

**ORAL ARGUMENT NOT YET SCHEDULED**

**No. 15-1385 (consolidated with Nos. 15-1392, 15-1490, 15-1491, and 15-1494)**

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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**MURRAY ENERGY CORPORATION,**

*Petitioner,*

**v.**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,**

*Respondent.*

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**On Petitions for Review of Final Action of the  
United States Environmental Protection Agency**

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**FINAL JOINT OPENING BRIEF OF INDUSTRY PETITIONERS**

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**CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**

Pursuant to D.C. Circuit Rule 28(a)(1), petitioners in Case Nos. 15-1385 and 15-1491 (jointly “Industry Petitioners”) state as follows:

**A. Parties, Intervenors, and *Amici*.**

Since these consolidated cases involve direct review of a final agency action, the requirement to furnish a list of parties, intervenors, and *amici curiae* that appeared below is inapplicable. These cases involve the following parties:

**Petitioners:**

Case No. 15-1385: Murray Energy Corporation.

Case No. 15-1392: State of Arizona, State of Arkansas, New Mexico Environment Department, State of North Dakota, and State of Oklahoma.

Case No. 15-1490: Sierra Club, Physicians for Social Responsibility, National Parks Conservation Association, Appalachian Mountain Club, and West Harlem Environmental Action, Inc.

Case No. 15-1491: Chamber of Commerce of the United States of America, National Association of Manufacturers, American Petroleum Institute, Utility Air Regulatory Group, Portland Cement Association, American Coke and Coal Chemicals Institute, Independent Petroleum Association of America, National Oilseed Processors Association, and American Fuel & Petrochemical Manufacturers.

Case No. 15-1494: State of Texas and Texas Commission on Environmental Quality.

### **Respondents**

Respondents are the United States Environmental Protection Agency (in all of the above cases) and Gina McCarthy, Administrator of the United States Environmental Protection Agency (in Case Nos. 15-1392, 15-1490, 15-1491, and 15-1494).

### **Intervenors**

Intervenors in support of Petitioners in Case No. 15-1392 are the States of Wisconsin, Utah, and Kentucky and, through a separate motion, the State of Louisiana.

Intervenors in support of Respondents consist of two groups: (1) American Lung Association, Sierra Club, Natural Resources Defense Council, and Physicians for Social Responsibility; and (2) Chamber of Commerce of the United States of America, National Association of Manufacturers, American Petroleum Institute, Utility Air Regulatory Group, Portland Cement Association, American Coke and Coal Chemicals Institute, Independent Petroleum Association of America, National Oilseed Processors Association, American Fuel & Petrochemical Manufacturers, American Chemistry Council, American Forest &

Paper Association, American Foundry Society, American Iron and Steel Institute, and American Wood Council.

### **Amici Curiae**

The American Thoracic Society has been granted leave to file a brief as *amicus curiae* in support of Petitioners in Case No. 15-1490. The Institute for Policy Integrity at the New York University School of Law has been granted leave to file a brief as *amicus curiae* in support of Respondents.

### **B. Rulings Under Review**

These consolidated cases involve final action of the United States Environmental Protection Agency entitled “National Ambient Air Quality Standards for Ozone,” published in the *Federal Register* at 80 FR 65292 (Oct. 26, 2015).

### **C. Related Cases**

These consolidated cases have not previously been before this Court or any other court.

## **RULE 26.1 DISCLOSURE STATEMENTS**

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, Industry Petitioners make the following statements:

*Murray Energy Corporation* (“Murray Energy”) is a corporation organized and existing under the laws of the State of Ohio. It is the largest privately owned coal company in the United States, and the largest underground coal mine operator in the United States, with combined operations that produce and ship approximately 80 million tons of bituminous coal annually. Murray Energy has no publicly traded parent corporation, and no publicly held company owns 10% or more of its stock.

The *Chamber of Commerce of the United States of America* (the “Chamber”) is the world’s largest business federation. The Chamber is a not-for-profit corporation that represents 300,000 direct members and indirectly represents the interests of more than 3 million companies, state and local chambers, and trade associations of every size, in every industry sector, and from every region of the country. A central function of the Chamber is to advocate for the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

The *National Association of Manufacturers* (“NAM”) is the largest manufacturing association in the United States. It is a national not-for-profit trade association representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than \$2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private-sector research and development. The NAM’s mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media, and the general public about the vital role of manufacturing to America’s economic future and living standards. It is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

The *American Petroleum Institute* (“API”) is a national not-for-profit trade association representing over 650 oil and natural gas companies from all segments of the industry, including producers, refiners, suppliers, pipeline operators, and marine transporters, as well as service and supply companies that support all segments of the industry. Its members are leaders of a technology-driven industry

that supplies most of America's energy, supports more than 9.8 million jobs and 8% of the U.S. economy, and, since 2000, has invested nearly \$2 trillion in U.S. capital projects to advance all forms of energy, including alternatives. API has no parent corporation, and no publicly held company owns a 10% or greater interest in API.

The *Utility Air Regulatory Group* ("UARG") is a group of individual electric generating companies and national trade associations. UARG's purpose is to participate on behalf of its members collectively in administrative proceedings under the Clean Air Act that affect electric generators and in litigation arising from those proceedings. UARG has no outstanding shares or debt securities in the hands of the public and has no parent company. No publicly held company has a 10% or greater ownership interest in UARG.

The *Portland Cement Association* ("PCA") is a national not-for-profit trade association representing companies responsible for more than 92% of cement-making capacity in the United States. Its members operate manufacturing plants in 35 states, with distribution centers in all 50 states. PCA conducts market development, engineering, research, education, technical assistance, and public affairs programs on behalf of its members. Its mission includes a focus on improving and expanding the quality and uses of cement and concrete, raising the quality of construction, and contributing to a better environment. PCA has no



parent corporation, and no publicly held company owns a 10% or greater interest in PCA.

The *American Coke and Coal Chemicals Institute* (“ACCCI”), founded in 1944, is an international trade association that represents 100% of the U.S. producers of metallurgical coke used for iron and steelmaking, and 100% of the Nation’s producers of coal chemicals, who combined have operations in 12 states. It also represents chemical processors, metallurgical coal producers, coal and coke sales agents, and suppliers of equipment, goods, and services to the industry. ACCCI has no parent corporation, and no publicly held company has 10% or greater ownership in ACCCI.

The *Independent Petroleum Association of America* (“IPAA”) is a national not-for-profit trade association that represents the thousands of independent oil and natural gas producers and service companies across the United States. Independent producers develop 90% of American oil and gas wells, produce 54% of American oil, and produce 85% of American natural gas. IPAA has over 6,000 members, including companies that produce oil and natural gas ranging in size from large publicly traded companies to small businesses, companies that support this production such as drilling contractors, service companies, and financial institutions. IPAA has no parent corporation, and no publicly held company owns a 10% or greater interest in IPAA.

The *National Oilseed Processors Association* (“NOPA”) is a national not-for-profit trade association that represents 12 companies engaged in the production of vegetable meals and vegetable oils from oilseeds, including soybeans. NOPA’s member companies process more than 1.6 billion bushels of oilseeds annually at 63 plants in 19 states, including 57 plants which process soybeans. NOPA has no parent corporation, and no publicly held company has 10% or greater ownership in NOPA.

The *American Fuel & Petrochemical Manufacturers* (“AFPM”) is a national not-for-profit trade association whose members comprise more than 400 companies, including virtually all United States refiners and petrochemical manufacturers, and supply consumers with a wide range of products and services that are used daily in homes and businesses. AFPM has no parent corporation, and no publicly held company owns a 10% or greater interest in AFPM.

## TABLE OF CONTENTS

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES .....	i
RULE 26.1 DISCLOSURE STATEMENTS .....	iv
TABLE OF AUTHORITIES .....	xi
GLOSSARY OF TERMS .....	xv
JURISDICTIONAL STATEMENT .....	1
STATEMENT OF ISSUES .....	1
STATUTORY PROVISIONS .....	2
INTRODUCTION .....	2
STATEMENT OF THE CASE AND FACTS .....	3
A. Pertinent Requirements of the CAA .....	3
B. Ozone in the Ambient Air .....	6
C. History of EPA’s Prior Revisions to Ozone NAAQS .....	7
1. 1997 Revisions .....	7
2. 2008 Revisions .....	8
D. EPA’s 2015 Revision of the NAAQS .....	11
1. Conclusions on Primary Standard .....	12
2. Conclusions on Secondary Standard .....	15
E. Implications of the Revised NAAQS .....	16
SUMMARY OF ARGUMENT .....	18
STANDARD OF REVIEW .....	20
STANDING .....	20

ARGUMENT .....22

I. EPA’s Failure to Take into Account the Impact of Background Ozone Levels on Achievability of the Revised NAAQS Was Unlawful. ....22

    A. Background Ozone Levels Inhibit Achievement of the Revised NAAQS. ....23

    B. EPA Has Unlawfully Failed to Account for the Impact of Background Ozone in Preventing Achievement of the Revised NAAQS .....25

