

No. 13-1235

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**In the Supreme Court of the United States**

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UTILITY AIR REGULATORY GROUP, PETITIONER

*v.*

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

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*ON PETITION FOR A WRIT OF CERTIORARI  
TO THE UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT*

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**BRIEF FOR THE FEDERAL RESPONDENT  
IN OPPOSITION**

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## QUESTIONS PRESENTED

1. Whether the court of appeals applied the correct standard of review when it upheld the determination of the Environmental Protection Agency (EPA) that a National Ambient Air Quality Standard for ozone at a level of 0.075 parts per million is “requisite to protect the public health,” “allowing an adequate margin of safety.” 42 U.S.C. 7409(b)(1) and (d)(1).

2. Whether the EPA, in conducting the statutorily-required reassessment of the ozone standard, 42 U.S.C. 7409(d), 7408(a)(2), adequately explained the reasons underlying its decision to revise the standard.

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**OPINIONS BELOW**

The opinion of the court of appeals (Pet. App. 1a-55a) is reported at 744 F.3d 1334. The final rule of the Environmental Protection Agency (excerpted at Pet. App. 56a-289a) is published at 73 Fed. Reg. 16,436.

**JURISDICTION**

The judgment of the court of appeals was entered on July 23, 2013. An order of the court partially granting and partially denying panel rehearing and entering an amended opinion was entered on December 11, 2013 (Pet. App. 290a-291a). On March 3, 2014, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including April 10, 2014, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

1. Under the Clean Air Act (CAA or Act), 42 U.S.C. 7401 *et. seq.*, the Environmental Protection Agency (EPA) has developed a list of pollutants that cause or contribute to air pollution that “may reasonably be anticipated to endanger public health or welfare.” 42 U.S.C. 7408(a)(1)(A). For each such pollutant, the EPA must promulgate “national \* \* \* ambient air quality standards” (NAAQS) sufficient to protect public health and welfare. As relevant here, the Act directs the EPA to establish “primary” NAAQS, which are “ambient air quality standards the attainment and maintenance of which in the judgment of the [EPA] Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.” 42 U.S.C. 7409(b)(1); see 42 U.S.C. 7408 (governing air quality criteria).<sup>1</sup>

To ensure that the NAAQS will keep pace with advances in science, Congress also required the EPA to “complete a thorough review” of each standard at least once every five years. 42 U.S.C. 7409(d)(1). Based on that review, the EPA must consider the “latest scientific knowledge” and revise the NAAQS as “appropriate in accordance with” its obligation to set the standard at a level “requisite to protect the public health” with an “adequate margin of safety.” 42 U.S.C. 7408(a)(2), 7409(b)(1) and (d)(1). In conducting its “thorough review” of the NAAQS, the EPA must

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<sup>1</sup> “Secondary” NAAQS must be set at a level that is “requisite to protect the public welfare,” 42 U.S.C. 7409(b)(2), which includes effects on vegetation and wildlife, 42 U.S.C. 7602(h). The court of appeals in this case remanded the secondary standard for ozone to the EPA, see Pet. App. 48a-55a, and that standard is not at issue here.

consider, and explain any significant departure from, the recommendations of the Clean Air Scientific Advisory Committee (CASAC), an independent committee that was established specifically to advise the EPA on air quality criteria and NAAQS. 42 U.S.C. 7409(d)(1) and (2)(B), 7607(d)(3); see *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 469-470 & n.2 (2001).

2. This case concerns the revised primary standard for ozone, a powerful photochemical oxidant and the principal component of smog. See *American Petroleum Inst. v. Costle*, 665 F.2d 1176, 1181 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982). Ozone is associated with several adverse health effects, including decreased lung function, increased respiratory symptoms, emergency department visits, hospital admissions, and increased premature mortality. Pet. App. 60a-61a. Those most at risk of these adverse health effects include people with asthma and other lung diseases, children, older adults, and outdoor workers. *Id.* at 214a.

a. The EPA first promulgated NAAQS for photochemical oxidants in 1971 and revised them in 1979, using ozone as the indicator for photochemical oxidants. 36 Fed. Reg. 8186 (Apr. 30, 1971); 44 Fed. Reg. 8202 (Feb. 8, 1979).

