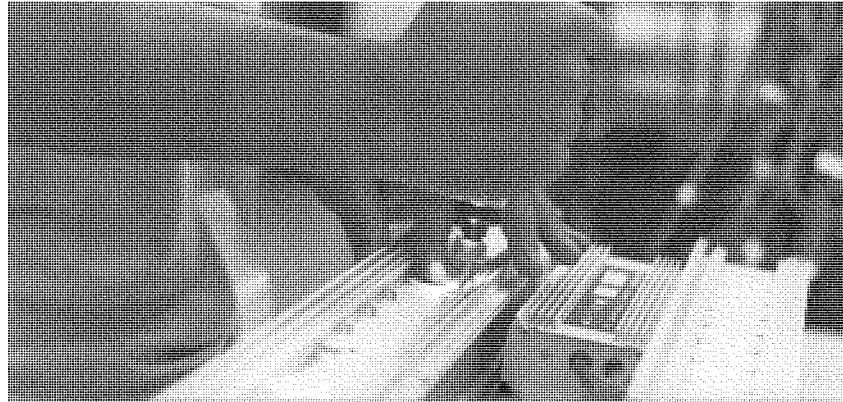


Figure 1: Core-Based Statistical Areas (CBSAs) and Rural Counties That Would Violate a 60 ppb Ozone Standard Based on 2011–2013 Data



Source: Based on 2011–2013 data accessed from <http://www.epa.gov/airtrends/> and <http://www.epa.gov/airdata/> on June 2, 2014.





Study Objectives

The study has the following objectives:

1. Estimate the costs and economic impacts of a large-scale wildfire using the best available data for at least five fire and other seasons and
2. Identify any gaps in existing EPA literature and analysis that would prevent the agency from accurately assessing the economic impacts of the regulations.

The study also includes a description of the data sources used in the study, a description of the methods used to estimate the costs and economic impacts of a large-scale wildfire, and a description of the results of the study.

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The results of the findings, which are summarized below, indicate that a 60 ppb ozone standard could have enormous costs and negative effects on the U.S. economy, employment and households. These impacts are even greater in the sensitivity case, which considers nonattainment limits to natural gas production.

Effects on U.S. GDP and Household Consumption

The potential macroeconomic effects of a new ozone regulation as measured by GDP and household consumption are shown in Figure 2. The 60 ppb ozone standard is projected to reduce GDP from baseline levels by about \$3.4 trillion on a present value basis (as of 2014) and by \$270 billion per year on an annualized basis (spread evenly from 2017 to 2040 but retaining the same present value). Average annual household consumption could be reduced by about \$1,570 per household per year.

Figure 2: Potential Impacts of a 60 ppb Ozone Standard on U.S. GDP and Household Consumption

	Annualized	Present Value
GDP Loss (in Billions of 2013 Dollars)	\$270/year	\$3,390
Household Consumption Loss (in 2013 Dollars)	\$1,570/year	N/A

Notes: Present value is from 2017 to 2040, discounted at a 5 percent real discount rate. Household consumption is an annualized value calculated using a 5 percent real discount rate.

The loss of economic output and the impacts on household consumption are even more pronounced in the sensitivity case assuming constraints on new natural gas development as demonstrated in Figure 3. In this sensitivity case, GDP is reduced by nearly \$4.5 trillion across the study period, and average annual household consumption would be reduced by about \$2,040 per year.

Figure 3: Potential Impacts of a 60 ppb Ozone Standard on U.S. GDP and Household Consumption (Sensitivity Case)

	Annualized	Present Value
GDP Loss (in Billions of 2013 Dollars)	\$360/year	\$4,480
Household Consumption Loss (in 2013 Dollars)	\$2,040/year	N/A

Notes: Present value is from 2017 to 2040, discounted at a 5 percent real discount rate. Household consumption is an annualized value calculated using a 5 percent real discount rate.

