ORAL ARGUMENT NOT YET SCHEDULED

No. 08-1200 (Lead) 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 REPLY BRIEF OF PETITIONER STATE OF MISSISSIPPI AND INDUSTRY PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

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

FEDERAL STATUTES

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

FEDERAL REGISTER

MISCELLANEOUS

GLOSSARY OF TERMS

Act	Clean Air Act
Agency	U.S. Environmental Protection Agency
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	U.S. Environmental Protection Agency
FEV	Forced Expiratory Volume
IQA	Information Quality Act
NAAQS	National Ambient Air Quality Standard
$PM_{2.5}$	Fine Particulate Matter
ppm	parts per million
Standard(s)	National Ambient Air Quality Standard(s)

SUMMARY OF ARGUMENT

The Environmental Protection Agency's ("EPA" or "Agency") 2008 revision of the national ambient air quality standards ("NAAQS" or "standards") for ozone, 73 Fed. Reg. 16436 (Mar. 27, 2008), JA__-__, failed to comply with the Clean Air Act's ("CAA" or "Act") mandate that NAAQS be set at the level that is "'requisite'—that is, not lower or higher than is necessary." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475-76 (2001), *on remand*, *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355 (D.C. Cir. 2002) ("*ATA III*") (quoting CAA § 109(b)(1)).[1] The record does not contain any material evidence that public health risk is different than in 1997 or of effects EPA had not already taken into account when it set the NAAQS in 1997. EPA's disregard of its previous determination in 1997 of the level of acceptable public health risk was arbitrary and capricious and violated the Act.

EPA also failed to comply with section 108 of the Act, which requires EPA to rely on air quality criteria that "accurately reflect the latest scientific knowledge." Finally, because EPA relied on the primary NAAQS in setting the secondary standards, the secondary standards are unlawful for the same reasons as the primary standard and should be set aside.

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

ARGUMENT

EPA must set primary NAAQS at the level "requisite to protect the public health" with "an adequate margin of safety." CAA § 109(b)(1). Similarly, EPA must set secondary NAAQS at the level "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." *Id.* § 109(b)(2). In *Whitman*, 531 U.S. at 475-76, the U.S. Supreme Court held that CAA § 109 "requir[es] the EPA to set air quality standards at the level that is 'requisite'—that is, not lower or higher than is necessary." The "requisite" language in the CAA is not an empty restraint on EPA's discretion, but provides the "intelligible principle" to which EPA "is directed to conform" to prevent this portion of the CAA from being an impermissible delegation of legislative power. *Id.* at 472, 475-76.

In 1997, EPA promulgated primary and secondary ozone NAAQS with an 8-hour averaging time at the level of 0.08 parts per million ("ppm"), a level it determined met the Act's "requisite" requirement, and this Court upheld that determination. *ATA III*, 283 F.3d at 358. Now, EPA has concluded the 0.08 ppm level is no longer "requisite" and has revised the 1997 NAAQS to the more stringent level of 0.075 ppm. 73 Fed. Reg. at 16436/3, JA__.

EPA contends the judgment it made in 1997 that the 0.08 ppm level was requisite is now irrelevant, and that "different Administrators … [can] reach[]

different judgments on the evidence before them." EPA.Br.61. Environmental Intervenors argue that "there is no presumption that the 1997 standard is requisite." Env.Int.Br.12. Not so. Accepting these arguments removes the "intelligible principle" of "requisite," giving EPA virtually unfettered discretion to set and revise NAAQS.

Because ozone is a "non-threshold pollutant" (meaning that "'it is not possible to select a level below which absolutely no [health] effects are likely to occur,'" *ATA III*, 283 F.3d at 376 (quoting 62 Fed. Reg. 38856, 38863 (July 18, 1997), JA__); 73 Fed. Reg. at 16443/1, JA__, making a "requisite" determination necessarily involves deciding what level of public health risk is acceptable. To revise a NAAQS without reference to the level of public health risk found acceptable in 1997 is arbitrary and capricious and violates the CAA's mandate that NAAQS be set "at the level that is 'requisite'—that is, not lower or higher than is necessary." *Whitman*, 531 U.S. at 475-76.

In fact, the record here shows that EPA has revised the ozone NAAQS not because a more stringent standard is needed to achieve the level of risk abatement found "requisite" in 1997, but because EPA has decided a more stringent standard is a virtue unto itself. But under the CAA and the Supreme Court's *Whitman* decision, EPA cannot employ a different "requisite" standard each time it revises a

NAAQS. To do so would defeat the intelligible principle Congress provided for setting NAAQS.

I. The 2008 Primary Ozone NAAQS Is Unlawful Because EPA Failed To Justify Why the 1997 Ozone NAAQS Was No Longer "Requisite" To Protect Public Health With an Adequate Margin of Safety.