The EPA next revised the ozone NAAQS in 1997. 62 Fed. Reg. 38,856, 38,873 (July 18, 1997). As part of that revision, the EPA effectively lowered the primary ozone NAAQS to 0.08 parts per million (ppm) over an eight-hour averaging time. In establishing this more protective NAAQS, the EPA reviewed clinical studies, epidemiological studies, toxicological studies, an exposure analysis, a quantitative risk assessment, other data, and the recommendations of the CASAC. Pet.

App. 236a, 239a-240a. Based on the totality of the evidence, the EPA concluded that ozone causes adverse health effects at concentrations as low as 0.08 ppm over an eight-hour exposure, and the agency set the NAAQS accordingly. 62 Fed. Reg. 38,859, 38,873 (July 18, 1997).

On a petition for review, the court of appeals decided that the EPA's interpretation of the CAA created an unconstitutional delegation of congressional power because there was no "determinate criterion" for setting the NAAQS. *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1034 (D.C. Cir. 1999), rev'd in part, 531 U.S. 457 (2001). This Court reversed, holding that the CAA provided an "intelligible principle" to guide the EPA in exercising its "judgment"—namely, that NAAQS must be "requisite," meaning "sufficient, but not more than necessary." *Whitman*, 531 U.S. at 473-474.

On remand from this Court, the court of appeals determined that the EPA had not "abused its discretion" in setting the level of the primary ozone NAAQS at 0.08 ppm. *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 363-364 (D.C. Cir. 2002) (*ATA III*). The court found particularly noteworthy both the "absence of *any* human clinical studies" on ozone concentrations below 0.08 ppm and the consensus of CASAC members that a standard lower than 0.08 ppm was not needed. *Id.* at 379.

b. In 2000, the EPA began its statutorily-required review of the 1997 ozone NAAQS by issuing a call for new scientific information. Pet App. 65a. In response, the EPA received strong new clinical evidence that healthy people exposed to ozone at concentrations as low as 0.08 ppm would experience adverse respiratory

effects, as well as substantial clinical and epidemiological evidence that sensitive populations, such as people with asthma, “are likely to experience larger and more serious effects” than healthy people. *Id.* at 238a, 184a, 213a-214a. Two new clinical studies provided “important” but “limited” evidence of adverse health effects on healthy adults at 0.06 ppm. *Id.* at 98a, 214a. Epidemiological evidence also associated ozone exposure with serious health effects, including hospital admissions and premature mortality at concentrations of 0.08 ppm and below. *Id.* at 238a. In addition, toxicological and other studies identified biologically plausible mechanisms by which ozone may impact not just the respiratory system, but the cardiovascular system as well. *Id.* at 163a, 104a.

In light of the new scientific evidence, CASAC members unanimously advised the EPA that there was “no scientific justification for retaining” the 0.08 ppm primary ozone standard, and that the standard needed to be “substantially reduced to protect human health, particularly in sensitive populations.” Pet. App. 117a.

In addition to the scientific studies and CASAC recommendations, the EPA prepared and considered an exposure analysis and a quantitative risk assessment. An exposure analysis is a scientific model that estimates the exposure of subpopulations to ozone, given their geographic location and breathing rates, among other variables. Pet. App. 83a-84a. The results of the exposure analysis are put into a risk assessment, which is another model that estimates the distribution of potential adverse health effects, given many assumptions about how adversely different subpopulations will respond to ozone at different con-

centrations. *Id.* at 81a-82a. For example, the risk assessment for the 2008 review projected, *inter alia*, that respiratory illness cases per 100,000 relevant population gradually decreased from 6.4 cases at 0.084 ppm to 4.6 cases at 0.064 ppm under certain circumstances. 72 Fed. Reg. 37,860-37,861 (July 11, 2007). The EPA described the evidence supporting its assumptions on the adverse health effects of ozone as generally stronger than in the 1997 review, but the agency recognized that there were still “important limitations and uncertainties” in the simulations. Pet. App. 201a. The EPA balanced these limitations and uncertainties by weighing the risk assessment alongside all the other scientific evidence available. *Id.* at 184a, 194a-195a, 213a-214a, 238a.

