ORAL ARGUMENT NOT YET SCHEDULED

No. 08-1200 (and Consolidated Cases)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

STATE OF MISSISSIPPI, *ET AL.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

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

JOINT BRIEF OF INDUSTRY INTERVENORS OZONE NAAQS LITIGATION GROUP, UTILITY AIR REGULATORY GROUP, AND NATIONAL ASSOCIATION OF HOME BUILDERS IN SUPPORT OF RESPONDENT

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Dated: July 23, 2012

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Industry Intervenors Ozone NAAQS Litigation Group, the Utility Air Regulatory Group, and the National Association of Home Builders state as follows:

A. Parties, Intervenors, and Amici

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

Petitioners:

Case No. 08-1200: State of Mississippi

Case No. 08-1202: State of New York; State of California, by and through Arnold Schwarzenegger, Governor of the State of California; California Air Resources Board; State of Connecticut; State of Delaware; State of Illinois; State of Maine; State of Maryland; Commonwealth of Massachusetts; State of New Hampshire; State of New Mexico; State of Oregon; State of Rhode Island; District of Columbia; City of New York

Case No. 08-1203: American Lung Association; Environmental Defense Fund; Natural Resources Defense Council; National Parks Conservation Association; Appalachian Mountain Club

Case No. 08-1204: Ozone NAAQS Litigation Group; Utility Air Regulatory Group

Case No. 08-1206: National Association of Home Builders

Respondent

The United States Environmental Protection Agency is the Respondent in all of these consolidated cases.

Intervenors and *Amici*

The County of Nassau is an Intervenor-Petitioner.

American Lung Association, Appalachian Mountain Club, Environmental Defense Fund, National Association of Home Builders, Natural Resources Defense Council, Ozone NAAQS Litigation Group, and Utility Air Regulatory Group are Intervenor-Respondents.

The Province of Ontario is an *amicus curiae* in support of Petitioners State of New York, et al.

B. Rulings Under Review

These consolidated cases involve final agency action of the United States Environmental Protection Agency entitled "National Ambient Air Quality Standards for Ozone," published on March 27, 2008, at 73 Fed. Reg. 16436.

C. Related Cases

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

DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, the following Industry Intervenors provide the following disclosures:

Ozone NAAQS Litigation Group **–** Ozone NAAQS Litigation Group ("ONLG") is a coalition of not-for-profit trade associations whose member companies represent a broad cross-section of American industry. The ONLG's purpose is to advance the interests of the companies represented by its member associations in the regulatory and judicial arenas. The ONLG has no outstanding shares or debt securities in the hands of the public and has no parent company. No publicly held company has a 10% or greater ownership interest in the ONLG.

Utility Air Regulatory Group **–** Utility Air Regulatory Group ("UARG") is a not-for-profit association of individual electric generating companies and national trade associations that participates on behalf of its members collectively in administrative proceedings under the Clean Air Act, and in litigation arising from those proceedings, that affect electric generators. UARG has no outstanding shares or debt securities in the hands of the public and has no parent company. No publicly held company has a 10% or greater ownership interest in UARG.

National Association of Home Builders **–** National Association of Home Builders ("NAHB") is a not-for-profit trade association organized for the purposes of promoting the general commercial, professional, and legislative interests of its

approximately 140,000 builder and associate members throughout the United States. NAHB's membership includes entities that construct and supply single family homes, as well as apartment, condominium, multi-family, commercial and industrial builders, land developers, and remodelers. NAHB does not have any parent companies that have a 10% or greater ownership interest in NAHB, and no publicly held company has a 10% or greater ownership interest in NAHB.

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MISCELLANEOUS

GLOSSARY OF TERMS

Agency	U.S. Environmental Protection Agency
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	U.S. Environmental Protection Agency
FA	Filtered Air
FEV	Forced Expiratory Volume
JA	Joint Appendix
NAAQS	National Ambient Air Quality Standard
ppm	Parts Per Million
PRB	Policy Relevant Background
standard(s)	National Ambient Air Quality Standard(s)

STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the Statutory and Regulatory Addendum to the brief of the United States Environmental Protection Agency ("EPA" or "Agency").

SUMMARY OF ARGUMENT

The Clean Air Act ("CAA") requires the EPA Administrator to set national ambient air quality standards ("NAAQS" or "standards") at the level that is "requisite to protect" public health with an adequate margin of safety and public welfare from known or anticipated adverse effects. CAA § 109(b)(1), (2).[1] The Supreme Court has clarified that "requisite" means "not lower or higher than is necessary." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2001), *on remand*, *Am. Trucking Assn's v. EPA*, 283 F.3d 355 (D.C. Cir. 2002) ("*ATA III*"). Contrary to the assertions of Petitioners American Lung Association, et al. ("Environmental Petitioners") and Petitioners New York, et al. ("New York Petitioners"), EPA did not violate the CAA by not setting the primary NAAQS for ozone at a level between 0.060 parts per million ("ppm") and 0.070 ppm or by not establishing a seasonal secondary NAAQS. Indeed, setting the NAAQS that

[1] All citations are to the CAA; the Table of Authorities provides parallel citations to the U.S. Code.

