No. 12-510

In the Supreme Court of the United States

ASARCO LLC, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

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

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably concluded that a maximum concentration of sulfur dioxide of 75 parts per billion over a 1-hour period is "requisite to protect the public health," "allowing an adequate margin of safety," within the meaning of the Clean Air Act, 42 U.S.C. 7409(b)(1).

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1-22) is reported at 686 F.3d 803.

JURISDICTION

The judgment of the court of appeals was entered on July 20, 2012. The petition for a writ of certiorari was filed on October 18, 2012. 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 United States 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 pollu-

tant, the EPA must promulgate "national * * * ambient air quality standards" (NAAQS) sufficient to protect public health and welfare. 42 U.S.C. 7409(b). 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 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). States then enforce these standards through implementation plans. 42 U.S.C. 7407(a), 7410(a)(2)(A) and (C). In establishing the primary standards, the EPA may not consider the financial costs of compliance. See *Whitman* v. *American Trucking Ass'ns, Inc.*, 531 U.S. 457, 471 (2001).

To ensure that NAAQS will keep pace with advances in scientific knowledge, Congress also required the EPA to review each standard at least once every five years and to revise it as appropriate. 42 U.S.C. 7409(d)(1). In conducting that review, the EPA must consider, and explain any significant departure from, the recommendations of the Clean Air Scientific Advisory Committee, an independent committee established by Congress specifically to advise the Administrator on air quality criteria and NAAQS. 42 U.S.C. 7409(d)(2)(B), 7607(d)(3); see *Whitman*, 531 U.S. at 469-470.

2. This case concerns the revised standard for sulfur dioxide (often referred to by its chemical abbreviation SO_2), "[a] highly reactive colorless gas smelling like rotten eggs, [that] * * * derives primarily from fossil fuel combustion." *American Lung Ass'n* v. *EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). Although it is "[b]est known for causing 'acid rain,' at elevated concentrations in the ambient air" sulfur dioxide "also directly impairs

human health." *Ibid.* Sulfur dioxide can affect healthy people at "concentrations above 2.0 parts per million" (ppm), but "below 2.0 ppm, it primarily affects people with asthma," who make up approximately 4% of the United States population. *Ibid.*

a. The EPA first promulgated a primary standard for sulfur dioxide in 1971. 36 Fed. Reg. 8186, 8187 (Apr. 30, 1971). That standard limited the average concentration of sulfur dioxide over a 24-hour period to 140 parts per billion (ppb) and the average concentration over a year to 30 ppb. See Pet. App. 5.

In 1996, after conducting its periodic reassessment of that standard, the EPA determined that there was no need to revise it. 61 Fed. Reg. 25,566 (May 22, 1996). On judicial review, however, the D.C. Circuit held that the agency had failed to adequately explain the basis for its decision. *American Lung Ass'n*, 134 F.3d at 391-393. In particular, the court found that the agency had not fully explained why "high-level SO_2 bursts"—"emissions of 0.50 ppm or more lasting at least five minutes" and typically emanating from power utilities and other industrial facilities—did not pose a public-health problem in light of the exposure of thousands of asthmatics to multiple such bursts each year. *Id.* at 390-393. It therefore remanded to the agency "to permit the Administrator to explain her conclusions more fully." *Id.* at 393. It cautioned that, although the relevant CAA provisions give the EPA "broad discretion to establish an 'adequate margin of safety' above and beyond what scientific certainty prescribes and to craft regulations that protect against unknown harms, * * * they do not necessarily establish the converse proposition—that the Administrator may decline to establish a margin of safety in the face of documented adverse health effects." *Ibid.*

b. In the rulemaking at issue in this case, the EPA addressed the deficiency identified by the D.C. Circuit in *American Lung Association* by establishing a new primary standard, with a 1-hour averaging time, that better protects public health against short-term sulfur dioxide exposures. Pet. App. 106 n.14, 109-120.

In developing the revised standard, the agency reviewed a large body of evidence, including two types of human health studies that had evaluated the effects of exposure to sulfur dioxide concentrations on public health. Pet. App. 7-9. The first were epidemiologic studies, in which ambient concentrations of sulfur dioxide were compared with indications of mortality or morbidity, such as emergency-room visits or hospital admissions. See *id.* at 8. The second were clinical studies, in which subjects with mild to moderate asthma were exposed to low concentrations of sulfur dioxide for 5 to 10 minutes while engaging in moderate exercise and were then evaluated for respiratory symptoms and changes in lung functions. See *id.* at 8-9.