The CAA does not require NAAQS to be set at a zero-risk level.[2] 73 Fed. Reg. at 16437/2, JA__ (citing *Lead Indus.*, 647 F.2d at 1156 n.51); *see also Whitman*, 531 U.S. at 494 (requisite standard "does not compel the elimination of all risk) (Breyer, J., concurring) (emphasis omitted); Miss.Br.23-24. Rather, the CAA requires primary NAAQS to be set at the level that is "requisite to protect the public health" with "an adequate margin of safety." CAA § 109(b)(1). Because ozone is a non-threshold pollutant, 73 Fed. Reg. at 16442/3-43/1, JA__-__; *ATA III*, 283 F.3d at 359-60, unless there is absolutely no ozone in the ambient air (an impossibility because ozone occurs naturally), some level of public health risk will be estimated for any ozone exposure level, however small. EPA's responsibility in

[2] Environmental Intervenors argue that the CAA requires "health-based NAAQS 'ensure' the 'absence of adverse effect[s] on [] sensitive individuals" and claim Mississippi Petitioners (hereinafter "Mississippi") suggest using "some sort of cost-based risk analysis." Env.Int.Br.6. First, Mississippi does not argue that cost is a consideration. Second, although the CAA requires that NAAQS be set in reference to sensitive populations, EPA need not eliminate *all* health risk for those populations. Indeed, *Lead Industries Ass'n v. EPA* (cited by Environmental Intervenors (at 6) to support their "zero-risk" argument for sensitive individuals) upheld a NAAQS that protected 99.5% of children (the sensitive population). 647 F.2d 1130, 1144 (D.C. Cir. 1980).

establishing NAAQS is determining what level of risk to public health is "reasonable," *NRDC v. EPA*, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (CAA requires "reasonable degree of protection" against known or suspected hazards) (quotation omitted; emphasis omitted), and "requisite," *ATA III*, 283 F.3d at 380.[3]

EPA must review NAAQS periodically and revise them "as may be appropriate in accordance with" sections 108 and 109(b) of the Act. CAA § 109(d)(1). Here, EPA justified making the NAAQS more stringent on the basis that this would provide "increased public health protection." 73 Fed. Reg. at 16472/1-2, JA__. As Mississippi pointed out (Miss.Br.25-28), a more stringent NAAQS always provides increased public health protection, but this does not mean that the more stringent standard is "requisite." Under EPA's "increased protection" approach, there is no way that a standard could ever be "lower … than

[3] EPA criticizes (EPA.Br.46-47) Mississippi's citation of *American Farm Bureau Federation v. EPA*, 559 F.3d 512 (D.C. Cir. 2009), which noted this Court had rejected EPA's "secondary NAAQS for fine particulate matter because EPA's 'analysis of the relative protection' of different alternative NAAQS did not satisfy the 'requisite' standard," Miss.Br.27-28 (quoting *Am. Farm Bureau*, 559 F.3d at 530). EPA states that the Court "in fact … faulted EPA because its 'analysis demonstrate[d] nothing about the relative protection offered by the different standards'—in other words, because EPA had not conducted a reasonable comparison between the alternative standards under consideration." EPA.Br.46-47 (quoting *Am. Farm Bureau*, 559 F.3d at 530) (emphasis omitted). This distinction is unavailing. Here, EPA conducted no comparison—reasonable or otherwise—of the risk at the various alternative levels under consideration to the risk deemed requisite in 1997. *See infra* Section II.

is necessary," *Whitman*, 531 U.S. at 475-76, creating a "freefall" with no indication—short of zero—of where EPA must stop.

EPA responds that it "did not merely decide to revise the 1997 standard based on an unqualified finding of 'increased protection.'" EPA.Br.47. EPA says it considered other factors like "the *nature and severity* of the public health impacts…; the *size of the at-risk population groups* …; and the *kind and degree of uncertainties* associated with evidence of ozone effects." *Id.* (emphases in original). EPA misses the point. Mississippi does not dispute that EPA examined those factors—and new studies— in the current NAAQS review. The fact that there are more studies now than in 1997, *id.* at 58, however, does not demonstrate that the public health risks from the 0.08 ppm NAAQS have changed since 1997. Without explaining how its consideration of those factors changes public health risk at 0.08 ppm, EPA's rationale that the 2008 NAAQS provide "increased protection" violates the CAA's requirement that NAAQS be "sufficient, but not more than necessary" to protect public health with an adequate margin of safety. *Whitman*, 531 U.S. at 473.

EPA also asserts that Mississippi's focus on public health risk discounts the importance of uncertainty in EPA's NAAQS decision. EPA.Br.49-54. According to EPA, it re-weighed all of the evidence before it (including evidence from the last NAAQS review) and found that the causal relationship between ozone exposure

and health effects had become more certain down to 0.075 ppm and remained too uncertain below that level. *See id.* at 58-61. To the extent that the science has changed in any appreciable way (the record suggests it has not, as discussed *infra* in section III and by Mississippi (Miss.Br.28-38)), generalized and conclusory statements about changes in certainty between 0.08 and 0.075 ppm cannot justify ignoring EPA's prior conclusions regarding the level of public health risk that is "requisite."

Because EPA replaced the "requisite" standard with an "increased level of protection" standard, the Court should set aside the 0.075 ppm NAAQS, leaving in place the 0.08 ppm NAAQS.

II. EPA's Disregard of Its Previous Determination Regarding the Acceptable Level of Public Health Risk Is Arbitrary and Capricious.