    C. The Alternative Regulatory Mechanisms Identified by EPA to Address Background Ozone Are Inadequate. ....30

II. EPA’s Failure to Take into Account the Adverse Impacts from Reducing the NAAQS Was Unlawful. ....31

III. EPA’s Failure to Provide a Reasoned Explanation for Its Change in Conclusions from the Relevant Scientific Evidence Was Unlawful.....36

CONCLUSION .....41

STATUTORY ADDENDUM (Separately Bound)

**TABLE OF AUTHORITIES\***

<b>Cases</b>	<b>Page(s)</b>
<i>Am. Petrol. Inst. v. Costle</i> , 665 F.2d 1176 (D.C. Cir. 1981), ), <i>cert. denied</i> , 455 U.S. 1034 (1982).....	26
* <i>Am. Trucking Ass’ns v. EPA</i> , 175 F.3d 1027 (D.C. Cir. 1999), <i>rev’d in part, aff’d in part on other grounds sub nom. Whitman v. Am. Trucking Ass’ns</i> , 531 U.S. 457 (2001).....	27
* <i>Am. Trucking Ass’ns v. EPA</i> , 283 F.3d 355 (D.C. Cir. 2002).....	8, 28
<i>Catawba Cnty., N.C. v. EPA</i> , 571 F.3d 20 (D.C. Cir. 2009) .....	36-37
<i>Corley v. United States</i> , 556 U.S. 303 (2009).....	33
<i>Dillmon v. NTSB</i> , 588 F.3d 1085 (D.C. Cir. 2009).....	37
<i>Lead Industries Ass’n v. EPA</i> , 647 F.2d 1130 (D.C. Cir. 1980), <i>cert. denied</i> , 449 U.S. 1042 (1980).....	26
<i>Michigan v. EPA</i> , 135 S. Ct. 2699 (2015) .....	33
<i>Mississippi v. EPA</i> , 744 F.3d 1334 (D.C. Cir. 2013), <i>cert. denied sub nom. Util. Air Regulatory Grp. v. EPA</i> , 135 S. Ct. 53 (2014).....	10-11, 32, 37
* <i>Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.</i> , 463 U.S. 29 (1983).....	22
<i>Pub. Citizen v. Fed. Motor Carrier Safety Admin.</i> , 374 F.3d 1209 (D.C. Cir. 2004) .....	22
<i>Sierra Club v. EPA</i> , 292 F.3d 895 (D.C. Cir. 2002).....	21
<i>Troy Corp. v. Browner</i> , 120 F.3d 277 (D.C. Cir. 1997), <i>reh’g denied</i> , 129 F.3d 1290 (D.C. Cir. 1997).....	37
* <i>Whitman v. Am. Trucking Ass’ns</i> , 531 U.S. 457 (2001).....	4-5, 31-33

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\* Authorities upon which we chiefly rely are marked with asterisks.

## Statutes

Clean Air Act (CAA), 42 U.S.C. §7401 *et seq.*

CAA §107(a), 42 U.S.C. §7407(a) .....	5, 25
CAA §107(d)(1), 42 U.S.C. §7407(d)(1) .....	17
CAA §108(a), 42 U.S.C. §7408(a) .....	3, 4
* CAA §109, 42 U.S.C. §7409 .....	1, 3-4, 19, 26, 33, 36
* CAA §110(a), 42 U.S.C. §7410(a) .....	4, 5-6, 16, 25
CAA §165(a), 42 U.S.C. §7475(a) .....	18
CAA §172, 42 U.S.C. §7502 .....	17
CAA §173, 42 U.S.C. §7503 .....	17, 18
CAA §182, 42 U.S.C. §7511a .....	17, 18
CAA §307(b), 42 U.S.C. §7607(b) .....	1
CAA §307(d), 42 U.S.C. §7607(d) .....	4, 20

## Federal Register

62 FR 38856 (July 18, 1997) .....	7-8
73 FR 16436 (Mar. 27, 2008) .....	8-10, 37
76 FR 3821 (Jan. 21, 2011) .....	33-34
79 FR 75234 (Dec. 17, 2014) .....	11, 14
*80 FR 65292 (Oct. 26, 2015) .....	1, 4, 6, 7, 11-16, 23-24, 26, 28-31, 38, 40

## Other

H.R. Rep. 95-294, 1977 U.S.C.C.A.N 1077 (1977) .....	4
Air Permitting Forum, Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule (Mar. 17, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-3578 .....	24

American Petroleum Institute , Comments on the National Ambient Air Quality Standards for Ozone Proposed Rule (Mar. 17, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-2465) .....	34
Electric Power Research Institute, Comments on Environmental Protection Agency, National Ambient Air Quality Standards for Ozone (Mar. 5, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-1394.....	24
EPA, <i>Integrated Science Assessment for Ozone and Related Photochemical Oxidants</i> (Feb. 2013), Docket ID No. EPA-HQ-OAR-2008-0699-0405 .....	6, 40
EPA, <i>Regulatory Impact Analysis of the Final Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone</i> (Sept. 2015), Docket ID No. EPA-HQ-OAR-2013-0169-0057, available at <a href="http://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0169-0057">http://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0169-0057</a> .....	17
Executive Order 13563, <i>Improving Regulation and Regulatory Review</i> , 76 FR 3821(January 18, 2011) .....	33-34
Langford, A.O., <i>et al.</i> , <i>An overview of the 2013 Las Vegas Ozone Study (LVOS): Impact of stratospheric intrusions and long-range transport on surface air quality</i> , <i>ATMOS. ENVIRON.</i> XX (2014): 1-18 (2014). In Docket ID No. EPA-HQ-OAR-2008-0699-3744 .....	24
Lefohn, A.S., and S.J. Oltmans, <i>Background Ozone and Its Importance in Relation to the Health Risk and Exposure Assessment for Ozone Assessment Document</i> (Mar. 13, 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0118 .....	24
Lin, M., <i>et al.</i> , <i>Springtime high surface ozone events over the western United States: Quantifying the role of stratospheric intrusions</i> , <i>J. OF GEOPHYSICAL RESEARCH</i> 117: D00V22 (Oct. 2012) .....	24
NERA Economic Consulting, <i>Economic Impacts of a 65 ppb National Ambient Air Quality Standard for Ozone</i> , Prepared for National Association of Manufacturers (Feb. 2015). Submitted by National Association of Manufacturers to EPA Docket. In Docket ID No. EPA-HQ-OAR-2008-0699-2463 .....	35

- \* Schelegle, E.S., *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. 180: 265- 272 (2009), Docket ID No. EPA-HQ-OAR-2008-0699-0198 ..... 13, 28, 38-39
- U.S. Chamber of Commerce *et al.*, *Comments on EPA’s December 2014 Proposed Revisions to National Ambient Air Quality Standards for Ozone (Mar. 17, 2015)*, Docket ID No. EPA-HQ-OAR-2008-0699-2397 .....34
- Waxman, Seth P., *Statement to Supreme Court in Am. Trucking Ass’ns v. Browner*, No. 99-1426, Oral Arg. Tr. at 35 (Nov. 7, 2000), *available at [http://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/99-1426.pdf](http://www.supremecourt.gov/oral_arguments/argument_transcripts/99-1426.pdf)*. ..... 27-28
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**GLOSSARY OF TERMS**

Act	Clean Air Act
ATS	American Thoracic Society
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	U.S. Environmental Protection Agency
FEV <sub>1</sub>	Forced expiratory volume in one second
FR	Federal Register
ISA	Integrated Science Assessment
JA	Joint Appendix
NAAQS	National Ambient Air Quality Standard
NO <sub>x</sub>	nitrogen oxides
O <sub>3</sub>	ozone
ppb	parts per billion
ppm	parts per million
RBL	relative biomass loss
SIP	State Implementation Plan
VOCs	volatile organic compounds

## **JURISDICTIONAL STATEMENT**

Industry Petitioners (Murray Energy Corporation and the Chamber of Commerce of the United States *et al.*) seek review of a final rule of the U.S. Environmental Protection Agency (“EPA”) entitled “National Ambient Air Quality Standards for Ozone,” issued under Section 109 of the Clean Air Act (“CAA” or “Act”).<sup>1</sup> 80 *Federal Register* (“FR”) 65292 (Oct. 26, 2015), Joint Appendix (“JA”) 290-467. Petitions for review were filed within the 60-day period prescribed by Section 307(b) of the Act. This Court has jurisdiction under that provision.

## **STATEMENT OF ISSUES**

Whether EPA’s adoption of the revised national ambient air quality standards (“NAAQS”) for ozone was arbitrary and capricious, an abuse of discretion, or contrary to the CAA because:

- (1) EPA failed to take adequate account of the impact of uncontrollable background levels of ozone in preventing achievement of those standards, and set standards that cannot be achieved in numerous areas given such background levels;
- (2) The above legal defect has not been and cannot be cured by EPA’s reliance on alternative regulatory mechanisms;

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<sup>1</sup> All statutory citations are to the CAA; the Table of Authorities provides parallel U.S. Code citations.