Based on the totality of the evidence, the EPA concluded that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term exposure to sulfur dioxide (*i.e.*, exposure for a period ranging from 5 minutes to 24 hours). Pet. App. 52-53. The EPA cited in particular "the consistency, coherence, and plausibility of findings observed in controlled human exposure studies of 5-10 minutes, epidemiologic studies mostly using 1-hour daily maximum and 24-hour average SO_2 concentrations, and animal toxicological studies using exposures of minutes to hours." *Id.* at 53. In addition, the Clean Air Scientific Advisory Committee, whose conclusions the EPA is required by law to take into account, found that there was a causal

relationship between respiratory morbidity and short-term exposure to sulfur dioxide. *Id.* at 86-87.

The EPA placed significant weight on the epidemiologic studies. Those studies demonstrated that, in locations in compliance with the 1971 sulfur dioxide standard, there were positive associations between ambient sulfur dioxide concentrations and respiratory symptoms in children, as well as with emergency-room visits and hospitalizations for all respiratory causes and with asthma across multiple age groups. Pet. App. 55-56. The agency considered whether these health effects were the result of pollutants other than sulfur dioxide, ultimately concluding that "the limited available evidence indicates that the effect of SO_2 on respiratory health outcomes appears to be generally robust and independent of the effects of [other] co-pollutants." *Id.* at 81. In particular, in three multi-pollutant epidemiologic studies conducted in the United States that attempted to isolate the impact of sulfur dioxide, the effect estimate remained statistically significant at sulfur dioxide levels between 78 and 150 ppb. *Id.* at 157-158.

In the clinical studies that the EPA examined, moderate or greater decrements in lung function occurred in some individuals with mild or moderate asthma who were exposed while exercising to sulfur dioxide concentrations as low as 200 to 300 ppb for 5 to 10 minutes. Pet. App. 54-55. Furthermore, at concentrations of 400 ppb and greater, the effects were often statistically significant at the group mean level (*i.e.*, at the level of the group in the particular clinical study) and frequently were accompanied by respiratory symptoms. *Ibid.* Due in part to ethical concerns, no available clinical studies examined individuals with severe asthma. See *id.* at 8; cf. *Matrixx Initiatives, Inc.* v. *Siracusano*, 131 S. Ct.

1309, 1319 (2011) (explaining, in the drug-safety context, that "ethical considerations may prohibit researchers from conducting randomized clinical trials to confirm a suspected causal link for the purpose of obtaining statistically significant data")

Based on the totality of the evidence, the EPA adopted a 1-hour standard (daily maximum[1]) of 75 ppb to provide protection from short-term exposures ranging from 5 minutes to 24 hours. Pet. App. 117-120. The EPA found that the epidemiologic evidence provided strong support for setting the standard at 75 ppb because that level is slightly below the lowest of the 1-hour concentrations in the three key epidemiologic studies finding adverse health effects (*i.e.*, below 78 ppb). The agency also concluded that the standard is consistent with the findings from the clinical studies because it will have the effect of substantially limiting 5-minute exposures equal to or greater than 200 ppb. *Id.* at 160-163. The EPA therefore determined that a 1-hour standard at 75 ppb would be requisite—that is, sufficient but not more stringent than necessary—to protect public health with an adequate margin of safety.

3. Petitioner, along with other parties, challenged the rulemaking by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit. The court of appeals denied the petitions, concluding that the EPA "did not act arbitrarily in setting the level of SO_2 emissions." Pet. App. 3.

a. The court of appeals began by articulating the basic standards governing judicial review of EPA rule-

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[1] The standard requires the 3-year average of the 99th percentile 1-hour daily maximum values—*i.e.*, the value in each year at the 99th percentile of the maximum 1-hour value for each day ranked from highest to lowest—to meet the specified level.

making under the CAA. Under the Act, it explained, "the EPA Administrator must set NAAQS at a level 'requisite to protect the public health,' 'allowing an adequate margin of safety.'" Pet. App. 14 (quoting 42 U.S.C. 7409(b)(1)). The court recognized that in *Whitman*, this Court had "held that NAAQS are set at the 'requisite' level if they are set at a level 'not lower or higher than is necessary' to protect public health." *Ibid.* (quoting *Whitman*, 531 U.S. at 475-476). It also observed, however, that in evaluating the EPA's conclusion that a level is "requisite," a court "will set aside the Agency's determination only if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 13-14 (quoting 42 U.S.C. 7607(d)(9)(A)). The court of appeals further explained that, because a court "owe[s] deference to the Administrator's determination regarding the reliability of scientific evidence," it "do[es] not look at the decision as would a scientist, but 'as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality.'" *Id.* at 14 (quoting *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 36 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976)).

b. Applying these standards, the court of appeals rejected each of the challengers' arguments that the EPA had acted unreasonably in promulgating the revised sulfur dioxide standard.