During the rulemaking, commenters explained that EPA could not conclude that the 0.08 ppm standard was no longer requisite to protect public health without addressing the level of public health risk deemed acceptable in 1997 and then explaining how public health risks had changed (or not) given changes in the science. *See* Miss.Br.39. In support of these comments, commenters offered comparisons of public health risks based on EPA's own 1997 and 2008 exposure and risk assessments, showing that public health risk at 0.08 ppm differed little in

2008 from the level EPA found to be "requisite" in 1997—or had even decreased as a result of new studies.[4]

As EPA has acknowledged, risk assessment for NAAQS is important to "put the scientific knowledge regarding ozone health effects 'into a broader public health context.'" EPA.Br.25 (quoting 72 Fed. Reg. 37818, 37823/3 (July 11, 2007), JA__); *see also* 62 Fed. Reg. 38652, 38655/2 (July 18, 1997) (risk assessment "provide[s] a broader perspective for judgments about protecting public health from … risks"), JA__. In fact, in the case of the ozone NAAQS, EPA has repeatedly used risk assessment to provide context for its public health risk judgments. 71 Fed. Reg. 61144, 61155/1 (Oct. 17, 2006) (using risk assessment to "reasonably … judge[] … importan[ce] from a public health perspective"), JA__; 62 Fed. Reg. at 38859/1-2 (risk assessments "provide a broader perspective for judgments about protecting public health from … risks"), JA__. Here, EPA

[4] *See, e.g.*, Alliance of Automobile Manufacturers, Comments on EPA's Proposal to Revise National Ambient Air Quality Standards for Ozone, at 8-9 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4191, JA__-__; ExxonMobil Corporation, Detailed Comments on EPA's Proposed Rule on the Ozone National Ambient Air Quality Standards, at 61-64 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4163 ("ExxonMobil Comments"), JA__-__; Alliance of Automobile Manufacturers, *et al.*, Comments on EPA's "*Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information (OAQPS Staff Paper–Second Draft)*" at 8-9, 13-14 (Sept. 18, 2006), Doc. ID No. EPA-HQ-OAR-2005-0172-0066, JA__-__, __-__.

explains it decided to revise the NAAQS "[b]ased on the scientific evidence *and* the exposure and risk assessments." EPA.Br.89 (emphasis added).

In response to Mississippi's risk comparisons, EPA argues that it "did not make an arbitrary choice to seek increased protection against ozone exposures unmoored from any consideration of whether those exposures would result in public health impacts." *Id.* at 48. Again, this misses the point. Consideration of public health impacts for a non-threshold pollutant is meaningless if it is "unmoored" from consideration of public health risks associated with those impacts, including those EPA previously found to satisfy the "requisite" standard.

EPA also asserts that it "refuse[s] to be bound by its 1997 quantitative risk estimates as the once and future measure of the 'risks … "requisite" to protect public health.'" *Id.* at 67 (quoting Miss.Br.41). Without comparing current risk estimates with those previously found "requisite," however, EPA has no way of ensuring that the NAAQS are set at a level neither more nor less stringent than necessary, and effectively reads out of the CAA the intelligible principle Congress provided to guide its discretion.[5] EPA's argument that "risk assessment simply

[5] Environmental Intervenors claim Justice Breyer's discussion of "comparative health risks" in *Whitman* "mean[s] simply … 'whether a proposed rule promotes safety overall.'" Env.Int.Br.8 (quoting *Whitman*, 531 U.S. at 495). The only way to evaluate whether safety is promoted overall is to compare the level of risk at 0.08 ppm in 1997 and in 2008. Only then can one know whether a change in the NAAQS would promote safety overall.

was not the driver of EPA's decision that a standard below 0.080 ppm is now necessary," *id.* at 74, contradicts both EPA's assertions that it relied on its exposure and risk assessments to put estimated health effects in a "broader public health context," *id.* at 25, and that such assessment constituted a part of the basis for its decision, 72 Fed. Reg. at 37823/3, JA__.[6]

Unmoored from public health risk, EPA's consideration of health impacts has no context. For example, EPA states that "significant proportions of sensitive populations such as children and asthmatics would still be exposed to ozone at levels associated with adverse health effects" if the 1997 NAAQS were retained. EPA.Br.45. But this was also true in 1997, 61 Fed. Reg. 65716, 65725, Table 1 (Dec. 13, 1996), JA__, and comparing those proportions of the sensitive populations EPA estimated would be exposed to those risks at 0.08 ppm in 1997 with 2008 provides necessary context for a reasoned public health judgment on whether the 1997 NAAQS was no longer "requisite."

Similarly, Environmental Intervenors argue that "the evidence '*provides a high degree of certainty* about the adverse effects of [ozone] exposure even in

[6] This does not mean that EPA could never change its mind about the acceptable risk level. *See Am. Farm Bureau*, 559 F.3d at 521-22. But in that event, EPA must offer a reasoned explanation for its different judgment. Because EPA never compared the risk present in 1997 with that present in 2008, it could not—and did not—offer any such explanation.

healthy people' at 0.080 ppm—a level *below* the 1997 standard." Env.Int.Br.8 (quoting 72 Fed. Reg. at 37879/1, JA__) (emphases in original). But this tells us nothing about the level of public health risk that is "requisite." That effects may occur at 0.080 ppm—even at a high degree of certainty—does not resolve whether the public health risk associated with those effects is greater now than the risk associated with a 0.08 ppm NAAQS in 1997. EPA never answers that question with regard to *any* of the adverse health endpoints at issue. Its failure to do so violates the CAA's requirement to set NAAQS at the level "requisite" to protect public health and is arbitrary and capricious.

