

**ORAL ARGUMENT NOT YET SCHEDULED**

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

No. 08-1200 (and consolidated cases)

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STATE OF MISSISSIPPI,  
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,  
Respondent.

---

Petition for Review of Final Administrative Action of the  
United States Environmental Protection Agency

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**PROOF BRIEF FOR ENVIRONMENTAL INTERVENORS**

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Environmental Defense Fund, Natural  
Resources Defense Council, and  
Appalachian Mountain Club*

**Dated: July 23, 2012**

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PROTECTION AGENCY,		)	
		)	
Respondent.		)	
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**CERTIFICATE AS TO PARTIES, RULINGS, AND  
RELATED CASES**

Environmental Intervenors American Lung Association,  
Environmental Defense Fund, Natural Resources Defense Council, and  
Appalachian Mountain Club submit this certificate as to parties, rulings, and  
related cases.

**(A) Parties and *Amici***

**(i) Parties, Intervenors, and *Amici* Who Appeared in the District  
Court**

This case is a petition for review of final agency action, not an appeal  
from the ruling of a district court.

**(ii) Parties to This Case****Petitioners**

The Petitioner in case no. 08-1200 is the State of Mississippi.

The Petitioners in case no. 08-1202 are the State of New York, the State of California, the California Air Resources Board, the State of Connecticut, the State of Delaware, the State of Illinois, the State of Maine, the State of Maryland, the Commonwealth of Massachusetts, the State of New Hampshire, the State of New Mexico, the State of Oregon, the State of Rhode Island, the District of Columbia, and the City of New York.

The Petitioners in case no. 08-1203 are the American Lung Association, Environmental Defense Fund, Natural Resources Defense Council, National Parks Conservation Association, and Appalachian Mountain Club.

The Petitioners in case no. 08-1204 are the Ozone NAAQS Litigation Group and the Utility Air Regulatory Group.

The Petitioner in case no. 08-1206 is the National Association of Home Builders.

**Respondent**

The U.S. Environmental Protection Agency is the Respondent in all these consolidated cases.

### **Intervenors**

On the side of petitioners New York et al. in case no. 08-1202 is the County of Nassau.

On the side of EPA in case nos. 08-1200, 08-1204, and 08-1206, American Lung Association, Appalachian Mountain Club, Environmental Defense Fund, and Natural Resources Defense Council.

On the side of EPA in case nos. 08-1202 and 08-1203, Mississippi, the Ozone NAAQS Litigation Group, the Utility Air Regulatory Group, and the National Association of Homebuilders.

#### **(iii) Amici in This Case**

*Amicus Curiae* in support of New York et al. and American Lung Association et al. is the Province of Ontario.

#### **(iv) Circuit Rule 26.1 Disclosures for Petitioners**

See the attached Environmental Intervenors' Rule 26.1 Disclosure Statement.

### **(B) Rulings Under Review**

Petitioners seek review of the final action taken by respondent at 73 Fed. Reg. 16,436 (March 27, 2008), entitled "National Ambient Air Quality Standards for Ozone."

### **(C) Related Cases**

This case has not previously been before this Court or any other court.

Petitioners are unaware of any related cases within the meaning of Circuit

Rule 28(a)(1)(C).

DATED: July 23, 2012

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**ENVIRONMENTAL INTERVENORS’  
RULE 26.1 DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1, Environmental Intervenors make the following disclosures:

**American Lung Association:** American Lung Association has no parent companies, and there are no publicly held companies that have a 10 percent or greater ownership interest in the American Lung Association.

American Lung Association, a corporation organized and existing under the laws of the State of Maine, is a national nonprofit organization dedicated to the preventing lung disease and promoting lung health.

**Environmental Defense Fund:** Environmental Defense Fund has no parent companies, and there are no publicly held companies that have a 10 percent or greater ownership interest in the Environmental Defense Fund.

Environmental Defense Fund, a corporation organized and existing under the laws of the State of New York, is a national nonprofit organization that links science, economics, and law to create innovative, equitable, and cost-effective solutions to the most urgent environmental problems.

**Natural Resources Defense Council:** Natural Resources Defense Council has no parent companies, and there are no publicly held companies that have a 10 percent or greater ownership interest in the Natural Resources Defense Council.

Natural Resources Defense Council, a corporation organized and existing under the laws of the State of New York, is a national nonprofit organization dedicated to improving the quality of the human environment and protecting the nation's endangered natural resources.

**Appalachian Mountain Club:** Appalachian Mountain Club has no parent companies, and there are no publicly held companies that have a 10 percent or greater ownership interest in the Appalachian Mountain Club.

Appalachian Mountain Club, a corporation organized and existing under the laws of the State of Massachusetts, is a national nonprofit

organization dedicated to promoting the protection, enjoyment, and wise use of the mountains, rivers, and trails of the Northeast Outdoors.