(3) EPA failed to take into account relevant contextual factors, including the adverse economic, social, and energy impacts of adopting these stricter standards; and/or

(4) EPA did not provide a reasoned explanation for changing its conclusions drawn from the same basic underlying scientific evidence considered in the prior NAAQS revision.

### **STATUTORY PROVISIONS**

Pertinent statutory provisions are reproduced in the Statutory Addendum (separately bound). No existing regulations are relied upon herein.

### **INTRODUCTION**

The CAA requires that NAAQS be achievable by regulation of U.S. sources. However, in revising the ozone NAAQS to a level lower than the prior standard, EPA failed to take into account the critical fact that naturally-occurring or internationally-transported background ozone that cannot be controlled under the Act can prevent achievement of those NAAQS in numerous areas of the country. That failure violated the Act.

Additionally, although the Supreme Court has held that, in setting NAAQS, EPA cannot consider the costs of implementation, EPA can and must consider contextual factors such as the acceptability of, and the public's tolerance for, the risks being addressed; and those contextual factors can all be influenced by the

overall adverse economic, social, and energy impacts that could result from a revised NAAQS. Yet EPA did not consider those impacts here.

Finally, despite the absence of any intervening study that changed the fundamental scientific understanding of ozone effects, EPA changed its conclusion regarding the acceptability of the risks from those drawn in the prior ozone NAAQS revision without providing a reasoned explanation for that change. That was arbitrary and capricious.

## **STATEMENT OF THE CASE AND FACTS**

### **A. Pertinent Requirements of the CAA**

Section 109 of the CAA directs EPA to set NAAQS for pollutants from numerous or diverse sources that may endanger public health or welfare. It requires EPA, based on its judgment, to set “primary” NAAQS at a level whose “attainment and maintenance” is “requisite to protect the public health” with “an adequate margin of safety,” and to set “secondary” NAAQS at a level “requisite to protect the public welfare from any known or anticipated adverse effects.” CAA §§109(b)(1)&(2). Section 109(d)(1) further requires EPA to review the NAAQS at least every five years and “make such revisions ... as may be appropriate” in accordance with Sections 108 and 109(b).<sup>2</sup> The NAAQS are implemented through

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<sup>2</sup> The CAA also provides that EPA’s scientific advisory group, the Clean Air Scientific Advisory Committee (“CASAC”), shall recommend to EPA any new or

state-adopted regulatory programs, known as state implementation plans (“SIPs”), which must provide for “the implementation, maintenance, and enforcement” of the NAAQS within the state. *Id.* §110(a)(1).

As EPA acknowledges, 80 FR at 65295 (JA 294), NAAQS are not intended to eliminate all risk or to reduce pollutant concentrations to “background” levels – *i.e.*, levels that would exist in the absence of anthropogenic emissions that are subject to regulation under the Act. Section 108 textually tethers NAAQS to pollutants that “result[] from numerous or diverse mobile or stationary sources,” not from nature. CAA §108(a)(1)(B). The House Report on the 1977 CAA amendments makes this clear:

Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe thresholds can be established, the ambient standards should be set at zero or background levels. *Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical.*

H.R. Rep. 95-294 at 127, 1977 U.S.C.C.A.N 1077 (emphasis added) (JA2130).

Further, as the Supreme Court has explained, “requisite to protect” means “not lower or higher than is necessary.” *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 476 (2001). Thus, EPA must determine the levels of a pollutant that are “sufficient, but not more than necessary” to protect the public health and welfare.

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revised NAAQS, §109(d)(2)(B), and that EPA must explain any important deviation from CASAC’s recommendations, §307(d)(3)&(6)(A).

*Id.* at 473 (internal quotation marks omitted). This requires an assessment of the extent to which the risks from exposure to the pollutant are unacceptable, and that assessment requires EPA to take into account contextual considerations. As Justice Breyer noted in *Whitman*, Section 109 “does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great.” *Id.* at 494 (Breyer, J., concurring in part and concurring in the judgment). Instead, when determining the levels “requisite” to protect the public health, EPA may consider various contextual factors, including: “the public’s ordinary tolerance of the particular health risk in the particular context at issue”; “the severity of a pollutant’s potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate”; “comparative health consequences”; and “the acceptability of small risks to health.” *Id.* at 494-95.

Consistent with the recognition that NAAQS are not intended to eliminate all risk or to be set at background levels that cannot be controlled under the Act, it is clear that NAAQS are to be standards that *can be achieved* by regulation of U.S. sources. This is demonstrated by the requirement in Section 107(a) that SIPs specify the manner in which the NAAQS “*will be achieved and maintained*,” and the requirement of Section 110(a)(2)(C) that SIPs include an enforcement and

regulation program “as necessary to assure that [NAAQS] are achieved” (emphases added).

## **B. Ozone in the Ambient Air**

This case involves EPA’s 2015 decision to lower the level of the NAAQS for ozone (“O<sub>3</sub>”). Ozone is not emitted directly from sources. It is formed in the air near the Earth’s surface through the reaction of certain precursor chemicals – notably, nitrogen oxides (“NO<sub>x</sub>”) and volatile organic compounds (“VOCs”). As explained by EPA, “[t]he precursor emissions leading to O<sub>3</sub> formation can result from both man-made sources (*e.g.*, motor vehicles and electric power generation) and natural sources (*e.g.*, vegetation and wildfires).” 80 FR at 65299 (JA 298). Further, “O<sub>3</sub> that is created naturally in the stratosphere can also contribute to O<sub>3</sub> levels near the surface.” *Id.* Finally, “[o]nce formed, O<sub>3</sub> near the surface can be transported by winds before eventually being removed from the atmosphere ....” *Id.* Due to such transport, emissions from Canada and Mexico and as far away as Asia contribute to ozone concentrations in the U.S. *Id.* at 65443 (JA 442).<sup>3</sup>

The ozone concentrations that come from sources other than anthropogenic U.S. emissions – *i.e.*, those arising from natural sources on the Earth’s surface and in the stratosphere and those resulting from international transport – are referred to

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<sup>3</sup> See also EPA’s Integrated Science Assessment for Ozone and Related Photochemical Oxidants (February 2013) (“ISA”), Docket No. EPA-HQ-OAR-2008-0699-0405, at Section 3.4.2 (JA 847-850).

as background. Since background contributions cannot be controlled through regulation of U.S. sources, even total elimination of all anthropogenic sources of NO<sub>x</sub> and VOCs in the U.S. (which is impossible) would not eliminate ozone in the ambient air. Further, as EPA has recognized, “O<sub>3</sub> concentrations in some locations in the U.S. on some days can be substantially influenced by sources that cannot be addressed by domestic control measures.” *Id.* at 65300 (JA 299). In fact, at some locations, “there can be events where O<sub>3</sub> levels approach or exceed the concentration levels of the revised O<sub>3</sub> standards in large part due to background sources.” *Id.* at 65436 (JA 435).

### **C. History of EPA’s Prior Revisions to Ozone NAAQS**

EPA initially adopted NAAQS for ozone in 1979 and has periodically revised them.

#### ***1. 1997 Revisions***

In 1997, EPA revised the primary NAAQS for ozone from a one-hour average standard of 0.12 parts per million (“ppm”) (with one allowable exceedance per year) to an 8-hour standard of 0.08 ppm, based on the annual 4<sup>th</sup> highest daily maximum 8-hour average concentration over a three-year period. 62 FR 38856 (July 18, 1997) (JA 4-15). EPA determined, *inter alia*, that, although a lower standard of 0.07 ppm, would be more protective, it was “not requisite to protect public health with an adequate margin of safety.” *Id.* at 38868 (JA 10). EPA’s



reasons included that, at levels below 0.08 ppm, the “most certain O<sub>3</sub>-related effects, while judged to be adverse, are transient and reversible” and the “more serious effects ... are less certain,” and that a standard of 0.07 ppm “would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O<sub>3</sub> precursors.” *Id.*

With respect to the secondary standard, which is based on the effects of ozone on vegetation, EPA noted that “the available scientific information supports the conclusion that a cumulative seasonal exposure index ... is more biologically relevant than a single event or mean index.” *Id.* at 38875 (JA 12). However, EPA set the secondary standard equal to the new 8-hour primary standard, considering the “substantial uncertainties” regarding whether increased welfare protection would result from a seasonal standard. *Id.* at 38877-78 (JA 14-15).

The primary and secondary NAAQS promulgated in 1997 were challenged as both overly stringent and not stringent enough, but were ultimately upheld against those challenges. See *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 378-80 (D.C. Cir. 2002).

