

No. 26-277

IN THE
Supreme Court of the United States

KENTUCKY, *et al.*,

Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

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

**AMICI CURIAE BRIEF OF WESTERN
STATES TRUCKING ASSOCIATION AND
CONSTRUCTION INDUSTRY AIR QUALITY
COALITION IN SUPPORT OF PETITIONERS**

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INTEREST OF *AMICI CURIAE*¹**Western States Trucking Association**

The Western States Trucking Association (“WSTA”) is a nonprofit trade association incorporated in 1941 that represents thousands of trucking companies, engaged in multiple modes of trucking from construction-related to general freight operations. WSTA’s diversified group of member motor carriers operate in intrastate, interstate, and foreign commerce and operate many different types and classes of commercial motor vehicles, including dump trucks, concrete pumpers and mixers, water trucks, port and border dray trucks, heavy-haul trucks, and class 8 over-the-road tractors, among others. Member companies range in size from one-truck owner-operators to fleets with over 350 trucks. The mission of WSTA is to advance the professional interests of their member trucking companies, including but not limited to interests affected by regulations governing the transportation industry.

Construction Industry Air Quality Coalition

The Construction Industry Air Quality Coalition (“CIAQC”) is a nonprofit trade association representing the interests of other California non-profit trade associations and their members whose emissions are regulated at

1. Pursuant to Supreme Court Rule 37.2(a), counsel of record for all parties received timely notice of the intent of amici curiae WSTA and CIAQC to file this brief at least 10 days prior to the due date thereof. Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund preparation or submission of this brief.

the federal, state, and local levels. In particular, CIAQC represents the interests of many multiple member construction companies that transport cargo and goods in connection with construction activities. CIAQC's purpose is to obtain and provide information to its members concerning environmental regulatory issues affecting the members, assist in the development of environmental regulatory strategies and legislation that will balance the goals of a healthy environment and a healthy local economy, act as a conduit for information from members to regulatory agencies and legislators concerning the effects of proposed regulations on its members, and to cooperate with other persons and associations in the development of reasonable and effective environmental improvement strategies.

WSTA, CIAQC, and their members are directly impacted by the decision of the D.C. Circuit Court of Appeals in this case because the state and federal implementations of new National Ambient Air Quality Standards ("NAAQS") will directly regulate WSTA and CIAQC's members. By lowering the NAAQS without sufficient scientific review, the Environmental Protection Agency ("EPA") has burdened huge swaths of the economy with high costs of compliance. If the D.C. Circuit's opinion is allowed to stand unreviewed by this Court, WSTA and CIAQC's members will be required to bear those costs, and ultimately pass those costs on to their customers.

SUMMARY OF ARGUMENT

This Court should grant the writ because EPA lowered the primary annual PM_{2.5} NAAQS without the thorough scientific review required by the Clean Air Act. EPA's abbreviated, off-cycle review relied on a narrow set of recent studies while disregarding peer-reviewed literature that questioned the assumptions underlying the PM_{2.5} standard. The information that EPA neglected to consider includes decades of concerns that NAAQS determinations necessarily involve policy judgment, not scientific certainty, and that EPA's reliance on linear concentration-response modeling and equal-toxicity assumptions for particulate matter has long been contested.

The failure to conduct the thorough review is not harmless error. Had EPA undertaken the required review, it would have encountered research by Dr. Roger O. McClellan, Dr. James Enstrom, Dr. Anne Smith, and Dr. Louis "Tony" Cox casting serious doubt on the asserted causal link between current PM_{2.5} levels and mortality, the reliability of EPA's mortality models, and the agency's claimed benefits from tightening the standard. Those methodological flaws matter because WSTA, CIAQC, and their members will bear the compliance burdens of a more stringent NAAQS. Allowing the decision below to stand would permit EPA to avoid judicial scrutiny when it decides to revise air quality standards under the Clean Air Act through an off-cycle process, undermining Congress's requirement of a comprehensive, transparent review.

