

**COMMENTS OF THE ATTORNEYS GENERAL OF NEW YORK,
CALIFORNIA, ILLINOIS, CONNECTICUT, DELAWARE, MARYLAND,
MASSACHUSETTS, MICHIGAN, MINNESOTA, NEW JERSEY,
OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA,
WASHINGTON AND WISCONSIN**

ON

**THE EPA ADMINISTRATOR'S REVIEW OF THE
NATIONAL AMBIENT AIR QUALITY STANDARDS FOR
PARTICULATE MATTER, 85 FED. REG. 24094 (APR. 30, 2020)**

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I. INTRODUCTION

The Attorneys General of New York, California, Illinois, Connecticut, Delaware, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington and Wisconsin submit these comments in strong opposition to the April 2020 review of the national ambient air quality standards (“NAAQS”) for particulate matter by the Administrator of the U.S. Environmental Protection Agency (“EPA”). 85 Fed. Reg. 24094 (Apr. 30, 2020). In particular, the Attorneys General strenuously object to the Administrator’s proposed decision not to strengthen the particulate matter NAAQS when such reductions are necessary to provide the “margin of safety” to protect human health and the public welfare protections that the Clean Air Act requires.¹

Particulate matter pollution harms human health and welfare in many ways. For example, just one subcategory, fine particulate matter, is estimated to be responsible for about 95 percent of the global public health impacts from air pollution worldwide, and is the largest environmental health risk factor in the United States, responsible for an estimated 63 percent of deaths due to environmental causes.² Scientific studies link particulate matter to many medical conditions, including:

- premature mortality;
- cardiovascular effects, including coronary heart disease, heart failure, stroke, hypertension and atherosclerosis;
- respiratory effects, including asthma, chronic bronchitis, impaired lung function in children and accelerated lung function decline in adults;
- lung cancer; and
- nervous system effects, including cognitive impairment and dementia.³

And a recent study shows that long-term exposure to fine particulate matter is also associated with higher mortality rates for persons infected with COVID-19.⁴ Particulate matter also harms

¹ 42 U.S.C. § 7409(b).

² M. Pinto de Moura *et al.*, *Inequitable Exposure to Air Pollution from Vehicles in the Northeast and Mid-Atlantic*, at 2 (June 2019), <https://www.ucsusa.org/sites/default/files/attach/2019/06/Inequitable-Exposure-to-Vehicle-Pollution-Northeast-Mid-Atlantic-Region.pdf>; C. Tessum, *et al.*, *Inequity in consumption of goods and services adds to racial-ethnic disparities in air pollution exposure*, 116 (13) *Proceedings of the National Academy of Sciences* at 1 (Mar. 11, 2019).

³ 85 Fed. Reg. 24094, 24106-24113, 24123-24125 (Apr. 30, 2020).

⁴ X. Wu, *et al.*, *Exposures to air pollution and COVID-19 mortality in the United States: A nationwide cross-sectional study*, at 2 (Apr. 20, 2020), <https://projects.iq.harvard.edu/covid-pm/home>; *see also* Office of Massachusetts Attorney General Maura Healey, *COVID-19’s Unequal Effects in Massachusetts: Remediating the Legacy of Environmental Injustice & Building Climate Resilience* (2020), <https://www.mass.gov/doc/covid-19s-unequal-effects-in-massachusetts/download>.

human welfare in a variety of ways, including reduction of visibility, and soiling and degradation of buildings, monuments and other outdoor objects.⁵

The States have a significant interest in ensuring that particulate matter pollution is controlled. Our residents experience all of these harms to health and welfare. State governments bear increased costs to treat illness to our residents caused by particulate matter pollution and to address soiling and degradation of buildings, monuments and other outdoor objects. And scenic views important to tourism and outdoor recreation in our states rely on good visibility unimpaired by excessive particulate matter in the air.

Pursuant to the Clean Air Act, previous Administrators have established several NAAQS for particulate matter. There are primary NAAQS to protect human health from both fine particulate matter, known as PM_{2.5} and larger particulate matter, known as PM₁₀.⁶ There are also secondary NAAQS to address particulate matter's impact on human welfare—specifically, its reduction of visibility.⁷

The Act requires that the Administrator review each NAAQS every five years.⁸ Since the last review of the particulate matter NAAQS was completed in 2012, scientists have produced a wealth of reliable new scientific analysis and other information that requires that the Administrator strengthen the current NAAQS or create of additional particulate matter NAAQS. States rely on the Administrator's promulgation of strong and lawful NAAQS as a key element of their efforts to protect their residents and their financial and other assets from the harms outlined above.

Notwithstanding this abundant evidence supporting more stringent NAAQS, the Administrator is now proposing to retain each of the particulate matter NAAQS without change. His analysis and proposed conclusions are procedurally and substantively flawed.

Of overarching significance, the Administrator arbitrarily and capriciously weakened the process he used in this NAAQS review, a decision that tainted the entire review and its results. Historically, the NAAQS review process for particulate matter and other criteria air pollutants has included preparation and public comment on of a variety of specialized reports, including an Integrated Science Assessment to provide an up-to-date synthesis of scientific knowledge regarding the harmful effects of particulate matter pollution, a Risk and Exposure Assessment, and a Policy Assessment. Also, prior reviews included official input from a panel of scientific and other experts with qualifications and experience related to particulate matter pollution known as the Particulate Matter Review Panel. That panel consulted and directly deliberated the issues with the Clean Air Science Advisory Committee, or CASAC, which is a seven-member scientific advisory board that the Administrator is required, by statute, to seek input from.

⁵ 85 Fed. Reg. at 24127-28.

⁶ *See, e.g.*, 85 Fed. Reg. at 24095.

⁷ *See, e.g.*, 85 Fed. Reg. at 24095, 24099.

⁸ 42 U.S.C. § 7409(d)(1).

In May 2018, however, the immediate prior Administrator Scott Pruitt issued a “Back to the Basics” memorandum in which he arbitrarily and unreasonably weakened the NAAQS review process in several ways, and the current Administrator used that weakened process in this particulate matter review. First, he eliminated several key elements of the process and consolidated others. For example, he eliminated public review of second drafts of the Integrated Science Assessment and Policy Assessment, and eliminated the separate Risk and Exposure Assessment, merging it into the Policy Assessment. Second, he illogically required public comment on the draft Policy Assessment before finalization of the Integrated Science Assessment, which is the source of the scientific conclusions on which the Policy Assessment relies. Separately, he has implemented additional changes that have limited EPA’s ability to rely on feedback from the best qualified experts. Unannounced, the Administrator disbanded the CASAC Particulate Matter Review Panel, with the result that the CASAC, and ultimately the Administrator, did not rely on that panel’s extensive, directly relevant expertise. Additionally, he applied an internal policy that arbitrarily and capriciously excluded scientific experts from serving on the CASAC solely because they received grant money from EPA. That policy was recently vacated by a federal district court, and EPA has announced that it will not appeal the decision. Each of these derogations of the previous review process resulted in the Administrator having less, and lower quality, evidence and information before him, thus impairing the entire review process.

Also troubling are the substantive problems in the Administrator’s proposal to leave the NAAQS unchanged. The weight of new scientific evidence and other analyses regarding harm to health from particulate matter since the last review, including important new evidence regarding adverse effects from exposure to particulate matter at levels below the current standards, demonstrates the need to strengthen those standards in order to meet the Act’s requirement to protect public health and welfare. For example, EPAs’ own analysis estimates that, in areas that meet the current NAAQS, long-term PM_{2.5} exposures are associated annually with up to 45,000 deaths, and 14,600 ischemic heart disease deaths in particular.⁹ Thus, annual deaths from long-term PM_{2.5} exposures may well exceed annual deaths from the flu in the United States, which were estimated at 34,200 during in the 2018-2019 season.¹⁰

The Administrator’s failure to strengthen the standards here contrasts sharply with decisions by previous Administrators to strengthen the particulate matter NAAQS when presented with comparable evidence of harm at ambient concentrations below the then-existing NAAQS. Contrary to the Administrator’s claim that purported uncertainty in the evidence supports leaving the current standards unchanged, the law requires the Administrator to establish more protective standards in the presence of uncertainty in order to provide the requisite margin of safety against harmful effects. And, with regard to effects on public welfare, the Administrator’s proposal ignores new evidence regarding particulate matter’s interference with visibility and applies the wrong standard of review.

⁹ EPA, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter at 3-93 (Jan. 2020).

¹⁰ Centers for Disease Control & Prevention, Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States—2018–2019 influenza season, <https://www.cdc.gov/flu/about/burden/2018-2019.html>.

Making the standards more protective is particularly important as a matter of environmental justice. The Administrator's conclusion that leaving the particulate matter NAAQS unchanged has no disproportionate impact on minority or other at-risk groups¹¹ is egregious and wholly contradicted by the record. For example, recent research has shown that Blacks, Latinxs and Asian Americans are exposed to particulate matter exposures at levels significantly greater than average in the northeast and mid-Atlantic regions, and that the relative health risk to Blacks from fine particulate matter is three times the overall average for the entire population.¹² States are very concerned with protecting such groups from disparate impacts and the current NAAQS does not do so.

In addition, the Administrator fails to adequately consider the important influence of particulate matter pollution from wildfires in his evaluation. EPA explicitly excluded data from areas where air quality was influenced by wildfires,¹³ resulting in underestimating the health impact of particulate matter,¹⁴ which disproportionately impacts individuals with lower socioeconomic status, such as farmworkers.

Because of these procedural and substantive problems, the Administrator's proposal to leave the particulate matter NAAQS unchanged is arbitrary and capricious and fails the statutory requirement to protect health with an adequate margin of safety and to appropriately protect public welfare. The Administrator should accordingly reverse the procedural changes in the NAAQS review process made in the 2018 memorandum, including reinstatement of the Particulate Matter Review Panel, and reopen the particulate matter NAAQS proceeding for implementation of a thorough and transparent process. An application of proper standards and consideration of the weight of the new evidence in conjunction with all prior evidence demonstrate that strengthening the primary and secondary NAAQS is warranted.

Copies of certain studies and articles cited in these comments are attached in a three-volume addendum to these comments.

¹¹ 85 Fed. Reg. at 24140.

¹² M. Pinto de Moura *et al.*, Inequitable Exposure to Air Pollution from Vehicles in the Northeast and Mid-Atlantic, at 3 (June 2019), *available at* <https://www.ucsusa.org/sites/default/files/attach/2019/06/Inequitable-Exposure-to-Vehicle-Pollution-Northeast-Mid-Atlantic-Region.pdf>; Letter from Dr. Christopher Frey to Administrator Andrew Wheeler, Attachment B at B-29 (Oct. 22, 2019) (citing Di *et al* (2017a)).

¹³ EPA, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter at C-23, fn. 16 (Jan. 2020).

¹⁴ Advice from the Independent Particulate Matter Review Panel on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft— September 2019) at C-38.

II. BACKGROUND

A. Particulate Matter, Its Sources and Its Harmful Effects

1. Types and Sources

Particulate matter or “PM” encompasses all airborne particles. It originates in two ways. Particles emitted directly from sources such as factories or automobiles are known as primary particulate matter. 85 Fed. Reg. at 24101. Secondary particulate matter, on the other hand, starts out as gaseous emissions, such as sulfur dioxide, nitrogen oxides, and volatile organic compounds, that undergo chemical reactions that produce small particles. *Id.*

Particulate matter comes in a wide range of sizes ranging from 0.1 to more than 10 micrometers (“ μm ”). The NAAQS are designed to limit exposure to two ranges of particulate matter, known as fine particulate matter and thoracic coarse particulate matter. Fine particulate matter is defined as particles with a diameter of 2.5 μm or less and is referred to as PM_{2.5}. *See, e.g.*, 85 Fed. Reg. at 24100. Thoracic coarse particulate matter is defined as particles with a diameter greater than 2.5 and less than or equal to 10 μm , and is referred to as PM_{10-2.5}. *See, e.g., id.* EPA has created a third classification for particulate matter with a diameter less than 10 μm , referred to as PM₁₀, which it uses as a proxy for limiting ambient concentrations of PM_{10-2.5}. There is also growing evidence and concern about the health and environmental impacts of ultrafine particulate matter, generally defined to have a diameter of 0.1 μm or less. *See, e.g., id.*

2. Harms to Health and Welfare

Particulate matter in the ambient air has multiple, significant effects on human health and welfare. For health, there is, at a minimum, evidence supporting a relationship between particulate matter and the following:

- premature mortality;
- cardiovascular effects, including coronary heart disease, heart failure, stroke, hypertension and atherosclerosis;
- respiratory effects, including asthma, chronic bronchitis, impaired lung function in children and accelerated lung function decline in adults;
- lung cancer; and
- nervous system effects, including cognitive impairment and dementia.

85 Fed. Reg. at 24106-113, 24123-125. In 2011, EPA estimated that among adults alone, reduced exposure to PM_{2.5} and ozone due to the Clean Air Act, including the NAAQS, prevented 160,000 premature deaths in 2010 and would prevent 230,000 premature deaths in 2020, with approximately 85 percent of those reductions in death due to particulate matter control.¹⁵

¹⁵ EPA, Clean Air Act Overview: Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study, <https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study>.

Particulate matter is also associated with a broad range of impacts on human welfare, including effects on visibility and exposed materials. For example, particulate matter impairs visibility because the suspended particles in the air scatter light and absorb it. 85 Fed. Reg. at 24128. And the deposition of particulate matter on exposed materials can produce physical damage, such as promoting or accelerating corrosion, degrading paints, and deteriorating building materials. 85 Fed. Reg. at 24127. It can also reduce the aesthetic appeal of buildings and objects through soiling. *Id.*

3. Impacts on Environmental Justice Communities

Particulate matter has a disparate impact on the health and safety of environmental justice communities. These communities have historically borne the brunt of increased air pollution and continue to suffer from these burdens today. Recent studies confirm that environmental justice communities face a disproportionate impact from facilities emitting particulate matter.¹⁶ Specifically, Black individuals are exposed to an average particulate matter burden far greater than the overall population.¹⁷ The particulate matter exposure disparity attributable to race is even greater than the disparity attributable to poverty.¹⁸ More information about the environmental justice implications of the Administrator’s proposal not to strengthen the particulate matter NAAQS is provided in section V.A.3 below.

B. The Clean Air Act and the Administrator’s Promulgation of the NAAQS

1. Statutory Authority Relevant to the NAAQS

The Clean Air Act aims “to protect and enhance the quality of the Nation’s air resources so as to promote the public health and welfare.” 42 U.S.C. § 7401(b)(1). One of the Act’s principal mechanisms for achieving this goal is the establishment of NAAQS for a set of pollutants known as “criteria” pollutants.

In simple terms, NAAQS are the maximum allowable concentrations of pollutants in the atmosphere.¹⁹ With regard to criteria pollutants, the Act requires the Administrator to identify and list specific pollutants that are released from stationary and mobile sources and are anticipated to endanger public health or welfare. 42 U.S.C. § 7408(a)(1). These pollutants are known as criteria pollutants because for each such pollutant, EPA is required to issue air quality criteria that “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare.” 42 U.S.C. § 7408(a)(2). Air quality criteria essentially summarize the state of the science regarding the pollutant and its impacts on health and the environment. Particulate matter is one of the criteria pollutants, and

¹⁶ See, e.g., I. Mikati, *et al.*, Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status, 108(4) *Am. J. Public Health* 480 (April 2018).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ See, e.g., Encyclopedia Britannica, “National Ambient Air Quality Standard,” <https://www.britannica.com/science/National-Ambient-Air-Quality-Standards-United-States>.

EPA current regulates exposure to this pollutant through its NAAQS for PM_{2.5} and PM₁₀. *See, e.g.*, 40 C.F.R. §§ 50.6, 50.7.

The Administrator must then use the criteria to establish the NAAQS for the criteria pollutants. 42 U.S.C. § 7409(b). Accordingly, the Act requires that the Administrator base the NAAQS on the most up-to-date scientific information.

For each criteria pollutant, the Act requires the Administrator to establish two types of NAAQS: primary NAAQS, which protect public health, and secondary NAAQS, which protect public welfare. 42 U.S.C. § 7409; *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 516 (D.C. Cir. 2009). The Act defines primary NAAQS as “ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on [the relevant air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.” 42 U.S.C. § 7409(b)(1).

The Act then defines secondary NAAQS as “specify[ing] a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.” 42 U.S.C. § 7409(b)(2). The range of effects on public welfare that the secondary NAAQS address is broad, including, but not limited to, “effects on soils, water, crops, vegetation, manmade 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 wellbeing.” 42 U.S.C. § 7602(h). As noted above, particulate matter in particular has effects on visibility and materials. *Am. Farm Bureau Fed'n*, 559 F.3d at 515-16; EPA, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (“Policy Assess.”) at 1-1 fn. 1 (Jan. 2020).

In setting NAAQS, the Clean Air Act requires the Administrator to base the standards solely on impacts to public health and welfare: the agency cannot consider the costs of achieving reductions necessary to meet the standards. *Whitman v. American Trucking Ass'ns*, 531 U.S. 457 (2001). To satisfy these statutory requirements, the Administrator looks at both the short-term and long-term impacts of each criteria pollutant on human health and public welfare. *See, e.g.*, 85 Fed. Reg. at 24104.

Accordingly, depending on the criteria pollutant targeted, the NAAQS may include a short-term standard, in the form of an hourly or daily average standard, designed to protect against acute exposure, and a long-term standard, in the form of an annual average standard, designed to protect against chronic exposure to lower levels of the pollutant. *See, e.g., id.* Also, because the Administrator is required to assure that the NAAQS protect human health *and* public welfare, there are instances where the primary NAAQS may be more stringent than the secondary, or vice-versa, depending on the pollutant and its specific impacts. *See, e.g.*, Policy Assess. at 1-6 (secondary annual standard for total suspended particles set in 1971 was more stringent than primary standard; secondary annual standard for PM_{2.5} set in 2012 was less stringent than primary standard).

After establishing the initial NAAQS, the Administrator is required to review and revise the air quality criteria and the NAAQS as may be necessary once every five years. 42 U.S.C. § 7409(d)(1). This further confirms that Congress directed the Administrator to periodically evaluate revising the NAAQS based on the most up-to-date information.