To illustrate the importance of this point, Mississippi compared some aspects of the 1997 and 2008 risk assessments in their comments and brief.[7] These comparisons showed that the risk of adverse public health effects associated with a 0.08 ppm NAAQS in 2008 differed little from the risk of such effects associated with the 0.08 ppm NAAQS in 1997. Miss.Br.41-43.

[7] EPA says that Mississippi did not provide citation to comments regarding comparison of the 1997 and 2008 risk estimates. Several comments compared the two risk assessments. *See supra* note 4. EPA responded to these comments, *see, e.g.*, EPA, Responses to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone at 75-77 (Mar. 2008), Doc. ID No. EPA-HQ-OAR-2005-0172-13079, JA__, leaving little doubt it was aware of them.

EPA says Mississippi's comparisons "offer little meaningful discussion of any increase or decrease in the public health risks that EPA considered." EPA.Br.72. But EPA offers no response to the comparisons Mississippi provides, all of which show, *based on EPA's own documents*, either that public health risk did not increase at 0.08 ppm or that any increase in risk resulted not from new science but from EPA's change in the background concentration assumption used in the risk assessment. *See, e.g.*, Miss.Br.41-44 (10% to 12% of individuals experience lung function decrements in 2008 at exposures of 0.06, down from 20% and 40% in 1997; risk estimates of respiratory symptoms in children provided in 1997 no longer provided in 2008 because of "lack of symptoms"; risk of hospital admissions in 1997 and 2008 based on *same study* by Thurston, with slight risk increase resulting from change in assumed background concentration).

Furthermore, EPA's assertion that the comparisons do not provide "any judgment about the full body of evidence regarding these effects," EPA.Br.72, misses the point. In the absence of public health risk comparison for any of the health endpoints examined by EPA, one cannot determine whether or why the level of public health risk deemed acceptable as the basis for the 1997 NAAQS is now no longer "requisite."

Environmental Intervenors for their part characterize Mississippi's comparisons as "utterly groundless," yet offer no substantive response, saying

instead that Petitioners are comparing "two very different assessments." Env.Int.Br.22. Actually, Mississippi carefully chose examples with comparable factors, including comparisons from the exact same studies.[8] As Mississippi's examples illustrate, risk comparison would have been possible and highly informative. Miss.Br.40. Indeed, EPA never asserts it could not have done a risk comparison; rather, EPA simply says it had discretion not to do so. EPA.Br.66.

That the Clean Air Scientific Advisory Committee ("CASAC") "praised the 2008 assessment's approach as 'well done [and] balanced'" also supports Petitioners' argument. Env.Int.Br.22 (quoting Letter from Dr. Rogene Henderson, Chair, CASAC, to The Hon. Stephen L. Johnson, Adm'r, EPA, at 12 (Oct. 24, 2006), EPA-CASAC-07-001, JA__). That the 2008 risk assessment was well done made it all the more important for EPA to compare the level of risk deemed acceptable in 1997 with the level of risk it estimated in 2008.

EPA argues further that new evidence has created more certainty now than in 1997 that ozone exposures are causally related to certain health endpoints.

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[8] EPA notes that ExxonMobil's comments stated that because the methodologies differed between the two risk assessments that "'it is somewhat misleading to directly compare the risk figures.'" EPA.Br.71 (quoting ExxonMobil Comments at 62, JA__). That is why Mississippi carefully chose the comparisons it did. EPA's comment that "the interaction between background levels and risk estimates for mortality says nothing about the risk estimates for respiratory morbidity effects," *id.* at 73 n.14, is a non sequitur. Reducing the assumed background level will increase risk estimates for any health endpoint.

EPA.Br.49, 54, 56. As Mississippi pointed out, however, EPA assumed ozone and its various health endpoints were causally related when it performed the risk assessment underlying the 1997 NAAQS. Miss.Br.35. "Increased certainty" cannot now justify a revision of that NAAQS, when EPA assumed that a causal relationship existed in its 1997 assessment of public health risk.

Finally, EPA argues that Mississippi's position would "prevent EPA from re-weighing existing uncertainties in light of new evidence" and "would also preclude different Administrators from reaching different judgments on the evidence before them." EPA.Br.61. Mississippi is not arguing that EPA cannot reweigh the evidence and reach different judgments in light of new evidence. Rather, EPA's reweighing, judgment, and consideration needs to be put into the context of public health risk judgments the Agency has previously made to ensure that NAAQS are set at the "requisite" level and to explain adequately any departure from those prior standards. Failure to recognize when and how current and past judgments differ, and to explain those differences, renders EPA's decision arbitrary and capricious.

III. The Record Does Not Contain Material Evidence of Effects that Were Unaccounted for in 1997.

EPA and Environmental Intervenors point out more scientific evidence was available in 2008 than in 1997. EPA.Br.49; Env.Int.Br.4. The mere fact that there are more studies does not answer the relevant question, i.e., do those studies show

anything new about public health risk? Here, as Mississippi explained (Miss.Br.28-38), the new studies simply confirmed EPA's position in the 1997 rulemaking, as is illustrated by the comparison of EPA's 1997 and 2008 risk assessments discussed above.

