

**ORAL ARGUMENT NOT YET SCHEDULED**

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

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

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**MURRAY ENERGY CORPORATION,**

*Petitioner,*

**v.**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,**

*Respondent.*

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

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**JOINT REPLY BRIEF OF INDUSTRY PETITIONERS**

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## GLOSSARY OF TERMS

Act	Clean Air Act
API	American Petroleum Institute
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
Env.Int.Brief	Brief of Health and Environmental Respondent-Intervenors
EPA	U.S. Environmental Protection Agency
EPA.Br.	Brief for Respondent EPA
FR	Federal Register
Ind.Pet.Br.	Joint Opening Brief of Industry Petitioners
ISA	<i>Integrated Science Assessment for Ozone and Related Photochemical Oxidants</i> (2013)
J.A.	Joint Appendix
NAAQS	National Ambient Air Quality Standard
O <sub>3</sub>	ozone
PA	<i>Policy Assessment for Review of the Ozone National Ambient Air Quality Standards</i> (Aug. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0404
ppb	parts per billion
SIP	State Implementation Plan
State.Am.Br.	Brief of State <i>Amici</i> in Support of Respondent by the States of Massachusetts <i>et al.</i>

## SUMMARY OF ARGUMENT

In response to Industry Petitioners' argument that the revised national ambient air quality standards ("NAAQS") for ozone unlawfully failed to account for the impact of background ozone levels that cannot be controlled under the Clean Air Act ("CAA" or "Act"), EPA advances three erroneous arguments. This Court should reject each one.

First, EPA asserts that background ozone levels will not prevent attainment of the standard. But that assertion refers to background ozone levels *by themselves*. EPA ignores that background levels can so significantly contribute to total ozone in some parts of the country that, in combination with *some* allowance for man-made U.S. emissions (which cannot be reduced to zero, as EPA does not dispute), they effectively preclude attainment.

Second, EPA argues that it cannot consider background levels in revising NAAQS. But Congress clearly intended that NAAQS be achievable through regulation of U.S. sources, from which it follows that the impact of non-regulatable background levels on a standard's achievability can and must be considered in setting the standards.

Third, EPA claims that nonattainment concerns stemming from background levels can be addressed through alternative relief mechanisms. But those mechanisms are inadequate to provide the necessary relief.

EPA further contends that Industry Petitioners' argument regarding overall adverse impacts is precluded by *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001). That decision, however, does not foreclose consideration of the public's tolerance for and acceptability of the incremental risks that would be addressed by lowering the standard. Because the overall adverse social, economic, and energy impacts of a lowered standard can, and likely would, affect that acceptability, those factors can and should be considered in this context.

Finally, EPA has not refuted Industry Petitioners' contention, based upon settled administrative-law principles, that EPA did not sufficiently explain its change in judgment from the last ozone review on either: (a) the acceptability of the types of responses reported in human clinical studies at the levels of interest; or (b) the basis for judging tree-growth effects to be adverse to public welfare.

## **ARGUMENT**

### **I. EPA Has Not Justified Its Failure to Account for the Impact of Background Ozone on Attainability of the Revised NAAQS.**

Industry Petitioners showed in their Opening Brief that EPA acted arbitrarily and contrary to the CAA by failing to adequately account for the impact of background levels of ozone – that is, naturally occurring or internationally transported ozone that cannot be controlled under the CAA – on the achievability of the revised NAAQS in areas of the country where those background levels are



high. Joint Opening Brief of Industry Petitioners (“Ind.Pet.Br.”) at 22-31.<sup>1</sup> EPA mischaracterizes this argument, asserting repeatedly that Industry Petitioners contend that EPA was required to set the standard above the highest background level observed in any area on any day. Brief for Respondent (“EPA.Br.”) at 98, 111, 112, 115, 116.<sup>2</sup> That is not Industry Petitioners’ position. Rather, in setting NAAQS, EPA must account for the influence of background ozone levels on the attainability of the standard, and may not set a standard at a level at which background levels make such a significant contribution that (in combination with *some* allowance for man-made U.S. emissions, which cannot be reduced to zero) they would preclude attainment in various areas in the country.