ARGUMENT IN SUPPORT OF THE WRIT

WSTA and CIAQC ask this Court to grant the writ for the same reasons outlined by the Petitioners in their brief. We write as friends of the Court to draw the Court's attention to certain information underpinning Petitioners' Question One, which asks "[w]hether EPA may revise a NAAQS without the 'thorough review' required by section 109(d)(1) simply because it acts 'earlier or more frequently' than mandated." Pet. at i. EPA has acknowledged that, during its off-cycle review of the NAAQS, it did not conduct a thorough review of peer-reviewed literature before setting the new primary annual standard for PM_{2.5}. Pet. at 5. Instead, EPA focused exclusively on a few recent studies. Pet. at 5-6.

EPA's decision to ignore pertinent research is not merely a procedural oversight. If EPA had conducted a thorough review, it would have encountered decades of research and methodological review casting doubt on the validity of the science on which it ended up relying.

I. According to Dr. Roger O. McClellan, EPA's NAAQS revisions are driven more by policy considerations than by scientific certainty.

Had EPA conducted a thorough review of the available research, it would have encountered the research of Dr. Roger O. McClellan, an air quality expert who has served as a member and Chairman of EPA's Science Advisory Board. McClellan initially addressed the scientific evidence relating to NAAQS for PM_{2.5} in his works *Role of Science and Judgment in Setting National Ambient Air Quality Standards: How Low Is*

Low Enough?, 5 AIR QUALITY, ATMOSPHERE & HEALTH 243 (2012) (questioning the unbiased nature of EPA NAAQS determinations) (hereinafter, “*Role*”), and *Providing Context for Ambient Particulate Matter and Estimates of Attributable Mortality*, RISK ANALYSIS, 2016; 36(9):1755-1765 (specifically addressing PM2.5 NAAQS) (hereinafter, “*Providing Context*”).

In *Role*, McClellan focused on EPA’s method of setting primary (health-based) NAAQS. *Role* at 243. When creating a primary NAAQS, the Clean Air Act allows the EPA Administrator discretion to “address uncertainties associated with inconclusive scientific and technical information at the time the Standard is set” to establish an “adequate margin of safety.” *Id.* at 245. Sensitive populations, particularly those with respiratory problems who are regularly exposed to ambient air, should be accounted for. *Id.* Given these criteria, McClellan noted a problem with interpreting the Clean Air Act: though NAAQS are intended to mitigate risk, the Act is unclear how much mitigation is required to satisfy the law. This vagueness may lead some groups to operate under the false assumption that risks from pollution in ambient air can be eliminated entirely. *Id.*

Furthermore, McClellan points out the nature of NAAQS revision is highly susceptible to politicization. For example, at its creation, the NAAQS for lead were “constrained and informed by the scientific information, but [were] ultimately based on the policy judgment of a politically responsible decision-maker, the EPA Administrator.” *Id.* at 246.

This politicization was especially obvious in the early days of the NAAQS, when EPA set the NAAQS largely without transparency. The earliest NAAQS were completed through informal rulemaking, which did not provide a sufficient basis for judicial review. *Id.* After the D.C. Circuit struck down one of EPA's early NAAQS, EPA developed a more rigorous method of documenting their decision-making process for NAAQS and making public their reasoning. *Id.* This reform, which was subsequently adopted by Congress (in a somewhat modified form) in the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, § 305, 91 Stat. 685, sacrificed speed in rulemaking but improved transparency, McClellan noted with approval. *Id.* at 247.

Even after the improved transparency, the extent to which PM2.5 NAAQS relied on policy judgments, rather than scientific rigor, continued to grow. McClellan explained that, in 1997, EPA chose to set a separate PM2.5 standard for the first time. Prior to that time, PM2.5 had been included under the standards for ambient particulate matter under 10 microns ("PM10"). *Id.* Discussions surrounding the first PM2.5 NAAQS were "very contentious" as the scientists on Clean Air Scientific Advisory Committee ("CASAC") had "a range of views" so complex that it took a table to diagram them. *Id.*

CASAC's internal disagreement was magnified by the D.C. Circuit's decision in *Am. Trucking Ass'ns, Inc. v. U.S. EPA*, 175 F.3d 1027 (D.C. Cir. 1999), which vacated the 1997 PM10 standards largely because they included the PM2.5 standards. Further, they determined that while EPA's factors used to determine degrees of public health concern related to pollutants were "reasonable,"

EPA lacked any clear criterion for determining NAAQS. However, the EPA Administrator was not allowed to consider the cost of implementing NAAQS when setting them. *Role* at 247.