A. The New Information EPA Cites Does Not Justify EPA's Revision of the 1997 NAAQS.

EPA claims three categories of "new information" exist: (1) "evidence that ozone more seriously affects asthmatics than healthy individuals"; (2) "stronger epidemiological evidence of serious adverse health effects at and below 0.080 ppm"; and (3) "very limited clinical evidence of ozone effects at levels down to 0.060 ppm." EPA.Br.54-55. As discussed below, none of this so-called "new" information shows anything materially different from what EPA knew and accounted for in 1997.

Asthma—EPA says that "new clinical and epidemiological evidence [shows] 'it is likely that more serious responses, and responses at lower levels, would occur in people with asthma and other respiratory diseases' as compared to healthy individuals." *Id.* at 55 (quoting 72 Fed. Reg. at 37863-64, JA__-__) (emphasis omitted). The 1997 review, however, explained that asthmatics typically have increased airway responsiveness at baseline and that the difference between baseline bronchial responsiveness between healthy individuals and sensitive asthmatics may be as much as 100-fold. EPA, EPA-452/R-96-007,

REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION: OAQPS STAFF PAPER at 35 (June 1996) ("1996 Staff Paper"), JA__. EPA's earlier review also explained that the clinical studies comparing the pulmonary function responses following ozone exposure in asthmatic and nonasthmatic subjects suggested that asthmatics may be more sensitive to acute ozone inhalation effects. EPA, EPA/600/P-93/004cF, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS, VOLUME III OF III at 7-23 (July 1996), JA__; *see also* 1996 Staff Paper at 55, JA__ ("Controlled studies on mild asthmatics suggest that they have similar lung volume responses but greater airway resistance changes to [ozone] than nonasthmatics. Furthermore, limited data from studies of moderate asthmatics suggest that this group may have greater lung volume responses than nonasthmatics."); 62 Fed. Reg. at 38859/3, JA__ ("Groups at increased risk of experiencing such effects include … individuals with preexisting respiratory disease (e.g., asthma…)."). EPA also took epidemiological evidence regarding asthmatics into account in 1997. 62 Fed. Reg. at 38864/1, JA__. In short, in 1997, EPA already recognized that both clinical and epidemiological evidence suggested that asthmatics are more sensitive to ozone effects than healthy individuals. That "new evidence" shows asthmatics have greater responses and at lower levels

merely confirms this evidence from 1997 regarding the greater sensitivity of asthmatics to ozone.

Epidemiological Evidence—EPA recognizes that "the great majority of the evidence below 0.080 ppm is epidemiological studies" and that those studies show "associations at those levels … *not* direct evidence of a causal link." EPA.Br.30 (emphasis added). This is no different than the nature of the epidemiological evidence in 1997. In fact, EPA can point only to two new studies (Mortimer (2002) and Gent (2003)) that it claims provide new information regarding lung function decrements, increased respiratory symptoms, and increased asthma medication use in asthmatic children, even when adjusted to account for the confounding effects of other pollutants. *Id.* at 59. EPA also states increased asthma medication use is a health endpoint that had not been extensively explored in 1997. *Id.*

First, EPA took all of these effects into account when it set the 1997 NAAQS. *See e.g.*, 62 Fed. Reg. at 38859/3 (lung function decrements (included in pulmonary function responses) and respiratory symptoms), JA__; *id.* at 38863/1 (increased asthma medication use in asthmatic children), JA__. Consequently, these two studies do not really present "new evidence" but merely evidence that is cumulative to what EPA considered in reaching its 1997 judgments.

Second, CASAC has noted that time-series studies such as Mortimer and Gent have inherent limitations in the ability to control for confounders like other pollutants. 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 (issues exist as to "the utility of these time-series studies in the NAAQS-setting process") (emphasis omitted), JA__. As CASAC pointed out, "[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 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." *Id.*

Third, with regard to increased medication use, Mortimer did not address this. 73 Fed. Reg. at 16445/3 (citing only Gent for this proposition), JA__. And, as EPA acknowledged, Gent suffers from "limited control for meteorological factors and the post-hoc nature of the population stratification by medication use." EPA, EPA/600/R-05/004aF, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS, VOLUME I OF III at 7-53 (Feb. 2006), JA__.

EPA admits that other new epidemiological evidence suggesting effects such as mortality, school absences, and cardiovascular effects did not play a part in the decision to revise the 2008 NAAQS. EPA.Br.60-61 (noting EPA made none "of

these effects the focus of its decision to revise the 1997 standard"). Consequently, the "new" epidemiological information is at best quite limited and provides no material new evidence supporting NAAQS revision.

Clinical Evidence—EPA states the "principal new clinical evidence" is the Adams studies, calling it "'very limited,'" *id.* at 62-63, and saying it cannot "appropriately be generalized to the U.S. population," *id.* at 21. In describing why it considered this new clinical evidence so "limited," EPA recognized its reanalysis of the Adams studies "did not appear in the Criteria Document,"[9] and that although its reanalysis "did find statistically significant results for the 2006 Adams study … [it did not] for the 2002 study … [and] the results of the 2006 study had not been replicated." *Id.* at 83, 93. In short, the clinical evidence in 2008 differed very little from 1997.