**A. Background Ozone Levels Can Preclude Attainment of the Revised NAAQS in Numerous Areas.**

EPA argues first that it properly found that background ozone levels will not prevent attainment of the revised NAAQS. EPA.Br. at 99-105. That argument misses the mark.

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<sup>1</sup> State Petitioners take the position that the background issue can also include interstate transport of ozone. Industry Petitioners use the term “background” to mean ozone that comes from sources other than anthropogenic U.S. emissions.

<sup>2</sup> Environmental Intervenors similarly mischaracterize Industry Petitioners’ position as arguing for “lowest-common-denominator standards: the lowest level that all areas can attain.” Brief of Health and Environmental Respondent-Intervenors (“Env.Int.Br.”) at 23.

EPA's argument is based primarily on its modeling-based finding that on days with high ozone levels, contributions from U.S. anthropogenic sources increase but background levels generally remain around the seasonal mean, thus contributing a smaller portion (about 35% on average) to the total ozone concentrations. EPA.Br. at 100; 80 Federal Register ("FR") at 65328 (Joint Appendix ["J.A."] \_\_\_\_). Even if true, this finding does not support EPA's conclusion because this analysis was based on a general assessment of high-ozone days across the country, and does not address the individual instances when background ozone concentrations themselves are high, well in excess of typical levels.

The heavy influence of background ozone concentrations in such instances is clear despite EPA's attempt to downplay it. EPA's brief does state (at 100) that "in a few high-altitude, rural locations in the Intermountain West, background ozone levels may rise above 70 [parts per billion ("ppb")] on rare occasions," but "EPA does not expect that these infrequent exceedances will preclude attainment." However, EPA's conclusion that background ozone levels will not prevent attainment is based on consideration of background levels *in isolation*, ignoring other situations where, as EPA recognizes in its final rule, background levels are elevated and can contribute significantly to nonattainment. *See, e.g.*, 80 FR at 65300, 65328 (J.A.\_\_\_\_, \_\_\_\_ ) (acknowledging that some locations can experience

episodic events where ozone concentrations “approach or exceed” the level of the NAAQS [and even the prior NAAQS] due largely to background concentrations, and that there may be “infrequent instances” in rural areas where “background O<sub>3</sub> would be appreciable but not the sole contributor to an exceedance”). Moreover, EPA’s conclusion relies on its assertion that the CAA provides alternative relief mechanisms to address high background ozone levels that could otherwise cause nonattainment. *See id.* at 65328 & 65436 (J.A.\_\_\_\_, \_\_\_\_ ) (noting that where background concentrations approach or exceed the standard, the “exceptional events” rule and/or other relief mechanisms can be employed). *See also* EPA’s Responses to Comments at 342-43, 346 (J.A.\_\_\_\_-\_\_\_\_, \_\_\_\_).

EPA’s analysis is flawed. First, despite EPA’s assertion, it has not demonstrated that the instances where it admits background ozone levels would exceed 70 ppb would not themselves cause nonattainment. More importantly, EPA disregards the fact that, even where background levels *alone* would not exceed 70 ppb, they can comprise such a significant portion of total ozone levels in an area that they effectively preclude attainment, given that NAAQS must allow for *some* man-made U.S. emissions. Such emissions are not required to be, and cannot be, totally eliminated – a point EPA does not contest. The significant contribution of background ozone concentrations is demonstrated by EPA’s own modeling results, presented in its Policy Assessment (“PA”) at 2A-25 (Figure 5c)

(J.A.\_\_\_\_),<sup>3</sup> as well as other studies Industry Petitioners cited (Ind.Pet.Br. at 24), which EPA does not dispute (EPA.Br. at 103-04).<sup>4</sup>

State *Amici* supporting EPA incorrectly claim that attainment of the standard in such instances is simply a matter of costs and use of innovative control measures. Brief of State *Amici* in Support of Respondent (“State.Am.Br.”) at 8-14. Even with the best available control technology, however, man-made emissions cannot be eliminated at any cost; and, in areas where background levels approach the standard, even low levels of man-made U.S. emissions combined with the background levels can preclude attainment.