DATED: July 23, 2012

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**FEDERAL REGISTER**

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73 Fed. Reg. 16,436 (Mar. 27, 2008)..... 6, 9, 10, 12, 14, 15, 17, 19, 20, 23, 24

## **GLOSSARY OF ACRONYMS AND ABBREVIATIONS**

Pursuant to Circuit Rule 28(a)(3), the following is a glossary of acronyms and abbreviations used in this brief:

ALA Comments	American Lung Association et al. Comments on proposed ozone standards
AMA	American Medical Association et al. Comments on proposed ozone standards
API	American Petroleum Institute
the Act	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CD	EPA Criteria Document, Feb. 2006
Dkt-	Document numbers in EPA docket EPA- HQ-OAR-2005-0172
EPA	U.S. Environmental Protection Agency
EPA Br.	Brief for Respondent
NAAQS or standards	National Ambient Air Quality Standards
Ozone	Ozone and other photochemical pollutants
PM <sub>10</sub>	Coarse particulate matter
ppm	Parts per million
RTC	EPA Responses to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone
SP	EPA Staff Paper, July 2007

UARG

Petitioners Utility Air Regulatory Group  
et al.

UARG Br.

Joint Opening Brief of Petitioner State of  
Mississippi and Industry Petitioners

## STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in an addendum to the Joint Opening Brief of Petitioner State of Mississippi and Industry Petitioners (“UARG Br.”) and the Brief for Respondent (“EPA Br.”).

## SUMMARY OF ARGUMENT

Contrary to claims by Utility Air Regulatory Group et al. (“UARG”), EPA expressly and soundly found that the 1997 primary ozone standard of 0.084 parts per million (“ppm”) was not requisite to protect public health, based on overwhelming evidence that ozone harms people at levels allowed by that standard. So compelling was this evidence that the Clean Air Scientific Advisory Committee (“CASAC”)—the body charged by Congress with advising EPA on setting clean air standards—unanimously found there was “no scientific justification” for retaining the 1997 standard, and recommended *an even stronger* ozone health standard than the one EPA ultimately adopted. UARG completely ignores these pivotal CASAC recommendations and the large collective body of evidence on which they were based—a telling omission, given that the Clean Air Act (“the Act”) requires EPA to justify any departure from CASAC’s advice.

The evidence did not merely replicate information available in 1997, as UARG wrongly claims, but included significant new chamber studies and dozens of new peer-reviewed epidemiological studies showing that ozone is markedly

more dangerous than previously thought. UARG's claim that the harms allowed by the 1997 standard should be deemed "acceptable" is contrary to the Act—which requires health standards to be set at a level where there is an *absence* of adverse effects—and untenable, for the impacts include asthma attacks, forced use of rescue medication, hospitalizations, emergency room visits, and premature deaths. Nor is there any basis for UARG's claim that EPA failed to adequately compare the evidence available in 2008 with that in 1997, as EPA exhaustively did so. Moreover, the Act required EPA to undertake a *new* assessment of all the evidence in 2008, and EPA was free to view the 1997 evidence differently as part of that review.

Finally, UARG's grab-bag attacks on individual pieces of evidence are both groundless and inconsequential.

## ARGUMENT

### **EPA LAWFULLY AND RATIONALLY FOUND THAT THE 1997 PRIMARY OZONE NAAQS WAS LESS PROTECTIVE THAN REQUISITE.**

Primary national ambient air quality standards ("NAAQS" or "standards") must be requisite to protect public health with an adequate margin of safety, without regard to implementation costs. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464-71, 475-76 (2001). These standards must "be set at a level at which there is an absence of adverse effect" on sensitive individuals. *Lead Indus. Ass'n*

v. *EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980) (internal quotation marks omitted). Thus, “[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *American Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also, e.g., Coal. of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010).

Under these governing principles, the compelling evidence before the U.S. Environmental Protection Agency (“EPA”) here not only allowed, but required the agency to revise the ozone NAAQS.

#### **I. The Record Overwhelmingly Supported Strengthening the NAAQS.**

EPA had before it a wealth of evidence that the 1997 standard allowed serious adverse health effects to persist, and a unanimous recommendation from CASAC that the standard needed to be strengthened. UARG offers meritless complaints about a few pieces of EPA’s analysis (further discussed below), but ignores the great body of compelling evidence showing that ozone is dangerous to breathe at levels allowed by the 1997 standard of 0.084 ppm. Collectively, the studies show that ozone levels at and below 0.080 ppm can leave people straining to breathe, send them to emergency rooms and hospitals, and kill them. *E.g.*, EPA-452/R-07-007 (“SP”) 6-7, 6-86 (EPA Staff Paper, July 2007), JA\_\_\_\_, \_\_\_\_; Dkt-

7185<sup>1</sup> (“RTC”) 6-7, JA\_\_\_\_-\_\_\_. Multiple controlled human exposure (“chamber”) studies showed that people exposed to ozone levels at, and below, 0.080 ppm—a level *below* the 1997 standard—suffer breathing harms that are “adverse” to those with asthma and other respiratory diseases. SP 6-58 to -59, JA\_\_\_\_-\_\_\_. More than a dozen peer-reviewed epidemiological studies linked ozone at levels allowed by the 1997 standard with serious health impacts, including emergency room visits, hospitalizations, impaired breathing in infants and adults, increased rescue medication use by asthmatic children, new cases of childhood asthma, and early deaths. *See* Dkt-4261 (“ALA Comments”) 51-79, JA\_\_\_\_-\_\_\_.

Contrary to UARG’s claim (at 28-38), the supporting evidence does not merely replicate studies considered in the prior review, but includes a large number of new studies—including new chamber studies and a large number of new epidemiological studies—that substantially expand on the evidence available during the 1997 review. *See* SP 3-1 to -2, JA\_\_\_\_-\_\_\_. UARG absurdly asserts (at 33-36) that the new epidemiological studies merely reaffirm that there is no threshold for ozone’s health impacts, when in fact many show strong links between various specific ozone levels below 0.080 ppm and harm to people’s health in the real world. *E.g.*, SP 6-12 to -13, JA\_\_\_\_-\_\_\_; SP App. 3B, JA\_\_\_\_-\_\_\_.