To assist this process, the Administrator is required to appoint a seven-member independent review committee, known as the Clean Air Scientific Advisory Committee, or CASAC. 42 U.S.C. § 7409(d)(2). The CASAC reviews the existing air quality criteria and NAAQS and recommends to the Administrator any new NAAQS or revisions of existing NAAQS as may be appropriate, as further described below. *Id.*

Once the Administrator sets, or revises, the NAAQS for a pollutant, each state must ensure that air quality in areas throughout the state meets that level. Areas whose air quality fails to meet the level set by EPA are designated as “non-attainment” areas, requiring the appropriate state and/or local air pollution control authority to impose emission reductions on sources of the pollutant within their jurisdiction to satisfy the NAAQS, sometimes with the assistance of pollution controls that upwind states may be obligated to impose on sources within their boundaries. *See generally* 42 U.S.C. § 7410.

2. The Requirements for the Administrator’s NAAQS Review, Including the Structure and Function of the Scientific Advisory Board

As noted above, after establishing the initial NAAQS, the Administrator is required to review the criteria and standards once every five years, and revise them as necessary so that they continue to protect the public health and welfare. 42 U.S.C. § 7409(d)(1). As part of the review process, the CASAC advises the Administrator on whether the air quality criteria and existing standards need revision. *Id.* § 7409(d)(2).

To satisfy its NAAQS review obligations under the Clean Air Act, EPA had developed a searching and rigorous process. Prior to the changes implemented by former Administrator Pruitt’s Back-to-Basics Directive from May 9, 2018, the review process included the following stages: planning, science assessment, risk and exposure assessment, and policy assessment.²⁰ Each of these stages of the review culminated in the preparation of a document that articulated the analysis and conclusions of EPA’s scientists and other experts on these topics, referred to as the Integrated Review Plan, the Integrated Science Assessment, the Risk and Exposure Assessment, or “Risk Assessment” and the Policy Assessment.²¹ Each of these documents was to be prepared sequentially and as separate documents, and each was to be published for review and comment by the CASAC and the public before finalization.²² And, in the case of the

²⁰ Memorandum from Lisa Jackson, Administrator, EPA, to Elizabeth Craig, Acting Assistant Administrator for Air and Radiation, EPA and Lek Kadeli, Acting Assistant Administrator for Research and Development, EPA, Re: Process for Reviewing National Ambient Air Quality Standards, Attachment: Major Elements of the Process for Reviewing National Ambient Air Quality Standards (May 21, 2009).

²¹ *Id.*

²² *Id.*

Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, EPA previously planned to issue first and second drafts of the documents to allow for two rounds of review and comment.²³

Importantly, this previously employed process was born out of a comprehensive “top to bottom review” of the NAAQS review process.²⁴ That evaluation and subsequent modification of the NAAQS review process included input not only from agency staff but also from current and former members of the CASAC, other stakeholder groups that had substantial experience with the NAAQS review process, and the public.²⁵ Significantly, the goal of these prior changes was to “improve the efficiency of the NAAQS review process while ensuring that the Agency’s decisions are informed by the best available science and broad participation among experts in the scientific community.”²⁶ As described in more detail below, the abandonment of these improvements to the NAAQS review process played a large role in its ultimate arbitrary and capricious proposal made here.

The Administrator’s appointment of the CASAC is governed by the Federal Advisory Committee Act (“FACA”). 5 U.S.C. App. 2. In compliance with FACA’s requirements, EPA has adopted formal procedures for selecting individuals to serve on its advisory committees, which are articulated in the agency’s Federal Advisory Committee Handbook.²⁷ The established process has three main steps: identifying potential candidates through a public nomination process, evaluating the nominees, and obtaining approvals and making final appointment decisions.²⁸ Relevant to the issues raised in these comments, the evaluation process requires that EPA staff recommend the best-qualified candidates to EPA management for each open position on an advisory committee.²⁹ The criteria EPA staff are to consider include the candidate’s relevant expertise, work in the subject area, and the point of view the candidate would bring to the committee.³⁰ The goal of the selection process is to have the best people who represent key interests and balanced viewpoints.³¹

²³ See, e.g., EPA, Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter at 1-19, Table 1-3 (Anticipated schedule for the review of the PM NAAQS) EPA-452/R-16-005 (Dec. 2006).

²⁴ Memorandum from Marcus Peacock, Deputy Administrator, EPA to Dr. George Gray, Assistant Administrator, Office of Research and Development, EPA and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation, Re: Process for Reviewing National Ambient Air Quality Standards (Dec. 7, 2006) (“Peacock Memo”).

²⁵ EPA, Review of the Process for Setting National Ambient Air Quality Standards, 15-17 (Mar. 6, 2006).

²⁶ Peacock Memo at 3.

²⁷ EPA, Federal Advisory Committee Handbook (Aug. 2017) (“FACA Handbook”).

²⁸ GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, 10, Table 1 (July 2019) (“GAO Report on EPA Advisory Committees”).

²⁹ FACA Handbook, at 5-4, 5-10, 5-15 through 16.

³⁰ *Id.* at 5-10.

³¹ GAO Report on EPA Advisory Committees, at 12; see also 5 U.S.C. § 5(b)(2) (committee “membership” must be “fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee”).

Ultimately, the FACA Handbook guides the Administrator to appoint individuals to an advisory committee based on the short-list developed by the agency’s staff.³² Importantly, this process helps ensure that the agency can show how the Administrator made appointment decisions to achieve the best qualified and most appropriate candidates for balanced membership.³³ *Id.* Also, the uniform federal ethics rules govern EPA advisory committee members to protect advisory committees from conflicts of interest, *see* 57 Fed. Reg. 35,006, 35,006 (Aug. 7, 1992) (Office of Government Ethics regulation establishing “uniform standards of ethical conduct” for all executive-branch workers), and agencies may not supplement these rules except through concurrence and joint issuance with the Office of Government Ethics. 5 C.F.R. § 2635.105; *Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634, 648-50 (D.C. Cir. 2020) (holding arbitrary and capricious EPA’s directive that prohibited the agency from appointing scientists to the agency’s scientific advisory boards, including the CASAC, if the scientist had received grant funding from the agency).

C. Standard of Review for Promulgation of NAAQS

Courts review the Administrator’s determination of whether and how to revise NAAQS under the “arbitrary and capricious” standard of Clean Air Act section 307(d)(9). 42 U.S.C. § 7607(d)(9). To satisfy this standard of review, the Administrator must “consider[] all relevant factors and articulate[] a rational connection between the facts found and the choice made.” *Miss. Comm’n on Env’tl. Quality v. EPA*, 790 F.3d 138, 150 (D.C. Cir. 2015) (quoting *Catawba Cnty. v. EPA*, 571 F.3d 20, 41 (D.C. Cir. 2009)). Applying this standard, courts have repeatedly cited the Administrator’s reliance on scientific experts, and particularly those on its scientific advisory boards, as a basis to uphold EPA actions. *See, e.g., City of Portland v. EPA*, 507 F.3d 706, 716 (D.C. Cir. 2007) (upholding drinking water standard based on analysis of the “best available, peer-reviewed science” using advice from the Science Advisory Board); *Ohio Valley Env’tl. Coal. v. Fola Coal Co.*, 120 F. Supp. 3d 509, 523 n.16 (S.D.W.V. 2015) (upholding EPA’s assignment of benchmark discharge levels and noting that “not only are there epidemiologists on the Science Advisory Board, there are some very fine epidemiologists serving in that capacity”); *United States v. Vertac Chem. Corp.*, 33 F. Supp. 2d 769, 778 (E.D. Ark. 1998), *rev’d on other grounds by United States v. Hercules, Inc.*, 247 F.3d 706 (8th Cir. 2001) (upholding EPA’s cleanup level calculations at Superfund site based in part on review by Science Advisory Board). Further, the courts only “defer to EPA’s judgment that the available evidence is too uncertain when the agency reasonably explains its decision.” *Murray Energy Corp. v. EPA*, 936 F.3d 597, 619 (D.C. Cir. 2019) (citing *Motor Vehicles Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 51-53 (1983)).

On the other hand, when an agency or its head disregards scientific or other relevant information before it or otherwise provides a rationale for its action that lacks coherence, no deference is available. *See, e.g., Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 48 (1983) (agency action is arbitrary and capricious when it “runs counter to the evidence before the agency”); *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) (no

³² GAO Report on EPA Advisory Committees at 17.

³³ *Id.*

deference owed to agency expertise when the agency's explanation for its action lacks any coherence); *Earth Island Inst. v. Hogarth*, 494 F.3d 757, 763 (9th Cir. 2007) (no deference when "agency ignored its own statistical methodology"). In addition, when an agency revises its review processes without adequate justification, courts find the revised review processes arbitrary and capricious. *See, e.g., Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S.359, 374 (1998) (agency process must be logical and rational as well as consistent with agency's authority); *United Keetoowah Band of Cherokee Indians in Okla. v. FCC*, 933 F.3d 728, 740-45 (D.C. Cir. 2019).

D. The Existing Particulate Matter Standards

1. Structure of the Standards

The NAAQS for each pollutant consists of four basic elements: an indicator, an averaging time, a form and a level. *Am Farm Bureau Fed'n*, 559 F.3d at 516; Policy Assess. at 1-2. The indicator identifies the substance that is the subject of the NAAQS, that is, the chemical species or mixture for which the concentration is measured. *Am. Farm Bureau Fed'n*, 559 F.3d at 516; Policy Assess. at 1-2. fn. 2. The indicators at issue in this proceeding are PM_{2.5}, as an indicator for fine particulate matter, and PM₁₀, as an indicator for thoracic coarse particulate matter.

The averaging time defines the period over which the concentration of the indicator is averaged or otherwise evaluated for the purpose of determining compliance with the NAAQS, for example annually or over a 24-hour period. *Am. Farm Bureau Fed'n* at 516; Policy Assess. at 1-2, fn. 2.

The form is the statistic that is used to evaluate whether an area attains the standard. *Am. Farm Bureau Fed'n*, 559 F.3d at 516; Policy Assess. at 1-2. fn. 2. For example, the form of the annual PM_{2.5} NAAQS is the average of annual mean concentrations over three years. Policy Assess. at 1-2 fn. 2. Finally, the level is the threshold value of the form that defines the legally acceptable concentration of the indicator. *Am. Farm Bureau Fed'n*, 559 F.3d at 516; Policy Assess. at 1-2. fn. 2. For example, the level of the current annual primary PM_{2.5} NAAQS is 12 micrograms per cubic meter ("µg/m³"). *See, e.g.,* 85 Fed. Reg. 24095.

2. The Primary Standards

EPA has focused on the annual PM_{2.5} standard as the principal means of providing public health protection against the bulk of the distribution of short-and long-term PM_{2.5} exposures. Policy Assess. at 3-13. It considers the 24-hour standard as a means of providing supplemental protection against the short-term exposures to peak PM_{2.5} concentrations that can occur in areas with strong contributions from local or seasonal sources, even when overall mean PM_{2.5} concentrations remain relatively low. *Id.*

A prior Administrator first set an annual PM_{2.5} standard in 1997. The annual standard was structured as the three-year average of annual arithmetic mean PM_{2.5} concentrations from single or multiple community-oriented monitors, and set at 15 µg/m³. 62 Fed. Reg. 38652,

38671-74 (July 18, 1997). EPA strengthened the annual standards in 2012 by setting them at 12 $\mu\text{g}/\text{m}^3$. 85 Fed. Reg. at 24097-99.

The prior Administrator first set a 24-hour standard for $\text{PM}_{2.5}$ in 1997. The standard was set at 65 $\mu\text{g}/\text{m}^3$ based on the three-year average of the 98th percentile of 24-hour $\text{PM}_{2.5}$ concentrations within a given area. 62 Fed. Reg. at 38652. The standard was intended to provide supplemental protection against days with high peak concentrations, localized hotspots, and risks arising from seasonal emissions that might not be well controlled by an annual standard. *Id.* at 38669. The form of the standard was selected to provide a balance between limiting the occurrence of peak 24-hour $\text{PM}_{2.5}$ concentrations and identifying a stable target for risk management programs. *Id.*

In 2006, a prior Administrator increased the stringency of the 24-hour $\text{PM}_{2.5}$ standard to its current level of 35 $\mu\text{g}/\text{m}^3$. 85 Fed. Reg. at 24097. EPA explained that this decision was based primarily upon an expanded body of short-term $\text{PM}_{2.5}$ exposure studies that reported statistically significant associations with mortality, hospital admission, and respiratory symptoms at levels around 39 $\mu\text{g}/\text{m}^3$. 71 Fed. Reg. 61144, 61155 (Oct. 17, 2006).

While the prior Administrator did not further lower the 24-hour $\text{PM}_{2.5}$ standard in 2012, she explained that, by lowering the *annual* $\text{PM}_{2.5}$ standard from 15 $\mu\text{g}/\text{m}^3$ to 12 $\mu\text{g}/\text{m}^3$, the annual standard would also provide additional health protection from *short-term* $\text{PM}_{2.5}$ exposure. 78 Fed. Reg. 3086, 3163 (Jan. 15, 2013).

EPA Administrators have maintained the annual standard for PM_{10} at 150 $\mu\text{g}/\text{m}^3$ since 1997. 62 Fed. Reg. at 38658. In 2006 and again in 2012, the Administrators in office at those times determined that the existing annual PM_{10} standard continues to be appropriate. 71 Fed. Reg. at 61202; 78 Fed. Reg. at 3089.

3. *The Secondary Standards*

In many cases, EPA Administrators have set a secondary standard for particulate matter at the same level as the primary standard. *See, e.g., Am. Trucking Ass'ns v EPA*, 175 F. 3d 1027, 1056 (D.C. Cir. 1999), *aff'd in part, rev'd in part, Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). Thus, in 1997 and 2006, the then-Administrators set the annual secondary standard at the same 15 $\mu\text{g}/\text{m}^3$ level as the primary standard, but in 2012 left the annual secondary standard at 15 $\mu\text{g}/\text{m}^3$ while lowering the primary standard to 12 $\mu\text{g}/\text{m}^3$. 62 Fed. Reg. at 38652; 71 Fed. Reg. at 61144; 78 Fed. Reg. at 3086. In 1997, the Administrator at that time set the secondary 24-hour standard for $\text{PM}_{2.5}$ at 65 $\mu\text{g}/\text{m}^3$, and later Administrators then lowered it to 35 $\mu\text{g}/\text{m}^3$ in 2006 and held the level constant in 2012. 62 Fed. Reg. at 38652; 71 Fed. Reg. at 61144; 78 Fed. Reg. at 3086. Also, the Administrator in 1997 set the secondary standard for PM_{10} at 150 $\mu\text{g}/\text{m}^3$, and subsequent Administrators have maintained it at the same level since then. 62 Fed. Reg. at 38652; 71 Fed. Reg. at 61144; 78 Fed. Reg. at 3086.

III. THE ADMINISTRATOR'S PROPOSED ACTION

A. Primary PM_{2.5} Standards

With regard to the Administrator's proposal to retain the current primary PM_{2.5} standards, the Administrator states that his review built on the decisions made in the last review, focusing on "evaluating the public health protection afforded by the annual and 24-hour standards." 85 Fed. Reg. at 24105. In the Administrator's judgment, he states, demonstrated relationships between PM_{2.5} exposure and harm to human health include the relationships between (a) long-term PM_{2.5} exposure and mortality, cardiovascular effects, respiratory effects; lung cancer and nervous system effects; and (b) short-term PM_{2.5} exposure and mortality, cardiovascular effects and respiratory effects. *Id.* at 24106-114. He states that he considered the advice of the CASAC, whose members were divided on the question of whether there was a robust causal relationship between PM_{2.5} exposure and mortality. *Id.* at 24114.

Based on his review, the Administrator proposes to retain the current annual and 24-hour PM_{2.5} NAAQS based on his conclusion that they are adequate to protect human health with an adequate margin of safety. *Id.* at 24121. He claims that there is "considerable uncertainty in the potential public health impacts of reductions in ambient PM_{2.5} below the concentrations achieved under the current primary standards" so that more stringent standards "are not supported." *Id.* at 24120. Among other things, he asserts that (a) epidemiological studies are not sufficiently reliable because of unexamined confounders and other factors; (b) experimental studies have not evaluated PM_{2.5} levels beneath the existing NAAQS levels; and (c) the risk assessment included in the Policy Assessment suffers from uncertainty because of alleged limitations in the epidemiological studies upon which it is based. *Id.* at 24119-120.

B. Primary PM₁₀ Standards

With regard to the Administrator's proposal to retain the current primary PM₁₀ standards, the Administrator states that he built on the decisions made in the last review, with consideration of the scientific information that has since become available, the Integrated Science Assessment's evaluation of that new information, and the approach taken in the Policy Assessment. 85 Fed. Reg. at 24122. The Administrator acknowledges that, since the last review, the evidence for a variety of health effects related to PM_{10-2.5} "has expanded, particularly for long-term exposures," and that this expansion "has broadened the range of effects that have been linked with PM_{10-2.5} exposures." *Id.* at 24126. The new or strengthened causality determinations include the relationships between PM_{10-2.5} exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects and cancer. *Id.* at 24126.

Nonetheless, despite the additional weight of evidence supporting these health effects, the Administrator proposes to retain the current PM₁₀ NAAQS—PM₁₀ being the proxy used to regulate exposure to PM_{10-2.5}—based on his conclusion that the available evidence does not call into question the adequacy of the health protection under those standards. *Id.* at 24126. As the basis for this proposed conclusion, he gives his belief that uncertainties in the evidence remain, including uncertainties in exposure estimates, the independence of health effects ascribed to

PM_{10-2.5}, and the amount of support for the biological plausibility of such health effects from controlled studies. *Id.* at 24126.

C. Secondary PM_{2.5} Standards

1. Visibility

The Administrator chose to generally use the methodology that the prior Administrator used in evaluating visibility effects of particulate matter in the 2012 NAAQS determination. In 2012, EPA analysis relied on an algorithm called “IMPROVE” that derives a visibility index for PM_{2.5}, which estimates light extinction based on PM_{2.5} chemical composition and relative humidity. *Id.* at 24128. Based on that analysis, the prior Administrator chose a 24-hour averaging time. She considered shorter averaging times that more directly correlate with light extinction, but noted data quality issues with hourly PM_{2.5} monitoring. *Id.* Finally, the prior Administrator chose a three-year average of annual 90th percentile values as the form, and chose a visibility index level of 30 deciviews. Deciview is a scale for characterizing visibility based on the degree of light extinction due to particulate matter or other interference with visibility; it is frequently used in scientific and regulatory visibility evaluations. Policy Assess. at 5-7. The prior Administrator determined that this level of visibility was widely acceptable, based on studies of public preferences for visibility. *Id.* at 24129.