This Court affirmed the basic holding of *Am. Trucking* two years later in *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). But the relationship between policy and science remained unclear. Writing in concurrence, Justice Breyer explained that “§109 does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of ‘hurtling’ industry over ‘the brink of ruin.’” *Id.* at 494. Justice Breyer sought to ease the problem posed by the Clean Air Act’s risk-avoidance language: the EPA Administrator has flexibility to avoid setting standards that chill industry activity and determine “the acceptability of small risks to health.” *Id.* Thus, Justice Breyer suggested, the EPA Administrator does not have to set NAAQS that aim at completely eliminating pollutants, as if such a thing were possible. Breyer’s opinion urged the Administrator to make his determinations about what level of protection and risk is “adequate” based on his policy judgments when crafting primary and secondary NAAQS.

McClellan states that a “paradigm shift” took place as the amount of scientific evidence regarding pollution’s health effects grew. *Role* at 248. Originally, because they lacked studies on the effects of pollution on human health, scientists agreed that the lowest level at which pollution could be determined “statistically significant” in laboratory animal studies served as the highest level

for the “adequate margin of safety.” *Id.* at 248-49.² This decision assumed that certain non-cancer health issues had a linear exposure response relationship to certain pollutants, an assumption which McClellan discusses further in his analysis. *Id.*

McClellan also noted the folly of EPA’s initial inclination to “identify levels where an increase in effects is observed and then set the Standard at a lower level.” *Id.* Eventually, EPA began linking their standards to pollutant concentrations averaged over multiple years. *Id.* This shift in the statistical forms underlying NAAQS produced challenges when certain studies fail to provide metrics for their data that would aid EPA in averaging. This difficulty “results in extremely stringent standards that at best are only very loosely related to the underlying data.” *Id.*

McClellan pointed out that EPA’s assumptions about appropriate background levels for certain pollutants, combined with ongoing acceptance of a possibly flawed statistical model for NAAQS, has hamstrung the agency’s ability to make NAAQS that reflect reality. *Id.* at 250. EPA assumed that its practice of categorizing concentrations of pollutants above the NAAQS in a linear manner, rather than determining “whether there is a threshold level below which the coefficient for excess risk does or does not hold.” *Id.* EPA’s insistence on this point has extended to estimating adverse health attributable to each pollutant

2. The wisdom of taking lab animal studies as determinative on this matter has been called into question, and EPA has introduced a factor in its NAAQS calculations that supposedly accounts for this discrepancy. *Id.* at 249.

“down to background concentrations.” *Id.* While admitting that he was originally in favor of this approach, McClellan did not expect that advocates of such quantification would take their measurements as “highly accurate projections ... sometimes without any indication of uncertainty.” *Id.*

Due to these statistical challenges, McClellan concluded that “decisions on the selection of specific levels and averaging times for the NAAQS are policy judgments properly reserved to the Administrator informed by the available scientific knowledge.” *Id.* at 249. In other words, the implications of Breyer’s opinion in *Whitman* extend to the statistical modeling underlying the NAAQS determination. EPA’s unreasonable decision to adopt linear modeling, in contravention of Justice Breyer’s directive that the Clean Air Act recognizes the need for policy judgment within its “adequate margin for safety” parameter is the paradigm shift McClellan previously mentioned.

McClellan then discussed the PM_{2.5} indicator. He participated in initial CASAC discussions on the first PM_{2.5} NAAQS in 1997 and notes that the committee members in large part wished to create a NAAQS that “would mandate the monitoring of PM_{2.5},” but also expressed reservations about setting the NAAQS too stringently given the “absence of convincing data on PM_{2.5}.” *Id.* at 251. He states that the Administrator’s initial annual NAAQS on PM_{2.5} was too stringent and “very precautionary,” while the 24-hour NAAQS was less so. *Id.* CASAC’s revision of this standard in 2005 recommended a tightening of both standards, with significant pressure to provide unanimous approval. McClellan believed this tightening “was not a scientific

decision, but rather a matter of policy judgment that should be left to the discretion of the Administrator.” *Id.* He and another colleague did not join CASAC’s recommendation. The Administrator tightened the 24-hour NAAQS while leaving the annual one where it was. *Id.* McClellan makes it clear that it is “not appropriate for CASAC to recommend a bright line upper bound on the NAAQS,” because that recommendation involves policy judgment beyond scientific analysis. *Id.* at 252. While the Administrator is authorized to make decisions about what constitutes appropriate risk and incorporate it into his standard-setting, CASAC’s narrow job is to provide the Administrator with scientific information that will factor into his final decision. *Id.*