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<sup>1</sup> All “Dkt-” references are to document numbers in EPA docket EPA-HQ-OAR-2005-0172 (e.g., “Dkt-0142” means EPA-HQ-OAR-2005-0172-0142).

findings of these studies are not based on extrapolations from assumed dose-response relationships, but on actual measurements of breathing impairments, as well as hospitalizations, emergency room visits, and deaths *at* specific ozone levels below 0.084 ppm. *E.g.*, SP 6-47 to -48, JA\_\_\_\_-\_\_; SP App. 3B, JA\_\_\_\_; Dkt-0142 (“CASAC 10-24-06 Letter”) 3-5, JA\_\_\_\_-\_\_; ALA Comments 46-80, JA\_\_\_\_-\_\_.

As further discussed below, a unanimous CASAC, the nation’s leading medical and health organizations,<sup>2</sup> and more than 100 leading air pollution scientists and physicians all agreed that (a) there was “no scientific support” for retaining the 1997 standard; and (b) there was “overwhelming scientific evidence” for a primary standard **even stronger** than the one EPA adopted. CASAC 10-24-06 Letter 4-5, JA\_\_\_\_-\_\_; Dkt-0102 (“CASAC 3-26-07 Letter”) 2, JA\_\_\_\_; *see, e.g.*, Dkt-4305 (“AMA”) at 1, JA\_\_\_\_; Dkt-4218 at 4 (American Heart Association et al.), JA\_\_\_\_; ALA Comments 27-29, 33-34, JA\_\_\_\_-\_\_, \_\_\_\_-\_\_.

Contrary to UARG’s claim (at 25-28), EPA explicitly found, based on this evidence, that the 1997 standard was not requisite to protect public health: “[T]he

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<sup>2</sup> *E.g.*, the American Medical Association, American Thoracic Society, American Academy of Pediatrics, American College of Chest Physicians, American Association of Cardiovascular and Pulmonary Rehabilitation, National Association for Medical Direction of Respiratory Care, American College of Occupational and Environmental Medicine, American Heart Association, American Lung Association, and American Public Health Association.

Administrator conclude[d] that the [1997] primary [ozone] standard is not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection.” 73 Fed. Reg. 16,436, 16,472/1-2 (Mar. 27, 2008) (emphasis added), JA\_\_\_\_. This conclusion was compelled by the requirement that health-based NAAQS “ensure” the “absence of adverse effect on [] sensitive individuals.” *Lead Indus.*, 647 F.2d at 1153 (internal quotation marks omitted). CASAC found, and EPA agreed, that people suffered “adverse human health effects at the [then-]current” NAAQS level of 0.084 ppm. CASAC 10-24-06 Letter 5, JA\_\_\_\_; 73 Fed. Reg. 16,470/1-71/2, JA\_\_\_\_-\_\_\_\_. Indeed, the adverse impacts on healthy individuals at 0.084 ppm alone required EPA to find the 1997 standard was insufficiently protective of public health.

UARG’s suggestion (at 23-24) that health harms allowed by the 1997 standard might be “acceptable” under some sort of cost-based risk analysis is outlandish and legally irrelevant. The adverse effects at (and below) 0.084 ppm ozone are not marginal or trivial matters, but include asthma attacks, forced use of rescue medication, emergency room visits, hospitalizations, and death.<sup>3</sup> Moreover,

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<sup>3</sup> That some ozone health effects are “transient and reversible,” UARG Br. 26, does not make them any less “adverse.” Non-fatal asthma attacks, for example, are transient and reversible with medication, but are nonetheless adverse to the people  
footnote continued on next page...

these impacts are not limited to just a few people: Hundreds of thousands—particularly children—are endangered in just the few cities analyzed in EPA’s risk assessment. 72 Fed. Reg. 37,818, 37,860 tbl.2 (July 11, 2007), JA\_\_\_\_; SP 5-63 to -79, JA\_\_\_\_-\_\_\_. Nor can EPA engage in some sort of cost-benefit analysis here, as the Act unambiguously bars EPA from considering implementation costs when it sets the NAAQS. *Whitman*, 531 U.S. at 464-71.

UARG (at 24) seeks support from Justice Breyer’s solo concurrence in *Whitman*, but that opinion is merely the view of one justice, not the controlling holding of the Court. Moreover, Justice Breyer “reach[ed] the same ultimate conclusion” as the majority opinion: that the Act “does not delegate to the EPA authority to base [NAAQS], in whole or in part, upon the economic costs of compliance.” 531 U.S. at 496 (Breyer, J., concurring). Whatever flexibility Justice Breyer considered EPA to have to “avoid regulating risks that it reasonably concludes are trivial in context” (a claim UARG does not raise), *id.*, that “context” simply does not include any issue of compliance costs. Nor did Justice Breyer state that EPA must evaluate risk in the context of prior NAAQS decisions, as UARG suggests (at 24). He merely suggested that EPA had discretion to consider

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...footnote continued

suffering them. See SP 3-72 to -73 (identifying “episodic respiratory illness” as an “adverse effect,” and asthma as one of the “more serious” of these), JA\_\_\_\_-\_\_.