In his current review, the Administrator states that he is generally building upon the approach taken in the 2012 review, informed by updated scientific evidence and technical information that has since been developed. After taking this new information into account, the Administrator proposes to determine that current secondary PM_{2.5} and PM₁₀ standards adequately protect against PM-related visibility impairment. *Id.* Among the updated information, the Administrator relies on a revised form of the IMPROVE algorithm that was developed in 2016, alongside the original algorithm. *Id.* at 24130, 24138.

Notably, the Administrator states that *no new visibility preference studies have been conducted since the last review.* *Id.* at 24138. And the Administrator states that there are potential limitations in the visibility studies he relies upon, including the following:

- The available studies may not capture the full range of visibility preferences in the U.S. population, particularly given the potential for preferences to vary based on the visibility conditions commonly encountered and the types of scenes being viewed.
- The available preference studies were conducted 15 to 30 years ago and may not reflect the visibility preferences of the U.S. population today.
- The available preference studies have used a variety of methods, potentially influencing responses as to what level of visibility impairment is deemed acceptable.
- Factors that are not captured by the methods used in available preference studies may influence people’s judgments on acceptable visibility, including the duration of visibility impairment, the time of day during which light extinction is greatest, and the frequency of episodes of visibility impairment.

Id. at 24138. Based on his review, the Administrator is proposing to maintain 30 deciviews as the level of visibility index, again arguing that the existence of uncertainties in the preference studies support this level of visibility rather than a lower level. *Id.*

2. *Materials*

With regard to the secondary NAAQS as they relate to effects on materials, the Administrator states that his evaluation built on the decisions made in the last review and the currently available evidence and information. 85 Fed. Reg. at 24129. He noted that material damage from particulate matter generally results from two processes, soiling and corrosion, that occur when particulate matter is deposited on exposed surfaces. *Id.* at 24133-35.

Soiling consists of the accumulation of particulate matter on the surface of an object that affects the object's optical characteristics or appearance, possibly resulting in harm to the aesthetic value or damage to the surface of the object. *Id.* The Administrator discusses a variety of new evidence supporting the relationship between particulate matter and soiling, including, among other things: progress on the theoretical understanding of soiling of cultural heritage; new approaches to determining the origin of chemicals forming crusts on stone monuments and the relationship between the crusts and local environmental conditions; and new evidence regarding soiling of glass and photovoltaic panels, which can impact the optical and thermal properties of the glass and can reduce the energy efficiency of the panels. *Id.* at 24134.

Corrosion occurs when the deposition of particulate matter on surfaces such as stone building materials degrades the material. *Id.* at 24134. The Administrator identifies a variety of new research further demonstrating such effects since the last review. *Id.* Those developments include, among others, advances on the quantification of degradation rates, further characterization of factors that influence damage of stone materials; and studies linking particulate matter with harm to iron, steel and aluminum. *Id.* at 24134 (citing studies).

Notwithstanding this new evidence, the Administrator asserts that there was not sufficient information in the record on the quantitative relationships between particulate matter and materials effects in the United States and that there were uncertainties in the extent to which such effects would harm the public. *Id.* at 24139. As a result, he proposes to decline to revise the current secondary particulate matter NAAQS or to establish a separate NAAQS to address materials impacts. *Id.* at 24137, 24139.

IV. EPA'S PROCESS TO REVIEW THE PARTICULATE MATTER NAAQS STANDARDS WAS DEFICIENT

The Administrator imposed several changes in the NAAQS review process that undermine the scientific credibility of his analysis and render his proposed decision to retain the current particulate matter NAAQS arbitrary and capricious. The changes undermining the scientific credibility of the review include the decisions to: (1) eliminate several key elements of the review process and consolidate others; (2) require public comment on the draft Policy Assessment before finalization of the Integrated Science Assessment; (3) disband the PM

Review Panel; (4) prohibit scientific experts that receive EPA grant funding from serving on the CASAC; and (5) implement several measures that eliminated transparency from fundamental components of the review process.

Taken together, these changes have shut out scientific experts from providing EPA guidance on the adequacy of the current particulate matter NAAQS, reduced the public's opportunity to meaningfully comment on the Administrator's proposal to retain the current particulate matter standards, and reduced the transparency of the process. Not only do these flaws in the process render the Administrator's proposal to retain the particulate matter NAAQS arbitrary and capricious for failure to consider all relevant factors, *Mississippi Comm'n on Env'tl. Quality*, 790 F.3d at 150, but also the failure to provide any reasoned explanation—or any explanation at all—for the changes to the review process has rendered the process itself arbitrary and capricious.

A. EPA Reduced Opportunities for Adequate Public Comment by Inappropriately Eliminating or Consolidating Key Documents Necessary to Sufficiently Review the Particulate Matter NAAQS.

As explained above, EPA has developed a rigorous and thorough process for reviewing the NAAQS. When EPA initiated its review of the particulate matter NAAQS, it planned to implement this established process.³⁴ Pursuant to this plan, EPA intended to issue first and second drafts of each of the key documents articulating EPA's analysis and review of the particulate matter NAAQS, including the Integrated Science Assessment, the Risk and Exposure Assessment, and the Policy Assessment.³⁵ This iterative process would have allowed multiple opportunities for the CASAC and the public to review and comment on EPA's scientific assessments and policy conclusions. Also, finalizing the Integrated Science Assessment *before* the second draft of the Policy Assessment was released for review and comment was fundamental to EPA's comprehensive review because the Policy Assessment necessarily draws on the scientific findings included in that Integrated Science Assessment.

Significantly departing from this plan, EPA never issued a second draft of either the Integrated Science Assessment or the Policy Assessment for review and comment.³⁶ Additionally, EPA combined the entire Risk and Exposure Assessment of the review with the Policy Assessment. *See* Policy Assess. at Appendix C. Finally, EPA only finalized the Integrated Science Assessment *after* the publication of the draft Policy Assessment and after the

³⁴ *See* EPA, Integrated Review Plan for the National Ambient Air Quality Standards For Particulate Matter, EPA-452/R-16-005, 1-5 (Dec. 2016).

³⁵ *Id.* at Table 1-3.

³⁶ Letter from Andrew R. Wheeler, EPA, Administrator to Louis Anthony Cox, Jr., Ph.D., Chair, Clean Air Scientific Advisory Committee, Re: Response to CASAC comments on Draft Integrated Science Assessment (Jul. 25, 1999) (explaining that the Administrator would not be issuing a second draft of the Integrated Science Assessment for review and comment) (“EPA Response to CASAC Comments on Draft Integrated Science Assessment”); Policy Assess., at 1-2 (“The final [Policy Assessment] is also informed by the advice and recommendations received from the CASAC during its review of *the* Draft [Policy Assessment].”)

window for review and comment on the Policy Assessment by the CASAC and the public had closed.³⁷

The Administrator's changes to EPA's established process critically undermine the legitimacy of the agency's particulate matter NAAQS review. First, the changes directly contravene the CASAC's recommendation for EPA to prepare separate documents for each key element of the particulate matter NAAQS review. As explained above, the goal of that recommendation was to help disentangle the scientific analysis from policy judgments and enable a full review of the best available science. *See* section II.B.2 above. Eliminating that sequential analysis, in combination with eliminating the public and the CASAC's opportunities to review and provide feedback on multiple drafts of the key documents, arbitrarily limits the Administrator's ability to incorporate valuable scientific feedback in his analysis of the data and its policy judgments. Indeed, the CASAC specifically noted that it needed an opportunity to review and comment on a second draft of the Integrated Science Assessment because it lacked the scientific expertise to meaningfully review and provide advice on all aspects of the review of the first draft of the Integrated Science Assessment.³⁸ The Administrator denied CASAC's request without explanation and has not addressed how his review accounted for this scientific gap. The Administrator's failure to provide the requested opportunity to review and comment on a second draft of the Integrated Science Assessment without explanation and without alternative measures being taken to address the scientific shortfalls the CASAC identified is arbitrary and capricious.

B. By Disbanding the PM Review Panel, EPA Has Critically Undermined CASAC's Ability to Meaningfully Review the Particulate Matter NAAQS Evidence and Proposal

The Administrator's particulate matter NAAQS review process is also arbitrary and capricious because it relies only upon on the seven-member CASAC to review and provide advice on EPA's technical and policy assessments, rather than the much larger panel of scientific experts previous Administrators have historically relied on. EPA has a long, important history of augmenting the CASAC, by forming a larger panel of subject-matter experts to assist the CASAC in reviewing the NAAQS. EPA has used such panels since at least 1982, and the last four PM Review Panels have had at minimum 15 members in addition to the members of the CASAC.³⁹

³⁷ *See* EPA Response to CASAC Comments on Draft Integrated Science Assessment at 2.

³⁸ CASAC, CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft—October 2018), Consensus Responses at 1 (Apr. 11, 2019) ("CASAC ISA Review").

³⁹ Letter from Christopher H. Frey, Ph.D., *et. al.*, Independent Particulate Matter Review Panel, to Louis Anthony (Tony) Cox, Jr., Ph.D., Chair, CASAC, EPA, re: CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft—October 2018), Individual Comments of Christopher H. Frey, Ph.D., E-38, Table 1 (Dec. 10, 2018) (EPA-HQ-ORD-2014-0859-0048) ("Independent Particulate Matter Review Comments on Draft Integrated Science Assessment"); Independent Particulate Matter Review Panel, The Need for

Traditionally, this larger panel has contained experts from a broad range of scientific fields with expertise relevant to the specific pollutant at issue.⁴⁰ It is this larger body that has reviewed and provided advice directly relevant to the Administrator’s review of the NAAQS.⁴¹ Specifically, this larger panel has traditionally reviewed and prepared comments on each of the documents that EPA prepares for the Administrator’s review of the NAAQS.⁴² The panel then provides those analyses to the CASAC, which in turn submits its views, as informed by the panel’s views, to the Administrator.⁴³

Tighter Particulate-Matter Air-Quality Standard, *New England J. of Medicine* (Jun. 10, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMsb2011009>.

⁴⁰ See, e.g., Memorandum from Fred Butterfield, Designated Federal officer, Clean Air Scientific Advisory Committee, to Daniel Fort, Ethics & FACA Policy Officer, re: Formation of Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel (Oct. 23, 2007) (justifying the formation of the panel because of a need for “nationally-recognized experts” in atmospheric science, human exposure and risk assessment/modeling, dosimetry, toxicology, controlled human exposure, epidemiology and biostatistics, effects on visibility impairment, ecological effects, other welfare effects, ecosystem exposure and risk assessment/modeling, and resource valuation); Independent Particulate Matter Review Comments on Draft Integrated Science Assessment, at Individual Comments of Christopher H. Frey, Ph.D., E-38-39.

⁴¹ See, e.g., Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, EPA, re: Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel’s Consultation on EPA’s Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (Jan. 3, 2008) (providing the PM Review Panel member’s individual written comments on the Draft Integrated Review Plan developed for EPA’s review of the particulate matter NAAQS that concluded in 2012) (“CASAC Comments on Integrated Review Plan for 2012 PM NAAQS Review”); Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to Lisa P. Jackson, Administrator, EPA, re: Review of EPA’s Integrated Science Assessment for Particulate Matter (First External Review Draft, December 2008) (May 21, 2009) (providing the PM Review Panel member’s individual comments on EPA’s first draft of the Integrated Science Assessment developed for EPA’s review of the particulate matter NAAQS that concluded in 2012) (“CASAC Comments on Integrated Science Assessment for 2012 PM NAAQS Review”); Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to Lisa P. Jackson, Administrator, EPA, re: CASAC Review of Policy Assessment for the Review of the PM NAAQS- First External Draft (Mar. 2010) (May 17, 2010) (providing the PM Review Panel member’s individual comments on EPA’s first draft of Policy Assessment developed for EPA’s review of the particulate matter NAAQS that concluded in 2012) (“CASAC Comments on Draft Policy Assessment for 2012 PM NAAQS Review”).

⁴² See, e.g., CASAC Comments on Integrated Review Plan for 2012 PM NAAQS Review; CASAC Comments on Integrated Science Assessment for 2012 PM NAAQS Review; CASAC Comments on Draft Policy Assessment for 2012 PM NAAQS Review.

⁴³ See, e.g., CASAC Comments on Integrated Review Plan for 2012 PM NAAQS Review; CASAC Comments on Integrated Science Assessment for 2012 PM NAAQS Review; CASAC Comments on Draft Policy Assessment for 2012 PM NAAQS Review.

This review cycle for the particulate matter NAAQS started out no different. In 2015, at the outset of this review cycle, EPA formed the PM Review Panel “to review and provide independent expert advice, through the Chartered CASAC, on EPA’s technical and policy assessments that support the Agency’s review of the [NAAQS] for [PM], including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.”⁴⁴ According to the charge, 26 experts in the following subject areas were selected for membership: “air quality and climate responses, atmospheric science and chemistry, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of particulate matter concentrations and light extinction, and visibility impairment and related welfare effects.”⁴⁵

But in 2018, three years into the review cycle, EPA disbanded the PM Review Panel without any notice or explanation. In its place, the Agency charged the seven-member CASAC with the complex review task originally assigned to the 26-member PM Review Panel.⁴⁶

The CASAC, however, lacks the necessary expertise to meaningfully review and provide advice on the Administrator’s review of the particulate matter NAAQS.⁴⁷ Indeed, the charge document for the newly formed CASAC states that the members only have expertise in toxicology, engineering, medicine, ecology, and atmospheric science.⁴⁸ Left out are the critical and highly specialized fields of air quality and climate responses, atmospheric chemistry, dosimetry, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of particulate matter concentrations and light extinction, and visibility impairment and related welfare effects—all critical to thorough assessment of the broad considerations required in reviewing the particulate matter NAAQS. The CASAC itself has acknowledged that “the breadth and diversity of the evidence to be considered [related to the review of the particulate matter NAAQS] exceeds the expertise of the statutory CASAC, or indeed any seven individuals.”⁴⁹ Most glaringly, as one of the members of the CASAC highlighted, not a single member of the CASAC is an epidemiologist.⁵⁰ This is

⁴⁴ Memorandum from Aaron Yeow, Designated Federal Officer, Science Advisory Board, EPA to Christopher S. Zarba, Director, Science Advisory Board, EPA, re: Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, 2 (Nov. 17, 2015).

⁴⁵ *Id.*

⁴⁶ Memorandum from Aaron Yeow, Designated Federal Officer, Science Advisory Board, EPA to Thomas H. Brennan, Acting Director, Science Advisory Board, EPA, re: Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS) at 2 (Nov. 7, 2018) (“Yeow CASAC Charge Memo”); *see also* EPA Press Release, Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee (Oct. 10, 2018).

⁴⁷ CASAC ISA Review, Consensus Responses at 1 (“the breadth and diversity of evidence to be considered exceeds the expertise of the . . . CASAC members”).

⁴⁸ Yeow CASAC Charge Memo.

⁴⁹ CASAC ISA Review, Consensus Responses at 1.

⁵⁰ CASAC ISA Review, Comments of Dr. Mark Frampton, A-81.

particularly troubling because a key statutory requirement of the NAAQS review is evaluation of particulate matter impacts on public health. *See* 42 U.S.C. § 7409(b)(1).

The Administrator’s attempt to address the problem he created by disbanding the PM Review Panel falls short. The formation of a “pool of subject matter expert consultants that the seven-person chartered CASAC, through the chair, [can] draw from as needed to support its particulate matter and ozone reviews,” does not remedy the CASAC’s lack of expertise. For starters, the consultant pool was only formed *after* the CASAC’s sole opportunity to review and comment on the Integrated Science Assessment had passed.⁵¹ As a result, the CASAC, the group that the Administrator is required to rely on to review the particulate matter NAAQS, did not have access to the pool of subject matter experts when it was reviewing and providing feedback on EPA’s main document analyzing the science of particulate matter pollution and its public health impacts.

Additionally, even once the expert pool was formed, the experts were not allowed to identify shortcomings or issues in EPA’s Draft Policy Assessment. Instead, EPA required that “[r]equests for feedback from [the expert pool] be submitted in writing through . . . the CASAC’s chair and the CASAC’s designated federal official.”⁵² This gatekeeper requirement stands in stark contrast to the transparent public meetings held for prior NAAQS subject matter review panels, where the members could respond to each other’s opinions and work toward consensus opinions. EPA’s siloed approach cut off the ability of the expert pool of consultants to independently raise issues and concerns in their areas of expertise. Without adequate expertise, the CASAC may have not identified problems with EPA’s analysis. As a result, the CASAC, oblivious to problems in EPA’s review of the NAAQS, may have failed to raise the issue with the members of the expert pool. Accordingly, EPA’s decision to disband the PM Review Panel has rendered its review of the particulate matter NAAQS arbitrary and capricious.

Further, there is no evidence that EPA considered the views of an independent group of appropriately qualified experts in its NAAQS review. After termination of the PM Review Panel, 20 members of the panel took the initiative to form a group they called the Independent Particulate Matter Review Panel (the “Independent Panel”) to continue the work they had been performing on the PM Review Panel.⁵³ Reconstituted from the disbanded PM Review Panel, the members of the Independent Panel have expertise in the following areas: air quality and climate responses, atmospheric science and chemistry, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of particulate matter concentrations and light extinction, and visibility impairment and related welfare effects.⁵⁴ The participation of each of the 20 members in the Independent Panel was subject to a good-faith ethics review by the former director of the EPA Science Advisory Board Staff Office.⁵⁵ The Independent Panel conducted its meeting to review

⁵¹ EPA Response to CASAC Comments on Draft Integrated Science Assessment at 2.

⁵² *Id.*

⁵³ *See, e.g.*, Letter from Dr. Christopher Frey to Administrator Andrew Wheeler at 1 (Oct. 22, 2019).

⁵⁴ *Id.* at E-1 to E-20 (professional qualifications of the Independent Panel’s members).