Furthermore, EPA cannot justify its conclusion that background ozone levels will not prevent attainment by relying on alternative relief mechanisms to address background-ozone-related nonattainment, because those mechanisms are insufficient to provide the necessary relief. *See* Section I.C, *infra*.

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<sup>3</sup> That figure shows numerous days where total ozone levels exceeded 70 ppb and background ozone alone was 60 ppb or higher, as demonstrated in State Petitioners’ Opening Brief (at 24). EPA’s claim that State Petitioners “mischaracterize” that graph (EPA.Br. at 103) is based on the erroneous premise that only background levels over 70 ppb can preclude attainment.

<sup>4</sup> Although these instances occur predominantly in the Intermountain West, that is a sizeable portion of the country. Moreover, high background ozone levels can also occur elsewhere. *See* EPA’s 2013 Integrated Science Assessment for Ozone (“ISA”) at 2-6 (J.A.\_\_\_\_) (noting high background concentrations are also found in northern New York and other areas bordering Canada and Mexico); EPA’s PA at 2-22 (J.A.\_\_\_\_) (showing contributions of background of 70% or greater to the seasonal mean in various parts of the country).

**B. EPA Was Required to Account for the Impact of Background Ozone on the Attainability of the Revised NAAQS.**

EPA's response to Industry Petitioners' argument that EPA was required to account for background ozone levels is also unavailing. As noted above, EPA sets up a strawman by claiming that Industry Petitioners contend that EPA was required to set the standard above the highest background level in any area on any day, and it then asserts that the CAA does not "unambiguously" so require. EPA.Br. at 111, 112. Industry Petitioners' position, however, is that EPA was required, under both the CAA and well-established principles of administrative law, to account for the overall impact of background ozone levels on the attainability of the standard, which it failed to do here.

This issue presents two questions: (1) whether EPA could consider background when revising a NAAQS; and (2) whether it was required to do so.

On the first question, EPA argues that because the CAA requires it to set NAAQS that are "requisite to protect" the public health and welfare, it cannot decline to do so based on consideration of background levels. *Id.* at 112. The implication of this argument is that EPA was precluded from considering background ozone here because it was compelled by the science to reduce the level of the standard. EPA does not appear to take its argument that far, resorting instead to its above-discussed mischaracterization of Industry Petitioners' position

and its repeated reliance on alternative relief mechanisms. *Id.* at 113, 119.

Environmental Intervenors argue more directly that EPA was prohibited by the CAA from considering background in setting NAAQS. *Env.Int.Br.* at 6, 16.

As shown in Industry Petitioners' Opening Brief (at 4-6, 25-26), Congress clearly intended that NAAQS be standards that can be achieved through regulation of domestic sources through State Implementation Plans ("SIPs"). This is demonstrated by Congress's recognition that NAAQS are not to be "set at ... background levels," H.R. Rep. 95-294 (1977) at 127 (J.A.\_\_\_\_), and by the requirements in Section 107(a) of the CAA that SIPs specify the manner in which the NAAQS "will be achieved and maintained," and in Section 110(a)(2)(C) that SIPs include an enforcement and regulatory program "to assure that [NAAQS] are achieved."<sup>5</sup> It follows that, in revising NAAQS, EPA can (indeed, must) consider the achievability of the revised standards given uncontrollable background levels.

This Court previously noted in *American Trucking Associations v. EPA*, 175 F.3d 1027, 1036 (D.C. Cir. 1999) ("*ATA I*"), *rev'd in part, aff'd in part on other grounds* in *Whitman*, 531 U.S. 457, that interpreting the CAA to bar setting a standard that cannot "be achieved throughout the country" due to background levels "may well be a sound reading" of the Act. It then confirmed in *American*

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<sup>5</sup> All statutory citations herein are to the CAA; the Table of Authorities provides parallel U.S. Code citations.

*Trucking Associations v. EPA*, 283 F.3d 355, 379 (D.C. Cir. 2002) (“*ATA III*”) that “relative proximity to peak background ozone concentrations” is a factor that “EPA could consider” when selecting a standard. In the present rulemaking, EPA was clearly not precluded from considering proximity to background ozone levels given the absence of a bright line between acceptable and unacceptable effects. See Ind.Pet.Br. at 28-29.

