ORAL ARGUMENT NOT YET SCHEDULED

No. 15-1385, consolidated with
Nos. 15-1392, 15-1490, 15-1491, 15-1494

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Murray Energy, *et al.*,
Petitioners,

v.

United States Environmental Protection Agency, and Regina A. McCarthy, Administrator,
Respondents.

On Petition for Review of the Final Rule of the United States Environmental Protection Agency

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AMICI CURIAE BRIEF BY THE AMERICAN THORACIC SOCIETY AND AMERICAN LUNG ASSOCIATION IN SUPPORT OF PETITIONERS SIERRA CLUB, ET AL.

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Dated: April 29, 2016

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT PURSUANT TO FEDERAL RULES OF APPELLATE PROCEDURE 26.1, 29(c) AND D.C. CIRCUIT LOCAL RULE 26.1

Amici curiae are nonprofit organizations. The American Thoracic Society and the American Lung Association do not have parent corporations, and no publicly held corporation owns 10% or more of their stock.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(c)(5)

Pursuant to Federal Rule of Appellate Procedure 29(c)(5), counsel for *amici curiae* hereby states that no counsel for any party to this litigation authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submission of this brief, and no person, other than the *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

CERTIFICATE OF COUNSEL AS TO PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1)(A), counsel certifies as follows: to the best of my knowledge, all parties and *amici*, rulings under review, and related cases are set forth in the Brief for the Public Health and Environmental Petitioners, Dkt. No. 1610087.

The American Lung Association has contacted all parties regarding its intent to participate in this case as *amici*, and filed a motion with the Court for leave to participate in this litigation on April 29, 2016.

Respectfully submitted,

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GLOSSARY

CASAC	Clean Air Scientific Advisory Committee
COPD	Chronic Obstructive Pulmonary Disease
EPA	United States Environmental Protection Agency
ISA	Integrated Science Assessment
NAAQS	National Ambient Air Quality Standards
ppb	Parts per billion
ppm	Parts per million

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

Amici, the American Thoracic Society and the American Lung Association, represent a broad spectrum of public health advocates working to combat the harmful health effects of air pollution. The American Thoracic Society represents over 15,000 members, including medical professionals and scientific experts dedicated to preventing, detecting, treating, and studying respiratory diseases and other human health harms that stem from air pollution. The American Lung Association is the nation's oldest voluntary health organization and the leading public health organization working to save lives by improving lung health and preventing lung disease.

A large body of scientific evidence supports a primary ozone standard lower than 70 ppb (parts per billion). Because of this scientific consensus, the final rule "National Ambient Air Quality Standards for Ozone," 80 Fed. Reg. 65,292 (Oct. 26, 2015) (to be codified at 40 C.F.R. pts. 50, 51, 52, 53, and 58), is not protective enough to satisfy the public health mandate of the Clean Air Act. The collective medical, scientific, and clinical expertise of the *amici* lead them to participate in this action to demonstrate the severity of the health impacts linked to ozone

[1] This Court granted the American Thoracic Society's motion for leave to participate in this action on February 26, 2016. Dkt. No. 1601082. The American Lung Association filed a motion to participate in this action on April 29, 2016.

pollution, articulate the scientific evidence that compels an ozone standard below 70 ppb, and illustrate the Agency's failure to select an adequate standard.

BACKGROUND

On October 26, 2015, Respondent, the United States Environmental Protection Agency (EPA) finalized the rule "National Ambient Air Quality Standards for Ozone," 80 Fed. Reg. 65,292, as part of EPA's ongoing obligation under the Clean Air Act to periodically review and update the National Ambient Air Quality Standards (NAAQS) for harmful criteria pollutants. 42 U.S.C. § 7409. Under sections 108 and 109 of the Act, EPA is required to establish, review, and revise, as appropriate, NAAQS for each of six harmful criteria air pollutants—including ground-level ozone (O_3), the pollutant at issue here. *Id.* §§ 7408, 7409.

The NAAQS program is "the centerpiece" of the Act's "complex statutory regime," and its health-based standards are of paramount importance in achieving the statute's public health goals. *American Trucking Ass'ns v. EPA,* 283 F.3d 355, 358–59 (D.C. Cir. 2002) ("*ATA*"). EPA is compelled to set a primary ozone standard that protects public health with an "adequate margin of safety." 42 U.S.C. §7409(b)(1). The Agency must set a primary standard that offers these same protections to vulnerable subpopulations and indicates the absence of adverse effects in sensitive subgroups. *Lead Indus. Ass'n, v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir 1980); S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970) (indicating

that primary standards should be set at a level "which will protect the health of any [sensitive] group of the population.").

EPA is directed to set air quality criteria that "accurately reflect the latest scientific knowledge," and the Agency is required to revisit this scientific evidence in 5-year intervals. 42 U.S.C. §§ 7408(b); 7409(d)(1). Prior to making any revisions, EPA conducts an Integrated Science Assessment (ISA), which provides the "scientific foundation" of any NAAQS review. In the ISA, the Agency reviews all available scientific evidence of the health effects of a pollutant. *Id*. § 7409(d)(2). In addition to EPA's assessment, an independent scientific review committee, the Clean Air Scientific Advisory Committee (CASAC), reviews the current science and makes recommendations to EPA for appropriate revisions to the ozone standards. *Id.* EPA is required to consider CASAC's recommendations and "must fully explain" any departure from CASAC's advice. *Mississippi v. EPA*, 744 F.3d 1334, 1354 (D.C. Cir. 2013). The Agency must issue a public notice of proposed NAAQS revisions and consider public comments, such as the comments submitted by *amici* along with a broad coalition of public health groups.[2]

[2] American Academy of Pediatrics et al., Comment Letter on proposed Ozone National Ambient Air Quality Standards (Mar. 17, 2015) www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0699-3863.