Furthermore, as Mississippi noted (Miss.Br.31-32), EPA recognized in 1997 that sensitive individuals had experienced forced expiratory volume ("FEV") decrements as large as 50% when exposed to ozone concentrations as low as 0.08

[9] By contrast, the Adams studies themselves, which Adams concluded "do[] not demonstrate a significant mean effect by ordinarily acceptable statistical analysis," William 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 ("Adams Comment"), JA__, appeared in the Criteria Document. CAA § 109(b) requires NAAQS be based on the Criteria Document—not reanalysis outside of it.

ppm. EPA responds that this finding "did not pertain to the effects of exposures below 0.08 ppm." EPA.Br.63 n.10. The idea, however, that someone could experience as large a decrease in FEV as 50% at a concentration of 0.08 ppm and not experience anything below that concentration level strains credulity. In fact, EPA's 1997 risk assessment reflected that FEV decreases would be experienced at concentrations below 0.08 ppm, and EPA's "requisite" determination in 1997 took that into account. *See, e.g.*, R.G. Whitfield, *et al.*, *A Probabilistic Assessment of Health Risks Associated with Short-Term Exposure to Tropospheric Ozone* at 32, Fig. 4 (June 1996), JA__. Here again, the new scientific evidence merely confirms the health evidence that EPA considered and the assumptions that EPA made in 1997 in concluding that a NAAQS of 0.08 ppm was the level requisite to protect public health.

B. EPA Accounted for Uncertainty in the Science in 1997, and Nothing in the New Evidence Identified by EPA Justifies Revising the NAAQS.

As Mississippi explained, when EPA set the ozone NAAQS in 1997, it "address[ed] uncertainties associated with inconclusive scientific and technical information" and "hazards that research has not yet identified" by setting the NAAQS at the requisite level of 0.08 ppm. 62 Fed. Reg. at 38857/1, JA__; *see also* Miss.Br.33-36. Now, EPA claims that Mississippi "disregard[s] the role of uncertainty in the 1997 and 2008 reviews, overlooking the significant impact of

new evidence on EPA's certainty regarding ozone's adverse health effects at various levels…." EPA.Br.49.

EPA, however, has failed to show that any of the new evidence offers anything materially new that would justify revising the NAAQS. As discussed above in section III.A, the cited new evidence at best confirms EPA's conclusions when it set the NAAQS in 1997.

Moreover, EPA concedes that very little is more certain now than it was in 1997. For example, EPA states that the "epidemiological studies do not provide direct evidence of a causal association between adverse health impacts and ozone exposure at a particular level," and that there are "important uncertainties about the causal relationship between ozone and adverse health effects at lower concentrations…." *Id.* at 90; *see also id.* at 91, 93, 98-99, 101-02, 104-06, 108, 110 (acknowledging further uncertainties).

Relying on the uncertainty remaining in the science, EPA properly rejected requests to set the NAAQS below 0.75 ppm. *See* Ind.Int.Br.20-22. Just as in 1997, there is nothing in the record that examined the 0.075 ppm level specifically, while many studies evaluated 0.08 ppm. 73 Fed. Reg. at 16476/2-3 ("strong body of clinical evidence … at exposure levels of 0.080 and above" as compared to "a very limited amount of evidence" below that), JA__. Moreover, reflecting the need to provide protection in the face of uncertainty, the Administrator assumed in his

public health risk assessments that there was no uncertainty in the estimates of risk of ozone-related health effects. *See, e.g.*, *id.* at 16451/2 (ignoring uncertainty bounds of 8.3% to 15.3% in stating that "up to about 11 percent" of asthmatic children might experience FEV decrements of greater than 10% upon attainment of the 0.08 ppm standard), JA__.

Indeed, if a public health risk comparison had been done for the 1997 and 2008 assessments, as commenters requested, it would have shown that public health risk in 2008 was no greater than the public health risk found acceptable to EPA in 1997, even assuming no uncertainty. Miss.Br.39-44. In the absence of any effort by EPA to respond to comments by providing such important public health context for its decision, the scientific uncertainty below 0.08 ppm should have led EPA to reject revision of the 0.08 ppm standard.

C. Environmental Intervenors Have Not Shown Anything Material Has Changed With Regard to the Scientific Evidence.

Environmental Intervenors repeatedly question Mississippi's discussion of the scientific evidence. *See generally* Env.Int.Br.13-22. None of these claims has merit; several of these mischaracterizations are highlighted below.