⁵⁵ *Id.* at 1.

the draft Policy Assessment following the same procedures as a CASAC meeting.⁵⁶ While the members were reimbursed for travel expenses incurred to attend the meeting by the Union of Concerned Scientists, they did not accept any honorarium or other compensation. No one other than the members of the Panel determined the content of the meeting or of the reports prepared by the Panel.⁵⁷

Because the Independent Panel has the relevant expertise that the CASAC, by its own admission, lacks, and its independence and processes are consistent with recognized EPA practices, the Panel's conclusions regarding scientific issues raised by the Administrator's current NAAQS proposal merit substantial weight and due consideration. The Independent Panel has provided its views to EPA regarding the current particulate matter NAAQS rulemaking in the form of two sets of comments on the draft Integrated Science Assessment and an October 2019 set of comments on the draft Policy Assessment, the latter of which is referred to herein as the "Independent Panel Report." *See generally* Letter from Dr. Christopher Frey to Administrator Andrew Wheeler and attachments (Oct. 22, 2019) ("Ind. Panel Rpt."). The Independent Panel Report found compelling evidence of effects beneath the current particulate matter NAAQS and concluded that the existing standards are inadequate to meet the statutory standard requiring protection of human health with an adequate margin of safety, as further described below. Ind. Panel Rpt. at B-20. But there is no evidence that the CASAC considered the Independent Panel's views, as expressed in the Independent Panel Report, in reaching its conclusions, as the CASAC's December 16, 2019 report on the draft Policy Assessment only mentioned the Independent Panel once, in passing.⁵⁸ EPA's failure to consider input from the Independent Panel, the group EPA previously deemed the best qualified scientist to review the particulate matter criteria and NAAQS, is arbitrary and capricious, rendering the proposed decision to retain the current particulate matter NAAQS unlawful.

C. EPA's Policy Prohibiting Scientists that Receive EPA Grants from Serving on EPA Advisory Committees Undermines the Scientific Credibility of the Review Process

EPA's recently invalidated agency-wide directive, generally barring scientists receiving EPA grants from serving on EPA advisory committees, prevented EPA from receiving important and necessary scientific feedback on the Agency's review of the particulate matter NAAQS. *See Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634 (D.C. Cir, 2020) (finding directive arbitrary and capricious); *NRDC v. EPA*, 19-CV-05174, --- F.Supp.3d ---, 2020 WL 615072 (S.D.N.Y. Feb. 10, 2020) (same).⁵⁹ That revised EPA policy runs counter to EPA's prior policy,

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ CASAC, CASAC Review of the EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft—September 2019), Consensus Response at 9 (Dec. 16, 2019).

⁵⁹ *See also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) (finding advisory committee directive judicially reviewable and remanding for determination whether directive "skewed composition of EPA committees in favor of regulated industries" in violation of Federal Advisory Committee Act and whether EPA "offered no rational reason for finding

which “allow[ed] EPA grantees to serve on advisory committees . . . in part to ‘ensure that the scientific and technical bases of its decisions . . . are based upon the best current knowledge from science, engineering, and other domains of technical expertise; and . . . are credible.’”⁶⁰

As many of the undersigned states argued in opposing the directive, leading experts on the scientific topics relevant to EPA’s rulemakings work at universities, hospitals, or non-profits, and rely heavily on government funding. Brief for State of Washington, *et al.*, as Amici Curiae Supporting Appellants, *Physicians for Social Responsibility v. Wheeler*, No. 19-5104, 2020 WL 6916010, at *11 (D.C. Cir. Dec. 18, 2019). As a result, the directive “disproportionately” excluded “independent, public-interest researchers” from advisory-committee service, skewing the composition of advisory committees toward industry-funded scientists. *See id.* at *12. For example, Dr. Charles Driscoll is a Distinguished Professor of Environmental Engineering at Syracuse University who has conducted extensive research on air quality issues and was previously a member of CASAC, was barred from serving on the CASAC during this review cycle. *Id.* at *12-*13. Dr. Driscoll was forced to step down from CASAC due to his receipt of an EPA grant to study particulate matter, ozone, and water quality issues. *Id.* Thus, the agency did not receive scientific input and advice from the very experts—like Dr. Driscoll—that EPA has deemed the most qualified to research the specific scientific issues relevant to the particulate matter NAAQS review.

Worse still, EPA has not identified *any* benefit or evidence supporting the directive. *Id.* at *14. Furthermore, there are serious concerns about the qualifications of the scientists EPA has appointed to the CASAC.⁶¹

EPA has conceded that its implementation of the directive was arbitrary and capricious.⁶² Although the federal court’s decision did not, of its own force, require EPA to reopen and reform advisory committees that had been selected under invalidated directive, the directive’s impacts on EPA’s ability to rigorously review the scientific bases of the particulate matter NAAQS has

that any benefits of the policy justified the alteration of balance and influence on the committees” in violation of the Administrative Procedure Act).

⁶⁰ *Physicians for Social Responsibility*, 956 F.3d at 647 (quoting Science and Technology Policy Council, EPA, Peer Review Handbook, A-4 (4th ed. 2015)); *see also id.* (finding EPA’s failure to even address its prior contrary conclusions “especially glaring given that the prior regime existed, in part, for the very purpose of facilitating the critical role played by EPA’s scientific advisory committees”).

⁶¹ Brennan Center for Justice, *Proposals for Reform, Vol. II*, 34 (2019) (explaining that the CASAC chairman has received funding from the American Petroleum Institute, and that six of the seven members of the committee are “state regulators with views outside the scientific mainstream”), https://www.brennancenter.org/sites/default/files/2019-09/2019_10_TaskForce%20II_0.pdf; S. Waldman, *Science Adviser Allowed Oil Group to Edit Research*, Climatewire, (Dec. 10, 2018), <https://www.eenews.net/climatewire/stories/1060109129>.

⁶² *See, e.g.*, EPA, EPA Will Not Appeal Adverse SDNY Decision Regarding October 31, 2017 Federal Advisory Committee Directive (June 24, 2020), <https://www.epa.gov/newsreleases/epa-will-not-appeal-adverse-sdny-decision-regarding-october-31-2017-federal-advisory>.

rendered its review arbitrary and capricious. Accordingly, EPA's concession cannot turn back the clock and does not correct the infirmities of EPA's scientific review that resulted from EPA's implementation of this misguided directive.

D. EPA's Lack of Transparency in Implementing These Changes Undermines the Scientific Credibility of EPA's Particulate Matter NAAQS Review

Finally, most of the process changes discussed above were adopted or implemented without any public process or even any explanation why such changes would improve the particulate matter NAAQS review process. The process and resulting particulate matter NAAQS are thus arbitrary and capricious for that reason, too. For example, EPA never informed the CASAC or the public about the changes to the Integrated Review Plan, whereby EPA consolidated the Policy Assessment with the Risk and Exposure Assessment and eliminated the opportunity to comment on multiple drafts of the Integrated Science Assessment and the Policy Assessment. Instead, CASAC only learned about these changes in Administrator Wheeler's response to the CASAC's comments on the draft Integrated Science Assessment.⁶³ Similarly, EPA did not inform anyone before disbanding the PM Review Panel. Importantly, neither the CASAC nor the public had an opportunity to comment on EPA's changes to the Integrated Review Plan for the particulate matter NAAQS or the disbanding of PM Review Panel before the changes were implemented.

The Administrator's inexplicable changes to the NAAQS review process and schedule undermine the transparency and conclusions of the NAAQS review process. Critically, these midstream changes hampered the CASAC's and the public's ability to plan and allocate the necessary resources to meaningfully review and provide feedback on the particulate matter NAAQS review. This feedback is an important component of the process because it helps assure that the Administrator receives and considers both additional relevant information that may not yet be in the record and comments that help the Administrator to properly understand the relevant information.

The lack of transparency also infected the Administrator's process for selecting the scientific experts he appointed to the CASAC and expert pool of consultants. The Administrator reconstituted the *entire* CASAC after adopting its new advisory committee directive governing the appointment of scientific experts. However, the Administrator has not disclosed the criteria he used to select the new appointees.⁶⁴ Furthermore, he appointed the CASAC members from the full roster of scientists nominated, not a short-list of the most qualified individuals developed by EPA staff as is required by EPA's FACA Handbook.⁶⁵ And EPA's creation of the pool of expert consultants, created in response to CASAC's request for EPA to reinstitute the PM Review Panel, is similarly tainted by a lack of transparency. Specifically, the entire selection process was condensed into a 37-day window, only allowing 14-days for EPA to receive nominations and no time for public comment on the nominations. 84 Fed. Reg. 38625, 38625

⁶³ EPA Response to CASAC Comments on Draft Integrated Science Assessment, at 2.

⁶⁴ U.S. GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, GAO-19-280, 17 (July 2019).

⁶⁵ *Id.*

(Aug. 7, 2019). Further, the Administrator directly vetted the candidates, rather than relying on a list that had been vetted by the EPA Science Advisory Board Staff Office.⁶⁶ The shroud EPA has draped over its selection process for the CASAC and the pool of expert consultants formed to assist the CASAC makes it impossible to determine whether the purported independent scientific advisors are in fact independent and unbiased. Accordingly, the lack of transparency on the changes to the review process, the schedule of the review, and its process for selecting scientist to review and advise EPA in the particulate matter NAAQS review undermine the scientific integrity of the process and render that review arbitrary and capricious.

V. THE EXISTING PRIMARY PARTICULATE MATTER STANDARDS DO NOT PROTECT PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY

As noted above, the Clean Air Act requires that EPA promulgate and revise NAAQS based on air quality criteria incorporating the “latest scientific knowledge.” 42 U.S.C. § 7408(a)(2). For primary NAAQS, EPA must make the NAAQS stringent enough “to protect public health,” with such protection including “an adequate margin of safety.” 42 U.S.C. § 7409(b)(1). Courts have rejected EPA determinations that there is no need to lower a NAAQS level to protect public health or to provide an adequate margin of safety when the agency has failed to properly consider relevant new evidence. *Am. Farm Bureau Fed’n* at 520-26; *see also Am. Lung Ass’n v. EPA*, 134 F.3d 388, 392-93 (D.C. Cir. 1998) (EPA must provide adequate explanation for failure to revise NAAQS in light of relevant evidence); *Lead Industries Ass’n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980) (EPA must “err on the side of caution” in favor of more protective standards when setting NAAQS).

Additionally, the Administrator’s proposed conclusion to retain the current standards does not merit the deference normally granted to agency decision making, because, as explained above, it did not rely on the best available science or the advice of the best qualified scientists with expertise in relevant scientific fields and relating to particulate matter specifically. *See, e.g., Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983) (agency action is arbitrary and capricious when it “runs counter to the evidence before the agency”); *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) (no deference owed to agency expertise when the agency’s explanation for its action lacks any coherence); *Earth Island Inst. v. Hogarth*, 494 F.3d 757, 763 (9th Cir. 2007) (no deference when “agency ignored its own statistical methodology”).

⁶⁶ *Compare* 84 Fed. Reg. at 38625 (“The Administrator shall select the expert consultants. In selecting these consultants, the Administrator will consider information provided by the candidates themselves, and additional background information) *with* 80 Fed. Reg. 6086, 6087 (Feb. 4, 2015) (stating that EPA’s selection of the subcommittee will be in accordance with procedures explained in the Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board).

A. The Administrator Must Reduce the Annual Primary PM_{2.5} Standard to Protect Public Health with an Adequate Margin of Safety

There is significant new evidence and information demonstrating harms to human health at concentrations lower than the current NAAQS, which strongly supports reduction of the annual primary PM_{2.5} level from its current level. Based on review of that new evidence, along with evidence considered in previous NAAQS evaluations, both the Policy Assessment and the Independent Panel Report have concluded that the existing level is inadequate to meet the statutory standard requiring protection of human health with an adequate margin of safety. Policy Assess. at 3-107 (“appropriate to consider revising the level of the current annual standard”); Ind. Panel Rpt. at B-20. The arguments that the Administrator presents for retaining the current level are without legal or rational basis.

1. New Evidence and Information Support Reduction of the Level

In the Policy Assessment, EPA staff summarizes the current state of knowledge as follows: “[s]tudies published since the last review have reduced key uncertainties and broadened our understanding of the health effects that can result from exposures to PM_{2.5}.” Policy Assess. at 3-106. As a result, the evidence and information now available “can reasonably be viewed as calling into question the adequacy of the current primary PM_{2.5} standards.” *Id.* at 3-106. Yet the Administrator disregards the views of EPA’s staff in deciding to keep the NAAQS unchanged. And that decision, lacking support from the agency’s staff or any information in the record, cannot be upheld based on the deference afforded to the agency’s scientific expertise.

The Independent Panel agrees that the evidence of adverse health effects beneath the current level is “compelling” and “has been strengthened in the most recent review.” Ind. Panel Rpt. at B-22. “The collective weight of the scientific evidence from the epidemiologic studies along with supporting experimental evidence from controlled human exposure studies and animal toxicology is unambiguous in showing serious human health effects of PM_{2.5} at levels below the current primary standards. *Id.* at B-21. As explained in section IV.B above, the Independent Panel’s views merit great weight because of the Panel’s expertise in relevant areas—expertise the CASAC does not have—and the careful process by which it was formed and operated.

Based on this evaluation, the Independent Panel agrees with the Policy Assessment’s conclusion that the scientific evidence, air quality analyses, and risk assessment “call[] into question the adequacy of the public health protection afforded by the current primary PM_{2.5} standards.” *Id.* at B-20. But the Panel is more emphatic, concluding, based on the scientific evidence, that “the current primary standards are unequivocally not adequately protective. The entire weight of scientific evidence supports more stringent standards.” *Id.*; *see also id.* at B-21 (“The collective weight of the scientific evidence from the epidemiologic studies along with supporting experimental evidence from controlled human exposure studies and animal toxicology [studies] is unambiguous in showing serious human health effects of PM_{2.5} at levels below the current primary standards.”).

The new materials supporting a reduction in the annual primary level fall into three categories: epidemiological studies, experimental studies and EPA's risk assessment, each of which support increasing the stringency of the standard.

a. Epidemiological studies

The Independent Panel's conclusion that the epidemiological evidence supports reduction of the primary levels was unequivocal:

the epidemiologic evidence is vast, particularly in terms of the geographic domain and number of subjects included, and provides an overall consistent scientific basis, supported by coherence with controlled human and toxicological studies, for finding that the current primary PM_{2.5} standards are not protective of public health.

Ind. Panel Rpt. at B-21.⁶⁷

The Policy Assessment reached the same conclusion: “[t]hese and other recent studies provide support for health effect associations at lower ambient PM_{2.5} concentrations than in previous reviews.” Policy Assess. at 3-104 (identifying studies by Lee *et al.* (2015), Di *et al.* (2017b) and Shi *et al.* (2016) showing statistically significant associations with annual average exposures of 12 µg/m³ or less).⁶⁸

Several studies from 2015 through 2017 found statistically significant associations between harm to health and annual exposures below 12 µg/m³. *Id.* at 3-104.⁶⁹

The Independent Panel explained that the new epidemiological evidence offered even more reliable proof of the association between PM_{2.5} emissions and harm below the current annual level because it includes multiple studies that considered large populations and reports effects below the current standard or because the average exposures are well below the annual

⁶⁷ See also *id.* (“The overall strength of evidence from the longstanding body of evidence presented and reviewed in the 2009 [Integrated Science Assessment] . . . has been further bolstered with new studies with a range of study designs. The strong evidence on mortality and morbidity endpoints, coupled with emerging evidence for less extensively studied health endpoints, such as nervous system effects, is scientifically credible.”).

⁶⁸ See also Policy Assess. at 3-103 (“recent epidemiological studies strengthen support for health effect associations at relatively low ambient PM_{2.5} concentrations”); *id.* at 3-106 (recent studies “provide support for generally positive and statistically significant health effect associations across a broad range of ambient PM_{2.5} concentrations, including for air quality distributions with overall mean concentrations lower than in the last review and for distributions likely to be allowed by the current primary PM_{2.5} standards”).

⁶⁹ See also *id.* at 3-113 (noting that studies have consistently found positive and statistically significant health effect associations down to 8.1 µg/m³, with some studies providing support for health effects at even lower concentrations).

standard. Ind. Panel Rpt. at B-22 (citing studies from Di, *et al.*, 2017a&b; Shi, *et al.*, 2016; Weichenthal, *et al.*, 2016a&b; and Pinault, *et al.*, 2016).

Importantly, as EPA staff, the Administrator, and the Independent Panel agree, there is no evidence of a threshold concentration for PM_{2.5} below which it has no effect on human health.⁷⁰

Yet another approach to evaluating information from epidemiologic studies—known as pseudo-design value studies—supports reduction of the current level. A pseudo-design value study takes air quality data for a given location or population and estimates exposure levels and health impacts by modeling air quality for that area under different hypothetical air quality scenarios, *e.g.*, 8 µg/m³, 10 µg/m³, and 12 µg/m³. Policy Assess. at 3-104; *see also id.* at 3-73 through 3-74. The resulting pseudo-design value studies are thus able to help extrapolate the epidemiologic study data to evaluate the predicted health impacts of just meeting the existing NAAQS, as well as the other standards under consideration. *Id.* at 3-11.

EPA's staff applied this approach to eight studies finding long-term health effects. Based on that analysis, six of those studies reflected situations in which the health effects occurred in areas where at least a quarter of the population experienced air quality meeting the current primary PM_{2.5} standards. Policy Assess. at 3-75 (Figure 3-9). Four of those studies reflected situations in which the health effects occurred where half of the population experienced air quality meeting the current primary PM_{2.5} standards. *Id.* And in two of the studies, the health effects occurred even though three-quarters or more of the population experienced air quality meeting the current standards. *Id.* Accordingly, the pseudo-design value analyses provided further statistically significant support for the notion that long-term exposure to PM_{2.5} is causing harm to human health even where the current NAAQS are being met. *Id.* at 3-80, 3-105, 3-106, 3-115. In addition, there are a number of similar studies finding short-term health effects that provide additional support for health effect findings. Policy Assess. at 3-74 to 3-75; *see also Am. Farm Bureau Fed'n*, 559 F.3d at 522 (finding that EPA's failure to consider short-term studies as relevant to setting annual PM_{2.5} standard was arbitrary and capricious).

Moreover, there are a number of recent papers not considered in the Integrated Science Assessment or the Policy Assessment that provide additional support for the conclusion that annual PM_{2.5} harms human health at ambient concentrations beneath the current NAAQS.⁷¹ We

⁷⁰ 85 Fed. Reg. at 24107 (“recent studies examine this issue, and continue to provide evidence of linear, no-threshold relationships between long-term PM_{2.5} exposures and . . . mortality”); Policy Assess. at 3-103 (“[s]tudies that examine the shapes of concentration-response functions over the full distribution of ambient PM_{2.5} concentrations have not identified a threshold concentration[] below which associations no longer exist”); Ind. Panel Rpt. at B-11 & B-22 (“[n]o evidence was found for a discernable population threshold”). That is another factor justifying reduction of the current levels. Ind. Panel Rpt. at B-22.