After conducting this process, EPA revised the level of the primary ozone standard from 75 ppb to 70 ppb.[3] 80 Fed. Reg. at 65,292. Petitioners now seek review of the final rule under 307(b)(1) of the Clean Air Act. 42 U.S.C. § 7607(b)(1).

SUMMARY OF ARGUMENT

Respondent, the United States Environmental Protection Agency (EPA), failed to establish a primary ozone standard protective enough to fulfill the Agency's statutory obligations under the Clean Air Act in light of the well-established science regarding the health effects of ozone pollution. A primary ozone standard with a level of 70 ppb is insufficiently protective of human health and has severe and deadly consequences for the American public, including increases in mortality, asthma exacerbations, and cardiovascular disease. Infants and young children, the elderly, and low-income communities are especially susceptible to harm from ozone pollution and suffer adverse effects at this level.

EPA's ozone standard also fails to address health impacts in other important ways. The degree of protection afforded by the ozone standard relies on several elements selected by the Agency including a level, averaging time, and form. 80 Fed. Reg. at 65,294. Because the Agency selected both an under-protective level

[3] EPA expresses these standards in parts per million (ppm), but this brief describes the level and all other ozone exposure values in parts per billion (ppb). To convert parts ppb to ppm, divide by 1,000. *See e.g.*, Public Health and Environmental Petitioners' brief (Public Health Petitioners' brief), Dkt. No. 1610087, note 4.

and deficient form, its standard cannot meet its obligations under the Clean Air Act. EPA's form allows for averaging of ozone levels across three years. This averaging allows regions that experience large spikes in ozone, and, therefore, acute harms to public health, to ignore days when ozone concentrations are well above levels the Agency acknowledges result in harmful health effects. The failure of the form is coupled with an inappropriate application by the Agency of findings from chamber studies to support its selected level. These flaws in the form and level result in a revised ozone standard that cannot adequately serve the health needs of the American public or meet the Agency's statutory obligations.

ARGUMENT

I. WELL-ESTABLISHED SCIENTIFIC EVIDENCE ESTABLISHES THAT EPA'S SELECTED LEVEL IS INSUFFICIENTLY PROTECTIVE OF HUMAN HEALTH

A deficient primary ozone standard will have severe impacts on air quality and, consequently, human health. The harmful effects of ozone for human health have been known for decades. *See ATA,* 283 F.3d at 358 ("Significant health effects associated with ozone pollution include coughing; throat irritation; aggravation of existing conditions like asthma, bronchitis, heart disease, and emphysema; and lung tissue damage."). Moreover, ozone's impacts on mortality, respiratory and cardiovascular health, development, and, in particular, the outsized burden of these impacts for vulnerable populations, were known to EPA at the time

of its rulemaking. The well-established scientific evidence regarding human health impacts of ozone demonstrates significant adverse health effects at levels above 60 ppb.

A. Ozone Pollution Increases Mortality

Ozone pollution kills. A growing body of scientific evidence demonstrates that a 70 ppb ozone standard is insufficient to protect against increases in morbidity and mortality. Levels of ozone down to 60 ppb are associated with increased cardio-respiratory morbidity and mortality.[4] EPA's own projections indicate that an additional 900 to 1,560 short-term ozone exposure-related premature deaths could be avoided annually by 2025 with the attainment of a 60 ppb ozone standard compared to a 70 ppb standard. U.S. ENVTL. PROT. AGENCY, EPA-452/P-14-006, REGULATORY IMPACT ANALYSIS OF THE PROPOSED REVISION TO THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR GROUND-LEVEL OZONE [hereinafter RIA], Table ES-11, (2014). EPA also estimated that an additional 3,220 long-term ozone exposure-related premature deaths could be avoided annually by 2025 with the attainment of a level of 60 ppb compared to 70

[4] M. Bell et al., *A Meta-Analysis of Time-Series Studies of Ozone and Mortality with Comparison to the National Morbidity, Mortality, and Air Pollution Study*, 16 EPIDEMIOLOGY 436, 442 (2005), ISA, lix; K. Ito et al., *Associations Between Ozone and Daily Mortality: Analysis and Meta-Analysis*, 16 EPIDEMIOLOGY 446, 455 (2005), ISA, 6-222; *see also* R. Smith et al., *Reassessing the Relationship Between Ozone and Short-Term Mortality in US Urban Communities*, 21 INHALATION TOXICOLOGY 37 (2009), ISA, 6-227, 6-238, 6-241, 6-253–55.

ppb. *Id.* Notably, those numbers exclude the entire state of California, which is not expected to meet these standards even by 2025.

The scientific link between ozone pollution and increased mortality has become increasingly strong over the last few years and has been replicated in multiple studies.[5] Even ten years ago, the 2006 ISA concluded that evidence was "highly suggestive" of a link between short-term ozone exposure and increased mortality. The 2013 assessment bolstered this conclusion, finding there is "[l]ikely to be a causal relationship" between increased total mortality and short-term ozone exposure. U.S. ENVTL. PROT. AGENCY, EPA/600/R-10/076F, INTEGRATED SCIENCE ASSESSMENT FOR OZONE & RELATED PHOTOCHEMICAL OXIDANTS, (2013), [hereinafter ISA] 1-5, Table 1-1. The same assessment noted that evidence now also suggests a causal relationship between long-term ozone exposure and increased mortality. ISA, 1-5.

