November 9, 2017

Via Federal Express
Mr. Scott Pruitt
EPA Adminisfrator
United States Environmental Protection Agency
EPA Headquarters
Mail Code 1101A
William Jefferson Clinton Building (North)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: PETITION IN MATTER OF: NATIONAL AMBIENT AIR OUALITY STANDARDS FOR PARTICULATE MATTER

Dear Administrator Pruitt:

Enclosed please find our Administrative Petition respectfully requestiT1g the Administrator to reconsider and make less stringent its current national ambient air quality standards ("NAAQS") for fine particulate matter ("PM2.5"), 78 Fed. Reg. 3086 (Jan. 15, 2013), because those standards are based upon faulty assumptions,

Thank you in advance of your careful consideration of the enclosed Administrative Petition.

Respectfully submitted,

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Theodore Hadzi-Antich
Senior Counsel
Center for the American Future
Texas Public Policy Foundation

Enclosure

INTRODUCTION

Pursuant to the Right to Petition Government Clause of the First Amendment of the United Sates Constitution,[1] the Administrative Procedure Act,[2] the Clean Air Act,[3] and the United States Environmental Protection Agency's ("EPA's") implementing regulations, Petitioners file this Administrative Petition with EPA's Administrator and, for the reasons set forth herein, respectfully request the Administrator to reconsider and make less stringent its current national ambient air quality standards ("NAAQS" or "standards") for fine particulate matter ("PM2.5"), 78 Fed. Reg. 3086 (Jan. 15, 2013), because those standards are based upon faulty assumptions. Such reconsideration should be part of the current five-year review cycle.

INTEREST OF PETITIONERS

Petitioner Delta Construction Company, Inc. ("Delta") is a California corporation engaged in the business of road construction, performing services such as road paving, reconstruction, shoulder widening, and fabric installation. After 73 years in business, Delta has been forced to close its doors and sell its assets mainly because of regulations governing particulate matter.

Petitioner Dalton Trucking, Inc. ("Dalton") Dalton Trucking, Inc., is a California corporation engaged in the business of operating and leasing loaders, dozers, blades, and water

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1 "Congress shall make no law . . . abridging . . . the right of the people . . . to petition Government for a redress of grievances." U.S. Const. amend. I. The right to petition for redress of grievances is among the most precious of liberties safeguarded by the Bill of Rights. *United Mine Workers of America, Dist. 12 v. Illinois State Bar Association,* 389 U.S. 217, 222 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms and has a sanctity and sanction not permitting dubious intrusions. *Thomas v. Collins,* 323 U.S. 516, 530 (1945). "Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank,* 92 U.S. (2 Otto) 542, 552 (1875).

2 5 U.S.C. Section 553(e).

3 42 U.S.C. Section 7401, *et seq.* (sometimes referred to here as the "CAA").

trucks and performs specialized services in open top bulk transportation, lowbed, general freight on flatbeds and vans, as well as rail, intermodal, and 3PL services. Dalton is subject to the PM2.5 standards.

Loggers Association of Northern California, Inc. ("LANC") is a nonprofit California trade association representing the interests of its members involved in the logging industry in Northern California. LANC members are subject to the PM2.5 standards

Robinson Enterprises, Inc. ("Robinson") is a California corporation engaged in various businesses, including forest products and fuels. Robinson is a third-generation family-owned California corporation engaged in harvesting and transportation of forest products, petroleum products, and transportation of various commodities. It has suffered unnecessary financial hardship as a result of various burdensome regulatory requirements, including the PM2.5 standards.

Nuckels Oil Co., Inc. dba Merit Oil Company ("Merit Oil Company") is a California corporation and is a petroleum jobber, wholesaler, and distributor. Merit Oil Company stores, transports, and wholesales a variety of petroleum products, including gasoline, diesel fuels, solvents, and kerosene, and operates a number of delivery trucks and is a family business that has operated in California for three generations. Merit oil Company is subject to the PM2.5 standards.

Western States Trucking Association, Inc. ("WSTA") is a nonprofit California trade association representing the interests of over 1,000 members involved in a variety of business throughout California whose members own and operate on-road and nonroad vehicles, engines, and equipment, which are subject to the PM2.5 standards.

