ORAL ARGUMENT NOT YET SCHEDULED

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

No. 08-1200 (and consolidated cases)

STATE OF MISSISSIPPI,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

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

FINAL REPLY BRIEF FOR ENVIRONMENTAL PETITIONERS

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

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

Br.	Brief for Environmental Petitioners
CASAC	Clean Air Scientific Advisory Committee
CASAC 10-24-06 Letter	CASAC's Review of the Agency's 2nd Draft Ozone Staff Paper
CASAC 3-26-07 Letter	CASAC's Review of the Agency's Final Ozone Staff Paper
Dkt-	Document numbers in EPA docket EPA-HQ-OAR-2005-0172
EPA	U.S. Environmental Protection Agency
EPA Br.	Brief for Respondent
NAAQS	National Ambient Air Quality Standards
Ozone	Ozone and other photochemical pollutants
$PM_{2.5}$	Fine particulate matter
ppm	Parts per million
RTC	EPA, Responses to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone
SP	EPA Staff Paper, July 2007

SUMMARY OF ARGUMENT

The ozone health standard is not set at a level where there is an absence of adverse effects, as the law requires. EPA does not dispute the extensive evidence of constricted breathing, hospitalizations, emergency room visits, and deaths suffered by real people at ozone levels below 0.075 ppm. The agency concedes that the Adams chamber studies showed lung decrements harmful to asthmatics at 0.060 ppm ozone, and EPA's bare assertion that these compelling results are "very limited" fails to rationally justify disregarding them in setting the standard—a failure not cured by post-hoc rationales concocted by its lawyers. Likewise, EPA cannot rationally disregard the harms shown below 0.075 ppm in the epidemiological studies merely by asserting that ozone's role in causing those effects is "increasingly uncertain" at lower levels. Not only is the claim arbitrarily vague, but EPA's own staff found that ozone at 0.060 ppm is "likely to cause adverse effects in sensitive groups," a scientific finding the agency did not and cannot refute on "policy" grounds.

EPA further failed to rationally explain its rejection of CASAC's unanimous recommendation for a health standard in the 0.060-0.070 ppm range. That advice was based on the "overwhelming" collective body of evidence, not just (or primarily) the Adams studies and risk assessment, as EPA wrongly claimed. Nor did EPA itself actually evaluate the collective weight of the chamber,

epidemiological, toxicological, and risk studies that convinced CASAC and the nation's leading medical societies of the need for a standard much stronger than 0.075 ppm. EPA also failed to explain how it provided an adequate margin of safety. The agency nowhere claimed it accounted for such a margin throughout the standard-setting process, as its lawyers assert, nor could such a claim be made, given the agency's repeated choices in that process to err on the side of less protection.

Finally, EPA illegally and arbitrarily set the secondary standard without first specifying levels of vegetation protection and air quality requisite to protect public welfare—something the agency did not accomplish (as its lawyers imply) by a bare statement that it "focused" on the weakest level in the proposed range.

ARGUMENT

I. EPA'S REFUSAL TO ADOPT A MORE HEALTH-PROTECTIVE OZONE STANDARD WAS UNLAWFUL AND ARBITRARY.

A. The Primary Standard Unlawfully and Arbitrarily Allows Adverse Health Effects to Persist.

1. The Adams Chamber Studies Showed Adverse Effects at 0.060 ppm Ozone.

EPA agrees that the 2006 Adams study showed that, at 0.060 ppm ozone, healthy young adults suffered statistically significant breathing symptoms and statistically significant lung function impairments, and some impairments adverse

to asthmatics. Brief for Respondent ("EPA Br.") 19-21, 65. The agency's only stated reason for disregarding the two Adams studies' results in setting the standard's level was the bare assertion that they were "very limited"—a claim that was unexplained and unsupported. Brief for Environmental Petitioners ("Br.") 18-21.