Effects on Energy Costs

A 60 ppb ozone standard would likely have significant impacts on U.S. energy sectors, largely because the more stringent regulation is projected to include the substantial premature retirement of additional coal-fired power plants. The study estimates that 101 gigawatts of additional coal-fired capacity (34 percent of all coal-fired capacity in the baseline) would be forced into retirement as one element of a tighter ozone standard. These retirements would be more than double the substantial number of power plants that are already expected to shutter as a result of current EPA regulations and would threaten electric reliability in many already strained electricity markets across the country.⁶

Figure 4 shows average energy price projections under the baseline and the 60 ppb ozone standard, analyzed without possible gas development constraints. Residential electricity prices are projected to increase by 3.3 percent and industrial electricity prices by 5.5 percent from 2017 to 2040. Delivered residential natural gas prices could increase by 7.3 percent, while industrial natural gas prices could jump by 12.0 percent.

Figure 4: Potential Impacts of a 60 ppb Ozone Standard on Energy Prices

		Average Baseline	Average 60 ppb	Change	Percent Change
Natural Gas Delivered (Residential)	\$/MMBtu	\$13.77	\$14.79	\$1.02	7.3%
Natural Gas Delivered (Industrial)	\$/MMBtu	\$8.43	\$9.49	\$1.06	12.0%
Electricity (Residential)	c/kWh	14.5¢	14.9¢	0.5¢	3.3%
Electricity (Industrial)	c/kWh	9.4¢	9.9¢	0.5¢	5.5%

Notes: Average is the simple average from 2017 to 2040. MMBtu stands for Million British Thermal Units, and kWh stands for kilowatt hour.

Energy costs skyrocketed in the sensitivity case in which potential constraints of natural gas production are included in the analysis. As shown in Figure 5, residential electricity prices could increase, on average, by 15 percent and industrial electricity prices by 23 percent from 2017 to 2040. Delivered natural gas prices could increase by 32 percent for the residential sector and 52 percent for the industrial sector. For manufacturers, particularly those in energy-intensive sectors, such as iron and steel, cement, aluminum, pulp and paper and chemicals, energy cost increases at these levels would be devastating in their ability to compete internationally.

Figure 5: Potential Impacts of a 60 ppb Ozone Standard on Energy Prices (Sensitivity Case)

		Average Baseline	Average 60 ppb	Change	Percent Change
Natural Gas Delivered (Residential)	\$/MMBtu	\$13.77	\$18.16	\$4.39	32%
Natural Gas Delivered (Industrial)	\$/MMBtu	\$8.43	\$12.79	\$4.36	52%
Electricity (Residential)	c/kWh	14.5¢	16.6¢	2.1¢	15%
Electricity (Industrial)	c/kWh	9.4¢	11.6¢	2.2¢	23%

Note: Average is the simple average from 2017 to 2040.

Effects on Employment

The impacts of a 60 ppb ozone standard on employment are substantial, as companies would have higher costs and lower labor productivity. To assess the effects on employment from new ozone regulations, the study expresses results in terms of job equivalents. A job equivalent is a metric that economists use to reflect the fact that impacts to labor from regulatory costs and burdens can come in the form of fewer hours worked, lower pay and lost jobs—and usually a combination of all three. Figure 6 shows that a 60 ppb ozone standard would result in lower wage earnings from 2017 to the end of the study period, with an average loss of 2.9 million job equivalents per year.

Figure 6: Potential Impacts of a 60 ppb Ozone Standard on Employment

	Average	2017	2020	2023	2026	2029	2032	2035	2038
Job Equivalents (Change from Baseline, in Millions)	-2.9	-0.9	-3.2	-3.0	-3.0	-3.3	-3.4	-3.3	-3.2

Note: Average is the simple average from 2017 to 2040.

The loss to workers is even greater in the sensitivity case with an average of 4.3 million fewer job equivalents per year. As demonstrated in Figure 7, job-equivalent losses exceed 5 million in the later years of the study, highlighting just how important domestic energy production and a low-cost energy supply are to employment now and in the future.

Figure 7: Potential Impacts of a 60 ppb Ozone Standard on Employment (Sensitivity Case)

	Average	2017	2020	2023	2026	2029	2032	2035	2038
Job Equivalents (Change from Baseline, in Millions)	-4.3	-1.1	-3.4	-4.1	-4.8	-5.1	-5.3	-5.4	-5.2

Note: Average is the simple average from 2017 to 2040.