The EPA had also conducted a risk assessment for the 1997 NAAQS revision. Pet. App. 195a. With new scientific knowledge, the EPA revised its simulation for 2008; the 2008 risk assessment studied different subpopulation groups in different geographic areas, using a wider range of annual air quality data, and projected additional health endpoints compared to the 1997 risk assessment. *Id.* at 195a-196a. The EPA explained that it had not performed a quantitative comparison of the 1997 and 2008 risk assessments for three reasons: (i) it would be “factually inappropriate” to compare models with different inputs and outputs, especially when “the 1997 estimates reflect outdated analyses that have been updated \* \* \* to reflect the current science”; (ii) such a comparison would fail to recognize that the “increased certainty” of risks in 2008 gave rise to “greater concern”; and (iii) such a comparison would not convey the results of the “integrative assessment” of all of the available

evidence that the EPA had conducted. *Id.* at 194a-195a.

Weighing the full body of evidence, the EPA concluded that the 0.08 ppm standard was no longer “requisite to protect public health with an adequate margin of safety.” Pet. App. 219a. The EPA had a “high degree of certainty” that exposure to ozone concentrations as low as 0.08 ppm caused adverse health effects even in healthy people, and it concluded that the standard should be set “appreciably below” that level to protect sensitive populations. *Id.* at 239a, 256a. The EPA also considered new, albeit limited, evidence of the adverse health effects of ozone at levels below 0.08 ppm. *Id.* at 237a, 125a. Taking into account the “strengths and limitations of the evidence,” *id.* at 266a, the EPA “judge[d] that the appropriate balance” was to set the primary ozone NAAQS at a level of 0.075 ppm. *Id.* at 268a-269a. The EPA concluded that this revised NAAQS was “neither more nor less stringent than necessary.” *Id.* at 269a.

c. Petitioner, along with other industry groups and the State of Mississippi, filed a petition for review challenging the 0.075 ppm standard as overly stringent. Pet. App. 12a. Environmental and public health groups and a collection of 13 other States also filed petitions for review, contending that the standard was not stringent enough. *Ibid.* The court of appeals denied the petitions in relevant part. *Id.* at 13a-48a.

The court of appeals observed that “[t]he Clean Air Act requires EPA to set primary NAAQS that are ‘requisite’ to protect the public health with an adequate margin of safety.” Pet. App. 13a (quoting 42 U.S.C. 7409(b)(1)). The court further observed that “[r]equisite’ means the NAAQS must be ‘sufficient, but not

more than necessary.” *Ibid.* (quoting *Whitman*, 531 U.S. at 473).

The court of appeals rejected the contention that the EPA “cannot determine why further risk reduction is ‘requisite’ without ‘putting risk in the context of earlier NAAQS decisions (and other risk-based decisions).” Pet. App. 14a (citation omitted). The court acknowledged 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.” *Ibid.* (quoting *Whitman*, 531 U.S. at 494-495 (Breyer, J., concurring in part and concurring in the judgment)). The court explained, however, that this “does not mean the initial assessment is sacrosanct and remains the governing standard until every aspect of it is undermined.” *Ibid.*

Instead, the court of appeals explained, the EPA must review a NAAQS in light of “contemporary policy judgments and the existing corpus of scientific knowledge.” Pet. App. 14a-15a. In any subsequent challenge to the NAAQS, a reviewing court must decide whether the EPA has reasonably determined that its proposed NAAQS “is ‘requisite,’” not whether “the prior NAAQS once was ‘requisite’ but is no longer up to the task.” *Ibid.* In conducting such review, courts “apply the same highly deferential standard of review that [they] use under the Administrative Procedure Act.” *Id.* at 12a (quoting *ATA III*, 283 F.3d at 362).