EPA's lawyers (at 93-95) try to cobble together their own explanation for the "very limited" assertion, but these post-hoc rationalizations cannot support the agency's action. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). The lawyers imply EPA found the number of subjects Adams studied "limited" for standard-setting purposes, EPA Br. 93, but the passage they cite says no such thing. *See* 72 Fed. Reg. 37,818, 37,857/3-58/1 (July 11, 2007) (discussing what model to use in risk assessment), JA0040-41. The lawyers also wrongly assert (at 94) that EPA minimized Adams' findings of adverse effects at 0.060 because Adams did not also look for three *other* types of adverse effects. Again, the cited passage says no such thing. *See* 73 Fed. Reg. 16,436, 16,481/2 (Mar. 27, 2008) (discussing weight given to exposure assessment results for 0.080 ppm), JA0148.

Significantly, EPA agrees that at 0.060 ppm, the Adams results showed lung function decrements that are adverse to asthmatics. *Id.* 16,454/3-55/1, JA0121-22. That is what matters for determining the level of the NAAQS. *Coal. of Battery*

Recyclers Ass'n v. EPA, 604 F.3d 613, 618 (D.C. Cir. 2010) ("*CBR*") ("if a pollutant adversely affects the health of…sensitive individuals, EPA must strengthen the entire national standard") (internal quotation marks and alteration omitted); *see also* EPA Br. 19, 65 (evidence of adverse effects is "most important finding" from Adams studies). And regardless of whether the precise percentage of healthy young adults suffering significant lung function decrements can be appropriately generalized "to the U.S. population," EPA Br. 95 (quoting 73 Fed. Reg. 16,454/2), Adams' results show effects that are adverse to sensitive *sub*populations like asthmatics at 0.060 ppm, effects against which the standard must protect.[1] *E.g.*, *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980); *see* 73 Fed. Reg. 16,455/1 ("it is important to look beyond group mean to the response of subsets of the group to evaluate the potential impact for sensitive or susceptible parts of the population"), JA0122.

The record further refutes the notion that the Adams results were somehow too limited. EPA confirms that the group mean lung function decrement observed in the 2006 study at 0.060 ppm was statistically significant and "consistent with the

[1] Because asthmatics are a subpopulation that NAAQS must protect, *see CBR*, 604 F.3d at 618, and because—for reasons stated in the text—the 2008 NAAQS unlawfully and arbitrarily denies them protection, this case does not present the question whether NAAQS must protect "the most responsive individual" within a subpopulation. *See* Joint Brief of Industry Intervenors 9-10 (emphasis added).

trend in responses to exposures at 0.040 ppm and 0.080 ppm."[2] EPA Br. 20-21 (citing Dkt-0175[3] at 5). And contrary to EPA's claim (at 96), the Adams results showing adverse lung function decrements were in fact replicated in two studies: one discussed in 2002 and the other in 2006. Br. 20.

Thus, the agency's "very limited" rationale runs counter to the evidence before it. EPA had multiple experiments in which people's lung function was impaired when breathing air polluted with 0.060 ppm ozone versus when breathing clean air. These tests were performed under carefully controlled lab conditions in which the only thing that changed between the tests was the ozone exposure. Br. 17. Because EPA identifies no substantial evidence rebutting the Adams results, its refusal to base the standard thereon was arbitrary. *See, e.g., Safe Extensions v. FAA*, 509 F.3d 593, 604 (D.C. Cir. 2007) ("it is impossible to conceive of a 'nonarbitrary' factual judgment supported only by evidence that is not substantial in the [Administrative Procedure Act] sense").

EPA's refusal to rely on this evidence in setting the level of the standard is all the more arbitrary given that the agency *relied* on the very same Adams results

[2] Contrary to EPA's assertion (at 93), Petitioners do not suggest EPA also reanalyzed the 2002 results to gauge statistical significance. Indeed, it could not, for it never had the data. Dkt-7185 ("RTC") 22, JA3060.