First, the court of appeals rejected the contention that the EPA had erred in its consideration of guidelines published by the American Thoracic Society, an organization that focuses on public-health issues involving respiratory diseases. See Pet. App. 15-16. The challengers had argued that the impacts on lung function seen in the clinical studies at concentrations below 400

ppb did not satisfy the guidelines' definition of an "adverse effect." *Id.* at 15. The court of appeals explained, however, that the EPA "was not bound to set the SO_2 standard according to [those] guidelines," which "merely provided one reference point to help [the] EPA and the public understand what should be considered an adverse effect of SO_2 on human health." *Id.* at 16. It further observed that the agency in setting the standard had considered not only the guidelines, but a substantial range of additional evidence as well, including "the advice and recommendations it received from [the] Clean Air Scientific Advisory Committee" and "epidemiologic studies." *Ibid.*

The court of appeals also pointed out that the EPA had sound reasons not to rely solely on clinical studies in setting the appropriate level for sulfur dioxide emissions. In particular, the "clinical studies did not test severe asthmatics or very young children." Pet. App. 16. Accordingly, the EPA had reasonably fulfilled the statutory requirement of ensuring an "adequate margin of safety" by "assum[ing] that those vulnerable populations would suffer more serious health effects than mild and moderate asthmatics." *Ibid.*

Second, the court of appeals rejected the challengers' argument that the EPA had erred in relying on certain epidemiologic studies without taking into account how the presence of other air pollutants might have affected their conclusions. See Pet. App. 17-20. The quotations from the rulemaking record on which the challengers relied, the court observed, were "taken out of their original context." *Id.* at 17. In fact, the cited portion of the record indicated that the "EPA did take other pollutants into consideration, and even when it did so, the results 'remained positive and relatively unchanged.'" *Id.* at 19

(quoting 75 Fed. Reg. 35,520, 35,531 (June 22, 2010)). Although the EPA had "concede[d] that there are 'uncertainties' associated with separating the various pollutants' effects," the agency had found that "'the limited available evidence indicates that the effect of SO_2 on respiratory health outcomes appears to be generally robust and independent of the effects of gaseous co-pollutants'" and "'particulate co-pollutants.'" *Ibid.*

The court of appeals also held that the EPA had "offer[ed] a reasonable explanation for why it relied most heavily on three particular epidemiologic studies." Pet. App. 19. The court explained that, out of the "fifty peer reviewed studies available," those three studies were "conducted in the United States and included multi-pollutant models to help address" the very methodological problem that the challengers had identified. *Ibid.* The court explained that, based on those studies and the clinical studies, the EPA had identified a "'causal relationship between respiratory morbidity and short-term (5-minutes to 24 hours) exposure to SO_2'" at "concentrations at least as low as 200 ppb," and had found that "a 75 ppb 1-hour limit would 'substantially limit asthmatics' exposure' to such concentrations, allowing a reasonable margin for safety." *Id.* at 20 (quoting 75 Fed. Reg. at 35,525, 35,548).

Finally, the challengers objected that studies on which the EPA had relied, which showed a correlation between decrements in asthmatics' lung function and short-term exposures to concentrations of sulfur dioxide of 200 ppb, were not statistically significant. Pet. App. 20-21. The court of appeals explained that clinical studies supported the view that sulfur dioxide emissions at that level affected the lung function of exercising asthmatics, and that the agency could reasonably presume

that "people with more severe asthma would suffer more serious health consequences from short-term exposures to 200 ppb SO_2." *Id.* at 21. Although the court of appeals could not "say that the studies necessitated a 75 ppb standard, [it] also [could not] say that such a standard is unreasonable or unsupported by the record." *Ibid.* The court accordingly sustained the EPA's rulemaking under the applicable standard of review. See *id.* at 21-22.