## **2. 2008 Revisions**

EPA issued revised primary and secondary NAAQS for ozone again in 2008. 73 FR 16436 (Mar. 27, 2008) (JA 28-106). EPA revised the primary 8-hour standard to a level of 0.075 ppm, concluding that the prior standard was not

requisite to protect the public health. EPA relied particularly on controlled human exposure studies (*i.e.*, clinical laboratory studies), which it said provided the “most compelling” evidence of ozone-related effects. *Id.* at 16444 (JA 36). EPA stated that those studies showed consistent evidence of respiratory effects (lung function decrements and respiratory symptoms) in healthy exercising subjects at ozone levels of 0.080 ppm and above, and it also cited two new studies (by Adams in 2002 and 2006) showing such effects in some subjects at lower levels (specifically, 0.060 ppm). *Id.* at 16476, 16478 (JA 68, 70). EPA also relied on information indicating that people with asthma or other lung disease are likely to experience larger and more serious effects, or effects at lower levels, than healthy people. *Id.* at 16476, 16480 (JA 68, 72). Further, EPA asserted that new epidemiological evidence showed significant associations of ozone exposure with a wide range of health effects at ozone levels at and below 0.080 ppm. *Id.* at 16471, 16476 (JA 63, 68).

Although CASAC had recommended setting the primary standard in the range of 0.060 to 0.070 ppm, EPA explained that the data did not warrant such a lower standard due to the “limited” human clinical evidence of effects at lower levels and the uncertainties in the epidemiological studies regarding causal exposure-effect relationships at levels below the then-current standard. *Id.* at 16479, 16483 (JA 71, 75).

EPA also revised the secondary standard to be the same as the primary standard. EPA again noted that a cumulative seasonal standard was the most “biologically relevant way to relate [ozone] exposure to plant growth response.” *Id.* at 16500 (JA 92). However, it determined that adopting such a standard was unnecessary due to the “significant overlap between the revised 8-hour primary standard and selected levels of the [seasonal] standard form being considered.” *Id.* at 16499 (JA 91).

In July 2013, this Court issued a decision on several challenges to the 2008 NAAQS. *Mississippi v. EPA*, 744 F.3d 1334 (D.C. Cir. 2013). It upheld the primary standard of 0.075 ppm, concluding that EPA reasonably determined that reducing the previous standard of 0.08 ppm was appropriate given the studies linking health effects to ozone levels below 0.08 ppm. *Id.* at 1345. The Court also held that EPA was not required to reduce the standard below 0.075 ppm, given EPA’s determinations regarding the limitations in the human clinical evidence and the uncertainties in the epidemiological studies regarding effects at lower levels. *Id.* at 1350-52. It noted specifically that the two Adams clinical studies reporting effects at 0.060 ppm “indicate some degree of risk that some number of individuals might continue to experience health effects at and below 0.075 ppm, but we have

previously acknowledged the impossibility of eliminating all risk of health effects from ‘non-threshold’ pollutants like ozone.” *Id.* at 1350-51.<sup>4</sup>

The Court remanded the secondary standard to EPA, holding that EPA had not satisfied the CAA’s requirement to identify the level of protection that was “requisite to protect the public welfare.” *Id.* at 1359. The Court concluded that EPA could not simply “compare the level of protection afforded by the primary standard to possible secondary standards and find the two roughly equivalent,” but was obligated to expressly determine the level requisite to protect public welfare. *Id.* at 1360-61.

#### **D. EPA’s 2015 Revision of the NAAQS**

After another review, EPA proposed further revisions to the ozone NAAQS on December 17, 2014, 79 FR 75234 (JA 111-289), and published its final revised NAAQS on October 26, 2015. 80 FR 65292 (JA 290-467). EPA reduced the level of the 8-hour primary standard from 0.075 to 0.070 ppm, equivalent to 75 and 70 parts per billion (“ppb”), respectively<sup>5</sup>; and it made the secondary standard the

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<sup>4</sup> The Court additionally held that EPA had adequately explained its reasons for not accepting CASAC’s recommendations, given the lack of clarity as to whether CASAC based those recommendations on scientific or policy grounds. *Id.* at 1355-58.

<sup>5</sup> One ppm equals 1,000 ppb. In the remainder of this brief, for consistency with EPA’s preamble to its final rule, ozone concentrations are generally expressed in ppb.

same as the primary standard. In doing so, EPA did not take into account the impact of background ozone concentrations in preventing achievement of those revised NAAQS. See Section I below.

### *1. Conclusions on Primary Standard*

EPA concluded that the 2008 primary standard of 75 ppb was no longer requisite to protect the public health with an adequate margin of safety, and that lowering the standard level to 70 ppb was necessary. *Id.* at 65346, 65365 (JA 345, 364).

EPA again put the greatest weight on the controlled human exposure studies. *Id.* at 65343, 65352, 65362 (JA 342, 351, 361). EPA noted that these studies show a “continuum” of respiratory effects over a range of ozone exposures, with “[t]he largest respiratory effects, and the broadest range of effects, ... following exposures of healthy adults to 80 ppb O<sub>3</sub> or higher,” a “combination of lung function decrements and respiratory symptoms in healthy [subjects]” at ozone levels “as low as 72 ppb,” and some effects (including lung function decrements) at levels “as low as 60 ppb.” *Id.* at 65343 (JA 342); see also *id.* at 65352, 65363 (JA 351, 362).

As EPA recognized, only one such study at levels below 80 ppb reported a “combination of lung function decrements and respiratory symptoms,” which EPA stated constituted a prerequisite for adverse effects under criteria developed by the

American Thoracic Society (“ATS”), referenced by EPA. *Id.* at 65309 (JA 308).<sup>6</sup> That study, by Schelegle *et al.* (2009) (Docket No. EPA-HQ-OAR-2008-0699-0198, JA 459-556),<sup>7</sup> evaluated healthy subjects exposed to mean ozone levels of 88, 81, 72, and 63 ppb during exercise. It reported a temporary decrease in lung function (a mean decrease of approximately 6% in the measurement of FEV<sub>1</sub><sup>8</sup>) and an increase in subjective symptoms (mean score of approximately 13 on a severity scale of 0-40) at the 72 ppb exposure level (but no significant effects at 63 ppb). See 80 FR at 65303, 65352-53 (JA 302, 351-352). EPA concluded that the effects reported in that study at 72 ppb constituted adverse effects,<sup>9</sup> and it relied heavily on this study for the determination that the primary standard must be set at a level below 72 ppb. *Id.* at 65343, 65353, 65363 (JA 342, 352, 362).

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<sup>6</sup> EPA noted that “there are no universally accepted criteria by which to judge the adversity of the observed effects,” *id.* at 65363 (JA 362), but used the ATS criteria as a guideline.

<sup>7</sup> The full citations for scientific references discussed herein are given in the Table of Authorities.

<sup>8</sup> FEV<sub>1</sub> stands for forced expiratory volume in one second, a common measure of lung function. The ATS considers a decrease of greater than 10% in FEV<sub>1</sub> as an abnormal response. 80 FR at 65303 (JA 302).

<sup>9</sup> This assertion was referring to responses of individual study subjects, because EPA (as well as ATS) admits that transitory FEV<sub>1</sub> decrements less than 10% (such as the group mean decrease of 6% in this study) are not adverse. 80 FR at 65346 (JA 345). Only six of the 31 study subjects exhibited an FEV<sub>1</sub> decrement of 10% or greater. Moreover, subjects that exhibited FEV<sub>1</sub> decrements at 72 ppb ozone were not always the same individuals that reported respiratory symptoms. See *id.* at 65330 (JA 329).

EPA also continued to assert, as it had in 2008, that “at-risk” groups, such as children and asthmatics, could experience larger and/or more serious effects or effects at lower levels. *Id.* at 65314 (JA 313). EPA recognized, however, that no controlled human exposure studies have evaluated such groups exposed to ozone levels at or below those involved here. *Id.* at n.55; 79 FR at 75273 (JA 151).

EPA placed less weight on epidemiological studies reporting associations of ozone levels with respiratory effects, 80 FR at 65341, 65359 (JA 340, 358), due to “important uncertainties and limitations” associated with these studies, such that they “lend only limited support to establishing a specific level for a revised standard.” *Id.* at 65335 (JA 334). These uncertainties and limitations include uncertainties regarding the actual ambient ozone concentrations in the cities where the studies were conducted and uncertainties stemming from the presence of co-occurring pollutants or pollutant mixtures. *Id.* at 65335, 65341 (JA 334, 340).

EPA rejected the need to set a primary standard at a level below 70 ppb. It noted that, at levels below 72 ppb, “the combination of statistically significant increases in respiratory symptoms and decrements in lung function has not been reported,” including in studies of exposures to 60 or 63 ppb. *Id.* at 65357 (JA 356). EPA also concluded that there is “greater uncertainty” regarding the adversity of effects at levels “as low as 60 ppb,” *id.* at 65361 (JA 360), and that a standard below 70 ppb “would be expected to achieve virtually no additional reductions” in

repeated occurrences of the exposures about which EPA is “most concerned,” *id.* at 65365 (JA 364).