EPA and Environmental Intervenors assert that this Court’s decision in *API v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981), precludes EPA from considering background when revising NAAQS. EPA.Br. at 114-115, 116-117; Env.Int.Br. at 16-18. That is wrong. The Court there rejected the city of Houston’s argument that the applicable ozone standards were arbitrary because “natural ozone levels and other physical phenomena in the Houston area prevent it from meeting the standards.” 665 F.2d at 1184.<sup>6</sup> In noting that “attainability” is not relevant, the Court simply relied on its prior holding in *Lead Industries Ass’n v. EPA*, 647 F.2d 1130, 1149 (D.C. Cir. 1980), that EPA may not consider “economic and technological feasibility” in setting NAAQS – a holding that does not address the impact of background levels on attainment. The Court further noted that EPA “need not tailor national regulations to fit each region or locale,” 665 F.2d at 1185,

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<sup>6</sup> As explained in State Petitioners’ Reply Brief (in Section II.A), Houston’s specific argument was that uncontrollable emissions exceeded half of the standard.

but that is not our argument here. The Court did *not* address whether EPA may or must consider background levels that could inhibit attainment of NAAQS in significantly more than a single area.<sup>7</sup>

EPA attempts to analogize the current situation to that of Houston by asserting that background ozone may exceed 70 ppb “in only a few high-altitude locations in the Intermountain West.” EPA.Br. at 117. But EPA does not address the broader situation where background ozone levels, in combination with *some* necessary allowance for man-made domestic emissions, can effectively prevent attainment of the revised NAAQS in various locations.

The fact that *API* did not resolve that broader issue is demonstrated by this Court’s subsequent statements in *ATA I* and *ATA III*. Environmental Intervenors attempt unsuccessfully to dismiss the significance of those subsequent decisions. Env.Int.Br. at 20-23. Although the issue of whether EPA may or must consider background levels in revising a NAAQS was not directly at issue in *ATA I* and *ATA III*, the above-quoted statements from those opinions indicate this Court’s view

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<sup>7</sup> Environmental Intervenors claim *API* held that “the issue of whether ‘natural background levels of ozone’ prevent attainment ‘in most areas of the nation’ is not relevant to establishment of national standards.” Env.Int.Br. at 18, quoting 665 F.2d at 1190 (emphasis in Env.Int.Br.). That claim is misleading. In that portion of its opinion, the Court upheld EPA’s refusal to docket certain post-comment documents submitted by *API* that *API* said related to the above-quoted issue. In doing so, the Court simply referred to its earlier conclusion on attainability, discussed above. 665 F.2d at 1190.



that background levels may be considered. For example, in *ATA III*, the Court noted that one of EPA's justifications for not adopting a standard of 70 ppb was that it "would be too close to peak background levels"; and it stated that in choosing among levels of 70-90 ppb, EPA "could consider" "relative proximity to peak background ozone concentrations." 283 F.3d at 379. The Court would not have made this statement if it had read *API* as precluding such consideration.<sup>8</sup>

The Court in both *API* and the *ATA* decisions left open the question whether EPA is *required* to consider proximity to background. As discussed above, Congress intended that NAAQS not be set at background levels and be standards that can be achieved through regulation of domestic sources under SIPs, as evidenced by Sections 107(a) and 110(a)(2)(C) of the Act.<sup>9</sup> It follows that, in revising NAAQS, EPA must consider whether the revised standards can be

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<sup>8</sup> Environmental Intervenors argue that, as between *ATA III* and *API*, "*API* controls because it is the older case." Env.Int.Br. at 22. However, the cited case, *United States v. Old Dominion Boat Club*, 630 F.3d 1039, 1045 (D.C. Cir. 2011), and the case it relied on, held that where a newer decision deviates from earlier, settled precedent, the Court was bound by the earlier precedent; and the Court held there that the newer decisions were not inconsistent with the prior precedent. *Id.* at 1046. The same is true here, since *API* did not address the broader issue of whether EPA may consider general proximity to peak background levels, as shown above.