McClellan next addresses the call for “sound science” to inform the Administrator’s standard-setting decisions. He supported the efforts of advocacy groups and NGOs to synthesize and submit helpful data for EPA’s NAAQS process. *Id.* at 254. However, McClellan heavily criticized the inclination of some groups to hold certain data as “true” or “false” based on who funded the study that produced the data, and expressed concern about the implicit expectations that “sound science” can provide perfect NAAQS:

Sound science does not in and of itself make for sound decisions. [S]cience alone cannot identify an acceptable level of health risk, since such levels inherently represent a policy judgment call. Sound science can only inform what are ultimately policy judgments or political decisions. This is especially the case for the setting of NAAQS, in the absence of a clearly

defined threshold, which involve decisions as to acceptable health risks which are linked to the level (and form) of the Standard.

Id.

McClellan concluded that while *Whitman* allows the Administrator to set NAAQS in a way that accounts for policy judgment, CASAC itself may not exercise the same judgment in making its recommendations. Instead, McClellan suggested that CASAC members draw on their diverse expertise to interpret and distill the vast quantity of scientific data on pollutants. *Id.* at 255. Most notably, McClellan believes that the Administrator would greatly benefit from CASAC's input on "the multiple factors that influence morbidity and mortality from respiratory and cardiovascular disease, the major health outcomes for key criteria pollutants." *Id.* at 256. He reaffirms that if Administrators seek to use the CASAC's unwarranted offering of acceptable ranges as scientific cover for their own political judgments, such action would "transform the Clean Air Scientific Advisory Committee into a *de facto* Clean Air Standards Setting Committee," a result not intended by Congress in enacting the Clean Air Act. *Id.*

II. Dr. McClellan's Research Illustrates the Weak Link Between PM2.5 NAAQS and Human Mortality.

If EPA had conducted a thorough review of the available science, it would have also considered McClellan's observations regarding the inadequacy of the available research to answer whether or not PM2.5 is actually a danger to human health.

In McClellan's 2016 paper, he specifically addresses PM2.5 NAAQS in light of new research, analyzing the extent to which PM2.5 may or may not contribute to increased mortality based on the new findings. *Providing Context* at 1755. McClellan summarizes the methodology of each study. Two of the four considered studies incorporated alternative methods of measuring acceptable levels of PM2.5, rather than (or in addition to) the commonly accepted linear concentration-response modeling that McClellan criticized in his 2012 paper. *Id.* at 1756. McClellan points out that in 2012, the Administrator revised and tightened the primary annual NAAQS for PM2.5 to 12 μ g/cubic m. The 24-hour standard held steady. *Id.* at 1757. McClellan notes that both standards "are based on mass concentration and the assumption that all of the PMs in each size fraction are of equal toxicity on a mass basis." *Id.* Based on new evidence, McClellan suggests that "this assumption needs careful review in the current PM review cycle." *Id.*

McClellan began his examination of the relation between PM2.5 and mortality by referencing a major long-term study on the subject called the Harvard Six Cities Study. It measures "changes in ambient PM2.5 concentrations in ... six cities from the mid-1970s through 2009." *Id.* The study demonstrates a sizable and steady decline in ambient PM2.5. *Id.* at 1757-58. McClellan next notes that the crude and age-adjusted death rates have seen marked improvement in the same time frame. *Id.* at 1758. He includes another table indicating the causes of death for the United States in 2010. *Id.* at 1759. This table lists heart diseases as the most common cause of death, followed closely by cancer. Chronic lower respiratory diseases are a distant third. *Id.* Overall, "it is widely

acknowledged today ... that the regulatory programs grounded in the CAA have had widespread positive impact” in terms of improved air quality. *Id.* This brings up the obvious question of whether current air quality requires stricter primary NAAQS for PM2.5. Such a question hinges on whether PM2.5 is still a significant cause of adverse health effects.