## ***2. Conclusions on Secondary Standard***

In revising the secondary NAAQS, EPA noted that the currently available information on the effects of ozone on vegetation “is largely consistent with the evidence available at the time of the last review,” although the newer information “has strengthened” the prior evidence in “some respects.” *Id.* at 65383 (JA 382). It also explained that the level at which ozone causes adverse welfare effects is not a “bright-line determination,” *id.* at 65376 (JA 375), and that identifying an appropriate level for the secondary standard depends on “judgments regarding the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O<sub>3</sub> exposures and judgments on the extent to which such effects in such areas may be considered adverse to public welfare.” *Id.* at 65398 (JA 397).

EPA concluded that the secondary standard needed to be revised and that the cumulative seasonal metric was appropriate for considering the level of protection. *Id.* at 65389, 65399 (JA 388, 398). EPA then concluded that, to provide the level of protection “requisite to protect the public welfare,” the revised secondary standard “should restrict cumulative seasonal exposures to 17 ppm-hrs or lower [using the seasonal standard form] in nearly all instances,” *id.* at 65408 (JA 407),



and that an 8-hour standard of 70 ppb using the current form would provide that level of protection, *id.* at 65409 (JA 408).

For this conclusion, EPA relied primarily on exposure-response information regarding the Relative Biomass Loss (“RBL”) in tree growth, particularly in certain protected areas. *Id.* at 65384, 65405 (JA 383, 404). EPA concluded that a median RBL benchmark of 6% was appropriate for defining welfare protection, that the standard should limit cumulative exposures to those associated with a median RBL estimate “somewhat lower than 6%,” and that a standard that limits cumulative seasonal exposures to 17 ppm-hrs or lower would “eliminate or virtually eliminate cumulative exposures associated with a median RBL of 6% or greater.” *Id.* at 65407, 65409 (JA 406, 408). EPA also considered information on visible foliar injury and crop loss, but gave it less weight due to the uncertainties and limitations in the exposure-response data on such effects and their significance to public welfare. *Id.* at 65388, 65390, 65407 (JA 387, 389, 406).

### **E. Implications of the Revised NAAQS**

Promulgation of revised NAAQS triggers requirements for States to adopt and submit to EPA revised SIPs that provide for achieving and maintaining the revised NAAQS within their borders. CAA §110(a)(1)&(2). Reductions in ozone levels can be achieved only by reducing the emissions of precursor chemicals (NO<sub>x</sub> and VOCs) from the myriad emission sources across virtually all sectors of

the economy, including manufacturing, energy, transportation, agriculture, construction, and general commercial services. Thus, States must develop revised SIPs with additional regulatory control requirements for sources of the ozone precursors. This will impose significant additional emission reduction obligations on existing, new, and modified sources. EPA has acknowledged that existing emission control technologies will not be sufficient to achieve the 2015 revised NAAQS, and that States, along with regulated sources, will instead have to rely on what EPA refers to as “unidentified controls” (which have yet to be developed) to further reduce ambient ozone levels to achieve those NAAQS.<sup>10</sup>

Additionally, because many areas of the country have ambient ozone concentrations that exceed the revised NAAQS (but not the prior NAAQS),<sup>11</sup> States will be required to designate many new areas as “nonattainment” for the revised standard and/or to expand existing nonattainment areas, and EPA will promulgate those nonattainment area designations. *Id.* §107(d)(1)(A)&(B). The CAA imposes rigorous SIP requirements for nonattainment areas generally (*id.* §§172-173) and additional requirements for ozone nonattainment areas specifically (*id.* §182). These involve stringent regulatory requirements for both existing and

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<sup>10</sup> See EPA’s *Regulatory Impact Analysis of the Final Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone* (September 2015), Docket No. EPA-HQ-OAR-2013-0169-0057, at ES-7, 4-1, available at <http://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0169-0057>.

<sup>11</sup> See page 34, note 17, *infra*.

new/modified sources within such areas, including that the latter must install emission controls more stringent than the control requirements applicable in other areas and must obtain emissions offsets at a greater than 1:1 ratio from other facilities in the region. *Id.* §§173(a)(2)&(c), 182.

Moreover, even in attainment (or unclassifiable) areas, permit applicants for new or modified sources must show that the source's emissions "will not cause, or contribute to, air pollution in excess of" the revised ozone NAAQS. CAA §165(a)(3). The revised NAAQS will make that showing significantly more difficult and burdensome.

### **SUMMARY OF ARGUMENT**

1. The CAA requires that NAAQS be achievable by regulation of U.S. sources through SIPs. Consequently, in setting NAAQS, EPA must consider whether those standards can be achieved through such regulation and may not set standards that cannot be achieved. In lowering the ozone NAAQS level, EPA did not take appropriate account of evidence that naturally-occurring or internationally-transported background ozone that cannot be controlled under the Act can, in some circumstances, prevent achievement of those NAAQS, particularly given that the Act does not require man-made U.S. emissions to be totally eliminated (which is impossible in any event). Although EPA claims that it was prohibited from considering the impacts of background levels on the

achievability of the revised standards here, that claim is unsupported by the Act, the case law, or common sense and is inconsistent with EPA's prior position. To the contrary, the Act *requires* such consideration. Further, EPA's identification of three alternate regulatory programs that it asserts would provide relief from nonattainment due to background does not excuse its failure to take background properly into account in setting the level of the NAAQS; and in any event, those programs would not provide sufficient relief. Thus, EPA's issuance of the revised NAAQS was arbitrary, capricious, and contrary to the CAA.

2. Although the Supreme Court has held that, in setting NAAQS, EPA cannot consider the costs of implementation, that holding does not preclude EPA from considering contextual "risk assessment" factors such as those described by Justice Breyer in *Whitman*, including "the public's ordinary tolerance for a particular health risk," "comparative health risks," and "the acceptability of small risks to health." See page 5, *supra*. In fact, the determination of levels "requisite to protect" public health and welfare necessitates such a contextual assessment. These contextual factors can all be influenced by the overall adverse economic, social, and energy impacts that could result from a revised NAAQS. Moreover, the separate requirement of Section 109(d)(1) that EPA is to revise the NAAQS as "appropriate" encompasses consideration of such impacts. Here, EPA did not

consider any of these contextual factors. That was also arbitrary, capricious, and unlawful.

3. EPA is required to provide a reasoned explanation for a change in a prior conclusion or interpretation. Here, no new study since EPA last revised the ozone NAAQS in 2008 changed the fundamental scientific understanding of ozone effects or the exposure-response relationships. Yet EPA changed its conclusion to find that levels of risk that were judged acceptable in 2008 are no longer acceptable, and it did not provide a reasoned explanation for that change in judgment. As such, its decision was arbitrary and capricious.

### **STANDARD OF REVIEW**

Section 307(d)(9) of the CAA provides that the Court may set aside EPA's action if it finds that action to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory ... authority."

### **STANDING**

Industry Petitioners include several business associations and a coal company (Murray Energy) that collectively represent much of the nation's leading manufacturing, energy, and other business sectors.

Murray Energy has standing due to its supply of fuel to facilities that emit ozone precursors and thus will be substantially affected by the regulatory requirements stemming from the revised NAAQS.

The business associations' standing is obvious because: (1) "at least one of [their] members would have standing to sue in [its] own right"; (2) the interests they "seek to protect are germane to [their] purpose"; and (3) neither their claims nor requested relief "requires that an individual member of the association[s] participate in the lawsuit." *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002).

First, the business associations each have many members that would have standing to sue because they own or operate facilities that emit ozone precursors, and thus will be substantially affected by the emission control and other requirements imposed in revised SIPs resulting from the revised NAAQS. Furthermore, members that wish to build or modify emitting facilities will be directly affected by the stringent new source review requirements that will apply to such facilities in newly designated nonattainment areas for the revised NAAQS, as well as additional requirements that will apply to such facilities in other areas.

Second, the interests that the business associations seek to protect – *i.e.*, to avoid undue burdens on their members resulting from revised ozone NAAQS – are germane to their organizational purposes of promoting the well-being of their member companies and industries.

Third, neither the claims asserted nor the relief requested requires the participation of the associations' individual members. The issues here relate to the

general lawfulness of EPA's action in promulgating revised NAAQS, and do not depend on the circumstances of any specific company or facility. Similarly, the relief requested – *i.e.*, vacating the revised ozone NAAQS – would apply nationwide, rather than only to specific companies.

## **ARGUMENT**

### **I. EPA's Failure to Take into Account the Impact of Background Ozone Levels on Achievability of the Revised NAAQS Was Unlawful.**

An agency decision must be set aside as arbitrary and capricious if the agency failed to consider an important aspect of the problem or the full range of factors required by Congress. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983); *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). The influence of uncontrollable background levels of ozone on the achievability of the ozone NAAQS was an important aspect of the problem faced by EPA in deciding whether to revise the NAAQS. Indeed, as discussed in Section A of the Statement of the Case and Facts (hereinafter "Statement"), the CAA requires EPA to consider the achievability of the NAAQS through regulation under SIPs and to set NAAQS at a level that can be attained through such regulation. Here, EPA failed to account for the influence of background ozone on the achievability of the revised NAAQS and, in fact, set standards that cannot be achieved in numerous areas of the country

because of background ozone that cannot be controlled by SIP regulation.