“comparative health risks,” which he meant simply as “whether a proposed rule promotes safety overall.” *Whitman*, 531 U.S. at 495.

Equally groundless is UARG’s argument (at 35-36, 44) that alleged uncertainty justifies disregarding the adverse effects allowed by the 1997 standard. EPA expressly found the evidence “*provides a high degree of certainty* about the adverse effects of [ozone] exposure even in healthy people” at 0.080 ppm—a level *below* the 1997 standard. 72 Fed. Reg. 37,879/1 (emphasis added), JA\_\_\_\_. CASAC concurred. CASAC 10-24-06 Letter 5 (“*[T]here is no longer significant scientific uncertainty regarding the CASAC’s conclusion that the current 8-hr primary NAAQS must be lowered*”) (emphasis in original), JA\_\_\_\_. UARG provides no basis for questioning the rationality of that finding. That EPA cited alleged uncertainty as justifying its decision not to set a standard below 0.075 ppm (a decision American Lung Association et al. challenge), *see* UARG Br. 44 (citing 73 Fed. Reg. 16,482/3, 16,483/1), says nothing about the certainty of harms at 0.084 ppm. And even if there were material uncertainty, that would still cut in favor of strengthening the standard given the Act’s precautionary bent. *E.g.*, *Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 378 (D.C. Cir. 2002) (“ATA”) (“EPA must err on the side of caution . . . , taking into account both the available evidence and the inevitable scientific uncertainties.”).

## II. EPA Reasonably Agreed with CASAC's Recommendation That a Stronger Standard Was Needed.

UARG effectively ignores CASAC's unanimous finding that the 1997 NAAQS was weaker than requisite to protect public health and required substantial strengthening. CASAC 10-24-06 Letter 4 (*"it is the unanimous opinion of the CASAC that the current primary ozone NAAQS is not adequate to protect human health."*) (emphasis in original), JA \_\_\_\_\_. Indeed, CASAC found that retention of the 1997 NAAQS *"is not supported by the relevant scientific data."* *Id.* (emphasis in original), JA \_\_\_\_\_. "A large body of data clearly demonstrates adverse human health effects at the current level of the 8-hr primary ozone standard." *Id.* 5, JA \_\_\_\_\_. CASAC cited the new chamber studies, as well as copious epidemiological studies, as "overwhelming scientific evidence" to support CASAC's recommendations on the primary standard. CASAC 3-26-07 Letter 2, JA \_\_\_\_; *see* CASAC 10-24-06 Letter 3-5, JA \_\_\_\_-\_\_\_\_. CASAC thus unanimously recommended *"that the current primary 8-hr standard of 0.08 ppm ... be substantially reduced to be protective of human health, particularly in sensitive subpopulations,"* ultimately recommending that EPA set the standard between 0.060 and 0.070 ppm, below the 0.075 ppm level EPA selected. *Id.* 4-5 (emphasis in original), JA \_\_\_\_\_. EPA staff and the nation's leading medical societies also agreed strongly that the 1997 standard was less protective than requisite and needed to be lowered. *E.g.*, 73 Fed. Reg. 16,443/3-49/2 (discussing staff

recommendations), JA\_\_\_\_-\_\_; *id.* 16,452/3-53/2 (discussing and agreeing with comments from medical, environmental, and public health groups that standard must be lowered), JA\_\_\_\_-\_\_.

The powerful recommendations from CASAC and organizations representing physicians and public health professionals strongly support EPA's decision to revise the NAAQS. Under the Act, CASAC's recommendations merit particular weight. Congress established CASAC to give independent, scientifically grounded recommendations to EPA on NAAQS revisions. 42 U.S.C.

§7409(d)(2)(A)-(B). CASAC's Ozone Review Panel consisted of 23 scientists, representing a broad range of perspectives and disciplines. ALA Comments 16, JA\_\_\_\_. CASAC reviewed the drafts of the Criteria Document and Staff Paper repeatedly and in great detail during the exhaustive NAAQS public review process. *Id.* 16-17, JA\_\_\_\_-\_\_. The Act "require[s] that EPA must either follow CASAC's advice or explain why the proposed rule 'differs . . . from . . . [CASAC's] recommendations.'" *ATA*, 283 F.3d at 378-79 (quoting 42 U.S.C. §7607(d)(3)) (alterations in original). After careful consideration, EPA lawfully and rationally concurred with CASAC's unequivocal recommendation that the 1997 NAAQS needed to be strengthened.

By contrast, UARG ignores CASAC's overall recommendations, and merely cites a few isolated instances in which CASAC (or individual CASAC members)

raised questions about specific evidence or analyses—questions that plainly did not deter CASAC from recommending a stronger standard. UARG has not shown that EPA acted arbitrarily in following CASAC’s advice to strengthen the 1997 NAAQS, and the record overwhelmingly supports that advice. UARG has thus provided no basis for overturning EPA’s decision to strengthen the standard. *See Coal. of Battery Recyclers*, 604 F.3d at 619; *ATA*, 283 F.3d at 378-79 (“Given this record evidence, our deferential standard of review, and the Clean Air Act’s requirement that EPA must either follow CASAC’s advice or explain why [it is not following that advice], Petitioners cannot seriously expect us to second-guess EPA’s conclusion regarding the inadequacy of the old ... standard.”).