Environmental and New York Petitioners endorse would have violated the CAA because the standards would not have been at the requisite levels.

The evidence before EPA does not support setting the primary NAAQS at a level between 0.060 ppm and 0.070 ppm. The only clinical study that examined health effects from ozone exposure at concentrations that low did not find any statistically significant evidence of impaired pulmonary function at concentrations below 0.080 ppm, and EPA properly placed little weight on this study. With regard to the epidemiological evidence before the Agency, numerous studies showed no statistically significant results at 0.08 ppm (the level at which EPA set the ozone NAAQS in 1997, upheld by this Court in *ATA III*), and EPA correctly determined the epidemiological evidence did not justify the more stringent NAAQS that Environmental and New York Petitioners seek.

Moreover, EPA's exposure and risk assessments do not justify a more stringent primary standard. Exposure estimates are less valuable in determining the requisite level for a NAAQS than risk estimates. And with regard to EPA's risk estimates, EPA's risk assessment contained numerous conservative assumptions that inflated the risk estimates, and EPA properly discounted the evidence at lower benchmark levels of concern.

EPA need not explicitly quantify the margin of safety, and Environmental and New York Petitioners' arguments that EPA failed to provide a reasonable

explanation regarding the margin of safety have no merit. EPA is also not required to follow every recommendation of the Clean Air Scientific Advisory Committee ("CASAC") in promulgating a NAAQS but need only provide a reasoned explanation for any such departure, which EPA did here.

With regard to the secondary NAAQS, it was not arbitrary and capricious for EPA to decline to set a secondary NAAQS in the form of a cumulative seasonal standard. EPA explained such a standard would be more stringent than necessary to provide the requisite degree of protection to welfare.

PRELIMINARY STATEMENT

Industry Intervenors are also petitioners in these consolidated cases and challenge EPA's 2008 revision to the ozone NAAQS.[2] Industry Intervenors argue the ozone NAAQS of 0.08 ppm – promulgated by EPA in 1997 and found requisite to protect public health and welfare by this Court in *ATA III*, 283 F.3d 355 (D.C. Cir. 2002) – remain at the requisite level. Industry Intervenors further argue that EPA's decision to revise the ozone NAAQS to the more stringent 0.075 ppm level was impermissibly flawed.

[2] The Ozone NAAQS Litigation Group and Utility Air Regulatory Group (petitioners in No. 08-1204) and the National Association of Home Builders (petitioner in No. 08-1206) filed their joint opening petitioners' brief, together with the State of Mississippi (petitioner in No. 08-1200) on April 17, 2012. Mississippi is not an intervenor-respondent in these consolidated cases.

Given this, Industry Intervenors disagree with Environmental and New York Petitioners that the 0.075 ppm NAAQS established by EPA in 2008, which are the subject of these consolidated cases, are not stringent *enough*. As Industry Intervenors explained when they moved for leave to intervene, Environmental and New York Petitioners' attempt to force even more restrictive standards through litigation clearly implicates their interests.[3] Industry Intervenors' arguments herein explain why Environmental and New York Petitioners' claims that EPA erred in not setting more stringent ozone standards have no merit; nothing herein should be construed as an endorsement of the Agency's revised 0.075 ppm NAAQS.

ARGUMENT

The Supreme Court has held that EPA must set primary NAAQS at the level that is "requisite," meaning the level that is "sufficient, but not more than necessary" to protect public health with an adequate margin of safety. *Whitman*, 531 U.S. at 473. This standard "does not compel the elimination of *all* risk; and it grants the Administrator sufficient flexibility to avoid setting . . . [NAAQS] ruinous to industry." *Id.* at 494 (Breyer, J., concurring) (emphasis in original). EPA neither has unfettered discretion to revise or establish NAAQS, nor is the Agency required to impose a standard that is "free of all risk." *Id.* Similar

[3] *See, e.g.*, Motion of the Ozone NAAQS Litigation Group and the Utility Air Regulatory Group for Leave to Intervene as Respondents (June 26, 2008) at 8.

principles apply to secondary NAAQS. Applying these principles here, it is clear that the arguments advanced by Environmental and New York Petitioners as to why EPA erred in not setting more stringent ozone NAAQS must fail.