Although EPA cited certain other regulatory mechanisms that it claims can help address nonattainment of the revised NAAQS due to background ozone levels, those mechanisms fail to cure that defect. Accordingly, EPA's decision was arbitrary, capricious, and contrary to the CAA.

**A. Background Ozone Levels Inhibit Achievement of the Revised NAAQS.**

As previously discussed, ozone in the ambient air results not only from emissions of precursor chemicals from U.S. sources, but also from sources that cannot be controlled under U.S. regulations, such as wildfires and vegetative emissions, atmospheric intrusions from the stratospheric ozone layer, and transport of ozone and ozone precursors from foreign countries. EPA acknowledged that, in some circumstances, ozone concentrations in U.S. ambient air “can be substantially influenced” by these uncontrollable sources. 80 FR at 65300 (JA 299). It stated further:

In particular, certain high-elevation sites in the western U.S. are impacted by a combination of non-U.S. sources like international transport, or natural sources such as stratospheric O<sub>3</sub>, and O<sub>3</sub> originating from wildfire emissions.... [A]t these locations, there can be episodic events with substantial background contributions where O<sub>3</sub> concentrations approach or exceed the level of the [prior] NAAQS (*i.e.*, 75 ppb).



*Id.* at 65300 (JA 299). More generally, EPA stated that “there can be events where O<sub>3</sub> levels approach or exceed the concentration level of the revised O<sub>3</sub> standards in large part due to background sources.” *Id.* at 65436 (JA 435).

Evidence in the record demonstrates further that background ozone concentrations can, in some areas and some times of the year, reach levels at or approaching the revised NAAQS of 70 ppb so as to cause exceedance of that standard. See, *e.g.*, Lefohn and Oltmans (2014) (Docket No. EPA-HQ-OAR-2008-0699-0118) at 7 (JA1274) (reporting background concentrations of 30-70 ppb at certain high-elevation sites); Zhang *et al.* (2011) (*id.*-3744, JA1991-1998) (estimating annual fourth highest background concentrations of 50-60 ppb in the Intermountain West, with some levels exceeding 60 ppb); Electric Power Research Institute (2015) (*id.*-1394) at 24-26 (JA1348-1350) (model showing fourth highest daily maximum background 8-hour levels close to 65 ppb in some locations); Air Permitting Forum Comments (2015) (*id.*-3578) at 9 (JA2039) citing Lin *et al.* (2012) (JA1951-1970) (finding that several stratospheric ozone incursions over a three-month period in 2010 elevated background concentrations to daily maximum 8-hour levels of 60-75 ppb); Langford *et al.* (2014) (*id.*-3744) at 16 (JA1097) (finding mean concentration of 67 ppb during two summer months at rural site predominantly influenced by background).

Given these reported background ozone concentrations, together with the undisputed fact that NAAQS are not intended to reduce all man-made emissions from U.S. sources to zero, it is clear that, in many areas, background ozone levels (even if they do not by themselves exceed 70 ppb) can and will prevent attainment and maintenance of the revised NAAQS.<sup>12</sup>

**B. EPA Has Unlawfully Failed to Account for the Impact of Background Ozone in Preventing Achievement of the Revised NAAQS.**

In reducing the level of the NAAQS, EPA did not take into account the proximity of the 70 ppb standard to background levels or the impact of background levels on the achievability of that standard. That failure – and EPA’s consequent issuance of a national standard that cannot be attained in numerous parts of the country given uncontrollable background ozone – was arbitrary, capricious, and contrary to the CAA.

As discussed in Statement Section A, Congress intended that NAAQS be achievable by regulation of U.S. sources through SIPs, as demonstrated by the requirements that SIPs specify the manner in which the NAAQS “*will be achieved and maintained,*” CAA §107(a), and include an enforcement and regulation program “*as necessary to assure that [NAAQS] are achieved,*” *id.* §110(a)(2)(C)

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<sup>12</sup> This is exacerbated by the fact that, as EPA acknowledges, no existing emission control technologies are sufficient to achieve the revised NAAQS. See Statement Section E.

(emphases added). Section 109(b) itself links the setting of “requisite” NAAQS to their “attainment and maintenance.” NAAQS were not intended to address pollution that is beyond the control of the States or EPA. It follows that, in revising NAAQS, EPA must consider whether the standards can be achieved through the regulation provided for by the CAA, and may not set a standard that is not achievable on a nationwide basis through such regulation, considering that NAAQS are not even intended to eliminate all anthropogenic U.S. emissions, much less naturally-occurring emissions.

In arguing to the contrary, EPA cited this Court’s decision in *API v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981), stating that “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS].” See 80 FR at 65328 (JA 327). EPA misconstrues that decision. In addressing attainability, the Court focused on cost and technological feasibility, not on other factors that prevent attainment. The Court merely quoted its opinion in *Lead Industries Ass’n v. EPA*, 647 F.2d 1130, 1149 (D.C. Cir. 1980), that “‘the Administrator may not consider economic and technological feasibility in setting air quality standards.’” Although the Court also addressed an argument by the city of Houston that natural factors made attainment impossible there, it decided only that Houston’s particular circumstances were not a basis for vacating a national standard. See *API*, 665 F.2d at 1186. That is very different from a situation where

numerous areas of the country cannot attain the NAAQS due to background levels. In the latter situation, setting a standard that cannot be achieved due to background levels conflicts with the Act's requirement that NAAQS should be broadly achievable and maintainable through regulation under SIPs.

This Court's subsequent decisions in *American Trucking* make clear that it did not resolve that broader issue in *API*, and support that position that setting a standard that cannot be achieved due to background is inappropriate. In its first *American Trucking* opinion, this Court addressed EPA's statement, in setting the 1997 ozone NAAQS, that a 70 ppb standard was inappropriate because it would be "closer to peak background levels that infrequently occur in some areas." *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1036 (D.C. Cir. 1999), *rev'd in part, aff'd in part on other grounds* in *Whitman*, 531 U.S. 457 (2001). The Court stated that this rationale may amount to "saying that, given the national character of the NAAQS, it is inappropriate to set a standard below a level that can be achieved throughout the country without action affirmatively *extracting* chemicals from nature"; and it noted "[t]hat may well be a sound reading of the statute, [although] EPA has not explicitly adopted it." 175 F.3d at 1036 (second emphasis added). In defending its interpretation before the Supreme Court, EPA did adopt that reading. See Statement of Solicitor General Seth Waxman in *Am. Trucking Ass'ns v. Browner*, No. 99-1426, Oral Arg. Tr. at 35 (Nov. 7, 2000) (JA2189) ("EPA

reasonably interprets the Clean Air Act as not either requiring or permitting it to set levels that are at or below background levels”). Following remand from the Supreme Court, this Court again relied, in part, on EPA’s determination that a standard of 70 ppb was too close to background, and stated that the “relative proximity to peak background ozone concentrations” was a factor that “EPA could consider” when selecting a standard. *Am. Trucking Ass’ns*, 283 F.3d at 379.

EPA has also claimed that it may consider background levels only “within the range of reasonable values” supported by the data and the Administrator’s judgments, and that it could not do so here because the scientific evidence compelled it to reduce the standard. 80 FR at 65328 (JA 327). That claim is incorrect. First, EPA recognizes that the scientific data show a continuum of respiratory effects, decreasing in magnitude and incidence, over a range of ozone levels from over 80 ppb to 60 ppb, *id.* at 65343 (JA 342), and that in choosing a specific level “requisite to protect the public health,” EPA must make a “judgment in the face of scientific uncertainty,” *id.* at 65327 (JA 326), where there is no scientific bright line between acceptable and unacceptable risks.<sup>13</sup> Similarly, for the secondary standard, EPA acknowledges that, within the range of interest here, there

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<sup>13</sup> To the extent that EPA may be claiming that the new human clinical study by Schelegle *et al.* (2009) provided such a bright line at 72 ppb, that is contradicted by the nature of the reported responses in that study, as shown in Section III, and in any event, could not justify setting the standard at 70 ppb.

is no bright-line level at which ozone causes adverse welfare effects, and hence the determination of the secondary standard level depends on judgments regarding the weight to give to specific vegetation-related effects and the extent to which those effects may be considered adverse to public welfare. *Id.* at 65398 (JA 397). In these circumstances, EPA was not legally precluded from considering background.

To the contrary, regardless of its judgments on these issues, the Act *requires* EPA to set NAAQS that can be achieved through regulation of U.S. sources, as shown above, and thus *requires* EPA to take into account the impact of background levels in order to ensure that the NAAQS can be achieved.