[3] All "Dkt-" references are to document numbers in EPA docket EPA-HQ-OAR-2005-0172.

in finding the 1997 standard deficient. 73 Fed. Reg. 16,454/3-55/2, 16,460/3, 16,470/2, JA0121-22, 0127, 0137; *see County of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999) (agency arbitrarily and capriciously used data for one purpose but refused to use it for another). Petitioners do not claim, as EPA falsely asserts (at 96-97), that the agency has previously viewed chamber studies in isolation, but that EPA has found even a single chamber study (of only *six* subjects) showing adverse effects to be highly probative, even absent statistical significance, thus showing the arbitrariness of EPA's terse dismissal of the two studies (covering 60 subjects) here. Br. 20-21; 44 Fed. Reg. 8202, 8207/3 (1979), JA3447; *see also Matrixx Initiatives v. Siracusano*, 131 S. Ct. 1309, 1319-21 (2011) (study's results need not be statistically significant to be probative).

Finally, CASAC hardly showed skepticism about the Adams results in recommending a standard of 0.060-0.070 ppm, as EPA suggests (at 95-96 n.19, 117), much less support for EPA's decision to set the standard *outside that range*. CASAC expressly found the Adams results to be "[i]mportant[]" and cited them as part of the body of evidence supporting its recommendation. Dkt-0142 ("CASAC 10-24-06 Letter") 3-5, JA1333-35. Notably, CASAC so found even before EPA reanalyzed the 2006 Adams study data and found it showed statistically significant lung decrements at 0.060 ppm. *See id.*, JA1333-35; Dkt-0175 (June 14, 2007), JA1184.

2. EPA Illegally and Arbitrarily Refused to Protect Against Adverse Effects Shown with Statistical Significance in Numerous Epidemiological Studies at Ozone Levels Below 0.075 ppm.

EPA does not dispute that a large number of epidemiological studies show statistically significant links between ozone levels below 0.075 ppm and serious adverse health effects, including asthma aggravation, hospitalizations, emergency room visits, and deaths.[4] Its sole stated basis for refusing to protect against these harms is a bare assertion that ozone's causal role becomes "increasingly uncertain" at lower ozone levels. *E.g.*, 73 Fed. Reg. 16,480/2-3, JA0147. But that rationale cannot be squared with the agency's own Staff Paper finding that ozone at 0.060 ppm is "*likely to cause* adverse effects in sensitive groups," SP 6-61 (emphasis added), JA1069. *Cf. Nat'l Envtl. Dev't Ass'n's Clean Air Project v. EPA*, 2012 WL 2948519, at *9 (D.C. Cir. July 20, 2012) ("a 'causal relationship' finding is the strongest finding" EPA staff can make). Contrary to its lawyers' claim (at 99-100), the Administrator cannot dismiss that scientific finding for "policy" reasons. *See Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 117-18 (D.C. Cir 2012) ("whether motor-vehicle emissions 'cause, or contribute to'" endangerment

[4] Intervenors offer a bare assertion (at 12) that statistical significance was lacking in two of the thirteen studies cited by Petitioners, but that claim is refuted by the record. EPA-452/R-07-007 ("SP") 3-10 (EPA Staff Paper, July 2007) (Ross study "report[ed] statistically significant associations"), JA0761; SP App.3B at 2 (showing Delfino 2003 study with a confidence interval of 1.09-40.88, connoting statistical significance), JA1131; *see also* SP 3-10 to -11, JA0761-62.

"require[s] a 'scientific judgment'…not policy discussions"). Moreover, EPA itself did not question staff's specific finding of likely causation at 0.060 ppm, much less state grounds for rejecting it. The lawyers cite general EPA statements about the Adams studies being "limited," but the staff finding of causation at 0.060 ppm came in a discussion of *all* the evidence, not just Adams. SP 6-58 to -61, JA1066-69.

The agency's reliance on uncertainty of causation below 0.075 ppm is all the more irrational given that it *agrees* that the Adams studies *support* ozone's causal role in producing the effects shown in the epidemiological studies below 0.080 ppm. EPA Br. 63 (Adams studies "provide support for the biological plausibility of epidemiological evidence of health effects below 0.080 ppm"). Nowhere did EPA suggest that this plausibility of effects terminated just below 0.075 ppm. To the contrary, EPA's concerns about uncertainty focused on ozone levels *below 0.060 ppm*. RTC 29 ("[B]iological plausibility becomes increasingly uncertain especially below 0.060 ppm, the lowest level at which effects were observed in controlled human exposure studies"), JA3067. Further, EPA relied on the full body of epidemiological studies—not just those at ozone levels above 0.075 ppm—to support its finding that the 1997 standard was not sufficient to protect public health. EPA Br. 58 ("The more than 200 epidemiological studies conducted since the prior review have provided a consistent, coherent, robust, and