### **III. UARG’s Reliance on the 1997 NAAQS Decision Is Misplaced.**

Contrary to UARG’s persistent claims (at 24, 28-29, 38-46), EPA carefully and thoroughly explained why the evidence in 2008 warranted a different decision than in 1997 about whether a 0.084 ppm NAAQS was requisite to protect public health with an adequate margin of safety. *See, e.g.*, EPA Br. 42-45, 55-62; *see also supra* Part I. Indeed, major portions of the Criteria Document, Staff Paper, and proposed and final actions are devoted to exhaustive discussions of why a stronger standard than that adopted in 1997 is warranted based on new evidence, better-developed analyses, and new conclusions reflecting the overall body of evidence. *E.g.*, 1 EPA 600/R-05/004aF (“CD”) 8-10 to -42, 8-55 to -81 (EPA Criteria

Document, Feb. 2006), JA\_\_\_\_-\_\_, \_\_\_\_-\_\_; SP 6-1 to -53, JA\_\_\_\_-\_\_; 72 Fed. Reg. 37,862/1-72/1, JA\_\_\_\_-\_\_; 73 Fed. Reg. 16,443/3-72/2, JA\_\_\_\_-\_\_.

UARG's claims to the contrary simply ignore the record.

In any event, there is no presumption that the 1997 standard is requisite. Rather, EPA must conduct a fresh assessment of the evidence each time it reviews standards: The Act requires EPA to “complete a thorough review” of the criteria and NAAQS at least every five years. 42 U.S.C. §7409(d)(1). It further requires CASAC to conduct a corresponding review and to recommend any new standards and revisions of existing criteria and standards “as may be appropriate.” *Id.* §7409(d)(2)(B). Likewise, based on its review and CASAC's recommendations, EPA “shall make such revisions in such criteria and standards and promulgate such new standards *as may be appropriate* in accordance with” sections 108 and 109(b) of the Act. *Id.* §§7409(d)(1), 7607(d)(3) (emphasis added). EPA thus cannot simply rest upon its prior judgment, but must make a new judgment in this review about what new and revised standards are “appropriate”—a judgment that takes into account new science and carefully reexamines existing evidence.

Nor do the judgments EPA made in the 1997 NAAQS lock it into a particular judgment or approach here. So long as EPA's decision is non-arbitrary, adequately explained, and consistent with the Act, the agency may take a new and different approach to setting the NAAQS, and may reach different conclusions

about prior evidence. *See, e.g., Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1037-38, 1042 (D.C. Cir. 2012) (new administration free to take different regulatory approach based on its re-evaluation of the facts).

UARG also mistakenly suggests (*e.g.*, at 29, 35) that this Court in *ATA* found the 1997 standard to be sufficiently protective of health. 283 F.3d at 378-80. In reality, the Court did not adjudicate a claim that the standard was insufficiently protective, as no party raised such a claim. The Court merely upheld the 0.084 ppm standard against an industry claim that EPA had failed to articulate a reasoned basis for picking that specific number. The Court found that EPA had articulated a plausible basis, and rejected industry's attempt to have the standard vacated. *See id.* at 379-80. Nothing in the opinion suggests that EPA could not or should not have set a more protective standard in 1997. *See Coal. of Battery Recyclers*, 604 F.3d at 619 (“Regardless of whether EPA sufficiently explained its decision not to follow the recommendation of CASAC and others to further reduce [adverse effects], a deficiency there would not lend support to petitioners’ contention that the revised ... NAAQS is overprotective.”).

#### **IV. UARG’s Claims About Individual Pieces of Evidence Are Meritless.**

EPA’s brief refutes UARG’s attacks on individual pieces of the evidence supporting a stronger health standard. Intervenors offer the following supplemental points.

**A. The Adams Studies Provide Strong Support for Revising the NAAQS.**

The Adams chamber studies<sup>4</sup> are the first controlled experiments exposing people to concentrations of ozone below 0.080 ppm.<sup>5</sup> Adams tested exposure to ozone at 0.080 ppm and 0.060 ppm, and found “[ozone]-induced lung function effects and respiratory symptoms in some healthy individuals down to the previously observed exposure level of 0.080 ppm”—*below* the level of the 1997 NAAQS of 0.084 ppm. 73 Fed. Reg. 16,450/1-2 (emphasis added), JA\_\_\_\_.

Adams’ 2006 study further showed that a group of 30 healthy young people exposed to ozone levels of 0.060 ppm—well below the 0.075 ppm level EPA eventually set—suffered “statistically significant group mean” lung function decrements and respiratory symptoms and that some of these healthy young adults suffered lung function decrements of at least 10%. *Id.* 16,444/1, JA\_\_\_\_; Dkt-0175 at 2, JA\_\_\_\_. The 2002 Adams study reported that 20% of 30 healthy young adult subjects also suffered 10% or greater lung function decrements. SP 3-8 to -9, JA\_\_\_\_-\_\_\_\_. EPA recognized that breathing impairments observed in the Adams studies “represent a level that should be considered adverse for asthmatic individuals.” 73 Fed. Reg. 16,454/3-55/1, JA\_\_\_\_-\_\_\_\_.

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<sup>4</sup> Some of these tests were performed using breathing masks rather than sealed chambers. For brevity, they are collectively referred to as “chamber” studies.