Scientific evidence indicates that increases in mortality are attributable to

[5] R. Peng et al., *Acute Effects of Ambient Ozone on Mortality in Europe and North America: Results from the APHENA Study*, 6 AIR QUALITY, ATMOSPHERE & HEALTH 445, 445–53 (2013); I. Romieu et al., *Multicity Study of Air Pollution and Mortality in Latin America (the ESCALA Study)*. 171 RES. REP. HEALTH EFFECTS INST. 5 (2012); A. Zanobetti & J. Schwartz, *Mortality Displacement in the Association of Ozone with Mortality: An Analysis of 48 Cities in the United States*, 177 AM. J. RESPIRATORY & CRITICAL CARE MED. 184 (2008), ISA, 6-201–24; M. Medina-Ramón & J. Schwartz, *Who is More Vulnerable to Die from Ozone Air Pollution?* 1 EPIDEMIOLOGY 672 (2008), ISA, 6-238, 6-262–63, 8-16–29; A. Zanobetti & J. Schwartz, *Ozone and Survival in Four Cohorts with Potentially Predisposing Diseases*, 184 AM. J. RESPIRATORY & CRITICAL CARE MED. 836 (2011).

ozone exposure at concentrations lower than previously reported, and lower than the new 70 ppb standard. Epidemiologic studies of multiple cities in the United States and Canada demonstrate associations between ambient ozone concentrations and mortality or morbidity in locations that likely met a 60 ppb to 70 ppb ozone level. For example, a 2009 study of twelve Canadian cites demonstrated "positive and statistically significant associations" between increased ozone exposure and higher cardiovascular mortality, with seven cities meeting the 70 ppb standard and five meeting an even lower 65 ppb standard.[6] U.S. ENVTL. PROT. AGENCY, EPA-452/R-14-006, POLICY ASSESSMENT FOR THE REVIEW OF THE OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS, (2014) [hereinafter PA] 4-13, Table 4-1. The results suggest that ozone exposures at a level of 70 ppb and even 65 ppb increase the risk of death from conditions like heart disease. PA, 4-17.

Additional epidemiological evidence bolsters these findings. For example, a long-term exposure study examining the effect of daily maximum ozone concentration on mortality demonstrated a two to four percent increase in the risk of death from respiratory causes with each 10 ppb increase in ozone concentration.[7] This study suggested an adequate safety threshold of ozone exposure was around 56 ppb. Several other studies support the conclusion that

[6] K. Katsouyanni et al., *Air Pollution and Health: A European and North American Approach (APHENA)* 142 RES. REP. HEALTH EFFECTS INST. 5 (2009), ISA, 6-135.
[7] M. Jerrett et al., *Long-Term Ozone Exposure and Mortality*, 360 N. ENG. J. MED. 1085 (2009) ISA, 4-27, 4-46, 4-50, 7-31–39, 7-88–90, 8-25.

ozone increases the risk of premature death, including an analysis of forty-eight cities in the United States,[8] a multicity study in Latin America,[9] and multicity studies in North America and Europe.[10] This body of recent scientific evidence presented to EPA during its ozone review clearly demonstrates the link between increased mortality and ozone concentrations at or below 70 ppb.

B. Ozone Pollution Exacerbates Asthma

Asthma is a chronic lung disease affecting as many as 25.7 million Americans—8.4 percent of the nation.[11] Asthma inflames and narrows the airways of the lungs, making it difficult for an individual to breathe.[12] People with asthma have heightened sensitivity to irritants like ozone, because airway irritation leads to asthma symptoms such as wheezing, chest tightness, shortness of breath, and coughing.[13] An asthma attack can be sudden and is often frightening; recurrent asthma exacerbations frequently require expensive treatment.[14] Left untreated, asthma attacks can lead to permanent airway and lung damage, limiting a person's

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[8] Zanobetti & Schwartz (2008), *supra* note 5.
[9] Romieu et al., *supra* note 5.
[10] Peng et al., *supra* note 5.
[11] L. Akinbami et al., *Trends in Asthma Prevalence, Health Care Use, and Mortality in the United States 2001-2010,* 94 CTRS. FOR DISEASE CONTROL & PREVENTION, NHCS DATA BRIEF 1 (2012).
[12] NAT'L HEART, LUNG, AND BLOOD INST., NAT'L INSTS. OF HEALTH, PUB NO. 09-7429, AT A GLANCE: ASTHMA 1 (2009).
[13] *Id.*
[14] S. Pollart et al., *Management of Acute Asthma Exacerbations*, 84 AM. FAMILY PHYSICIAN 40 (2011).

ability to work and exercise, and reducing overall life expectancy.[15] Asthma attacks can even result in death due to an inability to breathe.

Ozone pollution acts as a respiratory irritant and is particularly harmful to people with lung diseases like asthma and emphysema. Health experts maintain that air pollution is "one of the most under-appreciated contributors to asthma exacerbation."[16] The ISA concluded that "[t]he clearest evidence for health effects associated with exposure to [ozone] is provided by studies of respiratory effects." ISA, 1-6. A large number of studies have similarly found that people with asthma, particularly children with asthma, experience increased respiratory symptoms when exposed to ozone.[17] This has been demonstrated in multiple studies and cities, and at levels below 70 ppb.[18]

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[15] D. McLean et al., *Asthma Among Homeless Children: Undercounting and Undertreating the Underserved*, 158 ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 244, 247 (2004).

[16] G. Thurston & D. Bates, *Air Pollution as an Underappreciated Cause of Asthma Symptoms*, 290 J. AM. MED. ASS'N 1915 (2003).

[17] K. Mortimer et al., *The Effect of Air Pollution on Inner-City Children with Asthma*, 19 EUR. RESPIRATORY J. 699 (2002), ISA, 6-120–21, 6-160; G. O'Connor et al., *Acute Respiratory Health Effects of Air Pollution on Children with Asthma in US Inner Cities*, 121 J. ALLERGY & CLINICAL IMMUNOLOGY 1133 (2008), ISA, 6-43–70.