biologically plausible set of evidence that specifically supports associations between ozone and serious health effects…at levels *below* 0.080 ppm") (emphasis in original). EPA cannot and does not provide any reasoned basis for nonetheless disregarding those studies in determining the level of the standard. *See County of Los Angeles*, 192 F.3d at 1022.

Moreover, vague claims of "increasing" uncertainty are simply not a lawful or rational basis for rejecting stronger standards. Contrary to EPA's claim (at 101-02), *State Farm* is directly on point here, holding that a bare assertion of "substantial uncertainty" was not a reasoned basis for rejecting stronger safety protections. 463 U.S. at 52. Likewise, *Massachusetts v. EPA* held EPA could not rely on nebulous claims of uncertainty to evade making crucial judgments as to whether air pollution caused or contributed to adverse effects. 549 U.S. 497, 534 (2007). The flaw here is not only EPA's failure to expressly find the evidence "too" uncertain, EPA Br. 102, though that itself is telling, but its failure to find, or explain why, the evidence of causation was so uncertain as to justify refusal to protect against the significant adverse effects shown in the large number of studies at ozone levels below 0.075 ppm.

If a bare claim of "increased" uncertainty were sufficient, then EPA could arbitrarily disregard *even probable* adverse effects merely because effects at some higher pollution level are even more certain. Such an approach flouts the Act's

health-protective mandate and is hopelessly arbitrary. *See Bluewater Network v. EPA*, 370 F.3d 1, 21 (D.C. Cir. 2004) (vague rationale for identifying level of achievable emission reductions was arbitrary because same rationale could equally justify other levels); *Tripoli Rocketry Ass'n v. ATF*, 437 F.3d 75, 81-83 (D.C. Cir. 2006) (determination that propellant burns "much faster" than an ordinary fire does not provide reasoned basis for regulatory decision: "the vague description 'much faster' conveys no information at all"). EPA asserts there is no "bright line" for selecting a level, but that hardly leaves the agency without objective benchmarks to guide its decision. *See, e.g.*, *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) ("*ATA*") (EPA set annual standard for fine particulate matter ("$PM_{2.5}$") just below range of levels where epidemiological studies showed statistically significant associations with effects).

Far from authorizing EPA to assert any degree of uncertainty as a basis for weaker standards, as EPA suggests (at 100-01), *ATA* held that demands for a precise level of certainty cannot trump EPA's obligation "to promulgate protective primary NAAQS even where…the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" 283 F.3d at 369. Nor did *ATA* hold that a bare EPA claim of "less certainty" sufficed to justify a less protective NAAQS, as EPA claims (at 127-28). The Court relied on multiple factors in upholding EPA's decision, and found "[m]ost convincing…the absence of *any*

human clinical studies at ozone concentrations below" the level EPA set. 283 F.3d at 379 (emphasis in original). Here, in contrast, there *are* such clinical studies. The *ATA* Court also relied on the fact that not a single CASAC member supported a standard lower than the one EPA selected. *Id.* 377, 379. Here, CASAC *unanimously* supported a stronger standard than 0.075 ppm.

That ozone is a "non-threshold" pollutant, EPA Br. 111, does not justify EPA's action. The epidemiological studies here show that people have suffered breathing difficulty, been hospitalized, gone to emergency rooms, and died when exposed to various observed ozone levels below 0.075 ppm: The adverse effects were not extrapolated from some assumed dose-response relationship that has no low-end threshold. Petitioners are not arguing here for a "zero" risk standard that protects against all imaginable effects, as EPA claims, *id.* 110-11, but for protection against adverse effects that have actually occurred in real people at specific ozone levels. Regardless of whether a standard even lower than the ozone levels observed in these studies is warranted, EPA cannot set the NAAQS at a level where there is actual data showing adverse effects. *See, e.g.*, *CBR*, 604 F.3d at 618.