Why Would New Ozone Regulations Be So Expensive?

Attaining a 60 ppb ozone standard will require large reductions in NO_x and VOC emissions from power plants, manufacturing facilities and mobile sources, such as cars, trucks and off-road vehicles. These reductions come at a high cost per ton because significant investments have already been made to reduce emissions, leaving few low-cost control options as the ozone standard tightens. Efforts to control NO_x emissions drive the majority of the costs in the study. An explanation of why costs associated with reducing NO_x emissions to levels necessary to meet a 60 ppb ozone standard are so high is provided below.

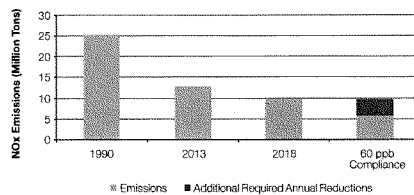
1. Despite Significant Emissions Reductions, Substantially More Would Be Required to Comply with a New Standard

NO_x emissions have declined substantially in recent years, from 25.2 million tons in 1990 to 12.9 million tons in 2013.⁷ In part due to other regulations already on the books, such as the Cross-State Air Pollution Rule and new air emission standards for passenger cars and light-duty trucks, the EPA projects that, in the absence of new ozone regulations, NO_x emissions will be reduced further to 9.7 million tons by 2018. Some of these regulations have not yet been fully implemented and will carry with them additional compliance costs on top of any that are estimated in this study.⁸

Based on information in the 2008–2010 EPA ozone review, NO_x emissions would have to be reduced even *further*—to about 5.8 million tons—to meet a 60 ppb ozone standard.⁹ Figure 8 shows declining NO_x emissions since 1990 and represents the further estimated reductions needed to achieve a 60 ppb ozone standard.

Despite the extensive controls already expected to occur through 2018 from other regulations and measures, another 3.9 million tons would need to be reduced to achieve a 60 ppb ozone standard nationally. This reduction is equivalent to about 40 percent of the EPA's baseline NO_x emissions for 2018, a 55 percent reduction from current NO_x emissions levels and a 77 percent reduction from 1990. Accounting for the effects of economic growth on emissions, this represents a 90 percent reduction in the emission rate.

Figure 8: Historical NO_x Emissions and Estimated Reductions Needed to Achieve a 60 ppb Ozone Standard



2. As Emissions Decline, Costs for Additional Reductions Increase

Traditionally, when ozone standards or other regulations have called for a reduction in NO_x emissions, regulators have looked first to large sources like power plants, requiring them to install control equipment. Large power plants, because of their size, historically have been a relatively cost-efficient way to achieve NO_x reductions in terms of dollars spent per ton of NO_x reduced. However, overall, the power sector has reduced its NO_x emissions by 73 percent from 1990 to 2013.¹⁰ With the majority of existing coal-fired power plant capacity equipped with some form of NO_x controls¹¹ and further controls expected to be installed because of other EPA regulations, the opportunity for further NO_x reductions from power plant retrofits is diminishing.

Thus, as the EPA has identified in its own analysis, to achieve a 60 ppb ozone standard, several other sectors, such as manufacturing and agriculture, and commercial and residential buildings will have to pay for controls or replace equipment, often at a very high cost. These expensive known controls only achieve about one-third of the necessary NO_x reductions.



Figure 9 provides a national summary of the EPA's known NO_x controls from sectors other than power plants that would be needed for compliance with a new ozone standard of 60 ppb.¹² The table shows the specific types of technologies and measures for each emission source category.