To answer that question, McClellan explains that EPA has a five-level hierarchy (ranging from “causal relationship” to “not likely to be causal relationship”) to classify the weight of evidence regarding the relation between a given pollutant and a health hazard. *Id.* at 1760. Notably, this level-based system does not speak to whether current PM2.5 levels in the United States increase the incidence of adverse health effects “over and above baseline rates.” *Id.* Even more seriously, this system does not establish whether any given ambient PM2.5 concentration has “a causal attributable effect on health outcomes,” including an increase in mortality rates simpliciter. *Id.* Many scientists incorrectly believe the conclusions of EPA’s level-based system bears some sort of implication for ambient PM2.5 concentration measurements. *Id.*

McClellan faulted the authors of the four studies his paper examines for making a related assumption. One study implies that the correlation between PM2.5 levels and excess risk of adverse health effects is reliable no matter the examined concentration and risk level—a proposal with which McClellan expresses reservations. *Id.* at 1760. He also questions why the studies failed to explain the EPA Administrator’s reasoning in lowering primary annual PM2.5 NAAQS so drastically in 2012. In that

instance, the Administrator considered a limited range of data in available studies as reliable evidence of a causal relationship between long term PM_{2.5} exposure and increased general death rates. *Id.* at 1761. This conclusion conflicts with the conclusion of all four researchers, who considered all data in their studies to be reliable. *Id.* Since data at all concentrations did not show an equal causal relationship between long-term PM_{2.5} exposure and increased all-cause mortality, this is a serious omission. The Administrator also entirely failed to consider the Six Cities Study, because it had not released numbers for PM_{2.5} as recently as other studies. *Id.* at 1760. McClellan calls the contrast between the Administrator's judgments and the seeming conclusions of the most reliable recent studies on PM_{2.5} "a critical issue at the interface between scientific information and policy choices." *Id.* at 1761.

McClellan criticizes the four studies at issue further, noting that even though the data does not necessarily support the conclusion that low concentrations of PM_{2.5} cause an increase in death rates, none of the studies discuss this fact. *Id.* "[T]he official assumption in the last EPA review that all PM_{2.5} is of equal toxicity on a mass basis," McClellan noted, is especially important in a modern context, when most PM results not from direct emissions but from "secondary reactions and associated changes in the chemical and size composition of PM." *Id.* Very little data that differentiates between directly emitted and secondarily derived PM exists. Such data is necessary to determine whether a mortality increase still correlates with both kinds of PM, and in what concentrations. *Id.* While one study has a more extensive discussion of causality than others, McClellan called its assumptions "simplistic and ... naïve" for oversimplifying

the way that outside stressors cause an increase in mortality. *Id.* He especially found the study's skepticism about a PM2.5 range of exposure where no mortality risk exists "unjustified," especially since the authors' own methods of measurement require them to "control for all other risk factors potentially associated with the disease endpoint of concern." *Id.* at 1762. These risks are manifold and complex.

In fact, McClellan identified "a growing body of evidence of a lack of influence of ambient PM2.5 concentrations on mortality." *Id.* In some states, like California, the risk of increased mortality associated with PM2.5 has decreased to the point of non-demonstrability. *Id.* Moreover, "[i]t is well recognized by scientists and clinicians... that none of the individual cases carry 'markers' or any characteristics that allow PM2.5 attributable cases to be distinguished from cases that are attributable to a myriad of other causes." *Id.* Because deaths are only attributed to PM2.5 "on a statistical and population basis," there is no hard evidence of any mortality increase directly attributable to PM2.5. *Id.*

The authors of the studies reviewed by McClellan did not discuss whether more well-documented risks could contribute to or account for increases in mortality currently attributed to PM2.5. *Id.* Given the complexity of determining what risk factors contribute to any given death (and the variance of contribution depending on time, place, and exposure level), this omission was glaring. McClellan suggests that "an expanded presentation of results" incorporating the Six Cities Study and exposure-response measurements would be more informative to future decision-making about PM2.5 NAAQS. *Id.* at