EXECUTIVE SUMMARY

On January 15, 2013, EPA published in the Federal Register a final rule reflecting the

results of its review of its PM NAAQS. 78 Fed. Reg. 3086 (Jan. 15, 2013). The Final PM Rule, with an effective date of March 18, 2013, revised the level of the primary annual NAAQS for PM that is less than or equal to 2.5 microns in diameter ("PM2.5") to 12.0 micrograms per cubic meter ("μg/m3 ") and contained provisions for implementing this standard.

In December 2014, EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the PM2.5 and PM10 NAAQS and issued a call for information in the Federal Register. 79 Fed. Reg. 71764 (December 3, 2014).

"All of the PM NAAQS set to date 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. This assumption needs careful review in the current PM review cycle." Roger O. McClellan, *Providing Context for Ambient Particulate Matter and Estimates of Attributable Mortality*, RISK ANALYSIS, 2016; 36(9):1755-1765 at 1757. Recent scientific analyses that cast doubt on the evidence of a causal link between PM2.5 and mortality provide ample reason to reconsider the necessity of the current PM2.5 standards. Given this, the EPA Administrator should not only decline to tighten the primary annual or 24-hour NAAQS for PM2.5, but should consider making the standards less stringent.

As set forth in more detail below, the PM NAAQS should be carefully reconsidered, and the Administrator should open the regulatory process to all interested stakeholders during the current five-year review, including the Petitioners.

STATEMENT OF LAW AND FACTS

I. OVERVIEW OF STATUTORY REQUIREMENTS

The CAA requires the establishment and periodic revision of the PM NAAQS. Section 108 of the CAA (42 U.S.C. § 7408) directs the EPA Administrator to identify and list "air pollutants" that, in his judgment, "cause or contribute to air pollution which may reasonably be

anticipated to endanger public health and welfare" and that the "presence [of which] . . . in the ambient air results from numerous or diverse mobile or stationary sources." He is also required to issue air quality criteria for any air pollutants that are so listed. 42 U.S.C. § 7408(a) & (b). These criteria are intended to "**accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air . . . .**" 42 U.S.C. § 7408(b) (emphasis added). Section 109 (42 U.S.C. 7409) requires the Administrator to propose and issue "primary" (health-based) and "secondary" (welfare-based) NAAQS for pollutants for which air quality criteria are issued under section 108. 42 U.S.C. § 7409(a).

Section 109(b)(1) defines NAAQS primary standards as those that "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). Section 109(b)(2) provides that secondary standards "shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air." 42 U.S.C. § 7409(b)(2). Such welfare effects as defined in CAA section 302(h) include "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being." 42 U.S.C. § 7602(h).

Section 109(d)(1) of the CAA requires that, at five-year intervals, "the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient

air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(1).

Sections 109(d)(2)(A) and 109(d)(2)(B) of the Act require that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(2).

The Clean Air Scientific Advisory Committee ("CASAC") conducts this review. CASAC has four responsibilities: (1) to advise the EPA Administrator of areas in which additional knowledge is required to assess the adequacy and basis of existing, new, or revised NAAQS; (2) to describe the research efforts necessary to provide the required additional information; (3) to advise the EPA Administrator on the relative contribution to air pollution concentrations of natural and anthropogenic activity; and (4) to advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of the NAAQS. Section 109(d)(2)(C).

The purpose of the primary standards is to provide an adequate margin of safety in order to take account of the inherent uncertainties due to inconclusive scientific information, and to provide a measure of protection against dangers not yet identified through research. Through the primary standards, EPA seeks to both prevent pollution levels that have been demonstrated to have adverse effects and to prevent lower pollutant levels that may pose unacceptable risks, even if those risks are, by their nature, not capable of being precisely identified as to their nature or degree. The decision on what approach to take is left to the EPA Administrator's policy judgment. The CAA does not require the Administrator to establish a primary NAAQS which eliminates all risk,

but rather to a level that reduces risk to the extent necessary to protect public health with an adequate margin of safety. *See Lead Industries v. EPA*, 647 F.2d at 1156 n.51 (D.C. Cir. 1980); *Mississippi v. EPA*, 723 F. 3d 246, 255, 262-63 (D.C. Cir. 2013).