Figure 9: National Summary of EPA Known NO_x Controls (Tons of Reduction)

	Reductions (Tons)
Point – Manufacturing and Other Industrial	825,400
Selective catalytic reduction (SCR) without low NO _x burner (LNB)	466,800
Low emission combustion (for internal combustion engines)	82,000
Selective catalytic reduction (SCR) and low NO _x burner (LNB)	80,800
Nonselective catalytic reduction (NSCR)	70,300
Selective non-catalytic reduction (SNCR)	61,400
OXY-firing (for glass manufacturers)	33,800
Low NO _x burner (LNB) without selective catalytic reduction (SCR)	20,700
Biosolid injection (for cement kilns)	8,200
Other	1,300
Area – Commercial and Residential	27,800
Low NO _x water and space heaters (for commercial buildings)	14,000
Low NO _x burner (LNB)	12,800
Switch to low sulfur fuel (for residential buildings)	1,000
Onroad Mobile – Cars, Trucks and Other Sources	256,100
Retrofit heavy-duty diesel with selective catalytic reduction (SCR)	137,700
Continuous inspection and maintenance	27,600
Elimination of long-duration idling	10,500
Commuting programs	4,400
Low Reid Vapor Pressure	1,000
Unspecified	74,800
Nonroad Mobile – Agriculture, Construction and Other Sources	45,000
Retrofit heavy-duty diesel with selective catalytic reduction (SCR)	45,000
No Details (Some Omissions in EPA Data for California and Texas)	130,100
Total	1,284,400

Note: All numbers are rounded to the nearest hundred.

"Point" sources include large stationary equipment, such as boilers and kilns at manufacturing and other industrial facilities. Of the NO_x reductions from known controls that the EPA identifies in its existing analysis, about half come from point sources. Many of these controls require retrofitting existing plants and equipment with expensive additional technologies.

Owners of smaller stationary sources, such as commercial and residential water heaters—referred to as "area" sources—would be expected to incur costs according to the EPA's analysis of known controls. Owners of area sources may have to replace their existing equipment altogether or switch to different—likely more expensive—fuels.

"Onroad mobile" sources, such as cars and heavy-duty trucks, would also be targeted for reductions, according to the EPA. Many states would likely have to put more resources into inspection and commuting programs. According to the agency, some heavy-duty truck owners would have to retrofit their vehicles with additional expensive controls.

Other sources have been targeted as well, such as agricultural and construction equipment (referred to as "nonroad mobile" in Figure 9).

3. The Majority of Reductions Come from Unknown Controls

The EPA has identified only one-third of the controls needed to reduce the 3.9 million tons of NO_x to achieve a 60 ppb ozone standard. As demonstrated in Figure 10, the remaining 2.6 million tons would need to come from unknown controls, or controls and measures that the EPA has yet to identify.

Unknown controls are expected to be substantially more expensive than known control options. In fact, in the EPA's 2010 analysis, the total costs for unknown controls were greater than the costs for known controls by a ratio of 19 to 1.¹³ The study estimates that the difference in costs between known and unknown controls could be even higher. Figure 11 illustrates this concept. Whereas the cost per ton for reductions from known controls may cost tens of thousands of dollars, costs for unknown controls could cost hundreds of thousands of dollars.

The steeply sloped marginal cost curve is explained, in part, by the expectation that to achieve a 60 ppb ozone standard, some power plants, manufacturing facilities and vehicles, along with other industrial, commercial, agricultural and even residential equipment, will have to be shut down or scrapped. For example, even after new ozone regulations force the shutdown of another 101 gigawatts¹⁴ of capacity, or nearly 9 percent of the entire U.S. power plant fleet, NO_x emissions would still be too high to achieve a 60 ppb ozone standard. Thus, as the study suggests, older cars, farm equipment and capital-intensive manufacturing equipment may have to be scrapped altogether. NERA has estimated that early retirement and scrapping of these types of equipment are much more costly per ton removed than the retrofits that largely comprise the known controls. Although NERA only analyzed a 60 ppb NAAQS for ground-level ozone, the same need to estimate costs for unknown controls would arise for other ozone standards within the range the EPA is considering.