<sup>5</sup> The studies were funded by the American Petroleum Institute (“API”), a member of petitioner Ozone NAAQS Litigation Group.

While the professor who ran these chamber studies may disagree with EPA's statistical analysis of the results at 0.060 ppm, UARG Br. 30-32, EPA offered ample rational basis for its analysis. EPA Br. 62-65, 80-84. CASAC members supported the statistical analysis EPA employed as "the preferred method for analyzing the ... lung function responses reported in this study." 73 Fed. Reg. 16,455/1-2, JA\_\_\_\_. Adams' disagreement with EPA's choice of analytical method does not stem from any sort of unique knowledge gained from his involvement in the studies, but merely represents his own views about how to analyze statistics. *See, e.g.*, Dkt-4783 at 4 ("I do not consider [the approach EPA took] preferable to the statistical approach used in my study"), JA\_\_\_\_.

Further, contrary to UARG's claim (at 31-33), the Adams studies indeed represented important new information. Chamber studies provide direct and powerful evidence of the effects of ozone on breathing, because they expose people to specific ozone concentrations under carefully controlled laboratory conditions that exclude other pollutants. CD 8-73, JA\_\_\_\_; AMA 4, JA\_\_\_\_. CASAC called "[i]mportant[]" the 2006 Adams study's finding that some study subjects suffered adverse lung function decrements at 0.06 ppm. CASAC 10-24-06 Letter 3, JA\_\_\_\_. CASAC highlighted the 2006 Adams study's results as "*indicat[ing] that the current ozone standard of 0.08 ppm is not sufficiently health-protective with an adequate margin of safety.*" *Id.* 3-4 (emphasis in original),

JA\_\_\_\_-\_\_\_. EPA staff found that the Adams studies together “strongly suggest that exposure to 0.06 ppm [ozone] causes small group mean [lung function] decrements in healthy adults with some individuals having notable effects.” SP 3-9 (emphasis added), JA\_\_\_\_\_. Leading medical and public health organizations and scientists also found the Adams studies to be “compelling.” AMA 4-6 (“chamber exposure studies have demonstrated health effects in healthy adults at levels at low as 0.060 ppm.”), JA\_\_\_\_-\_\_\_; *see also, e.g.*, Dkt-0101 at 2 (letter from scientists, doctors, and public health professionals), JA\_\_\_\_\_. The evidence the Adams studies provided was thus new and probative.

UARG’s claim that Adams “concluded” his studies “provided *no evidence* of health effects below 0.08 ppm” is false. UARG Br. 30-31 (emphasis in original). In the 2006 study, Adams reported statistically significant results for respiratory symptoms at 0.06 ppm under his own statistical analysis. EPA Br. 19. Similarly, in the 2002 study, Adams reported that group average lung function and respiratory symptoms “were numerically greater after 4 [hours] for the 0.06 ppm exposure than for the [clean air] exposure. Further, 6 of 30 subjects had [lung function] decrements of > 10%.” Adams, *Comparison of Chamber and Face-Mask 6.6-Hour Exposures to Ozone on Pulmonary Function and Symptoms Responses*, 14 *Inhalation Toxicology* 745, 747 (2002), JA\_\_\_\_\_. Thus, Adams plainly found that people suffered health effects at 0.06 ppm.

Finally, UARG falsely implies (at 52) that EPA had only one or two data points on which to base its finding that exposure to 0.060 ppm of ozone causes statistically significant breathing impairment. Not so: the finding of “statistically significant group mean” lung functions decrements and respiratory symptoms was based on responses in the full sample of 30 healthy young adults. *See* 73 Fed. Reg. 16,444/1, JA\_\_\_\_; Dkt-0175 at 2, 6, attach. 1, JA\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_.

**B. UARG’s Disagreements with EPA About Pieces of the Epidemiological Evidence Are Both Meritless and Inconsequential.**

Rather than confronting the large body of epidemiological evidence showing adverse health effects at ozone levels allowed by the 1997 standard (*see supra* Part I), UARG takes groundless potshots at a few pieces of evidence and analysis, often misstating the record. Intervenors supplement EPA’s responses to these attacks as follows.

- Contrary to UARG’s suggestion (at 15), EPA did find that the epidemiological studies, read along with other evidence, showed that ozone caused the adverse health effects shown in those studies. *E.g.*, SP 3-19 (“the overall evidence supports a causal relationship between acute ambient [ozone] exposures and ... [the] increased [emergency department] visits and hospitalizations during the warm season” shown in the epidemiological studies), JA\_\_\_\_; SP 3-73 (finding “likely causal association” between ozone and the premature deaths shown in

epidemiological studies), JA\_\_\_\_; SP 3-50, -57 (finding “consensus” as to how ozone causes the adverse effects shown in epidemiological studies and explaining “biological plausibility” of causal nexus), JA\_\_\_\_, \_\_\_\_\_. That chamber studies provide strong evidence of causation reinforces, rather than undermines, the conclusion that the adverse health effects shown in the epidemiological studies are caused by ozone. *E.g.*, SP 3-86 (time-series studies “showing robust associations [of ozone] with respiratory hospital admissions and [emergency room] visits are strongly supported by human clinical, animal, toxicologic, and epidemiologic evidence”), JA\_\_\_\_. Moreover, epidemiological studies complement chamber studies by providing real-world evidence about the broad range of harms ozone causes, such as asthma exacerbation, hospitalization, and premature death. *See, e.g.*, CD 7-1, JA\_\_\_\_; *see also* CASAC 10-24-06 Letter 4 (recommending EPA put more emphasis on epidemiological studies), JA\_\_\_\_; *ATA*, 283 F.3d at 368-72 (upholding against industry challenge particulate matter standard set without reliance on chamber studies).