I. Environmental and New York Petitioners' Arguments Regarding the Primary Standard Are Without Merit.

A. The Adams Studies Do Not Support Revising the Standard to a Level Between 0.060 ppm and 0.070 ppm.

Environmental and New York Petitioners take issue with EPA's treatment of the results from the clinical studies undertaken by Dr. Adams. Environmental Petitioners contend those studies "showed breathing impairment in healthy young adults exposed to 0.060 ppm ozone, with the degree of impairment sometimes reaching a level considered adverse to asthmatics and other sensitive populations." Envtl. Br. at 17; *see also* New York Br. at 19. Environmental Petitioners complain that although "EPA did not dispute the accuracy or validity of the Adams studies," the Agency "refused to base the standard on them, asserting in conclusory fashion they were 'very limited' evidence." Envtl. Br. at 18, 19 (quoting 73 Fed. Reg. 16436, 16476/1-2 (Mar. 27, 2008)). Environmental Petitioners argue "[s]uch a threadbare assertion is simply not a rational basis for dismissing evidence of this magnitude." *Id.* at 19.

First, Environmental Petitioners mischaracterize the findings of the Adams studies. Dr. Adams concluded that his studies provided *no evidence of impaired*

pulmonary function from ozone exposure to levels below 0.08 ppm. W.C. Adams, *Comparison of Chamber 6.6-h Exposures to 0.04-0.08 PPM Ozone via Square-wave and Triangular Profiles on Pulmonary Responses*, 18 INHALATION TOXICOLOGY 127, 130 (2006) (noting "[p]ostexposure percent change in [forced expiratory volume ("FEV")] for the [filtered air ("FA")] protocol … was not significantly different from those for the two 0.06 ppm exposures") ("Adams (2006)"), JA__; W.C. 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) (finding "no statistically significant differences in pulmonary function or symptoms responses from those observed for the FA exposure were observed" at 0.06 ppm), JA__; W.C. Adams, Comment on EPA Memorandum: The Effects of Ozone on Lung Function at 0.06 PPM in Healthy Adults at 4 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4783 (the FEV_1 measurements[4] "do[] not demonstrate a significant mean effect by ordinarily acceptable statistical analysis" from exposure to ozone levels below 0.08 ppm) ("Adams Comments"), JA__.[5] It is therefore unsurprising that, as EPA now

[4] FEV_1 is a common lung function measurement reflecting reductions in the volume of air that a subject can exhale in one second.

[5] In one of the two exposure regimens in Adams (2006) that examined prolonged exposure to 0.06 ppm ozone, Dr. Adams did report a statistically significant increase in the group mean total symptom severity score after 4.6 hours.

(Continued . . . .)

points out, the Agency "g[ave] 'very limited' weight to the Adams studies," and that the "heavy weight assigned" to this clinical evidence by Environmental and New York Petitioners was not warranted. EPA Br. at 92, 93 (citing *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998)).

Even without mentioning Dr. Adams' conclusions, EPA notes that there were "several sources of possible uncertainty regarding the Adams studies," including the fact that the 2002 and 2006 studies "involved only 30 subjects each." *Id.* at 93. Moreover, EPA's own "subsequent reanalysis" of Dr. Adams' data, as set forth in the Brown Memorandum,[6] found "statistically significant results" only for the data from one of the two studies. *Id.* And even for the one study for which EPA's reanalysis of the data purported to find statistically significant results, those results were not replicated, "leaving EPA with only one study of 30 subjects on which to base its conclusions regarding the impacts of exposures at 0.060 ppm on the population generally." *Id.*

Importantly, however, at that time during the exposure regime, the ozone concentration was 0.15 ppm – almost twice the 0.08 ppm limit of the 1997 NAAQS. Adams (2006) at 131, 133, JA__, __.

[6] Memorandum from James S. Brown, EPA, Memorandum to the Ozone NAAQS Review Docket (June 14, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-0175 ("Brown Memorandum"), JA__. The analyses in this unpublished memorandum may be what Environmental Petitioners rely on to argue that the Adams studies should be given greater weight. Those analyses should be given even less weight

(Continued . . . .)

Further undercutting the claims of Environmental and New York Petitioners that the Adams studies justify setting a more stringent standard is that the one group mean response at 0.060 ppm that was reported as statistically significant in the Brown Memorandum was too small to be considered adverse. A NAAQS need not protect against all responses that may be reported in humans exposed to a pollutant but only those effects that are "adverse" to public health. *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1156 n.51 (D.C. Cir. 1980). When effects are uncertain or of questionable health significance, it is incumbent on EPA to make a judgment concerning their adversity.