<sup>9</sup> EPA contends that those provisions do not expressly require it to consider attainability in setting NAAQS. EPA.Br. at 114-116. However, those provisions do show Congress's intention that NAAQS be achievable through regulation under SIPs, an intention EPA must consider and effect.

achieved on a nationwide basis through the regulation authorized by the CAA, and must therefore consider the impediment that uncontrollable peak background levels pose to attainment. Moreover, given the proximity of the revised ozone standard to peak background levels in many areas, the impact of such levels on the attainability of the standard was plainly “an important aspect of the problem,” which EPA was required to consider under established administrative-law principles. *Motor Vehicles Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

### **C. EPA’s Reliance on Alternative Relief Mechanisms Is Misplaced.**

EPA relies heavily on its argument that any nonattainment concerns stemming from background ozone can be addressed through alternative relief mechanisms under other CAA provisions – namely, the “exceptional events,” “rural transport,” and “international transport” provisions – and thus need not be considered in establishing the level of the standard under Section 109. EPA.Br. at 105-111. Environmental Intervenors and State *Amici* also rely on those relief mechanisms. Env.Int.Br. at 19, 24; State.Am.Br. at 16-19.

As explained in Section I.B, EPA was required to take into account the standards’ attainability in setting the NAAQS themselves. In any event, the alternative relief mechanisms EPA identifies do not adequately address situations where background ozone levels cause or contribute significantly to nonattainment

of the NAAQS. These inadequacies are demonstrated in State Petitioners' Reply Brief at Section I.B, which is incorporated by reference herein.

## **II. EPA's Failure to Consider the Overall Adverse Impacts from Lowering the NAAQS in the Context of the Public's Risk Tolerance Was Unlawful.**

Industry Petitioners showed that, although EPA may not consider implementation costs in setting NAAQS, it may and must consider contextual factors, such as the acceptability of, and the public's tolerance for, the risks being addressed, as described by Justice Breyer in his concurring opinion in *Whitman*, 531 U.S. at 494-95. Because those contextual factors can be influenced by the overall adverse economic, social, and energy impacts of a lowered NAAQS, EPA erred by failing to consider such impacts. Ind.Pet.Br. at 31-36.

EPA asserts that these are "just costs by other names," and that the Supreme Court in *Whitman* held unambiguously that the CAA prohibits EPA from considering such factors. EPA.Br. at 120-122. *See also* Env.Int.Br. at 28-31 (same arguments). Although the Supreme Court in *Whitman* did discuss certain broader impacts of more stringent standards, 531 U.S. at 466, that decision does not control Industry Petitioners' argument.

In *Mississippi v. EPA*, 744 F.3d 1334, 1343 (D.C. Cir. 2013), this Court stated that NAAQS are ultimately "governed by policy-driven approaches to uncertain science" and that "[d]etermining what is 'requisite' to protect the 'public

health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk" (citing Justice Breyer's *Whitman* concurrence). This is particularly true here, where there is no bright line between acceptable and unacceptable risks in the continuum of exposures/effects over the range of ozone concentrations under consideration, in terms of affecting "the health of the public," *Whitman*, 531 U.S. at 466. In these circumstances, the public's "tolerance" for, and the "acceptability" of, the small incremental risks between 70 and 75 ppb are clearly relevant contextual factors. In fact, their consideration is necessary to determine what level in the continuum is "requisite" to protect public health and welfare. These factors cannot be evaluated in a vacuum; they can and likely would be influenced by the overall adverse impacts of a lower standard on society, the economy, and energy prices. *See* Ind.Pet.Br. at 32.

*Whitman* does not prohibit consideration of such impacts *in this context*.