- Contrary to UARG’s suggestion (at 15-16), EPA found the evidence linking ozone to premature deaths to be significant, and found it supported revising the standard. RTC 6-7 (citing, as one basis for revising the standard, the “relatively strong evidence for associations between [ozone] and total nonaccidental and cardiopulmonary mortality, even after adjustment for the influence of season and

[particulate matter]”), JA\_\_\_\_-\_\_\_\_; SP 6-86 (citing mortality effects as a reason for strengthening the standard), JA\_\_\_\_.<sup>6</sup> Moreover, far from supporting disregard of the mortality evidence, UARG Br. 15, the finding that such evidence is “highly suggestive” that ozone causes deaths powerfully militates **in favor of** stronger standards, particularly given the Act’s precautionary approach for setting standards.

- UARG misleadingly truncates an EPA statement to say: “[T]he epidemiological association cannot be interpreted with confidence as providing evidence that the observed health effects can be attributed to [ozone] alone.” UARG Br. 15 (brackets supplied by UARG). The full quotation includes an introductory clause stating: “it is reasonable to judge that **at some point** the epidemiological associations cannot be interpreted....” 73 Fed. Reg. 16,461/1 (emphasis added), JA\_\_\_\_. Statements preceding this quotation make clear that EPA found the association at issue (between ozone and premature deaths) **was**

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<sup>6</sup> Likewise, in the proposal notice, EPA explicitly and repeatedly cited the mortality evidence as a basis for finding the 1997 standard deficient, and/or proposing more stringent levels. *See, e.g.*, 72 Fed. Reg. 37,869/3 (citing the mortality evidence as a basis for finding the existing standard inadequate), 37,879/1 (finding that revision of the standard is warranted “based on,” *inter alia*, mortality evidence), JA\_\_\_\_, \_\_\_\_\_. Thus, EPA’s statement in the final rule that it did not “focus” on mortality as a basis for the proposal, 73 Fed. Reg. 16,460/2, JA\_\_\_\_, cannot possibly be read to mean the proposal did not rely on that evidence, as the proposal itself shows otherwise.

“generally supported,” and that EPA was simply noting that uncertainty became a concern at lower levels, “especially **below 0.060 ppm**”—far below the 0.075 ppm level EPA chose for the 2008 NAAQS. *Id.* 16,460/3 (emphasis added), JA\_\_\_\_.

- UARG (at 15) cites two instances where EPA found that additional study was warranted to clarify ozone’s role in certain effects: specifically, school absenteeism and cardiac-related physiological endpoints. That EPA found more study was warranted as to these two effects, however, hardly undermines its findings that other effects, including breathing impairments, increased rescue medication use, emergency room visits, and hospitalizations, are well documented. *See, e.g.*, 73 Fed. Reg. 16,445/2-46/2, 16,455/3-56/1, JA\_\_\_\_-\_\_\_\_, \_\_\_\_-\_\_\_\_.

- Contrary to UARG’s claim (at 59), the 19-city study by Huang et al. found a statistically significant association between ozone and deaths occurring the day after exposure even **after** adjusting for the effects of coarse particulate matter (“PM<sub>10</sub>”). CD 7-104 (“when PM<sub>10</sub> was included in the model, the [ozone] effect estimate, on average, remained positive and significant”), JA\_\_\_\_. EPA noted a lack of statistical significance *only* as to effects occurring the same day as exposure, and even then found the “the lack of significance is likely attributable to higher statistical uncertainty due to the lack of daily PM<sub>10</sub> measurements,” rather than some fundamental doubt about the strength of the association. *Id.* 7-105, JA\_\_\_\_.

- UARG (at 59) claims that in one of the studies showing associations between ozone and breathing impairment, the relationship was not statistically significant after adjustment for other pollutants. As well as disregarding the numerous **other** studies showing statistically significant associations, the assertion is false, for impacts on persons with asthma or severe wheeze symptoms *remained* statistically significant. Korrick, S.A., *et al.*, *Effects of Ozone and Other Pollutants on the Pulmonary Function of Adult Hikers*, 106 *Envtl. Health Persp.* 93, 96-97 (Feb. 1998), JA\_\_\_\_-\_\_\_\_\_.

- UARG mischaracterizes (at 56-57) Sarnat 2001 and 2005's discussion of ambient, as opposed to personal, exposure measurements.<sup>7</sup> Although Sarnat 2001 cautioned against using ambient measurements as representative of "personal exposures without site-specific evidence to support that assumption," Sarnat 2005 *found* "site-specific evidence" in the city studied that indicated ambient measurements correlated to personal ozone exposures. RTC 40, JA\_\_\_\_; CD 3-75, JA\_\_\_\_. Thus, contrary to UARG's suggestion, the Sarnat studies support the conclusion that ambient measurements can serve as surrogates for personal

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<sup>7</sup> "Sarnat 2001" is Sarnat, J., *et al.*, *Gaseous Pollutants in Particulate Matter Epidemiology: Confounders or Surrogates?*, 109 *Envtl. Health Persp.* 1053 (Oct. 2001). "Sarnat 2005" is Sarnat, J., *et al.*, *Ambient Gas Concentrations and Personal Particulate Matter Exposures: Implications for Studying the Health Effects of Particles*, 16 *Epidemiology* 385 (2005).

exposures. Further, the CD made clear that studies “in various cities observed that the daily averaged personal [ozone] exposures from the population were well correlated with monitored ambient [ozone] concentrations.” CD 7-9, JA\_\_\_\_; *see also id.* 7-9 to -10 (explaining utility of studies based on ambient measurements), JA\_\_\_\_-\_\_.