In establishing secondary standards, the Administrator must set standards that are neither more nor less stringent than necessary to protect public welfare from any known or anticipated adverse effects associated with the presence of PM. This policy judgment should rely on scientific evidence and analyses about the effects of PM on public welfare, as well as unquantifiable judgments about how to manage uncertainty. The CAA does not require secondary standards be set to eliminate all adverse effects on welfare.

The EPA's task in setting both primary and secondary standards is to establish standards that are neither more nor less stringent than necessary, and it may not consider the costs of implementing the standards, attainability, or technological feasibility. *See generally Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001); *American Petroleum Institute v. Costle*, 665 F. 2d 1176, 1185 (D.C. Cir. 1981).

II. GENERAL SCOPE OF THE CURRENT NAAQS REVIEW

In December 2014, EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the PM2.5 and PM10 NAAQS. 79 Fed. Reg. 17164 (December 3, 2014). The multi-step review process lead to the release of the Final Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter ("IRP") in December 2016.

With regard to scope, the current review of the PM NAAQS is focused on the primary and secondary NAAQS for PM2.5 (fine particles) and PM10 (coarse particles). The current primary and secondary PM2.5 standards are meant to protect against the health and welfare effects, respectively, that have been associated with short-term (i.e., hours up to one month) or long-term

(i.e., one month to years) exposures to fine particles. The primary and secondary PM10 standards are meant to protect against the effects associated with exposures to coarse particles. Important aspects of the current review include EPA's assessment of the health and welfare effects that have been associated with short- or long-term exposures to PM based on size fractionated PM mass, with a particular focus on the PM2.5 and PM10-2.5 size fractions. In addition, as in the most recent review, EPA will assess the available scientific evidence for health or welfare effects associated with additional size fractions (e.g., ultrafine particles) and with particular PM components or groups of components, sources, or environments (e.g., urban and non-urban environments).

Based on the available scientific information, EPA is considering the extent to which the current PM2.5 and PM10 standards are requisite to protect public health and welfare, within the meaning of section 109(b) of the CAA. To the extent the available information calls into question the protection afforded by one or more of the existing PM standards, EPA has indicated tha it plans to consider potential alternatives that could be supported by the available scientific evidence and, as available, exposure-/risk-based information, in terms of the basic elements of the NAAQS (indicator, averaging time, form, level).

ARGUMENT

I. THE UNCERTAINTY OF THE SCIENCE REGARDING AMBIENT PARTICULATE MATTER CAUSING ADVERSE HEALTH EFFECTS IS GREATER THAN EPA HAS ADMITTED

> In the United States and some other industrial democracies, where people and their governments tend to be risk averse, legislatures, courts, and administrative entities usually create a presumption favoring more safety rather than less. The definitions of risk in law are often vague ("reasonable certainty of no harm" or "adequate margin of safety") and are likely to encourage an unrealistic belief that risks can be minimized or even eliminated altogether."

- Donald Kennedy, Editor-in-Chief, Science 309: 2137 (30 September 2005)

Roger O. McClellan addresses the scientific evidence relating to NAAQS for PM2.5 in his recent 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*") (attached as Exhibit A), and *Providing Context for Ambient Particulate Matter and Estimates of Attributable Mortality*, RISK ANALYSIS, 2016; 36(9):1755-1765 (specifically addressing the PM2.5 NAAQS) (hereinafter, "*Providing Context*") (attached as Exhibit B).