[18] J. Gleason et al., *Associations Between Ozone, PM2.5, and Four Pollen Types on Emergency Department Pediatric Asthma Events During the Warm Season in New Jersey: A Case-Crossover Study*, 132 ENVTL. RES. 421 (2014); R. Silverman & K. Ito, *Age-Related Association of Fine Particles and Ozone With Severe Acute Asthma in New York City*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY 367 (2010) ISA, 6-132, 6-143, 6-152–163, 7-16, 8-19; J. Glad et al., *The Relationship of Ambient Ozone and PM(2.5) Levels and Asthma Emergency Department Visits:*

C. Ozone Worsens Chronic Obstructive Pulmonary Disease

Studies also link ozone pollution with increased hospitalization among adults suffering from Chronic Obstructive Pulmonary Disease (COPD).[19] COPD is an incurable, progressive, and debilitating disease.[20] The Center for Disease Control reports that 15 million patients in the United States have physician-diagnosed COPD.[21] Studies have found that exposure to ozone increases risk of hospitalization among people with COPD, especially the elderly.[22] For example, a study including 13 years of hospital admission data for 36 cities in the United States found that for every 5 ppb increase in the two-day average ozone level, the number of COPD hospitalizations increased by 0.3%.[23]

D. Ozone Causes Cardiovascular Effects

Possible Influence of Gender and Ethnicity, ARCHIVES OF ENVTL & OCCUPATIONAL HEALTH 103 (2012); J. Halonen, et al., *Ozone and Cause-Specific Cardiorespiratory Morbidity and Mortality*, 64 J. EPIDEMIOLOGY & COMMUNITY HEALTH, 814 (2009), ISA, 8-19–23.

[19] M. Medina-Ramón et al., *The Effect of Ozone and PM10 on Hospital Admissions for Pneumonia and Chronic Obstructive Pulmonary Disease: a National Multi-City Study*, 163 AM. J. OF EPIDEMIOLOGY 579 (2006),.

[20] C. Halldin et al., *Changes in Prevalence of Chronic Obstructive Pulmonary Disease and Asthma in the US Population and Associated Risk Factors*, 12 CHRONIC RESPIRATORY DISEASE, 47, 47–60 (2015).

[21] CTRS. FOR DISEASE CONTROL & PREVENTION, *Chronic Obstructive Pulmonary Disease Among Adults—United States, 2011*, 61 MORBIDITY & MORTALITY WKLY. REP. 938, 938–43 (2012).

[22] Medina-Ramón et al. *supra* note 19; F. Ko & D. Hui, *Air Pollution and Chronic Obstructive Pulmonary Disease*, 17 RESPIROLOGY 395 (2012); Halonen, et al., *supra* note 18.

[23] Medina-Ramón et al. *supra* note 19.

Evidence also links ozone exposure to cardiovascular effects like premature death due to heart disease. A large, multi-continent study demonstrated an increased risk of premature death from cardiovascular disease triggered by ozone pollution.[24] Several other large epidemiologic studies from the United States,[25] Europe,[26] and Asia[27] have provided further evidence of premature death from cardiovascular effects, including two large studies that confirmed this effect after controlling for particulate matter exposure.[28] Previous studies have also shown adverse associations between ozone exposure and various cardiovascular effects, including alterations in heart rate variability in older adults,[29] cardiac arrhythmias,[30] strokes,[31] heart attacks,[32] and hospital admissions for cardiovascular

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[24] Katsouyanni, et al., *supra* note 6.
[25] Zanobetti & Schwartz (2008), *supra* note 5.
[26] E. Samoli et al., *The Temporal Pattern of Mortality Responses to Ambient Ozone in the APHEA Project*, 63 J. EPIDEMIOLOGY & COMMUNITY HEALTH 960 (2009), ISA 6-158, 6-201.
[27] C. Wong et al., *Public Health and Air Pollution in Asia (PAPA): a Combined Analysis of Four Studies of Air Pollution and Mortality, Part 5*, 154 RES. REP. HEALTH EFFECTS INST. 377, 377–418 (2010), ISA, 6-221–23.
[28] Katsouyanni et al., *supra* note 6; M. Stafoggia, *Susceptibility Factors to Ozone-Related Mortality: A Population-Based Case-Crossover Analysis*, 182 AM. J. RESPIRATORY & CRITICAL CARE MED. 376, 376–84(2010), ISA, 6-158, 6-163, 6-201, 6-202, 6-222–38, 6-258–63, 8-22–27.
[29] S. Park et al., *Effects of Air Pollution on Heart Rate Variability: The VA Normative Aging Study*, 113 ENVTL. HEALTH PERSP. 304 (2005), ISA 6-171–73.
[30] D. Rich et al., *Increased Risk of Paroxysmal Atrial Fibrillation Episodes Associated with Acute Increases in Ambient Air Pollution*, 114 ENVTL. HEALTH PERSP. 120 (2006), ISA, 6-168–70.
[31] J. Henrotin et al., *Short-Term Effects Of Ozone Air Pollution On Ischaemic Stroke Occurrence: A Case-Crossover Analysis from a 10-Year Population-Based*

diseases.[33] People with pre-existing chronic diseases, including COPD, appear to be at especially high risk for the cardiovascular effects of ozone exposure.[34] The ISA concluded that "[o]verall, the body of evidence indicates that there is likely to be a causal relationship between short-term exposures to [ozone] and cardiovascular effects, including cardiovascular mortality." ISA, 1-8.