The only statistically significant finding reported in the Brown Memorandum associated with exposure to 0.06 ppm ozone was a decrease in the group mean FEV_1 measurements of -2.82 percent. Adams Comments at 2, JA__. This is well below the level of FEV_1 decrease that both the EPA Staff and CASAC have indicated should be considered adverse for healthy individuals, or even for particularly sensitive individuals (such as asthmatics or others with lung disease). EPA, EPA-452/R-07-007, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: POLICY ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION at 3-76 (July 2007) ("2007 Staff Paper"), JA__. Accordingly, the

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than those by Dr. Adams himself, as the Adams studies were peer-reviewed and published and the Brown Memorandum was not.

Adams studies – and the Brown Memorandum – provide no support for the more stringent NAAQS that Environmental and New York Petitioners would have had EPA adopt.

Environmental Petitioners note that two of the thirty subjects in the Adams studies "experienced lung function decrements greater than 10%" after exposure to 0.060 ppm. Envtl. Br. at 20. It is not surprising that some individual responses were larger than the group mean response; that is the nature of a mean. For EPA to have drawn conclusions for an entire population based on the responses of those two individuals, however, and for the Agency to have based a more stringent standard on such conclusions, would have been unwarranted. *See* 73 Fed. Reg. at 16478/3 ("EPA disagrees … that the percent of subjects that experienced FEV_1 decrements greater than 10% in this study of 30 subjects can appropriately be generalized to the U.S. population.").

First, although NAAQS must protect sensitive subpopulations, they need not be set based on the most responsive individual in that subpopulation. *See*, *e.g.*, 44 Fed. Reg. 8202, 8210/1 (Feb. 8, 1979) (NAAQS should be set at the level designed to protect the health of a "representative sample of persons comprising the sensitive group rather than a single person in such a group."), JA__. Indeed, one member of CASAC described focusing on the most responsive individuals in the Adams studies as a "dangerous precedent." *See* Allen S. Lefohn, Ph.D., A.S.L. &

Associates, EPA's Proposed Rulemaking for the Primary Ozone Standard: The Evidence for Nonlinearity in Human Health Effects and Its Effects on EPA's Human Health Risk Estimates; Volume 3 at 10-11 (Oct. 8, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4184 (citing Letter from Dr. Rogene Henderson, Chair, CASAC, to the Hon. Stephen Johnson, Adm'r, EPA, at C-31 (Mar. 26, 2007), EPA-CASAC-07-002 (statement of Dr. Vedal)) ("Lefohn"), JA__-__. This is consistent with the general scientific approach of studying groups of people and drawing conclusions about the mean response of the group. By doing so, scientists avoid basing conclusions on a result that may be an outlier or not reproducible. The Adams studies were not designed to look at individual responses,[7] making it highly questionable for EPA to have done so.

Second, FEV_1 measurements are inherently highly variable. Generally, exercise alone leads to a decrease in FEV_1. In Adams (2006), the FEV_1 for one subject in the study actually increased (i.e., improved) when he exercised in clean air (0.0 ppm ozone) compared to his baseline measurement, which was taken in clean air while resting. The apparently large decrease in FEV_1 for this subject at 0.06 ppm – one of the largest in Adams' studies – was attributable primarily to the

[7] Adams reported all of his results in terms of group means. *See* Adams (2006) at 131-34, JA__-__.

uncharacteristic improvement in FEV_1 during exercise in clean air. Lefohn at 9, JA__.

In short, none of the human clinical evidence on which Environmental and New York Petitioners rely to argue that EPA should have established a standard within a range as low as 0.060 to 0.070 ppm support their claim. Far from lacking a "rational basis," Envtl. Br. at 21, EPA's rejection of this more stringent standard was consistent with the evidence in the record.

B. The Epidemiological Studies on Which Petitioners Rely Do Not Support Setting a Standard Between 0.060 ppm and 0.070 ppm.

Pointing to epidemiological studies that, according to Environmental Petitioners, "showed significant adverse effects due to ozone," including a "number showing adverse effects between 0.060 and 0.070 ppm," Environmental Petitioners contend that EPA had "no rational basis for dismissing the results" of what they characterize as a "mountain of … evidence." Envtl. Br. at 22, 24, 25; *see also* New York Br. at 17-18. Environmental Petitioners argue that "EPA's effective disregard of the epidemiological studies at lower ozone levels was not supported by any evidence that the epidemiological studies themselves were any less compelling or reliable at lower ozone levels." Envtl. Br. at 25.