1. The Adams Studies

Environmental Intervenors are incorrect that the "claim that Adams 'concluded' his studies 'provided no evidence of health effects below 0.08 ppm' is false." *Id.* at 16 (quoting Miss.Br.30-31 (emphasis omitted)). Dr. Adams stated in

comments to EPA that he "conclude[d] that the FEV_1 response in healthy young adults to 6.6 h[our] exposure to 0.06 ppm [ozone] in my study (Adams, 2006a) does not demonstrate a significant mean effect by ordinarily acceptable statistical analysis." Adams Comment at 4, JA __. Dr. Adams also refers to the two subjects who experienced greater than 10% FEV_1 decrements as "two clear outliers." *Id.*

Environmental Intervenors also disregard the limitations Dr. Adams placed on his findings when they state that "Adams plainly found that people suffered health effects at 0.06 ppm." Env.Int.Br.16. For example, Dr. Adams reported the results for respiratory symptoms at 0.06 ppm "were not significantly greater than those for the square-wave exposure (protocol 4) at 5.6 and 6.6 h," which were not statistically significant. William 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, 131 (2006) ("Adams (2006)"), JA__.

Environmental Intervenors also claim that Mississippi "falsely implies" (Miss.Br.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." Env.Int.Br.17. In fact, Mississippi appropriately cited a CASAC member's criticism of EPA's pointing to larger responses by a few of the Adams subjects. *See* Miss.Br.52 (quoting Letter from Dr. Rogene Henderson, Chair,

CASAC, to the Hon. Stephen L. Johnson, Adm'r, EPA, at C-31 (Mar. 26, 2007), EPA-CASAC-07-002 (statement of Dr. Vedal)), JA__.

2. Other Scientific Evidence

Environmental Intervenors assert that "EPA found the evidence linking ozone to premature deaths to be significant, and found it supported revising the standard." Env.Int.Br.18. But EPA did not say that, as is shown by EPA's own statements in its brief that it did not rely on mortality in deciding to revise the standard. EPA.Br.61 n.9 ("[T]he Agency clearly stated that … mortality evidence was not the focus of its decision to propose revision of the 1997 standard.") (citing 73 Fed. Reg. at 16460/2, JA__); *see also id.* at 60-61 (mortality among evidence EPA "did not make … the focus of its decision to revise the" NAAQS).

Furthermore, contrary to Environmental Intervenors' claims (Env.Int.Br.21), Mississippi's characterization of Korrick et al. (1998), Miss.Br.59, is correct. That pulmonary function changes attributed to ozone were not statistically significant when adjustment for fine particulate matter ("$PM_{2.5}$") and aerosol acidity were included is apparent from Table 2 of Korrick. S.A. Korrick, *et al.*, *Effects of Ozone and Other Pollutants on the Pulmonary Function of Adult Hikers*, 106 ENVTL. HEALTH PERSP. 93, 95 (Feb. 1998), JA__. As Dr. Korrick stated, "[a]djustment for $PM_{2.5}$ and strong aerosol acidity concentrations did not change the observed

inverse relationship between changes in FEV_1 and hikers' mean [ozone] exposures, but this association was no longer significant (Table 2)." *Id.*

IV. EPA's Revised NAAQS Do Not Accurately Reflect the Latest Scientific Knowledge.

EPA acknowledges CAA § 108 obligates it to "summarize and assess the latest science without misrepresenting it as a factual matter," but goes on to claim that, once it has accurately summarized the latest science, its obligation to ensure the revised NAAQS "accurately reflect[] the latest scientific knowledge" ends. EPA.Br.76, 79. EPA argues it may recharacterize the results of those studies to provide a factual basis to support whatever policy decision it wishes, provided it accurately summarizes the latest scientific studies. This is a stunning claim of administrative authority—one that effectively reads the requirement to "accurately reflect the latest scientific knowledge" out of the CAA.

Notwithstanding EPA's claims, a vast difference exists between weighing the results of various studies and making a reasoned policy decision different than some scientists might have made—a power EPA plainly enjoys under the CAA—and disagreeing with scientists on the results of their own studies, revise those results, and then using that revision as part of the basis for a new policy decision. In the former situation, EPA's policy decision could be said to "reflect the latest scientific knowledge," CAA § 108(a)(2), whereas in the latter, EPA's ultimate

policy decision does not reflect the latest scientific knowledge but rather the Agency's own rewriting of that science.

Perhaps because the 2008 ozone NAAQS do not reflect the latest scientific knowledge—indeed, the NAAQS are based on an admitted reinterpretation of that science—EPA argues Mississippi's reading of the CAA would require this Court to engage in a "[h]eightened [s]tandard of [r]eview," EPA.Br.75, that would require this Court to "'weigh the evidence anew and make technical judgments,'" *id.* at 77 (quoting *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981)). But that is not the case.

A court may ensure the basic quality of the scientific evidence upon which an agency relies without weighing that evidence or making technical judgments Congress committed to the agency. For instance, courts routinely consider the basic quality of scientific evidence under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), without encroaching upon the role of the factfinder. So too, here. For example, EPA concedes Adams (2006) provided a key basis for its decision to revise the NAAQS. 73 Fed. Reg. at 16449/2, JA__. That study, however, found no effects below 0.08 ppm. Adams Comment at 3-4, JA__. Contrary to section 108, EPA conducted an *unpublished, non-peer reviewed reanalysis* of that science that was not included in the Criteria Document, *see supra* note 9, and reached exactly the opposite conclusion of Adams.

EPA also argues Mississippi's arguments are premised on an attempt to import an "additional legal test into section 108 based on EPA's [Information Quality Act ("IQA")] Guidelines." EPA.Br.77 (emphasis omitted). But that, too, is not the case.