EPA has contended further that, even if it could consider background, its modeling analyses show that, even in remote locations, U.S. anthropogenic emissions make up part of the ambient ozone concentrations (10-20% or more), and that there are no locations where uncontrollable background levels *by themselves* are “expected” to totally preclude attainment of a 70 ppb NAAQS. *Id.* at 65328 (JA 327). That contention is unsupportable. As shown in Section I.A, there is evidence that background concentrations may actually reach 70 ppb in some areas, which EPA does not deny. *Id.* Even accepting EPA’s modeling-based assertion that background concentrations *by themselves* would not exceed 70 ppb, EPA concedes that situations exist where background concentrations would approach that level and thus be the primary contributor to an exceedance of the

standard, *id.* at 65428, 65436 (JA 427, 435); and the record bolsters that conclusion. As previously noted, because the NAAQS are not intended to require elimination of all anthropogenic emissions from U.S. sources, there must be *some* allowance for such emissions. Given that fact, in cases where background levels approach the standard, they *would* cause nonattainment of the standard. EPA has not taken those situations into account in reducing the level of the NAAQS, and thus has issued a standard that cannot be met in numerous areas.

In addition, as discussed below, a federal agency must provide a reasoned explanation for a change in a prior conclusion or interpretation. See pages 36-37, *infra*. Here, although EPA concluded in 1997 that a standard of 70 ppb would be too close to background (see Statement Section C.1), it has now concluded that, despite such proximity to background (which remains true), setting the standard at 70 ppb is appropriate.<sup>14</sup> EPA has not provided an explanation for that change in conclusion – which by itself renders its decision arbitrary and capricious.

### **C. The Alternative Regulatory Mechanisms Identified by EPA to Address Background Ozone Are Inadequate.**

Instead of taking unattainability due to background into account in determining the appropriate level of the ozone NAAQS (as required by law), EPA

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<sup>14</sup> In 2008, in deciding not to reduce the NAAQS below 75 ppb, EPA relied on the limited and uncertain evidence of effects at lower levels (see Statement Section C.2) and thus did not need to rely on proximity to background.

identifies three regulatory programs that it claims will provide relief for events where “O<sub>3</sub> levels approach or exceed ... the revised O<sub>3</sub> standards in large part due to background sources.” 80 FR at 65436 (JA 435). They are: (1) exceptional event exclusions, (2) treatment as rural transport areas, and (3) international transport provisions. *Id.* The theoretical availability of these regulatory mechanisms does not excuse EPA’s failure to comply with the Act by properly accounting for background ozone in setting the NAAQS. Moreover, EPA’s reliance on these regulatory mechanisms is arbitrary and capricious because none of them can provide sufficient relief for situations where background ozone causes or contributes significantly to exceedances of the revised NAAQS. This is demonstrated in Section I.C of the Opening Brief of State Petitioners, which is incorporated by reference herein.

## **II. EPA’s Failure to Take into Account the Adverse Impacts from Reducing the NAAQS Was Unlawful.**

Although the Supreme Court has held that EPA cannot consider the costs of implementation when establishing or revising NAAQS, *Whitman*, 531 U.S. at 464-71, that does not absolve EPA from considering the overall adverse economic, social, and energy impacts of the standards. As Justice Breyer explained in *Whitman*, “§ 109 [of the Act] does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of hurtling



industry over the brink of ruin or even forcing deindustrialization.” *Id.* at 494 (Breyer, J., concurring in part and concurring in the judgment) (internal quotations omitted). Instead, in determining what levels of a pollutant are “requisite to protect” the public health and welfare, EPA must necessarily make an assessment of the extent to which the risks from exposure to the pollutant are unacceptable, and this, in turn, requires EPA to take into account the contextual factors that Justice Breyer identified. This Court has confirmed that revising primary NAAQS “may indeed require [such] a contextual assessment of acceptable risk.” *Mississippi*, 744 F.3d at 1343.

As Justice Breyer noted, relevant contextual factors include “the public’s ordinary tolerance of the particular health risk in the particular context at issue,” the “comparative health risks,” and “the acceptability of small risks to health.” *Whitman*, 531 U.S. at 494-95 (Breyer, J., concurring in part and concurring in the judgment). Those factors can all be influenced by the overall adverse economic, social, and energy impacts that could result from a revised NAAQS. For example, the public’s “tolerance” and “acceptability” of a particular level of risk can be affected by the standard’s adverse impacts on the public through reductions in economic growth, job loss, increased energy prices, etc.<sup>15</sup> Indeed, where, as here,

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<sup>15</sup> Consideration of such broader impacts is not precluded by the Supreme Court’s decision in *Whitman*. Although the Court discussed other impacts from a stricter

there is a continuum of exposures/effects over the range of concentrations under consideration, consideration of the adverse impacts from reducing the standard is particularly important in judging what level in that continuum is “requisite” to protect public health and welfare.

The need to consider such impacts when evaluating a potential revision of the NAAQS is further supported by the requirement of Section 109(d)(1) that, during its periodic reviews, EPA is to make such revisions of the NAAQS “as may be appropriate.” That language must be given some effect. Under established statutory construction canons, all words of a statute must be given effect to avoid rendering any statutory language superfluous. See, *e.g.*, *Corley v. United States*, 556 U.S. 303, 314 (2009). That applies to the use of the word “appropriate” in Section 109(d)(1), and an evaluation of “appropriateness” must take into account the adverse socioeconomic and energy impacts of a standard.<sup>16</sup> Indeed, doing so would comport with Executive Order 13563, which requires generally that

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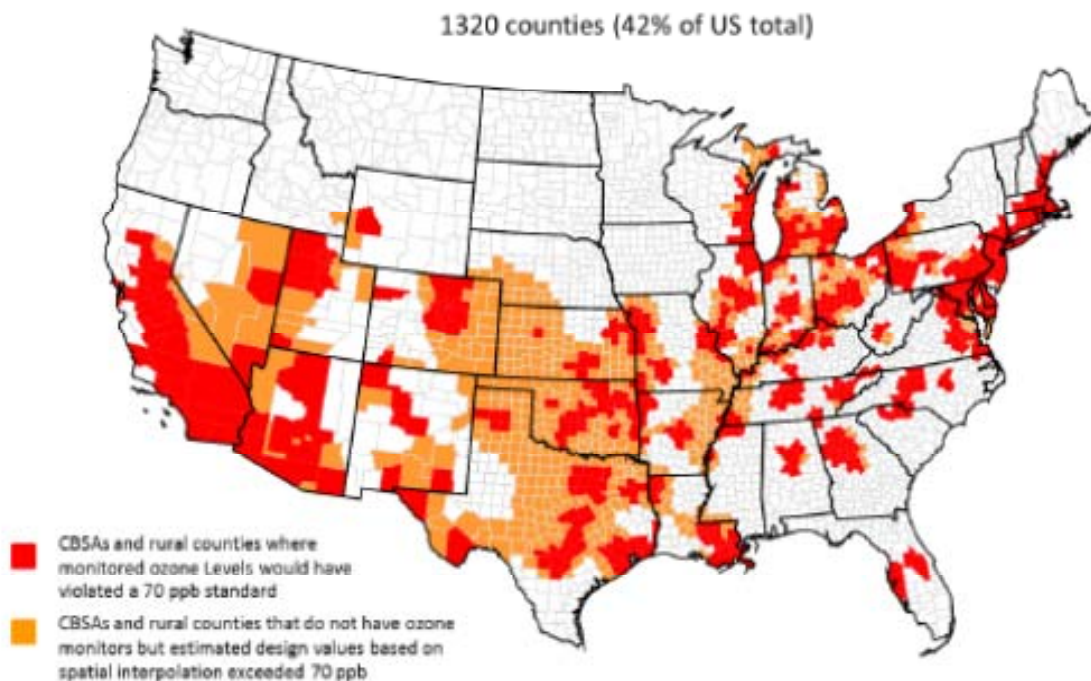
standard, 531 U.S. at 466, its holding was simply that EPA may not consider the costs of implementation. To the extent that decision, or prior decisions of this Court, are interpreted to preclude consideration of the broader impacts, they would be inconsistent with the Act.

<sup>16</sup> *Cf. Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015), noting that “‘appropriate’ is ‘the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors’” (quoting opinion of Judge Kavanaugh below). Although that decision involved a different CAA program and in fact distinguished *Whitman* on that ground, *id.* at 2709, it does support a broad interpretation of the term “appropriate.”

regulations “protect public health, welfare, safety, and our environment *while promoting economic growth, innovation, competitiveness, and job creation.*” 76 FR 3821 (Jan. 21, 2011) (JA2267) (emphasis added).

It is undisputed that the reduced NAAQS will have such impacts and that EPA did not consider them. The revised standard will dramatically increase the number of areas designated nonattainment for the ozone NAAQS, as shown on Figure 1.<sup>17</sup>

Figure 1:



<sup>17</sup> This figure was provided in Comments of American Petroleum Institute (Docket No. EPA-HQ-OAR-2008-0699-2465) at 116 (JA1567). See also Comments of U.S. Chamber of Commerce *et al.* (Docket No. EPA-HQ-OAR-2008-0699-2397) at Attachment A (JA1428) (showing that 15 of the nation’s top 20 metropolitan area economies would be classified as nonattainment for a 70 ppb standard, compared to 8 for the prior standard).