Applying that standard, the court of appeals held that the EPA had not acted arbitrarily or capriciously by determining that a primary ozone NAAQS at 0.075 ppm was “requisite.” Pet. App. 15a. The court explained that the EPA had amassed a “broad array” of evidence, including “numerous epidemiological studies

linking health effects to exposure to ozone levels below 0.08 ppm and clinical human exposure studies finding a causal relationship between health effects and exposure to ozone levels at and below 0.08 ppm.” *Id.* at 18a-19a. The court also noted that the CASAC had “unanimously concluded that ‘[t]here is no scientific justification for retaining the current primary 8-hr NAAQS of 0.08 parts per million,’ [and] that the primary NAAQS ‘needs to be substantially reduced to protect human health.’” *Id.* at 19a (citation omitted). Finding that the EPA had appropriately “evaluated the evidence as a whole,” the court upheld as reasonable the agency’s determination that the previous NAAQS was “insufficiently protective of public health.” *Id.* at 18a-20a.

The court of appeals also determined that the EPA had “reasonably explained how the scientific evidence” underlying the 2008 primary ozone NAAQS “had in fact changed since the 1997 review.” Pet. App. 15a; see *id.* at 18a (“[A]fter reviewing the record, we think it quite clear EPA’s rejection of the 1997 NAAQS was proper.”). As an example, the court compared the lack of “any human clinical studies at ozone concentrations below 0.08” in 1997 with the two new such studies in the 2008 review documenting adverse health effects at considerably lower ozone levels. *Id.* at 15a (emphasis omitted).

The court of appeals rejected the contention that the EPA was required to conduct a quantitative comparison of the 1997 risk assessment with the 2008 risk assessment. Pet. App. 16a n.1. The court explained that such a requirement would force the EPA to compare “apples and oranges,” since the two risk assessments had analyzed different health effects and had

used different geographic and demographic parameters. *Ibid.* (noting that, because “the 2008 risk assessment analyzed a number of health effects not included in the 1997 risk assessment, \* \* \* the ultimate value of comparing the two assessments would be limited”). In addition, the court explained, a comparison of the risk assessments would be of limited utility because the EPA’s final decision was based on “much more than just the risk assessment.” *Ibid.*

Just as it rejected the contention that the NAAQS was too stringent, the court of appeals rejected the argument by environmental and state-government parties that the standard was “too lax.” Pet. App. 26a; see *id.* at 26a-48a.<sup>2</sup>

#### ARGUMENT

Applying the familiar “arbitrary and capricious” standard that generally governs judicial review of federal agency action, the court of appeals correctly upheld the EPA’s determination that a primary ozone standard of 0.075 ppm is “requisite to protect the public health,” “allowing an adequate margin of safety,” 42 U.S.C. 7409(b)(1). The court’s decision does not conflict with any decision of this Court or of another court of appeals. Further review is not warranted.

1. The court of appeals applied the correct standard of review when it held that the EPA had reasona-

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<sup>2</sup> In a separate case, the EPA has been ordered to issue a notice of proposed rulemaking reviewing the ozone NAAQS at issue here no later than December 1, 2014, and to issue a final rule on that NAAQS no later than October 1, 2015. See Order Granting Plaintiffs’ Mot. for Summ. J. and Denying Def’s Mot. for Summ. J., *Sierra Club v. EPA*, No. 13-cv-2809-YGR (N.D. Cal. Apr. 30, 2014).

bly explained why a primary ozone NAAQS of 0.075 ppm was “requisite.” Pet. App. 13a-26a.