As Mississippi explained, "NAAQS decisions must be based on air quality criteria that '*accurately reflect the latest scientific knowledge useful in indicating* ... identifiable effects on public health or welfare' from the pollutant." Miss.Br.46. Mississippi then explained that, because "the IQA requires federal agencies to maximize and ensure the quality, objectivity, utility, and integrity of the information they use," the IQA's requirements should be "read *in pari materia* with" the accuracy and usefulness requirements embodied in the CAA. *Id.* at 48. Far from seeking to import an additional legal test into section 108, Mississippi merely argued the IQA serves "as persuasive authority" informing interpretation of the CAA, and the two statutes should be interpreted consistently with one another.[10] *Id.* at 47-48.

[10] Trying to prevent application of the *in pari materia* doctrine, EPA suggests it applies only when two or more statutes use the exact same word. EPA.Br.78. EPA's reliance on *Erlenbaugh v. United States*, 409 U.S. 239 (1972), is misplaced because there, the Supreme Court explained that, where, as here, two statutes "pertain to the same *subject*," they should be construed consistently with one another, "'as if they were one law.'" *Id.* at 243 (emphasis added).

But even if Mississippi's brief could be read as asserting an additional test, an agency must account for departures from its own non-binding guidelines. *See Am. Petroleum Inst. v. EPA*, 2012 WL 2894566, at *5 (D.C. Cir. July 17, 2012) ("*API*") (noting "agency must account for departure from non-binding plan") (citing *Edison Elec. Inst. v. EPA*, 391 F.3d 1267, 1269 & n.3 (D.C. Cir. 2004)). Moreover, unlike the internal, unpublished "meta-analysis" at issue in *API*, *id.* at *5, CASAC did not review the results of "EPA's statistical reanalysis," in the Criteria Document or Staff Paper. EPA.Br.83; *see also* Miss.Br.52-53. Rather, EPA attempted to rehabilitate its conclusions in a non-peer-reviewed memorandum to the docket filed six days before the proposed rule was signed. *See* 72 Fed. Reg. at 37828/2 & nn.15, 16, JA__. Thus, this case presents a question unanswered in *API*: whether EPA must account for departing from its own IQA Guidelines when relying on a non-peer-reviewed reanalysis.

EPA undoubtedly has scientific and technical expertise that it marshals when evaluating the latest science to make policy judgments. But a grant of authority by Congress to evaluate and make policy decisions that "accurately *reflect* the latest scientific knowledge" is not a license to rewrite that science to suit EPA's rulemaking ends. And the CAA certainly should not be interpreted to allow EPA to engage in a highly *un*scientific rewriting of peer-reviewed studies.

V. The Revised Secondary NAAQS Is Also Unlawful.

If the Court invalidates the primary NAAQS, it should also vacate the secondary NAAQS because that NAAQS was set "to be *identical in every way* to the revised primary standard." 73 Fed. Reg. at 16500/2, JA__ (emphasis added). EPA argues that it justified the secondary NAAQS independent of the primary standard. EPA.Br.119 (citing 73 Fed. Reg. at 16496-97, 16499/3-16500,[11] JA__-__, __-__). EPA claims that Mississippi did not challenge this independent basis. But, as Mississippi explained, EPA clearly relied on the primary standards in setting the secondary standard's level. EPA explained the two standards were identical because of "significant uncertainties" in the science that led EPA to be concerned that a secondary standard more stringent than the primary standard "may be more than necessary to provide the requisite degree of protection" for public welfare. 73 Fed. Reg. at 16500/1-2, JA__. EPA also found—relying on the same unlawful "increased protection" standard used for the primary NAAQS—that "a secondary standard set identical to the proposed primary standard would provide a significant degree of additional protection for vegetation as compared to that provided by the current secondary standard." *Id.* at 16499/3, JA__.

[11] EPA actually cites 73 Fed. Reg. at 16496-47, 16399/3-16500. EPA.Br.119. These appear to be typographical errors that Mississippi assumes EPA will correct in its final form brief.

Thus, EPA clearly based the secondary standards on the primary standards, "at least in part." *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1040 (D.C. Cir.), *modified in part on reh'g*, 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part, rev'd in part, and remanded sub nom. Whitman*, 531 U.S. at 457. As a result, as the Court did with the 1997 secondary standard for ozone, if the primary standard is declared unlawful, the secondary standards should be as well. Moreover, EPA relied on the same improper "increased protection" standard—rather than the CAA's "requisite" standard—to justify the secondary NAAQS, and for the same reasons "increased protection" cannot justify the primary standard, it cannot justify the secondary standard.

CONCLUSION

For the reasons stated in Mississippi's Opening Brief and herein, EPA should vacate the 2008 ozone NAAQS, leaving in place the 1997 NAAQS, which will protect health and welfare.

Respectfully submitted,

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Dated: August 13, 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 Reply Brief of Petitioner State of Mississippi and Industry Petitioners contains 6,971 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: August 13, 2012

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that I have, this 13th day of August, 2012, served a copy of the foregoing Joint Reply Brief of Petitioner State of Mississippi and Industry Petitioners electronically through the Court's CM/ECF system.

/s/ Allison D. Wood