These additional nonattainment area designations will require imposition of the very stringent extra requirements applicable in such areas. See Statement Section E. Moreover, EPA acknowledges that the revised NAAQS cannot be achieved by known controls, but would require currently unidentified controls. *Id.* The utter lack of control mechanisms only exacerbates the traditional economic harms caused by a nonattainment designation.

Stricter standards can stymie economic growth by forcing the early retirement of facilities unable to implement controls, contributing to job losses; discouraging existing businesses from expanding in nonattainment regions; and driving away potential new investments. Indeed, the record contains considerable information regarding these and other adverse impacts of lowered ozone standards. For example, a detailed analysis in the record estimated that, over the period from 2017 through 2040, a standard of 65 ppb could reduce the U.S. Gross Domestic Product by an average of about \$140 billion per year (totaling about \$1.7 trillion), result in a loss of approximately 1.4 million job equivalents, reduce the average U.S. household consumption by about \$830 per year, lead to the premature retirement of many coal-fired power plants, and cause the average residential cost of electricity to rise by 1.7%.<sup>18</sup> A standard of 70 ppb would have the same types of

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<sup>18</sup> See analysis by NERA Economic Consulting (2015) (Docket No. EPA-HQ-OAR-2008-0699-2463) at 11-13 (JA1432-1434).

impacts, differing only in degree, and EPA had an obligation to identify and consider such impacts. In any event, the adverse impacts of the stricter standards being considered constituted pertinent information that EPA had a duty to consider, even if it did not adopt those stricter standards.

EPA failed to consider any of this information in reaching its decision, and did not make its own analysis of the adverse economic, social, and energy impacts of the potential revised standards. Nor did EPA solicit CASAC's advice on this important issue, despite the Act's requirement that CASAC "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." CAA §109(d)(2)(C)(iv).

In these circumstances, it was arbitrary and capricious, an abuse of discretion, and contrary to the Act for EPA to revise the NAAQS without considering these broader contextual factors.

### **III. EPA's Failure to Provide a Reasoned Explanation for Its Change in Conclusions from the Relevant Scientific Evidence Was Unlawful.**

Where a federal agency issues a decision that changes a prior conclusion or interpretation, it must provide a reasoned explanation for that change; otherwise, its decision will be found to be arbitrary and capricious. See, *e.g.*, *Catawba Cnty.*

*v. EPA*, 571 F.3d 20, 52 (D.C. Cir. 2009); *Dillmon v. NTSB*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009); *Troy Corp. v. Browner*, 120 F.3d 277, 286 (D.C. Cir. 1997).

In revising the ozone NAAQS, EPA changed the conclusions it drew from the same basic scientific evidence considered in 2008 without providing a reasoned explanation. In adopting a primary standard of 75 ppb in 2008, EPA relied on three main bases: (1) The consistent body of clinical evidence of respiratory effects in healthy subjects at exposure levels of 80 ppb and above, as well as “some indication of lung function decrements and respiratory symptoms at lower levels”; (2) the clinical evidence indicating that asthmatics and other at-risk populations are likely to experience larger and more serious effects, or effects at lower levels, than healthy people; and (3) the epidemiological evidence indicating associations for a wide range of health effects at and below 80 ppb. See 73 FR at 16476 (JA 68). Based on these principal considerations, EPA determined that a standard of 75 ppb was “requisite to protect public health with an adequate margin of safety, including the health of sensitive subpopulations, from serious health effects,” and that a lower standard was not needed or warranted. 73 FR at 16483 (JA 75). This Court in *Mississippi* upheld that judgment.

Although EPA cites a handful of new but limited studies that became available after 2008, those studies do not alter in any fundamental way the information on which EPA relied in 2008. With respect to the controlled human

exposure studies, on which EPA continues to place the greatest weight, the prior studies showed, as EPA concluded in 2008, that the types of respiratory effects of concern occur at ozone levels at and above 80 ppb and decrease in size and severity and in the number of individuals affected down to 60 ppb. The newer studies simply confirmed that expected continuum, as shown by the following:

- In issuing the revised NAAQS, EPA continued to note that the “largest” and “broadest range” of effects has been reported in healthy subjects exposed to ozone levels at and above 80 ppb, and it continued to note the findings of some effects at lower levels. 80 FR at 65343, 65352, 65363 (JA 342, 351, 362); see also Statement Section D.1.
- Although EPA relied heavily on the study by Schelegle *et al.* (2009) reporting lung function decrements and respiratory symptoms in healthy subjects exposed to 72 ppb during exercise, that study simply confirmed EPA’s 2008 determination that the evidence provides “some indication” of lung function decrements and respiratory symptoms at levels below 80 ppb. This is especially true given that, at the 72 ppb level in that study: (a) the effects reported were admittedly small, namely, a mean FEV<sub>1</sub> decrease of approximately 6% (less than the ATS and EPA criterion of 10% for an abnormal effect) and a modest increase in subjective symptoms; (b) there were only 31 subjects, of whom only six exhibited an FEV<sub>1</sub> decrement of

10% or greater; and (c) individuals that exhibited FEV<sub>1</sub> decrements were not always the same as individuals that reported respiratory symptoms.

- The new reports of even smaller effects at 63 and 60 ppb (which EPA says are of “uncertain” adversity) provide further confirmation of EPA’s prior conclusions in 2008 of some effects at those levels, including its conclusions from the Adams studies (see Statement Section C.2).

Thus, the new studies did not provide any new basic information regarding the types or magnitude of healthy subjects’ responses at these ozone concentrations or the expected exposure-response relationship.<sup>19</sup>

Further, EPA has continued to claim that at-risk groups such as asthmatics are likely to experience larger and more serious effects, or effects at lower levels, than healthy people, but it recognizes that there are *no new* clinical studies on this topic. See Statement Section D.1. Moreover, although there are some new epidemiological studies, EPA has continued to acknowledge that important uncertainties remain in attempting to rely on those and the older epidemiological studies to attribute the effects to particular ozone exposure levels below 75 ppb, and it thus put less reliance on them. See *id.*

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<sup>19</sup> Even if EPA were correct (which it is not) that Schelegle *et al.* (2009) provided new evidence of adverse health effects at 72 ppb, EPA has not provided a reasoned explanation for selecting a standard of 70 ppb rather than 71 or 72 ppb, thus rendering that judgment arbitrary.



Similarly, EPA acknowledged that the newly available evidence on welfare effects “is largely consistent with the evidence available at the time of the last review” and simply “strengthened” the prior evidence. 80 FR at 65383 (JA 382); see also Statement Section D.2. EPA continued to recognize that the cumulative seasonal metric is appropriate for considering the level of protection and that there is no bright line in selecting a specific level for welfare protection. See *id.* Notably, the key exposure-response information regarding Relative Biomass Loss in tree growth, on which EPA placed primary reliance, came from studies that were considered in 2008,<sup>20</sup> but EPA has now re-interpreted that evidence to support a standard of 70 ppb. 80 FR at 65407, 65409 (JA 406, 408).

Given the absence of any fundamental change in the scientific understanding of ozone effects since the 2008 review, the main change is in the *conclusions* that EPA draws from the evidence – *i.e.*, its conclusions regarding the level of protection that is “requisite” to protect public health and welfare. EPA appears to have determined simply that levels of risk that were judged acceptable in 2008 are no longer acceptable. While EPA’s preamble contains lengthy discussions of the scientific evidence, including the new studies, it does not present a reasoned

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<sup>20</sup> See EPA’s ISA at 9-127 (JA 987), noting that since the completion of detailed analyses that were considered in 2008, “almost no studies have been published that could provide a basis for estimates of exposure-response that can be compared to [the prior estimates].”

explanation or justification for this apparent change in the policy judgment regarding the acceptable level of risk. As shown by the cases cited at the beginning of this section, in the absence of such a reasoned explanation, EPA's revised standard is arbitrary and capricious.

### **CONCLUSION**

For the foregoing reasons, this Court should vacate the revised NAAQS and remand them to EPA for: (a) consideration of their achievability in light of background ozone concentrations and establishment of NAAQS at a level that is achievable given background concentrations; (b) consideration of the adverse economic, social, and energy impacts of the standards; and (c) a reasoned explanation for any change in EPA's conclusions from the scientific effects evidence.

Respectfully submitted,

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Dated: September 26, 2016

## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure and Circuit Rule 32(e)(3), I hereby certify that the foregoing Final Joint Opening Brief of Industry Petitioners contains 9,356 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count (as supplemented by a manual count of the words in Figure 1), and that thus this brief together with the Joint Opening Brief of State Petitioners (which contains 9,639 words) are within the joint word limit of 19,000 words for those briefs together, as set by the Court in its Order dated March 9, 2016.

/s/ James R. Bieke

James R. Bieke

**CERTIFICATE OF SERVICE**

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that on this 26<sup>th</sup> day of September, 2016, I served one copy of the foregoing Final Joint Opening Brief of Industry Petitioners, as well as the Statutory Addendum thereto, on all registered counsel in these consolidated cases through the Court's CM/ECF system.

/s/ James R. Bieke

James R. Bieke