Figure 10: Estimating U.S. Compliance Emissions

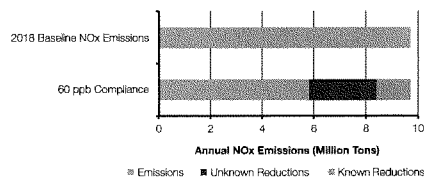


Figure 11: Illustration of a State NO_x Marginal Cost Curve Showing Known and Unknown Controls

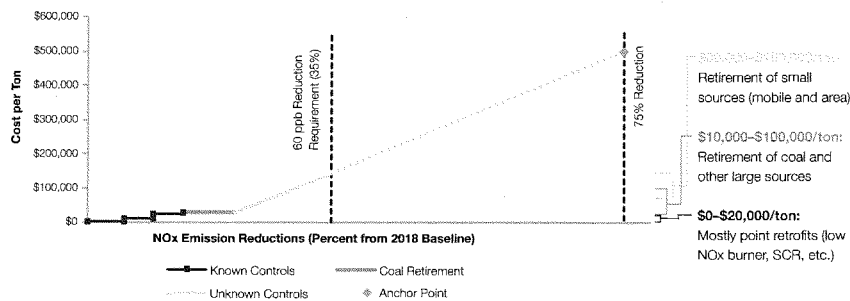
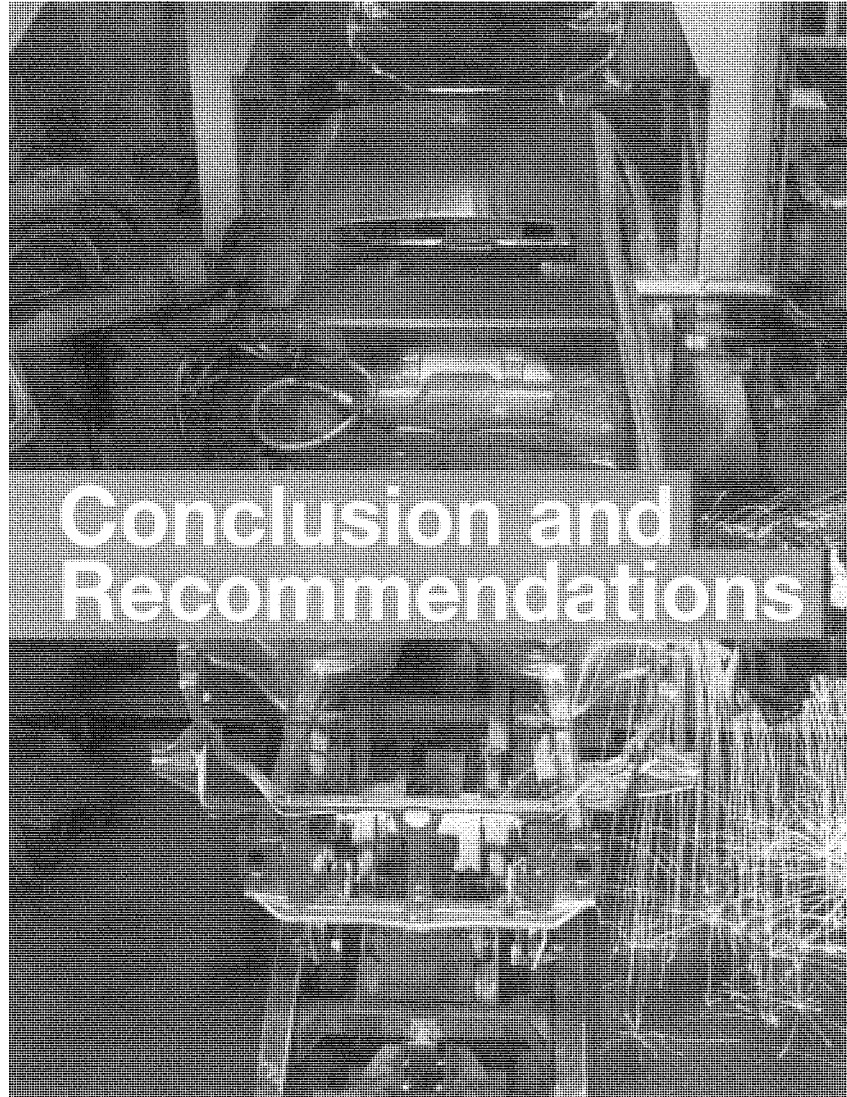