In *Role*, McClellan focuses on EPA's method of setting primary (health-based) NAAQS. *Role* at 243. The Clean Air Act in 1963 and its amendment in 1970 required "the listing of air pollutants that 'may reasonably be anticipated to endanger public health and welfare.'" *Id.* at 244. Subsequent amendments required reevaluation of the NAAQS in 1980 and every five years thereafter. *Id.* EPA also appointed an independent scientific committee called CASAC to conduct peer review for the NAAQS in 1977. *Id.*

When creating a primary NAAQS, 42 U.S.C. § 7409 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. Congress has also noted that sensitive populations, particularly those with respiratory problems who are regularly exposed to ambient air, should be accounted for. *Id.* Given these criteria, McClellan notes a problem with interpreting the Clean Air Act: though NAAQS are intended to mitigate risk, the Act is unclear about how much mitigation satisfies the law. This may lead some groups to operate under the false assumption that risks from pollution in ambient air can be eliminated. *Id.*

McClellan discusses the politicized nature of such revision. For example, at its creation, the NAAQS for lead were "constrained and informed by the scientific information, but ultimately based on the policy judgment of a politically responsible decision-maker, the EPA Administrator." *Id.* at 246.

Earlier NAAQS were completed through informal rulemaking, which did not provide a sufficient basis for judicial review according to the United States Court of Appeals for the District of Columbia Circuit. *Id.* After that court struck down one of EPA's 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 enacted subsequently by Congress in 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 notes with approval. *Id.* at 247.

In 1997, EPA chose to set a separate PM2.5 standard for the first time. Prior to that time, PM 2.5 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 the committee had "a range of views" so complex that it took a table to diagram them. *Id.* This disagreement was magnified by the D.C. Circuit's decision in *Am. Trucking Assn. v. U.S. EPA*, 175 F.3d 1027 (D.C. Cir. 1999). That decision 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.

The Supreme Court affirmed the basic holding of *Am. Trucking* two years later in *Whitman v. Am. Trucking*, 531 U.S. 457 (2001). Writing for the majority, Justice Breyer clarified further that "§109 does not require 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. This sought to solve 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 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 allows 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, lacking human studies on the effects of pollution on 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. (As an aside, in recent years, 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.) 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 notes 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 produces 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 points 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 make NAAQS that reflect reality. *Id.* at 250. EPA has 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 "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 concludes 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 *Whitman*'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 discusses the PM2.5 indicator. He participated in initial CASAC discussions on the first PM2.5 NAAQS in 1997. He noted that the committee members in large part wished to create a NAAQS that "would mandate the monitoring of PM2.5," but also expressed reservations about setting the NAAQS too stringently given the "absence of convincing data on

PM2.5." *Id.* at 251. He states that the Administrator's initial annual NAAQS on PM2.5 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, the 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 agrees wholeheartedly, and supports in principle the efforts of advocacy groups and NGOs to synthesize and submit helpful data for EPA's NAAQS process. *Id.* at 254. However, McClellan heavily criticizes the inclination of some groups to hold certain data as "true" or "false" based on who funded the study that produced the data, and expresses 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 concludes 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 wants CASAC members to 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.*

Moving on to 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 takes time to summarize the methodology of each study. Two of the four considered studies incorporate 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.

In the following section, McClellan points out that in 2012, the Administrator revised the tightened the primary annual NAAQS for PM2.5 to 12μg/cubic m. The 24-hour standard held steady. *Id.* at 1757. McClellan notes that both of these 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 begins 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, which McClellan next examines.

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 faults the authors of the four new studies his paper examines for making a related assumption. One examined 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 question 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 PM2.5 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 PM2.5 exposure and increased all-cause mortality, this is a serious omission. The Administrator also entirely failed to take into account the Six Cities Study, because it had not released numbers for PM2.5 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 PM2.5 "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 PM2.5 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 PM2.5 is of equal toxicity on a mass basis," McClellan notes, is especially important in a modern context, when most PM results not from direct emissions but "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 calls its assumptions "simplistic and . . . naïve" for oversimplifying the way that outside stressors cause an increase in mortality. *Id.* He especially finds 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 reveals, there is "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 associate with PM 2.5 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," we have no hard evidence of any mortality increase directly attributable to PM2.5. *Id.* The authors of the studies reviewed by McCllelan do 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 is 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 agrees 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.*

McClellan is not the only scientist to question the evidence of a significant link between fine particulate matter and mortality rates. James E. Enstrom's paper, *Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973-2002*, INHALATION TOXICOLOGY 2005; 17:803-816, (attached as Exhibit C), 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-μg/m3 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 recent paper, *Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis*, DOSE-RESPONSE: AN INTERNATIONAL JOURNAL January-March 2017:1-12, (attached as Exhibit D), 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 used 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/m3 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 5 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 were 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.