EPA correctly rejected claims that the epidemiological studies supported setting a standard below 0.075 ppm. 73 Fed. Reg. at 16456/1, JA__. Contrary to the arguments of the Environmental and New York Petitioners, the record here

confirms that the epidemiological data provide a poor basis on which to predicate a more stringent standard. For example, although Environmental Petitioners selectively identify a dozen epidemiological studies that they characterize as "show[ing] significant adverse effects … at 8-hour ozone levels extending well below 0.075 ppm," Envtl. Br. at 22, they fail to acknowledge that EPA had before it many other studies that showed no statistically significant results at even the then-current 0.08 ppm standard.[8] Indeed, the results of some of the studies that Environmental Petitioners tout were not statistically significant.[9] In light of this, EPA correctly judged that, at a minimum, the epidemiological evidence did not justify the more stringent standard that Environmental and New York Petitioners seek.

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[8] *See* 2007 Staff Paper, Appendix 3B, Ozone Epidemiological Study Results, JA__-__. For example, the following studies listed in that Appendix are among those that showed no statistically significant results at or above the 0.08 ppm level: Ostro et al. (2001) (respiratory symptoms); Neas et al. (1995) (respiratory symptoms); Wilson et al. (2005) (emergency department visits for respiratory disease); Stieb et al. (1996) (emergency department visits for respiratory disease); Linn et al. (2000) (hospital admissions for cardiovascular disease); Fung et al. (2003) (hospital admissions for cardiovascular disease); Ito (2003) (hospital admissions for respiratory and cardiovascular disease); Luginaah et al. (2003) (hospital admissions for respiratory disease); Thurston et al. (1992) (hospital admissions for respiratory disease).

[9] 2007 Staff Paper, Appendix 3B, Ozone Epidemiological Study Results, JA__-__. For example, the following studies relied on by Environmental Petitioners (*see* Envtl. Br. at 23) are not statistically significant or have mixed results: Delfino et al. (2003); Ross et al. (2002).

Moreover, the nature of most of the epidemiological studies precluded using these studies as the basis for a more stringent standard. Most of these studies are time-series analyses and, as CASAC explained, issues exist as to "the *utility* of these time-series studies in the NAAQS-setting process." Letter from Dr. Rogene Henderson, Chair, CASAC, to the Hon. Stephen L. Johnson, Adm'r, EPA at 3 (June 5, 2006), EPA-CASAC-06-007 (emphasis in original) ("Henderson"), JA__. Other scientists, too, dispute the usefulness of such studies, explaining that "ozone epidemiology provides only modest support at best for any standard setting." *See, e.g.*, Suresh Moolgavkar, M.D., Ph.D., Exponent, Inc., A Critical Review of the Staff Paper on Ozone at 2 (June 25, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-0493 ("Moolgavkar"), JA__.

One crucial limitation of the time-series epidemiological studies is those studies' failure to control for factors that confound the purported association between ozone and health effects. CASAC has acknowledged this problem, pointing out that "[n]ot only is the interpretation of these associations [between ozone concentrations and health endpoints] complicated by the fact that the day-to-day variation in concentrations of these pollutants is, to a varying degree, determined largely by meteorology," but the pollutants themselves are "often part of a large and highly-correlated mix of pollutants, only a very few of which are measured." Henderson at 3, JA__.

As CASAC explained, because the CAA "requires that NAAQS be set for individual criteria air pollutants using the best available science," and because "results of time-series studies implicate *all* of the criteria pollutants," the "findings of mortality time-series studies do not seem to allow us to confidently attribute observed effects specifically to individual pollutants." *Id.* (emphasis added). Although CASAC was referring here specifically to time-series studies of short-term mortality, its concerns are equally applicable to time-series morbidity studies, such as those of emergency room visits and hospital admissions, and to panel studies. *See* Moolgavkar at 3, 16, JA__, __. These considerations underscore that EPA did not err when it declined to establish a more stringent ozone standard based on the epidemiological studies on which Environmental and New York Petitioners rely.

C. Environmental Petitioners' Reliance on the Exposure and Risk Assessments Is Misplaced.

Environmental Petitioners take issue with what they characterize as EPA's having "arbitrarily refused to rely on results of its exposure and risk assessments," results that Environmental Petitioners claim demonstrate that "tens of thousands more children would suffer adverse health effects under a 0.075 ppm standard than at 0.070 ppm and 0.064 ppm." Envtl. Br. at 27. Environmental Petitioners disagree with EPA's determination that its risk assessment did not justify a more stringent standard, based on the Agency's understanding that the "causal

connection between ozone and adverse effects became more uncertain at lower ozone levels." *Id.* at 27-28.