**C. UARG’s Arguments About the 1997 and 2008 Risk Assessments Are Meritless.**

EPA correctly explains (at 66-74) why it was under no obligation to compare the 1997 and 2008 risk assessments and, in any event, could not meaningfully do so, given the substantial differences in how the assessments were designed and conducted. Because the two assessments are simply not rationally comparable, UARG’s attempt (at 41-44) to nonetheless compare their results (by claiming, for example, that risks found in 2008 were “no greater” or “less” than those in 1997) is utterly groundless. Moreover, in focusing on a meaningless comparison between two very different assessments, UARG ignores both the high quality and compelling findings of the 2008 risk assessment. CASAC praised the 2008 assessment’s approach as “well done [and] balanced.” CASAC 10/24/06 Letter 12, JA\_\_\_\_. EPA staff highlighted the many improvements in the risk assessment between 1997 and 2008, explaining that the exposure model (a computer simulation of levels of ozone inhaled by people in a given area) “has

been restructured, improved, and expanded to reflect conceptual advances in the science of exposure modeling and newer input data available for the model.” SP 4-6, JA\_\_\_\_. The model “has a strong scientific foundation,” and is quite accurate. *Id.* 4-13, 4-41, JA\_\_\_\_, \_\_\_\_.<sup>8</sup>

Among other things, the 2008 risk assessment found that, in just the 12 cities studied, at ozone levels meeting the 1997 standard, 610,000 children between the age of 5 and 18 would suffer lung function decrements found adverse by EPA. 72 Fed. Reg. 37,860 tbl.2, JA\_\_\_\_; 73 Fed. Reg. 16,451/2-3, 16,474/3-75/1 (finding that repeated moderate or greater lung function decrements are adverse and that decrement of 15% is moderate), JA\_\_\_\_, \_\_\_\_-\_\_\_. EPA noted that the assessment likely significantly underestimated the number and frequency of health impacts. *Id.* 16,465/2, JA\_\_\_\_. The assessment thus provides strong support for concluding that 1997 standard was not requisite to protect public health. *See American Lung*, 134 F.3d at 392-93 (rejecting EPA decision that would have allowed tens of thousands of asthmatics to suffer adverse health effects from sulfur dioxide

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<sup>8</sup> These improvements provide additional support for EPA’s sound argument (at 67-73) that it reasonably decided not to compare the 1997 and 2008 risk assessments. *See also* SP 4-30 (“there is no population group for which we can make a direct comparison of the exposure estimates for the two reviews.”), JA\_\_\_\_.

pollution where EPA failed to explain why harms did not amount to public health problem).

UARG suggests that a lower EPA estimate of background ozone levels was partially responsible for these risk estimates (because the risk assessment estimated health impacts only from ozone levels above background), but the claim is both irrelevant and meritless for reasons explained by EPA (at 72-73). In reality, EPA's total exclusion of background ozone levels when calculating health impacts led to a substantial understatement of ozone's adverse effects: An exposed person inhales the full dose of ozone in the air, not just the portion in excess of background. The Act requires EPA to gauge impacts of the pollutant, and makes no exception for so-called background levels. 42 U.S.C. §7408(a)(2) (requiring air quality criteria to include "those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant"); *API v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981) (rejecting argument that NAAQS is arbitrary and capricious when "natural factors make attainment impossible," for "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS]").

Finally, there is no basis for UARG's suggestion that adverse health effects allowed by the 1997 standard are presumptively acceptable. To the extent the 1997 risk assessment and other evidence available in 1997 showed that a 0.08 ppm

standard was not in fact requisite to protect public health, the standard was deficient even in 1997. In any event, EPA's job in 2008 was to make a new judgment based on all the evidence then available, and that evidence compelled the conclusion that the 1997 standard needed to be strengthened.

### CONCLUSION

For the foregoing reasons, the UARG et al. petitions for review should be denied. Even if the petitions had merit, the appropriate remedy would be remand without vacatur, as the alleged defect—a purported need for further explanation from EPA—is curable. *See Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 528 (D.C. Cir. 2009) (declining to vacate NAAQS in part because “the EPA’s failure adequately to explain itself is in principle a curable defect”).

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**CERTIFICATE REGARDING WORD LIMITATION**

Counsel hereby certifies that, in accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), the foregoing Proof Brief for Environmental Intervenors contains 5,512 words, as counted by counsel's word processing system.

DATED: July 23, 2012

/s/David S. Baron

David S. Baron

**CERTIFICATE OF SERVICE**

I hereby certify that on this 23<sup>rd</sup> day of July, 2012, I have served the foregoing **Proof Brief for Environmental Intervenors** on all registered counsel through the court's electronic filing system (ECF).

/s/David S. Baron  
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