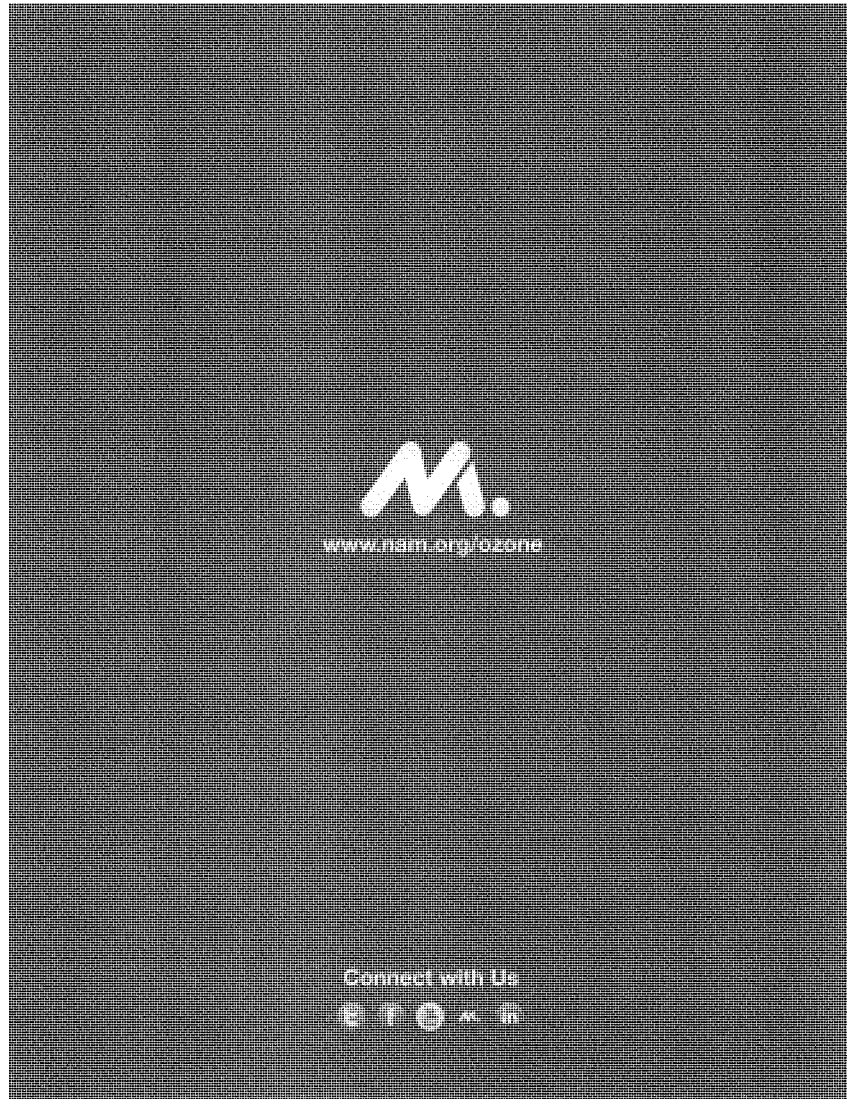
Figure 10: Estimating U.S. Compliance Emissions. The chart shows that to achieve a 60 ppb ozone standard, approximately 2.6 million tons of NO_x reductions are required from unknown sources, while approximately 4.3 million tons can be achieved through known reductions. This highlights the significant challenge of identifying and implementing unknown controls to meet the standard.



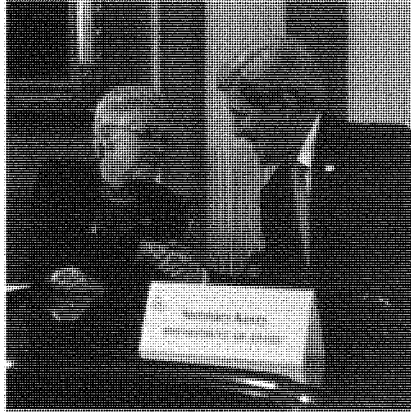
While this study is the latest to estimate the potential costs of new ozone regulations, it is certainly not the first. In the EPA's most recent analysis of a 60 ppb ozone standard, the agency estimated the costs of new ozone regulations could exceed \$100 billion per year in 2013. As this study explains, the EPA's analysis was incomplete in a number of key areas, and the actual costs would likely be substantially higher than the agency's estimates. A substantial portion of the costs in all of the analyses performed to date is driven by controls that the EPA has not yet identified, technologies that must be invented or the shutdown, scrapping and/or modification of existing facilities, equipment and vehicles.