ARGUMENT

The court of appeals correctly declined to disturb the EPA's determination that a primary 1-hour sulfur dioxide standard of 75 ppb is "requisite to protect the public health," "allowing an adequate margin of safety." 42 U.S.C. 7409(b)(1). Petitioner frames its highly fact-bound objection to that holding as demonstrating a legal conflict between the decision below and this Court's construction of the CAA in *Whitman* v. *American Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001). That argument lacks merit. The court of appeals faithfully applied both the text of the CAA and this Court's holding in *Whitman*. Further review is not warranted.

1. The court of appeals correctly held that the EPA had provided a reasonable justification for setting the sulfur dioxide standard at an average of 75 ppb over a 1-hour period.

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). As this Court has explained, "[r]eview 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, Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

This Court has also recognized that "[f]ederal judges lack the scientific, economic, and technological resources an agency can utilize." *American Elec. Power Co. Inc.* v. *Connecticut*, 131 S. Ct. 2527, 2539 (2011). For that reason, "[w]hen examining [a] * * * scientific determination . . . a reviewing court must generally be at its most deferential." *Marsh* v. *Oregon Natural Res. Def. Council*, 490 U.S. 360, 377 (1989) (citation omitted); see, *e.g.*, *ATK Launch Sys., Inc.* v. *EPA*, 669 F.3d 330, 336 (D.C. Cir. 2012) ("The court give[s] an extreme degree of deference to [the EPA] when it is evaluating scientific data within its technical expertise.") (internal quotation marks and citation omitted; first alteration in original).

b. The court of appeals correctly applied these well-settled standards to the EPA rulemaking at issue here. The agency reasonably explained the conclusions that it drew from the available evidence on the adverse effects of sulfur dioxide on public health, why it chose to give particular weight to certain studies in the record, the ways in which it accounted for potential shortcomings in the studies' methodologies, and how it determined that the 75 ppb level best satisfied the statutory mandate to set emissions standards that are "requisite to protect

the public health," "allowing an adequate margin of safety." 42 U.S.C. 7409(b)(1). None of the challengers below identified any legal error by the agency or any determination that was arbitrary or capricious.

Petitioner principally objects to the EPA's consideration of the clinical studies in the rulemaking record. See Pet. 12-13. But petitioner entirely ignores the epidemiologic studies cited by the EPA in the final rule—the primary evidence on which the agency based the revised sulfur dioxide standard. Those studies show that increases in emergency-room visits and hospital admissions are associated with increases in sulfur dioxide concentrations in cities with 99th percentile daily maximum 1-hour sulfur dioxide concentrations as low as 78 ppb. They therefore provided strong support for the EPA's conclusion that a standard with a level below 78 ppb is requisite to protect public health with an adequate margin of safety. Pet. App. 16-19, 161.

Moreover, as the court of appeals observed, the clinical studies "supported the plausibility of the associations reported in the epidemiologic studies" because they demonstrated decrements in lung function at 200 ppb and greater for some individuals suffering from mild or moderate asthma. Pet. App. 8, 19, 20-21. Taken alone, the clinical studies did not show statistically significant harmful effects when sulfur dioxide levels were below 400 ppb. But based on consideration of the epidemiologic and clinical studies together, as well as other evidence in the record, the agency reasonably concluded that there was "a causal relationship between respiratory morbidity and short-term * * * exposure to SO_2." *Id.*

at 20 (quoting 75 Fed. Reg. at 35,525).[2] Petitioner has identified no ground to deem that conclusion arbitrary or capricious.

2. Petitioner contends (Pet. 11-14) that further review is warranted because the decision below departed from this Court's construction of Section 7409(b)(1) in *Whitman*. That claim lacks merit.

In *Whitman*, this Court considered, among other issues, 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 "interpret[ed] [Section 7409(b)(1)] as requiring 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. Under that standard, the Court concluded, the "scope of discretion [Section 7409(b)(1)] allows is * * * well within the outer limits of our nondelegation precedents." *Id.* at 474.

Petitioner describes the decision below as holding that the EPA may "set the NAAQS at some level below that which produced adverse health effects without considering whether the level was lower than necessary simply because EPA has included a purportedly-adequate margin of safety," thereby "broaden[ing] EPA's discretion beyond the bounds of the agency's properly delegated authority." Pet. 11. That argument reflects a misreading of the court of appeals' opinion. The court explained that "NAAQS are set at the 'requisite' level if they are set at a level 'not lower or higher than is necessary' to protect public health." Pet. App. 14

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[2] The independent Clean Air Scientific Advisory Committee likewise interpreted the clinical evidence to show adverse effects at the 200 ppb level. Pet. App. 86-87.