E. Ozone Has Outsized Effects on Vulnerable Populations

Ozone exposure has disproportionate health effects on vulnerable subgroups. Recent studies demonstrate that children, the elderly, and adults with preexisting respiratory disease are especially susceptible to ozone pollution.[35] Low-income urban communities and outdoor seasonal workers also experience increased risk of health effects from exposure to this caustic pollutant. EPA has a statutory duty to set a standard that provides adequate protection for vulnerable subpopulations.

Study in Dijon, France, 64 ENVTL & OCCUPATIONAL HEALTH MED. 4439 (2007), ISA, 8-16–24.

[32] J. Ruidavets et al., *Ozone Air Pollution is Associated with Acute Myocardial Infarction*, 111 CIRCULATION 563 (2005), ISA, 6-172–74.

[33] P. Koken et al., *Temperature, Air Pollution, and Hospitalization for Cardiovascular Diseases Among Elderly People in Denver*, 111 ENVTL. HEALTH PERSP. 1312 (2003).

[34] J. Peel et al. *Ambient Air Pollution and Cardiovascular Emergency Department Visits in Potentially Sensitive Groups*, 165 AM. J. OF EPIDEMIOLOGY 625, 625–33 (2007), ISA, 6-185–91.

[35] S. Sousa et al., *Ozone Exposure and Its Influence on the Worsening of Childhood Asthma*, 64 ALLERGY 1046,1046–55 (2009), ISA, 7-9; P. Villeneuve et al., *Outdoor Air Pollution and Emergency Department Visits for Asthma Among Children and Adults: A Case-Crossover Study in Northern Alberta, Canada,* 6 ENVTL. HEALTH 40 (2007), ISA, 6-148–55, 8-19.

1. Children

Infants and young children are especially susceptible to harm from exposure to ozone pollution.[36] Even before birth, prenatal exposure of the pregnant mother to ozone may harm her baby's fetal lung and central nervous system development, and reduce fetal growth, resulting in lower birthweight.[37] Babies and children also face increased risks from ozone compared to adults, because their lungs are still developing, a process that continues throughout childhood and adolescence.[38] Further, children breathe more air per pound of body weight than adults, which increases the dose of inhaled pollutants.[39] Relative to adults, children spend more time outdoors where they are often more physically active, increasing the volume of polluted air that is inhaled.[40]

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[36] Villeneuve *supra* note 35; S. Lin et al., *Chronic Exposure to Ambient Ozone and Asthma Hospital Admissions Among Children*, 116 ENVTL. HEALTH PERSP. 1725, 1725–30 (2008), ISA, 8-19, 8-29.

[37] M. Salam et al., *Birth Outcomes and Prenatal Exposure to Ozone, Carbon Monoxide, and Particulate Matter: Results from the Children's Health Study*, 113 ENVTL. HEALTH PERSP. 1638 (2005), ISA, 7-45–57, 7-74.

[38] COMM. ON ENVTL. HEALTH, AM. ACAD. OF PEDIATRICS, *Ambient Air Pollution: Health Hazards to Children*, 114 PEDIATRICS 1699, 1699 (2004) (observing that eighty percent of alveolar function develops after the natal period).

[39] *See* Kent E. Pinkerton et al., *Ozone, a Malady for All Ages*, 176 AM J. RESPIRATORY & CRITICAL CARE MED. 107, 107 (2007) (collecting and summarizing studies that illustrate nature of and reasons for ozone's adverse impact on lungs of children).

[40] *Id.*

Acute effects from ozone exposure include difficulty breathing and hospitalization for respiratory illness among infants and toddlers,[41] and increased hospitalizations and medical care for asthma attacks among children.[42] Many studies have demonstrated a relationship between ozone exposure above 60 ppb and childhood asthma and hospital admissions.[43] A 2009 study demonstrated "increased incidence of asthma symptoms in children living where ozone levels were in the range of 50 to 60 ppb compared with those living where ozone levels

[41] E. Triche et al., *Low-Level Ozone Exposure and Respiratory Symptoms in Infants*, 114 ENVTL. HEALTH PERSP. 911, 911–16 (2006), ISA, 6-115–19; L. Darrow et al., *Air Pollution and Acute Respiratory Infections Among Children 0-4 Years of Age: An 18-Year Time-Series Study*, AM. J. OF EPIDEMIOLOGY (2014); R. Burnett et al., *Association Between Ozone and Hospitalization for Acute Respiratory Diseases in Children Less than 2 Years of Age*, 153 AM. J. OF EPIDEMIOLOGY 444, 444–52 (2001).

[42] P. Tolbert et al., *Air Quality and Pediatric Emergency Room Visits for Asthma in Atlanta, Georgia, USA*, 151 AM. J. OF EPIDEMIOLOGY, 789, 798-810 (2000); M. Strickland et al., *Modification of the Effect of Ambient Air Pollution on Pediatric Asthma Emergency Visits: Susceptible Subpopulations,* 25 EPIDEMIOLOGY 843, 843–50 (2014), ISA, 6-149–63; M. Strickland et al., *Short-Term Associations Between Ambient Air Pollutants and Pediatric Asthma Emergency Department Visits*,182 AM. J. RESPIRATORY & CRITICAL CARE MED. 307–16 (2010); Gleason et al., *supra* note 18; Lin et al., *supra* note 36; K. Moore et al., *Ambient Ozone Concentrations Cause Increased Hospitalizations for Asthma in Children: An 18-year Study in Southern California*, 116 ENVTL. HEALTH PERSP. 1063, 1063–70 (2008), ISA, 7-14; S. Yamazaki et al., *Modifying Effect of Age on The Association Between Ambient Ozone and Nighttime Primary Care Visits Due to Asthma Attack* 19 AM. J. OF EPIDEMIOLOGY 143, 143–51 (2009).