Finally, EPA fails to defend the premise for its uncertainty rationale: namely, that only the chamber studies at 0.080 ppm provided credible evidence of causation. Not only is that premise vitiated by the Staff Paper findings of likely

causation at 0.060 ppm, but the agency has no answer to the findings of CASAC, the Criteria Document, and the nation's leading medical societies, Br. 26-27, that chamber studies are not the only evidence of causation, and that epidemiological studies are probative of ozone's causation of impacts beyond those shown in chamber studies. Indeed, EPA itself has set NAAQS based on epidemiological studies where there were no adequate chamber studies at all. *ATA*, 283 F.3d at 365-72. EPA asserts (at 102-03) that in such cases it also relied on other evidence, but the same kinds of evidence were available here too, and the Criteria Document and Staff Paper found that evidence supported finding that ozone caused the adverse effects shown in the epidemiological studies. 1 EPA 600/R-05/004aF 7-175 to -177, JA0586-88; SP 3-73, JA0824.

3. EPA Arbitrarily Disregarded Adverse Effects Shown in the Risk and Exposure Assessments at Ozone Levels Below 0.075 ppm.

EPA's sole defense (at 103-05) for discounting the findings of its risk and exposure assessments at ozone levels below 0.075 ppm—uncertainty—is refuted above. Further, EPA's narrow focus (at 104) on the Adams studies as the sole basis for determining whether ozone levels below 0.075 ppm cause lung function decrements and respiratory symptoms irrationally ignores the statistically significant epidemiological studies finding precisely these outcomes at levels

below 0.075 ppm. Br. 23 tbl.1 (listing studies by Brauer, Mortimer, Delfino, and Ross).[5]

Unlike in *ATA* and *Farm Bureau* (relied on by EPA at 104-05), EPA has pointed to no technical aspect of the risk assessment itself that makes its prediction of adverse impacts less credible at levels below 0.075 ppm. *See Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 527-28 (D.C. Cir. 2009); *ATA*, 283 F.3d at 373-74. Instead, EPA agrees (at 26-27) that the assessments here were well done, underestimate impacts, and leave out unquantified but important health outcomes. CASAC and EPA staff likewise found the assessments credible. CASAC 10-24-06 Letter 12, JA1342; SP 4-13, 4-41, JA0867, 0884.

Finally, EPA contends irrationally and without explanation that a standard of 0.070 would provide no "'appreciably different'" protection than would a 0.075 ppm standard against exposures to various levels of ozone. EPA Br. 91 (quoting 73 Fed. Reg. 16,482/2). *But see* Br. 34-35. But why do 50,000 more children

[5] EPA's lawyers wrongly imply (at 104) that the epidemiological studies were "subject to the same uncertainties" as the Adams studies, but the agency itself never so found. To the contrary, on the page the lawyers cite, EPA says that thanks to numerous new studies, "confidence in the causal relationships between short-term exposures to [ozone] and various health effects reported in epidemiological studies has increased markedly since 1997." 73 Fed. Reg. 16,467/2, JA0134. EPA noted that the risk estimates should be "considered in the light of uncertainties about whether…effects occur at very low [ozone]" levels, but did not specify what levels it meant, much less find any uncertainties were so great as to justify refusal to protect against such effects. *Id.*, JA0134.

exposed to 0.080 ppm ozone, 500,000 more to 0.070, and over 1.5 million more to 0.060 with a 0.075 standard than with a 0.070 standard not amount to an "appreciabl[e] differen[ce]"?[6] *See* 72 Fed. Reg. 37,855 tbl.1, JA0038; *see also American Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998) ("Why are from 180,000 to 395,000 annual 'exposure events'…or some fewer number…so 'infrequent' as to warrant no regulatory action?"). The assertion is particularly irrational given the strengths of the exposure model and EPA's "recogni[tion] that national-scale public health impacts of ambient [ozone] exposures would be much larger than" those shown in the exposure assessment, 73 Fed. Reg. 16,447/1, JA0114.