Environmental Petitioners' reliance on the exposure and risk assessments as justification for a more stringent standard is misplaced. With regard to the exposure assessment, not everyone exposed to a given ozone concentration responds to – or experiences an adverse effect from – a given exposure level. As a result, estimates of exposure are far less valuable in determining whether a given NAAQS is "requisite" as compared to estimates of risk. *See* Comments of the Utility Air Regulatory Group on National Ambient Air Quality Standards for Ozone: Proposed Rule at 23 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4183, JA__.

With regard to the risk estimates, EPA has made numerous conservative assumptions that inflated the risk estimates. For example, EPA's risk assessment assumes a linear concentration-response relationship. *See* Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone; Report of a Working Conference held in Rochester, NY, June 5-6, 2007, at 64 (2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4727 ("EPA assumes that the change in population risk per unit change in ambient concentrations will be the same at much lower concentrations as it was for the particular levels of pollution that were present at the time the study was conducted."), JA __. There is, however, ample evidence in

both the epidemiological literature, *see* EPA, EPA 600/R-05/004aF, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS, Vol. I of III, 7-157 (Feb. 2006), JA__; Lefohn at 22-27, JA__, and the human clinical literature, *see* Lefohn at 29, JA__, that the relationship between ozone levels and health endpoints is nonlinear. The assumption of linearity in EPA's risk assessment is therefore conservative and the resulting risk estimates will be overstated.

Further conservatism in EPA's risk assessment results from the Agency's use of unrealistically low estimates of background ozone levels. The unrealistic background levels assumed in EPA's risk assessment has, in turn, produced unrealistically high estimates of health effects attributable to ozone above the true background level.

When estimating the potential health risks and benefits associated with alternative NAAQS, EPA reasonably considers only health effects that it associates with ozone above an estimated policy relevant background ("PRB") level.[10] *See* 2007 Staff Paper at 5-6, JA__. Based on results produced by modeling, EPA estimated this level to be in the range of 0.015 ppm to 0.035 ppm. *Id.* at 2-55,

[10] EPA defines PRB as the "distribution of [ozone] concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of precursor emissions (e.g., VOC [volatile organic compounds], NOx [nitrogen oxides], and CO [carbon monoxide]) in the U.S., Canada, and Mexico." 2007 Staff Paper at 2-48, JA__.

JA__. This model-derived estimate is far lower than levels observed at remote monitoring sites, including those that receive air coming off of the ocean for prolonged periods of time. Comments by the American Petroleum Institute on National Ambient Air Quality Standards for Ozone: Proposed Rule at 24-25 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4141, JA__-__. These monitoring sites experience higher background ozone concentrations than even the 0.04 ppm background ozone estimate that EPA used for its risk assessment in the previous review of the ozone NAAQS. 2007 Staff Paper at 2-55, JA__.

Finally, EPA acknowledged that "uncertainties concerning appropriate model selection are an important source of uncertainty affecting the specific risk estimates" in the Agency's risk assessment. 73 Fed. Reg. at 16459/3, JA__. The manner in which these uncertainties are treated in the risk assessment further ensures conservatism of the risk estimates. For example, the part of the risk assessment that relied on epidemiological studies based estimates of effects on studies that reported no statistically significant association of that effect with ozone. EPA, EPA 452/R-07-009, OZONE HEALTH RISK ASSESSMENT FOR SELECTED URBAN AREAS at 4-8 (July 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-6794, JA__. Moreover, it simply assumed causality. *Id.* at 4-27, 4-29, JA__, __. Similarly, for that portion of the risk assessment that relied on clinical studies, the risk assessment "estimate[d] responses at [ozone] levels below the lowest

exposure levels used in the controlled human studies," *id.* at 3-16, JA__, assuming a causal relationship at and below 0.04 ppm, even when the only studies to examine that level did not find a statistically significant association, *see supra* at 5-11 (discussion of Adams (2006)).

Because these conservative assumptions inflated EPA's risk estimates, EPA properly discounted the evidence at lower benchmark levels of concern. *See* EPA Br. at 103-04; *see also ATA III*, 283 F.3d at 373 (upholding EPA's judgment in the 1997 particulate matter NAAQS rulemaking that at lower exposure levels risks become increasingly uncertain).

Most fundamentally, the risk estimates that Environmental Petitioners point to are just that – estimates of risk, not evidence of adverse effects. Because section 109 of the CAA does not require "zero risk" standards, but only standards that reduce risk to a level that is "safe[]," *see Whitman*, 531 U.S. at 494 (Breyer, J., concurring) (The "requisite" standard of section 109 of the CAA "does not compel the elimination of *all* risk…") (emphasis in original), NAAQS necessarily reflect an EPA judgment as to an acceptable level of public health risk, *see, e.g.*, *NRDC v. EPA*, 824 F.2d 1146, 1165 (D.C. Cir. 1987) (en banc). As explained in the opening brief of Mississippi and Industry Petitioners, Miss. Br. at 38-46, under EPA's current risk assessment, the levels of risk associated with even a 0.08 ppm

standard are consistent with the risks EPA found earlier (and this Court agreed) would protect public health with an adequate margin of safety.