1763. He also suggests including baseline population and mortality data to provide context for such determinations. *Id.* at 1764. Regarding the most current models and studies on PM2.5, McClellan concludes that their estimates are “more likely to overestimate than underestimate the true PM2.5 attributable mortality.” *Id.* He also wonders whether the data on mortality attributable to certain PM2.5 concentrations have been skewed by the exposure of certain individuals born in or before the 1970s to PM2.5. *Id.* While he agreed that it is possible that improvements in air quality contributed to reduced mortality, “the impact of PM2.5 reductions is likely very small and difficult to tease out from the myriad of other factors that were likely involved” in this reduction, like widespread improvement in overall socioeconomic status. *Id.*

III. Dr. James E. Enstrom Found No Relationship Between Varying PM2.5 Levels and Mortality

McClellan is not the only scientist to question the evidence of a significant link between fine particulate matter and mortality rates. Dr. James E. Enstrom’s paper, *Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973-2002*, INHALATION TOXICOLOGY 2005; 17:803-816, found no relationship between levels of fine particulate matter (“PM2.5”) and mortality. Enstrom’s analysis used proportional hazards regression and, adjusting for age, sex, cigarette smoking, and other potential confounding variables, found that “[t]hese epidemiologic results do not support a current relationship between fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly before 1983.” *Id.* at 803. Enstrom’s research was based on 118,094 Californians

enrolled in the American Cancer Society's first Cancer Prevention Study. "For the initial period, 1973-1982, a small positive risk was found: RR [relative risk of death] was 1.04 (1.01-1.07) for a 10- $\mu\text{g}/\text{m}^3$ increase in PM2.5. For the subsequent period, 1983-2002, this risk was no longer present: RR was 1.00 (0.98-1.02). For the entire follow-up period, RR was 1.01 (0.99-1.03)." *Id.* at 803.

Similarly, Enstrom's paper, *Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis*, DOSE-RESPONSE: AN INTERNATIONAL JOURNAL January–March 2017:1-12, independently analyzed the findings in the 1982 American Cancer Society Cancer Prevention Study ("CPS II"), which had earlier found a positive relationship between PM2.5 and total mortality (and has been the basis for EPA's PM2.5 NAAQS levels).

Enstrom uses Cox proportional hazards regression on the original questionnaire data, examining results obtained from 292,277 participants in 85 counties with 1979-1983 EPA Inhalable Particulate Network PM2.5 measurements, as well as for 212,370 participants in the 50 counties used in the original 1995 analysis. The 1982 to 1988 relative risk ("RR") of death from all causes and 95% confidence interval adjusted for age, sex, race, education, and smoking status was 1.023 (0.997-1.049) for a 10 mg/m^3 increase in PM2.5 in 85 counties and 1.025 (0.990-1.061) in the 50 original counties. The fully adjusted RR was null in the western and eastern portions of the United States, including in areas with somewhat higher PM2.5 levels, particularly five Ohio Valley states and California. Enstrom concluded there was no significant relationship between PM2.5 and total mortality in the CPS II cohort was found when the best available PM2.5

data was used. Contrary to the original 1995 analysis's finding of a positive relationship by selective use of CPS II and PM2.5 data Enstrom found that the underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the PM2.5 NAAQS.

IV. Dr. Anne Smith and Dr. Louis “Tony” Cox found that current models used to attempt to establish associations between particular PM2.5 levels and mortality are flawed.

In addition to the peer-reviewed papers discussed above, Dr. Anne Smith called into question the validity of current methods of analyzing PM2.5's potential harmfulness. Smith's paper illustrates the use of alternative approaches to calculating the expected benefits of reducing the NAAQS for PM2.5 from 15 to 12 $\mu\text{g}/\text{m}^3$. Anne E. Smith, *Inconsistencies in Risk Analyses for Ambient Air Pollutant Regulations*, RISK ANALYSIS, 2016; 36(9):1737-1744. Smith described the inconsistency between the health risk analysis that EPA uses to support its NAAQS standards and in the Regulatory Impact Analyses (“RIAs”) related to each NAAQS rulemaking.