4. EPA Failed to Rationally Justify Its Decision in Light of the Totality of Evidence and CASAC's Unanimous Recommendation for a Stronger Standard.

EPA's only stated rationale for rejecting CASAC's unanimous recommendation for a standard between 0.060 and 0.070 ppm was that CASAC allegedly placed more weight on the Adams studies and risk assessment. That rationale arbitrarily ignored—and failed to refute—CASAC's express reliance on the whole panoply of evidence in recommending a standard between 0.060 and

[6] For asthmatic children, the respective figures are 10,000, 70,000, and 240,000. 72 Fed. Reg. 37,855 tbl.1, JA0038.

0.070 ppm. Dkt-0102 ("CASAC 3-26-07 Letter") 2, JA1444; CASAC 10-24-06 Letter 3-5, JA1333-35. CASAC nowhere stated or suggested that the Adams studies were more important than the other evidence, as EPA wrongly implies (at 117). Nor did EPA itself anywhere say (as suggested at EPA Br. 105, 118) that it viewed the evidence overall to be more uncertain than CASAC.[7] Indeed, EPA did not address CASAC's reading of the evidence as a whole at all. The agency failed to explain, for example, why CASAC was wrong in finding that the extensive information compiled in the Criteria Document and Staff Paper provided "overwhelming scientific evidence" in support of the 0.060-0.070 ppm range, or that the hospitalizations, emergency room visits, increased medication use, and deaths shown in the "broad range" of studies were important indicators of adverse effects. CASAC 3-26-07 Letter 2, JA1444; CASAC 10-24-06 Letter 4, JA1334. EPA's failure to rationally explain its departure from CASAC's recommendations renders its action unlawful and arbitrary. 42 U.S.C. §7607(d)(3), (d)(6)(A); *see*

[7] Equally groundless is EPA's claim (at 118) that CASAC recommended a range between 0.060 and 0.070 "based on uncertainties in the data." CASAC itself nowhere so stated.

Farm Bureau, 559 F.3d at 539 (relying on CASAC advice in reviewing EPA NAAQS decision); *ATA*, 283 F.3d at 378-79 (same).[8]

Nor did EPA otherwise conduct a reasoned evaluation of the evidence as a whole, as its lawyers assert. The agency's rationale for rejecting stronger standards focused on only two allegedly dispositive factors: the claimed lack of a "continuum" of health risks below 0.080 ppm and EPA's unwillingness to assume that health effects shown in the epidemiological studies are causally related to ozone at levels "well below" 0.080. 73 Fed. Reg. 16,483/2, JA0150. Not only does this rationale fail to confront all the evidence collectively (including the Adams, epidemiological, and toxicological studies, and the risk and exposure assessments), but it is arbitrary for reasons explained in Petitioners' opening brief (at 31-33). Indeed, EPA's brief does not even try to defend the "continuum" rationale that the agency itself identified as crucial to its decision.

B. EPA Illegally and Arbitrarily Failed to Provide an Adequate Margin of Safety.

EPA's lawyers suggest (at 106) the agency accounted for the margin of safety throughout the NAAQS-setting process, but EPA itself never so stated. The

[8] Although *Farm Bureau* accepted EPA's disagreement with CASAC on one detail, EPA Br. 115, the Court found the agency failed to rationally explain its rejection of CASAC's overall advice on the standard's level. 559 F.3d at 521.

agency offered *only* a bare assertion that its chosen standard would provide an adequate margin of safety without explaining how or why. 73 Fed. Reg. 16,483/1-2, JA0150. Although EPA can choose a reasonable method to provide for a margin of safety, it must explain how it did so, and provide a rational explanation "of why [it] chose one method rather than another." *Lead Indus.*, 647 F.2d at 1161-62.

Moreover, the lawyers' invented explanation is belied by the agency's repeated choices at key junctures in setting the level to err on the side of providing less protection. EPA effectively discounted the Adams studies' results based on their being "limited." Relying on a vague claim of "increasing uncertainty," it disregarded more than a dozen epidemiological studies showing statistically significant associations between adverse effects and ozone below 0.075. And choosing between two levels it found provided no "appreciably different" public health protection, it selected the less protective one. By making these choices, EPA effectively read the "margin of safety" language out of the Act, for it has not shown how it would have set the standard any differently in its absence.