⁷¹ *See* N. Sanders, *et al.*, Estimating Causal Effects of Particulate Matter Regulation on Mortality, 31 *Epidemiology* 160, 164 (Table 1) (Mar. 2020) (finding reduction in mortality rate from 5.084 to 4.617 per thousand associated with change in annual concentration from 10.99 to 9.33 µg/m³); G. Peterson, *et al.*, Impact of Reductions in Emissions from Major Source Sectors on Fine Particulate Matter-Related Cardiovascular Mortality, 128(1) *Environmental Health Perspectives*,

note that these studies are also evidence supporting a revision of the erroneous determination in the Integrated Science Assessment that there is only “suggestive evidence” of a causal relationship between having a pre-existing cardiovascular or respiratory disease and increased risk for PM_{2.5}-related health effects.⁷²

In addition, the NAAQS “must protect not only average, healthy individuals, but also ‘sensitive citizens’—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.” *Am. Lung Ass’n v. EPA*, 134 F.3d at 390 (citations omitted). “If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *Id.* at 389 (citation omitted); *see also* S. Rep. No. 91-1196, 91st Cong., 2d Sess. 410 (1970). This category of “sensitive individuals” includes individuals with pre-existing cardiovascular or respiratory disease. Accordingly, upgraded causal relationships between those conditions and PM_{2.5} health effects based on these new studies showing adverse effects at levels beneath the current NAAQS level for people with those conditions likewise warrants reducing the level of the primary NAAQS below its current level.

b. Experimental studies

EPA’s analysis has focused on two types of experimental studies—controlled human exposure studies and animal toxicology studies—both of which support lowering the level here. 85 Fed. Reg. at 24115. The importance of such studies is that they can demonstrate biologically plausible mechanisms through which exposure to particulate matter could cause harm to human health. *Id.* Human exposure studies have provided evidence of impacts from PM_{2.5} exposure on vascular function, blood pressure, cardiac conduction abnormalities and arrhythmia, changes in

at 4 & Supplemental Material, Table S2 (Jan. 2020) (finding change in annual concentrations from 9.458 to 6.668 $\mu\text{g}/\text{m}^3$ was responsible for 5.7 percent of total decline in cardiovascular mortality rates); C. Ward-Caviness, *et al.*, Associations Between Long-Term Fine Particulate Matter Exposure and Mortality in Heart Failure Patients, *J. Am. Heart Ass’n*, at 7 (Table 2) (2020) (for areas with annual PM_{2.5} concentrations less than the current 12 $\mu\text{g}/\text{m}^3$ standard, finding an overall 11 percent increase in all-cause mortality among individuals with heart failure for a 1 $\mu\text{g}/\text{m}^3$ increase in PM_{2.5} concentration); L. Wyatt, *et al.*, The contribution of improved air quality to reduced cardiovascular mortality: Declines in socioeconomic differences over time, 136 *Environmental International* 105430, at 4 (Fig. 3A) (2020) (showing increased cardiovascular mortality rate for increases in annual PM_{2.5} concentrations beneath the current 12 $\mu\text{g}/\text{m}^3$ standard); C. Zigler, *et al.*, Impact of National Ambient Air Quality Standards nonattainment designations on particulate pollution and health, 29(2) *Epidemiology*, 165, at 15-16 (Table 1) (Mar. 2018) (finding effects from change in annual concentrations from 11.59 to 9.39 $\mu\text{g}/\text{m}^3$); X. Wu, *et al.* Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly, *Science Advances* at 1 (June 26, 2020).

⁷² *See, e.g.*, Integrated Sci. Assess. at ES-19 to ES-20; Letter from Christopher H. Frey, Ph.D., *et al.*, Independent Particulate Matter Review Panel, to Louis Anthony (Tony) Cox, Jr., Ph.D., Chair, CASAC, EPA, re: CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft—October 2018), Attachment E at E-9, Attachment L at L-4 (Dec. 10, 2018).

heart rate variability, and changes in hemostasis that could promote blood clot formation. *Id.* Similarly, animal toxicology studies have reported a connection between PM_{2.5} exposure and impaired lung development and increased carcinogenic potential. 85 Fed. Reg. at 24116.

“Recent experimental evidence . . . strengthens support for potential biological pathways through which PM_{2.5} exposures could lead to the serious effects reported in many . . . epidemiologic studies. This includes support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects.” Policy Assess. at 3-102.

Again, the Independent Panel agrees: animal toxicology and human controlled exposure studies “support and strengthen” the conclusions from the epidemiological studies, and the animal studies in particular “support[] biologic plausibility for particulate matter effects on the cardiovascular, respiratory, and nervous systems, as well as for cancer effects.” Ind. Panel Rpt. at B-21 to B-22.

c. Risk assessment

While the evidence from the scientific studies is itself “sufficient to call into question the existing standards,” EPA’s risk assessment provides still more support for that conclusion. Ind. Panel Rpt. at B-22. The assessment estimates that current primary standards could allow a substantial number of deaths in the U.S., with the “large majority of those deaths associated with long-term PM_{2.5} exposures.” Policy Assessment at 3-105; *see also id.* at 3-106. With air quality just meeting the primary particulate matter standards, the risk assessment estimates “about 16,000 to 17,000 PM_{2.5}-related deaths from ischemic heart disease in a single year.” Policy Assessment at 3-105 (emphasis added).

As high as that number is, it likely significantly underestimates the true mortality rate in at least three ways: the underlying health effect estimates underestimate the true health effects, it is based on a limited population sample, and reflects a limited scope of causes of mortality. As discussed in the Integrated Science Assessment, biases caused by special variability in particulate matter exposure cause the health effects estimated by epidemiological studies to be underestimated.⁷³

This underestimation of health effects is compounded by the restriction on the data used in generating the risk assessment, the risk assessment “accounts for approximately one-third of the U.S. population that is age 30 or older. Therefore, the risk estimates are based on a large population but underestimate the national total.” Ind. Panel Rpt. at B-16. The estimated median annual “all-cause mortality from long-term PM_{2.5} exposure, based on 2015 air quality adjusted to just meet the existing standards, ranges from 13,500 . . . to 52,100.” *Id.* (citing Thurston, *et al.* (2016) and Pope, *et al.* (2015)).

In addition, when the analysis is restricted to the 30 areas where the annual primary NAAQS controls that just meet that NAAQS, the risk assessment estimated that long-term PM_{2.5}

⁷³ Integrated Sci. Assess. at 3-120 (“In summary, exposure error tends to produce underestimation of health effects in epidemiologic studies of PM exposure.”).

exposures are associated with up to 45,000 annual deaths, and 14,600 annual ischemic heart disease deaths in particular, with most of those deaths due to concentrations just below the current level between 10 and 12 $\mu\text{g}/\text{m}^3$. Policy Assess. at 3-93. Thus, annual deaths from long-term PM_{2.5} exposures are of the same magnitude, and may well exceed, annual deaths from the flu in the States, which were estimated at 34,200 during in the 2018-2019 season.⁷⁴

The risk assessment indicates that reducing the current annual primary level would produce significant reductions in PM_{2.5}-associated deaths. The results of the risk assessment show that “potential alternative annual standards with levels from 11.0 down to 9.0 $\mu\text{g}/\text{m}^3$ could reduce PM_{2.5}-associated mortality broadly across the U.S.” Policy Assess. at 3-115. The estimated mortality-related risk reductions “range from about 7 to 9% for a level of 11.0 $\mu\text{g}/\text{m}^3$, 14 to 18% for a level of 10.0 $\mu\text{g}/\text{m}^3$, and 21 to 27% for a level of 9.0 $\mu\text{g}/\text{m}^3$.” *Id.*

In short, as EPA staff concluded, the results of the risk estimates “support[] the potential for significant public health impacts in locations meeting the current primary PM_{2.5} standards” since “the large majority of PM_{2.5}-associated deaths for air quality just meeting the current standards are estimated at annual average PM_{2.5} concentrations from about 10 to 12 $\mu\text{g}/\text{m}^3$ ” and “key epidemiologic studies provide strong support for reported positive and statistically significant PM_{2.5} health effect associations” in that range. Policy Assess. at 3-105.

Similarly, the Independent Panel determined that, even after taking any uncertainties in the risk assessment into account, the assessment “is useful and scientifically robust in illustrating that reductions in the level of the annual standard will lead to proportional reductions in premature mortality.” Ind. Panel Rpt. at B-29. The Panel concluded that the estimated magnitude of premature deaths at the current level of the NAAQS as determined by the risk assessment was “unacceptably high.” *Id.*

Finally, given that the primary PM_{2.5} standards are intended to provide protection to sensitive sub-groups and not just the population as a whole, it is necessary that the impacts on individuals with medical conditions that make them particularly susceptible to harm from particulate matter, discussed above, be integrated into EPA’s risk analysis. But the risk assessment, and thus the Policy Assessment, does not incorporate such considerations. Ind. Panel Rpt. at B-29. That failure is another reason why the Administrator’s proposal to retain the current NAAQS is neither lawful nor reasonable.

2. The Administrator’s Arguments for Leaving the Current Annual Level Unchanged Are Legally and Scientifically Insufficient

The Administrator’s arguments for retaining the current standards are “not scientifically justified,” Ind. Panel Rpt. at B-20, and as a result are arbitrary and capricious or otherwise not in accordance with law, *see, e.g., Am. Farm Bureau Fed’n*, 559 F.3d at 525-26 (remanding rule maintaining existing level of NAAQS for lack of justification). The overarching basis for the

⁷⁴ Centers for Disease Control & Prevention, Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States—2018–2019 influenza season, at <https://www.cdc.gov/flu/about/burden/2018-2019.html>.

Administrator's conclusion that the existing annual primary PM_{2.5} standard protects human health with an adequate margin of safety is purported uncertainty in the validity of the new studies and analyses that show human health effects at concentrations less than the current annual primary PM_{2.5} standards.

That argument fails for at least two reasons. First, under the public health protective governing law, uncertainty in the evidence weighs *in favor of* more stringent standards to provide an adequate margin of safety. This is especially true here where the scientific conclusion is that any uncertainty has caused EPA to underestimate the health risks of exposure to particulate matter. Second, there is no material uncertainty: the evidence and analyses in the record conclusively demonstrate harms to human health beneath the current NAAQS that justify reduction of the NAAQS.

- a. *EPA's reliance on uncertainty to retain the existing standard is contrary to law, as uncertainty directs establishment of more stringent standards to ensure an adequate margin of safety*

As explained in section V.A.2.b below, there is little if any material uncertainty in the studies and other information in the record regarding whether significant adverse health effects occur from exposure to PM_{2.5} at levels below the current standard of 12 µg/m³. Additionally, any residual uncertainty is itself a basis to reduce the level enough to provide the statutory "adequate margin of safety," not to leave the level unchanged.

As the Administrator himself states:

the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified.

85 Fed. Reg. at 24119. The D.C. Circuit has ruled that the margin-of-safety requirement mandates more protective standards in the presence of uncertainty "to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Industries Ass'n*, 647 F.2d at 1154; *see also Env'tl. Defense Fund v. EPA*, 598 F.3d 62, 81 (D.C. Cir. 1978) (explaining that the term "margin of safety" originated in the field of engineering and was "meant to compensate for uncertainties and variabilities in design, materials workmanship, and so forth; the greater the variability, the larger the factor of safety"; Congress' borrowing of the term was meant "to take into account and compensate for uncertainties and lack of precise predictions in the area of forecasting the effects of . . . pollutants").

This statutory principle mandating more stringent standards is especially appropriate since "more often than not the 'margins of safety' that are incorporated into air quality standards turn out to be very modest or nonexistent, as new information reveals adverse health effects at pollution levels once thought to be harmless." *Id.* (citing H.R. Rep. No. 95-294, at 103-117). Thus, "Congress' directive to the Administrator to allow an 'adequate margin of safety' . . .

plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful.” *Id.* at 1155.

As discussed above, there is extensive evidence and information that PM_{2.5} causes those harms at levels below 12 µg/m³. And as discussed below, there is *no* evidence or other rational basis to conclude that the undisputed mechanisms producing those health effects above 12 µg/m³ suddenly and for unknown reasons stop operating beneath that level. Accordingly, under the statutory margin-of-safety standard, to the extent there is any uncertainty about the exact scope or extent of adverse effects beneath the current annual primary level, that uncertainty compels reduction of the level, not, as the Administrator proposes, preservation of the current level.⁷⁵

b. The Administrator’s specific uncertainty arguments lack foundation

Even if the Administrator were correct that uncertainty in the scientific evidence and information favored preservation of the current standards—which, as explained above, he is not—his reliance on purported uncertainty as a ground for retaining the existing standards fails because there is no material uncertainty. The Administrator claims that his conclusion that no change in the level is justified “neither overstates nor understates” the “strengths and limitations” of the relevant scientific and technical information, 85 Fed. Reg. at 24119. He cites certain members of the CASAC for the cautionary proposition that the “data . . . should not be interpreted more strongly than warranted based on its [*sic*] methodological limitations.” 85 Fed. Reg. at 24119 (quoting Cox, 2019a at 8).

In fact, however, the Administrator’s discussion of purported uncertainty overstates the limitations and understates the strengths of this new evidence. As the Independent Panel explained:

Together the evidence-based and the risk-based approaches show that the current PM_{2.5} standard is not requisite to protect public health, with the evidence-based approach appropriately given more relative weight. Together these approaches, with more weight given to the evidence-based approach, provide a scientific evidentiary basis for recommending alternative levels for the annual and daily PM_{2.5} standards. Findings from toxicological, controlled human exposure, and accountability studies are coherent with these observational findings.

Ind. Panel Rpt. at B-13.

The Administrator’s invocation of purported uncertainty is not a valid basis to disregard this abundant evidence and find the current NAAQS adequate to meet the statutory requirement

⁷⁵ The Administrator’s claim that the Clean Air Act does not require that the NAAQS provide a zero-risk level, 85 Fed. Reg. at 24119, is a red herring, since the Administrator has failed to explain why the substantial risks posed at 12 µg/m³ are lawful and has provided no evidence that anyone has suggested that the standard be set at the zero-risk level.

to protect health and welfare with an adequate margin of safety. Rather, as EPA staff explained, “a conclusion that current primary standards do provide adequate protection “would place little weight on the broad body of epidemiologic evidence reporting generally positive and statistically significant health effect associations, particularly for PM_{2.5} air quality distributions likely to have been allowed by current primary standards, or on the PM_{2.5} risk assessment.” Policy Assess. at 3-106.

The Independent Panel was even more insistent that the arguments for retaining the current levels gave too little weight to the very extensive evidence in the record. In the Panel’s view, those arguments are:

a scientifically unjustifiable interpretation of the evidence that over-emphasizes and inappropriately inflates the significance of uncertainties in biological pathways, inappropriately discounts the potential for public health improvements below the current NAAQS on the premise that accountability studies have not examined such levels yet, and inappropriately dismisses risk assessment as a tool. While the [Independent Panel] acknowledges that there remain uncertainties in these realms, the Panel concludes that this is an extreme misinterpretation which runs counter to all reasonable scientific views of the available evidence. The [Independent Panel] concludes that these arguments are not scientifically sound.

Ind. Panel Rpt. at B-23.

The Administrator’s general reliance on “uncertainty,” *see, e.g.*, 85 Fed. Reg. at 24120, as a basis for retaining the existing annual primary level is not sufficient because any of the uncertainties, whether in the scientific studies or the risk assessment, “do not in any way overcome the strong weight of scientific evidence in support of lowering the levels of the annual and 24-hour standards.” Ind. Panel Rpt. at B-23. Instead, “in order to accept the current standards as adequate, multiple implausible and scientifically unjustifiable assumptions and conclusions are necessary.” Ind. Panel Rpt. at B-25.

More specifically, as discussed below, the Administrator’s arguments in favor of retaining the current level are contrary to the weight of evidence and information provided by each of the types of analyses considered—epidemiological studies, experimental studies, and the risk assessment. Reaching conclusions contrary to the evidence before the agency is arbitrary and capricious. *See, e.g., Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

i. Epidemiological studies

The Independent Panel explained that “[t]o dispute the conclusion that the current PM_{2.5} standards are not sufficiently protective, it would be necessary to discard the scientific findings from epidemiologic studies.” Ind. Panel Rpt. at B-23. As discussed above, there are numerous recent studies that “are scientifically valid and policy relevant” and “provide new compelling

evidence of [adverse] effects at concentrations at and below the current primary PM_{2.5} standards based on very large cohorts.” *Id.*; *see also id.* at B-24. “[I]t is inappropriate to discard this voluminous and consistent body of epidemiologic evidence.” Ind. Panel Rpt. at B-24. Indeed, even the Administrator acknowledges that studies show associations across a wide range of concentrations, and the Policy Assessment concludes that the overall mean concentrations in several of these key studies “are likely below the long-term mean concentrations . . . in areas just meeting the current annual PM_{2.5} standard.” 85 Fed. Reg. at 24117. Furthermore, the Integrated Science Assessment concludes that the health impacts estimated by the epidemiologic studies likely underestimate the true health effects from exposure to particulate matter. EPA, Integrated Science Assessment for Particulate Matter at 3-120 (Dec. 2019) (“Integrated Sci. Assess.”).

Nonetheless, the Administrator invokes the concern of certain CASAC members that “associations” between PM_{2.5} and harm to health demonstrated in epidemiologic studies “are not necessarily indicative of causal relationships and such associations ‘can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias.’” 85 Fed. Reg. at 24119 (citing Cox 2019a at 8). But this argument does not make sense under the circumstances. The Administrator is proposing to conclude that associations demonstrated by statistically valid methods and analysis of actual data are not due to the tested variables but due to purported confounding factors that have not been tested and, because they are “potential,” may not even be present or have any effect. This is analogous to saying a student with consistently good grades throughout the year should not be on the honor roll because there may be some other, unknown reason why her grades were good other than intelligence and diligence.