D. Setting a Standard Between 0.060 ppm and 0.070 ppm Was Not Necessary To Provide an Adequate Margin of Safety.

Environmental Petitioners separately contend that, "[e]ven assuming *arguendo* that there were material uncertainties in the scientific evidence of adverse effects of ozone levels below 0.075 ppm, EPA illegally and arbitrarily resolved them in favor of a less protective standard," and thus "fail[ed] to provide 'an adequate margin of safety.'" Envtl. Br. at 33 (quoting 42 U.S.C. § 7409(b)(1)); *see also* New York Br. at 20 (EPA "failed reasonably to explain how the primary standard protects at-risk groups with an adequate margin of safety."). Both Environmental and New York Petitioners argue that the 2007 Staff Paper did not address the issue of a margin of safety at all, Envtl. Br. at 33; New York Br. at 21, and that, in the final rule, EPA provided only a "bare assertion" that the 0.075 ppm standard would provide an "adequate margin of safety," Envtl. Br. at 34; New York Br. at 21.

The 2007 Staff Paper, of course, is not EPA's final word on whether and how the standard satisfies the statutory requirements for a primary NAAQS. Indeed, the preamble discussions accompanying both the proposed standard and the final rule contained discussion of the "margin of safety." *See, e.g.*, 73 Fed. Reg. at 16475/3, 16477/1-2, 16483/1-2, JA__, __, __; 72 Fed. Reg. 37818,

37869/3, 37878/2, 37879/1-3, 37880/1-2 (July 11, 2007), JA__, __, __, __, __. Although EPA may not have explicitly *quantified* the "margin of safety" in those discussions, it has long been settled that this is not required. *See*, *e.g.*, *Lead Industries*, 647 F.2d at 1161-62. As EPA otherwise explains here, the Agency was under "no obligation to follow some particular script or adopt any specific method in selecting a margin of safety." EPA Br. at 110. To the extent Environmental and New York Petitioners argue otherwise and suggest that a more stringent standard is thereby required, those arguments are without merit.

E. EPA Adequately Explained Its Decision in Light of CASAC's Recommendations.

A recurring theme of both Environmental and New York Petitioners is that CASAC's recommendation that EPA consider a primary standard in the range of 0.060 to 0.070 ppm required EPA to set an even more stringent standard. *See*, *e.g.*, New York Br. at 20 (EPA was "arbitrary and capricious" in not following "CASAC's unanimous scientific opinion that a standard of at most 0.070 ppm is necessary to adequately protect at-risk groups."); Envtl. Br. at 30-32.

As this Court has made clear, however, EPA is not required to follow each and every CASAC recommendation in promulgating a NAAQS. Rather, the only obligation imposed on EPA by section 307(d) of the CAA is that the Agency provide a reasoned basis for its exercise of judgment, including an explanation for any departure from CASAC's recommendations. *Am. Farm Bureau Fed'n v. EPA*,

559 F.3d 512, 521 (D.C. Cir. 2009) ("By statute the EPA must explain its rejection of the CASAC's recommendation…."). Here, EPA explains that CASAC's recommendation "appears to be a mixture of scientific and policy considerations," and notes that "the choice of what is appropriate is clearly a public health policy judgment entrusted to the Administrator." 73 Fed. Reg. at 16482/3-83/1, JA__-__.

New York Petitioners argue that EPA "offered only a conclusory explanation" for why it did not set the primary NAAQS within the range of 0.060 to 0.070 ppm – namely that the Administrator "disagreed with CASAC on the weight it placed on the risk assessment and Adams studies." New York Br. at 22 (citing 73 Fed. Reg. at 16483/1). In reality, EPA offered a more fulsome explanation. With regard to the Adams studies, for example, EPA stated that:

> [S]ince the last review important new evidence includes demonstration of [ozone]-induced lung function effects and respiratory symptoms in some healthy adults down to the previously observed exposure level of 0.080 ppm, as well as very limited new evidence of the same effects at exposure levels well below the level of the current standard (Adams, 2002, 2006). EPA disagrees … that the percent of subjects that experienced FEV_1 decrements greater than 10% in this study of 30 subjects can appropriately be generalized to the U.S. population…. [T]he Administrator again concludes that while the Adams studies provide evidence that some healthy individuals will experience lung function decrements and respiratory symptoms at the 0.060 ppm exposure level, this evidence is too limited to support a primary focus at this level. Moreover, the Administrator notes that while the CASAC Panel supported a level of 0.060 ppm, they also supported a level above 0.060, indicating that they disagree with the commenters' view that the results of Adams studies mean that the level of the standard has to be set at 0.060 ppm.