Far from demanding protection against "*all* possible risks, no matter how much uncertainty attends them," EPA Br. 110 (emphasis in original), Petitioners argue that EPA must set NAAQS that incorporate an adequate margin of safety to

address uncertain risks, erring on the side of safety, and that EPA must explain rationally how it has done so.

II. EPA'S SECONDARY STANDARD IS UNLAWFUL AND ARBITRARY.

EPA flouted Clean Air Act §109(b)(2) and the holding in *Farm Bureau* by failing to specify the levels of vegetation protection and air quality requisite to protect public welfare. 559 F.3d at 529-30. The agency's lawyers assert (at 122) that EPA identified 21 ppm-hours as "a target level of protection," but the Administrator merely said he "focused his consideration" on that level. 73 Fed. Reg. 16,499-500, JA0166-67. He did not identify a requisite level of vegetation protection, much less determine that 21 ppm-hours was "a level…requisite to protect the public welfare from any known or anticipated adverse effects," as §109(b)(2) requires. 42 U.S.C. §7409(b)(2). EPA (at 129) apparently disagrees with reading *Farm Bureau* as holding the agency must identify a requisite level of protection for the welfare values at issue, but that is precisely what the decision says, and what the statute requires. 559 F.3d at 530 ("EPA's assertion that it need not determine what level of visibility protection is requisite to protect the public welfare fails under the plain language of the statute").[9]

[9] EPA asserts (at 129) that it should not have to identify a "separate" requisite level of protection for "each" welfare effect considered, but the claim is irrelevant, as

footnote continued on next page…

Beyond violating the statute, EPA's action on the secondary standard lacks any reasoned basis. The agency does not dispute that it *agreed* with comments that the proposed primary standards were *not* requisite to protect against adverse welfare effects on vegetation. Br. 37-38. EPA cites alleged uncertainties in the evidence, but uncertainty does not excuse its failure to identify a requisite level of protection. *Farm Bureau*, 559 F.3d at 529-30. Moreover, EPA fails to show why uncertainties precluded it from identifying a requisite cumulative standard when its own staff, CASAC, and the National Park Service recommended specific ranges and relevant factors for decision using the same evidence. *See Massachusetts*, 549 U.S. at 534; *State Farm*, 463 U.S. at 52. Contrary to assertions by EPA's lawyers (at 123), the agency itself never explained why it rejected CASAC's advice, but merely said that a cumulative seasonal standard "may be more than necessary" due to alleged uncertainties. 73 Fed. Reg. 16,500/1-2, JA0167. Nowhere did EPA address CASAC's specific and unequivocal findings that protection of vegetation "*requires*" a cumulative seasonal standard, that the primary standard was "not *appropriate*" as the secondary standard, that a cumulative standard would be "*far more effective*," and that a range of 7.5-15 ppm-hours was warranted based on the

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…footnote continued
here the agency did not identify *any* requisite level of protection for *any* welfare effect.

evidence. CASAC 3-26-07 Letter 3 (emphasis in original), JA1445; CASAC 10-24-06 Letter 7 (same), JA1337.

CONCLUSION

Petitioners respectfully request that this Court grant the relief sought in their opening brief on the grounds stated therein and above.[10]

DATED: August 27, 2012

Respectfully submitted,

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[10] Petitioners also concur in the reasons presented by New York et al. for finding the NAAQS arbitrary and unlawful.

CERTIFICATE REGARDING WORD LIMITATION

Counsel hereby certifies, in accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), that the foregoing Final Reply Brief for Environmental Petitioners contains 4,455 words, as counted by counsel's word processing system, and thus complies with the applicable word limit established by the Court.

DATED: August 27, 2012

/s/ David S. Baron
David S. Baron

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of August, 2012 I have served the foregoing **Final Reply Brief for Environmental Petitioners** on all registered counsel through the Court's electronic filing system (ECF).

/s/ David S. Baron
David S. Baron