[43] Strickland et al. (2010) *supra* note 42; Strickland et al. (2014), *supra* note 42; Gleason et al., *supra* note 18; Silverman & Ito *supra* note 18.

were lower."[44] Another very large study of children under the age of six in New York found that chronic ozone exposure was significantly associated with asthma hospital admissions and that this effect was strongest among very young children.[45] The risk of hospitalization for these children increased twenty-two percent with each 1 ppb increase in average ozone concentration during the summer ozone season, April through October.[46] These effects were observed at average ozone concentrations down to 37.3 ppb in New York City.[47] Another study of children in California demonstrated a nearly twofold increase in the odds of daily or weekly symptoms in children with asthma for each 10 ppb increase in annual average ozone concentration.[48] EPA estimates that 1.57 million missed school days result from ozone pollution could be avoided by 2025 with the attainment of a 60 ppb ozone standard compared with a level of 70 ppb. RIA, Table ES-11.

2. The Elderly

For the elderly and those with heart and lung disease, exposure to high levels

[44] R. Dey et al., *A Second Chance Setting a Protective Ozone Standard* 181 AM. J. RESPIRATORY & CRITICAL CARE MED. 297, 297–99 (2010).
[45] Lin et al., *supra* note 36.
[46] *Id.*
[47] *Id.*
[48] M. Wilhelm et al., *Environmental Public Health Tracking of Childhood Asthma Using California Health Interview Survey, Traffic, and Outdoor Air Pollution Data*, 116 ENVTL. HEALTH PERSP. 1254, 1254–60 (2008).

of ozone increases risk of hospitalization and death.[49] Older adults are more susceptible to the adverse health effects of exposure to air pollution, including ozone, because they have a higher prevalence of pre-existing chronic illness. In particular, these populations experience both heightened rates of heart and lung disease—conditions exacerbated by ozone exposure—and a gradual decline in the functioning of the body's systems that are involved in the body's response to ozone. ISA, 8-21. Even low levels of ozone pollution can increase emergency room visits for respiratory illnesses among older populations.[50] As discussed above, older adults are also most at risk of death from ozone exposure.[51]

3. Low Income Communities

Several large studies have determined that individuals who have low socioeconomic status or who live in communities with low socioeconomic status face higher risk of hospital admissions and emergency department visits associated

[49] Medina-Ramón et al. *supra* note 19; Zanobetti & Schwartz (2008), *supra* note 5; S. Cakmak et al., *Respiratory Health Effects of Air Pollution Gases: Modification by Education and Income*, 61 ARCHIVES OF ENVTL. & OCCUPATIONAL HEALTH 5, 5–10 (2006), ISA, 6-132–54, 6-188, 8-24–27.

[50] R. Delfino et al., *Emergency Room Visits for Respiratory Illnesses Among the Elderly in Montreal: Association with Low Level Ozone Exposure*, 76 ENVTL. RES. 67, 75 (1998).

[51] Medina-Ramón et al. *supra* note 19; A. Zanobetti & J. Schwartz *Air Pollution and Emergency Admissions in Boston, MA*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH 890, 890–95 (2008); S. Cakmak et al., *The Risk of Dying on Days of Higher Air Pollution Among the Socially Disadvantaged Elderly*, 111 ENVTL. RES. 388, 388–93 (2011), ISA, 6-222–38, 6-263, 8-22–27; Medina-Ramón & Schwartz, *supra* note 5.

with ozone pollution.[52] Communities with fewer homes with central air conditioning face greater risk of respiratory hospitalization due to ozone compared to those with more access to air conditioning.[53] People living in communities with high unemployment or other markers of low socioeconomic status are also at greater risk of premature death from ozone pollution compared to people of higher socioeconomic status.[54] Americans experiencing poverty may be more vulnerable to ozone pollution because they are more likely to have chronic diseases such as asthma and heart disease, conditions worsened by ozone.[55] These Americans also have reduced access to medication and medical care that could prevent the worst health consequences of ozone exposure.[56]

F. Ozone Has Adverse Health Effects at Levels Below EPA's New Standard

Even healthy adults experience decreased lung function when exposed to ozone at or below EPA's new 70 ppb level over a single day. Several large epidemiologic studies report respiratory health effects below 70 ppb in the general

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[52] Lin et al., *supra* note 36; Cakmak et al., *supra* note 52; T. Burra et al., *Social Disadvantage, Air Pollution, and Asthma Physician Visits in Toronto, Canada*, 109 ENVTL. RES. 567, 567–74. (2009), ISA, 6-151, 8-27.
[53] Medina-Ramón et al., *supra* note 19.
[54] M. Bell & F. Dominici, *Effect Modification by Community Characteristics on the Short-Term Effects of Ozone Exposure and Mortality in 98 US Communities*, 167 AM. J. OF EPIDEMIOLOGY 986, 986–97 (2008), ISA, 6-238–44, 8-27, 8-29, 8-34; Katsouyanni, et al., *supra* note 6; Smith et al., *supra* note 4.
[55] Lin et al., *supra* note 36.
[56] *Id.*

population. For example, a population-based cohort study of generally healthy adults in the Northeastern United States found that lung function was significantly lower after days when ambient ozone ranged from 59 to 75 ppb compared to days with levels under 59 ppb.[57] In its Policy Assessment, EPA reviewed several epidemiologic studies conducted in cities meeting the proposed 70 ppb standard that concluded that there is a "[p]ositive and statistically significant association" between respiratory hospital admissions or respiratory emergency department visits in cities that would have met 70 ppb and 65 ppb standards. PA, 4-13.