The Administrator also identifies further alleged “uncertainties”: (1) some studies reflect averaging of estimates over locations or time while NAAQS compliance looks at concentrations at specific monitors meeting data quality and completeness criteria; (2) some studies do not identify “specific exposures” that produce adverse health effects or “exposures below which effects do not occur”; and (3) exposure estimates in some studies “are based on hybrid modeling approaches for which performance depends on the availability of monitoring data and varies by location.” 85 Fed. Reg. at 24117.

The possibility of confounders and the other referenced uncertainties have been investigated and found not to be material given the overall strength and consistency of results from varying approaches. The Policy Assessment noted that studies have used “wide variety of approaches” to control for potential confounders. Policy Assess. at 3-102.⁷⁶ “[N]one of the covariates examined,” including temperature, humidity, day of the week, income, race, age, socioeconomic status, smoking and body mass index, “can fully explain the association with mortality.” *Id.* at 3-102; *see also id.* at B-28. The Administrator himself notes the conclusion in the 2019 Integrated Science Assessment that the “positive associations between long-term PM_{2.5} exposures and mortality are robust across analyses examining a variety of . . . approaches to controlling for confounders” and that “[r]ecent evidence further demonstrates that associations with mortality remain robust in copollutant analyses.” 85 Fed. Reg. at 24107.

⁷⁶ *See also* Letter from J. Vandenberg, Ph.D., to Dr. Tony Cox at 1 (Feb. 20, 2019) (“epidemiologic studies go to great pains to identify these factors and to ensure they are controlled for through study design and advanced statistical models”).

The Administrator's other professed concerns are equally invalid. First, the fact that the data used in some studies may not be the exact same type of data used for NAAQS compliance evaluation does not render the studies' conclusions regarding the association between PM_{2.5} levels and harm to health invalid. Second, the fact that certain studies may not offer conclusions as to specific thresholds for health effects is not surprising, given that the analyses are statistical in nature. Nor is it necessary for studies to provide conclusions regarding specific effects thresholds, as a conclusion as to a range in which health effects may occur or a conclusion that health effects occur generally beneath a certain concentration can be statistically valid and useful.

Third, the fact that certain studies use hybrid models for which data availability is a relevant factor and performance may vary is also not surprising, as those are features of virtually every epidemiological approach, and such models are well established, valid means for evaluating the role of PM_{2.5} in causing health impacts.⁷⁷

In any event, the overall strength of the evidence supports reduction of the standard notwithstanding any concerns about purported uncertainty in "some" studies:

Scientific findings since the last PM NAAQS review based on epidemiological and controlled exposure studies, relating to both short- and long-term exposure to PM_{2.5} and corresponding acute and chronic effects, provide a robust foundation for assessing the adequacy of the current PM_{2.5} standards. U.S. multicity epidemiologic studies, supported by Canadian multicity epidemiologic studies, coherent results from animal toxicology and controlled human exposure studies, and accountability studies that provide additional causal evidence, provide clear and compelling scientific evidence that the current PM_{2.5} standards are not adequate to protect human health.

Ind. Panel Rpt. at B-14.⁷⁸ Even after taking into account the uncertainties and limitations that exist in certain multipollutant models, the "inferences from the studies were valid and robust" given "the consistency of epidemiological findings, and the coherence among multiple lines of scientific evidence from epidemiology, controlled human studies, and toxicology, and biological plausibility." Ind. Panel Rpt. at B-14. There is, accordingly, no basis to disregard new epidemiologic studies that "reaffirm and substantially augment and strengthen" the evidence of increased mortality at PM_{2.5} levels "well below" the current level. *Id.* at B-24.

⁷⁷ See Ind. Panel Rpt. at 3 (hybrid approaches "represent important and impressive scientific progress"); *id.* at B-7 (hybrid approaches represent "the area where substantial improvements in characterizing ambient PM_{2.5} concentrations (exposures) over large areas have been made since the last PM NAAQS review" and "clearly lead to improved ambient concentration estimates in locations without samplers").

⁷⁸ See also *id.* at B-14 to B-15 (discussing specific new epidemiologic studies that support reduction of the standard, namely, Di, *et al.*, 2017a; Di, *et al.*, 2017b; Shi, *et al.*, 2016; Weichenthal, *et al.*, 2016b and 2016c and Pinault, *et al.*, 2016).

With regard to the pseudo-design value studies, the Administrator acknowledges that 17 studies address situations where 25 percent or more of the health events occurred in locations meeting the current standard, and 9 of the studies address situations where 50 percent or more of the health events occurred in such locations. 85 Fed. Reg. at 24117 (Table 1). They accordingly provide support for concluding that health impacts occur even where air quality meets the current standards. But the Administrator nonetheless maintains that there are “important uncertainties” in the pseudo-design value analyses, including: (1) in most key multicity studies, some locations would likely meet the standard while others would not; (2) studies estimate exposure levels based on data averaged over period of various lengths, not the three-year averages of actual design values; (3) analyses focus on areas with at least one monitor, while other areas are not included; and (4) recent changes to PM_{2.5} monitoring requirement are not reflected. *Id.*

Notwithstanding any uncertainties in these studies, the Independent Panel found them to be “useful in providing a systematic basis for comparing individual studies . . . with the current and alternative standards. Ind. Panel Rpt. at B-13. The fact that some locations would likely meet the standard while others would not is of no concern. Indeed, that also occurs within a county being designated for attainment or nonattainment: some monitoring locations may report compliance with the NAAQS while others may not. Concerns that the averaging period may vary somewhat from the three-year period used for actual design values is also a red herring, because the studies do not need to exactly follow design value methodology to be useful. And the fact that areas without monitors are not included is unexceptionable, since it is not clear what data would be used for those areas, and in any event does not invalidate the figures for areas used in the studies where monitors were present. In addition, use of the pseudo-design values can be conservative, as they are up to 10 percent higher than an actual design value. Ind. Panel Rpt. at B-29. In other words, if a pseudo design study shows health harms at a pseudo-design value equal to the NAAQS level, it may be the case that the actual NAAQS value is ten percent lower, so that the effects actually occurred at a pollutant level 10 percent below the NAAQS.

The Administrator also critiques purported uncertainty in so-called accountability studies, which are based on retroactive statistical analysis of actual reductions in pollution levels. The Administrator voices concern on several grounds: (1) the reductions “have not clearly reduced mortality risks, especially when confounding was tightly controlled”; (2) some studies have not evaluated PM_{2.5} specifically, did not show changes in PM_{2.5} air quality, or were not able to “disentangle health impacts of the interventions from background trends in health”; and (3) the lack of studies reporting health improvements “attributable to locations meeting the current standard,” plus “broader concerns regarding the lack of experimental studies examining PM_{2.5} exposures typical of areas meeting the current standards.” 85 Fed. Reg. at 24120.

These critiques fail for at least two reasons. First, the Policy Assessment acknowledges that there is at least one well-conducted accountability study that demonstrates adverse effects beneath the current level. Policy Assess. at 3-103, fn. 74. Second, the absence of a large number of accountability studies evaluating PM_{2.5} levels below the current standard does not create uncertainty about the evidence of harm beneath the current standard in light of the voluminous evidence from other sources, namely, the epidemiological and experimental studies. “It is a logical fallacy to claim that the absence of evidence is evidence of absence.” Ind. Panel Rpt. at B-24. Therefore, “it is inappropriate to give weight to the lack of existing accountability studies

below the current standard as a meaningful source of uncertainty in calling into question the current primary PM_{2.5} standards.” Ind. Panel Rpt. at B-24.

The Administrator also cites certain members of CASAC for the proposition that the recent studies “mainly confirmed what had already been anticipated or assumed in setting the 2012 NAAQS.” 85 Fed. Reg. at 24119. At a minimum, this statement is too vague to serve as a basis for decision making, as it does not explain what had purportedly been confirmed or anticipated in 2012. *See, e.g., Alabama Env'tl. Council v. Administrator, U.S. EPA*, 711 F.3d 1277, 1287-88 (11th Cir. 2013) (vacating EPA determination when agency failed to “clearly articulate” the basis for its determination); *Mitchell Energy Corp. v. FERC*, 651 F.2d 414, 418 (5th Cir.1981) (basis for agency action “must be set forth with such clarity as to be understandable”).

In any event, the conclusion makes no sense. If the CASAC, and by extension the Administrator, is saying that in 2012 it had been anticipated or assumed that evidence demonstrated adverse effects at levels beneath 12 µg/m³ sufficient to merit reducing the standard beneath that level, and more recent data confirms that conclusion, then the Administrator is now admitting that the standard should have been set at a lower level in 2012. That does not support leaving the 2012 standard in place.

On the other hand, the CASAC, and by extension the Administrator, may be saying that as of 2012 there was some evidence of adverse effects at levels beneath 12 µg/m³, but not enough to justify a more stringent level. If that is the case, then the Administrator is now saying that additional evidence confirming that prior evidence is not sufficient to revise the agency’s view and justify a lower level, without providing any explanation as to why the additional, confirmatory evidence is insufficient. If this is the Administrator’s position, then he is arbitrarily and capriciously saying that the new, confirmatory evidence does not change the agency’s views without explaining why.

Although not relied on by the Administrator in his proposed decision, there are several arguments related to epidemiological studies raised by certain CASAC members regarding the epidemiological studies that we address here. As regards those arguments generally, we note that procedural problems discussed in section IV above, such as elimination of the PM Review Panel, undermine the reliability and credibility of the CASAC and its judgments. Moreover, the CASAC itself recognized that it lacks the necessary expertise to evaluate the types of epidemiological and other issues at issue in this rulemaking.⁷⁹ Accordingly, any arguments from these CASAC members are of questionable value from the outset.

Turning now to the specific substantive arguments from the CASAC, first, some CASAC members suggest that there are certain “emerging causal inference methods for the analysis of individual studies” the use of which should be a requirement before EPA may consider any study in its NAAQS review. Ind. Panel Rpt. at B-21. However, because of their newness, “these emerging tools still require considerable development before they can be implemented in air

⁷⁹ CASAC ISA Review, Consensus Responses at 1 (“the breadth and diversity of evidence to be considered exceeds the expertise of the . . . CASAC members”).

pollution epidemiology studies.” *Id.* (citing Carone *et al.*, 2019). Accordingly, it would be “irresponsible” to disregard any of the epidemiologic studies “because they have not been analyzed using emerging un-vetted advanced statistical methods that are still in their infancy for application to air pollution studies.” *Id.*

The CASAC expressed its belief that exposure error in particular was a problem.⁸⁰ But, the Integrated Science Assessment makes clear that any exposure error “tends to produce underestimation of health effects in epidemiologic studies of PM Exposure.” Integrated Sci. Assess. at 3-120. Even so, the Policy Assessment responded that exposure error, to the extent it may exist in certain studies, is not significant enough to “call into question the fundamental findings of the broad body of PM_{2.5} epidemiologic evidence.” Policy Assess. at 3-102. “The consistent reporting of PM_{2.5} health effect associations across exposure estimation approaches, even in the face of exposure error, together with the larger effect estimates reported in some studies that have attempted to reduce exposure error, provides further support for the robustness of associations between PM_{2.5} exposures and mortality and morbidity.” *Id.* at 3-103.

In short, if the new evidence confirms significant adverse effects beneath 12 µg/m³, then the Administrator must lower the standard to provide an adequate margin of safety to protect public health, or must provide a reasoned explanation why he chooses not to do so. Whatever imperfections there may be in particular epidemiological studies, together they overwhelmingly confirm that the annual primary standard should be set beneath 12 µg/m³. Ind. Panel Rpt. at B-27 to B-28 (discussing alternative standards beneath 12 µg/m³).

ii. Experimental studies

A determination that the annual primary level should remain the same would also give too little weight to experimental studies providing extensive evidence of how PM_{2.5} causes harm to human health. As the Independent Panel puts it, “[t]o dispute the conclusion that the current PM_{2.5} standards are not sufficiently protective, it also would be necessary to discard the experimental evidence of the biological pathways and mechanisms of action for PM_{2.5} health effects.” Ind. Panel Rpt. at B-24. But as discussed above, the evidence of mechanisms causing cardiovascular effects, respiratory effects, cancer and other health problems from controlled studies is voluminous and continues to accumulate. *See id.* (identifying particular effects).

The Administrator notes that most of the controlled human exposure studies and the animal toxicology studies have evaluated exposures at concentrations above those allowed by the current PM_{2.5} standards. 85 Fed. Reg. at 24116. He bases his proposed decision not to lower the level on absence of confirming evidence of effects at lower levels from experimental studies. *Id.* He claims that statistical associations without supporting experimental evidence at similar concentrations “leave important questions unanswered” and suggests that there is “continuing uncertainty” about adverse effects “in areas meeting the current annual and 24-hour standards.” *Id.* at 24120.

⁸⁰ CASAC ISA Review, Consensus Responses at 8-9.

But there is no legitimate basis to disregard the strong experimental evidence of biological pathways and mechanisms of action for PM_{2.5} health effects on this ground. At a minimum, epidemiological studies show that these mechanisms continue to operate at levels beneath the current standards. Any uncertainties in animal and human studies completed since the last NAAQS review does not outweigh the robust inferences regarding those biological pathways provided in the studies to date. Ind. Panel Rpt. at B-24. Moreover, there are controlled human studies showing health effects for exposures over short averaging time period—over a few hours—that provide further evidence of the causal mechanisms. Ind. Panel Rpt. at B-15; *see also Am. Farm Bureau Fed'n*, 559 F.3d at 522 (finding arbitrary and capricious EPA's failure to consider short-term studies as relevant to setting annual PM_{2.5} standard).

In short, these studies demonstrate, without dispute, that science understands the mechanisms by which PM_{2.5} harms human health. The Administrator's position is irrational because he concludes that effects below 12 µg/m³ that are evidenced by this sound statistical evidence have, for some unknown reason, a causal mechanism due to confounders or other factors that differs from the acknowledged causal mechanism at concentrations of 12 µg/m³ or above. In other words, for reasons the Administrator does not explain, he presumes that causation changes drastically at lower concentrations, and for one or more unexplained reasons, that change occurs at the precise level of the current standard. Basing a conclusion on hypothetical, unsupported explanations is irrational.

There is thus no material uncertainty here, and to the extent there is uncertainty regarding the exact magnitude of effects at concentrations lower than the current standard, it is the type of uncertainty—strong evidence of one type, namely, epidemiological studies, that supports a finding of harm at lower levels that is not yet fully supported by evidence of another type, namely, controlled exposure studies at such levels—that circumstance requires lowering the standard to provide an adequate margin of safety, as explained in section V.A.2.a above.

iii. Risk assessment

The Administrator relies on the assertion that “all risk assessments have limitations” so that previous Administrators have given them less weight. 85 Fed. Reg. at 24120. He notes that certain CASAC members expressed concerns mirroring perceived limitations in the epidemiological evidence that provides “key inputs” to the risk assessment. *Id.* Based on these considerations, the Administrator proposes to determine that the conclusions of the risk assessment “do not comprise valid empirical evidence or grounds for revising the current NAAQS.” *Id.* (quoting Cox, 2019a at 9). As a result, he places “little weight” on the quantitative estimates from the risk assessment. *Id.* at 24120.

Uncertainties in the risk assessment are not sufficiently large, however, to make the assessment uninformative. Ind. Panel Rpt. at B-24 to -25. Instead, “[a] claim that the risk assessment is not informative is only possible if one completely discards the epidemiologic evidence [which underlies the assessment] as irrelevant to estimating population risk, and/or disputes most of the methods used and assumptions made in the risk assessment.” Ind. Panel Rpt. at B-25. But the Administrator takes neither of those approaches his attempt to discount risk assessment. Nor could he, as neither finds any record support.

The limitations of the risk assessment also do not “invalidate the qualitative conclusions that can be reached from its results, namely that the estimated magnitude of premature deaths attributed to PM-related mortality at the levels of the current primary PM_{2.5} standards is unacceptably high. . . . [I]t is inappropriate to over-emphasize and inflate the significance of uncertainty in the risk assessment to the point of calling into question the key insights afforded by the assessment.” Ind. Panel Rpt. at B-25; *see also id.* at B-20 (“considering all of the information about, and features of, the risk assessment approach, the robustness of the results is enhanced by key sources of variability and uncertainty that are taken into account” and “the risk assessment is . . . adequate for its intended purpose”).

Indeed, the risk assessment estimates *understate* the risk because, among other reasons, the assessment only focuses on three health outcomes (total mortality, ischemic heart disease mortality, and lung cancer mortality) without providing any rationale for that limitation, and omit evaluation of other health outcomes (long-term cardiovascular effects other than ischemic health disease mortality, such as stroke; short term cardiovascular effects other than ischemic health disease mortality; respiratory effects at any time scale; cancer mortality other than lung cancer; and nervous system effects). Ind. Panel Rpt. at B-17. The inconsistency between the record evidence of significant risk at the current NAAQS level and the Administrator’s refusal to reduce the NAAQS level to address that risk consistent with the Clean Air Act’s margin-of-safety requirement for primary NAAQS makes the Administrator’s proposal unlawful and arbitrary and capricious. *See, e.g.*, 42 U.S.C. § 7409(b)(1); *State Farm*, 463 U.S. at 43.

3. *The Administrator’s Proposal to Retain the Existing Annual PM_{2.5} NAAQS Fails to Address the Environmental Justice Implications of Particulate Matter*

The Administrator’s failure to address the environmental justice implications of the harms to human health, namely, that reducing the annual primary PM_{2.5} level is important for protecting vulnerable communities, would be grounds for invalidating the Administrator’s NAAQS proposal here should it be finalized. *See Am. Farm Bureau Fed’n*, 559 F.3d at 525-26 (remanding NAAQS for agency’s failure to evaluate whether the NAAQS provided an adequate margin of safety for vulnerable subpopulations).

The NAAQS “must protect not only average, healthy individuals, but also ‘sensitive citizens’—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.” *Id.* at 390 (citations omitted). “If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *Id.* at 389 (citation omitted); *see also* S. Rep. No. 91-1196, 91st Cong., 2d Sess. 410 (1970).