The Court's precise holding there was that, in setting NAAQS, EPA may not consider the costs of implementation.<sup>10</sup> Further, its discussion of broader impacts

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<sup>10</sup> The same is true of this Court's holding in *ATA I* (cited in EPA.Br. at 125) rejecting the petitioners' reliance on the use of the word "appropriate" in Section 109(d)(1). 175 F.2d at 1040. That holding pertained to consideration of implementation costs, not the effect of broader adverse impacts on the public's risk tolerance, and it preceded the Supreme Court's broad interpretation of the word "appropriate" in *Michigan v. EPA*, 135 S.Ct. 2699, 2707 (2015). *See* Ind.Pet.Br. at 33 n.16.

focused on the fact that economic costs can have adverse health effects. 531 U.S. at 466. Here, Industry Petitioners are arguing that the overall adverse social, economic, and energy impacts of a lower standard can affect the public's tolerance for and the acceptability of the incremental risks. That is a different issue, which EPA should have considered.<sup>11</sup>

### **III. EPA Failed to Provide Reasoned Explanations for Changing its Conclusions Regarding the Acceptability of Certain Respiratory Responses to Ozone and Regarding Tree-Growth Effects.**

Industry Petitioners' third argument is based on the long-standing administrative-law principle that where an agency changes a prior conclusion or interpretation, it must provide a reasoned basis for that change. Industry Petitioners showed that the studies that became available after EPA's 2008 NAAQS revision did not change the fundamental scientific understanding of ozone effects or the exposure-response relationships. Yet EPA changed its conclusion to determine that effects that it previously deemed acceptable were no longer acceptable, without providing a reasoned explanation for that change in judgment. Ind.Pet.Br. at 36-41.

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<sup>11</sup> However, to the extent that *Whitman*, or prior decisions of this Court, are interpreted to prohibit consideration of these broader adverse impacts (even in this context), Industry Petitioners preserve their position that that interpretation is inconsistent with the Act.

Although EPA and Environmental Intervenors spend many pages arguing that the overall scientific evidence justified EPA's decision to reduce the level of the NAAQS, their response to Industry Petitioners' more narrow point boils down to two arguments: (1) that this Court in *Mississippi* rejected Industry Petitioners' premise that EPA must provide a reasoned explanation for a change in conclusions, EPA.Br. at 42-44; Env.Int.Br. at 6-7; and (2) that the studies that became available since the last review *did* change the scientific understanding of ozone effects, EPA.Br. at 45-46; Env.Int.Br. at 8-13.

On the first point, the Court in *Mississippi* rejected an argument that EPA "cannot determine why further risk reduction is 'requisite' without 'putting risk in the context of earlier NAAQS decisions'" 744 F.3d at 1342. The Court stated that, although setting NAAQS requires a policy judgment about acceptable risk, "that does not mean the initial assessment is sacrosanct and remains the governing standard until every aspect of it is undermined..... The statutory framework requires us to ask only whether EPA's proposed NAAQS is 'requisite'; we need not ask why the prior NAAQS once was 'requisite' but is no longer up to the task." *Id.* at 1343. Further, the Court noted that petitioners' argument was "largely dependent on the conceptual error that EPA is somehow bound by the 1997 NAAQS." *Id.* at 1344.

These statements do not reject the established administrative-law principle that EPA must provide a reasoned explanation for a change in judgment, as held by the cases cited in Ind.Pet.Br. at 36-37. *See also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016) (holding that an unexplained change in position deprives a regulation of *Chevron* deference). Industry Petitioners are not arguing that EPA's 2008 judgment was "sacrosanct" or that "EPA [was] somehow bound" by it. The point is simply that EPA must provide a reasoned explanation for changing its policy judgment.<sup>12</sup>

On the second point, Industry Petitioners focused primarily on EPA's change in the conclusions drawn from the human clinical studies, on which EPA placed the "greatest weight." 80 FR at 65341, 65352 (J.A.\_\_\_\_, \_\_\_\_). At a minimum, EPA was required to provide a reasoned explanation for changing its judgment about the significance of the responses reported in those studies. On this issue, EPA and Environmental Intervenors point primarily to the new studies by Schelegle *et al.* (2009) and Kim *et al.* (2011),<sup>13</sup> claiming that they changed the scientific understanding of responses at levels below 80 ppb. EPA.Br. at 45-46;

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<sup>12</sup> To the extent that the Court interprets *Mississippi* as rejecting that requirement in the NAAQS context, Industry Petitioners believe that the Court should reconsider that interpretation, *en banc* if necessary

<sup>13</sup> Full citations for the scientific references discussed herein are given in the Table of Authorities.