Controlled exposure studies reviewed by the Agency also demonstrate health effects at or below 70 ppb from even short-term exposure to ozone. To evaluate lung function decrements below 80 ppb, the Agency combined many studies measuring symptoms from 6.6-hour exposures to ozone at levels as low as 60 ppb. In compiling this range of data, EPA's Assessment included several studies that demonstrate lung decrements, respiratory symptoms, and airway inflammation in young, healthy adults exposed to concentrations lower than 70 ppb. PA, 3-56, 3-58.

In sum, well-established scientific evidence links respiratory health effects to ozone levels at or below EPA's new ozone standard of 70 ppb. CASAC advised EPA that "[a]t 70 ppb, there is substantial scientific certainty of a variety of

[57] M. Rice et al., *Short-Term Exposure to Air Pollution and Lung Function in the Framingham Heart Study*, 188 AM. J. RESPIRATORY & CRITICAL CARE MED. 1351, 1351–57 (2013).

adverse effects, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation."[58] In addition to this scientific conclusion, CASAC also indicated that a level of 70 ppb may not be protective enough to fulfill EPA's mandate to adequately protect the public health, concluding that a level of "60 ppb would certainly provide more public health protection than a standard of 65 or 70 ppb and would provide an adequate margin of safety."[59] CASAC's advice underlines the unreasonableness of the Agency's conclusion that a 70 ppb level satisfies its mandate to protect public health.

Strong scientific evidence demonstrates that ozone exposures in the range of 60 to 70 ppb have adverse physiologic effects across the entire age spectrum—from infants to older adults. Based on this evidence, a scientific consensus has emerged among medical professional organizations, including the American Thoracic Society, the American Lung Association, American Academy of Pediatrics,[60] and the American Medical Association[61] that a standard of 60 ppb, not 70 ppb, is needed to protect public health with an adequate margin of safety.[62] By

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[58] C. Frey, Letter to Gina McCarthy, re: Clean Air Scientific Advisory Committee Recommendations Concerning the Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, 8 (June 26, 2014).
[59] *Id.*
[60] American Academy of Pediatrics et al., *supra* note 2.
[61] AM. MED. ASSOCIATION, POLICY FINDER, NAAQS STANDARD FOR OZONE D-135.989 (2011).
[62] M. Rice et al., *Scientific Evidence Supports Stronger Limits on Ozone*, 191 AM. J. RESPIRATORY & CRITICAL CARE MED. 501, 503 (2014).

instead selecting a standard of 70 ppb, EPA endangers the health and well-being of countless Americans.

II. EPA'S FORM IS DEFICIENT BECAUSE IT FAILS TO ACCOUNT FOR HIGH OZONE EXPOSURES OUTSIDE OF KNOWN SEASONAL VARIATIONS

EPA's selected ozone level of 70 ppb fails to provide adequate protection against the human health consequences of ozone exposure because it is coupled with a deficient form. The selected form for the new ozone standard is defined as the "fourth-highest daily maximum, averaged across three consecutive years." 80 Fed. Reg. at 65,294. As the Public Health and Environmental Petitioners explain, based on the evidence in the record that EPA agrees with, the form and level allow many areas throughout the country to repeatedly experience harmful ozone levels without ever slipping into nonattainment. Public Health Petitioners' brief at 19–24. For example, the selected form particularly fails to address events that occur outside of the predictable cycles of seasonal ozone variation, such as wintertime ozone formation. Winter ozone episodes result from the combination of locally generated precursor pollution with certain meteorological conditions, such as reflective snow cover and atmospheric conditions that trap pollutants near the surface. ISA, 3-17. The combination of those elements can result in extremely high ozone concentrations (as high as 140 ppb) that acutely harm the population in rural

communities experiencing these events.[63] Although scientific knowledge regarding the occurrence of these events is relatively new, evidence of wintertime ozone formation was before EPA during the ozone review at issue. The Agency failed, however, in its justification of its selected form, to adequately account for these events that do not occur every year and to consider the resulting health impacts on rural populations.

As noted, the degree of protection provided by any ambient air quality standard is a combination of many elements selected by EPA, including a "level," "averaging time," and "form." 80 Fed. Reg. at 65,294. The level, 70 ppb, is the numerical threshold for a given pollutant that air quality control regions are required to attain. Other components of the standard, such as the form and averaging time, direct air quality regulators how to measure their attainment with the standards.

Here, EPA selected an 8-hour averaging time, and a form of the "fourth-highest daily maximum, averaged across three consecutive years." 80 Fed. Reg. at 65,294. Practically, this combination of elements allows attainment with ozone standards to be determined based on a three-stage process. First, an 8-hour average is taken each day and the highest daily 8-hour average is selected. Next, after the

[63] R. Schnell et al., *Rapid Photochemical Production of Ozone at High Concentrations in a Rural Site During Winter* 2 NATURE GEOSCIENCE 120, 120–22 (2009), ISA, 3-17–18.

collection of an entire year's worth of data, the fourth-highest daily maximum is selected from those averaged levels—throwing out the top three most polluted days. Finally, an average is *again* calculated by regulators, blending the yearly fourth-highest daily averages from three consecutive years of data. The resulting average is the value that determines whether an area is in attainment with the NAAQS, in this case 70 ppb.

Averaging extreme concentrations over a three-year period allows regions that experience dangerous spikes in ozone levels in some years, but not others, to remain in attainment with the standard, in disregard of the attendant health consequences. By throwing out the top three polluted days and then averaging levels over three consecutive years, the form ignores events that are extremely harmful for public health, but may not occur regularly enough to be reflected after an averaging across three years. In this way, the form EPA selected amounts to a national standard that leaves health consequences due to wintertime ozone episodes unchecked and local pollution that causes these events unaccounted for.