In light of the findings of this study, manufacturers strongly recommend that the EPA rethink its approach to the NAAQS for ground-level ozone. It is not clear that a stricter new standard could even be achieved, resulting in prolonged nonattainment. Even if it could be achieved, a stricter standard could have enormous economic consequences. The existing 75 ppb ozone standard has not even been implemented, meaning society has neither borne the costs nor determined whether there are discernible benefits of that standard. Before the EPA initiates a process that could cost as many as 4.3 million job equivalents per year and threaten manufacturers' competitiveness, a more complete analysis is needed.

Manufacturers also strongly urge Congress to reevaluate the provisions of the Clean Air Act that govern NAAQS for ground-level ozone. In the four decades since its enactment, the Clean Air Act has driven major reductions in ozone. However, it is increasingly clear that most, if not all, of the low-hanging fruit has been picked, and further reductions will cost exponentially more while accomplishing less. Based on the way the EPA interprets the Clean Air Act, it is virtually ensured that the agency will recommend a stricter standard every five years. Yet, ozone levels are getting so low that a rapidly growing share of even urban areas' ozone concentrations now comes from either naturally occurring ozone or from ozone that has been transported from other states or countries. We have reached the point at which significant further reductions simply cannot be accomplished in any cost-effective manner. Absent recognition of this fact from the EPA, it is time for Congress to modernize the Clean Air Act.



INSIDE SOURCES



EPA Administrator Gina McCarthy meeting with Secretary of State John Kerry on Feb. 18 (via Twitter)

STUDY: Trillions in Costs, Millions of Jobs Lost from New EPA Ozone Regulation

Posted to [Energy](#) February 26, 2015 by [Shawn McCoy](#)

A new study published Thursday finds new ozone standards under consideration by the Environmental Protection Agency (EPA) would, on an annual basis through 2040, reduce GDP by \$140 billion, result in 1.4 million fewer jobs, and cost the average US household \$830 in lost consumption.

The study finds this would be the costliest regulation in US history.

This is a revised analysis of a study [conducted last July](#) that examined the potential costs of reducing current ozone standards from the 2008 level of 75 parts per billion (ppb) to 60 ppb. In November, the EPA announced it was weighing a range from 65 to 70 ppb. Based on this change, NERA Economic Consulting, commissioned by the National Association of Manufacturers (NAM), revised the July report to reflect higher ozone levels, though the EPA is still accepting public comment on lower levels.

“Manufacturers in the United States are in the midst of a resurgence that’s fueling job growth and economic recovery nationwide, but the proposed tightening of the ozone standard puts our momentum at great risk,” NAM President and CEO Jay Timmons said. “This data confirms our long-held concern that revisions to the ozone standard represent one of the most significant threats, not just to our manufacturing sector, but to our economy at large.”

Current ozone levels are near those that occur naturally in the atmosphere. The 2008 levels have still not been fully implemented. On Wednesday, in a House EPA budget hearing, EPA Administrator Gina McCarthy said she saw no problems with passing overlapping standards.

NAM argues that 65 ppb is “unattainable regulation.” The report notes: “More than 60 percent of the controls and technologies needed to meet the rule’s requirements are what the EPA calls ‘unknown controls.’ Because controls are not known, the new regulation could result in the closure of plants and the early scrapping of equipment used for manufacturing, construction and agriculture.”