73 Fed. Reg. at 16478/3-79/1, JA__-__.

> Similarly, with regard to the risk assessment, EPA explained that it
>
> more heavily weighs the implications of the uncertainties associated with the Agency's quantitative human exposure and health risk assessments…. Given these uncertainties, the Administrator does not agree that these assessment results appropriately serve as a primary basis for concluding that levels at or below 0.070 ppm are required for the 8-hour [ozone] standard.

Id. at 16483/1, JA__. EPA also noted "significant year-to-year variability in the annual health risk estimates upon just meeting the current and potential alternative standards," "noticeable city-to-city variability in estimated [ozone]-related incidence of morbidity and mortality," and numerous (specified) uncertainties in the part of the risk assessment based on effects reported in epidemiological studies. *Id.* at 16443/1, JA__.

For these reasons, Environmental and New York Petitioners' claims that EPA failed adequately to explain its decision not to set the primary NAAQS between 0.060 and 0.070 ppm have no merit.

II. Environmental and New York Petitioners' Arguments Regarding the Form of the Secondary Standard Are Without Merit.

Finally, both Environmental and New York Petitioners take issue with EPA's decision to set the secondary NAAQS at the identical 0.075 ppm level, and in the same form, as the primary standard. Envtl. Br. at 39-40; New York Br. 24-40. New York Petitioners, in particular, argue at length that EPA erred by not

promulgating the secondary ozone NAAQS in the form of a cumulative seasonal standard.

For its part, EPA allows that a "cumulative, seasonal form more directly matches the underlying scientific data regarding biologically relevant exposures that pose adverse vegetation and ecosystem effects than does an eight-hour form." EPA Br. at 121. But, the Agency explains, it "concluded that a cumulative, seasonal standard 'would result in uncertain benefits beyond those afforded by the revised primary standard, and therefore may be more than necessary to provide the requisite degree of protection.'" *Id.* at 123-24 (quoting 73 Fed. Reg. at 16500/1-2). This is because, as EPA recognizes, "significant uncertainties … remain in the available body of evidence of [ozone]-related vegetation effects and in the exposure and risk analyses." 73 Fed. Reg. at 16499/3, JA__. For example, studies have shown different vegetation effects in plants exposed to identical cumulative quantities of ozone. *See* Irving Consulting, Final Report to UARG on the Vegetation Effects Sections of the *Review of the National Ambient Air Quality Standards for Ozone*, U.S. EPA, July 2006 (Sept. 14, 2006) (Attachment 3 to Doc. ID No. EPA-HQ-OAR-2005-0172-0049), JA__-__. Moreover, modeling of communities of multiple tree species shows that some species may do better while others do less well under a given level of ozone. *Id.* at 8-9, JA__-__. Thus, EPA recognizes that a "high degree of uncertainty" remains concerning the relationship

between effects on individual plants and effects on ecosystems that contain numerous different plants. EPA, Responses to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone at 108 (Mar. 2008), Doc. ID No. EPA-HQ-OAR-2005-0172-13079, JA__. Accordingly, the Administrator properly could not determine that the cumulative seasonal standard for which Environmental and New York Petitioners argue would be "sufficient but not more than what is necessary" to provide the protection of public welfare required by section 109(b) of the CAA. 73 Fed. Reg. at 16500/1, JA__.

Environmental and New York Petitioners fail entirely to take these salient considerations into account in arguing for a cumulative seasonal secondary standard. For this reason as well, those arguments should be rejected.

CONCLUSION

For the foregoing reasons and the reasons set forth by EPA, Environmental and New York Petitioners' petitions for review should be denied.

Respectfully submitted,

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Dated: July 23, 2012

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure and Circuit Rules 32(a)(1) and 32(a)(2)(C), I hereby certify that the foregoing Joint Brief of Industry Intervenors Ozone NAAQS Litigation Group, Utility Air Regulatory Group, and National Association of Home Builders in Support of Respondent contains 5,568 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count, and therefore is within the word limit set by the Court.

/s/ Allison D. Wood

Dated: July 23, 2012

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that this 23rd day of July, 2012, a copy of the foregoing Joint Brief of Industry Intervenors Ozone NAAQS Litigation Group, Utility Air Regulatory Group, and National Association of Home Builders in Support of Respondent was served electronically on counsel of record through the Court's CM/ECF system.

/s/ Allison D. Wood