Risk estimates are prepared during the process of setting the NAAQS level using statistical relationships between measured pollutant concentrations and effects on human health. The final risk estimates are not directly used to set the NAAQS level. Instead, they are incorporated into a rationale for the standard intended to show compliance with the statutory requirement that the primary NAAQS protect the public health with a “margin of safety.” In a separate process, EPA relies on the same risk calculations to prepare estimates of the

health benefits of the rule that are reported in its RIA for the standard. Although NAAQS rules and their RIAs are released simultaneously, the rationales used to set the NAAQS have become inconsistent with their RIAs' estimates of benefits, with very large fractions of RIAs' risk reduction estimates being attributed to populations living in areas that will already be attaining the respective NAAQS.

Smith's paper explains the source of this inconsistency and provides a quantitative example based on the 2012 revision of the PM_{2.5} primary NAAQS. Smith showed that the total risk reduction estimate (avoided premature deaths in 2020) for two approaches. The first was the traditional approach used by EPA in developing RIAs, which assumes deaths are avoided regardless of the ambient concentrations of PM_{2.5}. The analysis in the RIA showed 456 avoided deaths with one concentration-response function using the American Cancer Society cohort and 1,034 avoided deaths using the concentration-response function from the Six Cities Study.

Smith also gives lower estimates based on the rationale that EPA used in the latest revision of the NAAQS for PM_{2.5}, with the number of residual avoidable deaths reduced to between 21 and 48, depending on the concentration-response function used. "The result is that the RIA benefits are substantially overstated compared to those that would more appropriately reflect the subjective weights expressed by EPA in its rationale for setting the standard at 12 μ g/m³." *Id.* at 1741.

Smith finds that a large majority of EPA's estimated health benefit from the 2012 PM_{2.5} NAAQS are

attributable to reductions of PM_{2.5} in areas that were already in attainment of the PM_{2.5} NAAQS. RIA calculations of risk reduction in areas already attaining the new NAAQS are given the same weight (i.e., subjective confidence level) as projected benefits from areas that would be exceeding the NAAQS. These RIA calculations are based on assumptions that are inconsistent with the rationale for that NAAQS. This causes RIAs' benefits estimates to be much more substantial than estimates of the expected benefits that could be reasonably inferred from EPA's NAAQS-setting rationale. The overstatement becomes nearly 100% for co-benefits from criteria pollutants in RIAs for non-NAAQS regulations. *Id.* at 1742-43.

Dr. Louis "Tony" Cox was invited to comment on Smith's paper. Cox points out the flaws in existing models purporting to predict how future changes in exposure to PM_{2.5} affect mortality. Louis Anthony Cox, Jr., *Rethinking the Meaning of Concentration Response Functions and the Estimated Burden of Adverse Health Effects Attributed to Exposure Concentrations*, RISK ANALYSIS, 2016; 36(9):1770-1779. Cox concluded that the modeling choices affect the concentration-response relations, but equally good varying choices lead to conflicting conclusions regarding any adverse effect from a given level of PM_{2.5} on mortality. This means that currently available data has questionable efficacy in predicting how future changes in PM_{2.5} concentrations will affect human health. *Id.* at 1770-75.

The reduced-form regression models used to attempt to establish associations between particular PM_{2.5} levels and mortality are flawed, but Cox believed that

other methods of modeling risk, from simulation to causal Bayesian networks, could be more efficacious in determining changes in responses from changes in exposure level. *Id.* at 1775-77. Given the flaws in the current data used by EPA, and the possibility of more accurate models as outlined in Cox’s paper, it would be irresponsible for EPA to tighten the PM2.5 NAAQS while still relying on the blanket of “scientific certainty.”

CONCLUSION

The analyses of McClellan, Enstrom, Smith, and Cox provide more than enough reason to question EPA’s extremely stringent PM2.5 standards. According to these four experts, the causal link between PM2.5 and mortality is tenuous at best and indemonstrable at worst. Moreover, EPA’s policy-driven pursuit of eliminating every health risk is neither attainable nor required by statute. These conclusions certainly would have been included in a “thorough review” of the available evidence when EPA decided to perform its off-cycle review.

The resulting neglect of the evidence is far from harmless error. EPA should have considered the methodological issues presented by these peer-reviewed journals before determining that it was necessary to drastically reduce the PM2.5 NAAQS. Indeed, any other conclusion would allow EPA to impermissibly ignore researchers it dislikes and adopt only the policy positions of researchers that it agrees with – so long as it does so in an off-cycle review.

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Respectfully submitted,

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