a. Challenges to EPA rulemakings are governed by familiar standards of judicial review of agency action. As relevant here, a court may vacate an EPA rule if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 42 U.S.C. 7607(d)(9)(A); see *Whitman v. American Trucking Ass’ns*, 531 U.S. 457, 476 (2001) (directing the court of appeals to apply this standard to review preserved challenges to NAAQS on remand). “Review under the arbitrary and capricious standard is deferential.” *National Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007). A court “will not vacate an agency’s decision unless it ‘has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.’” *Ibid.* (quoting *Motor Vehicle Mfrs. Ass’n of the United States v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

The court of appeals’ case-specific application of those established administrative-law principles to a particular NAAQS, see Pet. App. 13a-26a, does not warrant this Court’s review.

b. In any event, the record evidence amply supported the EPA’s decision that a NAAQS of 0.075 ppm was “requisite to protect the public health,” “allowing an adequate margin of safety.” 42 U.S.C. 7409(b)(1). The agency reasonably explained the conclusions it had drawn from the available evidence concerning the

adverse effects of ozone on public health; the ways in which it had accounted for sensitive populations; its basis for determining that a level of 0.08 ppm was no longer “requisite”; and the reasons that the 0.075 ppm level satisfied the statutory mandate. Pet. App. 219a, 238a, 269a.

Petitioner contends that reduced uncertainty about adverse health effects of ozone “alone and in isolation cannot justify revision of a NAAQS.” Pet. 17. In making that argument, petitioner disregards the rationale for the EPA’s decision. Petitioner ignores the “numerous epidemiological studies linking health effects to exposure to ozone levels below 0.08 ppm and clinical human exposure studies finding a causal relationship between health effects and exposure to ozone levels at and below 0.08 ppm,” which the court of appeals found supported the EPA’s decision. Pet. App. 19a. Petitioner also ignores new evidence of more serious health effects from exposure to ozone, especially on at-risk populations. See *id.* at 238a.

In any event, reduced scientific uncertainty is a permissible basis for the EPA to revise a NAAQS. In his concurrence in *Whitman*, Justice Breyer identified scientific uncertainty as a driving force behind the EPA’s statutory obligation to “allow[] an adequate margin of safety” to “protect the public health”: “The [CAA]’s words \* \* \* authorize the Administrator to consider the severity of a pollutant’s potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate.” *Whitman*, 531 U.S. at 495 (quoting 42 U.S.C. 7409(b)(1)). In adopting the NAAQS at issue here, the EPA reasonably explained that the increased certainty of ad-

verse health effects associated with ozone justified greater protection of public health. Pet. App. 18a-19a.

c. Petitioner contends that the court of appeals abandoned the “*Whitman* standard” in reviewing the EPA’s decision. Pet. 13-14. That argument conflates the standard the CAA requires the EPA to apply in setting the NAAQS with the standard of review courts apply in reviewing any resulting agency determination.

In *Whitman*, this Court considered, *inter alia*, whether Section 7409(b)(1) constitutes an unconstitutional delegation of legislative power to the EPA. See 531 U.S. at 462. In holding that it does not, the Court interpreted the CAA to require the EPA to “set air quality standards at the level that is ‘requisite’—that is, not lower or higher than is necessary—to protect the public health with an adequate margin of safety.” *Id.* at 475-476.

Here too, the court of appeals recognized that the EPA’s responsibility was to set a NAAQS that was “sufficient but not more than necessary.” Pet. App. 13a (quoting *Whitman*, 531 U.S. at 473); accord *Center for Biological Diversity v. EPA*, No. 12-1238, 2014 WL 2178785, at \*6 (D.C. Cir. May 27, 2014) (“The phrase ‘requisite to protect’ means that a \* \* \* standard must be neither higher nor lower than necessary.”) (citing *Whitman*, 531 U.S. at 473, 475-476). The EPA specifically determined that the 0.075 ppm standard was “neither more nor less stringent than necessary.” Pet. App. 269a. The question for the court of appeals, however, was not whether the revised NAAQS was *in fact* neither more nor less stringent than necessary to protect the public health, but

whether the agency had acted reasonably in so concluding. See, e.g., *id.* at 12a-13a, 19a, 26a, 28a.