The Administrator concludes that his proposal to leave the particulate matter NAAQS unchanged raises no environmental justice issues, 85 Fed. Reg. at 24140, but that conclusion is unjustifiable. The Administrator himself notes that “[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher PM_{2.5} exposures than non-Hispanic white populations” and “there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations.” 85 Fed. Reg. at 24114 (quoting

Integrated Science Assessment at 12-38). The Independent Panel explains that recent epidemiological studies “demonstrate[] that certain sub-populations have different risk,” with one study showing that “the relative risk for African Americans is three times higher than that of the entire population.” Ind. Panel Rpt. at B-29 (citing Di *et al.* (2017a)). Another analysis found that the average exposure of Latinxs, Asian Americans and Blacks in the Northeast and Mid-Atlantic regions to PM_{2.5} from cars, trucks and buses exceeded the average exposure in those regions by 42 percent, 40 percent and 31 percent, respectively.⁸¹

More recent analysis not included in the Integrated Science Assessment or Policy Assessment confirms that minority populations experience a disparate harmful impact to their health from PM_{2.5}. One study estimated that Blacks’ PM_{2.5} burden, as measured in tons of exposure per year, was 54 percent higher than the general population, and Latinx PM_{2.5} burden was 20 percent higher.⁸² The study also found that the PM_{2.5} burden for those living in poverty, as measured by household income less than the relevant Census Bureau threshold, was 35 percent greater than the general population.⁸³

Another study showed that Blacks’ average exposure to PM_{2.5} was 21 percent greater than the overall population.⁸⁴ The same study showed that Blacks and Latinxs bear a “pollution burden” of 56 percent and 63 percent excess exposure, respectively, as measured by comparing their actual exposure to the exposure caused by their consumption.⁸⁵ Other studies further confirm such disparate effects.⁸⁶

Another study has found a statistically significant relationship between long-term PM_{2.5} exposure and COVID-19 mortality, with a 1 µg/m³ increase in such exposure associated with an 8 percent increase in COVID-19 mortality rate.⁸⁷

⁸¹ M. Pinto de Moura *et al.*, Inequitable Exposure to Air Pollution from Vehicles in the Northeast and Mid-Atlantic, at 3 (June 2019), *available at* <https://www.ucsusa.org/sites/default/files/attach/2019/06/Inequitable-Exposure-to-Vehicle-Pollution-Northeast-Mid-Atlantic-Region.pdf>.

⁸² I. Mikati, Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status, 108(4) *Am. J. of Public Health* 480, 482 (Table 1) (Apr. 2018).

⁸³ *Id.*

⁸⁴ C. Tessum, *et al.*, Inequity in consumption of goods and services adds to racial-ethnic disparities in air pollution exposure, 116 (13) *Proceedings of the National Academy of Sciences* at 2 (Mar. 11, 2019).

⁸⁵ *Id.* at 1.

⁸⁶ *See, e.g.*, A. Rosofsky, *et al.*, Temporal Trends In Air Pollution Exposure Inequality In Massachusetts, 161 *Environ Res.* 76 (Feb. 2018); A. Rosofsky, *et al.*, The Impact Of Air Exchange Rate On Ambient Air Pollution Exposure And Inequalities Across All Residential Parcels In Massachusetts, 29 *J. Exp. Sci. Environ. Epidemiol.* 520 (2019); National Association for the Advancement of Colored People & Clean Air Task Force, Fumes Across the Fence-Line (Nov. 2017), http://www.catf.us/wp-content/uploads/2017/11/CATF_Pub_FumesAcrossTheFenceLine.pdf.

⁸⁷ X. Wu, *et al.*, Exposures to air pollution and COVID-19 mortality in the United States: A nationwide cross-sectional study, at 2 (Apr. 20, 2020), <https://projects.iq.harvard.edu/covid->

Notwithstanding this extensive scientific evidence, the Administrator’s discussion of environmental justice issues consists of one conclusory, pro-forma paragraph at the end of the Federal Register notice stating the Administrator’s determination that his proposal raises no environmental justice issues. 85 Fed. Reg. at 24140. There is no evidence that the Administrator conducted an environmental justice analysis consistent with EPA’s own 2016 Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,⁸⁸ or any other substantive environmental justice analysis. *See Friends of Buckingham v. State Air Pollution Control Bd.*, 947 F.3d 68, 92 (4th Cir. 2020) (“[E]nvironmental justice is not merely a box to be checked, and failure to consider the disproportionate impact . . . result[s] in a flawed analysis.”).

It is essential that the Administrator consider the fact that a particulate matter NAAQS standard that fails to protect the overall public health and safety will present an even greater threat the public health and safety of residents in these environmental justice communities. Instead, he merely concludes that the decision not to further reduce the particulate matter standards will not have a disproportionately high and adverse impact on minority and low-income individuals. 85 Fed. Reg. at 24140. As noted above, recent studies overwhelmingly demonstrate that this is incorrect, and an insufficiently protective NAAQS for particulate matter will disproportionately impact environmental justice communities. The Administrator must adequately consider these system race-based and income-based disparities as required by Executive Order 12898 and protect the public health and safety of all people, regardless of ethnicity or income level. Absent such action, these disadvantaged communities will continue to suffer disparate health and safety impacts.

This failure to address a requirement for setting the NAAQS is another important reason why the Administrator’s proposal not to strengthen the existing particulate matter NAAQS is unlawful, unreasonable and unconscionable.

B. The Existing 24-Hour PM_{2.5} Standard Does Not Protect Public Health with an Adequate Margin of Safety

1. Recent Monitoring and Scientific Studies Show the Current Standard Is Inadequate

Many communities continue to be exposed to ambient short-term PM_{2.5} concentrations that far exceed the current 24-hour standard of 35 µg/m³. Based on the form of the standard, a three-year average of the 98th percentile, the average 24-hour PM_{2.5} concentration for the nation between 2015 and 2017 was 20.9 µg/m³. Policy Assess. at 2-26. However, ambient concentrations during this period ranged from 9.2 µg/m³ to 111 µg/m³. *Id.* The parts of the

[pm/home](#); see also Office of Massachusetts Attorney General Maura Healey, COVID-19’s Unequal Effects in Massachusetts: Remediating the Legacy of Environmental Injustice & Building Climate Resilience (2020), <https://www.mass.gov/doc/covid-19s-unequal-effects-in-massachusetts/download>.

⁸⁸ https://19january2017snapshot.epa.gov/sites/production/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.

country with concentrations above the current standard are located predominately in California's Central Valley and the Pacific Northwest. *Id.* at 2-28. While much of the country has experienced significant declines in ambient particulate matter over the last 20 years, these particular areas have experienced no such changes since 2000. *Id.* at 2-30.

These findings are particularly troubling because EPA's 2019 Integrated Science Assessment for the current particulate matter review concluded that the evidence connecting short-term PM_{2.5} exposure to health effects is stronger than it was in 2009. There is increased evidence confirming the "likely to be causal relationship" between short-term PM_{2.5} exposure and respiratory effects. Integrated Sci. Assess. at 5-149. Similarly, a "large body of recent evidence confirms and *extends* the evidence" supporting EPA's conclusion of a causal relationship between short-term PM_{2.5} exposure and cardiovascular effects. *Id.* at 6-136 (emphasis added). New studies also suggest there is a relationship to metabolic and nervous system effects, whereas in 2009, there was no such evidence. *Id.* at 7-58, 8-15. Finally, recent evidence has also strengthened the conclusion that short-term exposure to PM_{2.5} increases total mortality. *Id.* at 11-58.

Additionally, EPA staff's review of the evidence shows that "positive and statistically significant associations" with mortality and short-term exposure to PM_{2.5} persist at concentrations as low as 25 µg/m³. Policy Assess. at 3-25. This includes multi-city studies documenting associations between mortality and average 24-hour PM_{2.5} concentrations below 35 µg/m³ (Lee et al., 2015), below 30 µg/m³ (Shi et al., 2016), and below 25 µg/m³ (Di et al., 2017a). *Id.* at 3-25. Indeed, the Policy Assessment readily admits that a "threshold below which [health impact] associations no longer occur is not identifiable from the available data." *Id.* at 3-43.

In line with these findings, EPA staff estimates that air quality meeting the current 24-hour PM_{2.5} standard of 35 µg/m³ would still cause 2,970 deaths annually within a subset of 11 urban study areas where the 24-hour standard is currently controlling, and that lowering the standard to 30 µg/m³ would reduce the estimated risk by 14 to 18 percent. *Id.* at 3-94. Similarly, the California Air Resources Board estimates that attaining a 24-hour PM_{2.5} level of 30 µg/m³ would save as many as 3,000 lives statewide, with 2,600 located in just the San Joaquin Valley and South Coast air basins alone.⁸⁹

2. *The Administrator's Proposed 24-Hour PM_{2.5} Standard Fails to Acknowledge the Harms to Health Established in the Recent Scientific Evidence*

The Administrator is proposing to retain the current 24-hour PM_{2.5} standard, having failed to "consider[] all relevant factors" by ignoring EPA's own analysis showing that reducing the

⁸⁹ The California Air Resources Board calculated these values using estimated population data from 2016-2018 and R statistical analysis software (R Core Team 2020) via a methodology based on US EPA's BenMAP benefits mapping and analysis software. These calculations are presented more comprehensively in Appendix B of the California Air Resources Board's June 29, 2020, comment letter to EPA regarding its April 2020 review of the NAAQS for particulate matter.

standard would have tremendous health benefits by reducing mortality and other significant health impacts.” *Miss. Comm’n on Env’tl. Quality*, 790 F.3d at 150. The Administrator’s reasoning behind that proposal to retain the current standard—that recent scientific evidence “does not call into question” the public health protection provided by the current standard—is arbitrary and capricious. 85 Fed. Reg. at 24,120. As discussed above, there are several studies that document increased mortality with exposure to PM_{2.5} at the current 24-hour standard. These studies “indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term PM_{2.5} exposures at levels as low as 25 µg/m³.” Policy Assess. at 3-25. Further, health impacts from these studies document cardiovascular and respiratory impacts at these lower ambient concentrations as well. EPA has determined that these health impacts have a “causal” or “likely causal relationship” with short-term exposure to PM_{2.5}, and the evidence supporting these conclusions has strengthened since EPA’s last review in 2009. Integrated Sci. Assess. at 5-154 (Table 5-18).

EPA previously concluded that such a connection between health impacts and exposure was sufficient to lower the PM_{2.5} annual standard from 15 µg/m³ to 12 µg/m³.⁹⁰ The Administrator has not provided any explanation why a similar level of confidence between exposure to PM_{2.5} and the resulting health risks is not sufficient to justify lowering the PM_{2.5} 24-hour standard during this review cycle. In essence, the Administrator’s proposal suggests that people living in areas most directly impacted by short-term exposure are not deserving of the same level of protection as people living in areas impacted by long-term exposure—a callous conclusion that will lead to 3,000-4,000 excess deaths in California alone.⁹¹

C. The Existing PM₁₀ Standard Does Not Adequately Protect the Public Health and Must Be Strengthened

EPA’s determination that retaining the current primary PM₁₀ standard will adequately protect the public health and welfare is also arbitrary and capricious. Decades ago, a prior Administrator determined that the current standard was necessary to protect public health with an adequate margin of safety. *See, e.g.*, 71 Fed. Reg. at 61201. Because of other related regulatory changes, however, the unchanged PM₁₀ standard has in fact become less protective than it was when originally set. The Administrator again ignores ample evidence that the standard falls short.

As EPA’s proposal notes, “the current PM₁₀ standard is intended to protect public health against exposures to PM_{10-2.5},” 85 Fed. Reg. at 24121. Under this framework, PM₁₀ is the indicator and PM_{10-2.5} is the target pollutant. *Id.* Therefore, the PM₁₀ standard serves as a proxy for regulating PM_{10-2.5}. EPA originally established the current 150 µg/m³ PM₁₀ 24-hour standard

⁹⁰ *See* 77 Fed. Reg. 38935 (“a standard level of 12 µg/m³ . . . is somewhat below the long-term mean PM_{2.5} concentrations reported in all the multi-city, long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of causal or likely causal relationship, including premature hospitalizations and emergency department visits for cardiovascular and respiratory effects as well as respiratory effects in children.”).

⁹¹ *Id.*

in 1987. 52 Fed. Reg. 24634, 24634 (July 1, 1987). At that time, however, the PM₁₀ standard was an indicator for all particulate matter pollution, and there was also an annual PM₁₀ standard of 50 µg/m³. *Id.* at 24634, 24639. When EPA promulgated PM_{2.5} standards in 1997, it retained the PM₁₀ 24-hour and annual standards as indicators to protect against the health risks from PM_{10-2.5}. 62 Fed. Reg. at 38652. In 2006, EPA subsequently eliminated the PM₁₀ annual standard, retaining only the 24-hour standard of 150 µg/m³. 71 Fed. Reg. at 61144. The PM₁₀ standard has remained the same ever since.

Because “PM₁₀ mass includes both coarse particulate matter (PM_{10-2.5}) and fine particulate matter (PM_{2.5}) . . . the concentration of PM_{10-2.5} allowed by a PM₁₀ standard set at a single level declines as the concentration of PM_{2.5} increases.” 85 Fed. Reg. at 24121. Of course, the converse is equally true, the concentration of PM_{10-2.5} allowed by a PM₁₀ standard set a single level increases as the concentration of PM_{2.5} decreases. Responding to a similar concern during the 2012 review cycle, the previous Administrator declined to lower the PM₁₀ standard because the impacts that lowering the PM_{2.5} standard would have on the PM₁₀ standard were uncertain.⁹² In doing so, the previous Administrator explained, it was not possible to predict how the change to the PM_{2.5} standard would impact the protectiveness of the PM₁₀ standard.⁹³ The previous Administrator determined that the reduction in the PM_{2.5} standard might alter the composition and toxicity of PM₁₀ pollution in a way that reduces the human health impacts from exposure.⁹⁴ However, as the current Administrator’s proposal notes, the evidence collected since the 2012 review demonstrates that the reduction in PM_{2.5} standard has not had such an effect, and the connection between PM_{10-2.5} and health impacts has only gotten stronger.

In fact, while the PM₁₀ standard has not changed in over 14 years, it has effectively become less protective against exposure to PM_{10-2.5}. As the PM_{2.5} standard has been reduced, the PM₁₀ standard has remained unchanged, resulting in increased exposure to PM_{10-2.5}. Specifically, previous Administrators have lowered the allowable PM_{2.5} concentration, reducing the 24-hour PM_{2.5} standard from 65 to 35 µg/m³ and reducing the annual PM_{2.5} standard from 15 to 12 µg/m³. Measured ambient concentrations of PM_{2.5} have declined over that period. The Administrator’s proposal notes that “[f]rom 2000 to 2017, national annual average PM_{2.5} concentrations have declined from 13.5 µg/m³ to 8.0 µg/m³, a 41% decrease.” 85 Fed. Reg. at 24101. Accordingly, the PM₁₀ standard has become less protective against exposure to PM_{10-2.5} because the amount of allowable and actual PM_{2.5} pollution has decreased over the years, thus the allowable concentration of PM_{10-2.5} has increased. Nevertheless, EPA’s proposal fails to even mention how this impacts the protectiveness of the current PM₁₀ standard.

The Administrator ignores the effective weakening of the PM₁₀ standard even though the scientific evidence linking exposure to PM_{10-2.5} with negative health impacts that has only become stronger over the years. “Since the last review, the Administrator notes that the evidence for several PM_{10-2.5} related health effects has expanded” and that “[s]uch studies provide an

⁹² EPA, Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (June 29, 2012; 77 FR38890), III-5 (Docket No. EPA-HQ-OAR-2007-0492).

⁹³ *Id.*

⁹⁴ *Id.*

important part of the body of evidence supporting the [Integrated Science Assessment]’s strengthened causality determinations . . . for long-term PM_{10-2.5} exposures and mortality cardiovascular effects, metabolic effects, nervous system effects and cancer.” 85 Fed. Reg. at 24126. Furthermore, even during the prior review completed in 2012, the CASAC concluded the available evidence was “sufficient to call into question the level of protection afforded by the [PM₁₀] . . . 24-hour standard of 150 µg/m³.”⁹⁵

Taken together, these facts clearly demonstrate that the Administrator’s proposal to retain the current PM₁₀ 24-hour standard of 150 µg/m³ is also arbitrary and capricious. Accordingly, the Administrator must revise the PM₁₀ standard downward to protect public health with an adequate margin of safety.

D. The Administrator’s Proposed Conclusion to Retain the Current Particulate Matter NAAQS Is Further Undermined by His Failure to Consider Exposure to Particulate Matter from the Increasing Frequency and Magnitude of Wildfires Caused by Climate Change

The Administrator failed to consider the health impacts of increased particulate matter due to future higher temperatures and the increased prevalence of wildfires. Wildfires are a significant source of overall particulate matter exposure, and by omitting data points impacted by wildfires, the analysis is skewed to minimize the serious health impacts that people will suffer from such increased wildfires and related particulate matter. The Administrator’s flawed analysis artificially decreases the benefits of a stricter particulate matter NAAQS, rendering his ultimate decision arbitrary and capricious.

1. Wildfires are a Significant Source of Particulate Matter Exposure

Fires represent one of the largest sources of primary particulate matter in the United States, contributing over 30 percent of primary particulate matter emissions per year. Integrated Sci. Assess. at 2-8. Wildfire smoke in particular contributes 17 percent of annual primary particulate matter, and prescribed burns contributing 15 percent. *Id.* Wildfires combust natural biomass creating smoke containing a complex mixture of particulate matter (including various gaseous particulate matter precursors), carbon dioxide, water vapor, carbon monoxide, hydrocarbons and other organic chemicals, nitrogen oxides, and trace minerals.⁹⁶ Over 90 percent of the particle mass emitted by wildfires consists of the smaller PM_{2.5} that is most injurious to human health.⁹⁷

⁹⁵ Letter from Dr. Jonathan M. Samet, Chair, CASAC, to Lisa P. Jackson, Administrator, EPA, Re: CASAC Review of Policy Assessment for the Review of the PM NAAQS—Second External Review Draft (June 2010), ii, 7, (Sept. 10, 2010)

⁹⁶ EPA, Wildfire Smoke: A Guide for Public Health Officials, EPA-452/R-19-901, p. 12 (August 2019) (“Wildfire Smoke”), <https://www3.epa.gov/airnow/wildfire-smoke/wildfire-smoke-guide-revised-2019.pdf>.

⁹⁷ *Id.* at 4; *see also* A. Vicente, *et al.*, Emission factors and detailed chemical composition of smoke particles from the 2010 wildfire season. 71 *Atmospheric Environment* 295 (2013).

Smoke from wildfires impacts ambient particulate matter levels across the nation. While western states are often most severely impacted during the late summer, most of the contiguous United States is affected by wildfire smoke during some part of the year, increasing exposure to particulate matter. Policy Assess. at 2-55 to 2-56.