Env.Int.Br. at 9. In fact, EPA states (at 46) that the Schelegle *et al.* findings at 72 ppb gave EPA “enough certainty to conclude that the 2008 standard was inadequate.”

Although there had been no prior study at a level between 80 and 60 ppb, the findings of Schelegle *et al.* at 72 ppb – modest and transient lung function changes and symptomatic responses in a small number of healthy subjects exposed during exercise – were entirely consistent with the expected exposure-response relationship based on the prior studies, as shown by Figure 6.1 of EPA’s ISA at 6-8 (J.A.\_\_\_\_). This is particularly true given that the prior studies by Adams (2002, 2006) had themselves shown small decreases in lung function (which an EPA reanalysis had found to be statistically significant in the 2006 study) and increases in respiratory symptoms (which were statistically significant) at 60 ppb. *See* 73 FR 16436, 16454 (Mar. 27, 2008) (J.A.\_\_\_\_).

As to Kim *et al.*, EPA and Environmental Intervenors note that this study showed statistically significant decreases in lung function and increases in airway inflammation at 60 ppb, although EPA explains that it had less confidence that these responses were adverse. EPA.Br. at 45. These findings are wholly consistent with EPA’s 2008 conclusion that, as shown in the Adams studies, some effects can occur at 60 ppb.



Thus, although the new human clinical studies provided some additional information regarding healthy subjects' responses at ozone concentrations between 80 and 60 ppb, they were consistent with the expected exposure-response relationship based on prior data and thus did not change the fundamental understanding of ozone effects on such subjects at these levels. Yet EPA's final rule makes clear that, while EPA also considered epidemiological studies and its exposure and risk assessments, the *principal* factor driving its decision to lower the primary standard consisted of human clinical results: the responses reported by Schelegle *et al.* at 72 ppb. *See* 80 FR at 65343, 65352-53, 65362-63 (J.A.\_\_\_\_, \_\_\_\_-\_\_\_\_, \_\_\_\_-\_\_\_\_). However, as noted above, those types of responses were not unexpected based on prior information, and EPA did not specifically explain its change in judgment as to why the expected responses at that level that it considered acceptable in 2008 are no longer acceptable.

Nor did EPA provide a reasoned basis for changing its conclusion from the same tree-growth data considered in 2008 to justify a lower secondary standard. EPA points to a new analysis of the prior exposure-response functions and new projections of potential growth impacts in "Class I" areas, EPA.Br. at 75-76, but does not explain how information that only "improves [EPA's] confidence in conclusions" reached in the last review while remaining characterized by "uncertainties" justifies lowering the standard. 80 FR at 65384-85 (J.A.\_\_\_\_-

\_\_\_\_). EPA also relies on CASAC's recommendation that 6% tree-growth loss is too high. EPA.Br. at 76-77. But that is not an explanation for changing its conclusion, especially since CASAC's recommendation was unsupported and EPA rejected CASAC's 2% recommendation for the same reason.<sup>14</sup>

### **CONCLUSION**

This Court should grant Industry Petitioners' petitions for review and vacate the revised NAAQS and remand them to EPA for reconsideration.

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<sup>14</sup> Environmental Intervenors argue that the remand of the secondary standard in *Mississippi* means that the 2008 standard was "unlawful" and thus cannot be an "anchoring point for rational analysis." Env.Int.Br. at 15. But the Court did not hold the prior standard unlawful; it remanded the standard due to an inadequate explanation by EPA.

Respectfully submitted,

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Dated: September 14, 2016

**CERTIFICATE OF COMPLIANCE**

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure and Circuit Rule 32(e)(3), I hereby certify that the foregoing Joint Reply Brief of Industry Petitioners contains 4,588 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count, and that thus this brief together with the Joint Reply Brief of State Petitioners (which contains 4,902 words) are within the joint word limit of 9,500 words for those briefs together, as set by the Court in its Order dated March 9, 2016.

/s/ James R. Bieke

James R. Bieke

**CERTIFICATE OF SERVICE**

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that on this 14th day of September, 2016, I served one copy of the foregoing Joint Reply Brief of Industry Petitioners on all registered counsel in these consolidated cases through the Court's CM/ECF system.

/s/ James R. Bieke

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