In a statement to *InsideSources*, the EPA spokesperson Liz Purchia said: “Based on the Administrator’s evaluation of more than 1,000 new studies since the last review, she believes that a standard in the proposed range will provide substantial public health benefits for millions of Americans by reducing both ozone and particle pollution. EPA estimates that reducing pollution to meet the standards in 2025 will yield annual health benefits of \$6.4 to \$13 billion annually for a standard of 70 ppb, and \$19 to \$38 billion annually for a standard of 65 ppb, except for California. This includes the value of preventing harm to health that includes, among other effects: 750 to 4,300 premature deaths; 790 to 2,300 cases of acute bronchitis in children; 1,400 to 4,300 asthma-related emergency room visits; 320,000 to 960,000 asthma attacks in children; 65,000 to 180,000 days when people miss work; and 330,000 to 1 million days when children miss school.”

Earlier this month, Senators John Thune (R-SD) and Jim Inhofe (R-OK) questioned the EPA on its decision to revise the expected economic impact projections for the rule at 65 ppb. In 2011, the EPA had studied the costs of a similar rule and come to different conclusions. That proposed rule was never

implemented. At that time, President Obama asked the EPA to abandon its plans because of his Administration's efforts to "underscore the importance of reducing regulatory burdens and regulatory uncertainty."

The Senators wrote in a letter to the EPA's McCarthy: "We do not believe the staggering economic costs of a lower standard have improved since 2011. Rather, the EPA's regulatory impact analysis is intentionally misleading in its incorporation of additional proposed regulations... which significantly impact forward year ozone forecasts and obfuscate the cost of compliance."

The NERA/NAM study foresees much different results than the EPA. "This updated analysis of our July 2014 report reaffirms that attaining a stricter ozone standard would require compliance costs at levels well beyond what EPA has admitted, and beyond what we have ever estimated for any other EPA regulation. Costs of this magnitude would clearly leave their mark on the U.S. economy," said NERA Senior Vice President and Environment Practice Co-Chair Anne Smith.

The EPA also noted in its response: "EPA's proposal is about setting a health standard and determining that level. By law, we cannot consider costs in doing so."

STATEMENT SUBMITTED BY REPRESENTATIVE ELIZABETH H. ESTY

ELIZABETH H. ESTY

*Statement and Questions for the Record
Hearing of the House Committee on Science, Space, and Technology
“EPA’s 2015 Ozone Standard: Concerns Over Science and
Implementation”
October 22, 2015*

Thank you, Chairmen Smith and Ranking Members Johnson for holding today’s hearing on the Environmental Protection Agency’s (EPA) final National Ambient Air Quality Standards (NAAQS) for ozone. Since rules of this size and significance always attract controversy, I appreciate the Committee’s attention to the scientific, technological, and public health implications of the EPA’s proposal to tighten ozone standards.

Our nation’s laws established in the Clean Air Act dictate that these standards are set at levels necessary for protecting America’s citizens. Primary standards are required to protect public health, and secondary standards must protect the public’s welfare, including ecosystems and surrounding environments.

I empathize with my colleagues who are focusing on the difficulty of achieving new ozone standards. Connecticut is a non-attainment state with the current standard of 75 ppb, so lowering the primary and secondary standards to 70 ppb will only make it difficult for Connecticut to reach attainment. A big factor in Connecticut’s current ozone problem is its location. The northeast tends to be on the receiving end of air currents that carry emissions from states in the south and Midwest, where coal-burning power plants are prevalent.

What’s more, most emissions that produce ozone in Connecticut come from cars, trucks and other mobile sources, not power plants. This background ozone –being produced outside of Connecticut’s jurisdiction and transported into the state –is the root cause of Connecticut’s continued noncompliance. Record low gas prices coupled with an improving economy could mean more and larger cars on the road. And even more ozone.

Despite this, a “do nothing” approach to regulating ozone levels is not an option. If anything, the EPA has not been active enough in ensuring adequate compliance with Clean Air Act Protections. Officials at Connecticut’s Department of Energy

and Environmental Protection (DEEP) have repeatedly urged the EPA to enforce the good neighbor provision of the Clean Air Act, holding states accountable for contributing to another state's non-attainment. DEEP has also recognize the EPA's failure to address mobile sector emissions in Connecticut. Connecticut, and other non-attainment states, can and will meet the 70 ppb threshold by pursuing an all-of-the-above approach to rectify the root causes of their pollution.