For example, EPA was presented with data from the rural upper Green River basin area in Wyoming[64] that showed ozone spikes as high as a maximum 1-hour average of 140 ppb and a maximum 8-hour average of 120 ppb. ISA, 3-17.

[64] The air quality control region where the study was undertaken, the upper Green River basin, is currently under a nonattainment designation, but has a recently published design value that is well in attainment—64 ppb.

Exposure to ozone at those levels is extremely dangerous. EPA itself has repeatedly acknowledged the well-established harms to human health occurring after exposure to levels of 80 ppb or higher, including decreased lung function, increased airway inflammation, increased respiratory symptoms, airway hyperresponsiveness, and decreased lung host defenses. *See e.g.,* 80 Fed. Reg. at 65,319. The health harms resulting from ozone levels over 100 ppb and up to 140 ppb are severe. Personal accounts from Pinedale, Wyoming, a town of 8,800 residents within the upper Green River basin area, detail ozone levels so high that, upon initial exposure to the outdoors, residents' eyes and skin burn.[65] At ozone levels up to 120 or 140 ppb, residents are unable to leave their homes.[66] The full extent of these harms may not even be known, because the exposure and risk analyses on which EPA justified its selected standard were unable to model these high ozone events.

The upper Green River basin area, among other areas, is particularly affected by wintertime ozone formation because of its proximity to a natural gas field, a local source of precursor pollutants for ozone formation. Given the rapid expansion

[65] *See e.g*., Kirk Johnson, *In Pinedale, Wyo., Residents Adjust to Air Pollution,* N.Y. TIMES (March 9, 2011) *available at* http://www.nytimes.com/2011/03/10/us/10smog.html

[66] *Id*.

of domestic natural gas drilling in other areas of the country,[67] it is possible that these same ozone events are increasingly being experienced elsewhere. Further, the form unreasonably results in many other regions experiencing several ozone episodes while still remaining in attainment with the new standard. *See* Public Health Petitioners' brief, at 22–23. For all of these reasons, EPA's selected form is deficient. In light of the evidence of these events before the Agency, it was unreasonable for EPA to select a form that cannot adequately account for extreme ozone episodes that do not occur every year and the health impacts of those episodes on communities.

III. EPA FAILED ITS STATUTORY OBLIGATION TO PROTECT HUMAN HEALTH BECAUSE ITS STANDARD DOES NOT ADEQUATELY ADDRESS ADVERSE HEALTH EFFECTS IN VULNERABLE SUBGROUPS

The Agency's rationale for its new standard—based heavily on the results of controlled human exposure studies rather than epidemiology studies—is flawed because it relies on faulty reasoning that does not adequately address adverse health effects in vulnerable populations documented in population-based epidemiological studies. As noted in the final rule, while EPA considered a broad range of scientific information, the Agency ultimately relied primarily on chamber

[67] ERNEST J. MONIZ ET AL., MASS. INST. OF TECH., THE FUTURE OF NATURAL GAS 17 (2011), https://mitei.mit.edu/system/files/NaturalGas_Report.pdf. ("[T]he role of natural gas is likely to continue to expand, and its relative importance is likely to increase even further when greenhouse gas emissions are constrained.")

studies to determine the ozone standard's level. *See* 80 Fed. Reg. at. 65,294. Because chamber studies allow researchers to precisely control ozone exposure levels and to immediately conduct post-exposure lung function tests on participants, they are useful in understanding the health effects of ozone exposures in healthy adults.[68] However, ethical considerations prevent exposure studies from being conducted on individuals from vulnerable subgroups, such as children, the elderly, or patients with serious comorbid conditions.

The Agency acknowledged that controlled studies do not provide needed information on the health effects of ozone exposure in these subgroups. 80 Fed. Reg. 65,331. But even after hearing commenters' concerns that these controlled exposure studies understate actual health effects that sensitive subgroups will experience, EPA relied on them to justify selecting its 70 ppb level. 80 Fed. Reg. 65,331. That level, based almost entirely on chamber studies of healthy adults, does not reflect a reasoned basis by the Agency for concluding that its level is sufficiently protective of vulnerable populations.

The Agency disregarded its obligations to protect vulnerable subgroups because it refused to supplement the information relied upon in controlled exposure studies with data from population-based epidemiological studies. These population-based epidemiological studies demonstrate that adverse health effects

[68] *See* Public Health Petitioners' brief, at 35.

occur in vulnerable populations at levels below 70 ppb. *See* PA, 4-13. While chamber studies provide useful information on the biological plausibility of associations observed in epidemiological studies, ISA, lx, by relying on chamber studies alone, the Agency failed to employ sound reasoning. The Agency's selection of a 70 ppb standard fails to meet its obligations under the Clean Air Act to protect the public health with an adequate margin of safety because a level of 70 ppb does not prevent adverse effects in vulnerable subpopulations.

CONCLUSION

For the foregoing reasons, the *amici* urge this Court to remand the primary ozone standard for reconsideration in light of overwhelming evidence that the revised standard allows ozone exposures at levels beyond what EPA has determined to be safe.

Respectfully submitted,

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Dated: April 29, 2016

CERTIFICATE OF COMPLIANCE

This motion complies with Federal Rules of Appellate Procedure 27(d)(1)&(2) because it meets the prescribed format requirements and contains 6,647 words. This motion also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(5)&(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

Dated: April 29, 2016

/s/ Sarah J. Fox

Sarah J. Fox

CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2016, I filed the foregoing document in person with the Clerk of the Court for the United States Court of Appeals for the District of Columbia. I also electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system for service on all registered counsel in these consolidated cases.

Dated: April 29, 2016 */s/ Sarah J. Fox*

Sarah J. Fox