Although the Court in *Whitman* held that the *EPA* must set the NAAQS no lower or higher than necessary, the decision did not suggest that *courts* should abandon their ordinary standards of review of administrative action when evaluating a newly-promulgated NAAQS. *Whitman*, 531 U.S. at 475. To the contrary, the Court in *Whitman* specifically directed the court of appeals on remand to review the remaining, non-constitutional challenges under the “arbitrary and capricious” standard of review. *Id.* at 476 (citing 42 U.S.C. 7607(d)(9)). On remand in *Whitman*, the court of appeals asked whether the EPA had abused its discretion. *American Trucking Ass’ns v. EPA*, 283 F.3d 355, 362-364 (D.C. Cir. 2002); see *id.* at 364 (explaining that “the search for a binding principle guiding Agency policy judgments differs in kind and degree from the familiar administrative law inquiry into whether an agency abused its discretion”). The court of appeals in this case correctly applied the same standard of review when it upheld the challenged NAAQS on the ground that the agency’s decision was “rational.” Pet. App. 26a (citation omitted).

2. Petitioner contends (Pet. 22) that the EPA failed to explain its departure from a previous “fact-based policy decision,” namely the 1997 NAAQS. That case-specific challenge does not warrant further review.

In any event, petitioner’s argument lacks merit. When an agency changes its position, it “need not demonstrate to a court’s satisfaction that the reasons for the new policy are *better* than the reasons for the old one,” but instead must only “provide reasoned explanation for its action.” *FCC v. Fox Television*

*Stations, Inc.*, 556 U.S. 502, 515 (2009). Assuming *arguendo* that this standard applies to the statutorily-mandated periodic NAAQS review, the EPA satisfied it here.

The EPA relied on numerous new studies that linked ozone to adverse health effects, demonstrated the sensitivity of at-risk populations, and showed adverse health effects at concentrations lower than the previous standard. Pet. App. 238a. The EPA also considered a risk assessment created using a revised methodology that projected adverse health effects on different subpopulations in areas different from those studied before. *Id.* at 195a-196a. The EPA detailed how the full body of evidence had led the agency to conclude that a more protective standard was warranted because the previous standard was no longer “requisite” to protect the public health with an “adequate margin of safety.” *Id.* at 219a. The agency also noted that its decision to revise the standard was consistent with the unanimous scientific advice of CASAC that the previous NAAQS did not afford adequate public health protection. *Id.* at 215a. The court of appeals in turn held that the “EPA reasonably explained how the scientific evidence had in fact changed since the 1997 review.” *Id.* at 15a; see *id.* at 15a-16a (discussing “new controlled human-exposure studies”).

In any event, the CAA itself mandates periodic re-assessment of NAAQS, and it makes clear that prior determinations are not entitled to any presumption of ongoing validity. See generally Pet. App. 14a-15a; *National Ass’n of Mfrs. v. EPA*, No. 13-1069, 2014 WL 1851919, at \*3 (D.C. Cir. May 9, 2014). In particular, the statute requires the EPA to conduct a “thor-

ough review” of existing NAAQS every five years, 42 U.S.C. 7409(d)(1) (cross-referencing 42 U.S.C. 7408), and to base any resulting revised NAAQS on the same standard for evidence used when originally promulgating a NAAQS, *i.e.*, “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air,” 42 U.S.C. 7408(a)(2). When the EPA conducts the required *de novo* review and concludes that adoption of a revised NAAQS is appropriate, the agency is not “chang[ing] course” within the meaning of ordinary administrative law principles (Pet. 21), but is instead fulfilling its obligation to make a new determination based on current scientific information.

#### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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