2. *The Frequency and Magnitude of Wildfires Is Increasing Because of Climate Change.*

Temperatures are rising globally, increasing the threat of wildfires and the associated particulate matter. The annual average temperature in the contiguous United States has increased by 1.2°F over the last few decades and 1.8°F relative to the beginning of last century.⁹⁸ Further increases in annual average temperature of about 2.5°F are anticipated over the next few decades, and increases ranging from 3°F to 12°F are expected by the end of the century.⁹⁹ Climate—largely through temperature and precipitation—influences the frequency of wildfires by impacting the availability and flammability of fuels. Indeed, EPA itself recognizes that our warming climate will affect the frequency, duration, and severity of wildfires, resulting in longer fire seasons and increases in drought conditions.¹⁰⁰ And the wildfire-related impacts from increased temperatures have already begun. In the past decades, climate change has resulted in longer fire seasons, more frequent fires, and significantly larger fires.¹⁰¹ As the following figure illustrates, the area burned by large wildfires and the severity of those fires has increased significantly in recent decades.¹⁰²

⁹⁸ USGCRP, 2018: Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II, p. 74 (“USGCRP Fourth National Climate Assessment”).

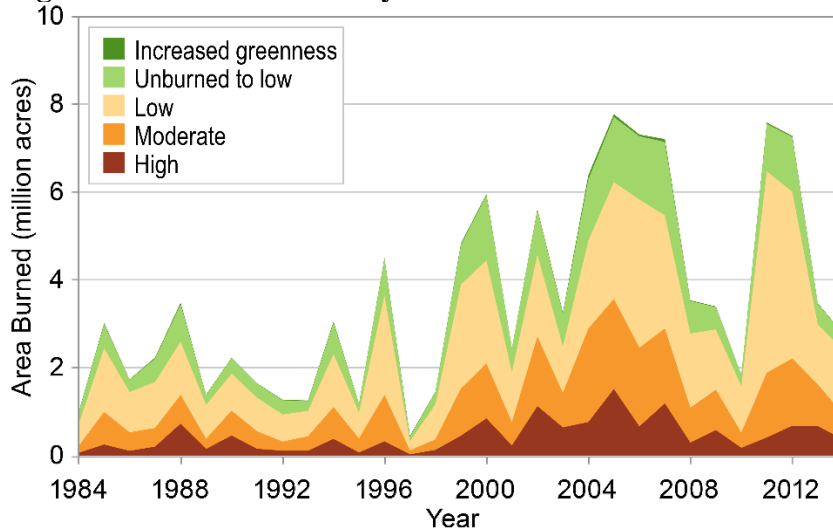
⁹⁹ *Id.*

¹⁰⁰ Wildfire Smoke at 14; A.L. Westerling, *et al.*, Climate and Wildfire in the Western United States, 84 *Bull. Amer. Meteor. Soc.* 595 (2003); and USGCRP Fourth National Climate Assessment.

¹⁰¹ Policy Assess. at 56 (citing Dennison, PE, Brewer, SC, Arnold, JD and Moritz, MA (2014). "Large wildfire trends in the 26 western United States, 1984-2011." *Geophysical Research Letters* 41(8): 2928-2933; and Jolly, WM, Cochrane, MA, Freeborn, PH, Holden, ZA, Brown, TJ, Williamson, GJ and Bowman, DMJS (2015). "Climate-induced variations in global wildfire danger from 1979 to 2013." *Nature Communications*, p. 6).

¹⁰² This figure illustrates the area burned by large wildfires (greater than 1,000 acres in the western United States and greater than 500 acres in the eastern United States) and the severity of the damage to the forest canopy for 1984–2014. USGCRP Fourth National Climate Assessment at Figure 6-5.

Figure 1: Area and Intensity of Wildfires in the United States



Additional studies have estimated that anthropogenic climate change has dramatically exacerbated wildfire risks by increasing fuel aridity by approximately 55 percent.¹⁰³ Such changes have substantially increased the amount of particulate matter to which the population is exposed.

This problem will only get worse as temperatures continue to increase and larger and more intense wildfires become more frequent, releasing ever-increasing amounts of PM_{2.5}.¹⁰⁴ Within decades, the area of land burned in the western United States alone could be two to six times greater than at present.¹⁰⁵ Furthermore, man-made development is expanding and increasing the wildland-urban interface. As wildfires become more prevalent the fires are more likely to enter human-occupied areas. This will result in the increased combustion of both residential and commercial structures, consuming man-made materials in addition to natural fuels and adding dangerous hazards to the ambient mix of particulate matter.

3. Failure to Adequately Consider the Impact of Increased Particulate Matter from Wildfires Undercuts the Administrator’s Rationale for Not Lowering the Particulate Matter NAAQS

Despite the substantial contribution of wildfires to the levels of particulate matter exposure impacting human health, the Administrator fails to adequately consider the impact of future larger and more frequent fires in his proposed particulate matter NAAQS. Instead, he improperly categorizes particulate matter from wildfires as “background” particulate matter that is “episodic” and “characterized by infrequent contributions to high-concentration events

¹⁰³ J. Abatzoglou, *et al.*, Impact of anthropogenic climate change on wildfire across western US forests, Dept. of Geography, Univ. of Idaho (October 18, 2016).

¹⁰⁴ M. Flannigan, *et al.*, Global wildland fire season severity in the 21st century, 294 *For. Ecol. Manag.* 54 (2013).

¹⁰⁵ USGCRP Fourth National Climate Assessment at 241.

occurring over shorter periods of times.” 85 Fed. Reg. at 24103. But such a characterization is no longer accurate, as wildfires become more frequent and burn for longer periods of time, increasing the amount of particulate matter to which populations are exposed.¹⁰⁶ The Administrator’s review of the particulate matter NAAQS standard glosses over this increasing source of particulate matter, failing to consider how it will impact the overall levels of particulate matter and resulting health impacts. After all, particulate matter from wildfires is no less toxic than particles emitted from other sources.¹⁰⁷ As the Independent Panel found, EPA’s approach “is too easily dismissive of the fact that there have been a growing number of human-induced wildfires during the past two decades which have had evident adverse health and environmental effects.”¹⁰⁸ While the States recognize that particulate matter from wildfires may be outside of local control and are often omitted from measurements to determine NAAQS compliance, EPA cannot simply ignore the increased threat to public health and safety from fires, which are already a substantial source of total particulate matter and will add even more particulate matter in the future. The Administrator cannot simply turn a blind eye to the increased threat to public health and safety from fires, which are already a substantial source of total particulate matter and will add even more particulate matter in the future. *See State Farm*, 463 U.S. at 43 (agency decision that entirely fails to consider an important aspect of the problem is arbitrary and capricious).

EPA also improperly excluded particulate matter monitoring sites impacted by wildfires from its modeling dataset, thus ultimately underestimating the extent of the health benefits from establishing a stricter PM_{2.5} standard. EPA originally identified 56 areas that satisfied its criteria for evaluating the health impacts in its risk assessment. But EPA automatically excluded seven of these areas from its analysis based on its determination that the air quality monitoring data from those areas was influenced by wildfires. Such excluded areas covered geographically diverse areas, ranging from Yakima, WA, to Knoxville, TN. Policy Assess. at C-23 fn. 16. As the Independent Panel determined, “[b]y explicitly excluding consideration of impact of wildfires, and local and seasonal sources (wood burning), the[] risk assessments will underestimate the total net health burden from PM_{2.5}.”¹⁰⁹ The Panel also notes that EPA’s exclusion of these sites impacted by wildfires is just one aspect in which EPA’s approach “is too easily dismissive of the fact that there have been a growing number of human-induced wildfires during the past two decades which have had evident adverse health and environmental

¹⁰⁶ *See* National Aeronautics and Space Administration, Six Trends to Know About Fire Season in the Western U.S. (Dec. 15, 2018) (“Over the past six decades there has been a steady increase in the number of fires in the western U.S. . . . Those fires are also burning more acres of land.”), <https://climate.nasa.gov/blog/2830/six-trends-to-know-about-fire-season-in-the-western-us/>.

¹⁰⁷ Wildfire Smoke at 4; S. DeFlorio-Barker, *et al.* Cardiopulmonary effects of fine particulate matter exposure among older adults, during wildfire and non-wildfire periods, in the United States 2008-2010. 127(3) *Environ Health Perspective* 37006 (2009).

¹⁰⁸ Advice from the Independent Particulate Matter Review Panel on EPA’s Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft— September 2019), at B-12.

¹⁰⁹ Advice from the Independent Particulate Matter Review Panel on EPA’s Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft— September 2019), at C-38.

effects.”¹¹⁰ By discounting and ignoring measurements impacted by increasingly common wildfires, the risk assessment fails to adequately consider whether the proposed particulate matter standard adequately controls for health effects throughout the nation, particularly those associated with short-term exposures. *See* 42 U.S.C. § 7409(b).

Worse still, the Administrator’s failure to consider wildfires is likely to affect environmental justice communities disproportionately. Evidence suggests that people of lower socioeconomic status are more likely to suffer negative health impacts from wildfire-related particulate matter exposure.¹¹¹ Outdoor laborers like farmworkers are disproportionately low-income earners and members of racial minority groups, and are also most likely to suffer from such particulate matter impacts, given the nature of the work and the overlap between wildfire and harvest seasons. Further, even for those able to remain indoors, lower-income persons are less likely to have access to measures to reduce particulate matter exposure like air conditioning.¹¹² It is critical that the Administrator evaluate and address—and not simply ignore—these disproportionate impacts from increased wildfires.

E. The Administrator’s Consideration of Ultrafine Particles and Black Carbon Is Inadequate

The Administrator also fails to adequately consider evidence of the harm of ultrafine particles and black carbon. The Administrator must “present an adequate basis and explanation” for his determination. *See State Farm*, 463 U.S. at 34. His cursory discussion of ultrafine particles and black carbon does not evaluate their full harms, incorporate their relationship to traffic pollution, or set an adequately protective standard.

Ultrafine particles are created in two ways: primary emissions and atmospheric new particle formation. *Integrated Sci. Assess.* at 2-20. Primary ultrafine particles are directly generated by many types of sources, including road traffic, ships, aircraft, power plants, incinerators, construction and demolition activity, vegetation fires and domestic biomass burning. *Id.* Atmospheric new particles form through atmospheric reactions of precursor gases such as volatile organic compounds. *Id.* at 2-4, 2-20.

The Administrator acknowledges that ultrafine particles have negative effects on the nervous system. *See* 85 Fed. Reg. at 24099, 24114. Yet, he neglects to discuss additional harms that happen at near-road exposure sites, and he does not develop a plan for how to monitor those exposures. *See Ind. Panel Rpt.* at B-10, B-36. The Administrator also does not address literature showing harms to cardiovascular health from traffic air pollution. *Id.* Notably, the Administrator also does not address the effects of long-term exposure of ultrafine particles and their relationship to traffic pollution. *See Ind. Panel Rpt.* at B-10, B-36, C-12.

Moreover, the Administrator fails to account for the potential relationship between PM_{2.5} emissions and ultrafine particle emissions. Setting more stringent PM_{2.5} standards would likely

¹¹⁰ *Id.* at B-12.

¹¹¹ *See Wildfire Smoke* at 17-31.

¹¹² *Id.* at 9.

have the additional benefit of reducing ultrafine particle emissions. *Id.* at C-10 to C-11. However, the Administrator does not address this possibility. Thus, his review unlawfully fails to set a standard that appropriately limits the known harm of ultrafine particles.

Along the same lines, the Administrator does not sufficiently address the harms from black carbon. Black carbon “is the sooty black material emitted from gas and diesel engines, coal-fired power plants, and other sources. It comprises a significant portion of particulate matter.”¹¹³

The Administrator knows that regulating emissions of black carbon is an important part of protecting public health and the environment. For example, he acknowledges prior research demonstrating a causal relationship between particulate matter, including black carbon, and effects on climate. 85 Fed. Reg. at 24127, 24131. Further, black carbon deposits on snow and ice-covered surfaces can lead to surface heating. *Id.* at 24132. The Administrator does little, however, to address black carbon to mitigate climate impacts and protect the public health. As the Independent Panel observed, there are also studies not addressed by EPA indicating that black carbon causes negative health effects. *See id.* at C-12 to C-15. The Administrator should have considered these additional studies in more detail to account for the harms of black carbon emissions in setting the particulate matter standards.

The Administrator’s limited discussion of the impacts of ultrafine particles on the nervous system and black carbon on climate change does not show an adequate basis for the Administrator’s decision. *See State Farm*, 463 U.S. at 34; *see also* 85 Fed. Reg. at 24099, 24114, 24127, 24131-24132. The Administrator’s failure to consider additional studies and then explain the basis for not setting a more stringent standard or specific standards for ultrafine particles and black carbon was arbitrary and capricious. *See State Farm*, 463 U.S. at 34.

VI. THE EXISTING SECONDARY PARTICULATE MATTER STANDARDS DO NOT PROTECT PUBLIC WELFARE

A. The Administrator’s Failure to Revise the Secondary PM_{2.5} Standards to Reduce Visibility Impacts Is Contrary to the Statutory Directive to Protect Against Harm to Public Welfare and Is Arbitrary and Capricious

The Administrator’s proposed secondary PM_{2.5} standards are not sufficient to protect the public welfare. Although the Administrator acknowledges that there is a causal relationship between particulate matter and visibility, 85 Fed. Reg. at 24128, as explained by the report of the Independent Review Panel, the current standard does not protect public welfare from the effects of PM_{2.5} on visibility. Among other errors, the Administrator accepts previous agency conclusions without adequate scrutiny and fails to consider several recent studies on visibility effects. For these reasons, the Administrator should at a minimum revise the current annual

¹¹³ EPA, *Black Carbon Research*, <https://www.epa.gov/air-research/black-carbon-research> (last visited June 9, 2020).

secondary PM_{2.5} standard to equal the revised primary annual PM_{2.5} standard and strengthen the 24-hour secondary standard. The Administrator should also consider additional changes to the standards. *See* Ind. Panel Rpt. at 2.

The Administrator's proposed decision incorporates mistaken assumptions from earlier agency determinations. The assessment states that in 2012, the agency determined that an alternative secondary NAAQS would not provide added protection to visibility over the existing standards. *See* 85 Fed. Reg. at 24136; *see also* Policy Assess. at 5-7. But, as the Independent Panel observed, the Administrator's approach, which relied on observations made by the prior Administrator in 2012, did not represent the current state of the science at that time and in fact was not even supported by the CASAC in 2012. Ind. Panel Rpt. at B-33. There is accordingly no basis for accepting that approach now as a basis for retaining the current NAAQS.

The Administrator also disregards important sources of information on visibility preferences. In general, the Administrator does not consider possible welfare gains from improvements in visibility beyond a level deemed "acceptable." *See* 85 Fed. Reg. at 24131, 24138. Recent research has evaluated how gains in public welfare could be achieved by even higher levels of visibility beyond "acceptable." *See* Ind. Panel Rpt. at B-34. For instance, high levels of visibility have economic effects on property values, derived from scenic views. These types of gains could also support strong standards to create greater levels of visibility. *See* Ind. Panel Rpt. at B-34 to B-35.

Furthermore, the Administrator's proposed decision completely fails to consider a recent meta-analysis of visibility preferences that analyzes "whether there is any specific level of light extinction that is universally acceptable." *See* Ind. Panel Rpt. at B-34. The Administrator should consider this recent analysis when determining visibility standards. Additionally, the Administrator should consider whether a single nationwide standard is in fact appropriate, given that studies indicate preference levels vary from place to place. *Id.*

Lastly, the Administrator has failed to consider alternative indicators for visibility effects, against the recommendations of the 2012 CASAC and the current Independent Panel Report. He should consider these alternative means, including direct measurement of particulate matter light extinction, using additional data sources of particulate matter monitoring in calculating visibility, and a daylight-only indicator for visibility. *See* Ind. Panel Rpt. at B-35.

Each of these failures renders the proposed secondary standards arbitrary and capricious and unlawful. *State Farm*, 463 U.S. at 43; *Am. Farm Bureau Fed'n*, 559 F.3d at 522.

B. The Administrator Should Further Evaluate the Impacts on Materials in Setting Secondary Standards

The Administrator does not adequately evaluate the impacts on materials in setting the secondary standards. He acknowledges that particulate matter has detrimental effects on materials. *See* 85 Fed. Reg. at 24133. The damage includes deterioration of surfaces and soiling of glass and solar panels, which decreases the efficiency of those panels. *See id.* at 24133-24134. He even discusses recent studies highlighting the extent of this damage. *See id.* However, he

then concludes that there was not sufficient evidence to perform quantitative analyses. *Id.* at 24,135. The studies cited by the Administrator show the importance of setting more stringent secondary standards to protect materials. Instead of refusing to set a standard, the Administrator should conduct further review of the impacts to materials, gather all necessary information, and perform a quantitative analysis.

VII. CONCLUSION

As explained above, the Administrator's proposed decision to leave the particulate matter NAAQS unchanged is based on an arbitrarily truncated review process, and the proposed decision is contrary to the weight of evidence in the record demonstrating significant harm to human health and welfare from particulate matter air pollution at levels lower than the current NAAQS. Particulate matter pollution is the largest environmental risk factor in the United States, responsible for an estimated 63 percent of all deaths due to environmental causes. And new epidemiological, experimental and risk evaluation evidence demonstrates that significant harm to health occurs beneath the level of the current standards, with particulate matter pollution estimated to cause up to 45,000 deaths a year in areas where long-term PM_{2.5} concentrations are *lower* than the current NAAQS. New evidence also demonstrates harm to public welfare, through interference with visibility, at the current secondary NAAQS level. But as a result of the Administrator's arbitrary weakening of the review process and his own conclusion that this important, reliable new evidence counts for little if anything, he has failed to propose revising the NAAQS as necessary to protect human health and welfare.

To fix the procedural and substantive errors in his review, the Administrator must reverse the procedural changes in the NAAQS review process made since 2018, including reinstatement of the Particulate Matter Review Panel, and reopen the current particulate matter NAAQS proceeding to allow for use of the more thorough and transparent prior process. Applying the proper standards and giving proper weight to the new evidence in conjunction with prior evidence demonstrates that strengthening the primary and secondary NAAQS is warranted to protect human health and welfare as required under the Clean Air Act.

Sincerely,

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