There have also been relevant contributions to a recent issue of *RISK ANALYSIS.* Anne 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 μg/m3. Anne E. Smith, *Inconsistencies in Risk Analyses for Ambient Air Pollutant Regulations*, RISK ANALYSIS, 2016; 36(9):1737–1744

(attached as Exhibit E). Smith describes 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, but 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 PM2.5 primary NAAQS. Smith shows 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 PM2.5. 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 gave lower estimates based on the rationale that EPA used in the latest revision of the NAAQS for PM2.5, with the number of residual avoidable deaths reduced to 21–48, dependent 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 μg/m3." *Id.* at 1741.

Smith finds that a large majority of EPA's estimated health benefit from the 2012 PM2.5 NAAQS are attributable to reductions of PM2.5 in areas that were already in attainment of the PM2.5 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.

Tony Cox was invited to comment on Smith's paper (as well as other papers). Cox points out the flaws in existing models purporting to predict how future changes in exposure to PM2.5 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 (attached as Exhibit F). Basically, 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 PM2.5 on mortality. This means that currently available data has questionable efficacy in predicting how future changes in PM2.5 concentrations will affect human health. *Id.* at 1770-75.

The reduced-form regression models used to attempt to establish associations between particular PM2.5 levels and mortality are flawed, but Cox believes 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.

The analyses of McClellan, Enstrom, Smith, and Cox provide more than enough reason to reconsider the necessity of the current extremely stringent PM2.5 standards. Given that the causal link between PM2.5 and mortality is tenuous at best and indemonstrable at worst, the EPA Administrator certainly should not tighten the primary annual or 24-hour NAAQS for PM2.5; rather, the Administrator should consider making the standards less stringent.

II. EPA Has Inherent Authority to Reconsider the PM NAAQS

"Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change. When an agency changes its existing position, it need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate. But the agency must at least display awareness that it is changing position and show that there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (internal citations and quotation marks omitted). Furthermore, "[a]n initial agency interpretation is not instantly carved in stone [although] reasoned decision-making ordinarily demands that an agency acknowledge and explain the reasons for a changed interpretation. But so long as an agency adequately explains the reasons for a reversal of policy, its new interpretation of a statute cannot be rejected simply because it is new." *Verizon v. FCC*, 740 F.3d 623, 636 (D.C. Cir. 2014). Accordingly, EPA is free to reconsider its prior decisions on PM NAAQS.

As the Supreme Court has observed, "[a]gency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework. . . . [I]n *Chevron* itself, this Court deferred to an agency interpretation that was a recent reversal of agency policy."). *Nat'l*

Cable & Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981-82 (2005) (citing *Chevron v. NRDC*, 467 U.S. 837, 857-58 (1984).

Accordingly, EPA may determine in connection with the current five-year review as a matter of policy that the PM NAAQS should be made less stringent in light of new scientific studies relating to harm to human health from PM and the new Administrator's policy judgment in evaluating the uncertainties of the evidence. *See Smiley v. Citibank (South Dakota), N. A.*, 517 U.S. 735, 742 (1996) ("[regulatory] change is not invalidating. . . ."); *Van Hollen, Jr. v. Fed. Election Comm'n*, 811 F.3d 486, 496 (D.C. Cir. 2016) ("An agency 'must consider varying interpretations and the wisdom of its policy on a continuing basis.'") (quoting *Brand X*, 545 U.S. at 981). Therefore, EPA is free to revisit the PM NAAQS based upon the instant Administrative Petition.

CONCLUSION

For these reasons, Petitioners respectfully request that, during the current five-year review, the Administrator reconsider the NAAQS PM2.5 standards in light of the issues brought to his attention in this Administrative Petition. The Petitioners also request that they be provided with the opportunity to actively participate in the five-year review as stakeholders with a keen interest in the outcome.

DATED: November 9, 2017

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