(quoting *Whitman*, 531 U.S. at 475-476). In accordance with the statutory text and *Whitman*, however, the court recognized that the EPA must provide for "an adequate margin of safety" in determining what level of protection is necessary. *Id.* at 14, 16 (quoting 42 U.S.C. 7409(b)(1)). As the D.C. Circuit has previously explained, Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n, Inc.* v. *EPA*, 647 F.2d 1130, 1154, cert. denied, 449 U.S. 1042 (1980).

Consistent with that statutory directive, the court below upheld as reasonable the EPA's conclusion that, although the results of the clinical studies "did not remain statistically significant when the [sulfur dioxide] concentrations sank to 200 to 300 ppb," a lower standard was necessary in order to account for the studies' limitations. Pet. App. 21. In particular, the "studies did not test severe asthmatics or very young children"—vulnerable populations whose health could be at risk if the standard set is too lenient. *Id.* at 16. That holding was fully consistent with this Court's construction of Section 7409(b)(1) in *Whitman*. And while petitioner suggests (Pet. 12-13) that the EPA should not have considered studies that failed to produce statistically significant results, neither *Whitman* nor the CAA's text restricts the scope of evidence that the EPA may consider or prevents the agency from making well-informed predictive judgments in light of the limitations of the evidentiary record. Cf. *Matrixx Initiatives, Inc.* v. *Siracusano*, 131 S. Ct. 1309, 1319 (2011) ("A lack of statistically significant data does not mean that medical

experts have no reliable basis for inferring a causal link between a drug and adverse events."). In any event, as discussed above, the final rule rested on a broad range of evidence in addition to the clinical studies.

Petitioner also suggests that *Whitman* requires a reviewing court to conduct a de novo evaluation of the record evidence to determine whether a given standard is set at the "requisite" level. See Pet. 13-14. Petitioner particularly objects to the court of appeals' conclusion that, although the studies in the record did not "necessitate[] a 75 ppb standard," the court could not conclude that "such a standard is unreasonable or unsupported by the record before us." Pet. App. 21. But nothing in *Whitman* suggests that courts must abandon their ordinary standards of review of administrative action when evaluating NAAQS. To the contrary, the Court explained that the CAA authorizes the EPA to exercise discretion in implementing its provisions. See 531 U.S. at 475-476.

That proposition is firmly grounded in the statute's text, which leaves the identification of emission levels "requisite to protect the public health" to "the judgment of the Administrator," 42 U.S.C. 7409(b)(1), and establishes deferential standards of judicial review, 42 U.S.C. 7607(d)(9)(A). The Court in *Whitman* observed in particular that "pollutants that inflict a continuum of adverse health effects at any airborne concentration greater than zero * * * require the EPA to make judgments of degree." 531 U.S. at 475. Although those judgments must be reasonable and consistent with the record evidence, a reviewing court "is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

Consistent with that principle, the court of appeals held that the EPA's choice of a 75 ppb limit was reasonable and supported by the administrative record, even though the clinical studies by themselves did not compel the choice that the agency made. See Pet. App. 21 ("We cannot say that the studies necessitated a 75 ppb standard, but we also cannot say that such a standard is unreasonable or unsupported by the record before us."). The court thus faithfully applied the principles of judicial review articulated in this Court's precedents, recognizing that it "owe[d] deference to the Administrator's determination regarding the reliability of scientific evidence." *Id.* at 14; see *Marsh*, 490 U.S. at 377. Petitioner has pointed to nothing in *Whitman* that calls into question the court of appeals' careful yet properly circumscribed evaluation of the challenged rulemaking.

3. Petitioner also contends (Pet. 14-17) that the practical importance of the EPA's role in setting air-quality standards makes this case appropriate for further review. The agency's administration of the CAA is surely critical to the national well-being. For the reasons discussed above, however, there is no sound basis for petitioner's contention that the court of appeals "obliterat[ed] the lower bound limit on EPA's authority to set NAAQS." Pet. 15. The court below did not commit any legal error or announce any new legal rule of broad continuing importance. And the fact that the challenged EPA rulemaking will impose economic costs does not call for further review, particularly in light of this Court's holding in *Whitman* that Section 7409(b) "unambiguously bars cost considerations from the NAAQS-setting process." 531 U.S. at 471.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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